Natural Resource Management and Policy
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Nicholas Kalaitzandonakes
Peter W.B. Phillips
Justus Wesseler
Stuart J. Smyth *Editors*

The Coexistence of Genetically Modified, Organic and Conventional Foods

Government Policies and Market Practices

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There is a growing awareness to the role that natural resources, such as water, land, forests and environmental amenities, play in our lives. There are many competing uses for natural resources, and society is challenged to manage them for improving social well-being. Furthermore, there may be dire consequences to natural resources mismanagement. Renewable resources, such as water, land and the environment are linked, and decisions made with regard to one may affect the others. Policy and management of natural resources now require interdisciplinary approaches including natural and social sciences to correctly address our society preferences.

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Editors
Nicholas Kalaitzandonakes
Department of Agriculture and Applied Economics
University of Missouri
Columbia, MO
USA

Peter W.B. Phillips
Johnson-Shoyama Graduate School of Public Policy
University of Saskatchewan
Saskatoon, SK
Canada

Justus Wesseler
Technische Universität München
Freising, Bayern
Germany

Stuart J. Smyth
University of Saskatchewan
Saskatoon, SK
Canada

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Editors and Contributors

About the Editors

Nicholas Kalaitzandonakes is MSMC endowed professor of agribusiness strategy and director of the Economics and Management of Agrobiotechnology Center at the University of Missouri.

Peter W.B. Phillips is a distinguished professor of public policy at the Johnson-Shoyama Graduate School of Public Policy, University of Saskatchewan.

Justus Wesseler is a professor and chair of the Department of Agriculture and Food at the Technical University of Munich and Wageningen University.

Stuart J. Smyth is an assistant professor at the University of Saskatchewan.

Contributors

Teresa Babuscio is secretary-general of COCERAL, the European association representing the trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats, and agrosupply.

Michael Blakeney is Winthrop Professor of Law at the University of Western Australia.

Kent J. Bradford is a distinguished professor of plant sciences and director of the Seed Biotechnology Center at the University of California—Davis.

Nancy Bryson was a partner at the law firm of Holland and Hart at the time of this writing and is former general counsel at USDA.

Lynn Clarkson is president of Clarkson Grain, a supplier of identity preserved non-GMO and organic maize and soy ingredients to the food manufacturing and animal feed industries.

Marcus Vinícius Segurado Coelho is coordinator of the Biosafety Division of the Ministry of Agriculture of Brazil.

Bruce Dahl is a research scientist at the University of North Dakota.

Henry Daniell is a professor of biochemistry at the University of Pennsylvania.

Koen Dillen is an economic and policy analyst with the Directorate General for Agriculture and Rural Development of the European Union.

Joseph M. DiTomaso is a professor of plant sciences at the University of California—Davis.

Konstantinos Giannakas is Harold W. Eberhard Professor of Agricultural Economics and director of the Center for Agricultural & Food Industrial Organization and the University of Nebraska—Lincoln.

Randal Giroux is vice president of Cargill, Inc., a firm that provides food, agriculture, financial, and industrial products and services to the world.

Barry K. Goodwin is William Neal Reynolds Distinguished Professor of Agricultural and Resource Economics at North Carolina State University.

Guillaume P. Gruère was an economist with the International Food Policy Research Institute at the time of this writing.

Michael Gumina was vice president for Production and Risk Management for Pioneer Hi-Bred at the time of this writing. He is now CEO of Rice-Tec.

William Hill is president of the Flax Council of Canada, a trade association.

Jikun Huang is a professor at the Chinese Academy of Sciences and director of the Center for Chinese Agricultural Policy.

James Kaufman is a project director with the Economics and Management of Agrobiotechnology Center at the University of Missouri.

William A. Kerr is a University Distinguished Professor of Bioresource Policy at the University of Saskatchewan.

Drew L. Kershen is Earl Sneed Centennial Professor of Law at the University of Oklahoma.

John Kruse is principal and director of quantitative analysis at World Agricultural and Economic Environmental Services, an agribusiness consulting firm.

Sarah Lukie is director of CropLife International, a plant science industry advocacy organization.

Alexandre Magnier is program director with the Economics and Management of Agrobiotechnology Center at the University of Missouri.

Carol Mallory-Smith is a professor of weed science at Oregon State University.

Michele Marra is professor emeritus of agricultural and resource economics at North Carolina State University.

Martin Phillipson is an associate professor of law at the University of Saskatchewan.

Nicholas Piggott is a professor of agricultural and resource economics at North Carolina State University.

Kai Purnhagen is an assistant professor of law and governance at the University of Wageningen.

Ivilin Rizov is a science and technical projects officer with the Institute for Prospective Technological Studies of the European Commission Joint Research Centre.

Emilio Rodriguez-Cerezo is coordinator for Action on GMOs with the Institute for Prospective Technological Studies of the European Commission Joint Research Centre.

Camille D. Ryan was a professional research associate at the University of Saskatchewan at the time of this writing.

Eric Sachs is Science and Policy Lead at Monsanto, a global firm supplying seeds, biotechnology traits, and crop protection chemicals.

Steven H. Strauss is a distinguished professor of forest biotechnology at Oregon State University.

C. Neal Stewart Jr. holds the Ivan Racheff Chair of Excellence as Professor of Plant Science at the University of Tennessee.

Janice Tranberg is vice-president for Western Canada of CropLife Canada, a plant science industry advocacy organization.

Rene Van Acker is a professor of plant agriculture at the University of Guelph.

Allen Van Deynze is a professional researcher with the Seed Biotechnology Center at the University of California—Davis.

Thomas J. Venus is a research associate with the Technical University of Munich.

William W. Wilson is Distinguished University Professor of Agribusiness and Applied Economics at North Dakota State University.

Philipp Wree is a scientific assistant at the Technical University of Munich.

Jun Yang is with the Center for Chinese Agricultural Policy and is a member of the Chinese Academy of Sciences.

Sanghan Yea was with the Hyundai Research Institute at the time of this writing and he is now a research fellow at the Korea-Africa Center, the Korean Foreign Ministry.

Kenneth Zahringer is a research fellow with the Economics and Management of Agrobiotechnology Center at the University of Missouri.

David Zilberman is the Robinson Chair and Professor of Agricultural and Resource Economics at the University of California—Berkeley.

Introduction to the Issue of Coexistence

Nicholas Kalaitzandonakes, Peter W.B. Phillips, Stuart J. Smyth and Justus Wesseler

In many ways, the debate about coexistence is about the future of the global food system and its capacity to meet the rapidly growing demand for food and nutrition. Since their commercial introduction in 1995 and 1996, genetically modified (GM) crops have been adopted by farmers around the world at impressive rates. In 2014, over 180 million hectares of GM crops were cultivated by more than 18 million farmers in 28 countries. Soybeans, maize, cotton, and canola are the primary GM crops worldwide, representing 50, 30, 14, and 5 %, respectively, of the global area devoted to GM production. Soybean producers have adopted GM varieties at the highest rate; over 80 % of global soybean area is planted with GM varieties. Nearly 70 % of cotton area, 30 % of maize area, and 25 % of canola area are produced using GM varieties. Overall, of all crops for which GM varieties are available, nearly half the production area is planted with GM varieties (James 2014). In the next decade, global adoption is expected to grow further as the research pipeline for new biotech traits and crops has increased almost fourfold in the last few years (Stein and Rodríguez-Cerezo 2010).

N. Kalaitzandonakes (✉)
University of Missouri, Columbia, MO, USA
e-mail: KalaitzandonakesN@missouri.edu

P.W.B. Phillips · S.J. Smyth
University of Saskatchewan, Saskatoon, Canada
e-mail: peter.phillips@usask.ca

S.J. Smyth
e-mail: stuart.smyth@usask.ca

J. Wesseler
Technical University-Munich, Munich, Germany
e-mail: justus.wesseler@wzw.tum.de

J. Wesseler
Wageningen University, Wageningen, The Netherlands

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The adoption of GM crops has led to increased productivity,reductions in pesticide use, fewer emissions of agricultural greenhouse gases, and other environmental benefits as well as broadly distributed economic benefits across the global food supply chain (e.g., Alston et al. 2014; Barrows et al. 2014; Klümper and Qaim 2014; Smyth et al. 2011a, b; Wesseler et al. 2011). Given the Food and Agriculture Organization's (FAO) estimate that food production will have to increase by some 70 % by 2050, biotechnology will remain an important tool in the food security tool box (Meyers and Kalaitzandonakes 2012). Whereas the first generation of biotechnology products brought about agronomic innovations (herbicide tolerance and insect resistance), second generation products are expected to play an important role in helping agriculture adapt to climate change (e.g. through drought tolerance, improved nitrogen efficiency and other traits) and expand its productive capacity.

Despite the rapid uptake of GM crops, the various social and economic benefits (Carpenter 2010; Gusta et al. 2011; Klümper and Qaim 2014) as well as the expanding rate of innovation,the use of GM crops remains controversial in many key consuming and importing parts of the world (Bennett et al. 2013). Even in countries where GM crop production is common, some parts of the population prefer to consume food products that do not contain GM ingredients. On global, national, and local levels there are sustainable, albeit smaller scale, markets for organic and non-GM, conventionally-raised crops. There is also an increasing number of specialty crops tailored for specific food or industrial applications, many of them GM. Thus the market is, and will only continue to become, increasingly segmented. As a result, coexistence among all such crops in the production landscape and in the market will be an important issue for the foreseeable future.

A more segmented market means a more diverse customer base for producers and suppliers. Market participants have every incentive to ensure that the supply chain, from production through retail sales, is coordinated so as to serve all customer groups efficiently and effectively. Seed developers, growers, and processors all benefit from innovating in ways that better meet diverse consumer demand at lower cost. Such innovation includes not only new products, but also managing the entire supply chain to ensure coexistence among products that consumers value and the agricultural resources that go into producing them. The market may not always work perfectly, however. Information on consumer demand may not be transmitted efficiently to producers, and consumers may not have complete information on product quality attributes. Such information asymmetries can distort decision making and lead to market failures. In the presence of externalities producers may not experience the full consequences of their actions, in terms of either benefits or costs, which can skew their decisions and the overall efficiency of market outcomes. In such cases there may be a role for government regulation to facilitate information flow and to address externalities. Market and policy changes may in turn generate property rights disputes among market participants as well as disputes over the proper role and scope of regulation that would need to be settled through the court system.

Discussions on the appropriate regulatory norms for GM crops and foods in various countries date back to the early 1980s (OECD 1986; Cantley 2008). Almost 30 years later, a consensus on norms remains elusive (Herring and Paarlberg 2016). While the safety of GM crops and foods prior to their commercialization is evaluated through more or less the same methods around the world (Kalaitzandonakes et al. 2007a), countries differ widely on the amount of time they take to complete their regulatory reviews (e.g. Smart et al. 2016; Zilberman et al. 2015) as well as on their treatment of GM foods that have been deemed safe for market introduction. Some countries, including the United States and Canada, consider the deregulated (approved) GM foods substantially equivalent to their conventional counterparts, while others, including the European Union (EU), Japan, China, South Korea, Brazil, and Australia have introduced various levels of control over where and how GM foods can appear in the market.

In some countries, stakeholder groups have opposed the introduction of GM crops; in response, governments have attempted to strengthen public confidence through changes in regulations. Yet regulations can lead to reductions in innovation, and in a global economy where GM crops and their derivatives are broadly traded, they can also cause distortions in national food production and trade leading to reduced social welfare. It is generally accepted that the optimal level of regulation in any nation depends on the potential benefits and costs thereof and is reached when the marginal benefits of additional regulation equal the marginal costs (Arrow et al. 1996).[1] By all accounts, settling on proper GM regulation has proven difficult for many countries.

Voluntary and mandatory GM labeling regimes are one attempt to facilitate information flow from producers to consumers. Both provide economic incentives for organic and non-GM crops to be segregated from production, through processing into their various derivatives, to their final form as retail food products. Some countries have let markets sort through the underlying supply and demand conditions as well as the allocation of risk and economic value in production, processing, and distribution. In some cases, markets have acted to supply consumers who want to avoid GM foods with alternatives, including 'non-GM' and 'GM-free' products as well as organics, all of which are voluntarily labeled (Kalaitzandonakes et al. 2007b). Other countries have intervened to actively regulate the market, enacting mandatory labeling regimes (Giannakas et al. 2011).

Courts in many countries have already played a role in coexistence and will continue to do so in the foreseeable future. In their dispute resolution capacity, courts have been asked to clarify property rights and decide on the proper scope of regulatory policy. In the US, two challenges against United States Department of Agriculture (USDA) approvals of new GM crops considered the government's regulatory authority and obligations in the context of coexistence. As of this writing

[1]Measurement of social benefits and costs can be complicated by various theoretical and empirical considerations including uncertainty, irreversible effects, the choice of discount rates, the aggregation of consumer utilities, and certain non-economic factors (e.g. individual ethical views). In the case of biotech crops, such considerations have often proven both complex and contentious.

a mandatory GM state labeling law in Vermont is under judicial review. Cases involving disagreements between GM and organic producers in Australia, Canada, Germany, and the US have clarified, to a degree, the apportionment of responsibilities for preventing or mitigating the effects of gene flow. There have been a number of damage suits filed in the aftermath of a trade disruption between the US and China that was attributed to a seed company commercializing a GM crop variety before it was approved in all import markets. All such cases have helped establish more clearly the responsibilities and rights of different stakeholders in maintaining coexistence. Courts will no doubt continue to play a significant role in coexistence issues in the coming years.

Governments, producers, and consumers in different countries have continued to support the growth and success of GM, organic, and conventional crops and foods. Each of these sectors has experienced significant growth over the last 20 years and will continue to do so in the foreseeable future. The rapid adoption of GM crops has coincided with the rapid expansion of organic food production in the US, Europe, and other parts of the world. At the same time, robust markets for segregated non-GMO crops have also developed over the years and conventional rice, wheat, sorghum, and other crops continue to play key roles in the global marketplace. Under these conditions, efficient government regulations and best industry practices that promote innovation and social welfare while considering uncertainty in domestic and international markets will be important. Unfortunately, at this time there is only limited analytical attention to these issues. The purpose of this book is to examine the balance among market forces, government regulation, and the role of courts in allocating property rights, limiting externalities, and facilitating information flow in the marketplace, within the context of coexistence.

What is the Issue?

There is not one precise, universally agreed upon definition for coexistence, but most stakeholders hold some basic concepts in common. The USDA defines coexistence as "the concurrent cultivation of conventional, organic, IP, and genetically engineered (GE) crops consistent with underlying consumer preferences and farmer choices" (USDA 2016). The EU takes a slightly different view, stating that "The objective of coexistence measures is to **avoid unintended presence** of GMOs in other products, preventing the potential economic loss and impact of the **admixture of GM and non-GM crops**" (European Commission 2016, emphasis in original). In addition to definitions, coexistence policies and market strategies can also vary widely from one part of the world to another. Still, there are some common elements.

First, all of the definitions assume that the technical, environmental, and food safety aspects of the GM variety have been assessed by at least one competent national regulatory authority and subsequently approved for commercial release in at least one market. So in that sense, coexistence does not incorporate any

discussion of the underlying safety of the product. Rather, the discussion centers on the task of maintaining a multi-track supply chain, and the economic and regulatory factors affecting its efficient operation.

Second, concerns about coexistence typically emerge from the unintended movement of GM material into markets where it is unwanted or not allowed. Thus coexistence is generally characterized as maintaining technical separation between GM, non-GM, and organic production in local, national, or international production and distribution systems. The failure to sustain technical coexistence usually results in the presence of unwanted traits either domestically or internationally in seed or commodity shipments. In all cases, the questions of where responsibility lies for coordinating the employment of technical coexistence measures and where liability for the costs of those measures rests are paramount and in many cases are as yet unresolved.

Third, situations unique to international markets and international trade—asynchronous approvals, asymmetric regulatory approvals, or expired approvals—can significantly complicate the task of maintaining coexistence and are quickly becoming a major source of tension. Individual national regulatory systems operate on their own agendas and schedules. Gleim et al. (2015) showed that it may take up to 7 years for specific GM traits in key commodity crops to be approved in all markets. Because of such delays and in order to avoid market disruptions, many biotechnology firms that develop GM crops are committed to a program of product stewardship whereby new GM traits are not commercialized until they are approved in major import markets. However, no system is perfect and commercialization of GM traits approved in some parts of the world but not in others sometimes occurs and the resulting low level presence (LLP) of unauthorized GM material in selected markets disrupts trade. Asymmetric introduction of new GM traits and lapsing authorizations in importing markets have not caused significant market disruptions until now but could become key coexistence issues in the future as their number in the biotechnology pipeline continues to expand. In all, such market coexistence issues are quickly taking center stage in the ongoing policy debate.

The Scale and Scope of Coexistence Issues

Successful coexistence ultimately starts with active management in the field, the production landscape and across the agrifood supply chain as well as with effective domestic policies. There is not much disagreement on the sort of technical measures that are necessary to achieve coexistence in agrifood production and distribution. There is more disagreement, however, on the stringency of such measures, on who should be responsible for implementing them, and on who should pay the associated costs. These issues are addressed by a number of authors in this volume and their contributions clarify that coexistence costs in segregated production and distribution systems can, in some cases, be significant.

Still, trade and LLP may be the most immediate and pressing coexistence issues. In 2014, the FAO undertook an international study (Atici 2014) that surveyed 193 countries with 21 questions related to GM crops, including their production, regulation, safety assessment, detection and quantification, LLP incidents, and the importance of factors contributing to the trade risks posed by LLP. The survey revealed that about 20 countries and the EU reported at least one LLP event in the last 10 years. Depending on the market and the trait, the non-compliant shipments were diverted to biofuel production, rejected, returned, diverted to other markets, held until approved, or destroyed. Some respondents noted some shippers were fined.

In some ways, the fact that there have been so few LLP incidents is testimony to the efforts of stakeholders across the agrifood supply chain to actively manage their products in order to ensure appropriate matching with market specifications. The North American Export Grain Association (NAEGA) reports firms and relevant industry associations are proactively engaged in sampling, managing, and coordinating shipments, and where potential LLP events are pending they report they step in and manage the shipment to avoid triggering regulatory penalties. While there is no definitive data, the sense the industry gives us is that most weeks (if not days) the industry detects LLP in shipments and has to make a decision about how to manage the flows, either by diverting the flows with asynchronously or asymmetrically approved varieties or by greater blending to reduce any measurable amounts below the regulatory thresholds in the destination market.

Objectives for This Book

Coexistence is an inherently complex issue, as it requires knowledge in genetics, biology, agricultural production practices, supply chain practices, international trade, law, and economics. A key contribution of this book is that it organizes a large body of knowledge in a non-technical fashion and makes it accessible to a broad audience including policy makers, regulators, economists, lawyers, industry executives, and scientists with an interest in coexistence policies and their impacts.

Governments and market stakeholders in many countries are grappling with policy alternatives that settle conflicting property rights, minimize negative market externalities and associated liabilities, maximize the economic benefits of innovation, and allow producer and consumer choice. Yet a synthesis of best available practices and a framework for proper policy analysis does not currently exist. This book is intended to fill these needs with contributions from the top theoreticians, legal and economic analysts, policy makers, and industry practitioners in the field. As the economics and policy of coexistence start to take shape, the book will serve as a comprehensive resource for those entering the area.

Agriculture serves one of the most basic human wants. By providing affordable, quality food, food producers enable individuals to lead healthier, more productive lives. As such, it is in everyone's interest for agricultural and food markets to

operate efficiently. When markets promote and reward innovation, when improved productivity leads to welfare gains for all stakeholders, and when information moves freely among market actors, the full range of diverse consumer demand is most likely to be served. In order for this to happen, all stakeholders must discover the right balance between freedom of action in the market and consistent, efficient rules provided by regulators and court decisions. Ideally, regulations provide predictability and fairness in market relationships without hampering the efficient functioning of the market. The contributions to this book provide insights on how to find that balance.

Structure of the Book

This book provides an overview of the key challenges for managing coexistence at the farm level and within national and international supply chains, as well as an examination of the roles of governments and markets. Contributors review existing and emerging government policies and market practices developed across major producing and importing countries to manage coexistence. The chapters discuss coexistence issues from crop science, market, regulatory, and legal perspectives, critically examining the existence and nature of potential market failures and the varied responses from stakeholders in both agricultural markets and government.

The book offers a comprehensive treatment of the basic issues impacting coexistence, beginning with a technical discussion of a primary factor in coexistence, pollen flow (Chapter "The Science of Gene Flow in Agriculture and Its Role in Coexistence"), including related production externalities and on-farm methods of managing pollen flow. Following is a practical treatment of what coexistence means for day-to-day operations in the seed industry (Chapter "Developing Market Driven Standards for Coexistence: Tolerances, Thresholds, and Other Technical Standards Used by the Seed Industry") and in grain handling and transportation (Chapters "Economic and Legal Principles of Coexistence Policy in North America" and "Organic Label Rules and Market Tensions: The Challenge of Satisfying Buyers"). Here industry experts discuss considerations around technical measures for segregation, the importance of workable thresholds, and what conditions might be necessary for effective grain handling operations. The perspective then shifts to look at some government responses to coexistence issues. The next two chapters discuss the technical and legal issues in EU regulations (Chapter "Developing Solutions for Coexistence in The EU—Legal, Technical, and Economic Issues") and the principles used in developing those regulations, with a critical assessment of how they are applied (Chapter "The Principle(s) of Co-existence in the Market for GMOs in Europe: Social, Economic and Legal Avenues"). Brazil offers a differing example of the impact of coexistence regulations developed with considerable industry input (Chapter "Coexistence in Brazil"). In the US, by contrast, coexistence has essentially been left to the market. This presents an opportunity to examine market outcomes and question whether there are significant market failures

that require regulatory intervention (Chapter "What Can We Learn About Coexistence from Commercial Non-GM Programs in the US?"). The third major player in coexistence issues is the court system. Significant court cases have answered important questions regarding the extent of government regulatory authority and how property rights can be justly allocated, but have also left other questions unanswered. Three chapters examine two landmark US cases that examined the role of the USDA in coexistence (Chapter "Lessons from the Legal Cases of GM Alfalfa and Sugar Beet Deregulation in the United States") and cases in Australia and the US that impacted the property rights of different classes of producers and biotech development firms (Chapter "Organic Versus GM Agriculture in the Courtroom in Australia and the USA"), as well some important facets of coexistence that are as yet unexamined by US courts (Chapter "Coexistence—Under-Explored Facets for a USDA Policy"). This first part of the book concludes with an economic analysis of a landmark case in the EU defining property rights and liabilities of GM and non-GM producers (Chapter "The "Honey" Judgment of Bablok and Others Versus Freistaat Bayern in the Court of Justice of the European Union: Implications for Coexistence").

As described earlier, asynchronous approvals are a major factor in coexistence issues in international trade. In this arena coexistence is manifested as LLP of biotech events that are not approved in specific jurisdictions. Several chapters examine the lessons from trade disruptions due to presence of unapproved GM material in markets for flax (Chapter "The Canadian and European Union Impacts from the Detection of GM Flax"), maize seed (Chapter "Consequences of Adventitious Presence of Non-approved GMOs in Seeds: The Case of Maize Seeds in Germany"), and canola (Chapter "Commercialization Strategies and Market Opportunities for GM Canola"). The next chapter looks at the reasons behind LLP events and examines how regulatory delays have changed over time as well as the impacts on grain marketers (Chapter "Regulatory Lags for Genetically Modified Crops: Legal and Political Perspectives"). The chapters then move on to examine the global effects of regulatory asynchrony on three sectors of the agriculture industry. Since the international regulatory system necessarily deals with new products, it is natural to expect that regulatory delays and asynchrony would affect innovation in general and research and development activity throughout agriculture (Chapter "Regulatory Approval Asynchrony, LLP, and Implications for Biotech R&D and Innovation"). Estimates of the impacts of varying degrees of delay in international markets for two important crops, soybeans (Chapter "The Economic Impacts of Regulatory Delays: the Case of HT Soybeans") and wheat (Chapter "Potential Economic Impacts of Low Level Presence (LLP) in the Global Wheat Market") are examined. Regulatory asynchrony is the result of particular decisions about the structure and functioning of the approval process in specific countries, so the impact of those decisions on the countries that make them is a critical subject of research. Therefore the book includes descriptions and estimates of the potential economic impact of LLP incidents on Korea (Chapter "Potential Economic Impacts of Asynchronous Approvals of Biotech Crops on South Korea") and China (Chapter "Low Level Presence and Asynchronous Authorizations of Genetically

Modified Products in China"), and the role of thresholds on the cost of LLP events in small countries, using the example of Vietnam (Chapter "Asynchronous Approvals and the Low Level Presence of Unapproved GM Products in Imports: How ¨Tolerant' Should Small Countries be?"). Finally, three chapters examine possible paths to solving, or at least minimizing the cost of, LLP problems through the WTO (Chapter "Low Level Presence Under the WTO"), national stakeholder cooperation in standard setting (Chapter "Forging the Future of LLP: Building an International Coalition and Developing a National LLP Policy"), and possible international cooperation to develop market-based methods (Chapter "Market Solutions to Coexistence and Regulatory Asynchrony").

Even the most efficient coexistence framework would entail some costs to the market from the use of scarce resources. It is thus important to examine the origins and nature of such costs and how they might be apportioned among market actors. A formal model of the conditions under which coexistence can happen and some of the patterns of resource use implied by those conditions (Chapter "Coexistence of Genetically Modified, Conventional, and Organic Food Products: A Framework and Analysis") begins the discussion of this topic. Subsequent chapters include an estimate of the final consumer costs of non-GM versus GM food baskets (Chapter "The Cost of a GMO-Free Market Basket of Food in the US") and some of the costs imposed by the non-GM voluntary labeling regime in the EU (Chapter "Lessons from EU Voluntary Labeling Schemes for GM-free Processed Food Products").

Finally, we offer some concluding thoughts on some fundamental considerations surrounding coexistence. It may well be that coexistence goes much deeper than simple technical questions about the appropriate levels of thresholds or how to devise an efficient regulatory system. By looking at the different philosophical paradigms represented by the different sides of the coexistence issue, both in developed countries (Chapter "Welfare and Co-existence") and in the country of origin of the world's premier cash crop (Chapter "GM Maize in Mexico: The Challenge of Coexistence in a Centre of Origin"), the authors attempt to plumb the depths of the less obvious facets of coexistence. In conclusion, there is a synoptic summary and synthesis of lessons learned, along with key challenges for the future of coexistence (Chapter "Conclusions and Synthesis").

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The Science of Gene Flow in Agriculture and Its Role in Coexistence

Allen Van Deynze, Kent J. Bradford, Henry Daniell, Joseph M. DiTomaso, Nicholas Kalaitzandonakes, Carol Mallory-Smith, C. Neal Stewart Jr., Steven H. Strauss and Rene Van Acker

Introduction

Managing Gene Flow in Agriculture

Gene flow is a natural process that occurs among sexually-compatible individuals in which cross pollination can result in viable seeds. Gene flow between individuals within and among populations via pollen occurs only when they have concurrent geography, overlapping flowering times, and share common pollinators. Given a population size sufficient to avoid genetic drift, alleles that have neither positive nor

A. Van Deynze (✉) · K.J. Bradford
Seed Biotechnology Center, University of California-Davis, Davis, CA, USA
e-mail: avandeynze@ucdavis.edu

K.J. Bradford
e-mail: kjbradford@ucdavis.edu

H. Daniell
University of Pennsylvania, Philadelphia, PA, USA
e-mail: hdaniell@upenn.edu

J.M. DiTomaso
University of California-Davis, Davis, CA, USA
e-mail: jmditomaso@ucdavis.edu

N. Kalaitzandonakes
University of Missouri, Columbia, MO, USA
e-mail: KalaitzandonakesN@missouri.edu

C. Mallory-Smith · S.H. Strauss
Oregon State University, Corvallis, OR, USA
e-mail: carol.mallory-smith@oregonstate.edu

S.H. Strauss
e-mail: steve.strauss@oregonstate.edu

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negative impact on fitness will persist in the population at an allelic frequency equal to their introduction level. Alleles for genes conferring a fitness effect will be selected naturally for or against depending on the selection pressure. For example, the frequency of alleles conferring disease resistance may increase in the population in generations where a certain pathogen is prevalent but not when it is absent, while alleles conferring herbicide resistance will neither increase nor decrease in the population in areas where the herbicide is not used (Brule-Babel et al. 2006). Favorable genotypes for a certain trait are usually fixed at a more rapid rate in self-pollinating than in outcrossing species. Genetic and biological features such as polyploidy, fecundity, and generation time also affect shifts in allele frequencies.

Genetic diversity is essential to make progress in plant breeding. Allele frequencies are shifted for traits of economic value, such as yield, quality, or seed shattering, and also for adaptation to environmental stresses or for disease and insect resistance. Plant breeders and even early farmers have sought the added genetic diversity conferred by gene flow among and within populations, and only subsequently applied purifying genetic selections by inbreeding and fixing traits to reproduce economically favorable lines or cultivars. In the latter process, both physical and genetic (e.g., male sterility) mechanisms have been developed to stabilize and reproduce a desirable variety (e.g., a specific genetic composition) for farmers to grow. Thus, the presence or absence of gene flow are essential for agriculture.

Understanding the Implications of Gene Flow

On a scientific basis, gene flow can be defined as the transfer and introgression of genetic material (genes in living plant materials) from one plant to another (Ellstrand 2014). Gene flow is a two-way process that is ubiquitous in both natural and agricultural systems, but the extent to which it occurs depends on many factors, as do the consequences. In the context of trade, gene flow is used in a broader sense as the simple presence of genes via seed or pollen dispersal where plant tissues having different genotypes or phenotypes are present in a population, even without genetic introgression. It can also include persistence in the environment through vegetative propagation. The term adventitious presence (AP) is used in the industry to represent this type of gene flow. It can be neutral in effect or can have economic and biological consequences. Negative consequences in agriculture are largely associated with the unintended presence of certain genes or traits in products that

C.N. Stewart Jr.
University of Tennessee, Knoxville, TN, USA
e-mail: nealstewart@utk.edu

R. Van Acker
University of Guelph, Guelph, ON, Canada
e-mail: vanacker@uoguelph.ca

require high genetic purity, such as in seed production or markets that restrict the presence of genetically engineered (GE) traits. Negative consequences in the environment could be associated with transfer of specific traits to related wild relatives, thereby altering their fitness or success relative to other plants.

Agriculture in the United States is a major supplier of many commodity and specialty crops in domestic and export markets. To maintain competitiveness in the global market, agricultural systems depend on innovation; they must also be flexible to allow multiple production systems to evolve and coexist to meet specific market demands. At least three production systems, conventional, organic, and biotech (using GE or transgenic crops), are used and employ different product purity standards. In addition, both domestic and international commodity handling systems can require different standards even for the same products. Because agriculture involves biological systems and production in open environments, it is difficult to achieve 100 % purity or 0 % "contamination". To develop practical non-zero thresholdsand realistic market standards, the biological basis for gene flow must be understood. Transfer of genetic material may be due to pollen, volunteer seeds, seed admixtures, or vegetative propagules. Furthermore, as novel agricultural products are developed, an understanding of their potential for spreading and persisting in specific environments or in wild populations and the consequences thereof are needed prior to release.

Until recently, gene flow has primarily been a concern for the seed industry, which has developed certification programs and quality standards to assure buyers of the genetic purity of its products. Currently, controversial aspects of gene flow in agriculture largely derive from concerns about the possibility of genes from GE crops moving to related wild relatives or to conventional or organic crops. In some instances, large economic losses have occurred due to zero tolerances for admixtures due to gene flow, none of which were a food or environmental safety concern. Nonetheless, in order to avoid market impacts and associated economic losses, a comprehensive understanding and control of gene flow as well as realistic thresholds are required for consistent marketing of agricultural commodities. The goals of this paper are to: (1) review the current knowledge of gene flow in biological systems using case studies; (2) review the current and potential mitigation strategies for gene flow; and (3) review the economic impacts of gene flow in agriculture.

The Seed Industry Model

The global seed industry provides a time-tested model for practical segregation and identity preservation strategies. Coexistence between seed growers and farmers not growing seed relies on mutual respect and cooperation, a clear understanding of the biological characteristics of crop production systems, and diligence and effort on the part of the seed grower to achieve required standards. Seed producers have developed these principles over the last 100 years, adjusting them as new information becomes available and as cropping systems evolve. For example, the

Association of Official Seed Certifying Agencies (AOSCA) develops, monitors, and coordinates standards for seed purity among 70 member countries. Similarly, the American Seed Trade Association (ASTA) works with its more than 800 members and the global seed industry (e.g., the International Seed Federation) to ensure that practical standards are developed to support market standards. Under current regulations, USDA/APHIS evaluates potential risks to agriculture and the environment of biotech-derived crops and the National Organic Program sets standards for materials and processes that may be used to produce certified organic products.

ASTA has developed practical guides for coexistence (ASTA 2011b) and seed production practices (ASTA 2011a). Current mitigation strategies are crop-specific, adjusting for the biology of the crop and the environment in which it is grown. For example, outcrossing rate, pollen type, pollinator type, sexual compatibility, presence of related species, fecundity, seed dispersal, and dormancy are considered when evaluating risk. Based on these factors, appropriate distances from compatible plants can be recommended for a desired level of purity. Crop rotations and specific handling techniques are also specified. One of the most important components in all identity-preserved production systems is to begin with certified seeds that meet high genetic and physical purity standards. Seed purity tests (e.g., varietal purity, weed seeds, and inert matter) as well as genetic tests (e.g., grow outs, percent hybridity, and allelic markers) are used to monitor the effectiveness of the coexistence and identity-preservation standards. The ASTA, AOSCA, and seed testing organizations (e.g., Association of Official Seed Analysts and International Seed Testing Association) continuously work with the industry to update criteria to address evolving market and agricultural standards (Dunkle 2011).

Crop Considerations

Gene flow among crop plants has been reviewed from various viewpoints (Kwit et al. 2011; Ding et al. 2014) and the potential for gene flow to wild relatives in the top 25 crops in the world has been compiled (Gealy et al. 2007). Sexually compatible wild relatives exist in the U.S. for cassava, cotton, grape, oats, oilseed rape, sorghum, sugarcane, sunflower, wheat, and most of the commonly grown forest trees. Examples of gene flow from transgenics to wild or weedy relatives have been reported in at least 13 species. Although hybridization has been shown in these species, introgression was studied only in Brassica, wheat, and creeping bentgrass. In those cases, none of the weedy relatives indicated signs of invasiveness or selective advantage due to herbicide or insect resistance (Kwit et al. 2011). A summary of gene flow studies in crops was reviewed by Chandler and Dunwell (2008) and for trees by Dick et al. (2008; see case studies for recent studies). Based on these, appropriate schemes can be recommended for a level of purity desired (see Table 1 in Sundstrom et al. 2003, and Sect. "The Seed Industry Model").

Self-Pollinating Species

Self-pollinating plants have flower structures that promote self-pollination, as the pistil and staminate flower parts mature at the same time and the structure and development of the flower facilitate transfer of pollen from the anthers to the stigma, sometimes even prior to opening of the flower. Although many crop plants are considered to be self-pollinating, such as cultivated tomato, rice, soybean, wheat, and barley, there are few that are completely self-pollinating, as some level of gene flow can generally be detected. In addition, there is variation for these traits within a species and its inter-fertile relatives. For example in pepper and tomato, the length of the pistil relative to the anther cone surrounding it can vary among varieties, with extrusion of the stigma beyond the anther cone facilitating gene flow. Furthermore, species such as safflower are considered to be self-pollinating, yet honeybees will travel up to 5 miles to collect its pollen (Chaney 1985). If gene containment is necessary, effort is still required even for self-pollinating species as gene movement from crop to crop can be substantive, as has been shown for wheat, where 0.4 % (0.0 to 4.2 %) gene flow was detected in certified seed and 1.3 % (0–11.3 %) in farm-saved seed (Gaines et al. 2007; Willenborg and Van Acker 2008). This discrepancy underscores the effectiveness of seed certification programs in maintaining seed purity. Nonetheless, self-pollinating plants generally require minimal mitigation strategies to contain pollen-mediated gene flow to acceptable levels for the seed industry with isolation distances less than 1320 ft (0.25 miles) resulting in gene flow less than 0.1 %, the Foundation seed limit (see Table 1, Sundstrom et al. 2003).

Outcrossing Crops

Outcrossing crops can be wind-pollinated, as for many grass and chenopod species, or insect-pollinated. Gene flow in outcrossing crops has been re-visited with the introduction of transgenics for the reasons mentioned above, but also because new tools such as herbicide resistance allow for much better sampling, accuracy and statistical confidence to measure gene flow (Halsey et al. 2005; Van Deynze et al. 2005). For example, isolation distances for mitigating gene flow have been refined for maize (Halsey et al. 2005), cotton (Berkey et al. 2003; Van Deynze et al. 2011), canola (Rieger et al. 2002), alfalfa (Van Deynze et al. 2008) and sunflower (Reagon and Snow 2006) based upon improved data using herbicide resistance as the marker (see Table 1, Sundstrom et al. 2003). In general, pollen-mediated gene flow decreases exponentially with distance from the pollen source (i.e., it is inversely proportional to the distance) and is affected by the type of pollinator and pollinator activity (Van Deynze et al. 2005, 2008). Gene flow among related species has also been shown to be asymmetric; for example, when outcrossing occurred, Pima (*Gossypium barbadense*) cotton was preferentially pollinated by upland

(*G. hirsutum*) cotton compared to the reverse (Van Deynze et al. 2011). Moreover, temporal isolation is an effective means to mitigate gene flow. For example, gene flow was reduced from 1 to 0.1 % in maize by offsetting planting (thus flowering) by 7 days (Halsey et al. 2005).

Case Studies

Alfalfa

Extensive research was done to study gene flow and trait persistence in the environment of alfalfa genetically engineered for resistance to glyphosate herbicide, the first perennial and obligate outcrossing transgenic crop, prior to its initial deregulation in 2005 (Van Deynze et al. 2004). For example, gene flow using the primary pollinators (leafcutter bees and honeybees) in the main seed growing areas, establishment and removal of herbicide-tolerant alfalfa, control of feral plants, management of herbicide-tolerant weeds, shifts in weed species, and seed production and dormancy were studied and results were published (Van Deynze et al. 2004, 2008; Teuber et al. 2007). In alfalfa, the number of honey bee visits decreases exponentially with distance from the hive (Hagler et al. 2011). Gene flow was directly correlated to the species and the number of bees foraging (Teuber et al. 2011). When alfalfa seed production fields were pollinated with leafcutter bees in the Northwest US, gene flow decreased below 0.5 % at 1000 feet with no gene flow detected at 2000 ft. In California, where honeybees are used as pollinators, gene flow decreased from 1.5 % at 900 ft to below 0.5 % at 2000 ft, continued to decline exponentially to 0.03 % at 15,840 ft (3 miles) and was not detected at 26,400 ft (5 miles, Van Deynze et al. 2008). Although these studies indicate that gene flow can be maintained at very low levels with 0.5 miles of isolation, the industry has voluntarily elected to use a 5-mile isolation zone for production of transgenic alfalfa seed when using honeybees as pollinators. These preliminary studies were verified in field-scale experiments in 300 seed lots in eight western states where gene flow ranged from 0.0 to 0.2 % when the industry Best Management Practices were used (National Alfalfa and Forage Alliance 2008). Furthermore, areas such as the Imperial Valley in California (where other transgenic crops are grown) have elected not to grow transgenic alfalfa hay or seed in order to avoid potential disruptions in large non-GE/organic export markets. A number of such voluntary "Grower Opportunity Zones" (GOZ), either permitting or banning transgenic alfalfa, have been established in alfalfa seed production regions in the western U.S. (National Alfalfa and Forage Alliance 2015). This type of self-regulation that responds to market demands independently of legal regulatory requirements is typical in the seed industry (see Sect. "The Seed Industry Model"). Importantly, these measures are designed to minimize gene flow and do not aim to eliminate it entirely.

It is important to note that although alfalfa is the 4th largest crop (by area) in the U.S., only 1 % of the crop area is produced for seed, mainly in the western states of

the U.S. Gene flow from and to hay crops is an order of magnitude lower than among seed fields, as hay fields are usually cut prior to bloom and little viable seed is found in hay (Teuber et al. 2007; Van Deynze et al. 2008). For example, in experimental field tests in California using honeybees as pollinators and simulating worst-case scenarios where hay was allowed to grow to 20–50 % bloom, gene flow to adjacent seed fields at peak bloom at 165 ft was <0.5 % and 0.01 % at 350–600 ft. In commercial fields, gene flow from hay to seed was at least an order of magnitude less than between seed fields (Teuber et al. 2007; Van Deynze et al. 2008). As hay fields are routinely cut prior to seed maturation (due to a reduction in hay quality with blooming), gene flow is reduced to non-detectable levels in most cases (Putnam 2006). The exposure or risk for gene flow in alfalfa for hay is therefore drastically reduced compared to alfalfa grown for seed.

Alfalfa has no sexually-compatible relatives in the U.S., therefore outcrossing is limited to neighboring fields and feral plants. Feral plants are common on roadsides and provide an opportunity to harbor and maintain transgenes in populations (Bagavathiannan and Van Acker 2009; Bagavathiannan et al. 2011b). Although fecundity and seedling establishment were reduced in feral populations due to reduced pollination and allelopathic effects, feral alfalfa populations may have increased adaptation for survival traits such as overwintering (Bagavathiannan et al. 2010b). Mowing of feral alfalfa or spraying with herbicides was an effective method of reducing feral populations but will not necessarily eradicate them, given alfalfa's ability to maintain a seed bank (Bagavathiannan et al. 2010a, 2011a). The relative size of feral populations (tens of plants) provides limited attraction and pollen source for pollinators relative to cultivated fields, resulting in a large dilution of gene flow from feral plants. However, unless completely controlled, feral plants provide an opportunity for persistence of transgenes in the environment. In areas of seed production, feral alfalfa populations must be managed as prescribed by seed certification standards.

Cereals

Cereal crops, including maize, wheat, sorghum and rice, differ in their potential for gene flow (Sundstrom et al. 2003; Gealy et al. 2007; Mallory-Smith and Zapiola 2008; Kwit et al. 2011; Mallory-Smith and Sanchez Olguin 2011). Although both sorghum and maize are outcrossing, maize has no cross-compatible species in the U.S., whereas sorghum can cross with other crop species including forage Sudan grass (*S. bicolor* ssp. *drummondii*), the invasive weed species Johnsongrass (*S. halpense*), and shattercane (*S. bicolor* ssp. *arundinaceum*). Current cultivars of sorghum have not been invasive, so breeding for increased biomass is not considered to be a risk. Adding traits that may give a natural selective advantage, such as tolerance to drought and salinity, may pose a risk if outcrossed to invasive weedy species. Similarly, traits that may compromise control of weedy cross-compatible

relatives, e.g. herbicide resistance, should be considered in risk assessments. As agronomic trials are conducted to evaluate traits prior to regulatory approval for release, parallel risk management studies should be conducted. Conditions for such trials should enable containment while not being overly burdensome to developers, growers, refiners, or regulators. Coordination among these groups will ensure that crops can be produced sustainably with an acceptably low risk of invasiveness.

Biofuel Crops

Perennial and annual grasses are being evaluated for their potential to produce large amounts of cellulosic biomass to be converted to biofuels. The main traits being selected for are vigor, rapid establishment and growth, and production of digestible cellulosic biomass to be converted into alcohol biofuels. Except for the latter, these traits are also characteristic of many invasive grass species. The risk assessment of these selected crops and species therefore should be done in the environments targeted for their production. Science-based risk assessment procedures are well established for potentially invasive plants based on matching climate and environmental models to each species' natural habitat and biology (Barney and DiTomaso 2010a, b; DiTomaso et al. 2010, 2011; Quinn et al. 2014; Smith et al. 2015). These include:

- Determine the potentially invasive range using climate-matching analyses under various assumptions (e.g., drought tolerance) and scenarios (e.g., irrigation, climate change).
- Evaluate environmental tolerance (e.g., soil moisture stress) of target biofuel crops.
- Quantify invasiveness in susceptible habitats (e.g., riparian areas, woodlands, rangelands).
- Perform propagule biology studies (e.g., seeds, rhizomes, stem fragments).
- Assess hybridization potential with related native and non-native taxa.
- Evaluate competitive interactions with desirable species within specific habitats.

Based on these studies, it is predicted that although switchgrass (*Panicum virgatum*) is marginally tolerant of low moisture conditions once established, it is unlikely to be invasive except perhaps in riparian environments where moisture is present throughout the year and competition with resident vegetation is low (Barney and DiTomaso 2010a; DiTomaso et al. 2013). Furthermore, it also is unlikely to be invasive in cultivated conditions because of its inability to compete with faster establishing crop plants and its susceptibility to tillage practices during the early years of growth. While seeds are the primary dispersal propagules, plants can also propagate by rhizomes under high moisture conditions. Switchgrass is a native species to the Midwestern U.S. and has coexisted with several congeneric species,

yet has not been reported to cross with any other *Panicum* species, either native or introduced.

Another proposed biofuel species, giant miscanthus (*Miscanthus* × *giganteus*), is even less tolerant of water stress and only thrives in high moisture environments without competition. Unlike switchgrass, it is sterile and does not pose a risk via seed dispersal. While it does propagate via rhizome fragments, it does not produce new shoots from older stem fragments and has no sexually-compatible relatives in the United States. These characteristics greatly limit its potential to be invasive under cultivated conditions or in natural areas within Mediterranean environments. In contrast, giant reed (*Arundo donax*), also being considered for biofuels, is highly invasive in California and Texas and while it does not produce viable seed, it readily regenerates from each stem node and is easily distributed by plant fragments (Boose and Holt 1999; Mann et al. 2013). No studies of within-species gene flow have been reported for the grasses mentioned above.

Trees

To meet the needs of the traditional forest industry as well as growing demand for wood-based biofuels, transgenic trees are being developed and evaluated to improve the sustainability and efficiency of producing woody biomass (Nehra et al. 2005; Harfouche et al. 2010; Hinchee et al. 2010). Though they have not been bred for the long time periods of many agricultural crops, some interspecies hybrid trees are highly domesticated while others are hardly domesticated at all. However, many tree species have the capability to disperse pollen and seeds widely. The large size of trees and their outcrossing mating systems allow for gene flow among populations and sexually-compatible species over very long distances. Pollen can travel several kilometers in forest trees, especially those which are wind-pollinated, and seed of species such as poplars and willows can move long distances in wind and water. For example, Slavov et al. (2009) used paternity analysis to discover that approximately half of the pollen that fertilized seeds came from beyond 1 km in an area of dense cottonwoods in western Oregon, and approximately one-third came from beyond 10 km in an area of widely dispersed cottonwoods in eastern Oregon. Thus, the potential for very long distance gene flow must be considered for such outcrossing tree species. This biological reality makes full containment of research trials that extend even a few years very difficult. Strauss et al. (2015) argued that in addition to mitigation methods for selected traits (discussed below), allowances for adventitious presence at the research and early breeding phase are needed for recombinant DNA methods to be useful in tree biotechnology. This is especially appropriate for traits important to protecting forest health or that employ familiar genomics-based genetic modifications.

Gene Flow Mitigation Strategies

For most crops, the underlying biology and practical management of gene flow are well understood, with many examples of segregation to meet defined market thresholds, such as among field maize, sweet maize, and popcorn maize. Gene flow mitigation strategies are utilized to the extent required to meet market requirements, particularly when there is a market premium for higher purity. This is exemplified by vibrant seed and identity-preserved specialty markets worldwide. In general, the premiums received for segregated commodities have been in line with costs of preventing gene flow and other admixtures in such markets (Kalaitzandonakes and Kaufman 2006).

Gene mitigation strategies can be classified into those that act pre-hybridization or post-hybridization. Pre-hybridization strategies include genic and cytoplasmic male sterility, delayed flowering, parthenocarpy (fruit production without fertilization), transgene excision, chloroplast transformation, and cleistogamy (pollination without flower opening; Kwit et al. 2011; Ding et al. 2014). Post-hybridization strategies include transgene mitigation and selective terminal lines (e.g., V-GURTs, see below). With our increasing knowledge of the genetic control of plant reproduction, many novel systems are being developed and evaluated for control of pollen (Stewart 2007; Verma and Daniell 2007), seed (Lee and Natesan 2006), and even flower production (Liu et al. 2008) to address gene flow mitigation. For example, delayed flowering has been suggested as a method to mitigate gene flow by naturally selecting, inducing mutations in or modifying the *Flowering Locus C* (*FLC*) or *TFL1* gene, a repressor of flowering (Boss et al. 2006; Kim et al. 2007). The use of such systems would be limited to determinate flowering crops or forage and biomass crops where seed and fruit are not the harvested commodity.

For new or developing cases (as mentioned above), risk assessment procedures are well established as are proven methods for segregation and gene flow mitigation. However, diverse international regulatory schemes for transgenes and markets with zero-tolerance thresholds, combined with the ability to detect transgenes at extremely low levels, have complicated trade as pragmatic product-based thresholds utilized in the past are no longer sufficient. Still, existing segregation systems may provide models on which to build.

Biological Gene Flow Mitigation Strategies

Biological gene flow mitigation strategies were first discovered in nature through self-incompatibility systems found in many species that prevent successful fertilization by the same or closely related plants. Such self-incompatibility systems have been utilized, particularly in Brassicas, to produce hybrid seeds (Nasrallah and Nasrallah 1988). However, their complexity, due to the multiple alleles and loci involved, has limited their use to carefully controlled seed production fields.

Natural fertility control systems based on male sterility have been discovered and utilized in many crops (maize, rice, onions, carrot, brassicas, cucurbits, etc.). These systems are used to control pollination between plants to produce hybrids. Recessive male-sterility genes have been utilized, but these must be maintained by heterozygous sister lines and require rogueing of fertile segregants in the field to prevent selfing of female lines rather than hybridization with pollen parent to produce hybrids. Alternatively, cytoplasmic male sterility (CMS) systems, commonly due to non-functional mitochondrial genes that often are derived from crosses to distantly related species, have been widely adapted for hybrid seed production, as in maize, sunflower, Brassica, radishes, carrots, and onions. Complementary naturally-occurring dominant nuclear restorer genes to overcome the CMS are introduced for effective crop production where fertility is required to allow production of fruits/seeds in farmers' fields, as in sunflowers, maize, and oilseed rape. Although effective, CMS can be unstable under high temperatures as in Brassicas (Niewhof 1990). In maize, the widely used T-cytoplasm CMS source was associated with susceptibility to Southern leaf blight that resulted in epidemic failure of the maize crop in the 1970s (Weider et al. 2009). In reversible male-sterility systems such as CMS, restorer genes will segregate in subsequent generations, allowing for fertile progeny and thus gene flow in following generations. Flow of transgenes can be limited during seed production of genetically engineered hybrids (e.g., sugar beets) by having the engineered gene only in the male-sterile female parent. An interspecific genetic incompatibility system is being studied to control gene flow in maize that creates male and female crossing barriers depending on the allelic makeup of specific genes, including *teosinte crossing barrier1* (*tcb1*), *gametophyte factor1* (*ga1*) and *ga2* (Irish et al. 1994; Evans and Kermicle 2001; Kermicle 2006; Kermicle and Evans 2010). Ploidy level can be used to mitigate gene flow via seed as in seedless watermelon, where a seedless triploid product is produced. On the other hand, it has been shown that herbicide resistance was introgressed from tetraploid *Brassica napus* to its diploid progenitor *B. rapa* (Warwick et al. 2008).

Genic Male Sterility

Multiple methods have being proposed to control gene flow using genic or cytoplasmic male sterility via modification of genes controlling pollen development, fertility, and dispersal (Daniell 2002; Feil et al. 2003). The majority of methods focus on genetic constructs that disrupt the tapetum, a layer of cells found within the pollen sac that is essential for pollen development (reviewed by Daniell 2002). Transgenic male-sterile plants were first demonstrated in tobacco by expressing a chimeric ribonuclease gene in the tapetum (Mariani et al. 1990). Pollen formation is disrupted by driving expression of cytotoxic bacterial proteins such as barnase from *Bacillus amyloliquefaciens* and diphtheria toxin A with tapetum-specific promoters (Koltunow et al. 1990; Hird et al. 1993; Lee et al. 2003). These strategies have been

developed in oilseed rape, several genera of forest trees (discussed below), and *Kalanchoe blossfeldiana* (Wei et al. 2007; Garcia-Sogo et al. 2010; Elorriaga et al. 2014a). Transgenic expression of the diphtheria toxin gene under the control of a pollen-specific promoter in tobacco resulted in pollen ablation (Twell 1995; Uk et al. 1998; Moon and Stewart 2011). A promising system being developed for pollen ablation is based on expression of an EcoRI restriction endonuclease driven by a pollen-specific promoter, which has shown 100 % pollen ablation in initial studies (Moon and Stewart 2011), including a test cross in which there was just one "escape" among 30,000–40,000 progeny screened per event for one-third of the transgenic events generated (Stewart 2013).

Combined with regulations, market restrictions for lumber and energy produced from transgenic trees, and the amenability of intensively grown tree species such as poplar, eucalyptus, and pine to commercial vegetative propagation, there has been considerable interest in producing male-sterile or completely sterile trees. Such trees might not only enable sexual containment, but grow faster due to reduced investment in reproductive organs, and in some cases avoid allergenic pollen that can cause local health problems. Several promising approaches are underway for engineering complete sterility using RNA interference or directed mutagenesis against crucial floral genes such as production of proteins with dominant negative amino acid changes or suppressor amino acid motifs (reviewed in Brunner et al. 2007). Klocko et al. (2015) reported complete and stable (multi-year) sterility due to RNA interference against the poplar homolog of the *LEAFY* gene in field grown poplars. Tested in female poplars, catkins failed to develop or produce any floral organs, and vegetative morphology and growth rate were normal. A new approach is to specifically mutate such genes essential for reproduction by directed mutagenesis or gene-editing approaches (e.g., zinc finger, TALEN or CRISPER/Cas9 nucleases), which appear to have high efficiency in targeting specific gene modifications (Maggio and Gonçalves 2015). Extremely high rates of biallelic mutation, near to or above 50 % of transgenic regenerants produced, were reported in poplar for a lignin biosynthetic gene (Zhou et al. 2015) and a floral gene useful for imparting sterility (Elorriaga et al. 2015). Such methods should provide the most stable, as well as a fully predictable (in juvenile trees), form of genic sterility. Additionally, high levels of efficiency (in laboratory studies) for pollen-associated excision of transgenes have been previously reported (Moon et al. 2010) as an approach to floral sterility. Multiple-year field trials with ablation-based sterility systems in which an anther-specific promoter drives the expression of a cell toxic gene such as barnase (Mariani et al. 1990) have shown that complete or nearly complete pollen sterility can be achieved. Field data supporting this view have so far been obtained in poplar, pine, and eucalyptus (Brunner et al. 2007; Zhang et al. 2012; Elorriaga et al. 2014b). Although the ablation strategy is being advanced in trees, research is complicated by the need to evaluate performance in field experiments over multiple years under contained conditions. None of these systems are currently deregulated in trees in the U.S., though cold-tolerant and male-sterile eucalypts are currently under review for deregulation by USDA APHIS.

CMS and Maternal Inheritance

As noted above, male-sterile plants can also be generated via CMS (Chase 2006) and can be utilized for limiting transgene escape via pollen dispersal (Feil et al. 2003). One approach to inducing CMS blocks the production of functional pollen using mutations in the plant mitochondrial genome (Hanson and Bentolila 2004). Genetically engineered CMS also has been developed for biological transgene containment by modifying the tobacco (*Nicotiana tabacum* L.) chloroplast genome with the *phaA* gene encoding β-ketothiolase (Ruiz and Daniell 2005). The transplastomic lines were normal except for the absence of viable pollen. Male fertility in the engineered CMS lines could be restored by increasing photoperiod, which enhanced acetyl-CoA carboxylase activity and diverted acetyl CoA from β-ketothiolase, thereby reversing male sterility.

Chloroplast genomes are maternally inherited in most crops. Chloroplast transformation facilitates both transgene bio-containment and high levels of transgene expression, without the possibilities for gene silencing or position effects (Verma and Daniell 2007; Clarke and Daniell 2011). Tobacco chloroplasts have been stably modified to express traits such as herbicide, insect, and disease resistance; drought and salt tolerance; CMS; and phytoremediation capability. Chloroplast transformation has been demonstrated in cabbage, carrot, cauliflower, cotton, eggplant, lettuce, oilseed rape, poplar, potato, soybean, sugar beet, tomato, tobacco, rice, and wheat (Lee et al. 2006; Verma and Daniell 2007; Clarke and Daniell 2011; Cui et al. 2011). High expression of genes that prevent the development of pollen or seeds is afforded in maternally inherited chloroplasts, simultaneously providing an efficient method for containment of transgenes, especially when the product is vegetative (Arlen et al. 2007). For example in tobacco, only six paternal transmissions were identified among 2.1 million seedlings screened (frequency of 2.86×10^{-6}), highlighting the efficiency of the system to control gene flow in crops (Daniell 2007; Ruf et al. 2007).

Transgene Excision

Site-specific recombinases linked to pollen-specific promoters allow excision of transgenes from pollen, preventing expression of transgenes in progeny seeds and mitigating pollen-mediated gene flow. For example, transgenes were effectively excised from pollen in tobacco using Cre recombinase (Mlynarova et al. 2006). Several recombinases, such as ParA and PhiC31, have been shown to excise transgenes in plants and have the potential to be used for pollen-specific transgene excision (Thompson et al. 2003; Kempe et al. 2010). One novel resolvase (CinHI), a nuclease that is involved in DNA recombination, was adapted for transgene pollen excision in plants (Moon et al. 2011).

Conditional Seed Viability

It has become apparent that male-sterility systems, i.e., those that focus on pollenablation or removal of transgenes from pollen, address only half of the gene flow mitigation equation. For example, transgenic canola (*Brassica napus*) has been shown to be distributed outside of expected cultivation areas (Pessel et al. 2001; Aono et al. 2006; Schafer et al. 2011). Distribution of canola by roadsides likely indicates unintended seed spillage and subsequent establishment of feral populations. Varietal gene use restriction technologies (V-GURTs) can be utilized to confer conditional seed viability (reviewed in Hills et al. 2007). Originally patented as a "technology protection system" by USDA scientists (Oliver et al. 1998), the system was criticized for its potential to prevent farmers from saving seed from their crops. This negative connotation persists (e.g., under derogatory name "Terminator" technology), even though the same system could be used to mitigate transgene flow via seeds (Van Acker et al. 2007). V-GURTs utilize a conditionally expressed toxin or enzyme targeting the embryo late in seed development that renders the mature seed non-viable. The seed crop commodity can therefore be produced without affecting seed composition, but the seeds will not be capable of germinating, preventing spread of viable seeds. An important feature is a chemically inducible off-switch for the system, without which commercial seed production would not be possible. The initial patent used the *Cre-Lox* recombinase system to remove blocking DNA to activate the synthesis of a ribosomal inhibitor protein, but there are various routes to achieve seed non-viability. For example, using a "recoverable block of function" approach, germination-specific expression of barnase (bacterial ribonuclease) prevented germination, but this function could be blocked by barstar (barnase inhibitor) expression, in this case, under the control of a heat-shock promoter (Kuvshinov et al. 2001).

Prospects for Engineered Gene Flow Mitigation Strategies

Although genic and CMS male sterility and seed non-viability systems are considered effective gene flow mitigation strategies, without a reversible mechanism, these systems are limited to crops harvested for their vegetative parts such as forage or biomass crops. In addition, the lack of pollen production could create negative impacts on the pollen-feeding insect food chain (Mlynarova et al. 2006), and strategies that include cytotoxins may have potential toxicity to non-targeted organisms or cells. A potential limitation of using CMS as a biological containment tool is the potential for transmission of the transgene from the cytoplasm to the nucleus. In crosses involving parents with an alien cytoplasm, transmission of paternally-inherited plastids and mitochondria occurs at low frequency (10^{-4} to 10^{-5}) in many plant species (Svab and Maliga 2007). As a result, fertility may be restored at some frequency in CMS breeding populations (Schnable and Wise 1998).

A survey of all US permits and notifications (18,104 between 1985 and 2012) indicates that 206 conferring altered fertility have been issued for field testing in maize, eucalyptus species, European plum, loblolly pine, poplar, rapeseed, sorghum, sweetgum, and switchgrass with 77 different gene construct combinations, many listed as "confidential business information" (USDA 2012). Of all the genetically engineered strategies described, only the barnase system has been de-regulated and commercialized successfully in Canada and the US for inducing male sterility in oilseed rape with a reversible system for fertility restoration (Mariani et al. 1990). The barnase system has also been approved (but not commercialized) in the U.S. in chicory and maize. Use of DNA adeninemethylase gene affecting male fertility is also approved in maize. A summary of strategies being developed is found in Table 1. While it is envisioned that appropriate gene expression and effective gene flow mitigation can be obtained using engineered strategies, a more pressing question remains one of politics and perception: are engineered male-sterility and seed non-viability

Table 1 Summary of technologies under development specifically to mitigate gene flow

System	Crop	Regulatory status[a]	Reference
Control of pollen			
Chloroplast transformation	Tobacco	Experimental	Daniell (2007), Ruf et al. (2007)
Genic male sterility			
Barnase	Oilseed rape	Deregulated/commercialized	Mariani et al. (1990)
Barnase	Chicory, maize	Deregulated	Mariani et al. (1990)
Barnase	*Populus*	Regulated field trials	Wei et al. (2007)
Barnase	*Kalanchoe blossfeldiana*	Experimental	Garcia-Sogo et al. (2010)
Barnase	*Pinus taeda*, Eucalyptus	Regulated field Trials	Zhang et al. (2012)
Diphtheria toxin gene	Tobacco	Experimental	Twell (1995)
Transgene excision			
Cre recombinase	Tobacco	Experimental	Mlynarova et al. (2006)
Restriction endonuclease	Tobacco	Experimental	Stewart et al. (2012)
PhiC31recombinase	Wheat	Experimental	Kempe et al. (2010)
ParA recombinase		Experimental	Thompson et al. (2003)
CinHI resolvase	Tobacco	Experimental	Moon et al. (2011)
Conditional seed sterility			
Cre-Lox	Tobacco, cotton	Regulated field trials	Oliver et al. (1998)
DNA adeninemethylase	maize	Deregulated	USDA Biotechnology Regulatory Service (2012)

[a]Experimental refers to in lab or greenhouse only

systems acceptable to the public for gene-flow prevention purposes? With the development of non-food crops such as for bioenergy feedstocks or for synthesizing pharmaceutical proteins, it might be that the first commercial use and need for such technologies could be to limit transgene spread.

Practical Implications of Gene Flow Mitigation Strategies

There can be significant practical considerations and costs associated with implementing gene flow mitigation strategies associated with coexistence and identity-preserved products. Agriculture is inherently complex and includes numerous production systems that pursue multiple product standards to meet the demands of dozens of markets, even for a single crop. A primary convention in the seed industry, for example, is that the grower and value chain requiring a higher purity or identity standard, and therefore generally also commanding a higher market value, is responsible for meeting the required standard. The higher market value of the product compensates for the additional expense required to meet the standard (Kalaitzandonakes and Kaufman 2006). In the seed industry, identity preservation is achieved by cooperation among neighbors and other growers of the same crop to synchronize isolation distances, planting dates, rotations, and other methods to minimize gene flow to meet genetic purity standards. In some situations, GOZs may be established in which the majority of growers in an area self-elect to produce a certain commodity to capture specific higher value markets. For example, GOZs for production of sweet maize (vs. grain maize) seed have long been established in Idaho and have been established in a number of locations for both GE and non-GE alfalfa seed.

As a practical consideration, the footprints of isolation zones associated with gene flow mitigation can have considerable impact (Bradford 2011). As the area of an isolation zone increases with the square of its radius (area = πr^2), a 5-mile isolation zone encompasses at least 78 square miles or 50,265 acres, compared to only 3.14 square miles or 2010 acres for a 1-mile zone (ignoring the size of the isolated field itself). The sizes of isolation zones, which are directly related to the degree of purity required in the final product, can therefore have large impacts on the crop choices of surrounding farmers or on the feasibility of producing a particular crop product in a specific location. For this reason, seed production areas are often distinct from areas of concentrated production of the same commodity crop when large isolation zones are required. Isolation zones should therefore be adjusted according to science-based, crop-specific isolation distances and pragmatic purity thresholds should apply. Implementation of isolation zones must also be flexible and location-specific. For example, ordinances banning certain crops or production systems on a county-wide basis, as have been enacted in some locations for herbicide-resistant alfalfa (Marmaduke 2015), would impact crop choices of farmers on over 50 % of alfalfa production acreage with the large counties where it is grown in California (Bradford 2011).

Organic, conventional and transgenic crops all have a place in U.S. agriculture, and practical gene flow mitigation strategies must be appropriately considered and deployed. Enactment of strict liability approaches that could displace cooperation and coexistence may be avoidable with voluntary identity preservation practices paired with biological strategies to limit gene flow. Practices that have long been used in seed and specialty crop production to maintain isolation and genetic purity, described earlier, provide models for how this can be achieved.

Diverse Markets and Economic Considerations

Maintaining genetic purity for crops can drive value of diversified markets, such as by product type (e.g., high amylase maize) or by production systems (e.g., organic). Consequently, changes in farm operations for preventing gene flow as well as testing and remediation that are typically implemented in such production systems involve additional segregation costs that can be both direct and indirect (Kalaitzandonakes et al. 2001). Payable costs such as those resulting from modification of operations, additional labor and management (e.g., contracting costs, testing costs, third party certification fees, etc.), and liabilities from product failures (e.g., demurrage costs, costs of dispute resolution, etc.) are considered direct costs. Non-payable costs resulting from efficiency losses (e.g., underutilization of land due to use of buffer zones) and lost markets are considered indirect costs (Kalaitzandonakes et al. 2001; Desquilbet and Bullock 2002).

The cost of maintaining genetic purity can vary immensely across commodities, regions, and over time, and it can be influenced by many factors. For instance, while segregation may be expensive in cross-pollinating crops such as maize, it is a negligible issue for self-pollinating crops such as soybeans. Similarly, costs for required tests in non-transgenic commodities are related to the number of transgenic events deployed in the crop (Kalaitzandonakes 2011). The most significant driver of such costs, however, is the tolerance or threshold level that must be achieved; as tolerances diminish beyond certain levels, segregation costs increase exponentially (Fig. 1; Kalaitzandonakes and Magnier 2004; Kalaitzandonakes and Kaufman 2006). Low tolerances also mean additional testing and greater numbers of product failures (Desquilbet and Bullock 2002; Kalaitzandonakes and Magnier 2004). Under zero or near zero tolerances, production and trade of segregated crops can be easily disrupted (Magnier et al. 2009).

Coexistence costs are also embedded in the expenses associated with the regulatory approvals of transgenic varieties (Kalaitzandonakes et al. 2007). Regulatory compliance costs are large and can discourage the development of transgenic crops/traits with limited market size (Bradford et al. 2006; Miller and Bradford 2010). The costs of segregating transgenic materials prior to deregulation can be substantial in their own right, as a zero threshold is mandated during development and testing prior to receiving regulatory approval for commercial release. These costs are incurred in the field, greenhouse and transport of regulated materials for

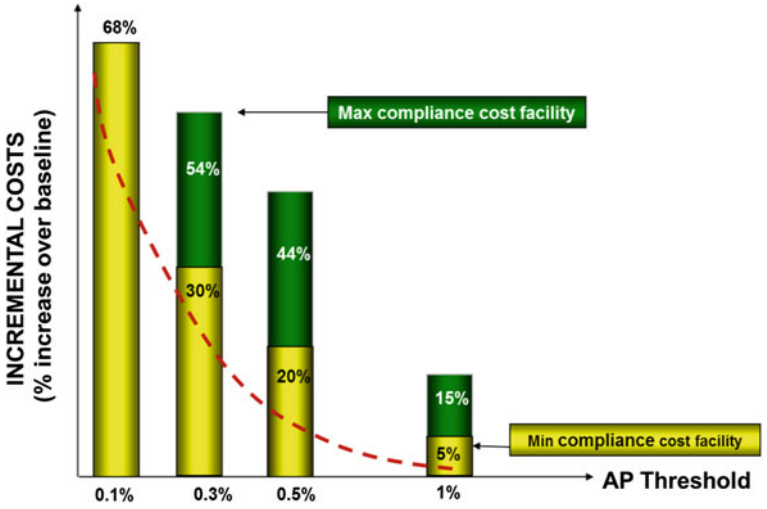

Fig. 1 Incremental cost incurred over standard practices (baseline) in segregated seed maize production programs (adapted from Kalaitzandonakes and Magnier 2004)

5–10 years prior to commercialization of individual transgenic traits (currently on an event-by-event basis), regardless of the trait. Once a transgenic trait is approved to be grown, it is allowed to be combined with non-transgenic commodities and marketed unsegregated in the US and other countries where it is approved. When the same commodities are to be marketed in countries where certain transgenic events are not approved, they must be channeled or segregated prior to entering those markets, i.e., identity preservation and stewardship programs must be developed to track the product from farm to final destination (Sundstrom et al. 2003). Failures to meet set standards and tolerances in segregated programs can result in market losses and liabilities. Such liabilities may involve legal claims or proposed compensation funds and their potential economic implications can be large (Bunge 2014).

Conclusions

The increasing complexity of U.S. and global agriculture requires coordination and application of practical coexistence systems. Gene flow is a natural two-way process that occurs among plants. Its impacts are specific to traits, crops, production systems, and environments. Gene flow mitigation strategies have been developed and are well-established in the seed industry. They currently serve the agricultural industry well for domestic and international trade in seeds and can serve as a model for crops with GE traits. They are based on knowledge of the biological/agricultural system, practical thresholds, coordination, and responsibility bestowed on the sector

requiring higher standards, which usually have higher market value to compensate for greater production costs. Except in the case of transgenic traits, they also incorporate pragmatic thresholds for low level presence. Emerging production systems and products such as transgenic biofuel crops and trees may require novel gene mitigation strategies, and possibly methods to impart both male and female sterility. Current and emerging biological technologies, including highly efficient mutagenesis methods such as gene editing, show promise for minimizing, and in some cases completely preventing, gene flow when strong containment is needed for biological, market, or legal reasons. Balanced risk assessments that evaluate both benefits and safety of new traits, including mitigation traits, are required to determine if a mitigation method is needed and what strategy is appropriate.

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Developing Market Driven Standards for Coexistence: Tolerances, Thresholds, and Other Technical Standards Used by the Seed Industry

Michael Gumina

The American Seed Trade Association defines coexistence as "The practice of growing, reproducing and handling seed products with different characteristics or intended markets with the goal of successfully achieving intended product integrity and maintaining economic value of such products." The principle of coexistence has been fundamental to the seed industry almost from the inception of creating specific populations of genetics intended for planting. In order for seed producers to successfully transfer the value created in a unique population, variety or hybrid, they must find ways to maintain purity and identification of those genetics throughout their life cycle. This can prove challenging in an environment dominated by commodity products of the same or similar species.

Over the centuries, seed producers have continually refined their practices to reliably deliver high quality seed to customers in a cost effective manner. In this chapter, we will briefly introduce an overview of some of these seed production best practices that have allowed the industry to coexist with other agricultural systems and more specifically with crops intended for food, feed, fiber or other materials. While this discussion is specific to seed production, many of the concepts can be directly applied to coexistence of other cropping systems. It will be clear that coexistence is not just a biotechnology issue and that multiple cropping systems have coexisted for many years.

The seed producer in this chapter is the person, company or entity striving to produce planting seed for the market. The seed producer may well engage other parties through contractual relationships to carry out various parts of the seed production process. These parties may include farmers, custom field equipment operators, field labor, insect pollinators, harvesting operations, pesticide applicators, quality assurance inspectors, contract drying, conditioning operators and others.

M. Gumina (✉)
RiceTec Inc., Houston, TX, USA
e-mail: mgumina@ricetec.com

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Seed Industry Best Practices

In seed production systems, the responsibility for meeting market and customer standards is borne by the seed producer. The producer must have a thorough understanding of the final quality requirements of the seed customers and the biology of the species they are striving to produce. With this knowledge, the grower can design systems that will consistently deliver to those final specifications.

Lot Tracking/Preventing Physical Mixing

Pollen from unintended sources is a challenge but physical contamination can also create problems with genetic purity. The seed producer must develop seed lot tracking and identification procedures and systems. These procedures and systems will maintain the history and characteristics of any lot of seed from research through production planning and seed production to customer use. Characteristics that would typically be tracked include parent seed lots used for production, seed field records, harvest records, storage location records, stabilization, conditioning, treating and packaging records and any other quality records or testing data.

Sanitation of planting, harvest and handling equipment is critical to maintaining the purity created in the seed field. Procedures must be developed to assure equipment is adequately cleaned of all seeds and weeds before use with a new batch of seed. These procedures often include checklists of critical points of cleaning where seeds can accumulate between seed lots. Cleaning methods include the physical removal and inspections using compressed air, vibration and water washing.

It is important to review all equipment designs and determine if modifications can be made to assure that any points that allow seed to accumulate after a seed lot run are eliminated or are at least safely accessible for cleaning.

Methods of Controlling Pollen Flow

The first step for any producer is to have an intimate understanding of the neighboring crops and any wild plant populations of a similar species in the geography in which they plan to grow the seed crop. This knowledge will allow the producer to quantify the risk of cross pollination from outside pollen sources. Forming an open and trusting dialog with other farmers in the area assures the seed producer will understand their plans ahead of the season and they will understand the producer's needs and goals.

With the information about other crops in the area, the producer can develop a plan to minimize exposure to external pollen sources. This is normally accomplished by creating distance between the seed crop and the potential cross pollinating crop or wild species. The distance required from the seed field to similar commercial crops or wild species depends upon the crop and the method of pollination of the seed crop. Self-pollinated species may require minimal distances whereas cross pollinated crops or insect pollinated crops may require significant distances. These geographic distances are known as isolation.

Other techniques also may be employed to minimize pollen flow into the seed field. These include the timing of the seed crop pollination to a period with low levels of pollen from nearby crops, planting border rows to dilute outside pollen sources and physical barriers such as tree lines, pollen nets or insect cages.

In the most progressive isolation programs, producers are able to work with neighboring farmers and other seed producers for multiple year planning and cooperation. These programs often use tools such as mapping and "pinning" to identify fields and the planned crop annually or for a two year period or more. Modern Geographic Information Systems (GIS) and Global Positioning System (GPS) software programs can be an aid to this type of planning.

The seed producer will observe the crop for phenotypic purity throughout the growing season. These observations will look for plant architecture, flower color, flowering dates, pubescent color, brace root color and other characteristics against the known true type. The producer will rogue out off-types as a way to remove impurities delivered with the parent seed or as volunteer seeds from a previous crop.

Season-long monitoring of the seed fields is an important step in documenting that intended isolations were actually achieved, the flowering intervals of potential outcross (unintended) sources with the flowering of the seed crop and the flowering timing (nick) of the seed crop parents. These observations will allow the producer to assess the potential for cross pollination with unintended sources. The producer can then plan for the segregation of harvest lots based on this assessment. The producer may segregate fields or portions of fields with higher risk until subsequent testing can give a higher level of clarity as to the actual purity levels achieved.

Seed Purity Testing

Once a batch has reached post-harvest storage, the producer will often assess the final purity. Since most of these tests are destructive, it is important to have a representative sample of the seed lot to test. These samples are normally collected using mechanical random sampling devices as the seed lot is being moved to a storage location. It may also be gathered using probing tools to access a cross-section of the storage unit. Other separation and mixing tools can help standardize and homogenize the lot so any test results can truly represent the characteristics of the entire seed lot.

A purity test could be a phenotypic assessment such as seed color, hila color or starch characteristics. Depending upon the species, the seed lot history, and customer requirements, these observations may be all that is required.

A traditional purity evaluation that will be more informative than seed characteristics is to grow-out a sample of the seed lot. The producer would plant a representative sample and make observations on uniformity of the plants in the test against the known characteristics of the desired product. These tests are effective but are very time consuming and expensive. The tests results can also be impacted by environmental conditions. The final results can give you a good indication of phenotypic uniformity but other techniques are needed to understand the true genetic profile.

Laboratory tests have been developed to assess genetic purity. Electrophoresis, a protein based test, has proven to be a good indicator of genetic purity for some crop species. Electrophoresis uses electricity to separate a known set of plant proteins across a gel medium. These proteins are mapped, are polymorphic for the crop being tested and can be used to form a genetic fingerprint against which the purity can be compared as an estimate of genetic purity. These specific protein profiles are referred to as markers. These tests are economical and fast but are limited by the number of markers and the overall resolution they give to genetic purity.

The latest generation of laboratory tests, such as SSR (simple sequence repeat) and SNPs (single nucleotide polymorphism), are DNA based. These tests provide many more markers and therefore much better resolution of overall genetic purity. These newly developed, sensitive tests are typically more expensive and require highly specialized equipment.

Various ELISA (enzyme linked immunosorbant assay) tests have been used to look for specific proteins often associated with transgenic traits or seed diseases. These tests can be run using sophisticated laboratory plate/colorimeter techniques or by using very simple lateral flow test strip protocols. These tests can be useful for understanding purity as it relates to a few specific proteins but they are not good indicators of overall genetic purity.

Any testing protocol carries with it a number of types of errors. The first exposure to error is in the sample. The extent to which a collected sample is truly representative of a seed lot is a measure of sampling error. Samples can be drawn to represent this population but the sample will never perfectly mirror an entire lot of seed. Efforts to minimize sample errors are critical to the quality of the test results.

The second type of error is assay error or testing error. Testing errors can occur from many different circumstances where the actual test protocol yields a result that is not accurate. Typically these types of errors result in either false positive or false negative results. Assays may also have some level of variability around the true result which can be measured using statistical analysis resulting in a coefficient of variation (CV). As we try to drive toward lower levels of detection in a test, the CV (variation) typically gets larger.

Seed Quality Programs

Some level of variability is inherent in any biological reproductive system and is reflected in applicable quality programs and standards. As a result, thresholds and tolerances are a component of most seed quality standards. These standards take into account the particular characteristics of the crop and the impact of impurities on the final performance of the crop in the next generation. The standards are normally consistent with quality requirements along the entire commercial supply chain and form the basis of industry practices related to coexistence. There are a number of local, national and international standards on seed quality. Three of the most referenced standards are those from the United States Federal Seed Act (FSA), the Association of Official Seed Certifying Agencies (AOSCA) and the Organization of Economic Cooperation and Development (OECD) Seed Schemes.

The FSA allows seed companies to label a product as a hybrid or variety as long as greater than 95 % of the viable seeds are true to the intended genetics. This standard also requires the seed producer to characterize the percentage of inert matter, weed seeds and other crops as part of the overall purity. It requires that seed shipped in interstate commerce be labeled with information that is truthful and allows seed buyers to make informed choices. The "Truth in Labeling" laws and regulations in the United States govern this program rather than third party verification before sale. The United States Department of Agriculture, through the State Departments of Agriculture, is responsible for sampling programs on seed that is offered for commerce to assure accurate labeling.

The OECD and AOSCA programs not only define post-control purity requirements but also define a number of in-process steps and measures that are leading indicators of final results. These measures include minimum isolation distances from unintended source crops, genetic uniformity standards for the parent seeds, pollen control standards, segregations and identification requirements, sampling and testing requirements. These are often referred to as certification standards and are required to be validated either through third party (outside) monitoring or audits of accredited company programs if you wish to certify a lot. These certification programs issue tags and certificates for those lots that meet the requirements to facilitate international movement of seed to markets that require quality certification (for example, Canada and European Union countries).

Some examples of OECD post-control purity standards are 97 % true types for single cross maize and sorghum, 90 % true types for Brassica species hybrids and 95.5 % for sunflower hybrids (2013 Scheme Rules and Directions).

Those seeds that do not match the description of the targeted genetics are referred to as off-types. Off-type can be disaggregated into four categories:

Self-Pollinated—a case where the seed parent pollinates itself rather than being cross pollinated by the intended pollen parent.
Male—a case where the intended pollen parent is inadvertently harvested and comingled with the cross pollinated seed.

Outcross—a case where the seed parent is pollinated by a source other than the intended pollen parent.
Other—a case where the genetics from neither parent is present in the genetics of the seed. This is usually the result of a physical mix somewhere in the production process.

A seed producer needs to have an intimate understanding of the final grain product specifications that their customers are trying to meet whether they use a certification program or not. While the certification standards and the FSA describe minimum levels of quality, many seed producers strive to greatly surpass these quality levels to better compete in the marketplace or to address requirements of specialty markets. Examples of some United States specialty grain channel contract requirements and tolerance are as follows:

- The maximum allowed for yellow endosperm maize in white maize is 2 %.
- The purity standard for amylopectin (waxy) maize content is 95 % minimum.
- Non-GMO soybean market growers must deliver to their buyers at 1 % maximum biotech traits.
- Clear hila soybean programs have a 0.5–1 % maximum for soybeans of other hila colors. The barge (bulk) market for clear hila soybean allows a 1 % maximum.
- In the U.S. non-GMO maize market, growers need to deliver to their buyers at 2 % maximum for GMO traits. There are a few smaller programs that have a 1 % maximum.

Biotechnology and Coexistence

It is clear that coexistence of biotechnology production systems with non-biotechnology production systems is driven by market conditions and demands and is not related to the safety of food, feed or the environment. Biotechnology products go through rigorous regulatory reviews that include product safety assessments before being released to the marketplace.

It is also clear that some segments in the marketplace prefer products that do not contain biotechnology elements and these preferences are described in various contracts and market specifications.

In many markets around the world, biotechnology enhanced species dominate commodity commercial production. Seed production in maize, soybean, canola and cotton that excludes traces of a biotechnology trait can be very challenging in these environments depending upon the thresholds and tolerances allowed. If the customer segments require levels of zero or very close to zero as a tolerance, seed producers must identify innovative practices above and beyond normal best practices to assure a favorable outcome. These practices will include parent seed that meets or exceeds the desired thresholds, isolation that minimizes biotechnology

pollen as a source and well defined handling programs that minimize the possibility of physical mixing of non-biotech seed with biotech materials. With the level of detection possible with the most modern assays, even residual biotech material dust can generate a test showing positive for biotech materials. All of this comes with a cost and additional producer risk to meet a step-change in purity required for these specifications.

Summary

The United States seed industry is committed to bringing quality seed to farmers around the world. Coexistence of agricultural systems is fundamental to the seed industry in meeting this quality commitment. The requirements of farmers and the grain market continue to evolve and the seed industry will strive to meet those changing needs. Current industry best practices will provide a solid base to deliver the product characteristics desired across these specific supply chains. No doubt new best practices will need to be developed to adjust to the biological and logistical realities of the specific product profiles and segment requirements.

Existing agricultural systems recognize the inherent variability in biological systems, so appropriate thresholds and tolerances have been put in place that allow for effective, efficient, and reliable supply chains. The markets and seed industry ideally would establish reasonable requirements. It is up to the seed producer to develop management programs that can meet or exceed the expectations of customers despite this inherent variability.

Resources

Organization for Economic Cooperation and Development Seed Schemes. The Organization for Economic Cooperation and Development Schemes for the Varietal Certification of Seed Moving in International Trade (OECD Seed Schemes) promotes the use of agriculture seed of consistently high quality. Certified seeds are produced—and officially controlled—according to common harmonized procedures in 58 participating countries. More information can be found at www.oecd.org/agr/seed.

Federal Seed Act. Under the Federal Seed Act (FSA), the United States Department of Agriculture (USDA) Agriculture Marketing Service (AMS) regulates the interstate shipment of agricultural and vegetable seeds. The FSA includes several definitions of seeds by class (Breeder, Foundation, and Commercial) as well as labeling requirements. More information can be found at www.ams.usda.gov/lsg/seed/geninfo.htm.

Association of Official Seed Certifying Agencies. The Association of Official Seed Certifying Agencies (AOSCA) sets out the minimum standards for seed purity and seed identity. It also recommends minimum standards for seed quality for the different classes of certified seed. More information can be found at www.aosca.org.

American Seed Trade Association Guide to Seed Quality Management Practices. General guidance for the development and production of seed products for the maintenance of product integrity and purity of both biotechnology derived seed and non-biotechnology seed, covering the stages of plant product life cycle from the point of incorporation of a trait into a breeding program through commercial seed production and sale. More information can be found at www.amseed.org/news_seedquality.asp.

Economic and Legal Principles of Coexistence Policy in North America

Randal Giroux

Introduction

Effective coexistence should assure the production of abundant supplies of safe and nutritious foods on a sustainable basis, while allowing customers and suppliers the freedom to choose whether to use conventional, organic, or agricultural biotechnology products consistent with these underlying consumer preferences and choices.

In the United States, several types of crops are grown, harvested, processed, packaged, and delivered to a diverse set of customers. Supply chains addressing these varying preferences have evolved several forms of successful coexistence that are commercially relevant and effectively meet the needs of the market. In the process of developing coexistence, stakeholders along those supply chains have discovered some basic principles that enable successful and sustainable supply chains. This chapter provides a general overview of commercial perspectives on managing coexistence, highlights some of these specific principles, and shares some lessons that Cargill has learned in both domestic and global food and feed supply chains.

Background

Cargill is a company that has been around for 150 years. Cargill started with a single grain elevator in Iowa in 1865. Over the decades the company has grown along with agriculture, agricultural producers, and customers of agricultural products.

R. Giroux (✉)
Cargill Incorporated, Wayzata, MN, USA
e-mail: Randal_Giroux@cargill.com

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Cargill generally has two customers. The first customer is the producer. Our producer customers range from small landholders in Côte d'Ivoire from whom Cargill buys cocoa all the way to large industrial farmers in Brazil who each may cultivate more than 100,000 ha. There is thus a broad spectrum, in terms of size and location, of producer customers that the company works with. The second customers are the processing or product companies that purchase products or processes from Cargill. Cargill is thus challenged to meet the demands of producers and end-use consumers. Cargill approaches coexistence as an interdependent system. Coexistence does not end at the farm gate; it ends at the consumer. It is a process that involves the entire supply chain for any specific product.

Agriculture has dramatically changed in the last 50 years, not only in the US but all over the globe. Even without the introduction of agricultural biotechnology, there have been major changes in the sector. Farmers in the US think about more than their local cargo facility: they think about the markets they sell their grain into, the types of specifications that end-use customers are demanding from grain handling companies, and the demands arising in the grain handling system itself. Agriculture has changed; it has become much more precise and considerably more customer driven. The balance of supply and demand has shifted. The US used to be a supply-driven country, but it is now largely demand driven. These demands are quite diverse, ranging from export market demands to the local demands of various meat and poultry markets. Previously, commodity markets were treated as "push" markets, where a new crop variety or food product was developed and then marketed to the consumers, in essence, pushing the product along the supply chain. Customers now tell us exactly what they want to buy from us and then we turn to our producer customers and tell them exactly what we need them to produce for those customers.

Sustainability and food security have come to drive the marketplace, often directed by a branded food company and framed around how many calories can be delivered at a price that people can afford to pay. This is the market definition of food security. Part of these discussions revolve around how we manage agricultural biotechnology and how we manage coexistence. Cargill's approach is to think about this as an opportunity. As with all opportunities that come along, some things have to be managed more than others. Coexistence cannot be discussed as simply a theoretical problem; it also has to be talked about as something that can be practically delivered through agricultural supply chains to customers. Secondly, coexistence is fundamentally about consumers—respecting the choices of consumers and finding ways that we can deliver to those consumers.

Critical Assessment

Coexistence is not a new concept in the US. There are lots of specialty products available in the US, delivered through both GM and non-GMO programs. There are many programs where there is some special attribute that an end-use customer is

asking to have delivered, e.g. specific starch properties or varietal purity, and Cargill has set up multiple supply chains of different sizes with different companies in the US to supply these special attributes. Some involve integrated supply chains, while others are a collection of different actors in the supply chain working together. Even without the issue of biotechnology in the food supply, these systems have emerged and will continue to evolve. There are some basic tenets of dealing with coexistence in the US that have grown as US agriculture has flourished.

Regardless of whether or not a commodity is a biotech commodity, there are four key tenets for coexistence systems. First, by necessity the specialty crop isolates itself from the generic commodity. It is important to clarify this up front. Often there is confusion what the commodity actually is. The commodity is not what commands the most acreage or is the largest volume being produced. A commodity has full or at least partial fungibility, which means that the market treats different allotments of the commodity as equivalent, or nearly so, with no regard to by whom or where they were produced. For example, #2 yellow corn is a commodity and would be bought and sold as equivalent whether it came from Ohio or Texas. During grain trading it can be swapped, sold, or substituted with other lots with the same designation. As soon as some additional specification is added to the commodity, it becomes a specialty product; it is no longer swappable with a generic product and substituting among lots is no longer possible.

A good example to demonstrate this difference is the non-GM canola market in Australia. Non-GM canola varieties are the most commonly grown, as GM canola was only recently commercialized in Australian market and the production of GM canola has not penetrated the market extensively at this point. So what would the commodity be in this case and which is the specialty? If a grain trader wanted to buy commodity canola in the market, they would likely get both GM and conventional, non-GM canola comingled in the marketplace if the grain trader had not specified that the canola has to be non-GM. If a grain trader goes to the market to buy non-GM canola and specifically asks for this as a specialty product, there will be limited fungibility for the seller to swap it in the open market. In this example, non-GM canola is the most widely grown product but it is still the specialty, value-added product.

During the launch of GM canola in Australia, the industry required that GM canola be segregated from the rest of the production. They treated the GM product as a specialty in the marketplace, when it had no added value to end-use customers and was being sold as generic canola. At some point in the future, if GM canola is successful in Australia, the marketplace will need to confront this mismatch in the marketplace and designate non-GM canola as a specialty product with a premium attached to it.

Second, by definition the customer or the consumer must be willing to pay a premium for a differentiated, specialty food product. The specialty product or commodity is the unique attribute that somebody is asking the market to deliver, whether that is pre-harvest or post-harvest applications of pesticides, non-GM, or organic. In the case of specialty markets, it is essential to define the marketing standards and thresholds to manage the products efficiently and effectively. In these

markets, the premiums paid by the end user should cover the full cost of commercialization. The customer that is demanding that the market deliver the specialty product must be willing to pay a premium for those special products. Specialty products have unique supply chains that in many cases do not operate as efficiently as regular commodity supply chains. For example, specialty product supply chains can often lead to half-full trucks, half-full elevators, smaller unit trains, additional testing, and isolation buffer zones, all of which impose incremental costs. And so, if the supply chain stakeholders cannot pass these costs along to the end-use consumer, somebody else in that supply chain will have to take on that additional cost burden, making business very difficult. So for a lot of these specialty supply chains to work there has to be an end-use customer who is willing to pay a premium for that specific attribute. A unique specialty product cannot and likely will not be provided to the market for free.

Third, coexistence systems involve explicit commercial agreements. It is always somewhat astounding that so much of the business with customers is done with a handshake. However, the delivery of specialty products requires contracts based on clear, verifiable and achievable specifications. A lot of business is done based on the trust relationship between the producer and the grain handler or between Cargill and our end-use customer, but there always is an underlying contract. The contract is verifiable and achievable and it underlies that transaction more so than it dominates the transaction.

Finally, for any kind of coexistence system to be workable we need to have identity preservation systems with market-based thresholds for accidental comingling or low-level presence (LLP). No agricultural system can deliver a product to an end user with 100 percent purity. There must be some threshold and tolerance for LLP. Zero tolerance is just not practically achievable in an agricultural system. The actual threshold level matters a lot. Figure 1 illustrates the challenges of trying to operate a coexistence system with low thresholds.

The challenge of trying to comply with zero tolerance thresholds, such as the one the European Union (EU) presently has in place for GM crop varieties that have not completed the EU regulatory system for GM crops is highlighted in Table 1. While

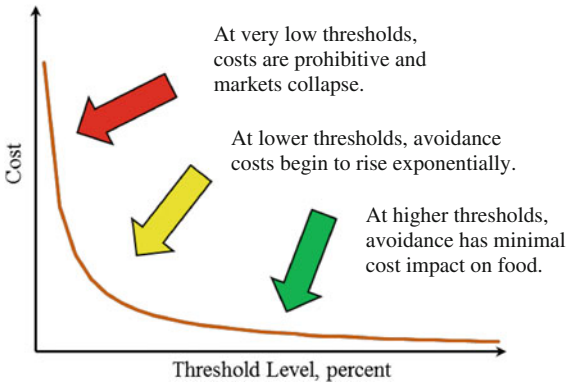

Fig. 1 Costs of managing low level presence of unintended comingling

Table 1 Relative scale of low level presence in various aspects of the bulk commodity trade

Shipment unit	Number of bushels	Number of metric tons	Number of soybeans (0.15 g/bean)	0.01 % of soybeans
Bushel	1	36.7 bushels/metric ton	181,333	18
Truck	918	25	166.4 million	16,640
Vessel	1.84 million	50,000	330 trillion	33 million

the concept seems easy, the relative scale of the challenge become daunting as produce is pooled and assembled for commercial shipment. The current scale of the unit shipment, be it the 25-ton truck or 50,000-ton vessel, suggests that even trace elements of GM events in a commercial shipment could lead to market disruptions.

Ironically, the EU has higher tolerance levels for extraneous materials, which are defined as insect fragments, stones, livestock antibiotics, chemical residues, weed seeds, and manure, than for GM elements. By almost all measures of risk management, those other factors have a much higher potential to be a food safety hazard than the low-level presence of GM crops.

Coexistence Consequences

Managing coexistence in the US has generated a lot of discussion about whether to fence-in or fence-out specific commodities. If coexistence in the US is taken as the example, then the specialty commodity can be viewed as isolating itself from the larger, bulk commodity or fencing the technology out. The specialty waxy corn grower, whose production commands a premium in the market, will isolate the product from commodity agriculture to ensure the market premium. In essence, this producer is fencing out other technologies. A non-GM or organic producer, for example, will use field buffer zones on their farm if they expect their neighboring commodity producers to grow GM crops.

If one looks at the history of agriculture in the US, this should not probably be a surprise. The concept of the minority isolating themselves from the majority has been common practice dating back over a century. One example in the history of US agriculture is the Open Range Laws. When farmers began to settle the American Midwest, there were more cows than corn. If a farmer decided to grow a crop, then it was that farmer's obligation to do something to ensure that this crop was not damaged by grazing livestock, so the farmer would put a fence around the field of corn. Hayter (1968, 106) observed that, the "traditional system of fencing crops in and livestock out gave rise to incessant quarrels and feuds."

As the demand to fence-in crops expanded across the US, agriculture was stalled in Illinois for a significant period of time because there was not enough fencing material for farmers to put fences around their crops. Over time though, as more

crops began to be produced and the number of grazing cows declined, there started to be a shift. The shift was not only between livestock and crops, but also in attitudes about who should pay and who is responsible for isolating one thing from something else. Subsequently, there have been changes in the Open Range Laws so that now it is the farmer who owns the cows who has to put a fence around his livestock. It would now appear, to some extent, that this discussion between biotechnology, conventional, and organic agriculture in the US is a replay of something that happened many years ago.

The notion that somebody (i.e. the technology developer) is responsible for fencing-in a new technology has a lot in common with the polluter-pays principle. This is an internationally recognized OECD environmental principle that has been codified in some countries, but not in others. This most often gets applied to instances and places where there are significant emissions of things that can be harmful to the environment. The question that arises in this situation is whether pollen can be classified as pollution to the same degree as air borne emissions or water pollution. Ludlow and Smyth (2011) discuss the challenges of taxing externalities and reallocating the revenue. Cross-pollination among crops, including GM crops, is not normally viewed as an environmental risk per se, but more of a marketing issue. Further discussions are required on whether it is appropriate to apply this principle to marketing issues.

Figure 2 illustrates how this may play out in global agriculture and individual nation states. Import nations appear willing to continue to adopt biotechnology. We expect to see differential productivity growth for GM crops driving further uptake and use, resulting in non-biotech crops becoming more of a specialty item (panel A). Price differentials will continue to grow between conventional and GM grain products. From a dollars-per-acre perspective most farmers will benefit from biotechnology because they generate higher per acre profits, not to mention some important benefits in terms of sustainability and productivity.

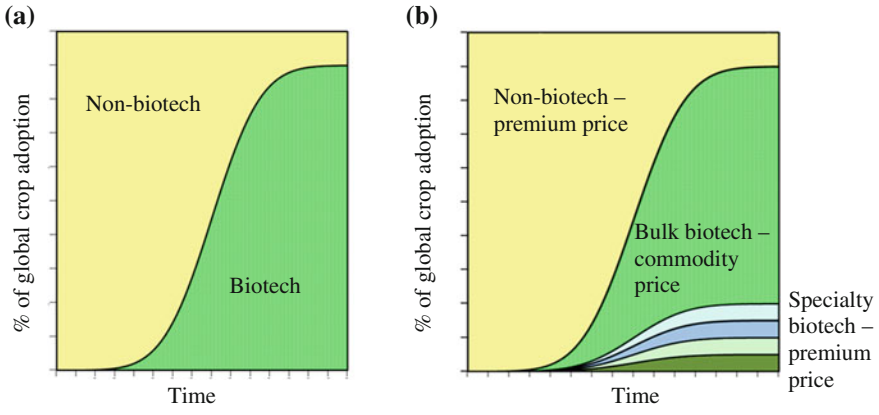

Fig. 2 Future trends in commodity agriculture

The efficiency penalty for not adopting biotechnology will continue to grow. Efficiency penalties for non-GM crop production arise because non-GM crops are usually less efficient than GM varieties in terms of production and sustainability. This should lead to price premiums for farmers growing non-GM crops (panel B). Farmers will have to receive higher and higher premiums per bushel to grow non-GM if the productivity gap continues to grow between GM crops and conventional or organic crops. But most importantly, non-biotech will become a niche product in the world (it already has in many countries). In the United States, the present market scenario would be very far to the right-hand side of panel B in Fig. 2 for a lot of our major commodities.

One area where Cargill sees a lot of growth potential over the coming decade is in value added opportunities for farmers from producing functionally-unique products. Products with unique functional characteristics could be high oleic soybeans or a specific corn variety for biofuel. These represent value-added opportunities for producers to be part of identity preservation systems that will be designed to meet consumer needs by supplying these types of products. There is a substantial potential for groups of farmers and supply chains to take advantage of more of these value added programs. Hopefully price premiums will emerge and continue in these markets and production of these products will continue to grow.

Managing coexistence requires a comprehensive view of the supply chain. Coexistence does not end at the farm gate. Sufficient information has been gathered about pollen flows, but we continue to lack some solid data on coexistence as product moves into highly efficient supply chains. If the US is taken as an example, three types of coexistence discussions have developed.

The first coexistence discussion is between conventional and GM crops. There have been numerous lawsuits in this area and numerous discussions are taking place. It is important to maintain our focus on the real issue here. Everyone involved in agricultural production has a stake in this and should be involved in finding a solution that works.

The second type of coexistence that is emerging in the US is coexistence between domestic and export markets. There is a lot of dialogue in the US regarding regulatory approval of new traits and the companies that choose to commercialize these traits ahead of a key export market approval. It is very possible that commercialization of events that are not approved in key export markets could create significant risks for exporters to those countries. With zero tolerance and aggressive testing of these massive shipments, there are huge potential risks in exporting and managing the export market. It is in the national interest for US farmers to both have access to the most innovative technologies and to sustain export markets. Aggressive commercialization of new traits creates significant risk for supply chains. It is important that all producers engage in discussions about this type of coexistence.

Lastly, coexistence is emerging between commodity products, such as generic grains and oilseeds, and those products with unique functional characteristics. The discussion is largely market and quality-risk based, incorporating issues such as knowing what these risks are, the managing these risks, and the balance between risk

and reward. In this discussion, it is crucial to remember that when introducing new speciality products, the market price must cover the full cost of commercialization.

These three very dynamic discussions are going on the US. They are not just about protecting organic and commodity crops but also about sustaining the GM commodity business in the face of sustained technological and product innovation. All of the sectors are stakeholders. While it is also important to have a positive environment for innovation and we have to find ways to innovate to improve agriculture, it is important to recognize that technology commercialization can create financial risks. This is at root about respect and recognition between stakeholders and the supply chains and using the courts will be the least desirable approach to find a commercial solution. Figuring out how to manage coexistence will provide a way forward that benefits everybody.

Summary

Coexistence is a long-standing issue in agriculture, with previous debates about fencing-in and fencing-out livestock and crop production providing a basis for current practice. Viewed from this perspective, coexistence is not just about GM and non-GM crops, but rather about delivering a specific product to consumers. As supply chains continue to differentiate into increasing numbers of specialty commodities, coexistence will become a more broad-based issue affecting all stakeholders in agricultural production and distribution. Resolution of the coexistence challenges requires input from all supply chain stakeholders and a shared responsibility to make this interdependent system work effectively and efficiently.

There are four principle considerations in arriving at a workable solution to coexistence: specificity of the products; consumer willingness to pay a premium; clear contractual agreements; and market-based thresholds for LLP. Zero tolerance thresholds are unrealistic compliance measures to impose on the grain trade industry as they are realistically not achievable.

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Organic Label Rules and Market Tensions: The Challenge of Satisfying Buyers

Lynn Clarkson

Introduction

Clarkson Grain has been in business since 1974 and manages trade in organic maize and soybean products. We handle organic, non-GM, and GM maize, including white, yellow, blue, and waxy varieties. Our client and producer base is global but concentrated in North America.

Coexistence is an important issue in our business. Our focus is on maize, because coexistence in maize is a bigger challenge than soybeans. The main challenge is to avoid contamination or "adventitious presence" of non-GE and organic maize through seed impurities, cross pollination and less than perfect handling control during and after harvest. How the commodity trade industry decides to deal with this will play an important role in determining how US agriculture will evolve over the next 20 years. We could continue the open-range argument or regulate to protect the market. Two key questions arise from this: How do we respect each other's rights? What tolerance levels do we accept?

Background

Clarkson Grain was satisfying numerous organic food processors prior to the National Organic Standards enactment in the US. The system of new rules had a dynamic effect on the presence of organic produce in the marketplace. In the US today, the organic market accounts for approximately 14 % of all fruits and vegetables purchased and 12 % of dairy products. These are not small numbers; they convert into huge dollar values. The grain market is still probably <1 % organic.

L. Clarkson (✉)
Clarkson Grain, Cerro Gordo, IL, USA
e-mail: lynn.clarkson@clarksongrain.com

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Currently, products displaying the USDA Organic Seal have to have at least 95 % certified organic products. There are a number of label categories, including "100 % organic" (all organic ingredients and processing aids), "organic" (at least 95 % certified organic ingredients), and "made with organic" (products contain 70–94 % organic ingredients). If a product is <70 % organic it is possible to put an organic ingredient on a product label, but the product cannot be called organic (USDA 2012).

The National Organic standards also include a list of excluded methods, things that cannot be done in producing organic crops. Genetic modification is an excluded method. Organic rules in the US started with the Organic Food Production Act in 1990, well before the introduction of GMOs into commercial production. The first draft of the National Organic Program (NOP) accepted GMOs, provoking over 200,000 comments to the USDA. It was without a doubt the most controversial proposal during the development of the National Organic Program (NOP). When the draft became the national standards in 2002. Genetic engineering was listed as an excluded method.

Organic certification is a process standard, not a tested standard. The NOP did not establish a tolerance level for GM comingling. Adventitious presence (AP) of a GM crop in organic products did not necessarily compromise the organic nature of the product and the buyer could rely on the organic certification passed along the chain of custody. The organic certificate meant that an organic product or food could be guaranteed as being organic due to the paper trail that was created. This provided some efficiency to market that did not previously exist. Prior to this standard, there were numerous disputes with respect to organics. The rules clarified a lot.

Some members of the food community have been concerned that a tolerance level does not exist in organic agriculture. The Non-GMO Project was established to be the lead on managing this situation. The Non-GMO Project is North America's leading third-party agent for verifying and labeling non-GMO food and products. Essentially this grafts private standards onto organic's officially defined process standard. In that way it is able to apply market pressure along the supply chain. Most consumers who wish to avoid GMOs in their food recognize organic as the gold standard. However, the market reality is that there is neither a zero tolerance policy nor guaranteed testing to support that demand. Unlike the EU, there is no official tolerance level for labeling and, more importantly, zero GMO presence is difficult if not impossible in open agriculture, given that more than 90 % of US maize uses genetically modified seeds. The reality is probably, truthfully, that no one knows what the level of GMOs are in organic food. Private collaborative efforts set a private tolerance standard and buy only organic products tested to that standard. Companies like Clarkson Grain that test every load received find that, on average, every non-GM maize shipment has approximately 0.5 % GM maize comingled.

The Non-GMO Project has more or less established a 0.9 % standard. This standard allows some flexibility in the system—it is not a deal-breaking standard to meet, but is a target that buyers would like to see. As this has moved into the

marketplace, buyers are now requesting organic with Non-GMO Project certification. This is a new ballgame for the organic world, as the creation of supply chain pressure changes the risk calculus for an organic farmer.

Organic farmers, and the entire supply chain that depends on their organic production, know that there will be a certain quantity of organic product demanded at harvest. But until the tested standard is applied to the final product after harvest, the individual organic farmer does not know whether his crop will be organic. That abruptly raises his risk. As a consequence, it becomes more difficult to find organic farmers in the US, since for many that risk outweighs the benefits of selling into the organic market. It may make us more reliant on imports from large foreign operations, especially farms that used to be collective cooperatives in China, where they are buffered by forests or other significant physical barriers. At the same time, it creates price and provenance uncertainties for consumers who are concerned about this issue. Uncertain supply often leads to high and volatile prices. As with virtually all things, there are pluses and minuses.

Critical Assessment

In the organic grain business, testing for GMO content is important, especially when consumers want to know if organic products are free of GMOs. The short answer is, no, they are not. However, to further clarify this, Miles McEvoy, who directs the National Organic Program with USDA in Washington, DC recently noted that "Under 7 CFR § 205.670(b) certifying agents may test organic products when there is reason to believe that excluded methods were used in production or handling of an organic agricultural product. Certifiers may also collect and test organic products from organic handlers to ensure that practices are in place to prevent commingling or contamination during handling and processing" (McEvoy 2011). Ideally, this means that organic agricultural products should have minimal, if any, GMO contaminants. However, USA standards for organic food products do not have a zero tolerance for the presence of GMO material.

Testing of organic products is difficult for buyers to understand. Certifying agents may test products when there is reason to believe that there is low-level presence, or any presence of GMOs. Based on testing results, we estimate that the average comingling of GM maize in organic shipments is 0.5 %, so one could always make the case that there are GMOs present and, therefore, tests could be run. In September 2011, our company learned that if GMOs are detected when testing, certifiers are now asking to be informed so they can investigate. The investigation goes back to the farm level to determine if the farm plan provided enough separation to avoid GMOs.

The concept of how much GMO avoidance is manageable is now being posed to organic producers and the trade. If we move to zero percent threshold for comingling, then the whole organic industry would likely be impossible. A threshold of 0.9 %, on the other hand, could be manageable. Ongoing discussions suggest that

the organic sector in the United States may come to agree on a tolerance level that would be around 0.9 %. At the present time, though, it is still uncertain what the end result will be.

It is important to realize that for years the standard way of handling market disrupting presences in the grain world has been blending. In a non-GMO world with realistic thresholds, blending can solve almost any AP problem. The difficulty is that with an organic product, it is prohibited under the rules to use GMOs anywhere. Therefore, blending is not allowed because it would entail introducing GMOs into the organic product being used to dilute the product. This eliminates one simple way of managing what can be a very expensive problem. For example, if GMO presence above 0.9 % is detected in a shipment that is destined for organic use, the lost value would be approximately $5 per bushel of maize or roughly $200 a metric ton. This is a significant amount given standard shipments of either 25 tons per truck (equal to $5000 per shipment) or 50,000 tons per vessel (equal to $10,000,000 per shipment).

One practical, market-orientated solution uses identity preservation (IP) protocols, which are well standardized in the seed industry. Based on our company's experience from testing every load we handle, the cost of the test kits is $20 per load and there is probably another $15 of administrative cost for each truckload, so the total testing cost is about $35. Occasionally we do reject a load, but not very often. Overall we have achieved a 0.9 % tolerance threshold that is satisfactory to most of the markets that we serve.

There are some common values emerging that can be used to grapple with coexistence. Coexistence is not just an organic or GMO issue or a seed issue, but an agricultural issue for the whole supply chain that focuses on purity and choice. Food processors are almost always concerned about product consistency; they want greater purity consistency. There are advantages to this, both product and process, which can amount to over 30 % differences in productivity in some process fields. One of the major grain firms in the US switched from a graded product to an IP product, which increased their process yield by 35 %. This is not inconsequential.

Today we have the issue of coexistence of GMOs with non-GMOs. The day may come when we have conflicting traits in the market, where one company's treasure is another firm's disaster. We will frequently have new GM trait introductions, with coexistence thresholds anywhere from one seed in a thousand to one in a million. This opens up the possibility of multiple conflicting traits in the supply chain at some point in the future. Under the current regulatory structure, it is very doubtful that we can have successful coexistence in this situation.

One example of this potential conflict is amylase maize that was approved in February 2011. Who wins with the commercialization of this variety? The seed salesman hopes to win and the ethanol industry undoubtedly wins as this is a fantastic feedstock for the production of ethanol. For the ethanol industry this is a wonderful development, as the maize comes equipped with its own enzymes. These enzymes digest corn starch to assist the process line for ethanol. The difficulty is the amylase maize is ill suited to many other maize product lines, and in some cases

may cause degradation of maize function. From the perspective of a firm that makes corn flakes or tortilla chips, such as Kellogg or Frito Lay, this could be a product disaster. If amylase maize comingles at a high enough level, they will not know whether the tortilla chip will be soggy or solid until the box sitting on the grocery shelf is opened. In my mind, this is a game changer for US agriculture. This is not meant to criticize or find fault with either the players involved or the USDA. They played the game the way it is supposed to be played. They used the rules that we have. However, we as a community could have better rules. To some extent this is a potentially beneficial situation, because it offers an opportunity to focus attention on possible improvements to the regulatory structure.

The difficulty facing wholesalers is that the comingling threshold level for action, where you change the nature of the crop in the field next door, is currently one part in 10,000 (based on information provided by the petitioner). Marketers and grain handlers cannot test for one part in 10,000 in the context of a fast moving, dynamic grain handling system. To be able to reliably test at this level requires more time than either the buyer or the farmer has available. The grain handler would need to hold a truck for a few days while waiting for the test results. They could not risk putting the shipment in a bin, because if it tested positive for a conflicting trait it could ruin the value of the grain already stored there. This cannot work. Something has to give.

The leading state for concentration of ethanol plants happens to be Iowa. If this is as good a product for the ethanol industry as it appears to be, there will be a migration of more and more acres in Iowa to amylase maize. Wholesale grain handlers who buy for and supply the food industry have to think about what they are going to do in placing contracts. In the absence of any new rules or processes, such a wholesaler may shy away from contracting for supply from the state of Iowa, because there is a new genetic variety out there that they, as a practical matter, cannot test for during a harvest situation. This will undoubtedly affect the choices of a lot of people.

One potential solution would be for amylase maize to have a color marker. It would not really have to be visible to humans because the white maize provided to tortilla makers, or any food company, is currently run through optical scanners. This process is probably about 99.8 % efficient, but it is not perfect. If there were a marker that could be sensed, even if it is infrared or ultraviolet (it does not have to be in the visual spectrum to be sensed by machines), this would allow grain marketers to be as close as possible to technologically pure. It would also be very helpful to have test kits available before a new trait or a new event is commercialized into the market. Ultimately, building in coexistence measures in the seeds themselves makes a lot of sense. One current option might be for the organic and the non-GMO industry is to use technologies like the PuraMaize gene in the construction of new varieties as one way to assist crops to resist pollen from other maize hybrids.

Coexistence Consequences

Farmer choice and buyer choice are important considerations in the food grain industry. Ideally we would have a good-neighbor policy where what a person raises on his farm does not determine what the neighbor's market is going to be. We cannot consider zero tolerance as a threshold—that is impossible to achieve—but there has to be some reasonable tolerance level that will make coexistence work. We need to find some balance that will encourage innovation. The organic agriculture sector does not need to oppose GMOs; GMOs can bring us some wonderful things. But there is a need to consider the economic and market impacts of new GM trait introductions before approving them.

This will require a change in legislation, a change in the authority granted to the USDA. This change could include a new governing committee, one that would be composed of stakeholders to take a look at and manage these issues. This new committee could work with the seed companies and have both broad national scope and more detailed local context. It is extremely important to the viability of organic agriculture that gene flow from a GM field not unreasonably damage a neighboring organic crop. So, any petitioner to this committee should be required to disclose all the important aspects of the new GM product. What is the action level for the new GM trait introduction: is it one part in 1000, 10,000, or 100,000? What segregation distances are appropriate? What does the seed provider expect the farmer to do? As policies emerge, one option that seems reasonable is that if buffer zones are required, half should be on each side of the fence, effectively sharing the burden of coexistence. All of this should be part of any petition process.

Tolerance levels can and probably should be different for different petitioners. There might be one standard of coexistence that is based on production style, versus another for traits. There are numerous aspects that could impact what the tolerance levels would be, such as good management practices and the geography of production. Some additional protection could be provided to farmers that follow these practices and less protection would be available to those that do not. Coexistence is quite possible; in fact, it is crucial to the future of American agriculture. However, there may be a need for change in both the regulatory structure and industry practice in order to have a workable coexistence regime.

Summary

Coexistence is not merely a GMO versus organic issue, but an issue of product purity and choice for the entire agricultural supply chain. As agricultural production becomes more differentiated and niche products, including conflicting GM traits, become more numerous, coexistence will become an even more important issue.

The ability to efficiently test for AP of GM traits and clear standards for acceptable levels of AP are essential ingredients of a workable coexistence regime. The inability to quickly and reliably test for the presence of some GM traits makes the labeling of some organic or non-GM products problematic. The lack of a GM threshold in the National Organic Program has created some challenges for the organic industry. A zero-tolerance threshold is unattainable and unworkable; realistic market-based thresholds are essential to the production and trade of differentiated agricultural commodities.

The regulatory approval process for GM crop varieties should take coexistence and other market issues into consideration. Necessary coexistence measures, acceptable AP levels, and test methods should be known and in place prior to commercialization of a new GM event. Ideally, some coexistence measures could be built into a new variety.

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Developing Solutions for Coexistence in the EU—Legal, Technical, and Economic Issues

Koen Dillen, Ivilin Rizov and Emilio Rodriguez-Cerezo

What Does Coexistence Mean for the EU?

Coexistence policy in the European Union (EU) is designed to avoid unintended and adventitious presence of genetically modified (GM) crops in other products, preventing the potential economic loss from admixture (European Commission 2010). Coexistence is a direct consequence of the decision to provide consumers with a well informed choice when it comes to food produced from GM crops. While a mandatory labeling regime identifies GM produce in the market place, the availability of both GM and non-GM depends on the possibility of a downstream supply chain to provide both goods. Therefore, what is commonly called "coexistence measures" are a set of technical, administrative, and liability rules set out to avoid the unintended presence of GM material in non-GM crops at the farm level. Hence coexistence measures are not environmental risk management tools but tools to resolve potential market failures arising from GM crop cultivation in the EU.

With the underlying assumption that at least some EU consumers prefer non-GM derived products, cultivation of GM crops could lead to a value loss for non-GM farmers when on farm admixture occurs, making it difficult for the non-GM farmer

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K. Dillen (✉) · I. Rizov · E. Rodriguez-Cerezo
European Commission Joint Research Centre, Institute for Prospective Technological Studies, Seville, Spain
e-mail: koen.dillen@ec.europa.eu

I. Rizov
e-mail: ivelin.rizov@ec.europa.eu

E. Rodriguez-Cerezo
e-mail: emilio.rodriguez-cerezo@ec.europa.eu

N. Kalaitzandonakes et al. (eds.), *The Coexistence of Genetically Modified, Organic and Conventional Foods*, Natural Resource Management and Policy 49,
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to commercialize his produce as non-GM. Sources of admixture are plentiful (e.g. Devos et al. 2009) and include impure seed, cross fertilization, volunteer development, and mixing of material in machinery. This wide variety of sources and the fact that GM admixture is often only discovered further along the supply chain leads to a situation in which the market fails to provide incentives for correcting possible crop value losses.

Heterogeneity in agricultural practices and legal environments among the EU Member States (MS) led the European Commission (EC) to the decision to apply the concept of subsidiarity for the implementation of coexistence regulations. According to this concept, developing specific coexistence strategies is a responsibility of the individual MS. However, the EC retains three roles when it comes to coexistence. The first role is to issue general policy guidelines. These guidelines frame the coexistence policy by explaining the background and rationale behind coexistence and the different coexistence measures. Secondly, the EC acts as mediator of information exchange through a network called the COEX-NET, in which all MS meet to discuss the state of play. Finally, a third role has been given in which the EC coordinates a technical working group, the European Coexistence Bureau, which issues technical advice and develops best practice documents.

On the first point, policy guidelines were issued in 2010 under the responsibility of the Directorate General for Health and Consumers, which is responsible for GM legislation within the EC (European Commission 2010). The 2010 guidelines update the definition of coexistence. The guidelines acknowledge the fact that there are private market standards that are different from the legal labeling threshold of 0.9 % (i.e. European Commission 2003). Hence Member States are given the freedom to target their coexistence measures to these private thresholds and not only to the European-wide mandatory labeling threshold (0.9 %). Furthermore, the 2010 guidelines, while favouring farm-level measures, acknowledge the fact that under certain economic and natural conditions the exclusion of GM crop cultivation from larger areas might be appropriate when it can be demonstrated that for those areas other measures are not sufficient to achieve coexistence. With these guidelines the EC expects the MS to develop transparent coexistence measures at the appropriate level through a strong interaction with stakeholders. Hence the technical nature of the measures remains the exclusive competence of the Member States.

This subsidiarity approach leads to a variety of practices and rules throughout the EU. The EC published a comparative analysis of coexistence measures in the EU (European Commission 2009), which took stock of the individual measures taken by the Member States and discussed the similarities and experiences in the different countries. Despite the fact that EU experiences with actual commercial cultivation of GM crops are limited to a handful of countries, over 15 Member States indicated they have coexistence legislation in place in the last report. The coexistence measures can be divided in two types, *ex ante* measures and *ex post* liability rules. *Ex ante* measures are designed to minimize the probability of adventitious presence of GM produce in conventional produce while *ex post* liability rules create an environment in which value losses through adventitious presence can be resolved. One thing all coexistence measures have in common is that MS

follow the "newcomer principle" when designing them, meaning that the measures fall under the responsibility of the GM crop grower. For a full overview of the different coexistence measures, refer to European Commission (2009) and (Devos et al. 2009). Instead, we focus on some of the general considerations in the remainder of this chapter.

Spatial isolation is the principal *ex ante* measure used by the MS to assure coexistence. One possibility is to define a minimum distance between the GM crop and its conventional counterpart. These isolation distances vary widely among MS and for maize range from 25 m in the Netherlands up to 600 m in Luxembourg. One of the ways used to reduce the required isolation distance is to plant the buffer zone area with conventional varieties but harvest it as GM produce. This so-called "buffer zone" acts as a pollen collector reducing the need for larger distances. The trade-off between isolation distance and buffer rows varies among MS, typically 1 row of maize is assumed equal to a 2 m isolation distance. Another way to facilitate spatial isolation is the clustering of fields, both within one farm or at a regional level. Some MS explicitly foresee the possibility for farmers to negotiate about spatial isolation distances with their neighbours while other MS require mandatory isolation even when farmers would be willing to cooperate. *ex ante* coexistence measures further include strategies to avoid adventitious presence through temporal separation, a specified time difference between sowing dates or a difference in maturity class of seeds used. Furthermore, MS specify administrative measures such as mandatory farmer training programs, procedures for information provision to neighbours or the wider society, and a compulsory registration of the GM plots.

Ex post liability rules are even more heterogeneous as explained in detail in Chap. 7 of this volume. One of the reasons is that even when no specific rules are designed, adventitious presence could be solved under general tort law. As the specificities of tort law differ between MS, the final outcome of a liability case could be different depending on the jurisdiction (Koch 2012). Moreover there is no case law that can be relied upon as no court cases to resolve adventitious presence of GM crops in an agricultural setting have occurred in the EU. Despite this coverage by tort law, some MS include coexistence specific *ex post* liability rules in their national legislation. A first approach is to establish a compensation fund to which GM farmers contribute through a levy on the GM seed. In the case of adventitious presence the fund will compensate the economic loss faced by the conventional farmer. Another proposed measure to redress adventitious presence is compulsory insurance for the GM crop farmer. However, no private insurer has such a product in its portfolio making it impossible to comply with this measure for the moment.

Although they are clearly distinct by nature, e*x ante* coexistence measures cannot be considered in isolation from *ex post* rules (Beckmann et al. 2010). As has been discussed in the literature of law and economics, the combination of both should be tailored to the specific characteristics of the market failure to be resolved (e.g. Shavell 1984). For the case of coexistence where the cause of adventitious presence is not straightforward and possibly unintended, *ex post* liability rules are needed from a welfare point of view. Some authors have argued that strong *ex post*

liability rules generate the possibility to be more flexible when it comes to implementation of *ex ante* measures (Demont et al. 2008, 2009, 2010). This freedom for farmers would allow the implementation of *ex ante* measures more adapted to the regional setting, acknowledging the heterogeneity in European farming. This is in line with the initial reason for applying the subsidiarity principle to coexistence at the EU level. However, it is not unreasonable to assume that a shift from personal liability under tort law towards a mutual liability through compensation funds or insurance might affect the implementation of *ex ante* measures by GM farmers. Due to the limited experience with *ex post* measures this trade-off is not yet well understood. Given this limited knowledge about practical implementation it is important to continue documenting and undertaking research efforts that unravel the exact impact of different coexistence rules on the final production of both GM and conventional crops in the EU, making sure the regulation fits its reason of existence.

The European Coexistence Bureau

An important role of the EC in coexistence policy is implemented by the European Coexistence Bureau (ECOB) as it gathers and harmonizes available technical and scientific information. Established in 2008, the ECOB's mission is to provide technical guidance and consensus on crop specific best practices for coexistence through intensive collaboration with the MS and stakeholders. The ECOB best practice documents are non-binding and have no legal nature. The scope is on agricultural practices, from sowing to the first point of sale. If deemed necessary, best practices for the seed producing sector could be included in the future, but the ECOB will not look at practices after the farm gate nor will it try to design guidelines or best practice on administrative measures or *ex post* liability rules.

The ECOB secretariat is hosted at the Institute for Prospective Technological Studies (IPTS), part of the EC's Joint Research Centre in Sevilla, Spain. For each consensus document, the secretariat takes the first step by organizing existing background information such as publications, experiments and common practices in each of the MS. From this initial draft the path towards the final best practice document includes online collaboration and plenary meetings with the MS delegated experts. Early versions of the documents are subject of formal stakeholder consultations to assure the practical information proves useful. All the documents and proceedings are public and can be found on the ECOB's website http://ecob.jrc.ec.europa.eu/. The first document produced by the ECOB covered coexistence practices in maize cultivation. The work was started in October 2008, when 19 MS were actively engaged in the process through their delegated experts. The report was published and disseminated in the summer of 2010 and is available on the aforementioned website.

A consensus was successfully reached on a number of points. One of these points is the definition of appropriate technical isolation distances between GM and conventional maize fields. The strength of the document is that it reflects the spirit

of the 2010 coexistence guidelines (European Commission 2010) that MS are free to decide which threshold to use as a basis for their coexistence legislation. Moreover, the use of different thresholds means that the information can also be used as a reference for commercial actors in the chain that would like to use their own threshold, for instance for a private GM free label. The consensus isolation distances for each threshold are depicted in Table 1.

For the construction of Table 1, the ECOB profited from its close collaboration with EC's Joint Research Centre (JRC), where its secretariat is hosted. Researchers at the JRC conducted a probabilistic analysis on more than 1400 observations of maize gene flow measured during field trials that had taken place in the EU. The results of this study provided a scientific and statistical basis for the consensus that was reached on the appropriate isolation distances for maize production (Riesgo et al. 2010). The ECOB also confirms the technical possibility to halve the isolation distance through the use of buffer zones of non-GM maize around the GM field. These buffer zones are easy to implement and can act as a refuge to delay resistance development at the same time. Similar to the recommendations regarding isolation distances, the ECOB also provides consensus guidelines for temporal isolation such as differences in sowing dates or in maturity class. Further issues documented include volunteer control and cleaning of machinery.

A comparison of the isolation distances shown in Table 1 and the MS national legislations demonstrate that the isolation distances defined in the different MS were not necessarily designed to sustain the labelling threshold of 0.9 %. This even before the 2010 EC guidelines on coexistence stated this possibility explicitly.

Although the ECOB recommendations mainly focus on measures that could be taken by individual farmers, the fact is that in Europe landscape situations exist where coexistence is difficult to achieve. This is mainly the case in situations where agricultural plots are fragmented (Sanvido et al. 2008). The ECOB consensus is that field clustering is therefore an appropriate solution in specific cases. Such clustering can be implemented in different ways, either voluntary or top down, either a GM

Table 1 Isolation distance guidelines as proposed by the ECOB

Admixture level (%)	Proposed isolation distances for	
	Grain maize (m)	Whole plant use (m)
0.1	105 to 250–500	85 to 120
0.2	85 to 150	50 to 65
0.3	70 to 100	30 to 55
0.4	50 to 65	20 to 45
0.5	35 to 60	15 to 40
0.6	20 to 55	0 to 35
0.7	20 to 50	0 to 30
0.8	20 to 50	0 to 30
0.9	15 to 50	0 to 25

Adapted from ECOB (2010)

production zone or a GM free production zone. Typically GM free zones are organized top down as is acknowledged in the 2010 coexistence guidelines. GM production zones, on the other hand, have been organized through voluntary action among farmers. As described by Skevas et al. (2010) and presented by the Portuguese government to the ECOB, voluntary GM production zones have been formed in the North of Portugal. Farmers internalize the *ex ante* coexistence measures through close cooperation with neighbouring farmers, often within a cooperative. After harvesting the produce from both the GM area and the conventional area are mixed and put on the market as GM.

The Way Ahead

The fact that farmers try to internalize coexistence measures indicates that *ex ante* coexistence measures bear a cost and subsequently impact the adoption of GM crops in the EU. Indeed, an important difference exists between the technical efficiency of *ex ante* coexistence measures and economic impact and hence the final application at the farm level. This is even more pronounced when farmers are given some flexibility and choice when it comes down to implementation of coexistence. Unfortunately the economic impact of specific coexistence measures is an area where information is scarce and consensus is hard to reach between experts and stakeholders. One of the reasons for this information gap is the limited adoption of GM crops in a handful of MS; another reason is the high cost of farmer surveys to gather this information. A naïve analysis would say that farmers are comparing the costs of coexistence with the benefits of GM crop adoption which results in a decision to adopt or not adopt. However, *ex ante* coexistence measures also have characteristics that cannot be monetized such as the complexity of measures, transaction costs, or the relationship with other farmers (Beckmann et al. 2006; Breustedt et al. 2008; Areal et al. 2012). Hence the burden of *ex ante* coexistence measures depends to a large extent on the perception of the individual farmer. Indeed, a study conducted in Portugal (Skevas et al. 2009) concluded that two groups of farmers seem to emerge: one group assesses the *ex ante* coexistence costs as being low and therefore adopts GM crops; the other group assesses the *ex ante* costs as being high and does not adopt. Ongoing research based on a survey among 1000 Spanish maize farmers seems to suggest the existence of a third group, the partial adopters (Dillen and Rodriguez Cerezo 2013). To this group of farmers, transaction costs with neighbours present the main burden for coexistence, hence they internalize coexistence within their farm leading to partial adoption of GM maize.

Another point often neglected in the study of practical implantation of coexistence is the effect of private standards on coexistence implementation. Although all MS legislation follows the newcomer principle, putting the responsibility for *ex ante* measures solely with the GM crop adopter, the market reality might be different. The European food industry and in particular the organic sector often

demand produce with a GM presence below the legal threshold of 0.9 %. As *ex post* liability rules, which are highly heterogeneous between different MS, are less clear on how the potential economic loss due to adventitious presence under private thresholds is settled, part of the responsibility for *ex ante* measures is shifted to those farmers aiming at lower private thresholds. To assure his produce can be sold as identity preserved non-GM, a conventional or organic farmer might implement extra *ex ante* coexistence measures within his own farm. This practice and the arising extra costs have not been considered when estimating the total impact of the coexistence legislations in the different MS.

This chapter, while providing an overview of the status of coexistence in the EU also highlights the hurdles on the way towards efficient and proportionate coexistence regulations (Demont et al. 2009). The ECOB has shown that a consensus can be reached among the experts of different MS on the appropriate technical measures depending on the thresholds sought. The knowledge about practical implementation and economic effect of coexistence measures in an agricultural landscape, on the other hand, is less evolved. However, this knowledge is of utmost importance when designing MS coexistence legislation and choosing between the different technical solutions to coexistence that are available. Policies should be proportionate and not put a heavier burden on farmers than what is strictly needed for coexistence. Moreover, more attention should be focused on the interplay between *ex ante* and *ex post* measures and the consequences of this interplay for the design of more flexible coexistence measures. This is exactly what the EC funded research project PRICE and other research should and will be focusing on.[1]

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[1]The EC funds a research project which will assess the cost of *ex ante* and ex post coexistence legislation and their effect on adoption. The project's details and results can be found at http://price-coexistence.com/.

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The Principle(s) of Co-existence in the Market for GMOs in Europe: Social, Economic and Legal Avenues

Kai Purnhagen and Justus Wesseler

Introduction

The market for GMOs in Europe is characterized by a highly complex regulatory framework, where multiple interests, wishes, and hopes meet cold scientific, legal, and economic facts (see Pollack and Shaffer 2009, 53–80; Purnhagen and Wesseler 2016, in this contribution; Beckmann et al. 2006; Purnhagen 2014a). In order to govern this complex framework, European Union (EU) policy relies, as it is common particularly in EU food law[1] and EU environmental law (de Sadeleer 2012), on a principle-based regulative model (See on principle-based vs. rule-based regulation Black 2008, 425; van der Meulen et al. 2014, 5–10). At the heart of this regulatory model of the EU GMO market lies the principle of co-existence, which "refers to the ability of farmers to make a practical choice between conventional,

[1]See e.g. Art. 1 (2) and 4 (2) of Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (hereinafter GFL).

K. Purnhagen (✉) · J. Wesseler
Wageningen University, Wageningen, The Netherlands
e-mail: Kai.Purnhagen@wur.nl

J. Wesseler
e-mail: justus.wesseler@wzw.tum.de

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organic and GM-crop production, in compliance with the legal obligations for labeling and/or purity standards."[2] In the eyes of the EU, "the ability to maintain different agricultural production systems" through co-existence policy is key to this principle of co-existence, as the EU needs to provide a "high degree of consumer choice".[3] This may seem ironic at best to outside observers, as most consumers in Europe dislike foods produced from GMOs (Eurobarometer 2010; Bredahl 2001), but it follows the established information paradigm of internal market regulation, described below. A sound understanding of this principle is hence needed in order to also understand the policy choices the EU makes in the area of co-existence. An important part is to realize that the information paradigm also has its limits. Consumer choice indeed determines the internal market, but finds its limits where the exercise of this choice leads to certain negative effects such as in cases of environmental, health, or property damages. In addition, governing a multi-level system such as the EU requires steering principles in order to give guidance on the exercise of participants' competences. For each of these cases, the EU upholds principles which need to be brought in line with the information paradigm and with each other.

We contribute with this piece to such an understanding by chartering and analyzing the different principles underlying the regulatory regime of GMOs from the perspective of principles-based regulation with regards to co-existence. We understand these principles to be of fundamental importance for the governance of the EU co-existence policy. We proceed in three steps. We will first introduce the concept of principles-based regulation and justify our method of selection of the respective principles. Subsequently, we will introduce, discuss and relate the respective principles that cover co-existence regulation in the EU. We will then conclude our findings, evaluate them and make policy recommendations.

Principles-Based Versus Rules-Based Regulation

When governing markets of risky products such as GMOs the regulator needs to make a choice with regards to how he will steer the behaviour of market players. Such a regulatory choice is crucial for market players as it determines what behaviour is expected from them. A regulatory framework such as this one determines when and how market participants' trust in regulation will be rewarded. The different regulatory models available have been studied extensively in the area of

[2]Recital 3 Commission Recommendation C (2003) of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming (hereinafter "Recommendation").

[3]According to Recital 2 Recommendation this lies in the heart of the co-existence policy.

financial markets (Black 2008), but can also be applied to other markets, such as food and agriculture (van der Meulen et al. 2014). According to this research, regulation can be characterized as either rules-based or principles-based. "Rules-based regulation tries to prescribe the content of the regulated behaviour to a maximum extent, avoiding regulatory gaps that leave room for interpretation. In principles-based regulation, however, principles deliberatively allow for such gaps, which are then filled by application" (van der Meulen et al. 2014, p. 5). According to Black et al. (2007, p. 191) there are three elements that characterize principle-based regulation:

1. broad-based standards in preference to detailed rules;
2. outcomes-based regulation; and
3. increasing senior management responsibility.

Within this paper, we will focus on illustrating which broad-based standards exist to govern the GMO market in the EU, with a particular emphasis on co-existence. We start from the premise that the EU market for GMOs is based on a principle-based approach to regulation. When GMOs are used for consumption, this becomes particularly evident in Recital 5 of the General Food Law (GFL), which stipulates that "it is necessary to approximate these [Member States', addendum authors] concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level." Most of these legal principles are then, according to Art. 4 (2) GFL, spelled out in Art. 5 to 10 GFL for the whole EU food market, including GMOs. When GMOs are prepared for release into the environment, principles of EU environmental law apply which stem mainly from Art. 191-193 of the Treaty of the Functioning of the European Union (TFEU). As GMOs are first and foremost also "goods" in the sense of the rules on the freedom of goods in the EU, general principles of internal market law as developed by the Court of Justice of the European Union (CJEU) apply as well. The Commission has acknowledged such a principle-based approach, most notably in its Recommendation and in ANNEX 2 of Recommendation 2010/C 200/01. Recital 9 of the Recommendation in 2003 first advised Member States to develop "a list of general principles and elements for the development of national strategies and best practices for co-existence", and then fleshed out European principles in ANNEX 2. In 2010 the Commission then added some "general principles for the development of national co-existence measures,"[4] also at the EU level. We chose these principles at the EU level for investigation and added other, fundamental ones that are of importance as they appeared in the doctrine of written legal documents and Court decisions.

[4]See ANNEX 1.1 of Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops 2010/C 200/01.

The Principle(s) of Co-existence in the EU

In this chapter we will illustrate which principles govern the GMO market in Europe with a particular view on co-existence. We will first flesh out the information paradigm as a major cornerstone of the internal market regulation of goods, which relates to co-existence policy in the EU. We will then explain how the principle of conditional mutual recognition of standards, the precautionary principle, and the principle that the polluter shall pay fits into this rationale of co-existence. We will then determine how the principles of subsidiarity and co-operation regulate the use of powers between Member States and the EU.

The Information Paradigm, or: The Right to Choose

In the eyes of the EU, "the ability to maintain different agricultural production systems" through co-existence policy is key to this principle of co-existence as the EU needs to provide a "high degree of consumer choice".[5] The EU has hence chosen both, against a prohibition of GMOs and unconditional allowance of GMOs on its market for the sake of the maintenance of a variety of consumer choice. This choice is based upon a series of judgments and careful considerations of EU regulators on how to govern the EU internal market of goods. At its heart lies the need to de-regulate the market for goods at EU level so that consumers may gain benefits from comparative advantage (de-regulation), while there is also a need to counterbalance negative externalities resulting from de-regulation (re-regulation), in particular to consumer's health and the environment (Purnhagen 2014b, p. 321; Weatherill 2014, p. 405: "central … in EU internal market law"). In other words, an effective, and sometimes also efficient, solution needs to be found as to when the EU or Member States shall be able to prohibit certain goods and when consumers shall be enabled to make the purchase choice themselves. For the marketing of goods, and therefore also for GMOs, the CJEU has established the following guidelines in its landmark decision *Cassis de Dijon*[6] (the following text is a slightly revised version of the passage already published in Purnhagen 2014b, 323):

- Producers can choose to comply with one Member State's regulation. Once producers of goods comply with the regulations of a Member State, they shall in principle be able to market their product all over the EU. The competition of legal orders and the deregulatory pressure on non-efficient legal regimes of

[5]Recital 2 Recommendation.

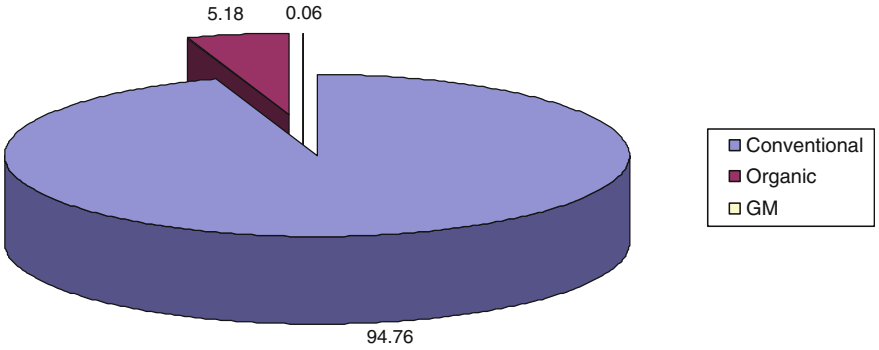
[6]ECJ, 120/78 REWE v Bundesmonopolverwaltung fuer Branntwein (Cassis de Dijon) [1979] ECR 649.

Member States will thereby over time lead to the harmonization of legal rules at the most efficient level.

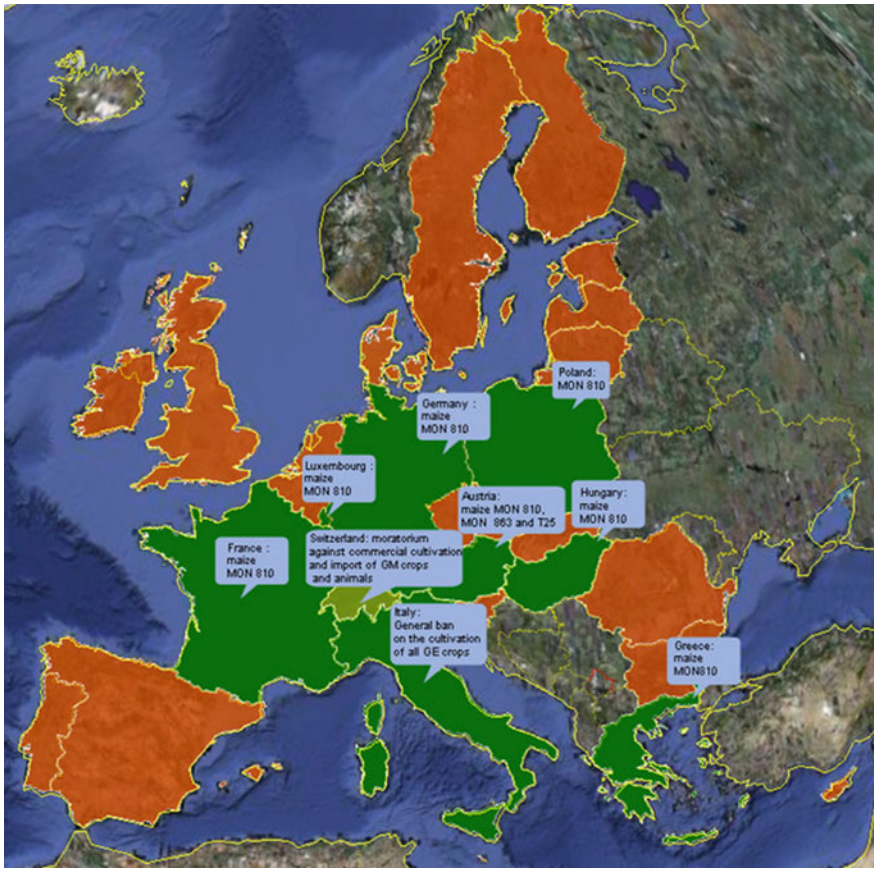
- Such a harmonization by competition of legal orders is, however, not envisaged for regulatory measures that fall within the scope of "mandatory requirements" such as consumer and environmental protection. Here, producers have to accept disparate regulation in Member States. If the EU legal order demands harmonization in these areas, it has to do so proactively via secondary law. This is particularly so when there is a threat to consumers' health.
- The limit to which producers have to accept disparate law in Member States' legal systems is not endless. Regulatory measures of Member States within the "mandatory requirements" still need to be proportionate. This means that whenever an information-related rule is sufficient to cure the problem, it shall be given preference over a content-related rule. In these cases it is hence for the consumer and not for the Member State to choose whether the risk of externalities is greater than the benefits from comparative advantage. In this way, the variety of products on the EU market is safeguarded.

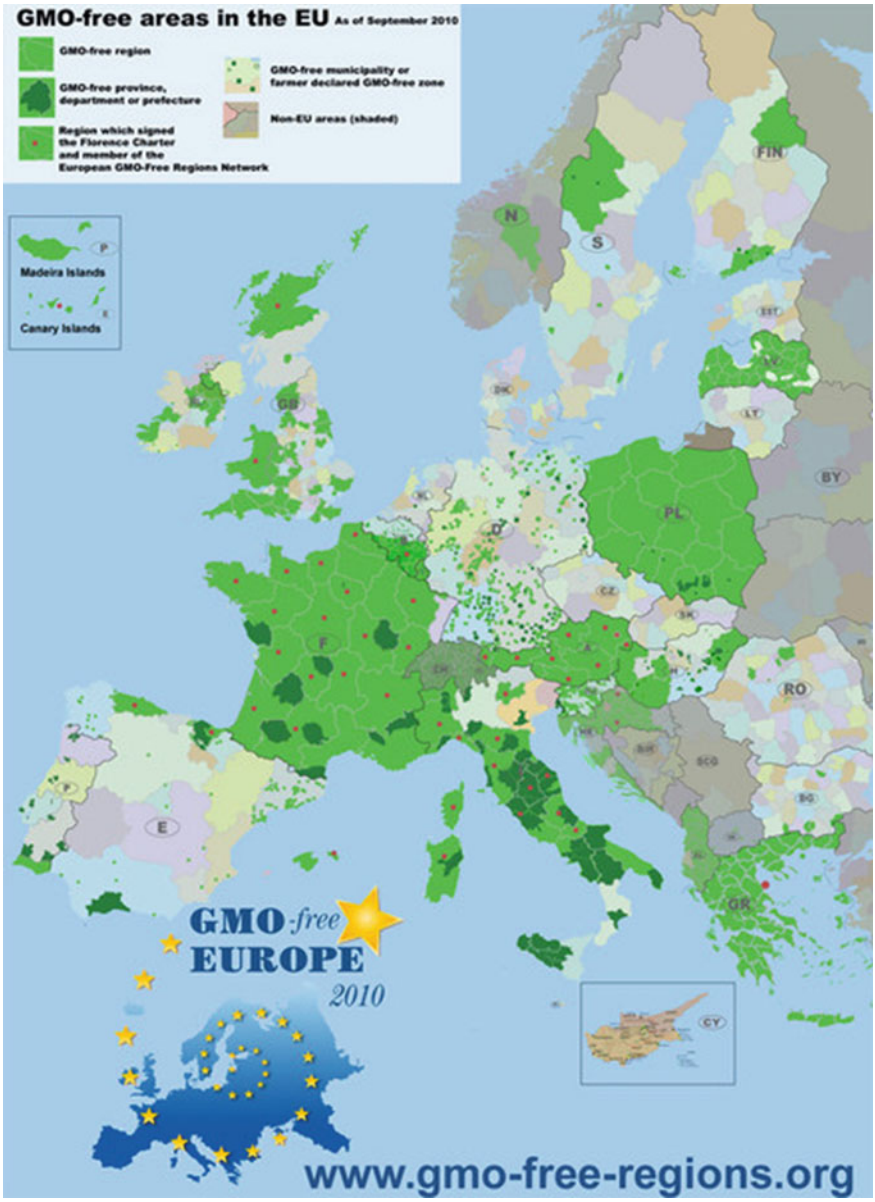
From this judgment it has become clear that, according to the proportionality principle, in areas where consumer and environmental protection is at stake, consumer choice instead of top-down regulation guides law-making procedures and regulation in the EU's internal market, by the so-called information paradigm (Purnhagen 2014b, 329–332; Usher 2001, 152–153). As it is also mainly consumer protection and environmental protection that is at stake when regulating GMOs, the EU law-maker has to take into account the above-mentioned principle when searching for a sound regulatory environment for GMOs. As providing a variety of consumer choice lies also at the heart of GMO regulation, the EU regulator has to offer a sound policy which enables such a choice between a variety of products in a safe way. In order to provide such a choice to consumers, the EU chose a co-existence policy between (authorized and hence safe) GMOs and non-GMO crops. In turn, farmers, in exercising their right to the fundamental freedoms of goods in Art. 34 TFEU and their freedom to conduct a business according to Art. 16 of the Charter of Fundamental Rights may choose between GM and non-GM farming.

In 2009, only 0.06 % of all utilised agricultural area in the EU was planted in GMO products. In addition, some of the Member States have issued bans on GM crops altogether, thereby not only hindering the provision of a variety of choice for consumers, but also making it difficult for farmers to exercise their right to choose.



Source Data based on http://www.transgen.de/anbau/eu_international/643.doku.html, http://www.organic-world.net/europe-data-tables.html, and http://epp.eurostat.ec.europa.eu





One could conclude that this Member States' practice jeopardizes the exercise of a variety of choice for consumers and farmers alike. If farmers cannot bring GM crops to the market, neither they nor consumers will be enabled to choose between GM and non-GM crops. However, in Recommendation 2010/C 200/01 the EU provided a different interpretation. The judgment *Bablok and others vs. Freistaat*

Bayern[7] brought to light that GM organisms can travel unexpectedly from GM crops to non-GM foods, thereby potentially circumventing labeling and authorization requirements (Lamping 2012; Purnhagen and Wesseler 2016, in this contribution). In Recommendation 2010/C 200/01, the Commission hence acknowledged that the rise of GM crops on the markets could also increase the possibility of an unintended presence of GM crops in non-GM crops, thereby eventually jeopardizing the co-existence policy in the EU. Consumers and farmers could not exercise their choice, as producers could not guarantee to get a comparative advantage from selling GM or non-GM products. As labeling requirements would also become ineffective, consumers could not exercise their choice relying on the labeling of the product. As a result, Recommendation 2010/C 200/01 proposed that Member States ban GMOs from certain areas on their territory in order to prevent an unintended presence of GMOs in conventional and organic crops.

Principle of Proportionality

Measures for co-existence shall furthermore "not go beyond what is necessary in order to ensure that adventitious traces of GMOs stay below the tolerance thresholds set out in Community legislation. They should avoid any unnecessary burden for farmers, seed producers, cooperatives and other actors associated with any production type."[8] The Recommendation thereby rephrases the principle of proportionality, a general principle of EU law,[9] which has as such already determined the information paradigm. As a limitation of Union action, it is stipulated in Art. 5 TFEU as follows: "Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties." When public authorities take action in the area of risk regulation, it is important to not only look at Union level, but into both levels of involvement—Union and Member State institutions (Fisher 2007, p. 211). As a general principle, it hence limits not only Union action but also Member State action when determining their margin of discretion (Purnhagen 2013, 715). This becomes particularly relevant in co-existence, when Member States have to define threshold levels such as how many GMOs may be permitted in conventional or organic crops or isolation distances for GM and non-GM crops. The exercise of their margin of discretion has resulted in a rag rug of isolation distances for all kind of crops across Europe, which

[7]CJEU, C 442/09, Bablok and Others v Freistaat Bayern [2011] ECR I-7419.

[8]ANNEX 2.1.4 of the Recommendation.

[9]ECJ, 8/55 1955/1956 Fédération Charbonnière v. ECSC High Authority ECR [1954-1956] 245, at 297, 311.

Table 1 Isolation distance requirements for GM crops in some Member States of the EU (metres). Note: Numbers in brackets indicate distances to organic fields if explicitly indicated. *Source* CEC (2009) and various country reports

Country	Maize	Oilseed rape	Sugar beet	Potato
Bulgaria	600–30000			
Czech Republic	70 (200)			3–10 (20)
Denmark	150 (150)		20 (20)	10 (10)
Germany	150 (300)			
Hungary	400 (400)			20–40 (30–60)
Ireland	50 (75)			
Italy	200 (1000)			
Latvia	200	4000	200	50
Lithuania	200	4000	50	20
Luxemburg	600		100	50
Netherlands	25 (250)		1.5 (3.0)	3 (10)
Portugal	200 (300)			
Romania	200			
Slovakia	200 (300)			
Spain	20			
Sweden	50			3

may call for intervention on the basis of the EU's proportionality principle. Table 1 illustrates the partly drastic differences on the example of isolation distances among EU Member States.

In practice, however, it needs to be remembered that Member States enjoy a wide margin in exercising their discretion when implementing EU law.[10] Due to the different cultural settings in the EU, EU institutions are reluctant to interfere with the exercise of this discretion and instead leave it to Member States to determine what is best for their country. It is hence unlikely that Union institutions will interfere and provide more consistent threshold levels.

Precautionary Principle

The precautionary principle is a general principle of both EU environmental law (Art. 191 (2) sentence 2 TFEU) and EU food law (Art. 7 GFL). It also underlies

[10]ECJ, C-112/00 Eugen Schmidberger, Internationale Transporte und Planzüge v Republik Österreich, [2003] ECR I-5659, at 82.

GMO regulation in the EU; when GMOs are released into the environment, Recital 8 of Directive 2001/18/EC[11] makes clear that "(t)he precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it." For GMOs in food, Art. 4 (2) GFL makes certain that the precautionary principle in Art. 7 GFL is of horizontal nature and hence also applies to GMOs. The principle has not been mentioned in neither of the documents that underlie co-existence policy in the EU. However, as a general and horizontal principle of GMO regulation in the EU, it will likely be applied also in co-existence policy. While the precautionary principle is well-established in EU internal market law, its borderlines, function, definition etc. are quite hard to grasp. We will not get into the jungle of different views and explanations of the precautionary principle here. Rather, we will use the elements of the precautionary principle that are well-established and assign them to co-existence policy and refer the reader to van den Belt (2003) and Purnhagen (2015) for additional details. Art. 7 (1) GFL stipulates that where "the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted." The common interpretation is that as long as scientific uncertainty persists with regards to health and environmental problems, Member States hence may even take provisional preventive measures in order to allow for a proper risk assessment (see for a more detailed analysis Purnhagen 2015). In the area of co-existence, Member States may take provisional measures as long as scientific data on the impact of GMOs and on non-GMOs are inconclusive. That means that as long as GMOs pose a non-quantifiable risk to the environment and to consumer health, Member States can take action in order to prevent a mix of GMOs and non-GMOs.

Principle that the Polluter Shall Pay

In European co-existence policy, "operators (farmers) who introduce the new production type should bear the responsibility of implementing the farm management measures necessary to limit gene flow."[12] This is a specific co-existence reading of the general principle in EU environmental law that the polluter shall pay (see Art. 191 (2) sentence 2 TFEU), also fleshed out in the Environmental Liability Directive (ELD).[13] The ELD applies also to damages caused by GMOs (see clearly Art. 18 (3) b) ELD and the reference in Recital 16 of Directive 2001/18/EC).

[11]Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration, OJ L 106, 17/04/2001 P. 1-39.

[12]ANNEX 2.1.7 of the Recommendation.

[13]Directive 2004/35/CE (sic!) on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage [2004] OJ L 143/56.

The ELD obliges operators to pay even without proof of fault for any "environmental damage" caused by the operator's dangerous activities defined in Annex III of the ELD. These "activities" are also any contained use, including transport, involving genetically modified micro-organisms as well as any deliberate release into the environment, transport and placing on the market of GMOs.[14] According to this provision, a system of strict liability has to be implemented by the Member States in case the activities GMOs are involved in cause any "damage". It can be debatable whether co-mingling between GM and non-GM crops is in itself a "damage" in the legal sense. A businesses loss of an organic label which results from such a mingling can be identified as such a loss (Repp 2000, 594–595). However, the "mingling" of GM and non-GM crops is often seen as a "damage", without substantiating further what the actual damage is (see e.g. Faure/Wibisana 2007 p. 197). One reason for this may be that farmers or producers may indeed suffer monetary damages resulting from non-labeling of a GMO product, which they then need to pass on to the respective "polluting" farmer. While this might be a reason for strict liability in torts, it is questionable whether this would also justify strict liability *in rem*, as it is the case for example under German law (Art. 36a GenTG). Either way, almost all EU countries have implemented rules that hold the GM crop holder liable for failing to implement segregation measures (Beckmann et al. 2015).

Subsidiarity Principle

Art. 26a of Directive 2001/18/EC provides that Member States may take appropriate measures to avoid the unintended presence of GMOs in other products. This article assigns responsibility with regard to what should be done in terms of co-existence measures *in concreto* to Member States. This lies in line with recital 7 Recommendation which stipulates that "[t]he European Commission considers that measures for co-existence should be developed and implemented by the Member States." The reason for this being that co-existence policies are governed by the internal market rationale, which according to Art. 4 (2) (a) TFEU belongs to the area of shared competence. In this competence area, according to the principle of subsidiarity as enshrined in Art. 5 (3) TEU "the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level".

[14]Activities No. 10 and 11 of Annex III ELD.

Economic Evaluation of These Principles

The implementation of co-existence regulations following the principles discussed above has some important economic implications. They will be discussed in light of the co-existence regulations we find in the EU (for a detailed overview see Beckmann et al. 2014). The information paradigm of the EU is closely linked with what particularly in a consumer and US policy context is often referred to as a "right to know". Both, the information paradigm and the right to know refer to the mandatory labeling of GMOs that provides the consumers with the information about the particularities of GM food product and how to distinguish them from non-GM products. For consumer advocates the "Right to Know" provides the basis at consumer level for the "Right to Choose". These rights require a definition of what is and what is not supposed to be a GM-food. While the regulation on GM food labeling provides the legal framework, its implementation generate substantial costs. The current policy by many leading European food retailers is to avoid GM food that needs to be labeled and to also introduce food labeled from animals fed with GM-free feed such as eggs, poultry meat, and dairy products. Considering the environmental benefits generated by GM crops this a very costly and environmentally damaging policy (Wesseler 2014).

The "Right to Know" requires that the identity of GM-free food will be preserved along the food supply chain and requires the avoidance of low-level presence of GMOs in GM-free food and feed products. Many EU Member States have implemented co-existence policies to ensure segregation at the farm level. Co-existence policies in the majority of Member States are a mix of ex-ante regulations and ex-post liability rules (Beckmann et al. 2006) that act as an indirect barrier to GMO cultivation, discriminate against smaller farms, and are often not in line with the proportionality principle, as they often discriminate against the cultivation of GM crops (Beckmann et al. 2014). The discrimination against the cultivation of GM crops is a result of the additional costs such regulations impose on farmers that would potentially cultivate GM crops (e.g. Groeneveld et al. 2013). At farm level the additional costs for having no access to insect and herbicide resistant maize in the EU vary. The European corn borer is mainly a pest in Southern parts of Europe such as Portugal, Spain, Greece, Italy, and parts of France, so the efficiency of the technology is dependent on pest pressure, while the herbicide resistant technology is more widely applicable. Depending on the crop, the losses range from a few to several million Euros per year (Demont et al. 2004; Wesseler et al. 2007; Groeneveld et al. 2011).

But it is not only the proportionality principle that comes into the spotlight, causing additional costs. Also the polluter-pay-principle did not get appropriate attention in the debate on GMOs. Some have argued that according to the polluter pays principle, GM-farmers should bear the costs of ensuring co-existence. Adventitious presence of GM pollen in non-GM fields is seen as "pollution", while the continuation of environmentally harmful agricultural practices is appropriate. As already mentioned, the empirical evidence tells a different story. The cultivation of approved GM crops has generated numerous environmental benefits, while

environmental damages in comparison to the non-GM counterpart have not yet been reported (Wesseler et al. 2011). A strict application of the polluter-pay-principle should encourage the cultivation of GM crops to support the objectives of EU policies to reduce environmental damages. Similar to the polluter-pay-principle, the application of the precautionary principle for the case of GM crops raises doubts. As van den Belt has pointed out, a logically consistent interpretation of the precautionary principle would call for a thorough benefit-cost-analysis of GM crop cultivation that takes uncertainty and potential irreversible effects explicitly into account (Wesseler 2009). The methodology has been developed and applied to a number of cases already mentioned (e.g. Demont et al. 2004; Wesseler et al. 2007). The most notable difficulty in the application of the precautionary principle is related to the introduction of Vitamin A enriched rice, where without any evidence of harm of the technology, unknown risks are put forward as an argument against the introduction of this life-saving technology resulting in substantial costs of delayed introduction (Wesseler and Zilberman 2014).

In the EU thesubsidiarity principle in the case of GM crops can be helpful. The principle provides flexibility and allows regions and Member States to identify co-existence policies they assess as being appropriate for their region or country. A closer look at the national coexistence polices reveals that the subsidiarity principle is not strictly applied. Many farmers argue they could handle issues related to co-existence at local level with their neighbours. Many of the current regulations do not provide the economic freedom for farmers to address the problem at local level themselves, as many of the policies are mandatory. In cases where issues can be addressed more easily by farmers themselves, as the case of Portugal illustrates (Skevas et al. 2010), this increases costs unnecessarily.

Conclusion

The European policy of co-existence follows a number of well-established social, economic, and legal principles. Those include the information paradigm, the principle of proportionality, the precautionary principle, the polluter-pay principle, and the subsidiarity principle. Those principles are directly or indirectly used within the debate on co-existence and co-existence policies, but often these principles are not strictly followed. A consequent application of the legal principles has the potential to reduce costs substantially, but for the case of GMOs the legal principles are often not well aligned with their purpose resulting in higher costs than needed.

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Coexistence in Brazil

Marcus Vinícius Segurado Coelho

Introduction

This chapter provides a general overview about Brazil's GM crop adoption and information on the implementation of specific coexistence rules for maize. While the current GMO situation and policy approaches are widely discussed, there has been an accumulation of practical experiences in Brazil, both from adopting producers and by enforcement of government policy that is less obvious. The chapter focuses predominantly on the Brazilian experience because, taken as a whole, Latin America has few coexistence policies or even coexistence practices that can be discussed.

Coexistence is an important issue for Brazil given that just over 20 % of the global GM crop production occurs in Brazil (James 2012). GM crop production in Brazil is dominated by soybeans, which accounts for 72 % of total GM crop production, with GM maize production and GM cotton production each accounting for 14 % of total GM crop production. Total GM crop production in Brazil was 36 million hectares in 2012. Brazil is a leading exporter of GM maize and soybeans. Hence having a functioning and efficient coexistence policy is of great importance domestically as well as internationally.

Background

Brazil's Biosafety Law, approved in 2005, established three distinct bodies for the regulation of GMOs (Government of Brazil 2005). The first is the National Biosafety Technical Commission (CTNBio), a technical body which is responsible

M.V.S. Coelho (✉)
Ministério da Agricultura, Secretaria de Defesa Agropecuária, Brasília, Brazil
e-mail: marcus.coelho@agricultura.gov.br

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for the risk assessment and establishment of rules for GMO activities, especially for research. The second is the National Biosafety Council (CNBS), an independent high level council constituted by 11 Ministries of the Republic that are involved with the authorization decision of specific or new technologies. Third, the Registration and Inspection Bodies are responsible for the enforcement of the law at the local, federal or national level. Four Ministries are involved with this body: Ministry of Agriculture, Livestock, and Food Supply; Ministry of the Environment; Ministry of Health; and the Ministry of Fishery. The Ministry of Justice also plays a role as it is responsible for labeling enforcement. CTNBio approves new GMOs by performing an assessment on human health, animal health, and environmental impacts. Then the CNBS decides on the commercial deployment, addressing any social or economic issue raised during the evaluation process. The Brazilian regulatory framework also has two decrees that play an important role. Decree Number 6041 established the national policy for biotechnology development and Decree Number 4600 established the rules for labeling food produced from GM products.

In Brazil's case, there are several advantages derived from separating the functions done by the technical body from those made by the body that examines non-biosafety related issues. The main advantage is that such arrangement effectively separates the risk assessment from risk management and communication issues that may obscure the technical assessment. It is important to note that the Brazilian system is similar to the one used by the EU. The main difference would be that the political process has to deal only with one country rather than many. Moreover, GM crops are successfully being approved in Brazil, whereas in the EU they are not.

The Biosafety Law establishes an obligation to perform a risk assessment for each GMO crop variety that will enter the Brazilian market. This is done on a case-by-case approach and is in line with guidelines established by the Cartagena Protocol on Biosafety and the Codex Alimentarius. The petitioner presents a biosafety dossier to the CTNBio, where a risk assessment for the applicant variety is then performed. Once CTNBio approves the dossier, the petitioner has to submit a specific petition to get an approval for seed production of that GMO. Once this is obtained, commercial release of the GMO in Brazil can occur. Brazil has a specific labeling regulation, which is based on the 1980 Consumer Law and is applied only to authorized GMOs. Specific wordings on the label are required to identify the product as a GM product and must be included if the GM content of the product is greater than 1 %.

Brazil does not have any specific policies for dealing with asynchronous approvals. The official view is that all countries have to look for a common agreement on how to manage asynchrony as it will continue to exist, especially because there are different GM crops being developed and commercialized for different markets around the world. For example, the GM variety of common beans in Brazil is a typical product that will be available only in Brazil; there is no intention, at least for now, to submit this bean variety for approval to other

regulatory systems. Embrapa, the Brazilian Agricultural Research Corporation, is presently evaluating whether they will submit new GM traits and varieties such as the GM common beans to regulatory systems in other countries.

Critical Assessment

As of late 2011 Brazil had 32 different GM crop varieties authorized for commercial production, 17 maize varieties, 9 cotton varieties, 5 soybean varieties and one recent approval for beans. The GM bean variety, developed by Embrapa, has been modified to protect plants against a specific mosaic virus found in Brazil.

Figure 1 illustrates the rate of adoption of GM crops in Brazil. It is possible to identify two significant moments that have affected GM crop adoption. First, the 2005 implementation of new legislation (i.e. the Biosafety law) established the regulatory framework which greatly contributed to the rapid increase in adoption of GM crops. Secondly, 2008 was the initial commercialization of GM maize in Brazil and the adoption rate since then has been substantial. In 2010 the first approvals for stacked gene varieties occurred in Brazil. Approximately 80 % of the maize and soybean production now uses GM varieties. It is important to note that, unlike most other GM adopting regions, Brazil has two crop producing seasons for maize, summer and winter.

Brazil has a specific law for the certification scheme and national registration of organic producers. Organic production represents 1.8 % of total agricultural output in Brazil. Organic production is concentrated mainly in livestock (42 % of organic

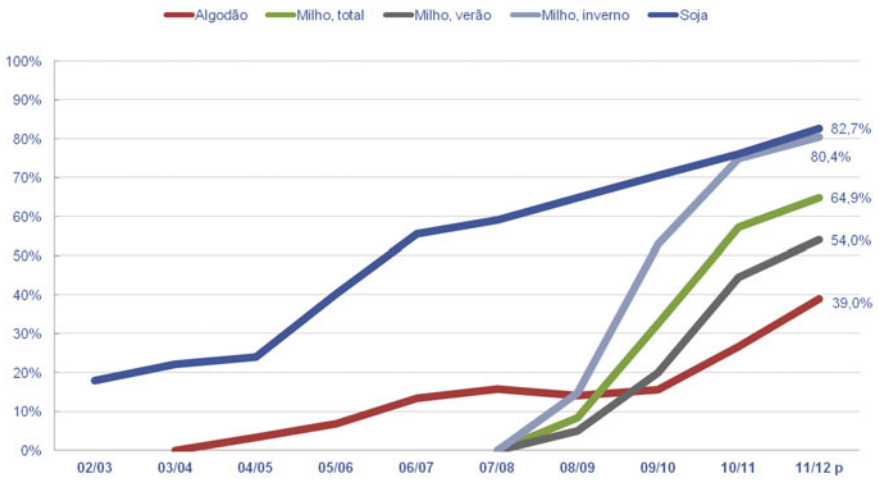

Fig. 1 Biotechnology adoption rate in Brazil (by crop). *Note* algodão—cotton, milho—maize, verão—summer, inverno—winter, soja—soybean

production), temporary crops (33 %) and some vegetable production (10 %). Large-scale organic commodity production accounts for 11 % of organic production. Organic vegetable production represents 4.4 % of all farmland dedicated to vegetable production. Sixty percent of Brazil's organic production is exported, mainly to the US, the EU, and Japan. The organic industry has established a 0 % threshold tolerance level for comingling between GM and organic production.

Brazil does not have a broad coexistence policy for the production of GM crops but does have a specific program explicitly for GM maize. Brazil is the third largest maize producer in the world, producing more than 70 million metric tons annually in 2011–2013. Maize is a very technical crop in Brazil and farmers are very innovative, with about 80 % of farmers using certified seed. As of 2011 there were 17 approved GM maize varieties: 6 insect resistant varieties, 3 herbicide tolerant varieties, and 8 varieties with stacked traits.

Table 1 presents the cumulative GM maize production over the two growing seasons. It is expected that in the first growing season 54 % of production will be GM maize and in the summer season or the second season, 80 %. Three-quarters of the maize production is intended to be used as feed, with only 1.4 % of maize production intended directly for human consumption.

Brazil has mandatory regulations for GM maize production. Following the implementation of the Biosafety Law in 2005, there was growing social pressure to ensure that GM maize production would not adversely affect producers choosing not to adopt the technology. The Environment and Consumer Protection Sector petitioned the Brazilian court to develop coexistence policies for the production of GM maize and the court decided to direct this to the government, which agreed to act. The 2007 resolution, published by CTNBio, established a mandatory rule applying to the commercial production of GM maize. The ruling is not applied to seed production because it is already regulated elsewhere; similarly it is not applied to research activities with non-authorized GMOs. Most importantly, the rule is not structured as a biosafety issue; it specifically regulates aspects of commercial GM maize production.

Brazil's coexistence policy requires the establishment of a 100 m buffer distance from the edge of a GM maize field to the start of a non-GM maize field. Alternatively, it is possible to use a 20 m buffer when there is a border of a minimum of 10 rows of non-GM maize on the outside of the GM maize field. Buffer zones of these distances were established by CTNBio based on gene flow studies and also by taking into account the national law or legislation for GM labelling which established a 1 % threshold for GM ingredients.

Table 1 GM maize estimates in Brazil (2011/12)

Region	1st season (%)	2nd season (%)
North	1	21
Northeast	30	58
Southeast	72	82
South	67	89
Midwest	82	79
Total	54	80

The coexistence policy addresses five potential scenarios for enforcement purposes. First, there can be an isolated field of GM maize, which would be a field that is distant from any other maize crops. Second, there can be what is called a non-isolate GM maize field, where a GM maize field exists in a region that typically grows maize, but without maize cultivation in the direct vicinity. Third, there can be a GM maize field next to another non-GM maize field, but with a separation distance of at least 100 m. Fourth, the situation could exist where a GM maize field is less than 100 m away from another non-GM maize field. Finally, there can be a GM maize field adjacent to another GM maize field, which would mean that there would not be any coexistence concerns.

The coexistence rule for the production of GM maize is enforced by the Ministry of Agriculture, Livestock, and Food Supply (MAPA). The legislation established the possibility for the application of fines in the case of noncompliance with the rules. Fines can range from $2000 Brazilian reals to $60,000 (US$1100–$34,000).

Implementation of the new policy required considerable organization and training. The initial phase of the policy was to make contact with producers to inform them about the new legislation. This contact was done by officials from MAPA. Contact was then made with organic and non-GM producers to identify where the areas of non-GM maize production were situated and to prioritize those areas during enforcement inspections. Advice about the new coexistence rules were also included on packages of seeds that would be available for purchase by farmers. Inspectors were trained and investments made in the official laboratories tasked with verifying any of the samples that required testing. Three official government laboratories were established and six private laboratories were audited and accredited by representatives from MAPA. Finally, field inspections were performed by MAPA's federal inspector, in each season and region of corn production, to verify compliance.

This initiative was strongly supported by the industry which helped a great deal in ensuring that the information about the new coexistence policies were both widely disseminated and that farmers were fully informed about the policy and the compliance testing. The industry produced leaflets that were shared with the producers, which explained the coexistence policy in greater detail. This was of great assistance in the success of the coexistence policy. Table 2 shows the total number of inspection conducted in 2009 and 2010. A total of 1215 inspections were conducted with only 96 violations reported, which represents a noncompliance rate of 7.9 %.

Coexistence Consequences

Some general observations can be made about Brazil's coexistence policy. Given that there has not been much experience with this legislation these comments are preliminary observations about the policy. First it is important to mention that there is little knowledge or even interest in coexistence rules among farmers who are dedicated to producing GM corn. These farmers are more concerned about refuge

Table 2 Coexistence inspections 2009–2010

Region/state	Number of inspections	Number of violations	Noncompliance rate (%)
North	17	0	0
Tocantins	17	0	0
Northeast	163	3	1.8
Bahia	163	3	1.8
Midwest	285	24	8.4
Mato Grosso	58	10	17.2
Goiás	79	8	10.1
Federal District	5	0	0
Mato Grosso South	143	6	4.2
Southeast	209	8	3.8
São Paulo	96	5	5.2
Minas Gerais	113	3	2.7
South	541	61	11.3
Rio Grande South	97	6	6.2
Paraná	344	46	13.4
Santa Catarina	100	9	9.0
Total Brazil	1215	96	7.9

area, which is important for the technology, than coexistence rules. There was a lot of criticism in 2009–2011 about the criteria used in adopting the rules, as non-GM maize farmers argued that staggered planting should be imposed to isolate flowering periods in order to ensure no pollen flow.

As mentioned above, 75 % of Brazil's maize production is directly destined for the animal feed market and very little is consumed directly by consumers. Government compliance officers have observed a lot of cases where arrangements between or among producers have been adopted to solve any compliance problems. Mutual agreements have been used to solve coexistence problems when they arise. For example, some farmers producing GM maize may buy the production of a neighbor's non-GM field. It has also been observed that most of the organic farms are normally away from areas with GM cultivation. As of late 2011 there were no reports of complaints or litigation between neighbors. The rapid and wide-spread adoption of GM maize has resulted in a decreased need to have coexistence strategies in place from field to field. The higher the number of events authorized for commercial release and production, including plants with stacked genes, the most complex the procedures of compliance verification in the field. There is a general consensus that the adoption of agricultural biotechnology in Brazil will continue to expand.

The adoption rate of GM maize in Brazil is very high and the tendency is for fewer situations of GM and non-GM coexistence in the field. New agricultural arrangements and practices based on identity preservation schemes and certification

may be developed in the future to address any specific demand for non-GM production of a crop commodity; government support policies may be necessary to accomplish this. Coexistence with organic crops tends to bring no significant consequences in Brazil considering the organic market is largely segmented into vegetables where there are no GM varieties. In other cases specific regulations address the outstanding concerns. In those instances with potential comingling, contract strategies may avoid the problem, such as for feed supply for organic poultry producers.

Finally, there are harmonized approaches to testing for the adventitious presenceof unwanted products and regulations establishing practical thresholds that help to ensure the continued functioning of the globe trade system. One issue of considerable concern is that coexistence in Brazil is commonly confused with biosafety. Efforts need to be invested to clarify the difference between the two systems for both different stakeholders and politicians. Mandatory rules or recommendations on coexistence need to be feasible and take into account not only distance or buffer zone criteria for field isolation but also differences in growth and flowering. Capacity building and infrastructure investments are needed to assist with detection of GM crops and for the management and monitoring of coexistence practices. The participation of the seed industry has been very helpful in the case of coexistence in Brazil.

The final lesson from the Brazil case is that the reality of coexistence is very different from the theory of coexistence. At the beginning of this policy process, many within MAPA were very concerned about the feasibility and what the cost of this policy might be in inspection terms but also in terms of trade and relationships among producers. The fact is that the practice has shown that there have not been many problems or troubles with this regulation.

Summary/Synthesis

Brazil has been a strong adopter of GM crops and is currently the second largest global producer of GM crops. In 2005, Brazil passed the Biosafety Law that provides the regulatory framework for the risk assessment and approval of new crop varieties that have been developed by biotechnology. This framework separates the risk assessment and risk management functions, which has proven beneficial. Brazil also requires labeling for all consumer food products with more than 1 % GM content.

Brazil's coexistence policy applies specifically to maize, rather than GM crops in general. Compliance testing with the coexistence system following the first few seasons revealed a very high compliance rate, with 92 % of compliance testing meeting the coexistence policy protocols. The theory of coexistence has proven to be considerably different from the practical realities of coexistence; the importance of industry co-operation and contributions cannot be understated.

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What Can We Learn About Coexistence from Commercial Non-GM Programs in the US?

Nicholas Kalaitzandonakes and Alexandre Magnier

When it comes to the coexistence of conventional, genetically modified (GM) and organic crops, different countries have taken different regulatory approaches. In some countries, like in the case of the US, governments have let the market and firms manage coexistence. In other countries, as in the case of the European Union (EU), governments have actively regulated coexistence through specific rules and allocation of property rights. Indeed, the EU has been the most active in the introduction of such regulations. Since the mid-2000s it has introduced policies to guide coexistence whose stated goal is to provide freedom of choice for farmers in their production decisions and for consumers in their purchasing decisions. In this context, a set of technical, administrative, and liability rules, collectively called coexistence measures, was established (European Commission 2010). Some of these rules can be characterized as *ex ante* and others as *ex post*. *Ex ante* measures seek to limit the accidental low-level presence (LLP) of GM material in conventional and organic crops by specifying minimum isolation distances between GM and other crops, the use of buffer zones, and other technical means to limit accidental outcrossing and genetic admixture. *Ex post* measures seek to compensate non-GM producers for economic losses when LLP is not prevented.

One of the fundamental principles upon which EU coexistence policy is based is the newcomer principle. Under the newcomer principle, the rights of existing farmers growing traditional crops take legal priority. Any farmer who decides to cultivate a different crop variety, i.e. GM crops, bears the liability for any damage, in the form of genetic contamination, to neighboring traditional, non-GM crops. Based on this principle, and because of existing attitudes towards GM crops in Europe, EU coexistence rules hold GM farmers responsible for implementing *ex ante* coexis-

N. Kalaitzandonakes · A. Magnier (✉)
University of Missouri, Columbia, USA
e-mail: magniera@missouri.edu

N. Kalaitzandonakes
e-mail: KalaitzandonakesN@missouri.edu

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tence measures and liable if LLP occurs. Because of the principle of subsidiarity, however, the practical details of coexistence rules have been left to individual EU member states and thus the rules tend to vary between member states.

Some authors have suggested that the isolation distances established in various EU countries are often arbitrary and too large to be practical for farmers who want to produce GM crops (Ramessar et al. 2010). EU isolation distances have also been criticized on the grounds that they are not informed by relevant economic factors such as price premiums in non-GM crop production or cost efficiencies in GM crop production, and therefore can be disproportional (Demont et al. 2009). Other authors have argued that *ex post* liability rules may act as a disincentive to GM crop production, especially in the presence of sunk costs linked to the decision to plant GM crops (Beckmann et al. 2006). While there may be additional factors at work here, the end result is that there is little or no GM crop cultivation over most of the EU.

In the United States (US) the extant property rights regime is different, and the management of coexistence between GM and non-GM production systems has been left to market forces. GM crops that successfully complete required regulatory safety reviews are considered substantially equivalent to conventional varieties and can be freely comingled in the commodity supply chain. Any US farmer may decide to cultivate GM crop varieties with no legal requirement to consider the potential effects of that decision on neighboring producers. Non-GM products that are kept separate from their GM equivalents and organic crops are treated as value-added crops commanding price premiums that vary according to prevailing supply and demand conditions. These premiums compensate non-GM farmers and traders for any incremental costs they incur, including those imposed by the segregation of non-GM from GM crops (through field isolation, buffer zones, etc.) and identity preservation (IP) throughout the supply chain. Hence, unlike the EU, in the US non-GM growers assume the costs of coexistence and, in turn, pass those costs on to purchasers of non-GM crops. There is an active non-GM crop production segment in the US that supplies both the domestic market and export destinations such as Japan, South Korea, and the EU.

But what are the characteristics of farmers who grow non-GM crops in the United States? Why do they choose to produce these crops and what kind of coexistence constraints do they face in doing so? Little is known about these questions. We provide some answers in this chapter with data from two surveys, of US maize and soybean producers we carried out in late 2013 and early 2014.

Survey of US GM and Non-GM Producers

Almost 15,000 producers were contacted by a market research firm via email and asked for their views on IP, value-enhanced maize and soybean production systems, including non-GM, through a web-based survey. The survey solicited producer perceptions concerning the relative profitability of value-enhanced maize and

Table 1 Maize and soybean acres planted in 2013

Acres	Non-GM growers (%)	GM growers (%)
100<	16.3	22.2
100–249	4.1	3.9
250–499	13.3	9.8
500–999	21.4	24.7
1000–2499	31.1	27.1
2500–4999	10.2	10.3
5000–7499	1.0	1.5
7500–9999	1.0	0.6
>10,000	1.5	0.0

Source Producer surveys

soybean production, potential constraints for segregation and IP, and the perceived suitability of such crops for the producer's operations. A total of 1175 growers provided complete survey responses; 299 had grown IP non-GM crops and 10 had grown organic crops in the 5 years prior to the survey.[1] To avoid excluding any small growers involved in non-GM maize and soybean production, we placed no minimum acreage requirement for participation in the surveys.

Demographics and Farm Characteristics

We first compared farm characteristics and farmer demographics of non-GM growers to those of GM growers. Roughly 15 % of the sample was composed of growers that grew less than 100 acres of maize and soybeans. Despite this, we found that non-GM maize and soybean growers had a similar size distribution to that of GM growers (Table 1). In fact, on average, non-GM farmers were slightly larger in size with 45 % growing at least 1000 acres of maize and soybeans in 2013, compared to 39.5 % of GM farmers in that size range.

We also found that non-GM growers have a similar distribution in terms of land tenure as GM growers. Almost 41.2 % of non-GM farmers and 49.5 % of GM farmers surveyed own 50 % or more of the land they cultivate, while 5 % of non-GM and 7.6 % of GM producers rent all of their land (Table 2).

[1]We note here a small number of US producers grow conventional (non-GM) crops that are not segregated and are not sold through IP non-GM supply chains but rather they are comingled with GM crops in commodity supply chains. Such producers, along with producers of GM crops, may be referred to as "commodity producers" since they grow undifferentiated crops. Because of the pervasive adoption of GM maize and soybeans in the US, however, the terms "GM growers" and "commodity growers" are used interchangeably here. In contrast, the term "non-GM producers" is used to indicate growers of segregated non-GM crops that are sold in IP non-GM supply chains at a premium relative to commodity crops. There are non-GM producers in our sample that grow exclusively non-GM crops but there are also non-GM producers that grow both IP non-GM crops as well as GM/commodity crops on their farms.

Table 2 Percentage of land owned by growers

%	Non-GM growers (%)	GM growers (%)
Exactly 0	4.5	7.6
0–10	4.5	4.8
10–20	13.1	8.5
21–30	16.1	13.0
31–40	8.5	9.9
41–50	12.1	7.0
51–60	11.1	13.5
61–70	6.5	9.0
71–80	3.0	7.3
81–90	5.5	5.9
91–99	2.5	5.1
Exactly 100	12.6	8.5

Source Producer surveys

Table 3 Grower demographic characteristics

	Non-GM growers (%)	GM growers (%)
Education		
High school education	23.5	22.2
Some college, but no college degree	19.4	23.9
Associates degree	14.3	15.2
Bachelor's degree	33.7	30.3
Master's degree	6.6	7.3
Ph.D. degree	2.6	1.2
Age		
Under 18 years	0.0	0.0
19–24	0.0	1.2
25–35	8.2	1.2
36–50	19.7	22.2
51–70	68.0	67.9
71–80	4.1	7.4
80+ years	0.0	0.0

Source Producer surveys

Non-GM growers have a similar age and educational profile as GM maize and soybean growers. Roughly three quarters are older than 50 years of age while most of the remainder are 36–50 years old. Only 5 % of growers are younger than 35 years of age. By comparison, GM growers are virtually identical in their age distribution, except that they have a slightly larger portion in the 71–80 year old category. Non-GM growers have a slightly higher level of education than GM growers: 45 % have studied at undergraduate or graduate school levels versus 38 % of the GM growers (Table 3). All in all, non-GM and GM maize and soybean growers are demographically quite similar.

Incentives for Participation in Non-GM Production

Opportunities associated with non-GM crop production were perceived differently by non-GM and commodity producers. Non-GM producers consider improved profitability the primary reason for undertaking non-GM production (Table 4). Specifically, 64 % of non-GM maize and soybean growers considered improved farm profitability as 'important' or 'very important' reasons for participating in IP non-GM production, more than any other potential factor, while only 50 % of GM growers expressed the same opinion. A large share of non-GM growers also listed other factors as being important or very important. These include: producing a crop that buyers want (47 %); diversification of the farm operation (42 %); management of financial risk (35 %); expansion of the operation (25 %); and setting their operations apart from others or producing a cutting edge product (22–23 %). These results suggest that non-GM growers primarily have economic reasons for participating in non-GM production and IP, but both pecuniary and non-pecuniary motives are involved.

It is not surprising to find that non-GM growers generally consider their farm operations to be well-suited for segregation and IP. Seventy-five percent of non-GM growers consider their operations well suited for such production systems, while only 7 % believe their operations are not well suited (Table 5). But a surprising 52 % of all GM producers also consider their operations to be well suited for non-GM production. Hence, while GM growers choose not to produce non-GM crops, operational constraints appear not to be a significant factor in that decision.

Table 4 Grower motives for raising non-GM crops

Q. Do you agree or disagree that the following are good reasons for you, personally, to raise non-GM maize/soybean?		
[percent indicates share of growers that considered reasons to be important or very important (6 or 7 in 1–7 Likert scale)]		
	Non-GM growers (%)	GM growers (%)
To improve profitability of operation	64.4	49.5
To manage financial risk	34.6	28.4
To diversify farm operation	42.3	31.3
To expand operation	24.5	16.6
To connect with industry stakeholders	15.3	13.3
To set operation apart	23.1	15.9
To produce a cutting edge product	22.0	17.8
To showcase operation to landowners	15.9	13.2
To produce what buyers want	47.2	34.2

Source Producer surveys

Table 5 Perceived suitability of farm for non-GM crop production

Q. In your opinion, how well-suited is your farm operation for production of non-GM crops?		
	Non-GM growers (%)	GM growers (%)
Not at all well-suited—1	1	8
2	6	13
3	3	12
Neutral	15	20
5	15	20
6	35	19
Extremely well suited—7	26	8

Source Producer surveys

Potential Constraints on Non-GM Production

To further explore the nature of potential constraints, we asked whether growers would be willing to participate in non-GM production and IP if there was an adequate price premium but also a requirement that a large share of their acreage would have to be allocated to non-GM varieties. Given that a large share of non-GM maize and soybean growers use only part of their land for non-GM crop production, the hypothetical non-GM program that we proposed in the survey required most farmers in the sample to consider potential constraints that could prevent them from engaging in large scale non-GM production. The survey listed a number of possible constraints, including inferior agronomic performance of non-GM crops relative to other crops, sufficient isolation of fields; non-GM seed purity, adequate storage for segregating the non-GM crop, adequate labor on the farm to perform equipment and other clean-up, and gaining cooperation from neighbors in avoiding pollen flow from neighboring fields. Respondents had the opportunity to add to the list of constraints if they believed other factors to be important.

On the whole, it does not appear that non-GM growers are particularly constrained by coexistence or other production factors from participating in large scale non-GM maize or soybean production (Table 6). Roughly a quarter of all non-GM growers consider negotiating isolation distances and cooperation from neighbors, adequate storage, or adequate agronomic performance of non-GM crops "a serious constraint" to their participation in large scale non-GM production. This result likely reflects the effectiveness of the process by which growers with well-isolated fields, adequate storage, and sufficient labor for clean-up and other segregation activities tend to self-select into participation in non-GM production in the first place. Perhaps the more surprising result is that almost 50 % of the GM growers also did not perceive coexistence, storage, or labor constraints as "serious constraints" for participating in large scale non-GM production. This suggests that there may be a large number of acres that could be potentially allocated to non-GM crops in the presence of a sufficient economic incentive.

Table 6 Perceived constraints to large scale non-GM crop production among producers

Q. If there was a non-GMO maize program in your area with adequate premiums but required a significant share of your acres would any of the following present a constraint?		
[percent indicates share of growers that considered the following factors a serious constraint, (6 or 7 in 1–7 Likert scale)]		
	Non-GM growers (%)	GM growers (%)
Agronomic performance of non-GM crops	23.6	43.2
Sufficient isolation	25.6	54.3
Seed purity	18.1	32.0
Grain storage	22.4	37.7
Labor for cleanups	16.2	38.2
Cooperation from neighbors	21.8	44.1
Other	42.9	31.4

Source Producer surveys

Conclusion: Is There a Market Failure to Correct?

On the basis of our survey, we conclude that non-GM growers of maize and soybeans in the United States are commercial farmers who are not much different in size, asset ownership, and demographic characteristics to farmers that only grow GM crops. Non-GM growers seem to self-select into participation in non-GM production because they tend to have fields that are sufficiently isolated as well as sufficient storage and labor to facilitate segregation and identity preservation. They grow non-GM crops primarily to improve farm profitability, but also to diversify their operations and manage financial risk. When faced with the requirement to adopt large-scale non-GM production requiring a significant share of their acreage, a large majority of farmers do not find coexistence issues (e.g. field isolation, cooperation with neighbors) or other production and storage factors to be particularly constraining. This is an important insight as farmers' perceptions are shaped within the context of the widespread adoption of GM crops in most US maize and soybean production regions—levels of adoption that exceeded 90 % of land area at the time of the survey (James 2014). Perhaps an equally important insight is that even farmers who do not produce non-GM crops do not generally perceive coexistence issues to be a major constraint. This suggests that it might be possible for production and storage capacity to switch to non-GM production if sufficient economic incentive existed.

It is also worth noting that the views of GM and non-GM farmers described here do not seem to suggest the presence of market failure in ensuring the coexistence of GM and non-GM maize and soybean production in the United States. Non-GM price premiums and other potential pecuniary and non-pecuniary gains seem to provide adequate incentives for well-placed farmers who devote all or part of their farm to non-GM production. Additional land and storage assets appear readily

available for additional IP non-GM production in the presence of relevant market signals. This is an important result since market failure appears to be the justification for coexistence regulations installed in the EU and in other countries.

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Lessons from the Legal Cases of GM Alfalfa and Sugar Beet Deregulation in the United States

Nancy Bryson

Overview

The United States Department of Agriculture's (USDA) regulatory review process for the introduction of genetically modified (GM) plant events has been the subject of extraordinary judicial scrutiny for the past 7 years. The process began in 2007 with a decision from the District Court for the Northern District of California vacating the USDA's deregulation of Roundup Ready Alfalfa (RRA) (the *Geertson I* litigation).[1] RRA contains a glyphosate resistance gene that enables the alfalfa to survive spray applications of the glyphosate herbicide. The *Geertson* petitioners successfully argued that the USDA Animal and Plant Health Inspection Service (APHIS) was required by the National Environmental Policy Act (NEPA) to conduct an environmental impact statement (EIS) on the effects of the deregulation and had failed to do so. The process concluded with a May 17, 2013 decision from the Ninth Circuit Court of Appeals approving the USDA's decision to again fully deregulate RRA on an administrative record that includes an EIS evaluating these effects (the *Geertson II* litigation).[2]

In the interim, the litigation passed through multiple phases and multiple courts, including the US Supreme Court. Simultaneous companion litigations by the Center for Food Safety (CFS) challenging the USDA decision to deregulate Roundup Ready Sugar Beets (RRSB) tested evolving USDA regulatory strategies to manage the re-regulation of widely commercialized GM organisms while conducting

[1] *Geertson Seed Farms v. Johanns*, 2007 WL 518624 at *12 (N.D.Cal. Feb. 13, 2007).
[2] *Center for Food Safety* et al. *v. Vilsack*, ____ F. 3d ____ (9th Cir., dec. May 17, 2013).

N. Bryson (✉)
Holland & Hart, LLP, Washington, DC, USA

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additional analysis of potential environmental effects (the *CFS I*, *II* and *III* litigations).[3] The factual dispute on the impacts of GM plant effects on organic and conventional production necessarily led to extensive and transparent evaluation of the effectiveness of various coexistence strategies.

The litigation has produced definitive answers to several important questions regarding the scope of the USDA's legal authority, the requirement for USDA consultation with the Fish and Wildlife Service (FWS) under the Endangered Species Act (ESA) and the role of mitigation measures under NEPA.

The USDA Mandate

Under the US Framework for the Regulation of Biotechnology, APHIS is responsible for plant health. The Plant Protection Act (PPA)[4] tasks the USDA and APHIS with the responsibility to prevent the introduction and dissemination of plant pests. A plant pest is defined in the law as "any living stage" of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus, infectious agent or other pathogen or an article similar to or allied with such that it "can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[5]

Pursuant to this mandate, APHIS has adopted regulations requiring submission of new GM plant traits for review and evaluation.[6] The regulations classify any organism produced through genetic engineering which APHIS determines is a plant pest, or has reason to believe is a plant pest, as a regulated article. Prior to deregulation, APHIS regulates the movement of all regulated articles in commerce, including release into the environment, through a system of notifications and permits. The owner of the technology can petition for deregulation of the trait based upon evidence demonstrating that it is not a plant pest. If APHIS concludes, based upon its review of the evidence and consideration of public comments, that the trait is not a plant pest, it will issue a decision deregulating the trait. APHIS issued such deregulation decisions for RRA and RRSB in 2005 based upon its determination that neither was a plant pest.

NEPA requires agencies to consider the impacts of major federal actions on the environment. This is a procedural requirement. NEPA does not expand the agency's substantive legal authority but mandates a 'hard look' at the consequences of the action being taken, including the cumulative, direct, and indirect effects. An environmental assessment may be conducted through which the agency concludes that its action will not have a significant impact on the environment. An EIS is

[3] *CFS v. Vilsack*, dec. 9/21/09 and 8/13/10 (CFS I); *CFS v. Vilsack*, (*CFS II*) and *Grant v. Vilsack (CFS III)*.

[4] 7 U.S.C. § 7701 et seq.

[5] 7 U.S.C § 7702(14).

[6] 7 C.F.R. Part 340.

required where the agency concludes that a significant impact may result. APHIS has adopted regulations governing its compliance with NEPA for its regulated article program.[7] APHIS relied upon environmental assessments for its NEPA compliance with both RRA and RRSB, a practice it had successfully followed for many prior deregulation decisions for other crops, including glyphosate resistant corn, soybeans, and cotton.

The ESA is designed to protect threatened and endangered species.[8] Where a discretionary decision of a federal agency may affect such species, it is required to consult with the federal wildlife resource agencies, generally the FWS. A Memorandum of Understanding between the USDA and the FWS describes how the consultation process will be conducted for new GM plant events under a decision tree flow analysis. Based on its determination that the RRA and RRSB plants themselves presented no risk to threatened or endangered species, the USDA concluded that the requirements of this law were met for RRA and RRSB.

Judicial Review

Any person adversely affected or aggrieved by final agency action is entitled to judicial review in the federal court system under the provisions of the Administrative Procedure Act (APA),[9] the PPA and other federal law. The standard of review is deferential to the technical findings of the expert agency. In particular, the court will examine and evaluate the following:

- Has the administrative agency done its substantive science-based risk assessment job?
- Has the administrative agency satisfied related procedural requirements, such as those created by NEPA?
- Has the administrative agency provided a rational explanation for its decision that is supported by the administrative record?[10]

Jurisdiction to review APHIS GM plant deregulation decisions is vested in the federal district courts, with opportunity for appeal to the federal circuit courts and the US Supreme Court.

[7] 7 C.F.R. Part 372.

[8] 16 U.S.C. § 1531.

[9] 5 U.S.C. Section 706.

[10] APA Section 706 authorizes reviewing courts *to inter alia* set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "without observance of procedure required by law," and "unsupported by substantial evidence."

The Geertson Litigation

The *Geertson* plaintiffs, a group of conventional and organic alfalfa growers as well as consumer organizations, argued that APHIS had violated its procedural obligation under NEPA by failing to conduct an EIS to examine the significant environmental impacts of its RRA deregulation decision. They identified three specific environmental impacts as the basis of their complaint including the following: (1) gene transmission from RRA would modify conventional and organic alfalfa through cross-pollination or mixing of genetically engineered seed with non-engineered seed; (2) alfalfa weeds resistant to herbicide would develop; and (3) the use of glyphosate would increase. In addition, the complaint alleged that RRA was a plant pest within the meaning of the PPA, and that APHIS was required to consult with FWS under the ESA, which it had failed to do.

The heart of the case, however, was the gene transmission claim. Plaintiffs argued that alfalfa seeds are pollinated by bees within a 2-mile radius, creating a realistic potential for gene transmission or 'contamination' between seed fields of genetically and non-genetically engineered alfalfa seeds located in close geographic proximity. They argued that contamination between the actual forage crops was also possible due to inability to strictly control harvest timing and potential for seed formation in those crops. They further argued that such contamination would have negative economic and socioeconomic effects on organic farmers who would lose organic market shares and on consumers who would lose choices allowing them to avoid GM foods.

The District Court determined that the plaintiffs had raised substantial questions which triggered the APHIS obligation to conduct an EIS. In so doing, the Court reviewed the rationale offered by APHIS in support of its conclusion to the contrary and found it to be wholly inadequate under applicable judicial review standards. Among other things, the Court found that while alfalfa is the fourth largest crop in the United States, APHIS had made no inquiry into whether farmers who do not want to grow genetically engineered crops could in fact protect their crops from contamination or what methods they could use to do so. Accordingly, the Court vacated the deregulation without ruling on the PPA or ESA claims, returning RRA to regulated article status and ordered APHIS to conduct the EIS.

In the interim, the Court entered an injunction preventing additional planting of RRA under specific gene transmission mitigation measures that had been developed and proposed by APHIS. These included:

- Mandatory isolation distances between RRA and non-genetically engineered alfalfa fields in order to mitigate the risk of gene flow;
- Mandatory harvesting conditions;
- A requirement that planting and harvesting equipment that had been in contact with RRA be cleaned prior to any use with conventional or organic alfalfa.
- Identification and handling requirements for RRA seed; and

- A requirement that all RRA seed producers and hay growers be under contract with either Monsanto or Forage Genetics, Inc. (FGI) and that their contracts require compliance with the forgoing mitigation measures.

APHIS, Monsanto (the applicant for the deregulation decision), and intervenor defendant RRA alfalfa farmers appealed this decision to the Ninth Circuit. They argued that the injunction was overbroad because it presumed irreparable injury (gene transmission) would occur without considering the effect of the APHIS recommended mitigation measures. The 9th Circuit, however, affirmed the District Court decision and injunction on June 24, 2009.[11]

The Supreme Court Monsanto Decision

The US Supreme Court agreed to hear the case on appeal and on June 21, 2010 held that the injunction was improper.[12] The Court ruled that upon finding that the deregulation was procedurally invalid, RRA was returned to regulated article status and to the jurisdiction of APHIS as the expert administrative agency. The Supreme Court decision on the use of RRA reaffirmed that APHIS has the regulatory authority for deregulation decisions and that it is proper for APHIS to make a decision of this nature, not the District Court.

Where it is determined that an EIS is conducted, an agency may still authorize actions that do not themselves have a significant environmental impact. The Supreme Court determined that APHIS could make such a finding based on mitigation measures that it might impose under its regulated article program, including partial deregulation and that any such agency decision would be based upon a new administrative record to which the right of judicial review would apply. Therefore, the Supreme Court found that the District Court did improperly presume that irreparable injury would occur from any additional RRA planting and exceeded its jurisdiction in entering the nationwide injunction on planting pending completion of the EIS.

The Court expressed no opinion on whether the potential for gene transmission actually was a significant impact on the environment since APHIS had not appealed the District Court's decision that it must conduct the EIS. It did hold, however, that both the RRA alfalfa farmers and Monsanto as well as the Geertson plaintiffs had standing to pursue their respective claims.

[11] *Geertson Seed Farms v. Johanns*, 570 F. 3d 1130, 1133–34 (9th Cir. 2009).

[12] *Monsanto Co.* et al. *v. Geertson Seed Farms* et al., 130 S. Ct. 2743 (2010).

The CFS Litigation

The CFS I Litigation

On the heels of the successful challenge to the RRA deregulation decision, CFS challenged the deregulation of RRSB as well in the District Court for the Northern District of California ("*CFS I*"). The complaint was filed on January 23, 2008, almost three full years after the APHIS deregulation had been issued and RRSB had been commercialized to the widespread acceptance by sugar beet producers.

Sugar beets, unlike corn, soybean or alfalfa, occupy a highly regulated market. Production of sugar for human consumption is closely regulated by the USDA through a system of statutory and regulatory allocation of rights. Sugar beets in the US are produced by a small number of cooperatives in the upper Midwest that decide what sugar beet seeds will be planted under a system of trials in which disease resistance and yield are evaluated over a period of several years. Based on the results of these trials, in which the seed producers compete, the cooperatives authorize seed purchase and planting.

Sugar beet seed is produced from sugar beet parent roots (stecklings) that are planted in the fall, allowed to overwinter in the ground, and then replanted in the spring in correct parent groups to flower, cross-pollinate and produce seed in the following summer for harvest in August or September. Sugar beet root that is grown by the cooperatives for sugar production is planted in the spring and harvested in the fall. Sugar beet is a member of the genus Beta and can cross-pollinate with red beet and Swiss chard in seed production.

Thus, 3 years after deregulation, the sugar cooperatives had evaluated RRSB in their seed trials, approved them for planting for production based on significantly enhanced weed control with concomitant disease resistance and yield improvements, and the seed companies had primarily moved to RRSB in their US production in the Willamette Valley of Oregon.

CFS did not seek a preliminary injunction and the case proceeded to decision on cross-motions for summary judgment. On September 21, 2009, the District Court granted summary judgment for CFS as it had in *Geertson*, finding that RRSB can cross-pollinate with and contaminate non-genetically engineered sugar beets, related swiss chard, and table beets; that pollen can travel by wind; and that seed for all three crops is produced in the Willamette Valley. The court held that these facts established that the RRSB deregulation would have a significant effect on the human environment and that APHIS's conclusion to the contrary was conclusory and not supported by its administrative record. Accordingly, the District Court ordered APHIS to conduct an EIS.

This case then moved into the remedies phase, at which point the Court permitted the seed producers, the sugar beet cooperatives, and Monsanto as the technology provider, to intervene. Two major issues in the remedies phase were (1) whether there was any actual evidence of gene transmission between seed crops in the Willamette Valley under the Willamette Valley Specialty Seed Association

(WVSSA) pinning and isolation distance requirements and (2) whether there was even enough viable approved conventional seed to plant a conventional sugar beet seed crop given the long lapse time between deregulation in 2005 and the court's ruling that an EIS was required. The court authorized limited discovery including interrogatories and depositions for further fact development.

On January 19, 2010, CFS filed a request for a preliminary injunction preventing further RRSB planting in the spring of 2010 pending completion of the remedies phase of the litigation. On March 16, 2010, the Court denied that request based largely on plaintiff's long delay in seeking such relief but stated that it was inclined to enjoin further RRSB use pending completion of the EIS and to require use of conventional seed based on its finding that gene transmission constituted irreparable injury. The summary judgment briefing on the remedy proceeded with APHIS again submitting to the court a set of enhanced mitigation measures based on the WVSSA requirements under which regulated RRSB production could continue in order to prevent risk to organic and conventional producers of red beet and swiss chard while also avoiding undue injury to US sugar beet production.

The Supreme Court's *Monsanto* decision issued while the CFS I court was considering its decision. The District Court immediately ordered additional briefing on the impact of the case. On August 13, 2010, the Court reaffirmed its decision to vacate the deregulation but simply remanded the matter to APHIS. It denied plaintiff's request for an injunction. The court's decision was limited to prohibiting the planting of RRSB after the date of the order.

The CFS II Litigation

The date of the final decision on *CFS I* in August 2010 fell in the middle of the planting season for the sugar beet seed for the 2012 root crop planting season. In order to preserve the potential of a 2012 RRSB crop should it again be deregulated after an EIS was conducted, APHIS thereafter issued permits to four seed companies for planting the remainder of that seed crop as regulated articles under it Part 340 regulations. The permits authorized planting of stecklings on limited acreage in defined geographic locations in Oregon and Arizona and included conditions prohibiting flowering or pollination before the permits expired on February 28, 2011. The permits were supported by NEPA "Decision Worksheets" explaining that such limited steckling growth would have no significant environmental impacts.

CFS plaintiffs immediately filed a second lawsuit (*CFS II*) challenging the permit decisions. It asserted that APHIS was flouting the court's ruling overturning RRSB deregulation by authorizing continued production of a commercial seed crop under permit while it was conducting the EIS. CFS requested a temporary restraining order and preliminary injunction requiring immediate destruction of seed crops planted under the permits. They argued that NEPA prohibited APHIS from taking any action to authorize additional planting of RRSB pending

completion of the EIS. The District Court agreed. It concluded that the CFS had demonstrated a likelihood of irreparable harm from the entire cycle of RRSB planting and production and entered a preliminary injunction ordering destruction of the seed plants.

APHIS, Monsanto, and defendant intervenor seed companies filed emergency motions with the Ninth Circuit for a stay pending appeal. These motions were granted. On February 25, 2011, the Ninth Circuit issued its opinion finding that the District Court had abused its discretion in granting this preliminary injunction. The Court found that the undisputed evidence demonstrated that the non-flowering stecklings presented a negligible risk of gene transmission as the plants were biologically incapable of flowering prior to expiration of the permits. Under the *Monsanto* ruling, such action was well within APHIS legal authority and any subsequent authorizations could be challenged again by the CFS. Accordingly, the Ninth Circuit vacated the preliminary injunction based on the absence of any irreparable injury and remanded.

Upon remand, the District Court dismissed the CFS permit litigation as moot as by that time, the permits at issue had expired and APHIS had taken further administrative action. On February 4, 2011, APHIS announced its decision to partially deregulate RRSB pending completion of the RRSB EIS based on an extensive environmental assessment and extensive public comment. The partial deregulation created a permit program for RRSB seed production under the Part 340 regulated article program and a compliance program for RRSB root crop production.

The CFS III/Grant Litigation

Both CFS and the sugar beet cooperatives and seed producers (the Grant Plaintiffs) filed challenges to the partial deregulation decision. The CFS filed its challenge again in the Northern District of California, and the Grant plaintiffs filed theirs in the District Court for the District of Columbia Circuit (DC District Court). Both cases were consolidated in the District Court for the District of Columbia (*CFS III*).

Shortly after consolidation in the DC District Court, the CFS withdrew its motion for preliminary injunction that had been filed in the Northern District of California and the case proceeded to briefing on summary judgment. APHIS then filed its substantial administrative record in support of its rationale for determination that continued production of RRSB under the rigorous protective conditions of the partial deregulation would not create any significant impact on the environment pending completion of the EIS and the case proceeded to briefing on summary judgment.

Prior to any merits ruling, APHIS issued the final RRSB EIS and deregulation decision on July 19, 2012. On September 25, 2012, the District Court determined that the Grant litigation was also moot, as it had been replaced by the final deregulation decision. No challenge to the final RRSB EIS has been filed.

The Geertson II Litigation

While the fate of the RRSB stecklings planted under permit was pending in the Ninth Circuit, APHIS also issued its final EIS for RRA. This EIS contained two co-preferred alternatives. The first was complete deregulation. The second was a partial deregulation through a combination of isolation distances and geographic restrictions intended to reduce the risks of transgenic contamination. In this alternative, a marketer of RRA would ensure that end users implemented the required management practices through contracts, licenses, or other means. In the final Record of Decision, alternative one was selected by APHIS and RRA was completely deregulated. As explained by APHIS, its final conclusion was that once it determined that RRA was not a plant pest, it had no discretion under the legal authority granted to it by Congress in the PPA to continue to impose any restrictions on its dissemination and use.

The Geertson plaintiffs, this time with the CFS as the lead plaintiff, returned to the Northern District of California to challenge this decision (*Geertson II*), arguing that APHIS had once again violated NEPA, the PPA and the ESA. In this case, however, the District Court addressed each of the claims and upheld the APHIS deregulation decision in all respects in a decision issued on January 5, 2012.[13] First, it held that the APHIS decision was fully compliant with the PPA. The APHIS record and explanation of its action established that RRA was not a plant pest—that is, not a living organism that could harm other plants. The Court affirmed the APHIS determination that the PPA does not require APHIS to take potential effects of cross-pollination on other commercial crops into account in making this decision based on the plain language of the statute (a 'plant pest' is a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or infectious agent or other pathogen). In addition the Court found that the PPA does not require APHIS to consider the effects of increased herbicide use or the development of herbicide resistant weeds in the plant pest risk analysis.

Second, because the PPA leaves APHIS with no discretion to regulate RRA once it determined that it was not a plant pest, the court found that the ESA consultation requirement was not triggered, as that requirement applies only to discretionary agency actions. And finally, the Court concluded that the APHIS EIS satisfied all of the NEPA procedural requirements applicable to the deregulation decision.

The CFS appealed the decision to the Ninth Circuit. On May 17, 2013, the Ninth Circuit affirmed the District Court decision, upholding the APHIS RRA deregulation decision in all respects. The Ninth Circuit ruled that under the PPA, APHIS jurisdiction over GM plants is limited to plant pests—i.e. organisms or associated articles that can cause widespread physical damage or destruction of other plants. The potential for pollen flow and cross-pollination with other plants is not a plant pest. Once APHIS determines that a GM event is not a plant pest, it has no

[13] *Center for Food Safety,* et al. *v. Vilsack*, 2013 U.S. App. LEXIS 9920, 43 ELR 20111, 2013 WL 2128324 (9th Cir. Cal. 2013).

discretion to continue to regulate that event. Thus, APHIS has no duty to consult under the ESA (a duty which is triggered only for discretionary agency decisions) and no authority for partial deregulation. Finally, the Court held that APHIS was not required by NEPA to look at the partial deregulation alternative absent any jurisdiction to adopt it and concluded that the extensive NEPA analysis undertaken in the EIS fully satisfied the requirements of NEPA.

Lessons Learned

This litigation cycle begins and ends with deregulation of RRA and, coincidentally, of RRSB. Through the course of the multiple court decisions and responsive actions by APHIS and the other litigants, the following principles have been established.

- APHIS jurisdiction under its current GM plant event regulatory review process is limited to plant pests—a defined group of organisms that can cause widespread physical damage or destruction of other plants.
- Pollen flow and cross-contamination are not plant pests.
- Increased use of the herbicide glyphosate is not a plant pest harm.
- Once APHIS concludes that a GM plant event is not a plant pest, it has no discretion to impose any continuing restrictions on use of that event.
- APHIS has no duty to consult with the FWS on nondiscretionary deregulation decisions.

Finally, with respect to the NEPA issues that launched the litigation, those courts that have considered the RRA EIS have both concluded that the robust discussion of coexistence measures that have evolved in the marketplace to facilitate coexistence pass the relevant NEPA procedural standards.

Organic Versus GM Agriculture in the Courtroom in Australia and the USA

Michael Blakeney

Introduction

The size of the trade in organic agriculture was estimated to be worth $US 64 billion in 2014[1] and has been increasing at a rate of 10 %. This valuable trade is of obvious interest also to developing countries which are primarily agriculture-based economies. As early as 2003 the European Commission identified that the cultivation of GM crops was likely to have implications for the organization of organic agricultural production. In a communication of that year it observed that the possibility of the adventitious presence of GM material in organic crops raised the question as to how producer choice for the different production types could be ensured.[2] Additionally, the successful segregation of GM from organic agriculture is indispensable in preserving access to the lucrative trade in organic products. This chapter looks at litigation in Australia and the USA concerning the liability which arises in circumstances where GM cultivation was said to have imperiled organic agriculture.

[1]Research Institute of Organic Agriculture (FiBL), *The World of Organic Agriculture. Statistics and Emerging Trends 2014*, 23. Available at https://www.fibl.org/fileadmin/documents/shop/1636-organic-world-2014.pdf.

[2]Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming. Available at http://ec.europa.eu/agriculture/publi/reports/coexistence2/index_en.htm.

M. Blakeney (✉)
University of Western Australia, Crawley, Australia
e-mail: michael.blakeney@uwa.edu.au

M. Blakeney
Intellectual Property and Agriculture, Queen Mary University of London, London, UK

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The Australian case, *March v Baxter*,[3] which commenced in the Supreme Court of Western Australia, concerned a dispute between two neighboring farmers in which one claimed that the loss of his organic certification was attributed to the harvesting practices of his GM producing neighbor. The US litigation: *Organic Seed Growers and Trade Association* et al. *v. Monsanto*[4] concerned an unsuccessful application by a number of farmers organizations seeking a declaration that should their crops become contaminated by the adventitious presence of patented genetic material they ought not be sued for patent infringement.

Australia's GMO Regime

The release of genetically modified organisms (GMOs) in Australia is regulated by a combination of Federal and State legislation. The *Gene Technology Act* 2000 (Cth) (GTA) and the *Gene Technology Regulations* 2001 (Cth) is Federal legislation which establishes the Office of the Gene Technology Regulator (GTR) to identify and manage the risks posed by gene technology.[5] The release of GMOs into the environment for agricultural purposes is prohibited unless authorized under the GTA.[6]

The GTA sets out requirements that the GTR must follow when considering an application for a license to release a genetically modified organism (GMO) into the environment. The GTR is authorized to grant a license if it is satisfied that any risks to human and environmental safety posed by the GMO can be managed. Licenses and public risk assessments are used to control GMO releases, and strict liability is imposed for breach of the regulations. The GTR can require license holders to maintain buffer zones or physical barriers between GM and non-GM crops, clean equipment, and introduce seed handling and transport regimes to reduce the chance of contamination.[7] However, it is not yet clear what distance between GM and non-GM crops is necessary to prevent cross-pollination and contamination.

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[3][2014] WASC 187.

[4]718 F.3d 1350, 1354 (2013).

[5]Australian Government Department of Health and Ageing Office of the Gene Technology Regulator, *Overview of the Gene Technology Regulatory System*, Fact Sheet, April 2008, http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gmofactsheets-3/$FILE/factregsysoverview08.pdf.

[6]*Gene Technology* Act (2000) Cth, ss 32(1) and 33(1).

[7]See M Young and S Haynes, 'Genetically Modified Organisms: Environmental Regulation in Australia' (2000) 52(5) *Australian Company Secretary* 295; C Lawson, 'Risk Assessment in the Regulation of Gene Technology under the *Gene Technology Act* 2000 (Cth) and the Gene Technology Regulations 2001 (Cth)' (2002) 19 *Environmental and Planning Law Journal* 195; K. Ludlow, 'Gene Technology Regulation and the Environment Protection and Biodiversity Conservation Act 1999 (Cth)' (2004) 30 Monash University Law Review165.

Monsanto was granted a licence for the release of Roundup Ready® canola "after extensive consultation on the risk assessment and risk management plan with the public, State and Territory governments, Commonwealth agencies, the Federal Environment Minister, the Gene Technology Technical Advisory Committee and local councils, as required by the GTA."[8]

The GTA does not deal with the economic liability to neighboring farmers adversely affected by genetic contamination[9] as the GTR does not consider the repercussions of a GMO release on the agriculture of third parties when it assess the risks of a release.[10] This means that neither the GTA nor state legislation give statutory immunity to farmers who comply with the regulations but nevertheless cause damage to others.[11] GM farmers could assert that the GTR has authorized a GM release, having struck a balance between the parties' competing interests, and the court should not seek to reopen the matter[12] however an argument of statutory authority or that the legislation 'covers the field' is unlikely to succeed, given that the risk assessments are not comprehensive.[13] In other words, the GTA may minimize the likely risks posed by GMOs by identifying some risks and seeking to minimize their impact through appropriate management, but the GTA does not establish a cause of action for any third parties affected by economic, health, or environmental loss or damage resulting from GMOs.

When developing its GM policy, the Commonwealth Parliament chose not to implement special liability arrangements for harm caused by GM contamination[14] because it intended that questions of liability for harm be determined by the common law remedies including negligence and private nuisance. They were therefore deliberately retained in the GTA.[15]

Under the GTA it is a matter for individual states and territories whether to allow GM crop production. In 2003, the West Australian Parliament passed the *Genetically Modified Crop Free Areas Act 2003* (WA) which permitted the West Australian Minister for Agriculture to designate GM crop free areas. The Western

[8]OGTR, Licence DIR 020/2002 for 'Brassica Napus'; decision to grant licence. http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/dir020notific-htm.

[9]C. Deakin, 'Resolving the Regulatory Conflict: Lessons for Australia from the European Experience of Regulating the Release of Genetically modified Organisms into the Environment' (2008) 25 *Environmental Planning Law Journal* 103.

[10]See Karinne Ludlow, 'The Economic Impact of Genetically Modified Organisms as Actionable Damage in Torts' (2005) 13(2) *Tort Law Review* 162.

[11]K. Ludlow, 'Genetically Modified Organisms and Private Nuisance Liability' (2005) 13 *Tort Law Review* 92.

[12]Karinne Ludlow and Stuart Smyth, 'The Quandary of Agricultural Biotechnology, Pure Economic Loss, and Non-Adopters: Comparing Australia, Canada and the United States' (2011) 52 *Jurimetrics* 27.

[13]Mark Lunney and Robert Burrell, 'A Farmer's Choice? Legal Liability of Farmers Growing Crops: A Farmer's Choice? Australian Centre for Intellectual Property in Agriculture (2006) 25.

[14]Australia, Senate Community Affairs References Committee, 'A Cautionary Tale: Fish Don't Lay Tomatoes—Report on the Gene Technology Bill 2000', Canberra, 2000, 149.

[15]Ibid, 151–152.

Australia, *Government Gazette*, No 49 (22 March 2004) carried the Minister for Agriculture's Genetically Modified Crop Free Areas Order 2004 which designated the whole of the state of Western Australia as an area where genetically modified crops could not be cultivated. Following a change of government at the 2008 state election, on 25 January 2010 the Minister for Agriculture issued an exemption order pursuant to the Act, exempting any person from growing GM canola in any part of Western Australia provided that it was licensed under the GTA.

GM Agriculture in Australia

The Australian Department of Agriculture takes the position that GM technology can assist in managing pressure on global food supplies and the management of pest and diseases.[16] Currently, the only GM food crops produced in Australia are canola and cotton, but a variety of other GM foods can be imported and used as an ingredient in packaged foods. Genetically modified cotton has been grown commercially in Australia since 1996. GM canola, modified for herbicide tolerance, was approved for commercial production in Australia in 2003. GM crops accounted for 15–20 percfood crops produced in Australiaent of Australia's 3.2 million ton canola crop in 2012/13[17] and the proportion has been growing. However, due to bans imposed by State governments GM canola is currently grown only in the states of New South Wales, Victoria and Western Australia. Food Standards Australia New Zealand (FSANZ) allows manufacturers to use a wide range of imported GM food ingredients, including GM varieties of soybeans, maize, rice, potatoes and sugar beet.[18]

Field trials of GM pineapple, papayas, wheat, barley, and sugarcane are under way in Australia and gene technology research is also under way in Australia on bananas, rice, and maize.[19]

It is estimated that currently agricultural biotechnology in Australia is worth between $1.5 billion and $5.8 billion in national economic gains to 2015.[20]

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[16]Department of Agriculture, Biotechnology and Australian Agriculture—Towards the development of a vision and strategy for the application of biotechnology to Australian Agriculture (2011) http://www.daff.gov.au/agriculture-food/biotechnology/reports/towards-development.

[17]Colin Packham, *'Australia risks organic export growth as it struggles to coexist with GMO'* (29 May 2014) Reuters http://www.reuters.com/article/2014/05/30/australia-gmo-organic-idUSL3N0OG0O720140530.

[18]See FSANZ, 'Genetically modified foods' available at http://www.foodstandards.gov.au/consumer/gmfood/gmoverview/Pages/default.aspx, accessed 4 November 2015.

[19]See OGTR, 'Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment' available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/ir-1, accessed 4 November 2015.

[20]S Apted, D McDonald and H Rodgers 'Transgenic Crops: Welfare implications for Australia' (2005) 12 Australian Commodities 532 at 540 cited in Deakin p 103.

Given the expectation that climate change will cause a decline in agricultural yields and a higher occurrence of extreme climate events which will interact to affect agricultural productivity, quality, pests, and diseases, it has been argued that Australians will have to accept GM food if the agricultural industry is to continue in an era of climate change.[21]

Concerns have been expressed in the farming community that those non-GM farmers exposed to GM material might lose their organic status and suffer consequential economic loss.[22] The Organic Federation of Australia has stated that the right to be "GM-free" is a fundamental right that must be preserved, as it is a responsibility that farmers have to ensure their actions do not impact upon others.[23] The GM industry, on the other hand, has said that we need to consider the concept of 'freedom to farm' and the ability and freedom of adjacent farmers to make their own decisions in respect of growing non-GM and GM crops.[24] The fact is that the nature of farming practices is such that it is impossible to achieve perfect coexistence in a situation where farmers could choose to either embrace or completely avoid GMOs.[25]

Non-GM farmers are concerned that GM crops will contaminate their crops in a great variety of ways; cross pollination can occur when pollen disseminates over long distances,[26] and pollen dispersal can occur by wind, insects, and other carriers. Seeds can also be dispersed during transport, cropping, or harvesting.[27] The loss of organic certification carries the risk of the loss of access to organic markets in which a premium price can be charged. For example, in 2014 Japan and South Korea were reported to have halted American wheat shipments after an Oregon wheat farmer's field tested positive for an unapproved GMO wheat variety.[28]

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[21]Professor Mark Tester from the Australian Centre for Plant Functional Genomics at the University of Adelaide has said that GM food should be embraced as farmers battle the effects of global warming, See 'GMO emergency laws too risky' *The Sydney Morning Herald* (Sydney, Australia) May 7 2007.

[22]Managing Genetically Modified Crops in Australia: GM Crops, Segregation and Liability in Australian Agriculture' (2005) prepared by Avcare for ACIL Tasman.

[23]Liability Issues Study, n 1, p 3 citing Submission No 54 to the Senate Community Affairs References Committee, Parliament of Australia (Canberra, October 2000) (Organic Federation of Australia).

[24]Liability Issues Study, n 1, p 4 citing Submission No 42 to the Senate Community Affairs References Committee, Parliament of Australia (Canberra, October 2000) (Florigene Ltd and Nugrain Pty Ltd (Vic)).

[25]Karinne Ludlow, 'Genetically modified organisms and private nuisance liability' (2005) 13(2) *Tort Law Review* 159, 160.

[26]Will Hardy, 'Preparing the Law for a GMO Outbreak' (2008) 4.

[27]Because of Australia's size, produce is often transported thousands of kilometres, for example in 2002 GM seed from New South Wales was spilled in Darwin on its way to Western Australia. See J Randerson, 'GM-food safety checks inadequate, says report' *New Scientist* 4 February 2002.

[28]Connor Adams 'Australian GMO 'Contamination' Case Could Have International Repercussions' (9 May 2014) The International Business Times http://www.ibtimes.com/australian-gmo-contamination-case-could-have-international-repercussions-1582157.

There have been few cases between organic and GM farmers and little Australian case law with respect to the analogous situation of the spread of conventional agricultural organisms from one property to another.[29] The recent decisions of the Supreme Court and Court of Appeals of Western Australia in *Marsh v Baxter*[30] have attracted widespread interest, both domestically and internationally, as it is thus understood to be the first legal proceeding of its kind: a claim for economic loss caused by a GM incursion brought by one farmer against his neighbor.

Marsh v Baxter in the Supreme Court of Western Australia

Steve Marsh and his wife, organic farmers from Kojonup, Western Australia, had entered into a contract for organic certification with the National Association of Sustainable Agriculture (Australia) Ltd (NASAA) for their farm, Eagle Rest. Their farm shared a boundary with a neighboring farm operated by Michael Baxter, which was on the opposite side of a 20 m road. In early 2010, Baxter planted a crop of Monsanto's Roundup Ready (RR) GM canola in the paddocks of his farm which were adjacent to Eagle Rest and he had notified Baxter of his intention to do so. On 29 September 2010 Marsh had hand delivered to Baxter a document entitled 'Notice of Intention to Take Legal Action', which stated, amongst other things that:

1. The use of genetically modified organisms in farming, including GM canola seed (GMOs) has the potential to cause catastrophic commercial losses to non-GM farmers and particularly to non-GM farmers that have been accredited as being organic (or sustainable) farms (Organic Farmers) if GMOs enter upon and contaminate a non-GM farm or non-GM farm production cycle;
2. The principal cause of the commercial losses to Organic Farmers as a consequence of GMOs contaminating a non-GM farm or non-GM farm production cycle is as a result of the forfeiture of the price premiums attached to the sale of the produce grown by Organic Farmers and/or the withdrawal of their accreditation as Organic Farmers. There may also be other costs and expenses incurred as a direct consequence of such contamination by GMOs;

On 25 October 2010, Marsh had published in local newspapers notices to the effect that Eagle Rest was a 'GMO Free Area'.

In November 2010, Baxter harvested the GM canola by the process of swathing. This involved cutting the not yet fully matured canola plant close to its base. The

[29]Parliament intended that liability with respect to GMO contamination be consistent with how contamination is dealt with in other areas: Science and Economic Policy Branch, Liability Issues Associated with GM Crops in Australia, Scoping Study (Dept of Agriculture, Fisheries and Forestry, September 2003) (Liability Issues Study) p 5, citing Senate Community Affairs References Committee, '*A Cautionary Tale: Fish Don't Lay Tomatoes—Report on the Gene Technology Bill 2000'*, Canberra, 2000, 140 and 146.

[30][2014] WASC 187.

swathes were then stood to ripen in the paddock for several weeks before being processed by a header to harvest the ripened seeds from each swathe. This was the first time Baxter had swathed his canola instead of direct harvesting.

A total of approximately 245 GM canola swathes were blown by the wind and landed on the Marshes' farm in late November/early December 2010.[31]

After inspection of the GM canola swathes, NASAA decertified approximately 70 per cent of Eagle Rest on the basis of an assessment that the RR Canola swathes and seed pods identified on Eagle Rest posed an "unacceptable risk" of contamination under NASAA Standard 3.2.9 which provided that "Organic certification shall be withdrawn where NASAA considers there is an unacceptable risk of contamination from [genetically modified organisms] or their derivatives."

The Marshes sued Baxter for $AU85,000 for the loss arising out of the loss of NASAA/NCO certification for 70 % of Eagle Rest, citing negligence and private nuisance as the two causes of action. These actions were dismissed by the Supreme Court of Western Australia[32] and the Court of Appeal of Western Australia.[33]

Negligence Proceedings in the Supreme Court of Western Australia

The Marshes claimed that the presence of GM canola swathes had caused them to lose their contractual right to apply the "NASAA Certified Organic" label when selling their organically grown crops and livestock. They claimed economic loss only and sought common law damages and a permanent injunction to restrain Baxter from swathing a GM canola crop in the eastern boundary of his farm.

The Marshes alleged that Baxter knew of their organic certification and did not take reasonable steps to prevent movement of his GM canola seeds to Eagle Rest. The Marshes claimed that Baxter breached his duty of care to ensure that there was no escape of GM material and no loss to the Marshes. The Marshes private nuisance claim centered upon an alleged unreasonable interference by Baxter in the Marshes' ordinary use and enjoyment of their land.

Mr. Justice Martin observed that the negligence claim "traverses into legally unchartered territory".[34] He said that the duty alleged was novel and faced a conceptual difficulty given the law's reluctance to expand the categories of cases in which economic loss is recoverable.[35] His Honor's key finding was that the Marshes loss was without precedent and that no basis in principle had been shown to extend the law regarding pure economic loss to the events.

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[31]Ibid at [660], [662], [669], [686].

[32]Marsh v Baxter [2014] WASC 187.

[33]*Marsh v Baxter* [2015] WASCA 169.

[34][2014] WASC 187 at [307].

[35][2014] WASC 187 at [328]–[330], [336]–[338].

Justice Martin commented that the duty alleged by the Marshes: "to ensure that the Marshes did not suffer loss" was absolute and set far too high in circumstances involving broad-acre farming which was exposed to uncontrollable seasonal weather.[36] If a duty of care was more specifically formulated, a plaintiff might have better chance of success. For example, from the point of causation, the Marshes' real grievance was Baxter's choice to harvest by swathing,[37] not his decision to grow GM canola, thus the alleged duty of care could have related to Baxter's choice of harvesting method. However, on the facts, it had not been shown that Baxter had acted negligently, either by growing or by swathing RR canola.

The closest Australian precedent for the court to consider was the Australian High Court decision in *Perre v Apand.*[38] Apand had supplied potato seeds that were infected with bacterial wilt to the Sparnons in South Australia. The Perres grew potatoes for export to Western Australia, where they received a considerably higher price than was available elsewhere in Australia. Regulations in Western Australia prohibited the importation of potatoes was if they had been grown on a property within 20 km of any bacterial wilt. The Sparnon's farm was within this zone and although none of the potatoes grown by the Perres were actually infected by bacterial blight but they could not legally be exported to Western Australia. The Perres sought to recover the economic loss caused by their loss access to the higher priced Western Australian market. The High Court unanimously held that Apand owed the Perres a duty of care to prevent economic loss.

Following this decision, Allsop P in *Caltex Refineries*[39] stated that there are 17 different 'salient features' which are potentially relevant to recognizing a duty of care with regard to pure economic loss. Australian courts will place heavy emphasis on policy considerations in determining whether there is a duty of care in these situations, even when the reasonable foreseeability requirements are satisfied.[40]

It was a fundamental requirement in *Perre v Apand* that the class of persons suffering loss could be ascertained to avoid indeterminate liability.[41] This is important because trace amounts of seed and pollen can be distributed over large distances.[42] If a GM farmer knows his neighbors are GM-free, he may owe them a duty of care because they are an identifiable class. There would be a stronger argument for foreseeability if GM crops were cultivated within a GM-free zone, such as those states in which moratoriums still exist. Nevertheless, the decision in *Perre v Apand* shows that it may be reasonably foreseeable that non-GM farmers

[36][2014] WASC 187 at [333]–[334], [335].

[37][2014] WASC 187 at [341]–[343].

[38]Caltex Refineries (Qld) Pty Ltd v Stavar [2009] NSWCA 258.

[39][2009] NSWCA 258.

[40]Karinne Ludlow and Stuart Smyth, "The Quandary of Agricultural Biotechnology, Pure Economic Loss, and Non-Adopters: Comparing Australia, Canada and the United States" (2011) 52 *Jurimetrics* 15.

[41]*Perre v Apand (*1999) 198 CLR 180, 194 (Gleeson CJ), 222 (McHugh J).

[42]Kathryn Garforth, 'When Worlds Collide: Biotechnology meets Organic Farming in Hoffman v Monsanto' (2006) 18 Journal of Environmental Law 459, 462.

could be harmed, even when there is no physical contamination, if the defendant has knowledge of the particular market conditions for non-GM produce.[43] Indeterminacy in respect of those who have suffered economic loss from GM farmers should therefore not be a basis for refusing to find a duty of care,[44] particularly in the context of neighboring farmers.

The vulnerability of the plaintiff is another important determinant of the duty of care. Callinan J in *Perre v Apand* stated that "the appellants were rendered powerless to abate or prevent the occurrence of the loss to which they were subjected… in no way did they act illegally, improperly or unreasonably or without regard for their own interests."[45] But GM farmers may assert that economic loss suffered by non-GM farmers is the result of adoption of voluntary standards, such as contractual arrangements with organic bodies, causing them to be specially vulnerable. As a matter of policy, an organic farmer who voluntarily adopts a form of agriculture economically susceptible to adverse consequences if GMOs are released, should not be able to force GM farmers to cease doing something they otherwise could. Compared to conventional farmers, for whom there is no special vulnerability as there is little evidence that conventional non-GM crops attract any price advantage over GM crops.[46]

A breach of duty could result from failing to adhere to 'good practice' in GM crop cultivation however, in *Perre v Apand* McHugh J stated that "as long as a person is legitimately protecting or pursuing his or her social or business interests, the common law will not require the person to be concerned with the effect of his or her conduct on the economic interests of other persons".[47] The non-GM and GM farmers may well be in competition with each other, therefore imposing a duty could even hinder competition and courts are reluctant to hamper market competition by protecting resultant losses of commercial interests, opportunities or advantages".[48]

With respect to the choice to grow GM crops over conventional or organic crops, McHugh J said in *Dovuro Pty Ltd v Wilkins*[49]:

> A defendant is not negligent merely because it fails to take an alternative course of conduct that would have eliminated the risk of damage…If inaction is a course reasonably open to the defendant, the plaintiff fails to prove negligence even if there were alternatives open to the defendant that would have eliminated the risk.

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[43]*Perre v Apand* (1999) 198 CLR 180; 164 ALR 606 at [13] per Gleeson CJ and [211], [213] and [409] per Gummow J.

[44]S*ee Dovuro Pty Ltd. v Wilkins* (2000) 105 FCR 476, 485-86 (Austl.) (describing the vulnerable class, comprising the ultimate purchasers of contaminated seed, as limited and ascertainable).

[45]*Perre v Apand Pty Ltd* (1999) 198 CLR 180, 328 per Callinan J.

[46]Managing Genetically Modified Crops in Australia: GM Crops, Segregation and Liability in Australian Agriculture' (2005) prepared by Avcare for ACIL Tasman, p 4.

[47]*Perre v Apand Pty Ltd* (1999) 198 CLR 180, 224 (McHugh J).

[48]Brenda McGivern, 'Tortious Liability for (Selected) Genetic Harm: Exploring the Arguments', (2002). 10 *Torts Law Journal* 41, 60.

[49][2003] 215 CLR 317 at 330.

While Mr Justice Martin in *Marsh v Baxter* noted that economic loss has been successfully recovered in *Perre v Apand*, on the facts in that case there was still physical damage (disease) caused to the potatoes, unlike in the instant circumstances where the canola swathes posed no risk health risk or a risk of any GM genetic trait transfer to any species.[50]

It should be noted that the negligence claim ultimately failed because of the break in the chain of causation arising from the conduct of NASAA. In this case, Justice Martin found that the 'vulnerability' concept from *Perre v Apand* did not extend to catch what was a different and 'self-inflicted' contractual vulnerability.[51] The Marshes' vulnerability to economic loss arose from their contractual relationship with NASAA.[52]

Negligence Proceedings in the Court of Appeal

On 3 September 2015, the Court of Appeal of Western Australia, by a majority of 2:1 upheld the decision of the court below and dismissed the appeal.[53] The majority judges, Newnes and Murphy JJA, observed that it was not in dispute "that in the particular circumstances of this case, the GM plant material that landed on the appellants' farm posed no risk of any genetic trait transfer to any species of crop or produce on the appellants' land".[54] They noted that although some 245 swathes had entered onto the appellants' land only eight volunteer GM canola plants were ever detected in the subsequent growing season and that these had been identified and pulled out by Mr Marsh, "presumably before they had set seed".[55]

> On the question of negligence the majority judges ruled that
>
> Ordinarily, in our view, the law would not require a farmer in Kojonup directing his or her mind at harvest time, to swathing or direct heading of the crop, to reasonably have in contemplation the effect of that decision on the economic interests of other farmers in the district, whether on adjoining farms or up to 10 km away. That would still ordinarily be the position, in our view, even where the owners of a neighbouring organic farming enterprise had informed others in the district about their organic certification by taking out advertisements in local newspapers, or by putting up signs on their fences to that effect.[56]

[50]Thomas Ambrose *'Supreme Court decides GM canola crop case'* (18 June 2014) Holding Redlich http://www.holdingredlich.com/agribusiness-rural-industries/supreme-court-decides-gm-canola-crop-case.

[51]*Marsh v Baxter* [2014] WASC 187 at [321].

[52][2014] WASC 187 at [741].

[53]*Marsh v Baxter* [2015] WASCA 169.

[54]Ibid at para 385.

[55]Ibid at para 426.

[56]Ibid at para 647.

They drew a distinction between a farmer deciding how to harvest his or her crop with other cases in which liability in negligence for pure economic loss had been found by the High Court, e.g. a solicitor who negligently draws a will, in effect disinheriting his or her client's intended beneficiary[57]; or the builder who negligently builds a suburban home with defective foundations[58]; or the dredger which negligently dredges and fractures a pipeline.[59] The majority judges observed that in those cases not only was the defendant's fault or blameworthiness, at least prima facie, more palpable, but it would be expected that the defendant in those cases would well understand the deleterious financial consequences that would almost certainly be visited upon the plaintiff in the ordinary course if the defendant were careless.[60]

The joint judgement ruled that the appellants did not established that a duty of care was owed in the particular circumstances of this case[61] and that in any event, reasonable foreseeability of the risk of economic loss was not in itself sufficient to generate a duty of care in the circumstances of the case.[62] Even if such a duty was feasible, the joint judges considered it to be too indeterminate on the facts of this case.[63]

The joint judgement left it open for a duty of care to be imposed in a subsequent case. In late 2010 the respondent had sound financial and farming reasons for swathing his canola crop. There was at that time no expectation that swathes would be picked up and carried across to the appellants' property by strong winds. However, the extreme weather events of that time could counsel prudence in the future and that harvesting should be by direct heading rather than swathing to avoid contamination of neighboring properties.

The minority judge was the President of the Court of Appeal, McClure P. She considered that "a reasonable person in the position of the respondent ought to have known that there was a real risk that GM canola swaths could be blown by strong winds" from his property onto Eagle Rest[64] and that "the respondent had no compelling reason to harvest his GM canola in late 2010 by swathing."[65] On these bases she challenged the trial judge's finding that "the respondent did not know, and ought not reasonably to have known, of the risk of GM canola swaths being carried by the wind from Sevenoaks to Eagle Rest and thus the risk of that occurrence was not reasonably foreseeable."[66] McClure P also found that in these circumstances the decertification of the appellant by NCO was not unreasonable.[67]

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[57]*Hill v Van Erp* (1997) 188 CLR 159.

[58]*Bryan v Maloney* (1995) 182 CLR 609.

[59]Caltex Oil (Australia) Pty Ltd v The Dredge 'Willemstad' (1976) 136 CLR 529.

[60]*Marsh v Baxter* [2015] WASCA 169 at para. 649.

[61]Ibid at para 745.

[62]Ibid at para 704.

[63]Ibid at para 744.

[64]Ibid at para 135.

[65]Ibid at para 136.

[66]Ibid at para 316.

[67]Ibid at para 212.

Nuisance in the Supreme Court of Western Australia

The Marshes argued that the presence of GM canola on Eagle Rest constituted an unlawful interference with their use and enjoyment of the land. In particular, it was submitted that the interference and consequential loss of certification resulted in the Marshes not being able to use Eagle Rest to cultivate certified organic crops or livestock. Mr Justice Martin focused on the balance between what Baxter was lawfully entitled to do on his farm and the Marshes' right not to have their use and enjoyment of Eagle Rest unreasonably interfered with.[68]

He observed that Baxter's conduct was not unreasonable as swathing was not a novel or unconventional method of harvesting.[69] Baxter could not be held legally responsible for growing a lawful crop and swathing (an entirely orthodox harvesting method), which he had undertaken on the advice of his agronomist. He had legitimate reasons for swathing as it would assist weed control.[70] Furthermore, Baxter did not intend to cause any loss to the Marshes and there was no recommended swathing buffer distance suggested for GM canola grown during the 2010 season. It was also noted that GM canola being blown onto Eagle Rest was not reasonably anticipated by Baxter and had been caused by unexpectedly strong winds.[71] Mr Justice Martin recognized that the level of experience of a GM farmer and the local farming community is a relevant factor in assessing liability.[72] Thus farmers, who make reasonable, considered, and commercially appropriate decisions, are legally entitled to utilize any variety of legal farming production practices to enhance their productivity and commercial interests.[73] However, Mr. Justice Martin commented that had the underlying facts been different, for example an incursion of a physically dangerous substance like a pesticide or herbicide causing physical damage, the nuisance action would be different.[74] The hurdle for organic farming plaintiffs is that GM material has so far proved to be benign.

The consideration of the plaintiff's vulnerability to economic loss in a nuisance action was treated the same as that undertaken from a duty of care perspective.[75] Mr Justice Martin was not willing to extend the vulnerability concept to a 'self-inflicted contractual vulnerability', especially where the conduct of the NCO/NASAA might

[68][2014] WASC 187 at [371].

[69][2014] WASC 187 at [714].

[70][2014] WASC 187 at [713].

[71][2014] WASC 187 at [717].

[72]Smith, Rebekah Gray, Joseph Elks, *'Love thy neighbour? The potential coexistence of organic and GM farming is examined by the Supreme Court'* (29 July 2014) Herbert Smith Freehills http://www.lexology.com/library/detail.aspx?g=ed87e0fe-4c8a-4bbf-bda4-61adb3e28a60.

[73]Nicolas Perpitch, 'Friends still foes but clears GM crops', *The Australian*, May 28 2014.

[74]Thomas Ambrose *'Supreme Court decides GM canola crop case'* (18 June 2014) Holding Redlich http://www.holdingredlich.com/agribusiness-rural-industries/supreme-court-decides-gm-canola-crop-case.

[75]*Marsh v Baxter* [2014] WASC 187 at [321].

be assessed as unreasonable, or even in breach of their contractual terms with the Marshes. As to the private contractual arrangements, Mr Justice Martin considered that idiosyncratic contractual arrangements might "be assessed as a wholly unreasonable status quo from the broader community perspective".[76] The judgment confirms that in an assessment of private nuisance, it is appropriate and necessary for the Court to conduct some high-level analysis of the workings of private contractual arrangements, in this case as between the Marshes and NASAA/NCO.[77]

Nuisance in the Court of Appeal of Western Australia

The appellants' case in nuisance depended upon establishing that the presence of the GM canola seeds from the swathes exposed them to the risk of decertification under the NASAA contract. The majority judges observed that in the district of Kojonup, "swathing was a conventional and moreover the generally preferred method of harvesting canola crops, and formed part of the common and ordinary use of the land".[78] The question then was whether the incursion of swathes involved an interference which was beyond what an ordinary average resident of the district ought reasonably to have expected under the circumstances.[79]

The joint judges noted that the GM canola swathes which were transferred to the appellants' land were benign in the sense that there was no risk of any genetic transfer to any species of animal, crop, or produce and there was also no prospect that the GM canola seeds could germinate and become a volunteer plant before the appellants harvested their wheat in early 2011.[80] They took account of a WA Department of Agriculture newsletter which said that non-GM canola and GM canola crops should be segregated, in the context of a trading standard for non-GM canola seed, which required a presence of less than 0.9 % of an adventitious approved GM canola in the seed.[81] In light of the foregoing, they held that the trial judge did not err in his conclusion that there was no unreasonable interference with the appellants' use and enjoyment of Eagle Rest as a result of the incursion of GM canola swathes.[82]

The dissenting judge upheld the appellants' nuisance claim.[83] She saw this claim to be whether the interference with the appellants' use and enjoyment of Eagle Rest

[76][2014] WASC 187 at [379].
[77][2014] WASC 187 at [381].
[78]*Marsh v Baxter* [2015] WASCA 169 at para. 779.
[79]Ibid at para 780.
[80]Ibid.
[81]Ibid at para. 781.
[82]Ibid at para. 782.
[83]Ibid at para 3.

"was substantial and unreasonable."[84] McClure P. noted that "the central issue not addressed by the trial judge is whether the harm to the appellants could have been avoided without appreciable prejudice to the respondent's interests," since the respondent had no compelling reason to swath his GM canola.[85] The President also disagreed with the trial judge's finding swathing was part of the "ordinary usages" of broadacre farming in the Kojonup locale as he did not address the real issue, "which is what was reasonable in the circumstances having regard to the fact that in 2010 GM canola was being grown in this State for the first time and was accompanied by public warnings from the Ag Department as to the care required to ensure the co-existence of organic, non-GM and GM farming."[86] Consequently, she ruled that in 2010 "the harvesting of GM canola, by swathing or otherwise, was not among the ordinary usages of broadacre farming in Kojonup".[87] And that the physical incursion of GM canola swaths, cultivated by the respondent, from his farmland onto the appellants' farmland which, following NCO decertification, had the consequence of preventing the appellants from continuing their business of producing certified organic products from 70 % of their farmland for three years.[88]

McClure P concluded that the evidence supported a finding, "that the respondent failed to harvest the GM canola crop in a manner which would have made it possible to avoid the damage caused to Eagle Rest without appreciable prejudice to his own interests."[89]

Given the majority decision in the Court of Appeal, with the strong dissent by McClure P., it would not be surprising if this case was appealed on to the High Court of Australia.

DNA Patenting in Australia

An appeal of Marsh v Baxter to the High Court would occur at a time when that court has set its face against DNA patenting. In *CancerVoices Australia* vs. *Myriad Genetics Inc.*[90] the Australian Federal Court at first instance ruled that isolated human DNA was patentable because the breaking of covalent bonds linking the gene to the rest of the chromosome made it sufficiently different from the gene as found in the human body. The Australian High Court had previously held in *National Research Development Corporation* vs. *Commissioner of Patents*[91] that

[84]Ibid at para 258.
[85]Ibid at para 271.
[86]Ibid at para 272.
[87]Ibid.
[88]Ibid at para. 274.
[89]Ibid at para. 274.
[90][2013] FCA 65.
[91](1959) 102 CLR 252.

the subject matter of a patent claim had to consist of an "artificially created state of affairs", which provided a new and useful effect of economic significance. The trial judge applied this decision in observing that isolated DNA was the product of human intervention and involved processes of extraction and purification, and immense research and intellectual effort.

The Full Federal Court followed the same approach as the trial court in upholding the patent.[92] By the time that the case came on before the Full Federal Court, the US Supreme Court had ruled that that a naturally occurring DNA segment was a product of nature and not patent eligible merely because it has been isolated. However, the Court noted that in Australia, there was no statutory or jurisprudential limitation of patentability to exclude "products of nature".[93] The Full Federal Court also noted that Myriad's patent claim was not, as the US Supreme Court considered, concerned '*primarily with the information contained in the genetic sequence* [rather than] *with the specific chemical composition of a particular molecule*'.[94]

The case was appealed to the High Court of Australia, which handed down its decision on 7 October 2015.[95] The High Court reversed the court below. The majority observed that despite the formulation of the claimed invention as a class of product, its substance was **"**information embodied in arrangements of nucleotides [which was] not 'made' by human action"[96] The majority observed that:

> Where an affirmative application of the concept is likely to result in the creation of important rights as against the world, to involve far-reaching questions of public policy and to affect the balance of important conflicting interests, the question must be asked whether that application is best left for legislative determination. The patentability of nucleotide sequences derived from human DNA is in that category. The inherent patentability of the invention as claimed would powerfully imply patentability of any claim for an isolated nucleic acid coding for a specified polypeptide.[97]

As a matter of policy the majority observed that there was a real risk that the chilling effect of the claims, on the use of any isolation process in relation to the patented gene, would lead to the creation of an exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the sequences coding for the protein.

The High Court's decision may raise a question as to whether it will support the glyphosate resistant patents which underpinned Marsh v Baxter.

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[92]D'Arcy vs. Myriad Genetics Inc [2014] FCAFC 115.

[93]Ibid at para [2.04].

[94]Ibid at para [2.16].

[95]D'Arcy v Myriad Genetics Inc [2015] HCA 35.

[96]Ibid at para. 4.

[97]Ibid.

Conclusion

Marsh v Baxter was not about the legality of growing GM crops—nor was it about GM contamination of crops or consumers' choice to eat GM-free food. The case seemed to be a platform for anti-GM sentiment and the ideological battle between organic farmers and GM farmers. In cases such as *Marsh v Baxter*, the issues publicized may bear little resemblance to those argued in the courts, and can lead to a public that is completely misinformed.[98] The judgment has been lauded as a triumph of common sense and freedom of farming choice.[99] A victory for the Marshes may have had broad and damaging implications for the GM community, especially those farmers who share boundaries with certified organic farmers. At the same time, the decision does not suggest that growers of GM crops have immunity or protection against similar claims in the future. Instead, it establishes that something more will be required for a claim of negligence or nuisance to succeed, for example, economic loss that is not caused by a self-inflicted vulnerability. Where adjoining farms grow a compatible crop species, genetic contamination is possible and physical damage, as well as economic loss because of decertification, could be suffered. A duty of care to take reasonable steps to prevent contamination could be owed in such circumstances. For this reason, the decision in *Marsh v Baxter* does not imply that plaintiffs who have suffered economic loss will be prevented from recovery against GM farmers.

The tort regime will not always compensate economic loss, as illustrated by *Marsh v Baxter*. A potential plaintiff may face difficulty and expense in establishing foreseeability and causation, and proving the extent of any damage because of the possible time lapse before damage is discovered and the scientific evidence that would be required.[100] They may also be prevented from recovery if their loss derives from a self-inflicted vulnerability such as an organic certification contract. This area of law and development remains very much unsettled. It is clear that further judicial or legislative consideration will be required to clarify the issues.[101]

Marsh v Baxter has highlighted contradictions between current Australian farming practices and the organic certifying regulations. Mr Justice Martin suggested that the major cause of the dispute in the case was the inflexibility of the NASAA guidelines. In some ways, the contradiction is unique to Australia, because the Australian organics industry has a zero tolerance to the presence of any GM

[98]http://www.lexology.com/library/detail.aspx?g=64a7af1d-8a54-4dc8-9e59-58f992fe1600.

[99]Michael Jones, '*WA's court verdict on GM crops is a dose of common sense'* (29 May 2014) The Conversation http://theconversation.com/was-court-verdict-on-gm-crops-is-a-dose-of-common-sense-27287.

[100]New Zealand Law Commission, 'Liability for Loss Resulting from the Development, Supply or Use of Genetically Modified Organisms' (2002) p 5.

[101]Andrew Gill, '*Is the answer still blowing in the wind after the GM canola case?*' (3 June 2014), Minter Ellison http://www.minterellison.com/publications/is-the-answer-still-blowing-in-the-wind-after-the-GM-Canola-Case/.

material in certified organic product.[102] In other countries, there is a tolerance for very small levels of legally approved seeds, pollen or other material to be found in a crop, even in organics.[103] In the United States, comments to the Voluntary Labelling standards adopted by the U.S. National Organic Program state that the inadvertent presence of GE material does not affect the organic status of a product or the land.[104] There is a 5 % tolerance threshold in the U.S. and even in Europe, where anti-GM sentiment is stronger, there is a 0.9 % tolerance,[105] recognizing that cross-pollination is considered an unavoidable consequence of large-scale farming. In the aftermath of *Marsh* v *Baxter*, the Western Australian government has lodged a request with the Organic Industry Standards and Certification Council for the tolerated threshold of GM trace elements in organic products to be increased from zero to 0.9 %, consistent with the approach in other countries.

Placing the threshold for contamination within a nationally consistent framework, like the GTA, is necessary because many issues raised by agricultural biotechnology are trans-border in nature.[106] Even NASAA General Manager, Ben Copeman, says that the court's decision in *Marsh v Baxter* not to recognize NASAA's decertification as warranted, highlighted a need for greater regulatory certainty for organic producers.[107] Once those tolerances are set, any farmers who voluntarily contract to meet stricter standards accept an increase in contractual risk in return for possible higher prices or greater market access and should bear the costs to fulfill such contracts accordingly.[108] This sort of reform would allow the common law remedies of negligence and private nuisance to compensate non-GM farmers appropriately for economic loss because it diminishes the issue of whether

[102]Catherine McAloon, '*Genetic modification test case highlights gaps in Australian regulations'* (28 May 2014) ABC Rural http://www.abc.net.au/news/2014-05-28/gm-court-case-debate/5349598.

[103]In the United States, for example, there are broad-scale examples of GM and organic crops being grown in close proximity. In fact, in some farming operations in the United States the same farmer will be using both GM and organic production. See Jon Entine, ''*No Such Thing as GMO Contamination 'Rules Australian Court in Landmark Decision, Rebuffing Organic Activists'* (28 May 2014) http://www.forbes.com/sites/jonentine/2014/05/28/no-such-thing-as-gmo-contamination-rules-australian-court-in-landmark-decision-rebuffing-organic-activists/.

[104]Organic Trade Association, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, April 21, 2014 available at https://ota.com/sites/default/files/indexed_files/OTA_Docket%20No_00D-1598_FDA_Final.pdf, accessed 4 November 2015.

[105]Michael Jones, '*WA's court verdict on GM crops is a dose of common sense'* (29 May 2014) The Conversation http://theconversation.com/was-court-verdict-on-gm-crops-is-a-dose-of-common-sense-27287.

[106]Claire Deaking (2008) 25 EPLJ 103.

[107]NASAA Media Release—29 May 2014.

[108]Managing Genetically Modified Crops in Australia: GM Crops, Segregation and Liability in Australian Agriculture' (2005) prepared by Avcare for ACIL Tasman, 8.

the loss was caused by a self-inflicted vulnerability and whether the level of contamination was 'reasonable'. More certainty will exist in the market for both GM and non-GM farmers as to their legal rights.

Organic Seed Growers & Trade Ass'n V. Monsanto[109]

Monsanto and "Inadvertent" Contamination

An issue which was not canvassed in *Marsh v Baxter*[110] was whether the Marshes would have been liable for infringing Monsanto's patents over GM canola if they had cultivated canola adulterated with Monsanto's proprietary genes. This issue had been addressed in the now notorious Canadian litigation between Monsanto Canada, Inc and a farmer, Percy Schmeiser. Schmeiser grew canola commercially in Saskatchewan. He had never purchased Monsanto's patented RR canola nor did he obtain a license to plant it. Yet, in 1998, tests revealed that 95–98 percent of his 1000 acres of canola crop was made up of RR plants. The origin of the plants is unclear. They may have been derived from RR seed that blew onto or near Schmeiser's land. Monsanto brought an action for patent infringement. In finding patent infringement the trial judge ruled that the growth of the seed, reproducing the patented gene and cell, and sale of the harvested crop constituted taking the essence of Monsanto's invention, using it without permission, and by so doing infringing the patent. By a majority of 5:4 the Federal Court of Appeal ruled that Schmeiser's saving and planting seed, then harvesting and selling plants that contained the patented cells and genes appeared to the Court, on a common sense view, to constitute "utilization" of the patented material for production and advantage, within the meaning of s. 42 the Canadian *Patent Act*.[111] The argument that the infringing seed had merely grown, as the result of wind pollination, or through the pollinating activities of birds and bees was rejected by the majority Judges as denying "the realities of modern agriculture." What was at stake in this case was sowing and cultivation, "which necessarily involves deliberate and careful activity on the part of the farmer". They noted that he had actively cultivated RR canola as part of his business operations, thus in light of all of the relevant considerations, Schmeiser had used the patented genes and cells, and infringement was established.

Monsanto's website (accessed 13 March 2015) states that "since 1997, we have only filed suit against farmers 147 times in the United States."[112] It suggests that this is "really a small number… when you consider that we sell seed to more than

[109]718 F.3D 1350, 1354 (2013).

[110][2014] WASC 187.

[111]*Monsanto Canada, Inc. v. Schmeiser.* [2004] 1 S.C.R. 902, 2004 SCC 34.

[112]'Saved Seed and Farmer Lawsuits' http://www.monsanto.com/newsviews/pages/saved-seed-farmer-lawsuits.aspx.

350,000 American farmers a year".[113] This small risk of litigation did not dissuade a coalition of 38 farmers, seed sellers, and agricultural organizations led by the Organic Seed Growers and Trade Association, to seek declaratory judgments of non-infringement and invalidity in the District Court for the Southern District of New York,[114] with respect to 23 patents owned by Monsanto Co. and Monsanto Technology, LLC (collectively, "Monsanto").[115]

Absence of Justiciable Dispute

The plaintiffs described themselves as growers, seed selling businesses, and agricultural organizations which grow, use, or sell conventional seeds, many of whom have organic certification and who did not want to use or sell transgenic seed incorporating Monsanto's technologies. Their principal concern was that, given Monsanto's patent enforcement policy, if their crops became contaminated by transgenic seed they could perversely be accused of patent infringement by the company responsible for the transgenic seed that contaminated them.

The plaintiffs' application for a declaration was refused by the District Court on the ground that there was no justiciable dispute between the parties. It noted that there was no evidence that Monsanto had commenced litigation against inadvertent users of patented seed and there was no evidence that any of the plaintiffs had experienced contamination from Monsanto's seed, or had ever been threatened by Monsanto for patent infringement. Shortly after they initiated the lawsuit, the plaintiffs had asked Monsanto for an express undertaking not to sue. While refusing to enter into such an undertaking Monsanto referred the plaintiffs to its website,

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[113]Ibid.

[114]*Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 851 F. Supp. 2d 544 (S.D.N.Y. 2012) (No. 11-CV-2163).

[115]U.S. Patent Nos. 5,322,938 ("DNA sequence for enhancing the efficiency of transcription"); 5,352,605 ("Chimeric genes for transforming plant cells using viral promoters"); 5,362,865 ("Enhanced expression convention in plants using non-translated leader sequences"); 5,378,619 ("Promoter for transgenic plants"); 5,424,412 ("Enhanced expression in plants"); 5,463,175 ("Glyphosate tolerant plants"); 5,530,196 ("Chimeric genes for transforming plant cells using viral promoters"); 5,554,798 ("Fertile glyphosate-resistant transgenic corn plants"); 5,593,874 ("Enhanced expression in plants"); 5,641,876 ("Rice actin gene and promoter"); 5,659,122 ("Enhanced expression in plants using non-translated leader sequences"); 5,717,084 ("Chimaeric gene coding for a transit peptide and a heterologous peptide"); 5,728,925 ("Chimaeric gene coding for a transit peptide and a heterologous polypeptide"); 5,750,871 ("Transformation and foreign gene expression in *Brassica* species"); 5,859,347 ("Enhanced expression in plants"); 6,025,545 ("Methods and compositions for the production of stably transformed, fertile monocot plants and cells thereof"); 6,040,497 ("Glyphosate resistant maize lines"); 6,051,753 ("Figwort mosaic virus promoter and uses"); 6,083,878 ("Use of N-(phosphonomethyl) glycine and derivatives thereof"); 6,753,463 ("Transformed cotton plants"); 6,825,400 ("Corn plants comprising event PV-ZMGT32 (nk603)"); RE38,825 ("Glyphosate tolerant plants"); and RE39,247 ("Glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthases").

which contained the statement that "It has never been, nor will it be Monsanto policy to exercise its patent rights where trace amounts of our patented seeds or traits are present in farmer's fields as a result of inadvertent means." Monsanto's attorneys by letter further expanded on the company's absence of any intent to sue persons in the position of the plaintiffs, declaring that:

> Monsanto is unaware of any circumstances that would give rise to any claim for patent infringement or any lawsuit against your clients. Monsanto therefore does not assert and has no intention of asserting patent-infringement claims against your clients. You represent that "none of your clients intend to possess, use or sell any transgenic seed, including any transgenic seed potentially covered by Monsanto's patents." Taking your representation as true, any fear of suit or other action is unreasonable, and any decision not to grow certain crops unjustified.

These representations were also taken into account by the District Court in ruling that there was no imminent dispute between the parties.

These factors were equally influential in the determination of the Court of Appeals that there was no justiciable controversy between the parties.[116]

The Supreme Court refused the grant of certiorari to allow an appeal to it.[117]

Observations on "Inadvertent Contamination"

Monsanto's undertaking not to bring patent infringement actions in cases of inadvertent contamination disposed of the plaintiffs' declaratory action, but the District Court noted the inevitability that conventional crops would be contaminated by trace amounts of windblown pollen or seeds from genetically modified crops or other sources.[118] The Court of Appeals noted Monsanto's acknowledgement that conventional crops could be exposed to "cross-pollination from nearby fields where biotech crops are grown" and that they "might inadvertently contain traces of Monsanto biotech genes (because, for example, some transgenic seed or pollen blew onto the grower's land)".[119]

The Court of Appeals referred to a study finding that, despite stringent precautionary measures meant to prevent any comingling of modified and conventional seed crops, a large majority of conventional seed samples had become contaminated by Monsanto's Roundup resistance trait.[120] The District Court found that due to contamination,

> …some unlicensed—and unintended—use of transgenic seeds is inevitable. Like any other seeds, transgenic seeds may contaminate non-transgenic crops through a variety of means,

[116] Organic Seed Growers & Trade Ass'n v. Monsanto Co. (Fed. Cir. 2013).

[117] *Organic Seed Growers & Trade Ass'n v. Monsanto Co*. cert. denied, 134 S. Ct. 901 (2014).

[118] *Organic Seed Growers*, 851 F. Supp. 2d at 548.

[119] Organic Seed Growers & Trade Ass'n v. Monsanto Co. (Fed. Cir. 2013) at p. 13.

[120] Ibid at p. 14.

> including seed drift or scatter, crosspollination, and commingling via tainted equipment during harvest or postharvest activities, processing, transportation, and storage.[121]

The Court of Appeals observed that genetically modified seeds cannot easily be separated from conventional seeds; thus, a grower who harvests and uses or sells contaminated crops risks incurring infringement liability. The Court of Appeals observed that "both parties seem to concede that at a minimum, using or selling patented seeds without a license is potentially infringing activity."[122] Thus for the purposes of the appeal before it the court assumed "(without deciding) that using or selling windblown seeds would infringe any patents covering those seeds, regardless of whether the alleged infringer intended to benefit from the patented technologies."[123]

The Court of Appeals conceded that there was a substantial risk that at least some of the appellants could be liable for infringement if they harvested and replanted or sold contaminated seed. In *SmithKline Beecham Corp. v. Apotex Corp.*[124] The Court of Appeals had observed that that the use even of "trace amounts" of a patented compound, might "place potential infringers in the untenable position of never knowing whether their product infringes because even a single undetectable [molecule] would infringe."[125]

The question of deliberate infringement had been considered by the US Supreme Court in *Bowman v. Monsanto Co*.[126] *Bowman* concerned a soybean farmer, who had purchased, harvested, and replanted Roundup Ready soybeans without a license.[127] He also used glyphosate on his fields, thereby favouring the survival of transgenic soybeans and eliminating conventional soybeans.[128] The Court carefully distinguished Bowman's use of the patented soybean seeds from the situation of inadvertent infringement. It ruled that patent exhaustion did not permit a farmer to reproduce Monsanto's transgenic seeds without a license.

The first consideration by the US Supreme Court of inadvertent contamination occurred in *Monsanto Co* v. *Geertson Seed Farms.*[129] This case aroses out of a decision by the Animal and Plant Health Inspection Service (APHIS) to deregulate a variety of genetically engineered alfalfa. The US Supreme Court, in holding that conventional farmers had standing to challenge the administrative deregulation of Roundup Ready alfalfa, recognized that there is a risk of "gene flow" from genetically modified crops into conventional crops.[130]

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[121] *Organic Seed Growers*, 851 F. Supp. 2d at 548.

[122] Organic Seed Growers & Trade Ass'n v. Monsanto Co. (Fed. Cir. 2013) at p.13.

[123] Ibid.

[124] 403 F.3d 1331 (Fed. Cir. 2005).

[125] Ibid at 1339–40.

[126] 569 U.S. U.S. at ___, 133 S.Ct. 1761 (2013).

[127] *Id.* at 1765–67.

[128] Ibid.

[129] 561 U.S. at ___; 130 S.Ct. 2743 (2010).

[130] Ibid at 2752-54.

Conclusion

The decision of the US courts in the Organic Seed Growers litigation is relevant to the US situation. The undertakings not to sue have no relevance to any disputes which might arise in other jurisdictions.

Even in the US, Monsanto's representations refer only to individuals producing crops having only "trace amounts" of its proprietary genes. The Appeal Court noted that

> At oral argument, Monsanto resisted our efforts to clarify whether it would assert its patents against a conventional grower who inadvertently uses or sells *greater* than trace amounts of modified seed, but who, for example, does not make use of the Roundup Ready trait by spraying the plants with glyphosate. Thus, we cannot conclude that Monsanto has disclaimed any intent to sue a conventional grower who never buys modified seed, but accumulates greater than trace amounts of modified seed by using or selling contaminated seed from his fields.[131]

All plaintiffs in the Organic Seed Growers litigation alleged that they were "using their best efforts" not to produce crops comprising more than "trace amounts" of recombinant seed, and thus they did not allege activities that would put them at patent infringement risk.

The US Supreme Court had held that parties "cannot manufacture standing merely by inflicting harm on themselves, based on their fears of hypothetical future harm".[132]

In any event, it has been observed that to date, "inadvertent infringement based upon genetic drift or the presence of trace amounts of contaminating patented seed in a farmer's field does not appear to have ever resulted in a lawsuit by Monsanto".[133] The finding against Schmeiser is explained by Holman on the basis that "the Canadian judges were convinced by overwhelming evidence that Percy Schmeiser was not the victim of drift and inadvertent contamination, but rather a disingenuous and willful patent infringer."[134] He states that "in every case involving an allegation of patent infringement of a Monsanto seed patent by a farmer that has been addressed at the appellate level (by the Court of Appeals of the Federal Circuit or Supreme Court) there has invariably been compelling evidence that the infringing farmer intentionally planted infringing seeds and benefited from the patented technology."[135]

This is a limited category of cases, as we do not know of those which were settled out of court.

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[131]Organic Seed Growers & Trade Ass'n v. Monsanto Co. (Fed. Cir. 2013) at pp. 17–18.

[132]*Clapper v. Amnesty Int'l USA*, 568 U.S. ___, _____, 133 S.Ct. 1138, 1151 (2013).

[133]Christopher M. Holman, 'How Real Is the Concern that Seed Patents Will Turn Farmers into Inadvertent Infringers?' (2014) 33(5) *Biotechnology Law Report* 165 at n.20.

[134]Ibid at 168.

[135]Ibid.

In any event, as Holman points out, it would be irrational for a farmer to spray glyphosate, which destroys all plant growth, unless he knows that at least a substantial percentage of his crop bears Monsanto's patented Roundup Ready resistance trait.[136] Intention to infringe has no bearing on whether patent infringement has occurred, but will have a bearing on damages. It should be noted that Monsanto's Roundup Ready patent expires in 2015, so cases concerning this particular patent will disappear. However, the principles which have been established concerning inadvertent infringement remain relevant.

[136]Ibid at 169.

Coexistence—Under-Explored Facets for a USDA Policy

Drew L. Kershen

Introduction

In the United States on November 19, 2012, the United States Department of Agriculture (USDA) Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) issued its report on coexistence (AC21 Report). AC21 (AC21 Report: 3) defined coexistence as follows: "Coexistence, for the purposes of this [report], refers to the concurrent cultivation of conventional, organic, IP [identity-preserved], and genetically engineered (GE) crops consistent with underlying consumer preferences and farmer choices."

AC21 issued its report in response to the Secretary of Agriculture's charge that the AC21 address three questions:

1. What types of compensation mechanisms, if any would be appropriate to address economic losses by farmers in which the value of their crops is reduced by unintended presence of genetically engineered (GE) material(s)?
2. What would be necessary to implement such mechanisms? That is, what would be the eligibility standards for a loss and what tools and triggers (e.g. tolerances, testing protocols, etc.) would be needed to verify and measure such losses and determine if claims are compensable?
3. In addition to the above, what other actions would be appropriate to bolster or facilitate coexistence among different agricultural production systems in the United States? (AC21 Report, p. 3)

Twenty-two of the twenty-three members of AC21 endorsed five recommendations. Eighteen members also appended specific comments explaining her/his endorsement or non-endorsement of the report and its recommendations (AC21

D.L. Kershen (✉)
University of Oklahoma, Norman, OK, USA
e-mail: dkershen@ou.edu

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Report, pp. 27–59). Of the five recommendations, Recommendation I was surely the most significant and controversial; it read in part:

> To strengthen the understanding of the impact of unintended GE presence in identity-preserved products, USDA should evaluate data it has gathered under Recommendation IV regarding actual economic losses by farmers who grow crops for identify-preserved markets. If the Secretary, in considering the loss data, determines that the situation warrants development of a compensation mechanism to help address such losses, the Secretary should implement such a mechanism based on a crop insurance model. … (AC21 Report, p. 14)

This author followed the AC21 process closely. For example, the author read transcripts of AC21 meetings, presentations made to a conference organized by AC21, and a white paper prepared to summarize the AC21 conference (Van Deynze 2011). In addition, the author has followed the debate, including published scientific and legal literature, about coexistence for many years (Smyth and Kershen 2006; Kershen 2004, 2005).

This chapter explores three facets of coexistence that have received, in the author's opinion, too little attention. The author presents these three under-explored facets in order to insure that these are raised explicitly and to advance a more robust, participatory understanding of coexistence policy in the United States.

National Environmental Policy Act

The National Environmental Policy Act (NEPA) of 1969 is codified at title 42, United States Code, §§ 4321–4370 (h). An under-explored facet of coexistence policy for the United States, under the aegis of the USDA, is the applicability of § 4332(C) which reads as follows:

> The Congress authorizes and directs that, to the fullest extent possible: (1) the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this chapter, and (2) all agencies of the Federal Government shall –
> …
>
> (C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on –
>
> (i.) the environmental impact of the proposed action,
> (ii.) any adverse environmental effects which cannot be avoided should the proposal be implemented,
> (iii.) alternatives to the proposed action,
> (iv.) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
> (v.) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented. …

Without question the USDA is an agency of the federal government and has long prepared environmental documents, either environmental assessments or the more

detailed environmental impact statements, conforming to the requirements of § 4332(C) (Lazarus 2012). With respect to the creation of a coexistence policy, the difficult question under § 4332(C) is what the language "every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment" means?

Outside of the USDA's statutory authority related to crop insurance programs, it is not clear that the USDA has statutory authority to create a coexistence policy regardless of the attributes of the policy (e.g. a policy with an agronomic focus such as isolation distances, with an economic focus such as a compensation fund, or with a geographical focus restricting where the crop can be grown). In the recent Ninth Circuit opinion, *Center for Food Safety v. Vilsack*, the court ruled that once the USDA determined that a transgenic crop was not a plant pest, the USDA had the obligation to release the crop from further regulation because its statutory jurisdiction ended with that determination (Center for Food Safety 2013). More specifically, the Ninth Circuit rejected the arguments of the Center for Food Safety (CFS) that the USDA had authority to condition the deregulation of transgenic crops upon the pursuit of environmental goals sought by CFS. Hence, it appears that if the USDA desires to create a coexistence policy, the USDA would be making "proposals for legislation" that would require the USDA to prepare a detailed statement on the environmental impact of the proposal before submitting the proposal to Congress.

The USDA could seek to create a coexistence policy indirectly by using the National Organic Program (NOP) to set standards for the USDA organic label, e.g. mandating isolation distances for organic farmers or thresholds for content purity such as the lowest testable level for the presence of transgenic material. While these NOP regulations would only apply to organic farmers, not directly to farmers who do not seek organic certification, such regulations would increase the political and popular outcry that organic farmers cannot coexist as long as transgenic crops are loosed upon the world.

However, NOP regulations such as those suggested in the preceding paragraph would change the present NOP regulations. At present, the NOP regulations deny the organic label only to organic farmers who intentionally use transgenic materials or who fail to take reasonable measures to avoid transgenic materials. Under current NOP regulations, neither organic farms nor their products lose organic status solely due to the inadvertent presence of trace amounts of transgenic materials on their farm on in their farm products (NOP Final Rule 2000). As one AC21 member wrote in comments to the report, "Moreover, not a single specific case was presented of a farmer who has lost crop value due to a breakdown in coexistence that is outside of her or her control. … In fact, I am not aware of any significant legal disputes among farmers related to coexistence or any cases of farmers being threatened for unintentional gene flow, as is often claimed." (AC21 Report, pp. 33–34)

If the USDA were to attempt to create a coexistence policy by changing the NOP regulations, the USDA action to adopt these regulations would be "major Federal

actions" under NEPA. Moreover, the impact of these new coexistence regulations almost assuredly would be actions "significantly affecting the quality of the human environment." As explained in a paper presented to the AC21 Conference of September 2011, isolation distances sought by organic producers (if adopted) would have the following impact:

> A circle of radius of 5 miles contains 78.5 square miles, or 50,265 acres (20,350 ha). Thus, one organic farm (of any size) would entail farmers in 50,000 surrounding acres being denied the opportunity to grow biotech varieties to enable the organic farmer to meet its market. Those farmers who are now unable to grow the biotech crop of their choice will suffer economic injury equal to the enhanced value that they would have received from those crops relative to growing non-GE varieties. (Bradford 2011, p. 6)

Adopting coexistence policies that allow one organic farmer to control 50,000 surrounding acres should be considered a significant effect on the quality of the human environment. Consequently, the USDA would have an obligation to prepare a NEPA environmental document (either an environmental assessment or an environmental impact statement) prior to the promulgation of the coexistence regulation. Moreover, once the human environment is affected, court decisions also mandate that the USDA take a hard look at the interrelated economic impacts of the proposed regulation (Center for Food Safety v. Vilsack 2009). As explained in the Bradford paper,

> So an industry growing 1.1 million acres of sugar beets and worth $ 1.5 billion in farm gate value alone could be unable to produce seed of its desired varieties in an established seed production area in order to protect [an organic grower] who claimed potential (not actual) lost value of $ 15,000 in chard seed. We seem to have lost any sense of proportion here, which is an essential underpinning of coexistence. (Bradford 2011: 4)

The potential environmental and economic impacts are pervasive, meaning that an environmental assessment, leading to a finding of no significant impact, arguably would fail to fulfill NEPA obligations. In light of the potential agronomic and economic impact of a USDA coexistence policy, it could be contended, in comments to the agency and in litigation against the agency, that the USDA must prepare a full environmental impact statement under NEPA prior to the creation of any coexistence policy.

Mitigation-of-Damages Doctrine

In light of the AC21 Report Recommendation I, quoted in part above, the report did not discuss the Secretary of Agriculture's charges of questions 2 and 3 concerning mechanisms and standards for compensation and other actions facilitating coexistence. If the USDA pursues further work on coexistence, a second under-explored concept is that of mitigation. Black's Law Dictionary provides a clear and succinct definition:

> Mitigation-of-damages doctrine. - The principle requiring a plaintiff, after an injury or breach of contract, to make reasonable efforts to alleviate the effects of the injury or breach. If the defendant can show that the plaintiff failed to mitigate damages, the plaintiff's recovery may be reduced. (Black's Law Dictionary)

Assuming that the USDA creates a coexistence policy providing compensation from transgenic farmers to organic farmers, identity-preserved farmers, or conventional farmers, those creating the policy should incorporate the legal obligation of mitigation-of-damages. If a farmer were to bring a civil lawsuit against another farmer over coexistence, the farmer would have the obligation to mitigate. Similarly, the USDA coexistence policy should reflect, for claiming farmers, the same legal obligations as those farmers would have in their private civil lawsuits.

Example One

Although no farmer in the United States has ever lost organic certification for farmland or for a product due to transgenic materials, let us assume that an organic farmer lost certification for farmland because of the unwanted presence of transgenic material. In order to regain organic certification, the farmer might be required to pass through a new transition period from non-organic to organic farmland—a three year process under NOP (NOP Rule, § 205.202(b)).

Using the mitigation-of-damages doctrine, the organic farmer should be entitled to compensation only if that farmer, using organic production practices, grew crops that could be sold as conventional crops. The organic farmer regaining organic certification should not be allowed to fallow the farmland for three years and claim three years of lost crops. The organic farmer should only be able to claim the difference between the value of the crops as organic crops and the value of the crops as conventional crops (Endres 2010).

Farmers presently making the transition from conventional or transgenic farming to organic farming take the same reasonable actions to farm in accordance with organic standards while producing, for the three years, crops that can only be sold as conventional crops. Farmers claiming compensation under any USDA coexistence policy should be in the same position as farmers who are taking steps for the first time to transition to organic status. USDA coexistence policy should not ignore the mitigation-of-damages doctrine because to do so would over-compensate the organic farmer.

Example Two

As explained previously in this chapter, the USDA-NOP comments that an organic farmer is not at risk of losing organic certification for a farm product due to the presence of trace amounts of transgenic material. So long as the organic farmer does not intentionally use transgenic materials or takes reasonable actions, in accordance

with the farmer's organic production plan, to avoid contact with transgenic material, the organic farmer produces organic crops.

Despite the USDA-NOP regulation, organic farmers may lose an organic premium price if the farmer voluntarily accepts a product specification (e.g. no testable presence of transgenic material in delivered organic produce) in a contract with an organic buyer. Similarly, some grocery chains are using the Non-GMO label and support that label through a contractual requirement that their supplying farmers deliver products that must test 0.9% or less for transgenic material (Non-GMO Project). If the contracting farmer fails to meet the contractual product specification, the farmer risks that the buyer will reject the delivery or will refuse to pay the premium price negotiated in the organic or non-GMO contract.

Obviously, in light of the information in the preceding two paragraphs, any USDA coexistence policy must decide a basic policy issue—should farmers who voluntarily contract to meet negotiated product specifications be entitled to any compensation when they fail to fulfill their own contractual obligations? The traditional legal rule is that a person (such as a farmer) accepting a contract specification, almost always in return for a premium to cover the additional risk, has no legal recourse against others when and if that person fails to satisfy their own contractual obligations. Unless someone else intentionally interfered to prevent fulfillment of the contract, a person who voluntarily accepted a contractual risk suffers the consequences when they do not fulfill their own contract (Brookes 2004; Redick 2012).

Let us assume that a USDA developed coexistence policy decides to compensate economic losses related to contractual specifications, i.e. to adopt a compensation rule different from the traditional Common Law rule. How would the mitigation-of-damages doctrine apply in that compensation scenario?

Let us think about the obligation to mitigate in the situation of an organic producer who has signed a contract for organic product that specifies no testable presence of transgenic material. Recall that under the USDA-NOP Rule that an organic farmer does not lose organic certification for a farm product based solely on the trace presence of transgenic material. Hence, if the organic farmer delivered an organically produced product that failed the contract product specification, the farmer still has delivered an organic product. What the farmer failed to deliver was the organic product meeting the contractual specification. With these facts, the mitigation-of-damages doctrine means that the organic farmer is entitled to damages only for the difference between the price of the contract specification product and the price of organic products for the same crop. The organic farmer must take reasonable steps to sell the organic product as organic for organic markets. If the USDA policy ignores the obligation to mitigate, the USDA policy would over-compensate the organic farmer.

During the period from 2000 to the present, the author has had several organic farmers discuss with him the fact that they failed to meet an organic contract specification. The organic buyer kept the product and paid a lower conventional (non-organic) price for the delivered product. The farmer was worried that the buyer then turned around and sold the product as an organic product. The author

informed that farmers that they had just experienced what is called "moral hazard". The buyer can enforce the contract but still obtain the benefit of the organic label. Anytime a farmer signs a contract specification that is stricter than the USDA-NOP organic standards, the farmer is at risk of the organic buyer manipulating the contract to the buyer's economic benefit while holding the organic farmer strictly to the contract terms.

Other examples of mitigation relevant to a coexistence policy could be hypothesized. However, the two examples discussed above show why the concept of mitigation should be part of any USDA policy on coexistence. Without an obligation to mitigate, the USDA policy would over-compensationthose making claims and would create the incentive for those claimants to engage in moral hazards and manipulate the policy for their own unfair economic advantage.

The Benefit Rule

Bt crops contain genes that are toxic to particular pests (e.g. European corn borer or cotton bollworm) of a particular crop (e.g. maize or cotton). Therefore, Bt crops have a genetic composition that makes that transgenic plant toxic to a pest. Like farmer's reactions to weeds, farmers are constantly trying to protect their crops and their harvests from pests. Bt crops provide farmers with protection against certain, limited insect pests for which farmers otherwise likely would use a broad-spectrum insecticide.

Two studies exist that discuss the benefits that farmers of Bt *(Bacillus thurengiensis)* crops provide for neighboring farmers with non-Bt crops (Hutcinson et al. 2010; Lu et al. 2012). These benefits are called "spill-over benefits" or the "halo effect" of Bt crops upon non-Bt crops. To explain these benefits, it is easiest and clearest to quote the studies:

> On the basis of these calculations, we estimate that cumulative benefits for both Bt and non-Bt maize growers during the past 14 years were almost $6.9 billion in the five state region (18.7 million ha in 2009) … Of this $6.9 billion total, cumulative suppression benefits to non-Bt maize growers resulting from *O. nubilalis* population suppression in non-Bt maize exceeds $4.3 billion – … – or about 63% of the total benefits. Direct benefits for Bt maize growers (…) were reduced because of the additional cost for Bt seed over the 14 growing seasons, … whereas non-Bt maize experienced lower *O. nubilalis* damage as a result of areawide suppression at no additional cost. … These results highlight the need to account for economic benefits of pest suppression for non-Bt maize, as well as for direct economic benefits of Bt maize (Hutcinson et al. 2010, pp. 224–225).

> Higher generalist predator population levels in Bt cotton lead to lower insect pest levels in the crop, and these predators might provide additional biocontrol services spilling over from cotton fields onto neighboring crops, although further work should be performed to document this last point. Broadly speaking, the deployment of Bt crops may favour bio-control services and enhance economic benefits not only in Bt crop fields but also in the whole agricultural landscape. … Our present study, demonstrating that biocontrol services are potentially provided by Bt crops throughout the agricultural landscape, may offer new options in developing conservation biological control measures at the landscape level (Lu et al. 2012, p. 365).

What these two studies documented through field research had been predicted in 1996, on theoretical grounds, as Bt crops began to be adopted for the first time that year (Alstad and Andow 1996; Hellmich 2011; Tabashnik 2010). For purposes of USDA coexistence policy, the under-explored issue is whether these "spill-over" benefits or "halo effect" should be taken into account as part of the policy. At the Common Law, benefits (sometimes called setoffs) that a defendant provides to a plaintiff can reduce, in certain circumstances, the award of damages to which a plaintiff is entitled. The Restatement of the Law (Second) on Torts, Section 920 describes the benefit rule as follows:

> When the defendant's tortious conduct has caused harm to the plaintiff or to his property and in so doing has conferred a special benefit to the interest of the plaintiff that was harmed, the value of the benefit conferred is considered in mitigation of damages, to the extent that this is equitable.

As an illustration of Section 920, the Restatement authors write:

> A tortiously digs a channel through B's land, thereby making it impossible to grow crops upon the land through which the channel runs. It may be shown in mitigation that the digging of the channel drains the remainder of B's land, making it more valuable. 9 p. 510)

What may be the meaning of Section 920 in the factual situation of "spill-over benefits" of Bt crops to non-Bt crops? More specifically, what may be its meaning for USDA coexistence policy?

Section 920 states that the benefit rule applies only to "a special benefit" to the plaintiff. In other words, transgenic farmers sued by a non-transgenic farmer cannot claim a damages offset on the basis that general farmland values have increased, due to higher production and easier insect control offered by Bt crops, for everyone in the community. By contrast, the transgenic farmer should be able to offer evidence of special benefits specifically identified to a particular non-transgenic farmer. Such special benefits might include lower insect control costs (including labor and purchased pesticides) and increased yield of the "spill-over" protected crop. If the transgenic farmer can prove these special benefits, courts should apply Section 920 to reduce any damages that the non-transgenic farmer proves against the transgenic farmer.

Section 920 also states that the benefits conferred can mitigate "to the extent that this is equitable." For instance, as discussed in first-year law classes around the US, a defendant cannot ask a court to reduce a plaintiff's damages when the defendant decides, without permission, to mow plaintiff's yard so as to improve the aesthetics of plaintiff's property. Even if the defendant and every other neighbor is happy with the mowed yard, plaintiff can choose her own yard aesthetics. Plaintiff cannot be made to accept a benefit that plaintiff did not request or desire.

In the situation of a non-transgenic farmer near a transgenic farmer, the non-transgenic farmer likely does desire the reduced pest pressure and the improved biocontrol offered by beneficial predator insects that survive because the transgenic farmer did not use a broad spectrum pesticide. Courts might well allow the transgenic farmer to introduce evidence that the non-transgenic farmer did not reject

these "spill-over" benefits because the "spill-over" benefits were in line with what the non-transgenic farmer would have desired and would have pursued through other agronomic methods.[1] The transgenic farmer has a solid argument that the plaintiff has benefitted and that it is equitable for the transgenic farmer to receive a setoff against other proven damages to plaintiff's crops.

The Common Law analysis of the benefit rule also imposes the limitation that the benefit to the plaintiff be to the same plaintiff's interest as the interest harmed. This "same interest" limitation seems interrelated to the limitation that the defendant's tortious conduct must cause the benefit for which defendant seeks a setoff. Assuming that the plaintiff complains of a market loss because plaintiff's crop cannot meet a contract specification for purity from transgenic material, would the "spillover benefit" that plaintiff produced more crop at lower cost, by being nearby to a Bt crop, be a benefit to the same plaintiff's interest? Would the defendant's tortious action of planting a Bt crop that wandered be the cause of the benefits to the plaintiff's yield and production costs?

The author asks these questions without attempting to provide an in-depth analysis for two reasons. First, the author did not find any court decisions that seemed particularly relevant on their facts. In other words, there did not appear to be similar fact patterns that could serve as persuasive precedent for the Bt spill-over benefit factual situation. Second, the concept of causation is itself a nebulous concept filled with policy decisions that are often unarticulated. Courts (and juries) often say "X caused Y" without clearly and convincingly explaining the causal connection or the meaning of the word "cause" itself. Causation may be hardly more than an unarticulated and assumed conclusion. Hence, it is hard to predict or explain whether a court, using the Common Law, would consider the Bt spill-over benefit to be to the same plaintiff's interest or to be the cause of plaintiff's benefit (Dobbs 1993).

In discussing mitigation-of-damages, the author urges that the USDA coexistence policy follow the common law on mitigation. It would make sense for the USDA policy to follow the Common Law on the benefit rule too. But there are two difficulties with the USDA doing so.

First, the Common Law benefit rule, in the situation of the spill-over benefit of Bt crops, is much less clear than the application of the mitigation-of-damages doctrine to transgenic crops. There is little disagreement that the Common Law would apply the mitigation-of-damages doctrine to disputes between conventional farmers, identity-preserved farmers, organic farmers and transgenic farmers. Thus, USDA coexistence policy can easily follow the Common Law on mitigation, but not so easily when the benefit rule is unclear in the coexistence context.

[1]It is possible that the non-transgenic farmer desires crop-devouring pests and can testify that the non-transgenic farmer wanted a natural landscape. In this instance, the transgenic farmer may not be entitled to the benefit rule. However, and outside the scope of this chapter, the transgenic farmer may have a lawsuit against the non-transgenic farmer for nuisance in promoting and protecting the infestation of neighbor farms with the crop-devouring pests. Farmers do have a neighborly and legal obligation to control weeds and pests from becoming a nuisance.

Second, those pushing for a coexistence policy, primarily the organic sector of agriculture, often request that the coexistence policy impose liability with:

- a lesser burden of evidence on the plaintiff by presuming harm from transgenic crops,
- a lesser burden of proof related to causation even making defendant prove that defendant did not cause the plausible alleged harm, and
- joint and several liability among all transgenic farmers so that the plaintiff does not have to prove causation against any particular, identified transgenic farmer (Fedtke 2010).

If the USDA coexistence policy were to adopt any of the changes to causation set forth in the immediately preceding paragraph, transgenic farmers would appear to have an argument to USDA that they too should receive a changed causation standard with regard to the benefit rule. In other words, transgenic farmers would urge that changes in the concept of causation should occur both for farmers claiming harm and for farmers claiming a setoff due to a spill-over benefit. Transgenic farmers could make the argument to the USDA body formulating the coexistence policy that it is equitable to incorporate the benefit rule into the policy despite difficulties with causation under Common Law analysis.

Conclusion

In this chapter, the author has sketched three under-explored facets of the complexities of a coexistence policy. Each of these under-explored facets deserves careful and thoughtful attention and discussion in any further USDA initiatives related to coexistence.

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The "Honey" Judgment of Bablok and Others Versus Freistaat Bayern in the Court of Justice of the European Union: Implications for Co-existence

Kai Purnhagen and Justus Wesseler

Introduction

Many consumers in Europe dislike foods produced with the help of genetically modified organisms (GMOs) (Bredahl 2001; Bonny 2003). Consumers in Europe also like honey so much that the European Union (EU), despite being the second largest producer of honey in the world,[1] cannot fulfil demand without imports. Honey is not a product whose production might need GMOs. However, the nectar from which honey is produced might contain pollen which originates from GM plants. As bees collect this pollen from anywhere in nature, it is particularly hard, if not impossible, to control whether they collect pollen from a GMO or a "natural" plant. A ban of GMOs in honey is hence likely to also affect the planting of all sorts of GMOs in nature, even if they were never intended to be used for the production of honey.

Against this background a case of GMOs in honey has been decided by the Court of Justice of the European Union (CJEU). In its judgment *Karl Heinz Bablok and Others v Freistaat Bayern*[2] the CJEU decided, among other things, that honey which contains GMO pollen or pollen harvested from GMOs has to be authorized for consumption to be admitted for marketing in the EU. To be sure, we do not contest the content of the judgment as it is well in line with EU law, at least within the boundaries of legal interpretation. The impact of the judgment on trade within

[1]See the website of the European Commission, agriculture and rural development, honey, available at http://ec.europa.eu/agriculture/honey/index_en.htm.
[2]CJEU, C 442/09, Bablok and Others v Freistaat Bayern [2011] ECR I-7419.

K. Purnhagen (✉) · J. Wesseler
Wageningen University, Wageningen, Netherlands
e-mail: Kai.Purnhagen@wur.nl

J. Wesseler
e-mail: justus.wesseler@wur.nl

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and outside of the EU and on the risk assessment procedure for GMO authorization might illustrate possible flaws of the underlying regulatory regime of GMOs in Europe. These might inspire the EU lawmaker to think about a more effective regulatory system. We would like to contribute to an impact analysis of the judgment from a law and economics perspective. We proceed in five steps. We will first introduce the background of the case and the regulatory environment, before we turn to describing the facts and the findings of the Court. We will subsequently illustrate the changes in the regulatory systems triggered by the Court's judgment, before we turn to a more thorough analysis of the judgment on the EU and the global trade system from a socio-economic perspective. From these findings, we will conclude with concrete policy recommendations.

Background of the Case and the Regulatory Environment

As with any new technology, GMO products promise benefits to consumers. Uncertainties regarding the potential hazards of such new technologies exist (van der Meulen et al. 2014). For this reason, the EU requires in Art. 2 (2) Directive 2001/18/EC[3] on the deliberate release into the environment of genetically modified organisms (hereinafter "Directive") market authorization for all "genetically modified organism (GMO) …, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination," which shall be released into the environment (For an overview of the regulatory environment, see Wesseler and Kalaitzandonakes 2011).[4] If used for consumption, Art. 4 (2) of Regulation (EC) 1829/2003[5] on genetically modified food and feed (hereinafter "Regulation") requires pre-market authorization of all food and feed which contain GMOs. Even if approved, Member States may still make use of a safeguard clause to prohibit marketing of the GMO (See Pollack and Shaffer 2009, 243; Poli 2013, 148–153). All GMOs introduced to the EU market, whether imported, manufactured or cultured for whatever purpose, hence need authorization from the competent authorities. The authorization is, however, only granted according to the scope of the respective procedure. If the applicant went through the application procedure of the Directive, the GMO is only approved for release into the environment. If the GMO was authorized under the

[3]Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106 of 17.4.2001.

[4]It is a peculiar thing of the EU market, however, that also GMOs produced within the EU require a special authorization just because they are GMOs. Other trading blocs such as the United States of America require authorization in particular for imports of GMOs or when used in special circumstances such as an additive (see Grossman 2012).

[5]Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268 of 18.10.2003.

Regulation, it is only approved for consumption, but not for release into the environment. If an applicant desires his or her product to be admitted for both uses, in principle he or she has to file through both procedures. The reason for this lies in the difference of environmental and consumer risks, which require different risk assessment procedures.[6] However, as some parts of the environmental and consumer risk assessments are similar, it would form an unnecessary trade barrier to conduct both separately for a single GMO. For this reason the Regulation established the "one door, one key" principle, whereby applicants can apply for an authorization for environmental release and consumption with only one procedure and risk assessment.

Companies seeking GMO market approval hence have four possibilities: Seeking approval only for environmental release, only for consumption, for environmental release and consumption under two different procedures and risk assessment or under one procedure and risk assessment. The risks involved with either strategy need careful balancing: If an applicant seeks authorization of a GMO only for release into the environment but the GMO travels to food products, companies might end up being liable for non-authorization. The honey-case already described is an example of this risk. If one can trace back GMO residues on farmland to a GMO food that was only authorized for consumption, the applicants might likewise face liability. Applicants could overcome this risk by seeking authorization for consumption and environmental release. To lower costs, they may make use of the "one door one key principle." This increases their risk, however, that the product will not be approved for neither consumption nor environmental release. If applicants choose the more costly version of filing both applications, they diversify this risk.

Thus the EU distinguishes between two authorization procedures: One for the release into the environment, so-called cultivation[7] and another one for consumption as food and/or feed.[8] If a GMO was authorized for the release into the environment only it might not be used for consumption as a food and vice versa. Honey is a product produced for consumption, but manufactured from plants that were released into the environment. Consider a GMO authorized for the release into the environment only, from which a bee collects pollen that later accidently travels into honey (Lamping 2012, 127) which is used for human consumption. Such a situation jeopardizes the fine regulatory line drawn by the EU regulators between the two authorization procedures. How to decide in a case when GMO pollen was found in honey? Should regulators approve such a case, as there is no way to control where bees collect nectar and pollen? Then EU consumers would have to face GMOs in products that were not authorized for consumption. Should the EU prohibit such a case? Then it will jeopardize the effectiveness of the authorization procedure for the release into the environment, as virtually any GMO that is intended for the release

[6]This fact is also stressed by the Court in CJEU, C 442/09, Bablok and Others, paras 101–102.

[7]Directive.

[8]Regulation.

into the environment only would be likely to need to also undergo the authorization procedure for consumption.

These decisions are particularly hard in an environment such as in the EU, where discussions about GMOs are highly political (Pollack and Shaffer 2009, 53–80). Any EU decision favoring the use of GMOs which does not take into account Member States' and European consumers' fears might result in the lack of trust in the regulatory capacity of the EU (Purnhagen 2014). Member States might fear losing the support of their citizenry if they do not oppose laxer EU standards with regards to GMOs. Member States have blocked EU GMO authorizations in the past by requesting ever more scientific data in the authorization process (Lieberman and Gray 2006; Lee 2008, 3–4).

Taking the consumers' and Member States' concerns into account can also have adverse consequences. The Member States' "quasi moratorium" of the late 1990s to early 2000s resulted in a WTO trade dispute with Argentina, Canada, and the US, who accused the EU of upholding a factual trade barrier with the de facto moratorium (Wesseler and Kalaitzandonakes 2011; Pollack and Shaffer 2009, 177–234). Listening to consumers' fears might end in a pyrrhic victory also: If consumers would not get honey in an amount and at a price they are willing to pay, trust in the EU as a market governing entity is equally at risk. This becomes obvious by looking at the global scale: The EU is dependent on honey imports to satisfy European consumer demands. If all GMOs in honey need authorization for consumption, importers of honey would have to make sure that their honey either does not contain GMOs or only GMOs that are authorized for consumption. Thereby, the EU regulator either forces importing countries to ban GMOs from their country or requires firms who release their GMOs into the environment in a honey exporting country to authorize their product for consumption in the EU. The EU would thereby enforce their regulatory standards on export-depending countries (Bradford 2012). This results in costs which can be so high that firms choose not to export honey into the EU any longer. This might result in the fact that EU consumers might not get any honey at all or at least not at a price they desire.

The problem is elevated to another level when one takes into account the requirements of risk assessment prior to the GMO approval in the EU. All authorization notifications for GMOs which are intended to be released into the environment in the EU have to contain data which need to be collected in field trials. GMOs in such field trials are, of course, not authorized as they are in the process of seeking authorization. As pollen from these fields could also travel via bees into honey, such trial fields might trigger uncontrollable litigation risks. None of these plants were authorized as GMOs, as they are in the procedure of authorization. The only way out is to shield GMO trial fields in such a way that they are not connected to the environment. This, however, creates an artificial research environment. If possible at all, this might result in harvesting data of low quality for the risk assessment procedure, which might also lower the ability to assess risks in order to ensure consumer and environmental protection.

EU institutions face a regulatory dilemma when deciding about GMOs in honey. On the one hand, the EU depends on imports of honey, which are at risk when honey imported to the EU from GM crop producing countries requires authorization of the GMOs for human consumption. On the other hand, European consumers require a strict legal regime with regards to the authorization of GMO foods, which grants the potential for EU institutions to win the trust of EU citizens in the EU's regulatory capacity (Purnhagen 2015). EU institutions furthermore interfere with the possibility to conduct field experiments, which are not only necessary for the authorization of GM crop cultivation in Europe but also for securing consumer and environmental protection.

The Judgment: Karl Heinz Bablok and Others v Freistaat Bayern

In practice, however, most applicants that file for environmental release apply also for authorization for consumption. This was different in the case for maize in the case of *Bablok and Others v Freistaat Bayern* at issue here.

Facts

Freistaat Bayern (Bavaria, Germany) owns plots of land on which the transgenic maize MON 810 has been cultivated for research purposes.[9] The hives of bee keeper Mr. Bablok were situated about 500 m from the plots of land on which the transgenic maize was grown.[10] From these hives, Mr. Bablok had produced honey and, up to 2005, also pollen for sale as a foodstuff in the form of a food supplement. Mr. Bablok feared that both products, the honey and the pollen might have been subject to a material interference by the GMOs and can no longer be marketed without authorization and labeling. Under German law, such an interference may also entitle Mr. Bablok to monetary compensation.

In 2005, MON 810 maize DNA and transgenic proteins (Bt toxins) were found in Mr. Bablok's pollen.[11] In addition, MON 810 maize DNA was also found in a small number of samples of Mr. Bablok's honey.[12] Mr. Bablok and others filed a lawsuit under national law. Within the main proceedings, the national Court had to "rule on an application for a declaration that, as a result of the presence of pollen from MON 810 maize in the apicultural products in question, those products are no

[9]CJEU, C 442/09, Bablok and Others, para 32.
[10]CJEU, C 442/09, Bablok and Others, para 36.
[11]CJEU, C 442/09, Bablok and Others, para 37.
[12]CJEU, C 442/09, Bablok and Others, para 37.

longer marketable or fit for consumption and, accordingly, that they have been subjected to a 'material interference' within the meaning of" the respective national legal statutes.[13] The interpretation of the term of 'material interference' depended on whether the products in question can be classified as GMOs under EU law.[14] Such questions about the interpretation of EU law are in the principle domain of the CJEU. The national Court hence referred the following questions regarding the interpretation of EU law to the CJEU:

1. Must the term [GMO] defined in Article 2.5 of [Regulation No 1829/2003] be interpreted as meaning that it includes also material from genetically modified plants (in this case, pollen from the genetically modified MON 810 strain of maize) which, although containing genetically modified DNA and genetically modified proteins (in this case, Bt toxin) at the time of entering a food (in this case, honey) or designation for use as a food/food supplement, does not possess (or no longer possesses) a specific and individual capacity to reproduce?

2. If Question 1 is answered in the negative:

(a) Does it suffice, at any rate for foods which, within the meaning of Article 2.10 of [Regulation No 1829/2003], are deemed to be "produced from GMOs", that the food contains material from genetically modified plants which previously possessed a specific and individual capacity to reproduce?

(b) If that is answered in the affirmative:

Must the term "produced from GMOs" within the meaning of Article 2.10 and Article 3(1)(c) of [Regulation No 1829/2003] be interpreted as meaning that, in relation to GMOs, no deliberate and targeted production process is required and the unintentional and adventitious admixture of food (in this case, honey or pollen as a food supplement) by (former) GMOs is also covered?

3. If either Question 1 or Question 2 is answered in the affirmative:

Must Article 3(1) and Article 4(2) of [Regulation No 1829/2003] be interpreted as meaning that any contamination of food of animal origin, such as honey, through genetically modified material lawfully present in the environment triggers the obligation for such to be authorised and supervised or can thresholds applicable elsewhere (for example, under Article 12(2) of the Regulation) apply mutatis mutandis?[15]

Judgment of the CJEU

The CJEU answered the first question, whether the organism has to have a specific and individual capacity to reproduce in order to be classified as GMO, in the

[13]CJEU, C 442/09, Bablok and Others, para 39.

[14]CJEU, C 442/09, Bablok and Others, para 47.

[15]CJEU, C 442/09, Bablok and Others, para 53.

negative. It provided a doctrinal argument by simply pointing to the definition of GMO in EU legislation.[16] According to Art. 2 (1) and (2) of the Directive and Art. 2.4 and 2.5 of the Regulation, GMOs are organisms which are genetically modified if their genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. This endorsed "conclusively two criteria which go together, namely viability and fertility".[17] Conclusively, as soon as the substance in question loses either one of these categories, it cannot be classified as a GMO.[18] It was hence for the referring Court to decide whether the substance at issue had both of these categories in order to classify as GMO.

The applicability of the EU legal regime on GMOs, however, does not only regulate "food containing or consisting of GMOs" (cf. Art. 3 (1) (b) Regulation), but also "food produced from or containing ingredients produced from GMOs" (cf. Art. 3 (1) (c) Regulation). Even if the pollen at issue would not classify as GMO, it could hence nonetheless be subject to GMO regulation at EU level if the pollen within the honey was "produced from … GMOs" (Art. 2.10 Regulation by reference to Art. 6 (4) (a) Directive) or classified as an "ingredient" according to Art. 2.13 Regulation, by reference to Art. 6 (4) (a) Directive, which was "produced from GMOs".

The Court answered the question, whether pollen was produced from a GMO, in a straightforward manner:

> The pollen at issue in the main proceedings is derived from MON 810 maize, that is to say, from a GMO. That pollen must be regarded as being 'produced from GMOs' within the meaning of Article 2.10 of Regulation No 1829/2003 when it can no longer be classified as a GMO since, in that case, it no longer consists of a GMO and no longer contains a GMO.[19]

In the case at issue it was thus without question that the pollen was produced from a GMO and hence needed authorization.

What was subject to debate was whether pollen would qualify as an "ingredient" of honey, which then, according to Art. 12 (1) (b) Regulation would have to be labeled as such. The Commission brought forward the argument that a distinction needs to be made between what qualifies as an "ingredient" and a "natural component" of the product.[20] The Court, however, followed a different argumentation. It stipulated that a reasoning such as the one submitted by the Commission does not take account "of the particular conditions under which pollen is incorporated into honey or of the voluntary maintenance of that pollen in the composition of the end product."[21] It undermined "the objective of protecting human health, since a foodstuff such as honey would escape any safety checks, even though it might contain significant quantities of genetically modified material", and would

[16]CJEU, C 442/09, Bablok and Others, para 55.
[17]CJEU, C 442/09, Bablok and Others, para 55.
[18]CJEU, C 442/09, Bablok and Others, para 62.
[19]CJEU, C 442/09, Bablok and Others, paras 70, 71.
[20]CJEU, C 442/09, Bablok and Others, para 80.
[21]CJEU, C 442/09, Bablok and Others, para 81.

"disregard the determining criterion for the application of Regulation No 1829/2003, […] namely that as to 'whether or not material derived from the genetically modified source material is present in food'".[22] In essence, the Court brings two arguments: One is the protection of consumer's health and the other is that if one followed the Commission's interpretation, the Court would undermine the European legislature's decision for the application criteria of the Regulation.

The third question is as well answered in the negative by the Court. The 0.9 % threshold level as laid down in Art. 12 (2) Regulation cannot be applied mutatis mutandis elsewhere, e.g. on the Directive, as the two have different goals.[23] While the Directive aims at environmental protection, the Regulation emphasises the protection of human health, thereby introducing "an additional level of control".[24] Within this argument, what counts as a de minimis threshold for environmental protection cannot be applied by way of analogy to issues concerning human health or vice versa, neither across different regulatory acts, nor within the provisions of one act. As a consequence, if more than 0.9 % of the pollen contained GMOs, it had to be labeled as such.

Interpretation of the Judgment

The mainly doctrinal answer to the questions of the court has rightly been criticized as being "textually-oriented" and taking little account of its impact on trade (Alemanno 2011). Such a doctrinal argumentation is often used to hide policy arguments behind a seemingly neutral text (Purnhagen 2013). Indeed, as the Court faced particularly difficult and highly political questions, it was well advised to tie its argumentation closely to the wording of the provisions at stake in order to be able to "hide behind" the legislative text and assign responsibility for change to the EU regulators.

While question one evidently required a doctrinal answer, this cannot be said that easily for question two. Indeed the straightforward argument for determining whether pollen was derived from a GMO is appealing, as the underlying wording of the Regulation left little to no room for a different understanding. Whether it has to be classified as an "ingredient" in the way the Court did is, however, not that clear. The legislature has given very little guidance on how to understand what an "ingredient" is. A doctrinal analysis will hence prove to be difficult. The Commission proposed to distinguish between "ingredient" and "natural component," a solution which is naturally appealing but hard to base on the underlying law. The term "natural component" was, at the time of the Court decision, known to neither the Directive nor the Regulation. The Regulation, however, refers in its recital 25 to

[22]CJEU, C 442/09, Bablok and Others, paras 82–83.

[23]CJEU, C 442/09, Bablok and Others, paras 95-101.

[24]CJEU, C 442/09, Bablok and Others, paras 101.

"genetically modified materials in a food or feed or in one of its components," presupposing that food might contain GMO components. The distinction made by the Commission between an "ingredient" and a "component" is hence a meaningful one. How this distinction is to be drawn, however, was still hard to determine. The Court chose a doctrinal approach to delineate between "ingredient" and "natural component", thereby running the risk of hiding policy arguments behind a technical reasoning (Lamping 2012, 127: The "Grand Chamber approached this question from a technical standpoint but ended up giving a political answer.") Instead of looking at the possible impact of the judgment on trade, the Court preferred to refer bluntly to human health and an alleged circumvention of the scope of the Regulation.

In sum, the Court's answer on the second question, while supportable when contrasted with the legal norms available, is problematic from both a doctrinal and an external point of view.

A Doctrinal View: Why the Bablok Judgment Hinders Risk Assessment From a doctrinal perspective, the Court's interpretation of the term "ingredient" in Bablok was in line with the term "ingredient" of Art. 6 (4) lit. a) of Labelling Directive 2000/13/EC (Hagenmeyer 2011, 293), a directive which has meanwhile been replaced by the Food Information Regulation.[25] Art. 2 (2) lit. f) of the Food Information Regulation stipulates that "residues shall not be considered as 'ingredients'," which would clearly qualify "pollen" not to be an "ingredient" within the meaning of the Food Information Regulation. As this Regulation was not effective at the time of the judgment was issued and the preliminary effect of secondary legislation to date is only accepted for Directives,[26] the Court did not need to take into account this new interpretation. However, currently, at least in the area of GMO labeling in Art. 12 Regulation, the term "ingredient" would have to be interpreted according to the Food Information Regulation (Art. 1 (2) Food Information Regulation).

But also the Court's clear-cut analysis of whether pollen was produced from a GMO is at closer inspection problematic from a doctrinal perspective. One of the main objectives of the Regulation is, according to its Art. 1 (a), to "provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed." It is well known that the Court applies, for very good reasons, a very strict regime when human health is at stake.[27] For that matter it makes sense to

[25]Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304 of 22.11.2011.

[26]ECJ, C-192/96, Wallonie, ECR I-997, I-07411, para 50.

[27]ECJ, C-183/95, Affish, ECR I-4362, para 43.

not compromise on trade restrictions as soon as human health is at stake. But was this the case in Bablok? The Court made nearly all GMO plants somehow released into the environment subject to authorization also for consumption, even though data was inconclusive whether this would form a threat to human health and/or the environment. In such cases, EU food law resorts to the precautionary principle as it was laid down in Art. 7 of the General Food Law,[28] a provision not mentioned by the Court. When risk assessment is inconclusive, Member States and EU institutions may provide for measures in order to protect human health. However, in EU food law such measures must be only "provisional" (Art. 7 (1) GFL) (Szajkowska 2010). These measures are "provisional" as they shall also enable science to conduct further risk assessment to gain knowledge on whether the product is potentially dangerous (Purnhagen 2015b). Bablok, one could argue, envisages exactly that: By asking for an authorization as GMO food for all plants which could potentially contain GMOs, the judgment enables such a risk assessment. Ironically, however, the opposite is true. The judgment Bablok jeopardizes this approach, as field research on GMO plants, which are necessary for the authorization of GMO foods, have become virtually impossible or at least subject to very severe restrictions.[29] In fact, by its doctrinal approach, the Court not only presumed incidentally and politically that consumer health was endangered; by disregarding the mechanism of the precautionary principle in Art. 7 GFL it ignored established EU law and made scientific risk assessment within the geographical area of the EU virtually impossible.

An External View: Why the External Effects of the Bablok Judgment Might Call for a Reconsideration The judgment will also have a severe impact on co-existence of conventional, organic and genetically modified farming inside of the EU and also on the marketability of honey, particularly when produced outside of the EU (Lamping 2012, 128). Most of the dangers, such as uncontrollable liability risks and WTO trade disputes, were already mentioned. For a more detailed treatment see the socio-economic analysis below. It would have been desirable for the CJEU to have taken these implications into consideration in the Bablok case. EU food law would have had equipped the Court with means to do that: Art. 5 (3) GFL obliges Union institution to take international standards "into consideration". Art. 13 GFL enables the EU institutions to "contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards" and to "promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organisations". Even more, they shall also "promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced."

[28]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, 1.

[29]See the assessment under 5.

Implications of the Judgment

The judgment had implications not only for the referring Court's decision, but also for EU legislation.

Under German law, Mr. Bablok might be entitled to a compensation in rem by sec. 36a Law on the Regulation of Genetically Engineering (GenTK)[30] in conjunction with sec. 906 of the German Civil Code (BGB).[31] This was one of the reasons why Mr. Bablok brought action in front of the national court. The Bavarian Court of Administration decided as a follow-up on the CJEU's judgment that Mr. Bablok indeed has such a right to compensation if he can prove that the honey was contaminated by pollen from maize not authorized for consumption.[32] At the same time Mr Bablok cannot claim, however, injunctive relief according to sec. 1004 (1) BGB, when the operator fulfils all precautionary and prevention measures according to the best practices as stipulated in sec. 16b GenTG. A follow-up claim on the latter topic of injunctive relief was dismissed by the German Federal Court of Administration as the producer had meanwhile sought for authorization for consumption.[33]

The judgment also influenced EU legislation. While the criticism was hard on many accounts (Lamping 2012, 127–129), the particular legal issues of the judgment targeted mainly the classification of pollen as an "ingredient" in light of changing EU food information legislation (Hagenmeyer 2011, 293). As a consequence, Directive 2014/63/EU[34] amended Directive 2001/110/EC in such a way that pollen is now defined as a natural constituent of honey, rather than as an ingredient. This means first that pollen does not need authorization as an "ingredient" in honey, and second that GMO pollen now needs labeling only if it makes up more than 0.9 % of the honey. This rules out the somewhat awkward situation that arose after the Bablok judgment, which required pollen to be labeled if it contained 0.9 % GMOs (and not the honey).

Socio-Economic Analysis of the Judgment

The ruling of the CJEU has implications as already mentioned for the approval of GM crops for cultivation. It has also implication on research. Field trials with GM crops have become costly as only GM crops that do not expose GM pollen can be

[30]Gesetz zur Regelung der Gentechnik.

[31]Bürgerliches Gesetzbuch.

[32]Decision at Bavarian Court (compensation issues, etc.) judgment of 27. March 2012, Az. 22 BV 11.2175, para 81 ff.

[33]BVerwG 7 C 13.12.

[34]Directive 2014/63/EU of the European Parliament and of the Council amending Council Directive 2001/110/EC relating to honey.

used. The ruling can also have important implications for international trade in honey. The EU is a large net importer of honey (see Fig. 1). Countries exporting honey into the EU but also producing GM crops (see Figs. 2, 3, 4, 5 and Table 1) may face export difficulties if some of the GM crops they produce have no authorization for imports into the EU. When looking at the trade implications, the main beneficiaries will be EU honey producing countries as competition from non-EU countries will be reduced. The major countries exporting honey to the EU are Argentina and China, which are also countries growing GM crops as well as

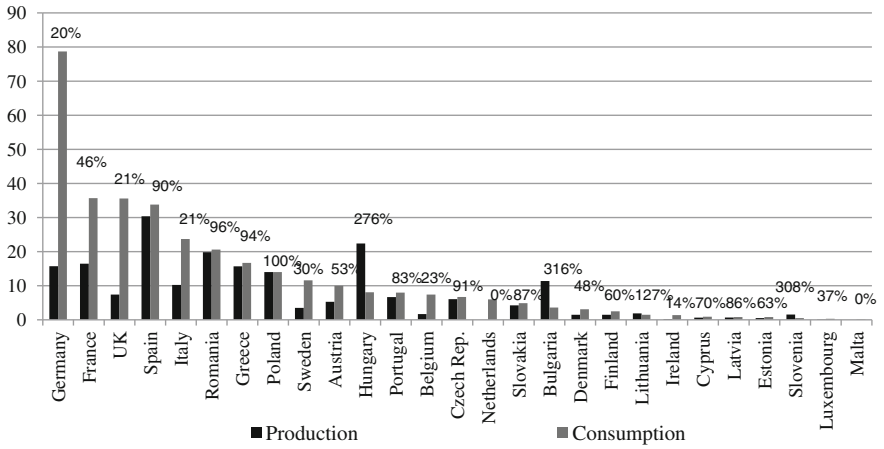

Fig. 1 EU honey production, consumption ('000 ton), and self sufficiency (%) 2008

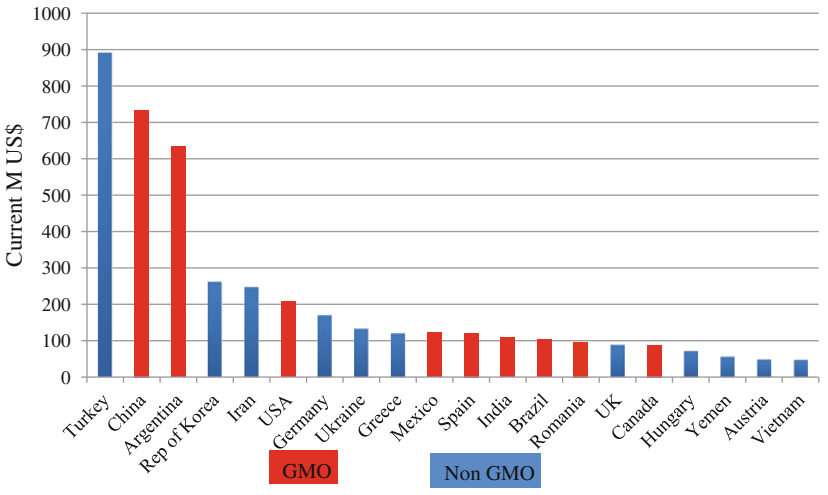

Fig. 2 Gross production value (M US$) of honey, top 20 counties, 2009

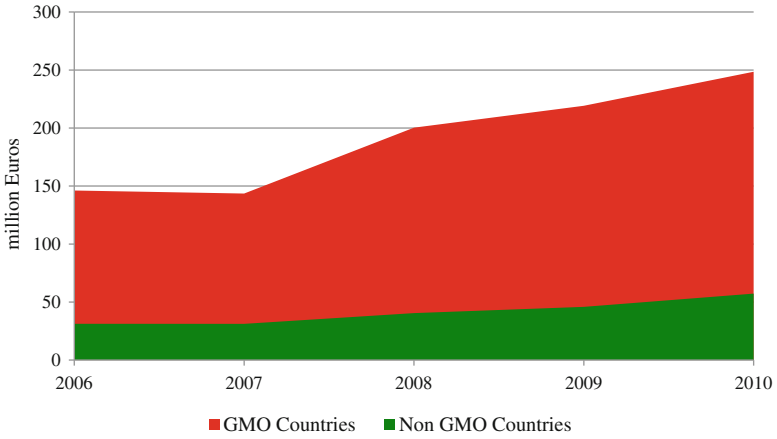

Fig. 3 Value of honey imported to EU from GMO and Non GMO countries, 2006–10

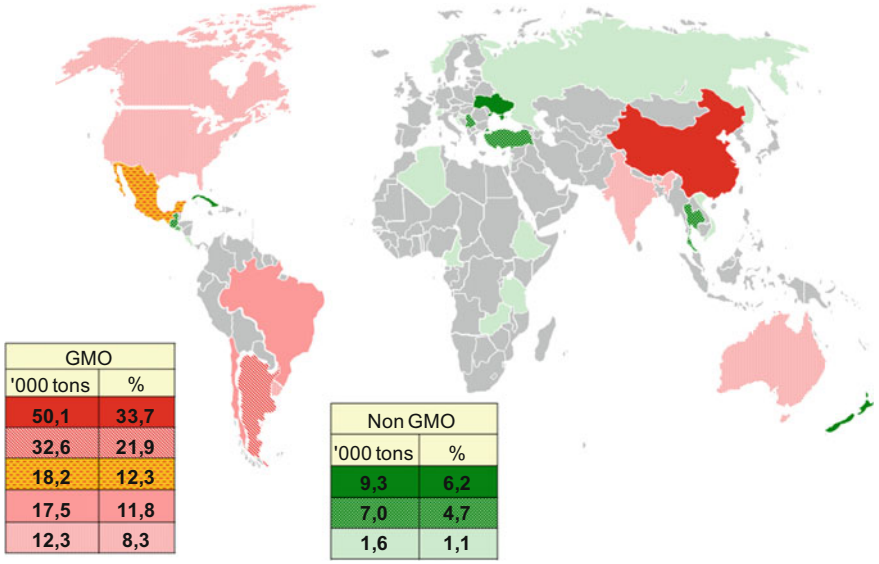

Fig. 4 Countries (GMO and Non GMO) Supplying EU with Honey, 2010

major honey producers. They can be expected to lose export opportunities to the EU. The price of honey within their country will decrease as export markets will be lost and more honey needs to be sold internally. The honey producers in those countries will be on the losers' side. Their consumers gain as the domestic price for honey decreases. Honey exporters to the EU that do not cultivate GM crops such as New Zealand and Ukraine will gain as they have opportunities to fill the decline in honey exports from GM countries resulting in an increase in the honey prices in

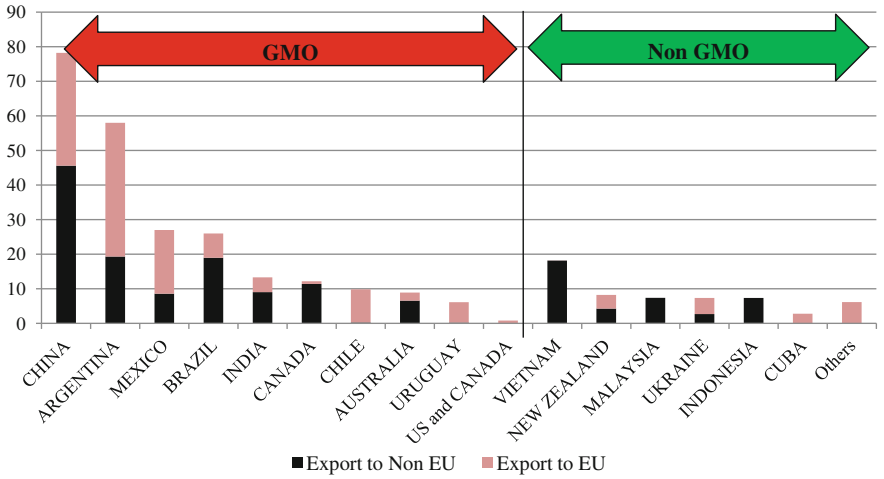

Fig. 5 Quantity ('000 t) of honey exported to EU and non EU countries from the world's top producers (GMO and non GMO Countries), 2009

Table 1 Honey exported to the EU as a proportion of total exports by the world's top producers (GMO and non-GMO countries), 2009

Country	Quantity (1000 metric tons)		Proportion exported to EU (%)
	Total exported	Exported to EU	
GMO countries			
China	78.22	32.62	42
Argentina	57.97	38.66	67
Mexico	26.98	18.42	68
Brazil	25.99	7.01	27
India	13.31	4.29	32
Canada	12.16	0.78	6
Chile	9.85	9.58	97
Australia	8.91	2.34	26
Uruguay	6.13	5.92	97
Non-GMO countries			
Vietnam	18.18	0.01	0
New Zealand	8.21	3.92	48
Malaysia	7.38	0.00	0
Ukraine	7.36	4.66	63
Indonesia	7.36	0.00	0

their domestic markets. But the gains for the honey producers (producer surplus) will be larger than the losses consumers (consumer surplus) face due to higher honey prices. Within the EU, honey producers from countries also cultivating GM crops, such as Romania or Spain, may lose simply through the possibility their honey may contain GM pollen. Honey producers in the EU from countries that do not cultivate GM crops will gain, such as those located in Italy and France. There will be also third country effects. As the overall effect on the world market price for honey will be negative, honey producers in honey net importing countries, such as Japan, will lose because of the price decrease while consumers in those countries will gain. Consumers outside the EU will gain as the world market price for honey declines, while consumers within the EU will lose as they have to pay a higher price for honey caused by the more restrictive requirements for GM-free honey. The size of the effects will depend on the change in actual quantities and prices in honey traded, but in the end EU consumers and honey exporters from China and Argentina will pay the price, while honey producers in Italy, France, New Zealand, and the Ukraine will gain.

The increase in producer rents will not only stay with honey producers, but is likely to be passed on to consumers. In addition to the honey producers in non-GM cultivating countries, testing laboratories and certifying agencies will also gain as the demand for such services within the EU as well as outside the EU will increase. Some of these costs will also be paid for by consumers in the EU.

Conclusion

The judgement by the CJEU on the legality of GM pollen in honey challenges the approval process for GM crops in the EU and has implications for international trade in honey. The judgment increases the difficulty of GM crop field trials in the EU substantially with negative implications for research and approval of GM crops for cultivation in the EU. The judgment also illustrates the problem of the EU approval process. The approval process is intended to protect human health and the environment. The way it is currently exercised might jeopardize the achievement of those ends. In the balancing exercise, the process excessively considers the hazards of GMOs while not paying sufficient attention to the benefits. While the precautionary principle indeed requires taking preliminary measures in case health and environmental risks are uncertain, in the area of GMOs the principle is often used to also justify preventive action. Because it is hard to prove a negative (i.e. "does not exist"), any unauthorized ingredient or natural component, whether a GMO according to Directive 2001/18 or any other substance, in combination with a zero tolerance is interpreted as requiring a removal from the market in its entirety regardless of the potential harm caused. This stretches the possibilities of the precautionary principle, which enables the EU lawmaker to impose only preliminary measures, to a maximum extent. The EU system might hence provide opportunities for using the GMO approval system as an unjustified barrier to international trade.

The case of the honey judgment illustrates this kind of trade effects. In the short run EU honey producers gain at the cost of honey producers in Argentina and China but also some consumers in the rest of the world that have to pay a higher price for honey. All in all, the judgment transfers rents from consumers and honey producers in Argentina and China to honey producers mainly in France and Germany. From their perspective, the CJEU judgment has been a great success paid for by honey producers in developing countries and honey consumers all over the word.

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The Canadian and European Union Impacts from the Detection of GM Flax

Teresa Babuscio, William Hill, Camille D. Ryan and Stuart J. Smyth

Introduction

Tolerance levels exist for many undesirable attributes in food where there is a general consensus regarding the potential food safety hazard: insect fragments, stones, livestock antibiotics, chemical residues, weed seeds, manure, etc. Yet much of the current debate about zero tolerance relates to the presence of genetically modified (GM) material, with far less consensus regarding the acceptability of traces of GM material and the role of science and technology as the arbiter of a safety threshold. The result has been international trade tensions, and increased complexity in supply chain relationships. Embedded in zero tolerance for GM material are divergent perceptions encompassing what constitutes 'high' and 'low' quality and an extension of the use of zero tolerance requirements beyond food safety to encompass different notions of food quality. Thresholds exist for a variety of materials that are commonly found in not only food but also in the trade of agricultural products. Even while knowing that trade in agricultural products cannot function at zero percent, it was decided by European legislators that if any GM variety was detected in agricultural product imports, or found growing in the

T. Babuscio (✉)
COCERAL, Brussels, Belgium
e-mail: teresa.babuscio@coceral.com

W. Hill
Flax Counsel of Canada, Winnipeg, Canada
e-mail: hillw@flaxcouncil.ca

C.D. Ryan
Department of Bioresource Policy, University of Saskatchewan, Saskatoon, Canada
e-mail: cami.ryan@usask.ca

S.J. Smyth (✉)
University of Saskatchewan, Saskatoon, Canada
e-mail: stuart.smyth@usask.ca

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European Union (EU), and if the variety was not approved for import or processing, its use would be illegal and therefore the tolerance threshold was established at zero. Zero tolerance standards for GM material in international food markets and the discovery in 2009 of trace amounts of a deregistered GM variety of Canadian flax in bakery goods in Germany lead to the closure of the EU market to Canadian flaxseed.

History

The Crop Development Centre (CDC) at the University of Saskatchewan conducted research on several varieties of transgenic flax and after several years of field trials, selected variety FP967 (commonly known as CDC Triffid) to submit for registration in February 1994. Full variety release was approved by the Canadian Food Inspection Agency (CFIA) in 1996.

The implementation of the 1998 EU moratorium on GM crops and foods presented a formidable obstacle to the Canadian flax industry. Approximately half of the flax production in Canada at the time was exported to the EU and the commercialization of a GM flax variety alarmed European importers. While the canola industry was able to effectively identity preserve their GM varieties and continue to supply the EU and Japanese markets from 1995 to 97 (Smyth and Phillips 2001), the flax industry did not have this option because of the dominant role of the EU market. European importers were adamant that they would halt Canadian flax imports if GM flax was grown commercially.

Varietal registration (which allowed for seed multiplication but not commercial production) was granted in May 1996, and pedigreed seed production was initiated, continuing until 1997. By the end of the 1997 harvest, there was an estimated 5000 tonnes of pedigreed CDC Triffid seed in Canada. That year turned out to be the final year for multiplication of GM flax. At that point, existing seed stocks of CDC Triffid were identified and contained in separate grain bins in compliance with pedigreed-seed production regulations.

In late 1997 and early 1998 it became apparent to the Canadian flax industry that the proposed (at that time) EU moratorium on GM crops would proceed. The Flax Council of Canada (FCC) initiated discussions about how to handle the situation. The Council determined that all of the existing contained seed stocks would remain that way until a suitable location could be found to crush the flax seed. Coordinated by the FCC, a CanAmera Foods oilseed crushing plant in Manitoba was ultimately contracted to crush the flax. The resulting flax meal was mixed into livestock feed and fed to Canadian livestock, while the oil from the crush was diverted into industrial application. Any and all breeder seed stock held by the CDC was incinerated. This effectively removed all pedigreed seed from growers that were contracted to multiply the seed.

To ensure that CDC Triffid flax would not jeopardize future export markets, the developers of the variety applied to deregister the transgenic flax variety. This

process was initiated in 2000, and by 2001 the CFIA had officially deregistered CDC Triffid flax. This meant that it was illegal to produce or distribute this variety as seed anywhere in Canada but was not illegal to grow it. Varietal deregistration in 2001 represented an end to Triffid and any trade issues associated with GM flax. The Canadian flax industry believed that GM flax would no longer be an issue for them. Unfortunately, this was not to be the case.

In July 2009, the EU reported that a Canadian shipment of flax had tested positive for the NPTII marker, indicating a GM event. At this point, it was assumed that GM canola or another GM crop variety had comingled in the shipment. However, by September 2009 the EU's Rapid Alert System for Food and Feed (RASFF) was notified by a German company that its bakery/cereal products had tested positive for Triffid. Notification on the RASFF system is equivalent to an air raid siren going off in the EU—it is an incredibly effective communication tool. This notification in September was the first of more than one hundred such notifications over the next several months that would report Triffid in bakeries, cereals, and other products made by companies throughout the EU.

The Canadian seed-trade industry was quick to respond to the initial notification. Industry stakeholders—Flax Council of Canada, the CFIA, and the Canadian Grain Commission (CGC)—moved in quickly to try to mitigate the impacts of what threatened to close market access for Canadian flax producers. With winter approaching and the looming closing of the St. Lawrence Seaway, there was an impetus to ensure that markets opened before the winter freeze-up, usually sometime in December. This export option is not available for the three winter months of January, February, and March. When compared to the crop year just prior to the detection of GM flax, Canadian flax exports to the EU were down by 51 % (Fig. 1).

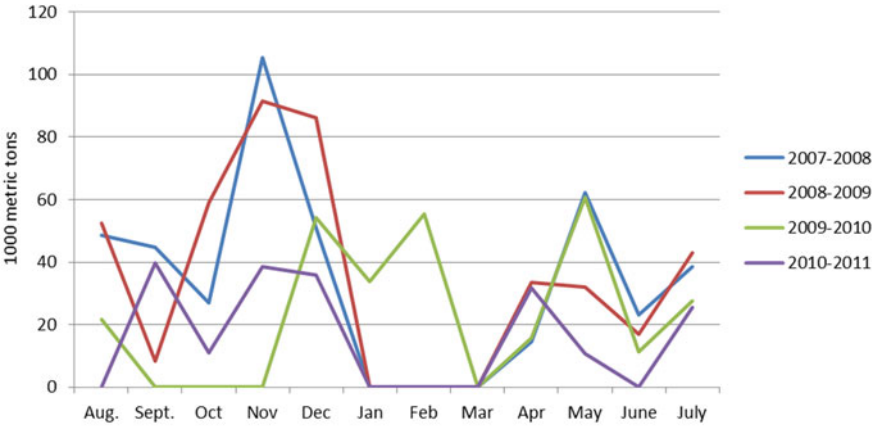

Fig. 1 Month over month flax exports to the EU. Data Source: Canadian Grain Commission database, available at: http://www.grainscanada.gc.ca/statistics-statistiques/ecgwf-egcfb/ecgm-megc-eng.htm

On October 19, 2009, representatives of the FCC and the CFIA met with representatives from the Directorate General for Health and Consumer Affairs (DG Sanco) and other EU stakeholders in Brussels, to work towards developing a testing protocol to manage the situation in Canada (European Commission 2009). The protocol, launched immediately in the Canadian market, quickly established a system of sampling (one test for every 5000 bushels) and testing of on-farm flax stores as part of the Farm Stewardship Program. Samples that tested positive for Triffid at levels greater than or equal to 0.01 % would not be accepted for import into the EU market (FCC 2009). According to James (2010), Canadian flax averaged a failure rate of 20 % at EU ports during the last six months of 2009. Farmers, at this point, were encouraged to plant certified seed. But by early 2010—following much speculation—the source of the Triffid contamination was identified by the Flax Council of Canada as originating from two of the CDC breeders' seed flax varieties—CDC Normandy and CDC Mons. Thus, the Farm Stewardship Program extended into the testing of farm-saved seed as well to allow for the use by farmers of farm-saved seed.

The widespread low-level presence of Triffid flax across the Canadian growing belt was speculated to be due to pollen or gene transfer during the seed multiplication process. The notion of 'flow' and spread of flax seed, however, is much more complex than that. Flax primarily self-pollinates, so seed-mediated gene flow is probably a more important factor in terms of gene flow. Plots of CDC Normandy and Triffid were grown in adjacent plots at a time when the standard distance between plots of the same variety was three feet.

Testing was conducted on CDC Normandy and CDC Mons in January 2010, and both tested positive for Triffid at 0.01 %. These two varieties—now both essentially obsolete—were withdrawn from the program, and seed stores were destroyed. By early March 2010, after extensive testing, extremely low indications of Triffid contamination were discovered on a limited number of other breeder seed samples of four other varieties: CDC Bethune, CDC Sorrel, CDC Sanctuary, and CDC Glas. These varieties tested positive at trace levels well below the 0.01 % detection level. Rather than being withdrawn and destroyed, these latter varieties were reconstituted. Individual plants were tested for the presence of Triffid and those that were deemed Triffid-free were used as a seed source for the reconstitution process. The reconstitution process was completed in 2012 and the seed transported back to Canada for introduction into the foundation seed program and was distributed to seed growers and to seed companies and multiplied. Reconstituted seed will be available to producers for planting in the spring of 2014.

As part of the requirements for the EU, and in keeping with the contractual obligations of the protocol, testing of Canadian flax is ongoing. In fact, testing is conducted repeatedly all along the value chain—from farm-held stores of flax to the elevator and at ports where flax shipments await export. The Canadian federal government subsidized testing through a provision of C$5 million. Early results suggest a widespread but extremely low-level presence of Triffid in Canadian flax. As of September 2011, almost 26,000 tests were been conducted on more than 10,000 seed lots. Every tested lot is represented by a 250 g sample which is further

split into four sub-samples of about 60 grams each containing 10,000 seeds. As the EU detection limit is fixed at 0.01 %, if one seed out of these 10,000 seeds (0.01 %) is found to contain Triffid, the lot cannot be shipped to the EU. Only about 4 % of producer samples are testing positive at or below the 0.1 % mark with many testing at only trace levels. Despite progress in reducing the presence of Triffid in Canadian flax production system it is unlikely that it will be completely eliminated.

Critical Assessment

Flaxseed and flaxseed oil are imported into the EU and used for industrial purposes while flaxseed meal is used in livestock feed. More recently, flax has been used for human consumption. Flaxseed has an oil content of about 40 %. The seed is crushed in a two-step process: a first cold press to obtain a very pure first grade oil (raw flaxseed oil), then a second warm press to extract the maximum amount of oil, thereby creating flaxseed meal. More recently the flaxseed meal has been used for poultry feed meal, as it increases the level of omega-3 fatty acid in eggs. Raw flaxseed oil and products are used for a wide range of manufacturing purposes. The high content of linolenic acid makes flaxseed oil one of the quickest drying vegetable oils with a variety of applications in the coatings industry: oil-based paints and varnishes; stains and printing inks; alkyd resins; rubber; sealants; plastics; and in the manufacture of linoleum flooring. Moreover, a market is developing for whole seed in health foods, for example, as a source of dietary fiber and medicine. Whole seed is used in the baking and confectionery industries where its health benefits are recognized. Approximately 70 % of the flaxseed supply is used as an input to the crushing industry and the remaining quantities for other purposes (baking, confectionery, health foods, pet foods, etc.).

In the EU, the volume processed by the operators for all uses is between 500,000 and 600,000 tonnes annually. Prior to 2009 approximately 80 % was imported from Canada; the remaining volume came either from other available origins or from European production (Table 1). More recently, however, Russia, Ukraine and Kazakhstan have ramped up production accounting for 70 % of supplies of flax for the EU as recently as 2011/12. European importers are mainly Belgian and German. In fact, the majority of flaxseed operators (trading companies, store keepers and crushers) are situated in those two countries. The EU crushing industry is mainly composed of small/medium sized companies. The Belgian operators are mono-flaxseed crushers and their customers are solely based on flaxseed products. The crushers process flaxseed, obtaining about 33 % crude flaxseed oil and 64 % flaxseed meal. These companies are not equipped to switch to crushing canola and have no other option but to shut down their operation if insufficient flaxseed is available at competitive prices. The European flaxseed crushers would not be able to cope with substantially higher prices as the domestic production of flax could not respond to the increased market demand signals quickly enough to offset the higher

Table 1 EU 27 flaxseed imports (1000 metric tons)

Exporter	Aug/Jul 2004/05	Aug/Jul 2005/06	Aug/Jul 2006/07	Aug/Jul 2007/08	Aug/Jul 2008/09
Canada	388	361	567	518	477
USA	31	105	37	53	8
Russia	19	11	36	37	43
Ukraine	13	7	34	3	16
Argentina	18	5	15	9	2
China	2	2	3	5	4
Belarus	4	3	0	0	1
Moldova	0	0	0	2	0
Norway	0	0	2	0	0
Kazakhstan	0	0	4	4	0
ROW	3	3	2	2	2
Total Imports	478	497	700	633	553
% from Canada	81.17	72.64	81.00	81.83	86.26

Source Oil World (2013)

prices. Moreover, the estimated gross income for flaxseed is too low for farmers to make it an attractive alternative to other oilseed production such as rapeseed.

The profitability of flaxseed crushing is determined by a combination of three elements: the price of flaxseed delivered to the crushing plant, the price of the flaxseed oil ex-plant, and the price of the flaxseed meal ex-plant. The price of imported flaxseed into the Belgian port of Ghent rose from an average price of US $501/tonne in the 2008–2009 crop year, to US$644/tonne in January 2010. This represents a rise in price of 28.5 %. In terms of the price of flaxseed oil ex-plant, to be shipped out of Rotterdam, the price in the 2008–09 period averaged US $975/tonne, rising to US$1156/tonne in January 2010, an increase of 18.6 %. Over the corresponding period, flaxseed meal increased in price from US$346/tonne to US$440/tonne, a rise of 27.2 %.

Taking the average prices of a 'normal' year (October 2008–September 2009), the crush margin (the difference between the price paid for the flaxseed and the revenue obtained from the sale of products, through product prices multiplied by yield) was around US$32 per metric tonne. Taking the average January 2010 prices, the crush margin was reduced to about US$9 per metric tonne (Table 2). These circumstances caused a reduction of the production of flaxseed oil, in several cases of around 20 %.

In September 2009, a sharp reduction of the export of flaxseed oil occurred. European Union traders usually export approximately 40,000 tonnes of flaxseed oil per year. The impact of the detection of GM flax was immediate and substantial as from October 2009 to January 2010 the EU exported only 7700 tonnes of flaxseed oil.

Table 2 Crush margin on flaxseed 2008–09 versus 2010 (US$)

	Oct. 2008–Sept. 2009		Jan. 2010	
Flaxseed import price		511		654
Flaxseed oil price	($975 × 33%)	322	($1156 × 33%)	381
Flaxmeal price	($346 × 64%)	221	($440 × 64%)	282
Product revenue		543		663
Gross crush margin	$32		$9	

Source COCERAL/FEDIOL (2010)

American crushers were able to buy Canadian flaxseed (as FP286 had received full approval in the US in 1998) at substantially reduced prices, where trades were occurring at US$385/tonne and US$365/tonne delivered to US crush plants, when the price (CIF—cost, insurance and freight) in Ghent was US$550/tonne. European Union flaxseed crushers buying GM-free flaxseed paid a risk premium of around US$50 per metric tonne. This explains why the price of flaxseed in Europe increased substantially more than the price of the other oilseeds. In many instances, European Union flaxseed importers were unable to secure adequate amounts of raw flaxseed and had to resort to importing flaxseed oil from their competitors.

Twenty percent of the imported flaxseed is used for different food applications such as low-fat dairy products, bakery and confectionery products, amounting to approximately 150,000 tonnes per year. The GM flax issue has brought about extra costs related to consumer complaints, the inability to commercialize Canadian flaxseeds products, and decreases in the contribution margin. The sudden supply squeeze due to the detected low level presence of GM flax caused a steep price appreciation. This price surge for flaxseed imports both from Canada and other origins caused an increase in the price of flaxseed products destined for foodstuffs applications. Moreover, as the risk of having a positive test response on flaxseed imported from Canada in late 2009 was too high, Canadian flaxseed could no longer be used by the food sector. Traders therefore sought flaxseed imports from alternative origins, such as the Black Sea area and Eastern Europe. The approved Canadian flaxseed imports to the crushing industry shipped under the above described protocol, also increased in value, resulting in EU operators paying a premium price for those imports. The above mentioned market contractions increased costs by around 30 % compared to the October 2008–September 2009 period.

Extra costs had to be incurred related to the baked goods that had been already delivered for sale to grocery retailers, but due to the positive Triffid results could not be sold in the EU. A large amount of raw material and foodstuffs containing flaxseed (bread, muesli, cookies, etc.) had to be recalled and thus withdrawn from the market. Numerous products were taken off of the supermarket shelves. Most of these goods were stored in warehouses by traders or store keepers. For the operators this entails extra costs related to freight, storage and additional monitoring and sampling plans. Only a small proportion of these goods were destroyed by the traders or the food industry. It is estimated that the total cost of the

Table 3 Total extra costs for flax food industry in the EU (1000 Euros)

Cost category	Cost to industry
Decrease of the contribution margin	1700
Recalled products	2100
Destroyed products	1300
Storage cost of unsellable products	130
Customs' claims	18,000
Purchase of replacement flaxseed	15,000
Other costs	900
Shutting down operations	300
Total financial loss	39,430

Source COCERAL/FEDIOL (2010)

non-commercialized flaxseed would not be less than 3.5 million Euro (US$4.5 million). This situation caused a substantial number of customers' claims all over the EU. The industry counted additional costs of around 18 million Euro (US$ 23 million) in managing customer complaints. This analysis does not cover all the incurred costs, however; from all the collected data, it appears that the overall economic and financial repercussions would have a significantly negative impact on the entire flaxseed supply chain (Table 3).

The limitations on imports of Canadian flaxseed had a direct impact in terms of employment. In certain small and medium size enterprises the persistence of the crisis resulted in the closure of crushing plants which, in most cases, were not equipped to crush other seeds (e.g. rapeseed). In total, the number of direct jobs at risk was estimated by sector representatives to amount to 300. The figure for indirect jobs at stake is more difficult to assess, as the crisis affected a number of actors along the supply chain (traders, store keepers, retailers etc.). However, there was a consensus among the industry that there would be a negative impact on indirect jobs. Taking indirect effects into account the overall figure for lost jobs would exceed 600. For larger companies the lost activity due to the interruption of flaxseed imports from Canada would not necessarily result in direct job losses. However, the lost business is estimated to be in an order of magnitude of millions of Euros. Indeed, certain operators indicated that there is very little chance of future business.

Thanks to their financial solidity and to the strong structure of the EU flaxseed industry actors, many managed to resume their business operations as the detection of GM flax diminished due to the testing protocol implemented in Canada. The cost of resuming business activity was high for EU industry. It would be extremely difficult for them to sustain such losses over the long term.

In Canada, costs associated with the Triffid issue are conservatively estimated at almost C$30M (Table 4). These costs are estimated across a number of factors including quarantine, testing, segregation, etc. On a more optimistic note, flax prices recovered settling the dissatisfaction of growers and other industry participants. It was fortunate for Canada that China recognized a market opportunity and bought up a majority of Canadian flax in early 2010. This helped to offset some of the economic losses that the Canadian flax industry incurred. Increased shipments

Table 4 Total estimated costs associated with the triffid event in Canada (C$000's)

Cost category	Cost
Demurrage/quarantine costs	$12,000[a]
Testing costs	$3900[b]
Cost of segregation, other costs for: breeders, certified seed suppliers, producers, grain companies, AAFC and SaskFlax	$13,185[c]
Total estimated costs	$29,085

Source Ryan and Smyth (2012), Dayananda (2011)

[a]This cost estimate is calculated (as of September 2010) as follows: C$30,000 per day which is equivalent to C$1million per month. We conservatively estimate a total of 12 months with this level of costs

[b]Based on the number of tests conducted (26,000) as reported by FCC and assuming a conservative (average) cost per test at C$150, we estimate total testing costs (2009 to 2011) at almost C$4 million (2009 to 2011)

[c]2009 to 2011

to the US (where the Triffid event has full regulatory approval) also occurred during this time.

Despite managing the Triffid issue relatively quickly and efficaciously, the problem has not been completely resolved in Canada. According to Canada's agreement with the EU, the Canadian flax industry still has to test for the presence of GM flax, which represents ongoing costs for Canada's flax industry. According to the Flax Council of Canada, however, "…the situation *is* workable…" (Hill 2011).

Economic impacts related to these kinds of scenarios are very difficult to quantify. Some costs are explicit while others are less so—and time or opportunity cost related. This makes it difficult to attach a specific number to costs associated with the Triffid issue. One thing is for certain though: significant direct and indirect costs were incurred by both the EU and Canada. Thus it is anticipated that the overall cost to the global flaxseed industry will be greater than what has been assessed in this chapter. In addition, significant shifts in trade have occurred where Canadian shipments have increased to China and the USA while production has increased in Eastern Europe and is largely supplying the EU marketplace.

Lessons Learned

- Given the proliferation of genetically modified crops in the world, zero tolerance standards for GM material in international food markets are not sustainable/manageable.
- A detection limit of 0.01 % does not provide consistent results causing commercial risk management issues for both Canada and the EU.
- The low detection limit makes the sampling process a critical component, but it can be inconsistent. Canada currently does not have a low-level presence policy

and needs to adopt one in order to lead global efforts in this area and to better manage any forthcoming issues that may arise.

- Industry needs to be proactive in anticipating these kinds of problems in order to better manage processes, products, and international relations and trade with partners.

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Consequences of Adventitious Presence of Non-approved GMOS in Seeds: The Case of Maize Seeds in Germany

Philipp Wree and Justus Wesseler

Introduction: Adventitious Presence of GMOs in German Fields

In Germany, seeds have a zero tolerance for traces of GMOs which are not approved for cultivation in the EU (Bundesverwaltungsgericht 2012). However, adventitious presence of unapproved events in seeds may happen. That can be the cause for unintended release of GMOs into the environment. Two of these cases have been broadly discussed in the media. In 2010, the BASF GMO potato variety Amadea appeared in fields of the BASF GMO potato variety Amflora in Sweden. In contrast to Amflora, Amadea was and is not an approved variety for commercial cultivation in the EU. In another case, seed samples of the maize variety PR38H20 from Pioneer, dedicated for the German market, were tested positive for the Monsanto GMO event NK603. Varieties including this event are not approved for cultivation by the EU. But by the time positive test results have been announced, relevant maize seeds were sold to farmers and sown. Problems that appeared during the practical handling of that issue revealed that there is a lack of legal guidelines and regulations for the situation of unintended release of unapproved GMO varieties in the EU. In the following case study we will focus on the PR38H20 case.

P. Wree (✉) · J. Wesseler
Technical University - Munich, Munich, Germany
e-mail: philipp.wree@tum.de

J. Wesseler
Wageningen University, Wageningen, The Netherlands
e-mail: justus.wesseler@wzw.tum.de

N. Kalaitzandonakes et al. (eds.), *The Coexistence of Genetically Modified, Organic and Conventional Foods*, Natural Resource Management and Policy 49,
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History of the Adventitious Presence of GMOs—The Amflora and the PR28H20 Case

In 2010, the BASF GMO potato variety Amadea was found in fields of the BASF GMO potato variety Amflora in Sweden. The harvest of the fields was assigned as commercial plant material for the Amflora potato. However, while, Amflora is an approved variety for commercial cultivation in the EU, Amadea was only authorized to be cultivated for research.

In the case of the unintended presence of the Amadea potato in Amflora fields, it is important to mention that those fields were not cultivated by usual farmers for the consumer market. The harvest was assigned as plant propagation material for the Amflora potato. BASF documented that of the 680,000 potato plants on Amflora fields, 47 were identified as Amadea potatoes. Even though the rate of admixture was under 0.01 %, the entire harvest was destroyed (BASF Plant Science 2010).

Also in 2010 229 German farmers in the federal states of Lower Saxony, Bavaria, Baden-Wuerttemberg, Brandenburg, Rhineland-Palatinate, Mecklenburg-Hither Pomerania and Hesse were requested to destroy their maize fields with a total area of 1650 hectares, on which they probably cultivated GMOs unintentionally (agrarheute 2010). The detailed development of this case was as follows:

In February 2010 the Lower Saxony State Office for Consumer Protection and Food Safety found traces of GMOs in various seed lots of Pioneer's maize variety PR38H20 that they analyzed. By the middle of March 2010, the Ministry of Agricultural for Lower Saxony should have been informed about suspicious test results showing traces of GMOs in maize seed samples of PR38H20. In such a situation, the Agricultural Ministry usually informs the seed company immediately and the seed company has time to withdraw the suspicious or positive tested seeds from the market prior to their sale to farmers. However, the Ministry of Agricultural for Lower Saxony only informed other federal agricultural ministries and Pioneer at the end of April 2010 (Bioland 2010). Simultaneously the ministry asked Pioneer for detailed information about their supply chain for the relevant seeds. At first Pioneer refused to supply this information. Only after a verdict from the Administrative Court of Lower Saxony dated the 4th of June 2010 did Pioneer disclose the names of the relevant seed traders (Bioland 2010). By that point in time farmers had already sown their maize crops. In the beginning of June 2010, the respective federal agricultural ministries contacted the relevant seed traders and gathered information about the farmers that bought PR38H20 maize seed with the identification numbers D/H4629/556W and D/H4629/831W. Only those lot numbers tested positive for traces of NK603. By the middle of June, the farmers who planted the specific PR38H20 seeds received a letter from their federal agricultural ministries with the decree to destroy their maize plants probably planted with adventitious presence of NK603. The decree did not include any guarantee of financial compensation. At that time of the year it would have been very difficult to replant a new crop and obtain an adequate yield. The farmer's union—Deutscher Bauernverband (DBV)—stepped in and advised the farmers to file a case against

the state's decree (TopAgrar 2010) and simultaneously announced that they would file a case against the federal state of Lower Saxony and Pioneer. Meanwhile, as requested, the farmers destroyed their crops and documented their steps.

Thereafter there was recrimination between the federal state of Lower Saxony and Pioneer. Eventually, after negotiations with the federal state of Lower Saxony and the DBV, Pioneer offered an immediate compensation payment of € 1800 per hectare to the affected farmers. By November 2010, Pioneer announced that 228 out of 229 affected farmers had accepted their offer (agrarheute 2010).

Critical Assessment of the PR38H20 Case

Currently, in the EU only Monsanto's GM maize MON 810 is cultivated. Nevertheless, in Germany the cultivation of the approved GMO variety MON 810 was only authorized from 2005 to 2008. The cultivation of the Amflora potato was permitted in 2010. However, since 2012 no planting of Amflora potatoes has taken place in the EU (BASF Plant Science 2013).

What distinguishes the BASF Amflora and the Pioneer PR38H20 cases is that farmer's compensation was not an issue in the case of Amflora. Situations similar to the BASF Amflora case, in which seeds are tested positive for adventitious presence of non-approved GMOs and therefore are rejected for the European seed market, occur regularly. In general, in Europe seed lots with an identification number entering the market are tested for adventitious presence of unapproved events. In 2013, for example, 498 maize seed lots were tested in Germany, and 10 of them were not approved because they contained traces of GMOs (TopAgrar 2013). As yet, there are no EU regulations about a threshold level for GMOs in conventional seed material. That means there is a de facto zero tolerance for traces of GMOs in conventional seed material—an interpretation confirmed for Germany in February 2012 by the Federal Administrative Court (Bundesverwaltungsgericht 2012).

Seed companies and breeder associations such as the Bundesverband Deutscher Pflanzenzüchter (BDP) have demanded the implementation of a more practical threshold (TopAgrar 2013) as, for example, maize seeds are often produced in countries such as Chile or Argentina where a number of events are cultivated that have no approval for cultivation in the EU. Adventitious presence of GMOs in seeds due to cross-pollination is difficult to avoid in those areas. Before seeds are sold to farmers, seed samples are taken annually by the federal states of Germany to test for traces of GMOs. As mentioned earlier, in 2013, 498 such samples were taken for maize seeds. By contrast, around 252,000 different identification numbers for lots of maize seed are sold annually. The samples are often deliberately taken from seed lots originating in countries like Chile or Argentina, since the chance for adventitious presence of GMO is more likely.

Usually a seed company will be informed when a federal institution takes a sample from its seeds; thereby the seed company also has an opportunity to take a sample from the same seed lot.

After the federal institution takes the sample, it usually takes about two weeks before the seed company is informed of the test results. Seed companies often halt the sale of their seeds with the relevant identification number for this time period or until they receive the information of no presence of unapproved events from the federal institution. Seed companies are not obligated to halt sales, and obviously that did not happen in the PR38H20 case.

The tests are done by a standardized polymerase chain reaction (PCR) method. Considering that samples are tested for very low concentrations, these being at the limit of detection, breeders and seed companies have another reason to demand a reasonable threshold level (Sauter 2013).

In February 2010, the tests results of the seed samples for the maize variety PR38H20 from Pioneer with the identification numbers D/H4629/556W and D/H4629/831W indicated GMO contaminated seed material (TopAgrar 2010). Comingling or cross-pollination were possible causes as the amount present was quite low. The tests done by the Lower Saxony State Office for Consumer Protection and Food Safety only showed "conspicuous" signs for GMO presence in the seed sample. For an actual proof of GMO-contaminated seeds the concentration (under 0.1 %) was too low (TopAgrar 2010). Nevertheless, with such a test result seeds would not be approved and would not enter the market.

As mentioned before, seed material testing positive for traces of GMO is not unusual but what happened in the Pioneer PR38H20 case was that the identification numbers involved were not withdrawn from the market but instead delivered to the retailers and planted by the farmers. In particular, that facts revealed the weaknesses of the current protective system against GMO-cultivation in Europe. It showed the practical problems and legal uncertainties market participants face when GMOs are unintentionally present in seeds.

The farmers were the group of market participants who suffered as they have to trust the seed companies and the federal institutions who guarantee the quality of the seed material they purchase. When the relevant farmers were requested in writing by their federal agricultural ministry to destroy their crops planted with PR38H20 maize with the identification number D/H4629/556W and D/H4629/831W, their compensation for correcting a third party's mistake was not mentioned. Within the decree of destruction the federal states justified the action by referring to the genetic engineering law, stating that genetically modified material which is not approved as harmless should not be released into the environment (TopAgrar 2010). However, this law does not regulate the reimbursement of farmers for cases like this. According to the German government, the genetic engineering liability law (Gentechnikhaftungsrecht) only regulates the handling of approved GMOs. For liability claims in context with non-approved GMOs, the regular civil law applies.

Further, farmers faced practical difficulties when they were requested to destroy their maize. The later the request came during the growing period the more difficult it became for the farmers to destroy their maize plants. Simple tillage was often insufficient to completely eradicate the crop. Thus, the farmers often had to perform multiple treatment procedures. Some farmers planted a new maize crop immediately

after a first tillage. Those farmers often experienced problems as some plants survived the initial tillage treatment intended to eliminate them. In these cases hand weeding of the surviving old maize plants was often the only possible solution left. Even if the farmer destroyed the crop immediately after the state issued its request, it was more than one month after the recommended planting date for a new maize crop. An alternative was to plant a cover crop such as clover. However, the climatic conditions (heat and drought) at that time of the year are not ideal for establishing a new crop. Additionally, some farmers had contracts for the delivery of their maize to biogas plants and anticipated penalties if they were unable to fulfill their commitments (TopAgrar 2010).

Farmers claimed compensation payments for their extra work as they could not be held responsible for the adventitious presence. Neither Pioneer nor the federal states contradicted the claim at any point in time. But since there are no regulations for such an event, it was unclear who was responsible. The federal state of Lower Saxony did not acknowledged any mistakes in the handling of the case; instead it blamed Pioneer for placing the seeds on the market before they had knowledge about the test result. Furthermore, the federal state of Lower Saxony complained that Pioneer did not give voluntary information about their supply chain (TopAgrar 2010). Conversely, Pioneer never claimed responsibility, but argued that the Lower Saxony Ministry of Agricultural knew about the suspicious test results for more than 10 weeks before they were informed on the 26th of April 2010 (TopAgrar 2010).

Pioneer was under considerable pressure to assist the affected farmers. Pioneer decided to offer immediate financial support or compensation payments without admitting guilt. They planned on getting reimbursed for such a payment after suing the Federal State of Lower Saxony (Pioneer Du Pont 2010).

When Pioneer negotiated with the DBV about the compensation payments their initial intention was to pay under certain conditions only. Pioneer's liability to the farmers should be clarified in a test case against a farmer. Therefore, at least one farmer should sue Pioneer to bring about a test case. If the farmer would lose the lawsuit, there would have been the option for the farmers to pay the compensation payment back to Pioneer. Pioneer argued that a voluntary payment to the farmers will lower Pioneer's chances of getting reimbursed in the event of the later suing the federal state of Lower Saxony (TopAgrar 2010). The condition of the test case was not included in the final offer Pioneer made to the farmers (TopAgrar 2010).

After several meetings and negotiations with the federal State of Lower Saxony, the DBV, and farmers, Pioneer agreed on paying a compensation of €1800 per hectare to the affected farmer. 228 farmers (out of 229 affected farmers) accepted the offer. In total Pioneer paid €2,970,000 for 1650 hectares (agrarheute 2010).

By the end of 2010, Pioneer announced that there would be three objectives for law suits. Measures are currently underway for achieving these objectives.

- First, there is a test case at the Bavarian civil court in which a Bavarian farmer sued Pioneer for supplying seeds with adventitious presence of a GMO. Pioneer welcomes the accusation since the law case should clarify liabilities for future

Table 1 Details of court cases

Subject of the law case	Parties involved	Aim
Supply of seeds with adventitious presence of GMO	Bavarian farmer sues Pioneer	Clarification of liabilities
Liability claim for neglect communication duty	Pioneer sues the federal state of Lower Saxony	Reimbursement of Pioneer for the financial support paid to the farmers
Administrative court process about the decree to destroy an established maize crop	A Bavarian farmer, supported by Pioneer, sues the federal state of Bavaria A Lower Saxon farmer, supported by Pioneer, sues the federal state of Lower Saxony	Support of the farmers and clarification of liabilities

Table is confirmed by Pioneer

similar cases. In the initial trial, Pioneer was not held responsible. The case is currently under appeal.

- Second, Pioneer sued the federal state of Lower Saxony at the Lower Saxony administrative court for neglecting their communication duty after testing samples of PR38H20 positive for adventitious presence of GMOs.
- Third, two affected farmers (one from Bavaria and on from Lower Saxony) sued the federal states of Lower Saxony and Bavaria, respectively, for the decree to destroy an established maize crop. In both cases Pioneer gave legal support to the farmers in the trails at the respective administrative courts. The case against the federal state of Bavaria is currently under appeal after the farmer sued the federal state of Bavaria on his own and the case was dismissed (TopAgrar 2010) (Table 1).

Lessons Learned

– Adventitious presence of unapproved GMO events in seeds can result in legal insecurity. Especially, since there is a zero tolerance for GMOs in conventional seeds.
– As long as legal standards have not been implemented that assign responsibilities and regulate liabilities in cases of infringement, adventitious presence of GMOs in conventional seeds can result in extra costs for all parties involved.
– Communication between the different players (state, seed companies, farmers association and farmers) plays an important role in reducing costs due to adventitious presence in seeds.

– Currently, from a legal perspective, farmers who unintentionally and unknowingly sow the "wrong" seeds have to bear extra costs at least initially. A legal framework for reimbursement in such a case is not in place yet.

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Commercialization Strategies and Market Opportunities for GM Canola

Stuart J. Smyth and Peter W.B. Phillips

Introduction

Canola, the third most important edible oil crop in the world behind maize and palm, has had an almost unique history among those crops that have been targets of genetic modification. It was one of the earliest and most rapidly adopted GM crops; it has developed and tested market structures for three generations of technology (i.e. higher-yielding traits, quality-enhancing attributes and industrial uses); it emerged from a global research effort that was not driven from the US or EU; it has significant competition in the seed market, with five of the multinationals engaged in developing and marketing new varieties; it was one of the earliest crops to use an identity preserved production and marketing (IPPM) system to quality assure GM-free product; it has ongoing segregation programs to manage non-food varieties throughout Canada; it has developed a system to manage ongoing technology recalls and seed quality; and it has been the focus of litigation related to the conflict between patents and farmers' rights and coexistence between organic and GM crops (Phillips and Khachatourians 2001). In that sense, canola offers a number of lessons for other crop sectors considering if or how to manage the introduction of GM technology.

Herbicide tolerant (HT) canola was initially introduced in Western Canada in 1995 and by 2008 only 1 % of seeded acreage used conventional seed (CCC 2010). There are currently three HT systems available to producers, two developed through genetic transformation (GMHT) and one through mutagenic breeding. Bayer CropScience's Liberty Link™ and Monsanto's Roundup Ready™ varieties, com-

S.J. Smyth (✉) · P.W.B. Phillips (✉)
University of Saskatchewan, Saskatoon, Canada
e-mail: stuart.smyth@usask.ca

P.W.B. Phillips
e-mail: peter.phillips@usask.ca

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monly referred to as GMHT varieties, have about 46 and 47 % of the market respectively. Pioneer-Hi-Bred's imidazolinone-tolerant Clearfield™ varieties, developed by mutagenesis, captured up to 25 % of the canola seed market in 2001; since then market share dropped to 6 % in 2010. The main driver for the rapid adoption of GMHT is the agronomic advantage of the varieties. The Canola Council of Canada (CCC 2012) reports yields have risen from an average of 20 bushels per acre in the mid-1990s to 35 bushels per acre in the past few years and total seeded acreage has more than doubled.

This chapter discusses the commercialization and diversification processes for a range of differentiated canola traits over the past 15 years.

History

In March 1995, the Canadian and US governments approved two GMHT canola varieties (AgrEvo's HCN92 marketed as Liberty Link™ and Monsanto's GT73, sold as Roundup Ready™). The new varieties were initially commercialized in Canada before approval had been received in Japan or the European Union (EU). Those two markets absorbed almost 50 % of the total Canadian production in the three years immediately before the introduction of GMHT canola (Smyth and Phillips 2001). The industry expressed strong concern at the time that if the new GMHT canola varieties were allowed to comingle with conventional varieties export markets would be jeopardized.

Given the anticipated accelerating flow of new products, Monsanto, AgrEvo (now part of Bayer CropScience) and the canola industry had three options. First, the companies could commercialize their GMHT varieties, comingle production and lose access to the EU and Japanese markets, which most believed would have crippled the industry. Second, the companies could withhold the varieties until they were approved in all key markets, which would delay adoption and any commercial or economic returns. Third, Canadian producers and exporters could accept responsibility for differentiating GMHT canola from conventional canola and develop a system to provide quality assurance of delivery to the key export markets, which would involve Canadian export companies developing new systems of IPPM.

The industry ultimately chose to self-regulate the commercialization of GMHT canola, which set the stage for extensive market-led product differentiation. One result was the rapid and virtually total adoption of HT canola by 2007. A survey conducted in 2007 revealed that the new technology generated between C$1.063 billion and C$1.192 billion net direct and indirect benefits for producers over 2005–2007 period, partly due to lower input costs and partly from better weed control (Gusta et al. 2011). The survey also identified significant environmental benefits, as producers removed summer fallow as part of their crop rotations. The adoption of HT canola varieties, combined with new conservation tillage practices, allowed farmers to extend the number of years that they could go without having to till a

field. In 1999, 89 % of canola acres were heavily tilled; by 2007 64 % of producers used zero or minimum tillage (Smyth et al. 2011a). There have also been significant changes in herbicides usage. Comparing 1995 and 2006, the toxicity of agro-herbicides applied to canola decreased 53 %, with a reduction of 1.3 million kg of active chemical active ingredient applied (Smyth et al. 2011b). The cumulative environmental impact per hectare (EI/ha) of the top five herbicides used dropped by 37 % in the first decade of adoption.

A range of other novel traits have followed. Seed developers and farmers have developed new varieties to deliver novel edible oils (in both GM and non-GM seeds), non-food industrial oils and plant-made pharmaceuticals (PMPs). At the same time, a small subset of farmers attempted to maintain an organic canola business. These different ventures have drawn extensively on the GMHT experience, using a mix of IPPM systems for edible oils, segregation for non-food industrial oils and PMPs and traceability for organic production.

Critical Assessment

Three specific examples of efforts to sustain coexistence in the canola industry in Canada warrant discussion: segregation for non-food industrial oils and PMPs; IPPM for GMHT varieties; and traceability for the organic canola industry (Phillips and Smyth 2004; Smyth and Phillips 2002).

Segregation Systems for HEAR and PMP Varieties

Ever since the development of rapeseed low in erucic acid and glucosinolates—trademarked as canola in Canada and called double zero or oilseed rape in Europe—there has been an effort to sustain some production of high erucic acid rapeseed (HEAR) for industrial applications where that particular oil has beneficial properties. Conventional rapeseed prior to canola had about 30–40 % erucic acid content, which was not high enough to be valued for industrial applications but too high for safe human consumption. After low erucic acid varieties were developed, the University of Manitoba developed a rapeseed breeding program to increase the level of erucic acid to 55 %. The first HEAR variety was commercialized in 1982 in conjunction with CanAmera Foods, a regional oilseed crusher. HEAR varieties are used as biodiesel feedstock, in the non-digestible synthetic fat Olestra, as coating for fish feed, as a slip agent for plastic film manufacture, as a stabilizer in peanut butter and as a plasticiser in perfumes, nylons and lubricants (McVetty 2009).

In Canada, the industry has segregated HEAR production to prevent the industrial oil from entering supply chains that have products destined for human consumption. Contract registration, mandated at the time of varietal registration by

the Canadian Food Inspection Agency (CFIA), specifies conditions for segregating the crop in the field and the supply chain.[1] Seed companies are required to sign production contracts with producers who are required to follow specific containment strategies. Under contract registration, regulators from the CFIA have the right to inspect all HEAR fields to ensure compliance with segregation requirements (Smyth and Phillips 2002).

The largest cost for HEAR producers initially was the buffer zone. The required isolation distance was initially set at 100 m, but research by CanAmera on comingling due to cross-pollination with canola resulted in the distance being lowered to 5 m. Producers are required to harvest the portion of the crop that falls in the isolation area separately and sell it as animal feed, thus losing the opportunity of premiums for an estimated 1.13 % of the yield from a standard 160 acre production contract. There is also additional paperwork required with the production of HEAR. Producers have to complete post-seeding surveys and map all fields under production. Producers are required to purchase pedigreed seed on an annual basis and deliver all of their production under the contract. Producers are also required to bin all HEAR separately from other crops, using visually distinguishable coded grain confetti provided by the processor; this frequently leads to under-utilized on-farm storage.

The grain handling company is responsible for the overall management of the system, writing and enforcing the contracts with the individual farmers and the processor. The processor is highly engaged in the day-to-day management of the system, constructing and maintaining the policy manual that is submitted annually to the CFIA, offering producer education programs, delivering and documenting the grain confetti, and organizing the crush of the HEAR varieties. Generally firms would call-in HEAR supplies to be crushed at the end of a cycle of food-grade crush and just before a scheduled shutdown for cleaning of the equipment. This minimizes the costs of producing quality-assured oils. One final cost is that the CFIA conducts random audits of the system, focusing on the role of the processor in maintaining the integrity of the segregation (Smyth et al. 2004).

In the late 1990s, producers received financial benefits in three distinct forms. First, they received a premium of C$1/bushel (C$44/tonne) above the market price for canola at the time of delivery. Second, all producer freight costs (f.o.b. farm) were paid by CanAmera, which was worth around C$10/tonne. Finally, producers were compensated C$25/tonne for dockage, to offset the limited weed control options available for this rapeseed variety. This proved to be a complex formula and by the early 2000s, the contracts evolved to paying a flat-rate premium of $10/acre to offset these and other related costs. A key challenge historically was that HEAR was susceptible to most agriculture chemicals and most farmers were not able to spray for weed control. This created weedy fields for both the HEAR crop and raised weed control costs in following years. This was addressed in recent years with the commercialization of GMHT varieties of HEAR (both Roundup Ready

[1] http://www.inspection.gc.ca/english/plaveg/variet/proced/regproe.shtml#a43.

and Liberty Link). Recent output trait research is focused on developing SHEAR (super high erucic acid rapeseed), with erucic acid content in the 60–65 % range.

The total identifiable costs to CanAmera for this segregation system ranged between C$82–84 per tonne in 1998–2003. Given canola prices of about C$345, this translated into about a 24 % premium over the cost of handling conventional canola. The cost of this segregation system may have ranged as high as 30 % of the market price in the early to mid-1990s when canola prices were lower. While there is no evidence of the premium that CanAmera receives for supplying erucic acid, it must exceed C$85 per tonne to justify continuing the HEAR program. In the past decade the volume of acreage under production contracts for HEAR varieties is estimated at a maximum 2 % of the overall canola area, or about 400,000 acres.[2] To date there have been no major incidences of comingling between HEAR varieties and food-grade canola.

Segregation through contract registration has also been used to manage a number of transgenic industrial oils and PMP crops. In Canada in the late 1990s Calgene developed and had approval for two canola varieties that expressed genes for laurate, a valuable industrial input in laundry detergent. As approved by the CFIA, they introduced those varieties through a contract-registration scheme that contained the seeds in a closed-loop system. This system operated for a few years but failed to meet the commercial needs of the partners and has wound down. Another test of the contract registration system that was less successful was the effort by SemBioSys of Calgary to develop and commercialize PMP canola varieties. Based on the company's proprietary oleosin-partitioning technology for separating and purifying recombinant nutraceutical or pharmaceutical proteins, SemBioSys partnered with Dow Canada to develop commercial-scale PMP production using canola as the vector. While they largely proved up the technology using greenhouse cultivation, Canadian regulators were unwilling to permit open-field production of transgenic canola that expressed genes for interferon-A or hirudin. Ultimately SemBioSys shifted the technology to safflower and undertook commercialization in Idaho, bringing to an end this experiment in segregation of a PMP in a food crop.

IPPM Systems for GM Canola

By the spring of 1996, Monsanto and AgrEvo had developed a variety of IPPM systems to manage the differentiation of GMHT canola from the conventional canola stream (Table 1). All parties in the canola sector agreed that the HT technology could bring real value to producers and wanted to accelerate adoption of the technology. Moreover, both AgrEvo and Monsanto accepted that if these varieties were comingled in the export system, then Canadian canola would be shut out of export markets. In response, the firms agreed to release materials only if they were

[2] http://www.statcan.gc.ca/pub/96-325-x/2007000/article/10778-eng.htm.

Table 1 Key elements in the canola-based IPPM systems, 1995–1999

Traits	AgrEvo liberty Link™ varieties	Monsanto roundup Ready™ varieties			
Species	*B. napus*	*B. napus*	*B. napus*	*B. rapa*	*B. rapa*
Variety names (year approved)	Innovator (95)	Quantum (95); Quest (96)	LG3295 (96)	41P50 and 41P51 (96)	Hysyn 101 RR (97)
Seed developer (s)	Ag. Canada and Plant Genetics Systems in collaboration with AgrEvo	University of Alberta and Alberta Wheat Pool for 3 Pools	Limagrain	Pioneer Hi-Bred	Zeneca/Advanta
Organizer/grain merchant(s)	Saskatchewan Wheat Pool, Alberta Wheat Pool, Manitoba Pool Elevators	Saskatchewan Wheat Pool, Alberta Wheat Pool, Manitoba Pool Elevators	Cargill	United Grain Growers (UGG)	Cargill
#Farmers involved					
1995	310	480	0	0	0
1996	2375	1700	incl	0	0
1997	0	0	0	Minimal	incl
1998	0	0	0	625	incl
1999	0	0	0	800	incl
Arranged trucking	Pools	Pools	Cargill	UGG	Cargill
Crushers	Canbra at Lethbridge, CanAmera at Altona and Harrowby	CanAmera at Nipawin and Lloydminster	Cargill at Clavet	Archer Daniels Midland at Lloydminster	Canbra at Lethbridge

Adapted from Smyth and Phillips (2001)

approved in the 'key canola markets', defined as Canada, Japan, US and Mexico by the Expert Committee for Canola of the Pest Management Review Agency.

The product proponents worked with the CCC, the wholesale sector, crushers, the provincial canola development commissions and federal regulators and policy officials to construct an IPPM system that would effectively identify preserve and deliver GMHT canola only to the North American market. Monsanto had two separate systems—one with the Saskatchewan Wheat Pool, Alberta Wheat Pool and Manitoba Pool Elevators and the other with Limagrain and Cargill—while AgrEvo worked exclusively through the three Pool elevator companies. In 1997 Monsanto added two additional IPPM systems for Roundup Ready™ *B. rapa* varieties. Each of these systems involved an agreement between the research company, a breeder, a grain merchant, farmers, truckers and an oilseed crusher. The objective of the IPPM system was to differentiate GMHT canola from traditional canola marketing

channels. This meant that the GMHT canola not touch any part of the export handling system, including elevators, rail cars and port terminals. The 1996 production was delivered to Canadian oilseed crushing plants that had markets for the oil and meal in Canada and the US. In each case, the grain merchant acted as the operating agent for the system, managing the supply chain from seed multiplication to processing.

As shown above, each of the supply chains began with a specific variety which included a proprietary HT gene which was backcrossed or inserted into a plant by either a contract breeder or by a partner company. Once the variety was registered, Monsanto or AgrEvo contracted with a grain merchant to manage the development and management of the IPPM system. That company then contracted to multiply the seed, undertook production contracts with specific farmers, arranged delivery from farms to a processor with contract truckers, and arranged for a custom crush and diversion of the resulting oil and meal into the North American market.

Cost estimates for two of the five IPPM systems suggest that transaction costs for IPPM systems are quite high (Smyth and Phillips 2001). There were five main areas where additional costs were incurred: by the producer ($1/tonne), during transportation ($6.50–$13/tonne), by the processor ($3–$5/tonne), in administration ($4–$5/tonne) and through opportunity costs ($15–$20/tonne). In total, the two IPPM systems were estimated to cost between $33/tonne and $41/tonne. Based on the acreage involved, it is estimated that the IPPM systems adopted in 1995–1996 cost between $2.8–3.5 million for the AgrEvo system and $750,000–930,000 for the Monsanto systems. As noted, all the stakeholders in the IPPM process shared the costs. The producers assumed both the identified on-farm costs and some increased transportation costs and did not receive any formal price premium; in some cases, their production contracts called for delivery when the spot prices were relatively unattractive, which some viewed as a further cost. The grain companies assumed the dead freight costs, a portion of the freight inefficiency and part of the administration cost, which were at least partly compensated through their normal operating margins. The crushers picked up most of the incremental crushing costs. The remaining costs (opportunity cost, administration and other subsidies) were paid by Monsanto and AgrEvo, based on the acreage they had under cultivation. In Monsanto's case, they expensed this additional cost to research and development costs related to the development of the technology.

The total cost of the IPPM systems amounted to about 12 to 15 % of the average farm-gate price, which could not be justified simply based on the immediate benefits of the technology. Most studies calculate that in those years farmers gained upwards of $10/acre or $5/tonne from the new technologies, which would have more than compensated most farmers for their added costs. The grain merchants and processors most likely saw this as a market development effort. While the margins on the small volumes involved in the IPPM systems would not have compensated for the added costs, the industry has gained in the long-run as GMHT varieties now make up more than 90 % of the market and the volume of trade has more than doubled. Finally, the biotechnology companies more than recouped their expenses in the medium-term. Smyth and Phillips (2001) estimate that the two

companies accelerated adoption by at least one year, which was estimated to have increased the net present value in 1995 by more than C$100 million.

In 1997 the IPPM systems for GMHT varieties were wound down, as Japan approved GMHT canola. While the EU never did fully approve these crops, the industry judged that it was unlikely to be a major market in the future—beginning about 1995 the EU realized increasingly large exportable surpluses due to significant public investments in plant breeding and large price supports for oilseeds under the Common Agricultural Program.

While the industry no longer targets to operate a full-scale IPPM system for trade purposes, some of the cooperation among the Canadian actors remains. One aspect that requires continued vigilance is maintaining market acceptance of the germplasm in use in Canada. As biotechnology firms de-register GM varieties in Canada that are no longer part of their commercial programs, it is important to ensure that shipments to foreign markets do not contain de-registered varieties. The CCC, on behalf of the industry, has an 'export-ready' program that involves an annual education and advocacy campaign to encourage farmers to replace outdated seed to ensure market acceptance (CCC 2011).

Traceability and Organic Canola Production

Like most segments of the food industry, the canola sector has contested the organic market, but with limited success. The organic sector has largely adopted a traceability system to ensure product differentiation. Production is programmed according to one or more of the publicly accepted organic standards. In the first instance, farm operations are certified by a third-party audit that they conform to the appropriate standards. Then the specific operations of an organic producer are disclosed in producer records and commercial contracts. On-going conformity to the standard is not so much tested as audited. Buyers, processors or branded food companies employ organic certifiers to validate the practices and performance of those farmers who are supplying them with organic produce.

While there are differences both internationally and regionally in some aspects of the organic standard, most national rules now stipulate that transgenic seeds may not be used as part of an organic production system. This compels farmers to use conventional seed and adopt appropriate production and handling practices to isolate and quality assure their produce as free from non-organic factors.

In the context of canola in Canada, litigation about the coexistence of organic production and GM crops highlight the nature of the challenge. In 2003 a group of organic growers and certifiers filed a class-action lawsuit against Monsanto and Aventis, alleging that the introduction of GM canola hurt the markets and incomes for organic canola producers in Saskatchewan. In the course of the case, the organic certifiers revealed evidence on the extent of the industry and the nature of the challenge of differentiating their product. In brief, the evidence showed that while between 720 and 1250 of the 51,000 producers in the province were certified and

producing organic crops, only 76 individual producers could be identified as having ever grown certified organic canola in 1990–2001. Only 23 producers grew organic canola for more than one year in 1990–2001 and there were fewer than 20 sustaining organic canola producers. Only 14,074 acres were planted over the 12 years considered in the court evidence, equal to an annual average of only 1170 acres (compared to the average of 5 million canola acres in the period). The largest area planted in any year was 2537 acres in 1998 (after GMHT canola) and the smallest acreage was 250 acres in 1992 (before any GM crops were approved). The range of canola planted by any producer in any single year ranged from a low of 5 acres to a high of 1370 acres. One producer was reported to have cultivated 2010 acres in the period, equal to 15 % of the total organic canola area (Phillips 2003a).

The plaintiff asserted that organic canola production was hampered by the presence of GMHT canola. The argument was that the potential for GM seeds to comingle or cross pollenate with organic canola inhibited organic production because producers might not be able to affirm their organic status to the satisfaction of either North American buyers or EU regulators. While this issue was never adjudicated by the courts, the evidence produced in the discovery process suggested there were a number of factors at work here. Industry observers reported that widespread adoption of GMHT canola varieties in Western Canada made it more difficult to find isolated fields—which was a strategy organic producers use to manage coexistence. The fact that canola is generally regarded as a weedy crop compounded the difficulties; as a small seeded crop canola tends to have a lot of weed seed admixtures, causing extensive downgrading and price discounts. Without effective weed management options, organic canola was less competitive than other organic crop opportunities. A final difficulty was the high transportation and handling costs to access offshore markets, like the EU, especially when compared with East European competitors. Moreover, there was no evidence that price premiums compensated for these competitive disadvantages. While there is undoubtedly growing demand for organic whole foods (e.g. vegetables and fruit) and semi-processed organic cereals (e.g. wheat and oats, which are readily identifiable in bread and cereals), highly processed foodstuffs such as oils, proteins, sugars and starches from canola, soybeans and sugar beets do not seem to have the same market presence. In most cases these highly processed ingredients comprise a very small amount of any individual processed food and manufacturers often use the 5 % "non-organic" clause in order to buy and use conventionally-produced highly-processed inputs (Phillips 2003b).

In the end, the Court of Queen's Bench ruled against certifying the class action and the case was abandoned. Since then there are reports that a few organic producers continue to cultivate organic canola, but the market is restricted to a tiny fraction of the canola acreage, not because of the challenge of coexistence but because of the economics of production and marketing organic oils.

Lessons Learned

The Canadian canola industry has been challenged to manage the coexistence of conventional, organic, GM, and industrial crops all in the same space. At first glance, one might be tempted to conclude the industry has failed because the conventional and organic markets are vanishingly small. But a more nuanced conclusion is that the profound competitive advantage of GMHT varieties has dominated (both in the food and HEAR categories), with less profitable non-GMHT market segments withering. The capacity to coexist exists, but the economics does not support it. Perhaps the most telling lesson of this story is that the market dominance of GMHT varieties has not ended the debate about coexistence. The CCC and canola industry are key participants in the Canadian effort to develop an AP/LLP policy that will sustain market access over the long-term (see Chapter "Market Solutions to Coexistence and Regulatory Asynchrony").

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Regulatory Lags for Genetically Modified Crops: Legal and Political Perspectives

Martin Phillipson and Stuart J. Smyth

Introduction

The emergence of the phenomenon of genetically modified (GM) 'regulatory lag' has the potential to significantly impact the development and commercialization of new transgenic crop varieties. GM 'regulatory lag' occurs where there are significant delays in approval of a GM product in an emerging export market, or differences in the regulatory approval timetable between significant export markets. Several recent lawsuits involving Syngenta's Viptera maize product line raise significant issues for technology developers, producers, handlers, processers and shippers in instances where 'regulatory lag' is occurring or is possible. The chapter will examine the legal implications of GM 'regulatory lag' for these parties and offer one possible solution to an increasingly significant industry problem.

Background

The time required for technology development firms to receive regulatory approval for a GM crop, and thus the ability to commercialize the technology, has consistently increased over the past two decades. Jaffe (2005) reported that in spite of no new traits being regulated, the United States Department of Agriculture (USDA) consultation process had more than doubled over the first decade of GM crop

M. Phillipson (✉) · S.J. Smyth (✉)
University of Saskatchewan, Saskatoon, Canada
e-mail: martin.phillipson@usask.ca

S.J. Smyth
e-mail: stuart.smyth@usask.ca

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regulation. The average number of months to get regulatory approval in the US between 1994 and 1999 was 5.9 months and between 2000 and 2004, it took 13.6 months. A 2011 report released by EuropaBio that examined regulatory approval times between Brazil, Canada, the European Union (EU), and the United States (US) documented that the average time to approve a GM crop in the US had risen to 25 months (EuropaBio 2011). An industry report prepared by Phillips McDougall (2011) identified that the average number of months required for a GM event to receive regulatory approval in 2011 was 65 months, up from 49 months in the 2008–2012 period. The total cost of receiving variety approval in key markets was estimated to be US$136M. Figure 1 illustrates the regulatory time in months for the four leading GM crop producing nations.

With regulatory assessment times increasing in strong GM crop adopting countries such as the US, this creates an international regulatory lag. Strong GM adopting nations are able to approve GM crops more expeditiously than other nations. For example, the EU is essentially in regulatory gridlock, having only approved one GM crop for cultivation in the past decade. At present, the EU has 74 pending variety submission packages (Dewar 2014). Another example is offered by the Chinese regulatory system, which will not even accept submission of a package for regulatory review until the new variety has been approved in another jurisdiction. Regulatory inefficiencies create substantial regulatory delays in securing international approvals for new GM crop varieties (Fig. 2), thus triggering substantial concerns for the commodity handling and trading industries. The nature of these concerns lie predominantly with the low level presence of approved GM varieties in two types of commodity shipments. First, small quantities of GM varieties may show up in lots of non-GM commodities bound for international markets expressing a preference to avoid GM products. In addition, when an importing nation's regulatory approval system lags behind those of exporting

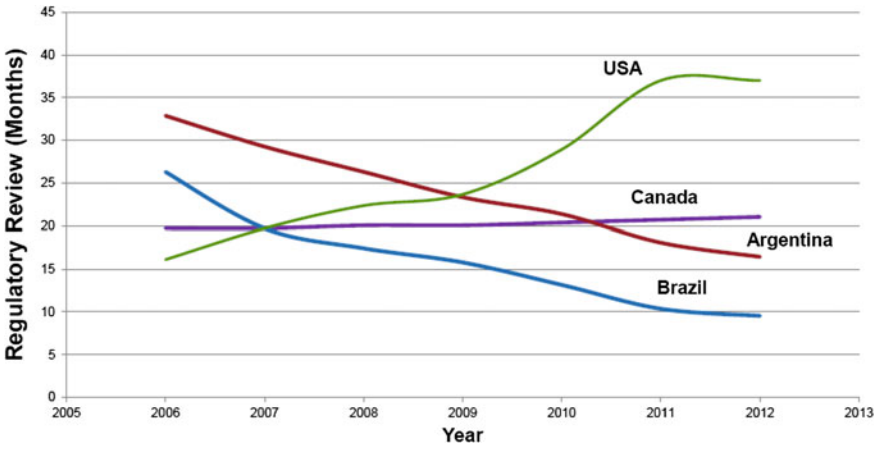

Fig. 1 Regulatory cultivation approval times. *Source* Dewar (2014)

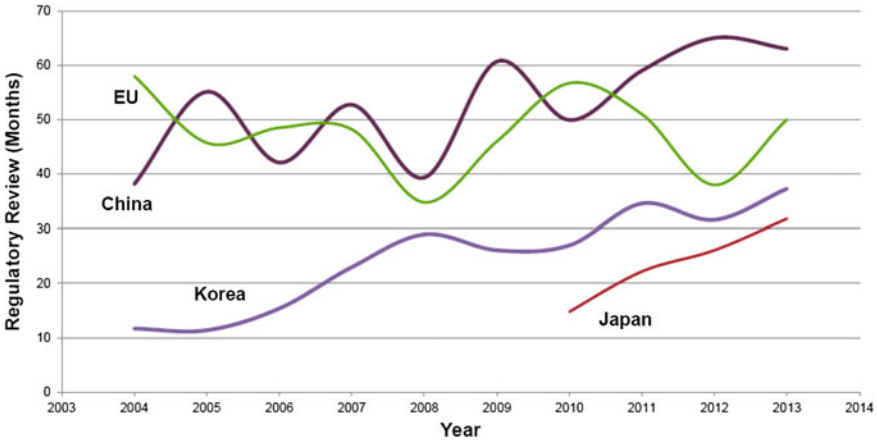

Fig. 2 Regulatory import approval times. *Source* Dewar (2014)

nations, a GM crop approved by the exporting country but not the importing country may be present in a shipment of a fully approved GM commodity.

This chapter offers a unique perspective on asynchronous approvals by examining the legal implications of situations where a lag exists between key jurisdictions in the approval of a specific GM crop. In particular, the chapter focuses on the legal ramifications of a delay in Chinese approval of Syngenta's Agrisure product line containing the MIR162 insecticidal trait.

Critical Assessment

US regulators approved a Syngenta-developed variety of maize call Agrisure Viptera for sale in 2010; the product was commercially launched in August 2010 in advance of the 2011 planting season. In addition to domestic approval, Syngenta also received import approval from Canada, Japan, Australia, Brazil, Mexico, New Zealand, South Korea, Russia and Taiwan. Significantly, import approval was also sought from China but had not been achieved by product launch. Court documents filed by Syngenta asserted that it hoped to have import approval from China by March 2012 (Syngenta 2011) but it was not received until December 2014. During this delay China began rejecting shipments of US maize due to the presence of the MIR 162 trait. Although other factors may be at work (including a significant price correction for US maize), US maize exports to China have subsequently dropped by 85 % and many assert that the rejection of unapproved GM maize is a significant causal factor (Tidgren 2014).

Three distinct lawsuits have emerged as a direct consequence of this regulatory lag and its impact on US maize exports to China.

Syngenta v Bunge

Bunge North America is a US corporation operating 71 grain and milling facilities and 66 elevators in the US. In 2011, Chinese imports of US maize grew by 500 % over the previous year and imports had been increasing significantly since 2009 (Tidgren 2014). This increased demand led Bunge to enter into several large contracts to export US maize to China in the spring of 2011. As Bunge was aware of China's 'zero-tolerance' policy towards the presence of unapproved GM traits, they began (in line with long established company policy) refusing any Viptera maize at any of its facilities in July 2011. The policy was to remain in place until import approval from China was received. In response to this policy change, Syngenta commenced legal action against Bunge in August 2011 seeking damages for lost profits and irreparable harm to its reputation (Syngenta 2011). The United States District Court rejected Syngenta's request for an injunction and rejected statutory claims against Bunge. In December 2014, the dispute was settled out of court shortly after China agreed to allow imports of Viptera maize.

While Syngenta was the plaintiff in the aforementioned suit, it has subsequently been named as defendant in two other disputes following China's rejection of US maize shipments containing traces of MIR 162 in November 2013. Neither dispute has yet gone to court, but the litigation is likely to be lengthy and expensive in both instances.

Cargill v Syngenta

An April 2014 National Grain and Feed Association (NGFA) commissioned study estimated that Agrisure Viptera related trade disruptions had already cost US maize and soy farmers between $1 billion and $2.9 billion in losses (Fisher 2014a). A companion study also estimated that Syngenta's impending release of a second generation product, Viptera Duracade, prior to Chinese import approval could increase these losses by between $1.2 and $3.4 billion (Fisher 2014b).

On September 12, 2014 Cargill commenced legal action against Syngenta alleging that it has lost over $90 M because Syngenta began selling Viptera maize prior to obtaining Chinese export approval. Cargill alleges that Syngenta's decision led to widespread infiltration of MIR 162 into the US maize supply and that any shipment of maize to China would be likely to contain traces of Viptera.

A fascinating aspect of this litigation is that some suggest that the extent of the damage suffered is not solely attributable to regulatory lag, but may actually be exacerbated by Syngenta's marketing strategy:

> Syngenta made a conscious decision to market MIR 162 despite knowing that such action had the potential to cause large losses to others involved in the supply chain. Does that constitute a legitimate basis for this legal action? It's unclear, but the disgruntlement of Cargill and other grain handlers is not difficult to understand. Yes, the company no doubt

> spent several years and millions of dollars in developing MIR 162, so its interest in commercializing the technology is obvious. But the potential benefit to Syngenta from marketing MIR 162 in the current year likely would be measured in millions of dollars. The loss in value to the rest of the agriculture/food supply chain–including farmers– is being measured in billions. The potential costs could multiply quickly due to Syngenta's decision to allow limited planting in 2014 of a newer trait–Agrisure Duracade–that is not approved for importation by either China or the European Union. Syngenta seems to be rolling the dice (Pearson 2014).

Trans Coastal Supply v Syngenta

Given the sums involved, and the clear displeasure with Syngenta's commercial decision-making, lawsuits of this nature are likely to be pursued vigorously by Cargill and other actors in the US grain system. Indeed, the same day that Cargill filed its case, Trans Coastal Supply Company, another US maize exporter, filed a putative class action against Syngenta alleging that Syngenta's 'premature release' of Viptera caused Trans Coastal to lose around $41 million (Tidgren 2014).

In spite of these lawsuits, and ongoing and future losses predicted to be in the billions of dollars, Syngenta placed Agrisure Duracade onto the US market for the 2015 growing season in the absence of Chinese (and EU) import approval. (Pearson 2014).

The litigation highlighted above dramatically illustrates the legal consequences of regulatory lag. The marketing of a product caught in a regulatory lag has resulted in years of expensive and time-consuming litigation that will ultimately resolve little. It may indeed rectify problems associated with regulatory lag by placing a chill on the market and making developers less likely to put products to market in a timely fashion. While the goal of achieving a truly harmonized and completely synchronous global approval system is very unlikely, are there methods, means, or precedents that can be employed so GM regulatory lag, and its attendant legal consequences, can be reduced or minimized? The following section identifies an existing international framework that, if adapted, could conceivably address the period of time required to receive international market approvals, thus allowing trade to flourish.

The Patent Cooperation Treaty

There are several similarities between seeking international regulatory approvals for GM crops, and the process for seeking intellectual property protection for inventions in multiple jurisdictions. As with GM crops, inventors must seek patent protection from national patent offices, just as import approval for a GM crop must be received from individual national authorities in the putative importing state. Just

as there are no 'international' approvals for GM crops there is no such thing as an 'international' patent. However, efforts to harmonize and streamline the international patent system have been ongoing since the drafting of the Paris Convention in 1883 and culminated with the development of the Patent Cooperation Treaty (PCT). As Nepelski and De Prato (2013) state:

> The Patent Cooperation Treaty is one of the major undertakings in the process of patent harmonization. It is an international treaty for rationalization and cooperation with regard to…patent applications and the dissemination of the technical information contained therein. The PCT does not give the right to "international" patents…the task of granting patents remain exclusively in the hands of national patent offices.

Negotiations for the Patent Cooperation Treaty were concluded in 1970 and it entered into force in 1978. Its membership now extends to 148 countries. As stated above, the PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an 'international' patent application. The PCT is administered by the World Intellectual Property Organisation (WIPO). While WIPO does not grant patents, or provide any legal protection for inventions, WIPO believes the PCT provides advantages for the applicants, national patent offices and the general public.

In simple terms, the international patent application process under the PCT provides a more streamlined and cost-effective application for multiple jurisdictions. Furthermore, by subjecting the application to an 'international' search at one of the member national patent offices, all patent authorities in the 148 nations will be able to assess the initial patentability of the invention via a common source of information. However, the PCT does not interfere with the sovereignty of these national offices in that they still make the ultimate decision re patentability and are free to seek additional information and analysis beyond that produced by the initial international search.

In 2013 over 200,000 PCT applications were made worldwide, a 5 % increase on the previous year. Fifty seven percent of the growth came via US applicants with a further 29 % of the growth attributable to Chinese applicants. Over 57,000 applications came from US applicants. Panasonic Corporation of Japan was the single largest applicant filing over 2700 applications. (PCT Yearly Review 2014).

To reiterate, the PCT does not replace national patent offices and does not provide international patent protection. However, it is argued that a PCT-type model for GM crop approvals could assist in reducing regulatory lag considerably. In essence, the PCT system is intended to reduce unnecessary duplication among patent offices and supports work sharing between those offices. If countries with an interest in importing GM crops could create a regime whereby a common application containing all necessary scientific and other information could be used then the possibility of a limited form of synchronous approval becomes possible. If national sovereignty concerns necessitated a PCT-like model where the final approval decision still rests with a national body, a common application and accompanying data set could nevertheless streamline and harmonize the application

process across multiple jurisdictions thus significantly reducing the potential for damaging regulatory lags such as those encountered by Syngenta's Viptera maize.

However, the PCT is not without flaws or critics. While WIPO and others may cite impressive growth in PCT applications and laud its accomplishments (Boutillon and Erstling 2006), other research suggests that the PCT process is only suited to certain types of particularly sophisticated technologies. Koury (2012) states:

> Wadhwa et al. have shown that only sophisticated patents are filed through the PCT track. They blame this on the "costly and time-insensitive application process for PCT patents." In essence, the PCT as it stands today has become a hamlet for rich innovators and for applications that have "market potential in multiple countries, global visibility, or diverse applications."

While such a position will be of little concern to major global life science corporations, it may be of concern that some research (Nepelski and DePrato 2013) suggests that the PCT has not necessarily improved the process of international patent protection or that PCT membership does not necessarily result in technology transfer to developing countries after they have joined the PCT. They also indicate that some businesses still prefer to seek national patent protection directly in target markets, rather than using the PCT as their 'default' patenting process when seeking to enter foreign jurisdictions.

Ultimately, one's opinion of the success of the PCT will depend on whether it is viewed as a tool for streamlining application processes and reducing delay and duplication, or whether it is viewed as a vehicle for the ultimate harmonization of the international patent system. If its goal is viewed as the former, then there is clear potential for a PCT-like regime to be applied to approvals for GM crops in like-minded jurisdictions. At a minimum, the PCT warrants further study as a model for a regime that could reduce or eliminate damaging regulatory lags in the GM crop approval process.

As with any international governance issue, challenges exist regarding agreement on protocol, precedents and implementation. We summarize three of the most pertinent issues facing the development of a PCT-type structure for asynchronous approval.

First, identifying a champion (or champions as the case may well be) is problematic. With the present trans-Atlantic gap regarding regulatory approval of GM crops, it would be a logical assumption that this issue is not going to be easily, or readily, addressed through such a mechanism. Establishing a new international protocol would take several years of discussion to reach a consensus on the scope, objectives and structure of such an agreement, to be followed by a further period of several years whereby enough nations would have to not only sign, but ratify the agreement prior to it coming into effect. For example, when the Cartagena Protocol on Biosafety was agreed upon in 2000, it required the ratification by 50 nations prior to coming into effect as an international agreement. This process took three years.

What incentives exist that could encourage non-GM crop producing nations to participate in such an agreement? While international trade is disrupted from the detection of the low level presence of unapproved GM events, this has a higher cost on the exporting nation than the importing nation as the importing nation simply rejects the shipment and is not required to deal with it after this point. It is up to the exporter to find an alternative market for a rejected shipment. Even nations that produce GM crops, such as China, are taking significant amounts of time to approve GM events for import, indicating that there is little incentive for these countries to increase their regulatory efficiency. It is quite doubtful that non-GM crop producing nations would recognize efficiencies to improve their regulatory import approval process.

Finally, monitoring and/or enforcement of any new agreement will be a daunting challenge. Assuming that if nations were provided with a period whereby approved GM events could not be used to disrupt international trade as regulatory approvals were pending, establishing a mechanism that would be capable of enforcing some type of punitive means on those nations that took longer than was agreed to in the approval of GM events, is highly unlikely. Domestic sovereignty would seem to be increasing in importance and national governments that propose ceding sovereignty to an international agreement or protocol within this present time period, would be viewed as most unpopular. Separating the political realities, and indeed the politics, from this issue might well be a challenge that proves insurmountable.

In spite of these challenges, which in general terms are applicable to the negotiation of any international agreement, we strongly assert that efforts to streamline GM crop approval processes are a worthwhile endeavor. The legal consequences of GM regulatory lag are significant and ongoing. Unless action is taken to address these consequences, a rapidly decelerating approval process could grind to a complete halt. Negotiations may be difficult, and a modest goal of streamlining approvals may be a long way from the end goal of asynchronous approvals, but the status quo is not a viable option. The development and operation of the PCT provides a model worth pursuing with some vigour.

Coexistence Consequences

Non-scientific and overtly political factors are re-emerging as factors in domestic regulatory frameworks for biosafety risk assessments and the regulation of new GM crop varieties, particularly in the EU (Smyth and Phillips 2014). Similar issues continue to undermine international trading agreements, such as the EU's acceptance of trade retaliation measures following its refusal to accept hormone beef from Canada. The ongoing work of the Cartagena Protocol on Biosafety represents further evidence of efforts to ensure that the international regulation and trade of GM crops and products moves from being a purely science-based regime towards one that places significant emphasis on socio-economic factors. The infiltration of non-scientific factors in regulation and trade is increasingly visible.

What does this mean for coexistence? The renewed politicization of GM crop regulation establishes the incentive for domestic governments to use the regulatory approval of a GM crop variety for expeditious reasons. Not all trade in GM crops and products is done within market economies. Incentives exist (within command economies in particular) to use the regulatory system for political advantage, or for political retaliation. Indeed, rumours persist that China's approach to the approval of Syngenta's Viptera maize discussed earlier was a direct response to US criticism of China's human rights record. While the validity of such an observation cannot be verified conclusively, the incentive exists for a policy response such as this to occur.

Political interference in regulation and trade is on the rise. Action is required to limit the adverse effects of such interference on the timely regulation of GM crops and the international trade in these products. Some form of international agreement is required to protect and maintain trade in new GM crop varieties that are undergoing multiple risk assessments in major trading partners. If the status quo is allowed to continue then significant disruption in the production and trade in GM food is inevitable. In the absence of international action, problems such as those discussed above will proliferate further. At the very least, a grace period within which shipments undergoing risk assessments cannot be rejected due to low level presence would mitigate the infiltration of overtly political factors into the regulation and trade of GM crops. In the longer term, some form of international agreement aimed at streamlining and harmonizing approvals is imperative.

Summary/Synthesis

- Regulatory lags for GM crops pose a significant challenge to global food production and trade.
- These differences in approval times between key import and export markets have significant legal implications for technology development firms.
- Differences in approval times may be caused by a variety of non-scientific and political factors necessitating the development of frameworks to mitigate their effects.
- Ongoing litigation further highlights the need to resolve issues of GM regulatory lag.
- While not a panacea, international legal mechanisms such as the Patent Cooperation Treaty offer potential solutions to this problem.

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Regulatory Approval Asynchrony, LLP, and Implications for Biotech R&D and Innovation

Eric Sachs

Overview

Progress toward sustainable and profitable farming systems using a full technology toolbox is needed to accelerate agricultural productivity globally. Increasing agricultural productivity is one of the keys to ensuring global food security. Food security is a serious issue for many countries that are dependent on commodity markets to meet their needs or supplement domestic agricultural productivity. High dependence on imports places countries at risk of production shortfalls, supply constraints, and price volatility due to growing global demand and competition for grain commodities. Prolonged regulatory timelines due to asynchronous approvals coupled with a lack of harmonized policies on low-level presence of unapproved events contribute to uncertainty that directly impacts product launches and indirectly affects the pace of research, development, commercialization, and import of innovative products. The public and private sector technology pipelines are producing new discoveries and developing innovations that promise to increase the pace of crop genetic improvement. While the opportunities for delivering more productive, pest resistant crops that use less water and inputs per unit production are real, success will depend on establishing efficient, predictable, and rational evidence-based regulatory frameworks.

E. Sachs (✉)
Monsanto Company, St. Louis, USA
e-mail: eric.s.sachs@monsanto.com

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Introduction

There is an opportunity to address some real and important challenges that are impacting the ability of the public and private sectors to deliver innovations designed to make food more abundant and the world more food secure. While this chapter is aimed at a broad audience, it will become obvious that government policy makers and regulators can have the greatest influence on how the regulation of genetically modified (GM) crops moves forward. We all share accountability for what the future holds and must work together to bring about needed changes that will serve the public good.

The Regulatory Process

Delivering a new GM crop to the market requires an understanding of commodity flows and national regulations to ensure market access and unhindered global trade, as many countries have established independent regulations for importing foods derived from biotech crops. Prior to commercialization, technology developers conduct a Market and Trade Assessment that provides information on export, import and production trends of key crops and their by-products in different countries and regions of the world. This assessment identifies key export markets for commodities, such as maize, soybean, canola and cotton, and assures that regulatory authorizations will be obtained in the source production country and in import countries with functional systems so that the presence of GM-derived by-products in imported commodities are legal. The process requires robust data sources from countries all over the world so that trade of all globally traded by-products, e.g., soybean grain, oilcake and solid residues, crude oil, and refined oil, is understood. At the conclusion of the Market and Trade Assessment, the key countries requiring production and import approvals are identified, and planning can commence for regulatory data development, drafting and timely submissions of regulatory dossiers in multiple countries. Regulatory requirements vary for different countries according to their biosafety laws and frameworks. Applicants with new products that are regulated by national authorities under law conduct the relevant studies using protocols designed to meet different countries' regulatory requirements and submit dossiers to the competent authorities for review.

For example, a GM soybean that would be produced in the United States, Brazil, Argentina, Paraguay, or Uruguay, once harvested would likely enter the commodity grain market and be exported to numerous countries around the world as food, feed, or processed goods. To support this global trade, dozens of dossiers have to be submitted to authorizing agencies globally. In many countries there is not a single regulatory authority, and there may be multiple agencies (as many as seven) that have the responsibility of assessing a particular aspect of safety. These regulatory dossiers containing extensive safety data are then subjected to review by

independent risk assessors and scientists across a wide range of disciplines. Each agency has its own formatting and review processes, often requiring translation into an official national language and leading to significant differences among countries in the amount of time taken between submission and authorization. There is also large product-by-product variation in the range of questions posed by regulators that contributes to differences in review times. To support the import of GM grain intended for processing, some countries also require a local field trial or local feeding study. Altogether, making submissions to multiple agencies in multiple countries for each and every product under development is a substantial logistical challenge. Applicants can plan for many of the challenges so that the process can be accomplished in the least amount of time but unnecessary or unpredictable delays add time to the commercialization process.

Factors that Impact the Regulatory Approval Process

Asynchronous approvals happen when authorizations occur in some countries but are delayed in others. That means that the potential exists for unauthorized GM products to be detected at very low levels (known as low-level presence or LLP) in a commodity grain shipment, and consequently rejected upon import into a country that has not completed its regulatory approval process. This risk of import rejection stems from the ability to detect GM crops at increasingly lower levels (below 0.1 %), combined with continuing import policies that have a zero tolerance on unapproved GM crops. GM crop developers have implemented industry-wide stewardship practices, such as the "Excellence Through Stewardship" program, to minimize potential LLP issues, but these practices add significant cost to the product development phase and delay broad product launches. Thus, the risks to the developer and traders associated with the potential for LLP of an unapproved GM crop are large and it is important to avoid or mitigate these risks whenever possible. This is especially true when one considers the potential economic risks resulting from LLP relative to the potential food or feed safety risk posed by the presence of low levels of a GM crop product that has already been reviewed and approved for full use in one or more countries.

While there can be many reasons that approvals are delayed, several prominent examples are: (1) extended reviews by risk assessors, administrative delays, and capacity constraints; (2) new and inexperienced regulators, evolving processes, or changing requirements, resulting in added regulatory steps or complexity; (3) new or expanded data requests or limited data transferability between countries despite similar and relevant experimental conditions; and (4) litigation or political influence that interferes with approval processes or decision-making by regulatory authorities or introduces uncertainty on the durability of authorizations once granted. While most regulations have general timelines for completion of the regulatory process, one way to get past the mandated timelines is to ask multiple rounds of questions, which allows the regulators to "stop the clock" while the developers prepare

answers to these questions. For example, European authorities take years to debate modifications to their guidance documents and regulatory requirements. Once finalized, they retroactively apply requirements to products already under review. This results in additional rounds of questions; in some cases the developers must initiate new studies to conform to new data requirements, study designs, or statistical methods, which may have no bearing on the quality of the risk assessment.

When the approval process for cultivation and import of a GM product is delayed, there also is a delay in commercialization, which limits the utilization of innovative products with benefits for farmers and society. Uncertainty and delays in the approval process also serve as a barrier to academic institutions, government research laboratories, and small biotechnology start-ups, who could develop meaningful solutions for farmers but are limited due to the high cost and extensive time required to navigate the global regulatory landscape. Unfortunately, the consequences to society caused by delays in regulatory processes are yet to be widely recognized outside of the industry and public sector developers, grain traders, and regulatory community. Individual parties developing new GM crops must work diligently to manage the regulatory process, the potential for delays, and the associated business risks and uncertainty. Disruption of trade due to asynchronous approvals has heightened engagement from global traders and various government agencies from many exporting countries. Although the reality today is that regulatory processes are often unpredictable and challenging, there also is hope that continued dialogue among regulatory authorities, as well as positive actions taken by progress-oriented countries, will help bring about improvements in regulatory process and function.

A closer examination of the process of submitting regulatory dossiers to different regulatory authorities reveals how the complex regulatory submission process creates uncertainty in the timing of product introduction. Figure 1 illustrates both the ideal or best case scenario and the reality today. The different color horizontal bars represent theoretical timeframes for the submission, review and approval of a new GM crop with a novel trait, as well as the submissions and approvals of combined-trait GM crops, called stacked products. In some countries, the approval of stacked products follows the approval of the single trait product and requires additional data and review by regulatory authorities. This adds more time for regulatory approval. Ultimately, the applicant must obtain all required authorizations for the products introduced into the market, which are increasingly stacks rather than single trait products and in some cases are GM trait combinations that are used in production of hybrid crops or appear in the harvest as a result of natural segregation processes.

In principle, under the best case scenario, applicants would generate the required data, prepare dossiers for the needed authorizations and submit the dossiers simultaneously to all regulatory agencies so that approvals would occur on a parallel track. This in concept could occur if the regulatory processes in different countries were harmonized and operated on a similar set of criteria. Under this scenario, the regulatory authorizations could occur within a short window and applicants could plan for seed manufacturing and commercial introduction of new

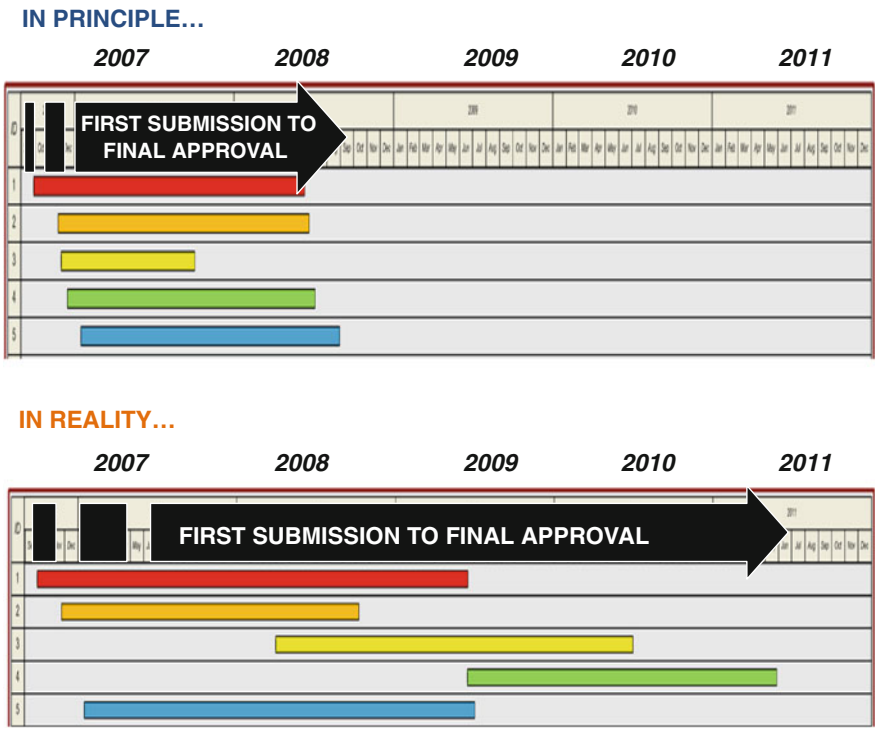

Fig. 1 A comparison of regulatory submission timelines

GM crops with a degree of certainty and predictability. Unfortunately, in reality, regulatory processes are neither certain nor predictable, and in some cases not based on science; consequently the actual situation today is depicted in the lower graphic.

For simplicity, the lower graphic features the most common cases: (1) an extended process for approval of the GM crop in countries that review single traits and stacks in parallel, depending on the national biosafety framework (red and blue bars), (2) a sequential process in countries that review single traits and stacks sequentially (orange and yellow bars), and (3) the case of China (green bar) where GM crops must first be approved in a country where cultivation will occur before the process of local field testing, local animal feeding studies and dossier review can begin in China (USDA 2014).

The requirement for sequential review of single traits and stacks (e.g., the European Union) lengthens the approval process and results in redundant review of the same data. After the regulatory authorities review the single trait product and all of the requisite data and authorize use of the single trait, the regulator then requires submission of a new dossier for the stacked-trait product that includes all of the same data for the new single trait just approved, as well as the additional data needed for approval of the stack. The result is an inefficient process that results in

delayed release of the new stacked-trait product to farmers. In this case, the review of the new single trait product is only a step in the process and does not lead to a commercially relevant approval. Farmers are not interested in switching to new single traits but instead demand that traits that improve productivity and profit be combined and offered together as stacked products.

Similarly, in China the GM crop import approval process can only begin after at least one cultivating country has reviewed and fully approved the GM crop. The approval process includes permission to do the locally conducted field study as well as a rat study. This is followed by a long process to obtain testing approvals, gene detection method clearance and national and provincial phytosanitary approvals to ship seed/grain into China for officially accredited and appointed institutes to conduct the local studies required to obtain import approvals. China is one of two countries that requires a locally conducted 90-day rat study with imported grain prior to reviewing the application for approval of import of a given biotech event (Russia is the other country where this applies). The requirement for approvals to occur sequentially also dramatically lengthens the commercialization process and delays GM crop technology from being utilized by farmers. In addition to the requirement for local studies, they also have three time periods in a year when submissions can be made for renewal of an application for conducting studies or gaining the final approval. Reports of the final decisions and subsequent paperwork can take an additional 3–6 months.

The GM crop production and import approval process is hampered by regulatory uncertainty, unpredictable delays and lengthy timelines that limit the realization of GM crop benefits for farmers and society. This is challenging for the private sector and even more onerous for the public sector that is less experienced and equipped to navigate the different regulatory frameworks and processes around the world.

The Need for Science-Based Regulatory Frameworks

Dysfunctional GM crop regulatory oversight in some countries is an increasing concern and the implications for society are becoming more serious. In spite of the fact that GM crops are providing important environmental, economic, and consumer benefits on a global scale, the timeframe for regulatory reviews and decision-making is increasing. The United States is the world's largest exporter of grains and producer of GM crops. China and the European Union are the largest importers of grain and processed products but also have the longest approval times. It is very evident that improvement in regulatory systems is possible. For example, a comparison of the cultivation and import approval timeframes in countries known to conduct a thorough science-based safety assessment reveals significant differences in timeframes for decision-making. The process in Canada (also Brazil and Argentina) leads to a cultivation approval in approximately 18–24 months, while approvals for import take about 45 months in the EU and about 54 months in China

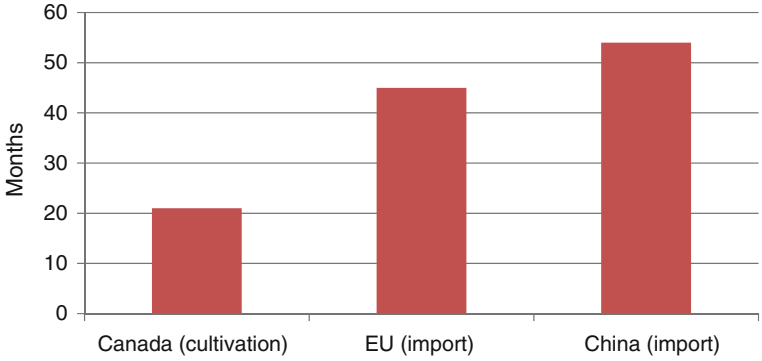

Fig. 2 Average approval timelines for cultivation of GM crops in Canada and import among the largest global grain importers

after first global regulatory submissions are made (Fig. 2). These important differences in approval times produce asynchrony and economic risks that arise when trade disruptions occur in response to delays in GM crop approvals.

Disruptions in trade can have serious consequences for the meat industry, which relies on imported grain for use in animal feed. When grain supplies are short, sometimes caused by interruptions in trade that create local supply shortages, grain prices can rise and ultimately impact the price of food for consumers. Countries dependent on the grain trade should consider how regulatory asynchrony can affect supply and demand and how expanding global markets can increase the risk of price volatility throughout the supply chain.

The biotechnology regulatory frameworks in countries like Canada, Australia and New Zealand, Brazil, and the United States often serve as a model and are described as positive reference points for other countries to follow. This is largely because these regulatory frameworks continue to focus on transparent science-based safety evaluations and continue to function administratively, resulting in predictable and timely approvals. Unfortunately, the US review process has become more complex, unpredictable, and longer over time (Fig. 3). For example, the number of USDA deregulations has declined as the timeline for review has increased. Prior to 2000, it took less than 12 months for review but since 2008 the review time has increased to 24–36 months (Jaffe 2005). While USDA has been able to reduce review times since 2011, overall timelines remain longer than they were when biotechnology-derived crops were first reviewed. The reasons for this are varied but there are several primary factors that have had the greatest influence on the regulatory process in the US. All of the factors affect the USDA's capacity to provide timely reviews and make decisions on new biotechnology-derived traits in the queue. The principle factor that routinely consumes agency resources and puts pressure on agency capacity is frequent allegations from GM crop opposition groups that GM products are unsafe, harm the environment, threaten organic specialty markets and were inappropriately authorized because of an inadequate review

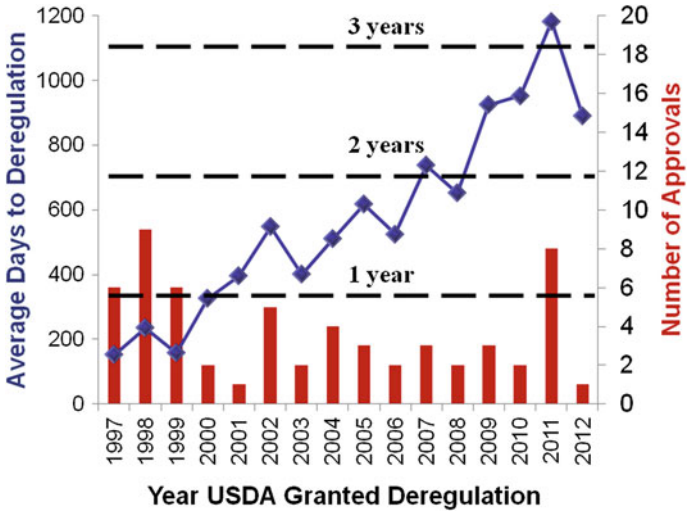

Fig. 3 The number of USDA deregulations that occurred between 1997 and 2012

by authorities. The USDA and other agencies must take these allegations seriously and determine independently whether they are scientifically valid or not. Such allegations rarely are evidence-based and often refer to risks that are common to other agricultural practices. In other cases the allegations lead to lawsuits and long term pressure on agency capacity. Certainly, fewer unsupported allegations and unmerited lawsuits would help ensure that agency capacity is focused on product assessments and the deregulation process. But whatever happens, the USDA and other agencies will function better if they have adequate resources and funding to make the system work. Congressional action may be needed to reform the US approval system to limit the impact of spurious lawsuits on US agencies.

Ironically, the slowing of the US regulatory process for GM crops has occurred in spite of the fact that the agencies have more than 20 years of experience reviewing GM crops and the weight of evidence in the scientific literature reinforces their safety. As the rate of deregulation slows, the backlog of products waiting to enter the market is growing. As of October 2012, there were 24 products in the queue at USDA—that's double the number of products deregulated during the prior 5 years. This is a very serious situation and steps must be taken by policy makers to make the process more efficient, predictable and timely. There is really no other option as technology providers are continuing to innovate and develop advanced products to help farmers improve productivity and meet the needs of a growing global population.

Regulatory Process Improvements and Approval Asynchrony

Brazil has made significant process improvements and has implemented a robust scientific process for authorization of cultivation of GM crops (Fig. 4). Since 2005, Brazil has approved more than 30 products from all technology providers (ISAAA 2015). Importantly, since 2009 CTN Bio has predictably completed thorough GM crop reviews and issued timely decisions for single events and stacks for cultivation without compromising strict compliance and science-based safety standards. By comparison, in Korea the timelines for import authorization of single and stacked-trait products have doubled or tripled since 2005 and a significant backlog of pending applications has resulted (Fig. 5). The longer review times for the two leading regulatory agencies in Korea (MFDS and RDA) increases uncertainty and can make it difficult to anticipate when to submit dossiers and predict import approvals.

The net result of regulatory asynchrony and uncertainty is a delay in farmer access to new products and the risk of LLP of unauthorized traits in commodity streams to export markets, which can cause trade disruptions. This not only results in economic losses for traders but often leads to supply shortages and higher prices. Taken together, these business risks also threaten innovation and delivery of technology benefits to society.

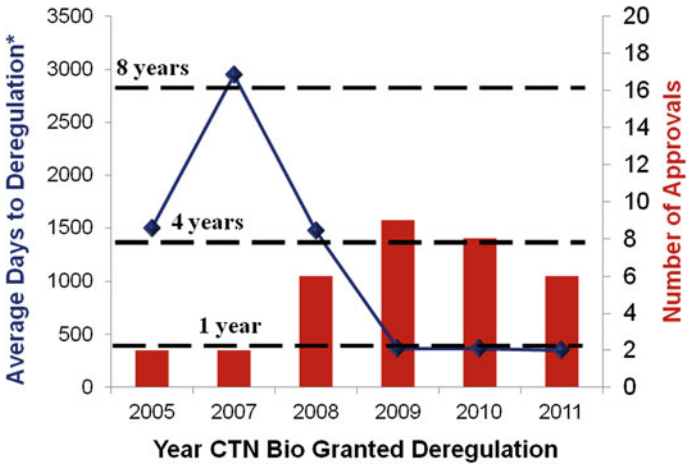

Fig. 4 The time required for CTNBio approval of GM single trait products for cultivation in Brazil

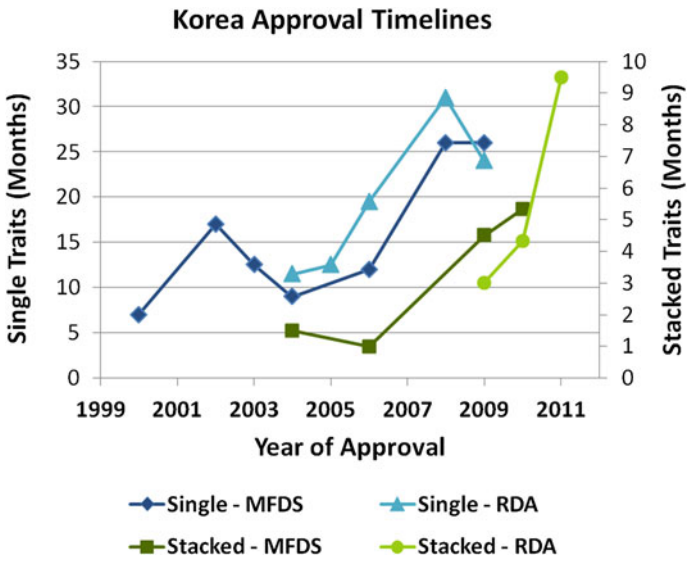

Fig. 5 The average time required GM crop approvals in Korea

Regulatory Asynchrony and Benefits of Innovation

The GM crop pipeline under development by industry is full of promising traits to improve agricultural productivity while conserving natural resources (Fig. 6). It is estimated based on current industry pipelines alone that more GM traits could be deregulated by USDA during 2011–2020 than in the previous 16 years. However, this prediction may be optimistic. Technology providers are developing next-generation traits to manage weeds and pests more sustainably, to improve abiotic stress tolerance, to increase nutrient use efficiency, and to improve plant function and yield potential. Near term traits include crop tolerance to additional families of herbicides that will enable farmers to adopt a diversified approach for more sustainable weed management. Additional herbicide tolerance traits will increase the farmer's ability to apply herbicides with different modes of action in mixtures, sequences, and across seasons to combat herbicide resistance in weed populations. Additional insect protection traits will enable farmers to protect crops from more pests and utilize multiple, complementary modes of action in the same crop to counter pest adaptation. Longer term traits in the pipeline will increase yield by making crops more tolerant to different forms of drought stress, reduce fertilizer use and greenhouse gas emissions by increasing nitrogen use efficiency, and increase the yield potential of crops by improving plant function, such as photosynthetic efficiency. These traits will make important contributions to the rate of yield gain in key agricultural crops, as breeders work in parallel to improve yield performance using other modern methods of crop improvement.

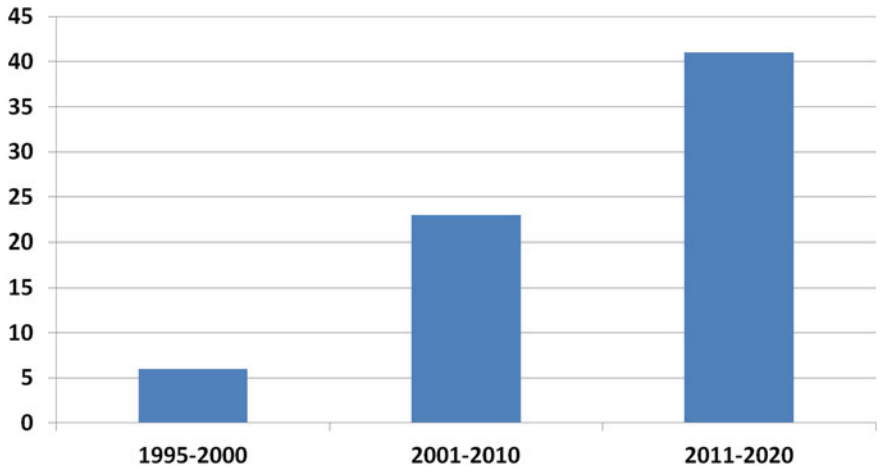

Fig. 6 The number of crop biotech traits that have been launched or are in industry pipelines. *Sources* USDA deregulation database and Monsanto internal estimates

Importantly, the opportunity to improve crop productivity and food security is not limited to large acreage crops. However, given the cost and length of the global regulatory burden to date, only large acreage agronomic crops provide sufficient economic return on investment to justify GM trait development. Many uses of biotechnology for subsistence, vegetable and fruit crops have been pursued by public sector research programs with limited success. A key barrier to approval and utilization of GM traits in small acreage crops is the cost and knowledge of how to navigate the complex, unpredictable, and lengthy regulatory process. Consequently, the GM regulatory process also constrains use of biotechnology in other nutritionally important crops globally. If existing constraints that limit the efficiency of regulatory frameworks in the US and abroad are addressed, farmers globally will have available a full range of biotechnology-derived tools to combat yield-limiting weeds, pests, and diseases, as well as climatic stress, in all crops that contribute to healthy nutrition and food security. Not doing so will limit the potential benefits of innovations already in development and discourage investment in future technologies.

Confidence in a Functional Regulatory Process Would Increase Technology Investment and Utilization

A course correction is needed to deliver the promise of GM crops. The most important cost of regulatory delays is the loss of societal benefits, rather than the added cost of research and studies to meet changing or uncertain regulatory requirements (Fig. 7). Bayer et al. (2010) estimated the unrealized value to society

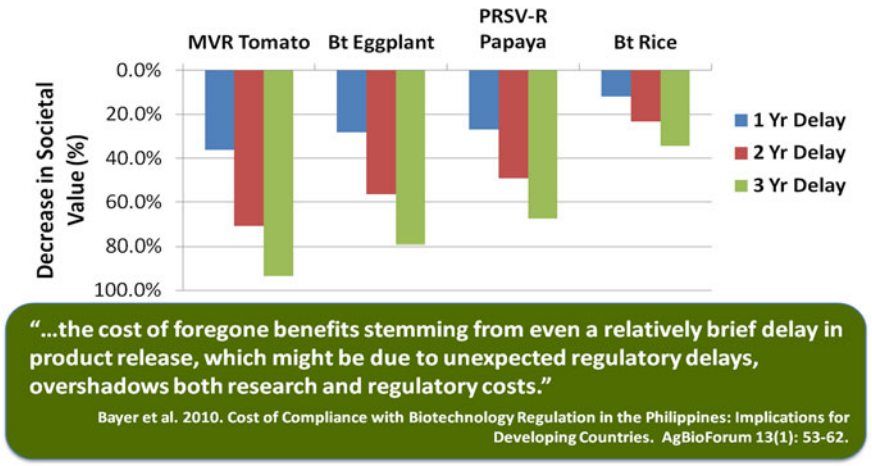

Fig. 7 The decrease in societal value associated with delayed market introduction of four different experimental GM crops in the Philippines. *Source* Bayer et al. (2010)

(also known as opportunity cost) associated with delays in regulatory approval for 4 different experimental GM crops in the Philippines. They showed that even brief delay in a product's release, which might be due to unexpected regulatory delays, could have large impacts on the value to society from reduced use of the improved crops. They also showed that the cost of foregone benefits differed based on the crop and length of delayed release. For example, for multi-virus resistant tomato, Bt eggplant and virus resistant papaya, a 1 year delay reduced societal value by more than 20 %, a 2 years delay by 48–70 %, and a 3 years delay by 65–93 %. Since delays in approval are unpredictable, when the potential impacts on customer value and therefore economic return are large the risk to developers can stifle investment. While this study is but one example, there are many examples of technologies that were delayed or were slowly adopted and the benefits to society reduced, including pharmaceuticals, healthcare, agricultural chemicals, energy, and telecommunications. Lessons from these industries will hopefully provide an impetus and direction for future decision-making.

Ultimately, the goal is to restore confidence in the regulatory process that enables use of new technology and its benefits, while ensuring the safety of the products introduced. A functioning and predictable regulatory system will in turn drive more technology investment and expand the number and variety of improved crop technologies available to farmers. Some countries (e.g., the European Union, China and Korea) have increased the complexity and length of the regulatory process to enhance public confidence in the safety of GM crops. Unfortunately there is little evidence that public acceptance of GM crops has improved despite ongoing efforts by scientists and stakeholders to inform the public and counter misinformation perpetuated by opponents of GM technology. If achieved, greater confidence in the regulatory process and investment will promote public-private

partnerships, shorten innovation cycles and increase the rate of productivity gain. More productivity means greater supply and improved price stability. More productivity and tools to improve conservation of limited resources also will produce more sustainable agricultural systems.

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The Economic Impacts of Regulatory Delays: The Case of HT Soybeans

Nicholas Kalaitzandonakes, Kenneth Zahringer and John Kruse

Introduction

Crops developed through biotechnology must undergo regulatory approval to ensure their environmental, food and feed safety before they are commercially introduced in the marketplace. This regulatory process necessarily lengthens the time required to bring such new crops to market. Insofar as this delay is necessary to ensure their safety it is regarded as worthwhile. Efficiency is crucial, though; there are many possible ways that the regulatory review process can be structured. If the approval process goes on longer than necessary to ensure safety with reasonable scientific certainty, the opportunity cost of missing out on innovation can mount (Bradford et al. 2005; Van Eenennaam 2013). The primary conclusions drawn from these and other studies are that foregone benefits due to delayed innovation can often be substantial and ongoing, and that developers, producers, and consumers all lose from regulatory delays.

Overall, regulatory delays tend to slow down the biotechnology innovation process in general. In the short run, such delays mean that innovations ready to be marketed to agricultural producers are sitting idle. During this time the welfare of

N. Kalaitzandonakes (✉) · K. Zahringer
University of Missouri, Columbia, MO, USA
e-mail: KalaitzandonakesN@missouri.edu

K. Zahringer
e-mail: zahringerk@missouri.edu

J. Kruse
World Agricultural Economic and Environmental Services (WAEES), Columbia, MO, USA
e-mail: jkruse@waees-llc.com

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both producers and consumers is reduced. Operating costs and market prices are both higher than they would be without such innovations on the market (Huang and Yang 2011). In the long run, excessive regulation may exert an overall dampening effect on the innovation process. The high cost of pursuing approval in jurisdictions where the process is longer and more expensive as well as the loss of revenue for technology developers tend to discourage innovation in general (Braeutigam 1979; Qaim 2009; Blind 2012). These long run costs are as certain as they are difficult to measure. The costs take the form of research programs never embarked upon, innovations never developed, firms never started, jobs never created, and products that never reach the hands of producers or consumers (Bastiat 2007).

In this chapter we estimate the foregone economic benefits to world markets because of delayed adoption of new biotech innovations. We focus our analysis on new herbicide tolerant (HT) soybean varieties already in the biotechnology development pipeline and the economic implications of a potential delay in their market introduction. As we discuss in detail below, first generation HT biotechnologies, especially glyphosate tolerance, have lost some of their effectiveness after 20 years of intensive use. As a result, producers in some parts of the world are currently experiencing increased weed control costs. The new HT soybean varieties can provide alternatives for cost-effective weed control. In this context, we examine the economic implications of making these new HT soybean varieties available to farmers later rather than sooner and we do so by estimating the impact of the timing of these market changes on supply, demand, prices, and overall welfare.

The rest of the study is organized as follows: in the next section we outline the benefits that have resulted from the first generation of biotech soybeans, then go on to describe current problems with weed resistance and how new traits in the biotech pipeline might address that issue. In the following section we examine in some detail the issue of asynchronous regulatory approvals of new biotechnology traits and its potential effects on innovation and adoption, in general. After discussing the conceptual basis for our model, we describe the construction of our scenarios and the model in detail. Following this we present our empirical results and concluding remarks.

Initial Benefits of Biotech Soybeans

The introduction of Roundup Ready™ (RR) soybeans, tolerant of the herbicide Roundup™ (glyphosate), in 1996 prompted dramatic, swift, and worldwide changes in soybean production. With RR soybeans, one or two applications of the broad spectrum glyphosate replaced multiple applications of more selective herbicides. In this way, RR soybeans and the expanded use of glyphosate, an inexpensive, less

toxic, and more readily degradable herbicide, helped farmers achieve effective weed control at lower cost and shortened their production cycle, while increasing low- and no-till farming practices.[1]

The impact of this innovation, coupled with a parallel strong expansion of global soybean demand, has been significant. Among the leading soybean producing countries, area devoted to soybean production increased by one-third in the United States while roughly tripling in both Argentina and Brazil. Modelling indicates that world soybean prices are 2–5 % lower than they would have been in the absence of the RR technology, due to the increased supply brought on by lower production costs (Alston et al. 2014).

Producers have captured a large share of the benefits of RR soybeans, though consumers have benefitted significantly as well. The total world economic surplus created by this innovation from 1996 to 2009 has been calculated at almost $50 billion, of which more than 85 % went to producers and consumers and 14 % to the innovators. Most of the surplus came as a result of decreased production costs. On average, adoption of RR soybeans has allowed producers in the US to save $28.70/ha per year, in Argentina $22.70/ha per year, and in Brazil $32.40/ha per year in weed control costs (Alston et al. 2014).

Livestock producers using soymeal as feed have also benefited from both lower prices and expanding supplies. As a result, livestock industries in many countries have experienced fast growth in the last 20 years. For instance, China's dairy production has quadrupled since 2000 while pork and poultry production have also increased by almost 50 % over the same period (USDA 2015b). Increased access to high quality animal protein has improved food security worldwide (FAO et al. 2014). Consumer surplus in both producing and importing countries experienced substantial increases.[2] In the European Union, the second largest importer of soybean products, RR soybeans added $1.5 billion to consumer surplus in 1996–2009. In China, the world's largest soybean importer, RR soybeans added almost $3 billion to consumer surplus over the same period. In the end, people around the world benefitted from the decrease in world soybean prices to the tune of $15 billion from 1996–2009 (Alston et al. 2014).

[1]The ability to use a more effective, broad spectrum herbicide has lessened the need for weed control through cultivation, so no-till practices has become more prevalent in many leading soybean areas. This also makes for a shorter growing season; some South American farmers have been able to double crop soybeans after wheat, leading to increases in annual farm income of over $200/ha (Brookes and Barfoot 2014).

[2]Consumer surplus is a measure of economic benefit enjoyed by consumers when they purchase goods at market prices lower than the maximum they would have been willing to pay. When innovation leads to lower market prices, therefore, the resultant change in consumer surplus indicates the economic benefits from the innovation that accrue to the consumers. Producer surplus, on the other hand, measures the benefit to producers when they sell goods at prices higher than the minimum they would have been willing to accept.

Diminishing Benefits—Weed Resistance to Glyphosate

Almost 20 years after the introduction of RR soybeans, the value of this herbicide tolerance has begun to diminish in some parts of the world due to the gradually increasing presence of weed biotypes resistant to glyphosate. Herbicide resistant weeds are not a new phenomenon; plant scientists have been grappling with this issue for some time (Retzinger and Mallory-Smith 1997). At last count, 443 species of weeds have biotypes that have become resistant to members of 22 different herbicide groups. Glyphosate has fared better than some; to date glyphosate resistant biotypes have been reported in 31 species worldwide (Heap 2015). Weed resistance to glyphosate, however, is a significant problem due to glyphosate's status as the most widely used herbicide in the world, and one that does not have a ready replacement that is as effective, economical, and safe (Duke and Powles 2009).

In the US, farmers have noticed a decline in the effectiveness of glyphosate due to weed resistance on 44 % of the planted area. On those fields where weed resistance exists, expenditures on agricultural chemicals have increased by nearly $48/ha as farmers attempt to effectively control weeds and minimize yield losses (NASS 2012). Costs in other producing countries are comparable. Although detailed numbers on the share of acres are not readily available, herbicide resistant weeds have been found in all areas of Argentina. For fields with resistant weeds, increases in herbicide expenditures have been estimated to range from $18/ha to $121/ha as compared to fields without resistant weeds. Gross profits on farms with resistant weeds were, on average, $81/ha lower than those without, while growers in some areas registered net economic losses due to increased weed control costs.[3] In the case of Brazil, it has been estimated that in the Rio Grande do Sul region some 50 % of the soybean area had populations of *Conyza* spp. (horseweed) and *Lolium multiflorum* (ryegrass) resistant to glyphosate. Some earlier estimates found that in 2010 4.3, 1.4 and 0.1 million soybean hectares across the country had populations of glyphosate-resistance *Conyza* spp., *L. multiflorum* and *Digitaria insularis* (sourgrass), respectively (Kleffmann Group 2010). Potential yield losses are estimated at up to 44 % (Cerdeira et al. 2010), and farmers have reported average increased costs of $35/ha for weed control.

New soybean traits that provide expanded herbicide tolerance are expected to be important for managing weed resistance in the future. Glyphosate resistance developed primarily where intensive and exclusive use of glyphosate has been the norm for growers (Foresman and Glasgow 2008; Powles 2008). Studies suggest that the key to managing resistance and preserving glyphosate as a viable weed

[3]Similar incremental costs have been estimated in "Economic Impact of Weed Resistance in Argentina". Ing. Sebastián Senesi, Food and Agribusiness Program.UBA. FAUBA where the total incremental cost of weed control has been calculated at $1.3 billion (REM 2014).

control alternative in the future lies in restoring diversity to farmers' weed management strategies (Duke and Powles 2009; Owen 2011). Diversity could expand by using multiple herbicides with different modes of action, preventing weeds from becoming resistant to any one of them (Dill et al. 2008; Owen 2008; Powles 2008; Beckie 2011). Using multiple herbicides, especially if they are applied post-emergence, could be facilitated by crops that are resistant to multiple herbicidal modes of action.

The bulk of the new biotech soybean products that have been recently released or are in the pipeline feature stacked events, combinations of both established and newly developed herbicide tolerance traits. Since 2013, nine new events have been approved for production in the US and Canada and for use in a variety of other countries; six of these are stacked herbicide tolerance traits. None of these traits have yet been approved in China (some have not been submitted yet due to China's approval policies, described below) and only one has been approved for import into the EU.[4] Several more stacked HT trait varieties are in the pipeline and expected to be ready for approval in the next 5–10 years.[5] It is broadly anticipated that stacked HT traits complementary to multiple herbicide modes of action will be an important ingredient in integrated weed management systems in the coming years. Even if some portion of a local weed population contains genes conferring resistance to a particular herbicide, these genes cannot be passed on to future generations if the plants are killed by another mode of action herbicide. Crops with stacked HT traits allow farmers to use a suite of herbicides to attain better weed control. More complete weed suppression is an important tool in limiting the development of resistant weeds by limiting the breeding population.

Regulatory Approval Delays and Asynchrony

In order for these new soybean biotech traits to enter the market they must first gain regulatory approval in countries where they might be produced or marketed. This approval process can slow down commercialization in two ways.

[4]Dow AgroSciences has received cultivation approval for its Enlist™ soybeans, resistant to glufosinate and 2,4-D, and also Enlist E3™ soybeans, developed in cooperation with MS Technologies, resistant to glyphosate, glufosinate, and 2,4-D. Bayer CropScience, is similarly in the process of commercializing its Balance™ GT soybeans, resistant to glyphosate and isoxaflutole. Monsanto has gained North American approvals for its Genuity RR2 Xtend™ trait, resistant to glyphosate and dicamba. Finally, Bayer CropScience and Syngenta is releasing a soybean variety resistant to mesotrione and glufosinate (ISAAA 2015).

[5]A new soybean variety from Bayer CropScience and Syngenta, resistant to mesotrione, glufosinate, and isoxaflutole, is currently undergoing regulatory review in the US, Canada, and the EU. These two firms are also developing a cultivar resistant to glyphosate, glufosinate, and HPPD (4-Hydroxyphenyl Pyruvate Dioxygenase) inhibitors. BASF is developing an imidazoline tolerant form of its Cultivance soybean in cooperation with Brazilian researchers (Context Network 2014).

First, the length of time to gain approval has been becoming longer in many jurisdictions. Regulatory approvals for new biotech events took an average of 13.6 months in the US in the mid-2000s (Jaffe 2005). Events approved in 2014 and 2015, on the other hand, were pending for an average of 28.3 months (USDA 2015a).[6] In some other countries approvals can take much longer. In the EU, for example, the European Commission has approved only nine new biotech events since the beginning of 2010 (ISAAA 2015). The backlog of applications in the EU has been steadily growing; there are now 18 events awaiting approval, with an average pendency of over 6 years. Over 2004–2011, the average pendency time was 45 months (USDA 2014b; EuropaBio 2015). Such delays not only slow down new product introductions in the global markets but also affect the flow of biotech innovations submitted for consideration to the EU regulatory authorities. The decision of BASF to withdraw three varieties of GM potatoes from the EU approval process in 2013, one of which was in the final stages, is but one example. The company cited expense and uncertainty as the reasons for the decision (James 2013). Approval delays are increasing in some smaller countries as well; in South Korea, pendency time has nearly doubled since 2009 (Kalaitzandonakes et al. 2015).

Second, some countries' policies lengthen the overall process by putting restrictions on when applications can be submitted. The government of China, for example, requires that proof of approval for use and sale in the exporting country be submitted as part of the application for import approval in China. By delaying the submission date, China significantly extends the total time required for the approval of new biotech traits. The ensuing approval process involves several government agencies at both the federal and provincial level, and requires further field tests and animal feeding studies. The process has traditionally taken around 2 years, but, as in the other countries described above, has become significantly slower recently (USDA 2014a).

Because of slower or asynchronous national approvals, some new biotech crops may be produced in exporting countries before they are approved for use in all importing countries. This situation, especially when combined with a zero-tolerance policy for unapproved events, has the potential to cause international trade disruptions. For example, in 2007 low levels of Herculex maize, approved in the US but not the EU, were found in the commodity maize supply chain in spite of segregation efforts by producers and importers. As a result, EU imports of US maize gluten feed and distiller's dried grains dropped to nearly zero and stayed there for an extended time (Kalaitzandonakes 2011). This incident may have cost

[6]Own calculations, based on the most recent receipt date of the petition and the final decision date. Many petitions were initially submitted earlier and revised multiple times. Calculations using the initial petition date would result in even longer average pendency.

EU livestock producers as much as €1.6 billion in 2007/2008 (Stein and Rodríguez-Cerezo 2010). In 2014, China rejected over one million tons of maize and maize products due to detection of the biotech event MIR162, approved in the US in 2010 but not in China until December of 2014. Industry analysts estimated the losses from this trade disruption in the hundreds of millions of dollars (USDA 2014a). Such potential losses affect the cost of both producers and biotech innovators. In an attempt to avoid trade disruptions and the associated revenue losses, biotech firms have self-regulated by adopting a policy not to release a new biotech trait to farmers until it has been approved for use in major markets with functioning regulatory systems (Crop Life International 2015) (e.g. Monsanto 2013; Dow AgroSciences 2014; Syngenta 2014). There is a tradeoff here, though. In the end, avoiding the trade disruption often means that it is that much longer before farmers and consumers enjoy the benefits of new biotech varieties.

Estimated Costs of Delayed Adoption

The societal economic benefits from innovation can be measured as the increase in consumer and producer surpluses generated in the market, compared to what was the next best alternative before the innovation was introduced. As innovations decrease production costs or increase product quality, supply and demand relationships change. Such changes are manifested in the market as differences in the quantities sold and the market prices paid. Producers who adopt the new technologies benefit as lower costs and increasing supplies can lead to increased income. Consumers benefit as they get more for their money when price decreases and/or quality increases (Just et al. 2004). Regulatory delays mean that both groups see these benefits later than they otherwise would have, and most likely at lower levels. The forgone producer and consumer benefits constitute the most immediate costs of regulatory delays on innovation.

Estimating the foregone benefits from delayed innovation is less than straightforward and requires a proper counterfactual. For that purpose, both the economic value of the realized innovation path and the economic value of the innovation path that would have been realized but for the regulatory delay must be calculated. These are generally unobservable and as such they must be estimated through economic modeling techniques.

A few previous studies that have estimated the opportunity costs of regulatory delays, in terms of foregone economic benefits of biotech innovations, have used a variety of analytical methods to approach that task. Most of these studies are backward looking, attempting to discover the difference between an actual past course of events and an unknown counterfactual. Pray et al. (2005) investigated the impact of partial regulatory delays on the introduction of certain Bt cotton varieties

in India. They compared the production and income results of Bt cotton growers with those farmers' experience prior to adopting Bt cotton and with the current experiences of non-adopting farmers to estimate the implied regulatory costs of delayed introduction Bt cotton in India. They found that, in total, Indian cotton farmers were deprived of some $70 million in total income for in the 2004/05 crop year alone because the specific Bt cotton varieties were not approved in a timely fashion. Wesseler et al. (2007) developed a cost-benefit analysis framework for this type of study. They calculated a potential increase of €87/ha–€135/ha in annual gross profit for farmers in France had Bt maize been approved there. They estimated that France experienced total foregone net benefits of €310 million over a five-year period as a result of not approving this crop for cultivation. Demont et al. (2004), and Kikulwe et al. (2008) also used that framework to estimate foregone benefits in years prior to the approval of biotech sugar beets and bananas, respectively. Demont et al. (2004) estimated that not approving biotech sugar beets has cost EU farmers €199/ha annually in lost income, and that the EU as a whole has foregone total benefits of €169 million each year. Kikulwe et al. (2008) calculated total foregone benefits of $179 million–$365 million for each year of regulatory delay of adoption of biotech bananas in Uganda. Most of this cost was borne by farmers in the form of lost income. Finally, Wesseler and Zilberman (2014) used a health accounting framework to estimate disability-adjusted life years (DALYs) that could have been saved by introducing Golden Rice in India and thereby avoiding cases of vitamin A deficiency that actually occurred. By assigning an accepted value to each DALY they were able to estimate that India had lost out on benefits of at least $199 million per year in improvements in health by not approving beta-carotene containing Golden Rice in 2002.

This study differs in that it is forward looking. That is, we wish to estimate the difference between two possible future economic paths—one where new varieties of biotech soybeans are approved at a "normal pace" in import markets, versus one where regulatory approvals and commercial introduction are delayed. Thus both possible paths lie in the future and are unobservable; both must be estimated. This is a task similar to a study concerning the indirect costs of regulatory compliance in the Philippines. Using an augmented economic surplus model, researchers estimated that each year of regulatory delay in the Philippines decreased the net present value of future farm income from biotech crops by 12–36 %, depending on the specific crop (Bayer et al. 2010).

In this study we are interested in the potential economic costs of regulatory delays of HT soybean biotechnologies currently in the pipeline. Our investigation is grounded in the real world concern with possible farmer responses to weed resistance to glyphosate. The current standard program of exclusive and intensive use of glyphosate has become insufficient in some production areas. As a result, some farmers are currently incurring elevated costs for weed control. Alternative control methods at their disposal include additional crop rotations, a return to selective

herbicides, and/or increased tillage, all of which have added operational and capital costs (Mueller et al. 2005; Beckie 2011; Edwards et al. 2014). Different combinations of these tactics can be effective under different conditions, resulting in a broad range of costs of weed management when the RR system must be augmented.

When the new HT varieties described above are approved for cultivation and export and can be deployed commercially, they could enhance the options available to farmers for managing weeds at lower cost, primarily with multiple herbicides supplemented with other methods as needed. If the new HT varieties are delayed in reaching producers, it would at least entail a continuation of current increased costs of managing resistant weeds where they occur. In addition, weed resistance to glyphosate may expand beyond its current levels, which would increase weed management costs in the future to deal with a larger problem. The continuation of these increased costs constitute the cost of delayed introduction of the new varieties. On this basis we will be examining the economic implications of a normal versus a slower commercialization and adoption of new HT soybean varieties.

Model Structure and Scenario Development

In this study we use a global partial equilibrium model previously developed and validated by Alston et al. (2014). The model simulates global agricultural markets for various oilseeds, substitute and complement crops, and livestock production for all major producing and consuming countries. We specify separate supply and demand functions for all oilseed crops and the meal and oil products produced from them in different countries and regions, including the major producing countries (US, Brazil, and Argentina), the major importers (the EU and China), and other significant players in international agriculture markets such as India, South Korea, Japan, Canada, Mexico, and others. The equations below are used to calculate the market clearing supply and demand conditions for each specific commodity in each country or region. The country- and region-specific prices generated by supply and demand conditions are all interconnected via price linkage equations that include tariffs, taxes, and other relevant factors.

$$Beginning\ Stocks_t = Ending\ Stocks_{t-1}\ (Oilseeds, Meals, Oils) \tag{1}$$

$$Production = Harvested\ Area * Yield\ (Oilseeds) \tag{2}$$

$$Production = Crush * Crushing\ Yield\ (Meals, Oils) \tag{3}$$

$$Total\ Supply = Beginning\ Stocks + Production + Imports\ (Oilseeds, Meals, Oils) \tag{4}$$

$$\begin{aligned} Total\,Demand = {} & Crush + Food\,Use + Other\,Use + Exports \\ & + Ending\,Stocks\,(Oilseeds) \end{aligned} \tag{5}$$

$$\begin{aligned} Total\,Demand = {} & Food\,Use + Feed\,Use + Industrial\,Use \\ & + Ending\,Stocks\,(Meals, Oils) \end{aligned} \tag{6}$$

$$Domestic\,Use = Crush + Food\,Use + Other\,Use + Ending\,Stocks\,(Oilseeds) \tag{7}$$

$$\begin{aligned} Domestic\,Use = {} & Food\,Use + Feed\,Use + Industrial\,Use \\ & + Ending\,Stocks\,(Meals, Oils) \end{aligned} \tag{8}$$

Our model provides forecasts over a 10-year period for all relevant commodities and markets and is calibrated by ensuring that the baseline simulation accurately reproduces historical market conditions, particularly supply, demand, stocks, hectarage, prices, trade and other relevant variables, across commodities and geographies. Our analysis involves evaluation of alternative future adoption paths of new HT soybean varieties during the period 2015–2025. The model baseline represents the global agricultural sector over the same 10 year period and assumes no adoption of new HT soybeans. In this way, the economic impacts from the adoption of these innovations can be evaluated by comparing the scenarios, where normal or delayed adoption occurs, against the baseline, where no adoption occurs.

The impacts of regulatory delays on new HT soybean biotechnologies are modeled as a continuation of the production costs presently incurred by farmers, some of whom must manage weeds without the benefit of RR or new HT soybean varieties. Potential cost savings from using the new HT soybean varieties are then estimated as the difference between reported actual costs currently being incurred by farmers in the US, Brazil, and Argentina in managing glyphosate resistant weeds and weed control costs when no such resistance is encountered (NASS 2012; REM 2014). Based on such figures we use an average cost savings of $44.50/ha in all our calculations when the new HT technologies are used.

In our scenarios, the normal adoption path of new HT traits is based on historical patterns of adoption of HT varieties in the North and South America as well as future expected pipeline releases. Regulatory delays cause a deferral of the normal adoption path but the rate of adoption after the delay remains similar. After calculating the projected market outcomes from the introduction and adoption of HT soybean varieties, in terms of prices and quantities supplied and demanded, we can then determine the difference in consumer and producer surplus between each scenario outcome and the baseline. The surplus changes are specified as follows:

$$\Delta PS_{R,S} = P_0 Q_0 (K - Z)(1 + 0.5 Z \varepsilon_s) \tag{9}$$

$$\Delta PS_{R,O} = -P_0 Q_0 Z (1 + 0.5 Z \varepsilon_o) \tag{10}$$

$$\Delta CS_{R,O} = (P_0 - P_1)C_0 + 0.5(C_1 - C_0)(P_0 - P_1) \quad (11)$$

where ΔPS is the difference in producer surplus, ΔCS is the difference in consumer surplus, the subscript R denotes a particular country or region, the subscript S denotes soybeans, and the subscript O denotes all other crops in the model. P_0 is a baseline price and P_1 is a scenario price. In parallel fashion C_0 and Q_0 are baseline quantities demanded and supplied, respectively, and C_1 and Q_1 are scenario quantities demanded and supplied. Our model estimates all these market effects.

Our scenarios model the adoption of new HT soybean varieties in two different time frames. We will compare timely approvals and normal pace of commercialization and adoption of the new HT soybean varieties (scenario 1) and regulatory delays and asynchrony in major importing countries that lead to a three-year delay in commercialization and adoption of such varieties (scenario 2). When farmers are able to adopt the new HT varieties they realize $44.50/ha savings in variable costs. Adoption paths in both scenarios are such that 80 % of hectarage is planted with HT soybean varieties, both new and traditional RR, within 10 years from their commercial introduction and adoption remains at that level thereafter.[7] The adoption paths in the US, Brazil and Argentina assumed here are therefore more conservative than those historically observed for RR soybeans in these countries. Given these scenarios, we can evaluate the economic implications of regulatory delays by comparing the economic impacts of a normal adoption path (scenario 1) against those of a slower adoption path (scenario 2).

Results

In our scenarios we examine the economic impacts of new varieties of HT soybeans on projected grain markets. In the first phase, scenario 1, as commercial introduction and adoption of new HT soybean varieties progress at a normal pace, farmers realize reductions in weed management costs and the associated efficiency gains in their production systems. Cost efficiency gains result in expansion of soybean hectarage and supplies among adopting producers, with the expected results. As Fig. 1 shows, production volume in the three major soybean producing countries, Argentina, Brazil, and the USA, increases steadily, with the net increase standing at over 850,000 metric tons more than in the baseline case by 2025. Importing countries share in the greater availability of soybean products, as our model indicates that exports from these three countries increase along with production.

[7]The adoption level of 80 % as well as the cost savings are generally considered conservative and are maintained as such by design. For instance, adoption of herbicide tolerant soybeans in most countries has exceeded 95 % of hectarage.

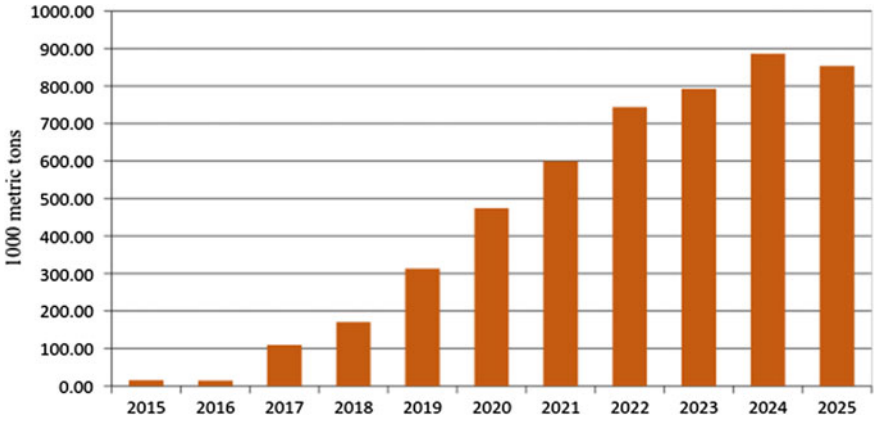

Fig. 1 Change in production—ARG, BRA, & USA

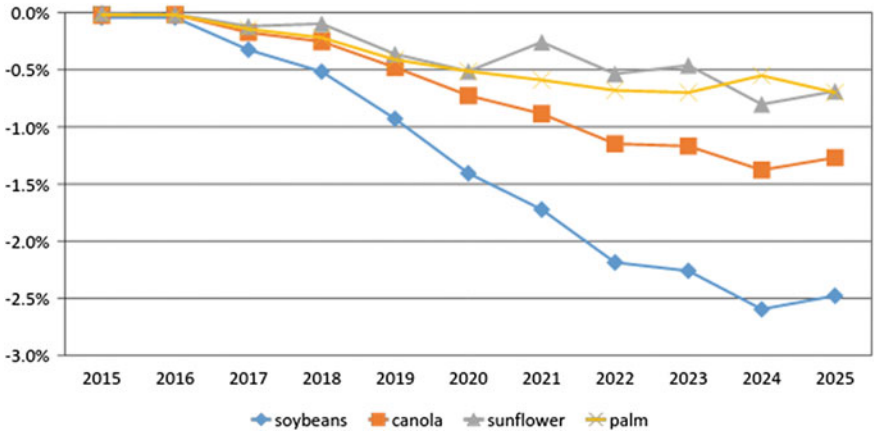

Fig. 2 Oilseed price changes

The increase in supply of soybean products leads to a decrease in market prices not only for soybeans but for other oilseeds as well, as they are substitute products. Figure 2 illustrates the soybean price declines gradually as cost efficiencies expand across greater hectarage until it is 2.5 % lower than the baseline case by 2025. As soybeans become cheaper relative to other oilseeds, overall demand shifts away from other oilseeds in favor of soybeans. With the lower demand, prices of other oilseeds decline as well (Fig. 2). The lower prices benefit consumers of all oilseed products, especially consumers of soybean products. Producers lose on a per unit basis from lower prices, but the increase in production efficiency and higher volume

Table 1 Change in producer and consumer surplus from adoption of HT technologies—2015–2025 (in $million)

Scenario 1—Normal adoption path										
	Soybeans		Rapeseed		Sunflower		Palm oil		Total PS	Total CS
	PS	CS	PS	CS	PS	CS	PS	CS		
United States	9749	2885	(35)	59	(27)	23	–	31	9687	2998
Argentina	4567	2899	–	–	(71)	57	–	–	4496	2957
Brazil	10,894	2683	–	–	(4)	4	(10)	13	10,880	2701
European Union—28	(81)	721	(718)	794	(184)	175	–	153	(982)	1842
Ukraine	(245)	106	(60)	4	(216)	212	–	–	(521)	322
China	(629)	5515	(470)	550	(49)	45	–	186	(1148)	6296
Japan	(9)	161	0	75	–	–	–	15	(9)	251
India	(698)	690	(234)	234	(15)	15	(1)	259	(948)	1198
Indonesia	(30)	165	–	–	–	–	(923)	307	(953)	472
Thailand	(3)	104	–	–	–	–	(58)	43	(62)	147
Vietnam	(14)	100	–	–	–	–	–	17	(14)	117
Egypt	(1)	101	–	–	0	2	–	31	(1)	133
World	22,066	17,598	(2206)	2180	(867)	857	(1664)	1499	17,329	22,134

more than make up for the decline for those who adopt the new HT varieties. Producers in countries where they are restricted from adopting biotech soybeans are faced with lower selling prices and much more limited options on controlling costs and as a result experience an overall decline in profitability and welfare.

The introduction of new HT soybean varieties as described in Scenario 1 generates almost $40 billion in economic value in worldwide soybean markets in 2015–2025. Of the total net welfare gains resulting from this innovation path, producers capture approximately 56 % ($22.06 billion) and consumers 44 % ($17.59 billion). Producers in large adopting and exporting countries (the US, Brazil, Argentina) and consumers in large importing countries (China, the EU) benefit the most. Table 1 outlines the changes in producer and consumer surpluses (in $ million) from the changes in market prices and quantities brought about in scenario 1, relative to the baseline case. Across all oilseed markets, lower prices cause consumer surpluses to increase even more and producer surplus to decrease, as producers face lower prices with no change in production costs. Overall, consumers claim the greater share of benefits from the timely introduction of new HT soybeans, as total consumer surplus increases by $22.1 (56 % of total surplus created).

If regulatory approvals are delayed, as in scenario 2, the benefits described above accrue to producers and consumers at a later time and at lower levels. In this scenario, commercialization is delayed by 3 years, so the adoption process begins later. The market effects of adoption follow a substantially similar, although not

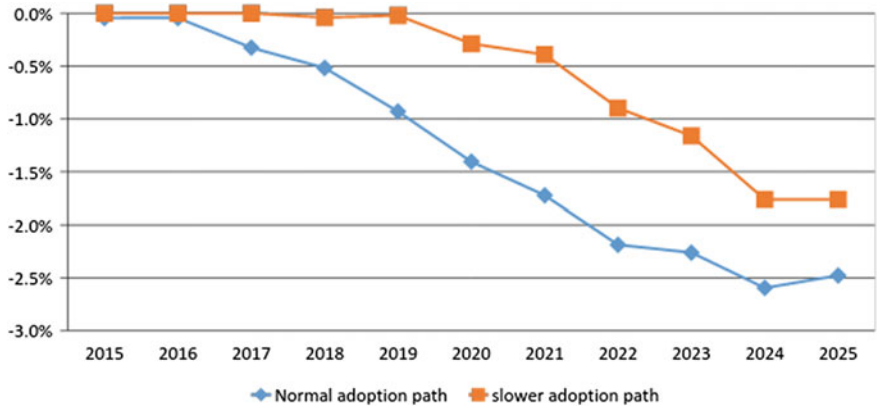

Fig. 3 Soybean price changes from baseline, normal vs. slower adoption path

Table 2 Change in producer and consumer surplus from adoption path of HT technologies—2015–2025 (in $million)

Scenario 2—Slower adoption path										
	Soybeans		Rapeseed		Sunflower		Palm oil		Total PS	Total CS
	PS	CS	PS	CS	PS	CS	PS	CS		
United States	5356	1271	(15)	27	(11)	9	–	(2)	5330	1306
Argentina	2661	1293	–	–	(30)	24	–	–	2631	1317
Brazil	6342	1205	–	–	(2)	2	1	(1)	6341	1206
European Union —28	(36)	315	(323)	358	(76)	73	–	(7)	(435)	739
Ukraine	(111)	47	(27)	2	(90)	89	–	–	(229)	138
China	(277)	2472	(212)	247	(20)	19	–	(10)	(510)	2727
Japan	(4)	70	(0)	33	–	–	–	(1)	(4)	103
India	(312)	309	(106)	106	(6)	6	–	(13)	(425)	408
Indonesia	(13)	73	–	–	–	–	49	(16)	36	57
Thailand	(1)	46	–	–	–	–	3	(2)	1	44
Vietnam	(6)	44	–	–	–	–	–	(1)	(6)	43
Egypt	(0)	44	–	–	(0)	1	–	(2)	(1)	43
World	12,959	7837	(995)	983	(362)	358	86	(78)	11,688	9100

identical, path as in scenario 1 after the late start. As a result, cost savings and market effects (e.g. production increases, prices changes) realized are smaller. As illustrated in Fig. 3, by 2025 soybean prices under scenario 2 drop by 1.8 %, compared to the baseline, rather than the 2.5 % we saw in scenario 1. The smaller price change limits the economic benefits to both producers and consumers. Producer and consumer surpluses shown in Table 2 are about half of those shown earlier for

Table 3 Cost of slower innovation—Scenario 1–Scenario 2—2015–2025 (in $million)

	Soybeans		Rapeseed		Sunflower		Palm oil		Total PS	Total CS
	PS	CS	PS	CS	PS	CS	PS	CS		
United States	4393	1614	(19)	33	(16)	13	–	33	4358	1692
Argentina	1906	1606	–	–	(41)	34	–	–	1865	1639
Brazil	4552	1478	–	–	(3)	3	(10)	14	4539	1495
European Union—28	(45)	406	(395)	436	(108)	102	–	160	(547)	1103
Ukraine	(135)	59	(33)	2	(125)	123	–	–	(293)	184
China	(351)	3043	(258)	303	(29)	27	–	196	(638)	3568
Japan	(5)	90	(0)	41	–	–	–	16	(5)	148
India	(385)	381	(128)	128	(9)	9	(1)	272	(524)	790
Indonesia	(17)	91	–	–	–	–	(972)	323	(989)	415
Thailand	(2)	59	–	–	–	–	(61)	45	(63)	104
Vietnam	(8)	56	–	–	–	–	–	18	(8)	74
Egypt	(1)	57	–	–	(0)	1	–	33	(1)	90
World	9107	9761	(1211)	1197	(505)	499	(1750)	1577	5641	13,034

the case of timely approvals and normal adoption paths. Worldwide, the economic impact of the slower adoption of new HT soybean varieties is almost $21 billion. The distribution of economic gains in the world soybean market is also slightly more skewed in favor of farmers; the producers' share is about 62 % ($12.9 billion) while consumers' share is 38 % ($7.8 billion). The overall economic gains from the new HT soybean varieties are about half of those realized in scenario 1. The share of total surplus claimed by farmers is slightly less at 56 % ($11.7 billion), but this is a dramatic change from scenario 1, where consumers experienced the greater overall benefit.

While the welfare gains in scenario 2 are far from trivial, they are significantly less than those in scenario 1. We can define the cost of regulatory delay as the difference between these two estimates of producer and consumer surplus—roughly $19 billion worldwide for the 2015–2025 period. Table 3 shows the distribution of such costs. Both producers in large exporting countries (US, Argentina, Brazil) and consumers in large importing ones (China) incur the largest losses from the slower introduction of new HT soybean varieties. In the global soybean market producers and consumers share the cost of delay nearly equally. Across all oilseed markets, however, consumers bear more than twice as large a burden as producers. The difference in total consumer surplus is $13 billion, 70 % of the total cost of regulatory delay.

Conclusion

In this study we have analyzed the economic impact of a delay in the commercialization and adoption of new soybean technologies caused by regulatory delays. Our results demonstrate how the national regulatory decisions of importing countries can be transmitted through trade networks and affect global markets. Regulatory Regulatory decisions in different countries are a significant consideration in decisions by biotech firms regarding the commercialization of new crop varieties. While commercialization of new biotech crops may be delayed in order to avoid the costs of trade disruptions due to the presence of unapproved varieties in international commodity shipments, such delays also incur opportunity costs, which we have attempted to quantify here.

Our model was built around the current issue of weed resistance to weed resistance, the most widely used herbicide in the world. New varieties of herbicide tolerant soybeans, designed to enable famers to continue to effectively manage weeds at reasonable cost, are approaching commercialization. In our scenarios these biotech innovations have been assumed to enter the market with a 3 years lag due to regulatory delays and asynchronies across key importing countries. Such regulatory delays are in line with those experienced over the last decade. We find that when these new soybeans are approved and commercialized in a timely fashion the economic benefits from their adoption are large—$40 billion for the 10 years period we analyzed—and all market participants benefit, including both producers and consumers. If the new traits are delayed in reaching the market, however, not only are the economic benefits reduced significantly but their distribution is changed as well. Consumers lose a disproportionate share of the welfare gains from innovation as the commercialization of the new soybean varieties is delayed.

It is important to note here that we are not able to measure the economic impacts of all possible outcomes due to regulatory delays of new HT soybean varieties. We have not considered the environmental impacts of cropping systems and practices that may be used when new HT soybean varieties are not available. Biotech HT crops have been designed around herbicides that control weeds with less machinery use, less energy use, and less tillage. In the absence of such crop-herbicide systems, some soybean growers may need to resort to weed control methods with greater environmental impact, including increased fossil fuel consumption and soil erosion. We have also restricted our analysis to the soybean market; other crops traded on world markets, notably maize, canola, and cotton, have also experienced systematic regulatory delays and asynchronous approvals in recent years and may do so in the future. Delays in the introduction and adoption of new technologies in these crops could greatly increase the global welfare costs of delays and asynchrony in the biotechnology regulatory process. There are also the unseen, long-term effects of the overall slowdown in research and development due to the cost of the approval process, in terms of both money and time. These include further delays in innovation and products that are delayed or never developed, as well as firms that are

never started and jobs never created. The costs are nearly impossible to quantify but are nonetheless real.

The social welfare changes estimated here also have important implications for food security, especially in lower income countries. Food security is sometimes thought of only in terms of the availability of a sufficient quantity of food, but nutritional content is just as important. In particular, access to protein of sufficient quality and quantity, including animal protein, is a critical component of a comprehensive definition of food security (FAO et al. 2014). A reliable, economical supply stream of livestock feed is crucial to providing consumers worldwide with affordable, quality protein-based foods. Thus significant regulatory delays resulting in asynchronous approvals can not only impact farmers and seed developers, but also restrict consumer access to adequate nutrition. This is a potentially fruitful topic for future research.

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Potential Economic Impacts of Low Level Presence (LLP) in the Global Wheat Market

William W. Wilson and Bruce Dahl

Introduction

Development of genetically modified (GM) crops has begun and is continuing on numerous fronts and in several countries. Wheat will be one of the first food grains where GM traits are introduced and will likely be a precursor to similar developments for other food grains. GM wheat is currently being developed in a number of countries (e.g., United States, Australia, United Kingdom, China) and by a number of companies (e.g., Monsanto, Bayer Crop Science, Dow Agrosciences, and Limagrain, in addition to several research organizations, including the University of Adelaide, CSIRO, and Victoria Agribiosciences Center—now AgriBio and in the United Kingdom). Traits under development using GM techniques include fusarium resistance (Huso and Wilson 2005; Tollefson 2011; Valliyodan and Nguyen 2006), drought resistance, and protein quality. Indeed, much of the groundwork in GM wheat development is emerging from Australia and setting the stage for development in other countries.

Since the late 2000s, all major agbiotechnology companies have made announcements indicating intentions to enter the GM wheat market, and there have been field trials by a number of companies in the United States during 2011–2013 and in Australia for 4 years. The most common traits being pursued include yield enhancement, drought tolerance (DT), and nitrogen-use efficiency.

The purpose of this chapter is to describe the new wheat partnerships that are forming and the challenges related to LLP that will be confronted as GM wheats are introduced. The first section below describes the reinvigoration of research on

W.W. Wilson (✉) · B. Dahl
North Dakota State University, Fargo, USA
e-mail: william.wilson@ndsu.edu

B. Dahl
e-mail: bruce.dahl@ndsu.edu

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developing new technologies for wheat. Most of these are in the form of partnerships between germplasm providers and technology companies. The second section summarizes the existing literature on models for coexistence of GM and non-GM wheat. The third section highlights recent issues that are emerging in wheat and the final section provides an analysis of issues related to LLP in wheat.

New Technology Initiatives in Wheat

Wheat has been losing its competitiveness relative to other crops, particularly those with GM technology, notably corn, soybeans, cotton, and canola (Wilson et al. 2003; Sosland 2012; Wilson 2008). While this is commonly recognized in North America, it is becoming more apparent in other countries.[1] The effect of this has been to induce most if not all the major technology companies to expand in recent years into technology development in wheat.

Wheat Research Partnerships

In the period prior to 2004 there were several firms working on GM wheat. Monsanto was working on commercializing Round-up Ready wheat (RRW), and Syngenta was working on fusarium resistant wheat (FRW). The development of RRW was technically feasible and ultimately was approved by the US Food and Drug Administration (FDA). However, there were numerous pressures against GM wheat which were apparent at that time. Notably these were issues related to Japanese importers and their resistance to GM wheat and positions taken by the Canadian Wheat Board, among others. In addition, it is important that GM wheat at that time would have to compete for acres with GM soybeans and canola. These were much more profitable at that time and had less consumer and agropolitical resistance. In response to these pressures, Monsanto chose not to commercialize RRW in mid-2005.

After suspending their commercialization efforts on Roundup Ready wheat, Monsanto was the first company to announce its re-entry into GM wheat research in 2009. This followed a period of time which included tightening of supply/demand fundamentals for most crops, and the further proliferation of GM technologies in other competing crops, notably soybean, canola and corn. It also followed a period in 2008 during which, due to crop shortages, wheat prices escalated very sharply.

[1]A recent workshop addressed similar problems in the European Union (Vigani et al. 2013). The concerns were about declining rate of productivity growth, prospects of climate change and they pointed to the decline in the wheat yield growth rate, especially in France, Germany and the UK.

Concurrent with that were efforts to provide agropoltical support for development of GM wheat in the United States, as well as other countries, including both producer groups and end-users. These ultimately provided further support to Monsanto about the potential for both broader based agropoltical support and demand for the technology.

Monsanto's re-entry was followed, within months, by announcements from BASF, Bayer Crops Sciences (BCS), Limagrain, and Dow (DAS).[2] Work on GM wheat had been initiated earlier in Australia by Victoria Agribiosciences Center (VABC, now AgriBio) and Commonwealth Scientific and Industrial Research Organization (CSIRO). Indeed, much of the initial and early work was done in Australia where the primary focus was on drought and, more recently, frost tolerance. These projects were in addition to nearly simultaneous development initiatives for GM wheat in China (Xia et al. 2012). Finally, GM wheat is also being developed in the United Kingdom with field trials during 2012.

In the case of wheat, which contrasts with other crops in which GM has been adopted, most of the germplasm that exists is in the public sector. While this varies around the world, and is still evolving, it important that (1) in the United States, most breeding programs have been public; (2) the Australian breeding system has recently evolved from largely public to largely private; and (3) pressures are emerging for finding varying ways of privatizing wheat breeding in Canada. The publicness of wheat breeding is important from a germplasm ownership perspective. In addition, in wheat there is a high degree of heterogeneity in quality, disease, and agronomic suitability which varies geographically. For all these reasons, a major challenge in developing new technology in wheat is access to germplasm.

As a result of these differences, most of the technology companies have approached development in the case of wheat through various forms of partnerships. A summary of these are shown in Fig. 1. Each of the companies has entered via combinations of germplasm acquisitions (e.g., Westbred by Monsanto), technology investments (e.g., Evogene by BCS), research partnerships (e.g., DAS and DEPI); and germplasm partnerships (e.g., Monsanto, BCS, DAS). These technology partnerships are in addition to those focused on hybrid development (e.g., Syngenta, DuPont). Ultimately, these partnerships and investments will result in substantial investment in new technology for wheat and, once development begins to evolve, substantial pressures for developing channels for commercialization.

Traits Under Development

Several technologies exist for improving wheat, including conventional breeding, marker-assisted-selection (MAS), gene-editing and genetic modification (GM). These

[2]The DAS announcements are available at: Business Wire (2013, 8 April) and Dow AgroSciences (2013). Retrieved 16 April 2013, from http://www.exzactprecisiontechnology.com/why/.

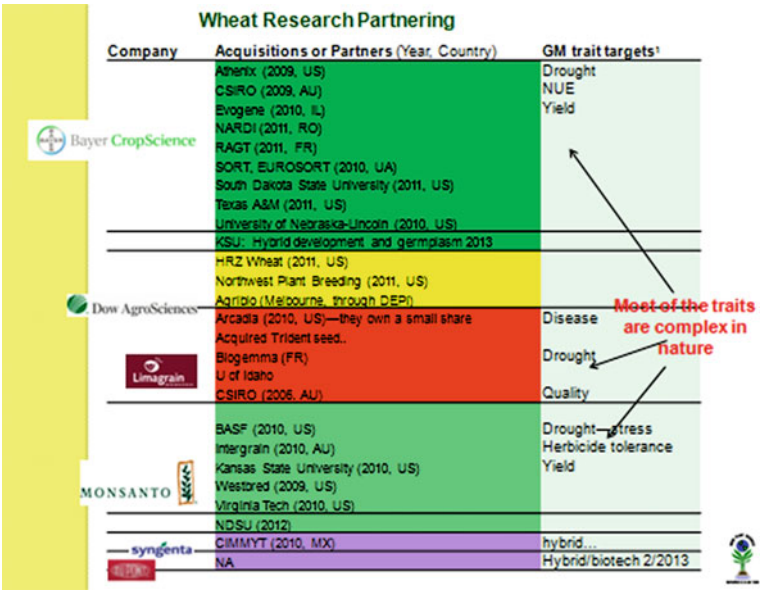

Fig. 1 Recent wheat research partnerships

are in addition to other advanced technologies [e.g., Apomixis, EXZACT™ as being used by Dow AgroSciences (2013)] being applied to wheat. Integrating these breeding technologies (conventional, MAS, gene-editing, and GM) has brought about a paradigm shift in crop development that is referred to as "seeds and traits." This is now a business function that combines novel genetic traits with elite germplasm to develop crops that thrive while expressing the desired trait. The steps include discovering novel genes; transferring them into plant cells; optimizing the genetic trait's expression in the correct plant tissues, at the appropriate time, and in sufficient levels; and incorporating the genetic trait, through breeding, into commercially viable varieties or hybrids. As a business strategy, the introduction of genetic traits using biotechnology neither reduces the importance of superior germplasm in the host plant nor replaces the need for plant science and breeding (Dow AgroSciences, n.d.; Kaehler 2006).

Each firm and organization has made claims about the traits it intends to develop, including yield, drought tolerance (DT), and nitrogen-use-efficiency (NUE). Most likely, these choices were a result of experiences with other crops, plant stress, and anticipated geographical production changes, in addition to concerns about future water availability and cost (Rice Today 2012; James 2011; Sindrich 2012).

Trait development strategy is fraught with randomness and extended periods of development, resulting in substantial risks. Typically, the trait pipeline is referred to as having phases ranging from proof of concept to regulatory approval. Each step is costly, takes several years, and has an uncertain outcome. Finally, revenue streams from trait development do not ensue until a period following regulatory approval, and they are random. GM commercialization also is impacted by regulations

regarding GM content, not only in the home country but by all major importing and exporting countries.

Drought tolerance (DT) is an example of a stress trait and has been described in numerous articles.[3] In the case of corn, DT has been a target for many years using non-GM techniques, and Mertens (2012) indicated that "research in the past decades has yielded plants that are much better at withstanding [drought] conditions…" Longer-term results indicate that "today's corn is three times more drought tolerant than varieties from the 1930s" (Mertens 2012). It is unclear the extent to which water efficiency can be improved using conventional or GM breeding techniques, or a combination of the two (Leber 2012). GM trait development for DT involves prospective genes being identified as activated by drought. The efficiency gain by the drought-resistant gene is realized when drought occurs and avoids any yield penalty that potentially could occur with non-drought activated genes in normal conditions. It is thought that "drought tolerant crops look to be one of the most promising upcoming biotech traits in the pipeline, providing the ability to produce 'more crop per drop' of water" (Fatka 2008).

Work with DT corn is more accelerated than other crops, including wheat (Rice Today 2012) and rice (Reyes 2009). Monsanto's GM DT corn was deregulated in 2011, and large-scale field trials were started. Early results were anecdotal but suggested efficiency gains. The 2012 field trials indicated that "corn farmers will lose one-quarter less of their crop than they did during the 1988 drought" (Mertens 2012). Results in Texas and Kansas illustrated up to a 6-bushel advantage over competitor hybrids (Monsanto 2012), and another observation in Indiana suggested "a significantly higher yield, by 30–50 bushels" (Leber 2012). A few studies have alluded to these issues. One pointed to the multiyear implications of drought and irrigation (Peck and Adams 2010) and Diaz indicated that "nearly half of all droughts in the U.S., for example, are multiyear events" (Diaz 1983).

GM wheat continues to be a focus of agricultural technology development in Australia. Since 2005, there have been 17 GM wheat products brought to field trial stage in Australia. Primarily two Australian organizations have relatively advanced GM wheat technologies with current field trials, specifically Agriculture Victoria at AgriBio and CSIRO. Current trials are evaluating a number of traits including abiotic stress (drought, heat, salt, aluminium); increased yield and yield stability; nitrogen use efficiency; altered grain composition and resistance to fungal disease.

A challenge in valuing GM traits is that development time is long, that it is highly risky as a result of uncertainties for numerous random variables, and that it is costly (Shakya et al. 2013; Wilson et al. 2015). Typically, trait development, including regulatory review, takes about 10+ years, costs about $100 million, and consists of a number of distinct phases. Estimates of these costs are difficult because they are ultimately firm-level activities and information is not always published. Goodman (2004) estimated that developing a GM trait costs $60 million and can

[3]As examples, see: Kesmodel (2012), The Economist online (2011), Tollefson (2011) and Wall Street Journal (2012).

take 15 years. Estimates for deregulation costs are in the $6–15 million range (Bradford et al. 2006; Just et al. 2006). A recent study (McDougall 2011) indicated that the average cost of GM trait development is $136 million and that it takes 13 years, although there is substantial variability for these estimates across firms and traits. Monsanto indicated that it will spend at least $150 million on its wheat initiative; this cost includes germplasm and breeding in addition to MAS and GM. These costs reflect what are commonly referred to as discovery, proof of concept, early and advanced product development, and the regulatory phase, although the labels for these functions vary across firms. Given these phases, costs and risks, the models by Shakya et al. (2013) and Wilson et al. (2015) provide a real options framework for valuing technology in GM corn and wheat respectively, at different stages of the product development process.[4]

Alternatives for Mitigating Risks in GM Wheat Marketing

In response to the anticipated commercialization of GM wheat in the mid-2000s, there were a number of studies that examined varying ways of facilitating coexistence in wheat marketing channels between GM and non-GM varieties. Generally, these studies sought to identify strategies that could be used to provide incentives and contractual relationships necessary to keep non-GM wheat segregated from GM wheat. A summary of some of these studies is described below.[5]

Methods of testing and tolerance for GM wheat were examined by Wilson and Dahl (2005, 2006) and Wilson et al. (2007, 2008b). Wilson and Dahl (2005) determined optimal strategies to induce segregation in the US marketing system for export. These studies represent work that sought contract/market based solutions to control GM contents; though close to LLP initiatives, discussed in Sect. "Alternatives for Mitigating Risks in GM Wheat Marketing", these are not the same. The models included risks of adventitious comingling at various stages in the marketing chain and determined optimal sampling and testing strategies to minimize disutility of additional system costs due to testing and rejection that can occur throughout the

[4]In addition to these, similar methodologies were used by Wynn (2014a, b, c, d) using of real options and Monte Carlo simulation to estimate the Australian market value of canola that had been genetically modified to be drought tolerant. The results showed the GM canola to be more profitable than conventional canola and also quantitatively demonstrated that a yield advantage across rainfall levels is necessary for the trait to have market value. Other studies (Wynn 2015a, b, c, d) demonstrated use of real options, Monte Carlo simulation and multicriteria analysis to estimate the global market value of canola that has been genetically modified to be drought tolerant. The results showed the GM canola would be more profitable than conventional varieties and also quantitatively demonstrated that it would not be profitable to pursue commercialisation of GM canola in certain regions, such as Europe.

[5]These are in addition to numerous other studies that had addressed these issues in varying ways and claims regarding segregation. See, as examples: Furtan et al. (2003), Carter et al. (2005) and Bullock et al. (2000).

marketing chain. The studies illustrated that the risks and costs of segregation increased as the tolerance level decreased. These are illustrated in Figs. 2 and 3 and discussed below.

These studies were specified as stochastic optimization models with risks of sampling where random tests were assumed to have accuracies less than 100 %, introducing risks of false positives and false negatives which impacted both buyers and sellers risks. Growers were assumed to declare varieties at the point of first entry into the marketing chain and their declaration was subject to a probability distribution, i.e., grower truthfulness was assumed to be random. Risks of

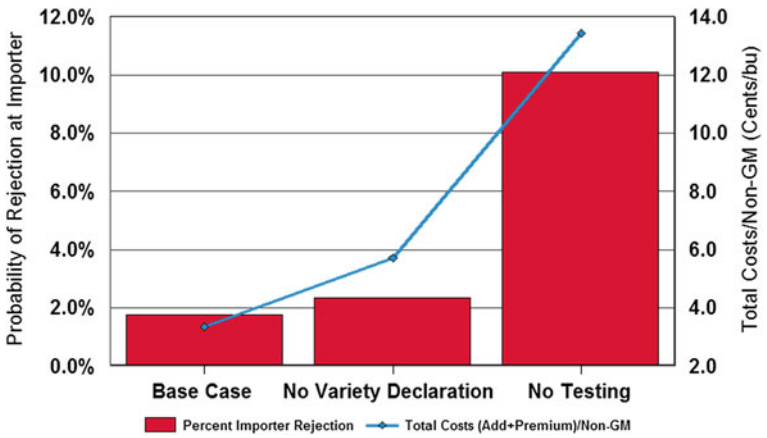

Fig. 2 Effects of variety declaration on adventitious comingling in wheat

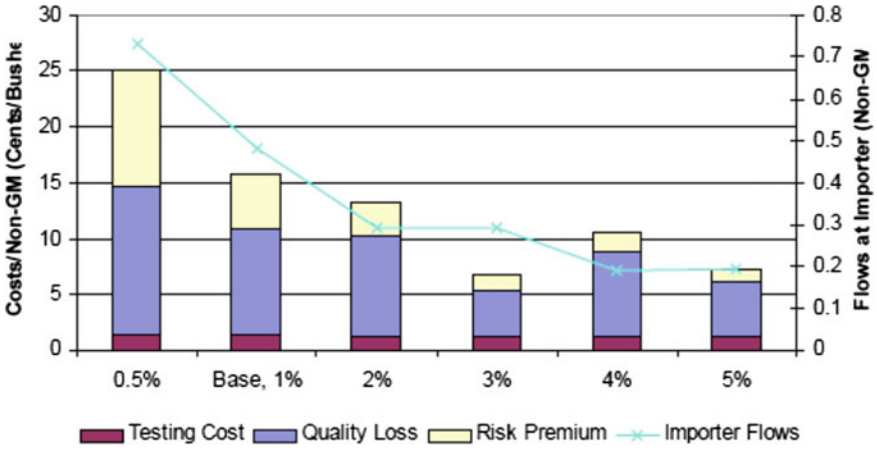

Fig. 3 Effects of importer tolerances on costs and importer flows for non-GM bushels

adventitious comingling were introduced at various points within the marketing chain where comingling can occur. Lots rejected by the importer were assessed a penalty or rejection cost, while those diverted earlier in the marketing chain were assumed diverted to GM wheat segregations.

The base case was a system of testing and tolerance assuming 20 % GM adoption and farmer variety declaration resulted in seller risks of 1.75 % (lots rejected at importer), and buyer risks of 0.02 % (percent of lots exceeding tolerance entering importer flows) at a cost of less than $0.02/bu with the testing and tolerance adding a risk premium of about $0.01/bu over a commodity flow without GM. Total costs for this system per non-GM bushel were about $0.034/bu.

Wilson et al. (2007) expanded the analysis of Wilson and Dahl (2005) by including choice of testing technology or tolerance applied at locations throughout the marketing chain. The optimal testing strategy involved testing at less restrictive tolerances at country elevators and at more restrictive tolerances for ship holds. This strategy results in seller risk of 2.83 % where flows are rejected at importer which do not exceed tolerances, and buyer risk of accepting flows exceeding tolerances of 0.000154 %. Total costs of this system including the risk premium were about $0.16/non-GM bushel.

Wilson et al. (2008b) focused their analysis on EU traceability conformance. Wilson et al. (2008b) found an optimal testing strategy conforming to EU traceability standards would result in increased costs of about $0.50/non-GM bu with a risk premium for the dual traceability system of about $0.21/non-GM bu over a system with no traceability. Seller risk was about 1.7 % of shipments that would be rejected when they are within tolerance limits and 0.01 % of non-conforming flows entering the EU marketing chain.

Testing and tolerance strategies can result in strategies that have low costs and risks to both buyers and sellers. However, test technology and tolerance limits have improved and, as Stephens (2011) notes, current technology allows identification of dust from other crops to indicate positive results for unapproved traits. This results in increased risks of false positives for sellers, which should increase costs as part of the added system costs are rejection costs. The alternative to these types of strategies is trade disruption/exclusion.

Rogue Oregon Wheat and Recent GM Cargo Rejections

Concurrent with accelerated technological development in wheat are two important sets of events, both of which will impact commercialization of new technologies. One can be referred to as the Rogue GM Wheat Found in Oregon; and the other as the Persistent Chinese Rejection of GM Corn Shipments. Each is discussed.

Rogue GM Wheat Found in Oregon

In late April 2013, an Oregon grower detected volunteer wheat that did not die after the field was sprayed with glyphosate. Samples were tested by an Oregon State University weed scientist and determined that they were resistant to glyphosate. Results were reported to USDA and a series of interventions ensued.

As background, Monsanto had field tested Roundup Ready wheat in 16 states from 1998 to 2005. The last tests in Oregon were in 2001. The fields where the sample was found had not been a prior field testing site. To date, USDA has not found evidence that the trait had entered the commercial stream and USDA-APHIS was still unsure how the plants got into the field. In response, both Japan and South Korea temporarily suspended new wheat purchases, and others considered similar actions. It is important that Japan had 2+ months of stocks which facilitated the implicit embargo. Purchases were cancelled and after finding they could not find like qualities elsewhere they recommenced tenders when stocks were at 30 days supply. South Korea's millers evaluated French and EU imports. Though they did make some purchases from elsewhere and considered the more costly Australian wheat, South Korea resumed purchases after an intensive testing program was initiated.

Though what happened was unfortunate and still not resolved, there were some important lessons learned from the process. First, the fact that the GM trait in question had previously been determined to be safe by the FDA was critical. Second, USDA continued its letterhead informational item for export sales indicating *"There is no commercially grown GM wheat grown in the US…"* Finally, an important strategic communication initiative was adopted and the major message was used that it was a single field, from a single farm, of a trait that was deemed safe.

Chinese Rejection of GM Corn Shipments

Concurrent behind the scenes of the above development is the rejection of US cargoes containing GM traits by China. Specifically, the variety was known as Agrisure Viptera developed by Syngenta which is insect resistant with the MIR162 GMO strains. It had been approved in the United States and 15 countries including the EU and had been under review by China since 2010. "The company has applied for safety certification for import for use in processing many times, and after an (earlier) evaluation by our country's biosafety committee, we considered their testing data and related materials to be incomplete and that problems still existed," citing a Chinese authority.

This is an example of a variety being released prior to gaining approval in all import countries (allegedly with on-going discussion with National Corn Growers Association and grain traders in anticipation of commercial release versus international approvals).

Sometimes with known late approvers (like the EU) there may be an understanding about the expectation of LLP until the final approval is granted (and product that is likely to carry the new GM trait, based on growing region, will be "channeled" to other ports).

LLP Status and Issues Regarding Wheat

Low-level presence (LLP) is defined as the presence of small amounts of GM traits that are approved in the exporting country but unapproved in the importing country, contained within shipments of approved varieties. The development of GM traits and differences in licensing and approval procedures and timelines in different countries has resulted in traits being developed and released in exporting countries which have not been licensed in importing countries. This asynchronous approval system across countries can result in unapproved traits being comingled at low levels with traits approved in both exporting and importing countries. This can result in short term trade disruptions whose severity varies according to the limits of tolerance applied and can be more severe when zero tolerance policies are employed.

Adams (2012) references Kalaitzandonakes who lists traits approved by selected exporters and importers showing the extent of the dichotomy of approvals. As the pace of release of new traits increases, the differences in traits approved by countries will only increase, further increasing the chances of LLP occurring in trade flows. Gruere (2009) developed a welfare model of asynchronous approval to analyze different policies. These alternative policies included total ban of GM, 0 % LLP, tolerance levels applied to LLP, and total pass through of LLP comingled shipments. Results are shown in Table 1. Gruere (2009) evaluated the probability of

Table 1 Summary of main effects of regulatory options

Option	Probability of rejection	Price effect	Risk effect	Cost effect	Conclusions
GM Ban	1	High	0	Very high	Valid only if any perceived risk exceeds total costs
0 % LLP	~ 1	High until approval	Larger variance	Very high	Valid if high perceived risk and no trust in export
τ % LLP	Moderate	Moderate	Larger variance and mean	Moderate to high	Best solution from trade's perspective
All Pass	0	0	Much larger variance and mean	None	Valid if prices matter more than anything else

Source Gruere (2009)

rejection, price, risk, and cost effects of each strategy and concluded where each type of policy would be adopted. He found a total GM ban would have very high price and cost effects and would only be valid if perceived risks exceed total costs. The 0 % LLP would likely arise when perceived risks were high and there was no trust in the export market. The best solution from the trade's perspective would be tolerance levels applied to LLP. All Pass systems would be valid where price matters most.

Issues

Since the development and release of genetically modified traits, there have been limited cases of inadvertent comingling, including LLP. These have included different crops and different trait events and have resulted in trade disputes and disruptions. One of the more recent is the finding of the Roundup Ready trait in a volunteer wheat field which was responded to with stoppages of specific imports from US sources. Kalaitzandonakes (2011) classifies these types of comingling into four main categories (1) biotech events approved for some uses but not others, (2) biotech events approved for all uses in one country but not others, (3) experimental events unexpectedly found in commercial food/feed supply chain, and (4) biotech events that were reviewed and were granted time limited approvals which have expired. As the pace of biotechnology trait approvals increases in exporting countries, many importing countries do not have procedures for biosafety evaluation or procedures may be based on other means such as decrees, etc. Further, some importing countries do not have the resources to evaluate biosafety, suggesting that importing countries may consider joining with other countries or groups of countries to perform biosafety evaluations. As a result, as the pace of trait releases increases, the potential for asynchronous approvals increases.

Stephens (2011) indicates that zero thresholds are often defined as detectable at the 0.01 % level which is equivalent to 1 seed in 10,000 seeds. This level of measurement is so fine that dust particles included in a sample have resulted in positive detection. He cites recent examples where dust in soybean shipments to the EU indicated inclusion of 3 corn traits not approved there, stopping EU soybean trade for an extended time period. Thus he argues that the advances in LLP detection have effectively made zero threshold policies impossible to achieve in any industry.

LLP Initiatives

In 2008, the Codex Alimentarius Task Force on Foods Derived from Biotechnology adopted international guidelines for food safety assessment in the case of

asynchronous approval and Low Level Presence. The Codex Annex specifically covers assessment guidelines for food/feed safety in the presence of LLP.

OECD working groups have been working on parallel efforts to the Codex Annex focused on environmental assessment of risks for LLP in seeds (Kalaitzandonakes 2011). Specific countries are also developing LLP initiatives. Existing policies in some countries, however, tend to make LLP incidents resulting from asynchronous approvals more, rather than less, likely. For example, China's biosafety regulations require full regulatory approval in the host country prior to the start of China's import regulatory process. This process takes 2–3 years which results in significant time lags in commercialization, and/or the prospect for asynchronous approvals, leading to the problems manifested in the current corn market (Huang and Yang 2011).

Canadian Policy

Canada assesses risk and employs measures designed to return to compliance. Canada employs border alerts and testing of flows which continue until events are approved for use in Canada. Canada currently does not differentiate between LLP and events that have never been approved. Stephens (2011) argues that current policy has been effective to date on a regulatory basis, but may not be adequate as the pace of release of events increases and is not effective from a trade perspective.

Stephens (2011) discusses several recommendations for improved LLP Policy including redefining zero tolerance to 0.1 % plus 0.2 % for uncertainty (for total of 0.3 % requirement for detection) to preclude identification through dust particles alone. Then employ options (1) synchronize approvals among major trading partners, (2) mutual risk assessments, (3) international risk assessment, and (4) proactive LLP assessment.

Canada is in the process of revising their LLP policy framework. A proposed policy framework was disseminated for comment from November 2012 to January 2013 (Agriculture and Agrifood Canada 2012). The policy framework will be refined and a final framework will be presented to the Canadian government. Refinements focus on the tolerance level, where those would be set based on the event and by crop.

Summary and Implications

One of the next major frontiers in development of genetically modified crops is in wheat. All of the major biotechnology companies have expanded with new initiatives in wheat and varying forms of partnerships. Due to these initiatives and competitive pressures, it is very likely by the early 2020s there will be several new traits moving forward in the deregulatory system, probably competing with traits

from other companies and countries. Hence, the pressures to expedite commercialization and therefore regulatory approval will likely be immense.

Several characteristics are important for GM wheat. First, it is a large acreage crop which is grown in many countries and imported by many more countries than either corn, soybeans or canola. Second, wheat is viewed as a food grain and hence development of GM wheat may be more subject to regulations and consumer acceptance. Third, our studies (Wilson et al. 2008a), albeit dated, suggested about 35 % of the market would require some level of segregation to facilitate trade. This is much greater than in other crops.

Segregation is already common in wheat. Segregation occurs with respect to color, grade, and class, in addition to informational factors such as protein level and dockage; increasingly more common are measures of fusarium content, variety, stability, and other measures of end-use performance. Hence, segregation with respect to GM content should work relatively smoothly. Prerequisites to efficient segregation are variety declaration, testing procedures, and contract terms.

The evolution of GM wheat will put pressure on the system of segregation and on LLP in regulatory systems across exporting countries developing new traits and importing countries which may or may not have approvals. Already, there have been concerns about GM wheat that has been found in production, despite the fact that field trials ceased many years ago. Though systems do exist that can induce segregation, at a cost, the issues of LLP are more regulatory and ultimately impact commercial relationships. This is problematic for all crops going through deregulation as well as GM wheat. Indeed, a recent wheat industry official indicated "There are going to have to be tolerances in place once GM wheat is introduced to the market so that's the first place to start … we need to work on getting those in place so there's no regulatory problem when these things occur." (Sosland 2013, p. 34)

The structure of the trait development industry is such that there will be immense pressure for commercializing traits. More likely that will result in Asynchronous approvals, hence making issues related to LLP very important. LLP policies and the Codex Alimentarius Annex are mechanisms to handle LLP when there are differences in approval of traits between importing and exporting countries. While some countries are developing LLP policies, others may not have the capabilities to assess approvals or may have approval mechanisms that instead foster asynchronous approvals. The pace of trait development and asynchrony of approvals between exporting and importing countries will compound any issues that might arise.

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Potential Economic Impacts of Asynchronous Approvals of Biotech Crops on South Korea

Nicholas Kalaitzandonakes, James Kaufman, Sanghan Yea and Kenneth Zahringer

Introduction

Biotech crops represent a substantial share of key agricultural commodities traded in international markets, primarily maize, soybeans, cotton, and canola. Unique among agricultural innovations, though, biotechnology is strictly regulated. In most countries it is illegal to cultivate or trade any biotech crop unless the specific genetic event has been approved by governmental authorities. To date, 181 unique biotech events in 26 different crop species have been approved for use or cultivation in various countries (ISAAA 2015). At least 38 countries[1] have regulatory systems that have handled submissions seeking regulatory approval for the cultivation and/or importation and use of new biotech crops while a number of other countries are in the process of developing their own regulations. Since regulation and approval happens at the individual country level, each country formulates its own

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[1]EU 27 is counted as a single entity here.

N. Kalaitzandonakes (✉) · J. Kaufman · K. Zahringer
Economics and Management of Agrobiotechnology Center,
University of Missouri, Columbia, MO, USA
e-mail: KalaitzandonakesN@missouri.edu

J. Kaufman
e-mail: kaufmanj@missouri.edu

K. Zahringer
e-mail: zahringerk@missouri.edu

S. Yea
Korea-Africa Center, Korean Foreign Ministry, Seoul, Republic of Korea
e-mail: syeahk@naver.com

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procedures for assessment and approval of new biotech events and each country's approval process proceeds according to its own time schedule. Thus there are significant differences in the regulatory procedures used by different countries, including the amount of time required to complete the approval process (Kalaitzandonakes et al. 2006). This all but guarantees some degree of asynchrony in international approvals.

At one extreme the US, Canada1, Japan, and some other countries have continued to review and approve new biotech crops at variable but similar speeds. For example, regulatory approvals for new biotech events took an average of 13.6 months in the US in the mid-2000s (Jaffe 2005). At the other extreme, the European Union (EU), China, Turkey and some other countries have been slow and unpredictable in reviewing and approving new biotech crops. In the EU, for example, the review process averaged 30 months in the mid-2000s, over twice as long as in the US (DG AGRI 2007; FEFAC 2007; Stein and Rodríguez-Cerezo 2010).[2] Some policies compound this condition. Biosafety policy in China, for example, mandates that applications for approval of new events can only be submitted after the event in question has been fully approved in the country where it was developed (USDA 2014a). Overall, regulatory approvals of new biotech crops across different countries have become less synchronized over time (de Faria and Wieck 2014).

The biotech pipeline is not slowing down; if anything, the pace of development of new biotech varieties is quickening (Waltz 2010; Parisi et al. 2016). As progress in biotechnology continues, a large and increasing number of new biotech crops are likely to receive regulatory approval for use and cultivation in one or more countries while still unauthorized in others. For internationally traded agricultural commodities, this situation can cause serious problems. Given the realities of the extant agricultural supply chain, it is essentially impossible to prevent the low-level presence (LLP) of small amounts of crop varieties in shipments bound for a country where they are not approved for import (Demeke and Perry 2014). This situation has led to costly trade disruptions in the past and could do so again in the future (DG AGRI 2007; Backus et al. 2008; Philippidis 2010; Stein and Rodríguez-Cerezo 2010; Kalaitzandonakes et al. 2014). The LLP issue can become even more critical and potentially disruptive if the destination country has a zero-tolerance policy for LLP. A zero-tolerance policy could lead to a complete shutdown of trade in a particular commodity between two countries in the event of an LLP incident (Kalaitzandonakes 2011).

In order to further understand the possible economic impact of asynchronous approvals and their associated potential trade disruptions, in this chapter we explore such potential impacts for one medium-sized country that is a fairly significant player in international agricultural markets, South Korea. For the sake of brevity and concision we will restrict our discussion to the maize market, but the scenarios described here are equally applicable to international markets for soybeans, cotton,

[2]Because of divergent policies as well as other factors, there are also significant discrepancies in the number of new biotech events that have been approved by different countries. For instance, the US has approved 171, Japan 201, and Canada 155 while the EU has approved 73 and China 55 new biotech events, including approvals of stacked traits.

or canola. It is important to stress that our purpose here is illustrative; we are not predicting that South Koran policies are likely to bring about the scenarios described later in this paper in the near future. Nonetheless, current trends in biotech regulatory approvals do indicate an increasing chance of asynchrony with primary agricultural commodity suppliers in global markets and make the choice of South Korea as the subject of this case study particularly relevant. Our discussion will proceed as follows: in the next section we will describe the South Korean review and approval system and some current policy trends that influenced our choice of South Korea as the subject of this case study. In Sect. "South Korea and the World Trade Network" we place the South Korean maize trade in a global context. Section "Impacts of Asynchronous Approvals on Trade" describes our model, data, scenarios, and the empirical results from our trade model. In Sect. "Impact on Korean Iivestock Market" we assess the impact of those results on the Korean livestock market. Section "Conclusion" concludes.

Biosafety Policy in South Korea

South Korea ratified the Cartagena Protocol on Biosafety (CPB) on October 2 2007. Shortly thereafter, on January 1, 2008, it implemented the LMO Act, which is the implementing legislation for the CPB and the overarching law governing the country's biotechnology related rules and regulations. In South Korea biotech crops are required to undergo a food safety assessment and environmental risk assessment. Several different agencies are involved in the overall assessment process. The Rural Development Administration (RDA) conducts the environmental risk assessment under consultation of three different agencies: the National Institute for Environmental Research (NIER), the National Fisheries Research and Development Institute (NFRDI) and the Korea Centers for Disease Control and Prevention (KCDC). Separately, the Korea Food & Drug Administration (KFDA) conducts a safety assessment for food grains containing biotech events. The KFDA review process includes consultations with RDA, NIER, and NFRDI. The overlaps between the reviewing agencies, particularly between KFDA and KCDC, and redundant data requirements have in some instances led to delays in the approval process (USDA 2013, 2014b).

Since the passage of the LMO Act of 2008 the biosafety review process in South Korea has become slower. As Table 1 shows, the average approval time for single biotech events prior to 2009 was about 15 months for food approvals from KFDA and about 19 months for feed approvals from RDA. After passage of the LMO Act food approvals took an average of 33 months and feed approvals nearly 28 months. In addition, there appears to be a trend of increasing approval delays over time, especially in the case of KFDA. If the approval process in South Korea is systematically slowing down it can increase the risk of a LLP-based trade disruption that could have severe negative impacts on Korean farmers and consumers and also cause lesser problems for world agricultural markets.

Table 1 Number of approved events in Korea (as of July 31, 2013)

Year		Before LMO was in place					After LMO was in place				
		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Single events											
KFDA	No. of approvals[a]		5	3	2		3	5	3	1	3
	Average months taken to get approval		10.8	12	22		26.7	29.2	34.7	37	37.3
RDA	No. of approvals	9	6	4	1	2	4	4	4	5	0
	Average months taken to get approval	11.7	12	18.8	24	29	25.5	24.8	34.5	26.2	NA
Stacked events											
KFDA	No. of approvals	8		9	1	2	3	7	2	5	8
	Average months taken to get approval	2.5		1.3	2	3	5	5.7	7.5	12.6	10.1
RDA	No. of approvals					19[b]	4	2	10	7	1
	Average months taken to get approval					3.5	4	9	8.6	9.6	6

Source Author (NK) calculations based on data from company surveys

Stacked events had not been regulated by RDA until 2007 since it was a voluntary regulation system. RDA started the risk review of stacked event in November 2007, just before the LMO Act became effective

NA not applicable

[a] "Other approval" (i.e. commercial production discontinued at submission) and "re-registration approval" were excluded from this summary table

[b] 17 out of 19 stacked events were approved in a lump in early January 2008

South Korea and the World Trade Network

Because of the interconnectedness of world trade in agricultural commodities it is necessary to consider South Korea in a global context. Maize accounts for the largest volume of agricultural trade in the world, with soybeans a close second. Table 2 shows the major exporters and importers that make up the global maize market. The US is by far the largest producer and exporter of maize in the world, while Argentina, Brazil, and Ukraine contribute significant amounts to the global trade of maize every year. Together these top four exporters accounted for 86 % of global maize exports during the last 5 years. In the last 5 years Japan has been the largest global maize importer followed by Mexico and South Korea. Although a number of key importers (e.g. EU, Mexico, Egypt, and China) have significant domestic production, most Asian importers (e.g. Japan, South Korea, and Taiwan) must import virtually all of their domestic maize consumption. This makes the potential impact of trade disruptions most significant for these latter countries. An LLP issue with one major maize exporter, especially the US, would affect a large portion of world trade. On the other hand, if any one importer, such as South Korea, experienced an interruption of imports, it would have a major impact on its maize consumption.

South Korea has long been a major importer of maize. Import volume has generally been in the 8–9 million metric ton range since the mid-1990s. There have been significant shifts in South Korea's maize trading partners over the last few decades, mainly in that the USA and China have alternated in the role of the primary source of imports. The consistent pattern, though, has been one of procuring the bulk of maize imports from one major supplier. From 2007 to 2011, as China transitioned from a net exporter to a net importer of maize, US imports accounted for 70 % of South Korea's total maize imports (FAOSTAT 2015). The reasons for this relationship include the availability, dependability, and quality of US maize supplies as well as the somewhat lower freight and tariff costs compared to other major exporters. Under such circumstances, asynchronous approvals between the US and South Korea could lead to meaningful trade and economic disruptions (Fig. 1).

South Korean imports of maize are mostly used for animal feed, and the largest share of imported maize is biotech. Of the 7.8 million metric tons of maize imported in 2011, 5.8 million metric tons were biotech. A like amount, 5.8 million metric tons, was used in the feed industry, all of which was imported. Thus not only is the feed industry dependent on imported maize, it also accounts for the lion's share, 74 %, of all imported maize (KBCH 2012; KOFEED 2012; FAOSTAT 2015). As a result, the feed industry could be disproportionately affected by any trade disruptions stemming from asynchronous approvals. This impact could be passed on directly to livestock producers, increasing their production costs and thereby impairing their competitiveness and profitability. Consumers could ultimately experience this as higher meat prices. Pork, poultry, and beef are all widely consumed in South Korea (KMTA 2013). Increased imports of meat products could

Table 2 Maize production, use and trade, avg. 2010/2011–2014/2015 (1000 MT)

Top ex/importers	Exports	Imports	Production	Total consumption	Exports/production (%)	Imports/consumption (%)
United States	39,470	1411	322,792	284,126	12.23	0.50
Brazil	19,738	810	73,280	52,800	26.93	1.53
Argentina	16,437	6	24,440	8080	67.25	0.08
Ukraine	14,179	46	23,006	8540	61.63	0.54
Percentage of global market (%)	86.14	2.28	50.10	40.53		
Japan	0	15,095	1	15,120	0.00	99.83
European Union	2295	9756	64,742	71,800	3.55	13.59
Mexico	461	9391	21,491	30,150	2.14	31.15
South Korea	0	8785	78	8900	0.00	98.70
Egypt	10	6803	5870	12,640	0.17	53.82
Iran	0	4440	1728	6110	0.00	72.67
Taiwan	0	4261	73	4345	0.00	98.08
Colombia	1	3703	1669	5440	0.05	68.08
Malaysia	9	3193	73	3320	11.85	96.18
Algeria	0	3193	1	3180	0.00	100.40
Percentage of global market	2.66	68.84	10.81	18.46		
World total	104,273	99,680	885,217	872,335	11.78	11.43

Source USDA, PS&D Database

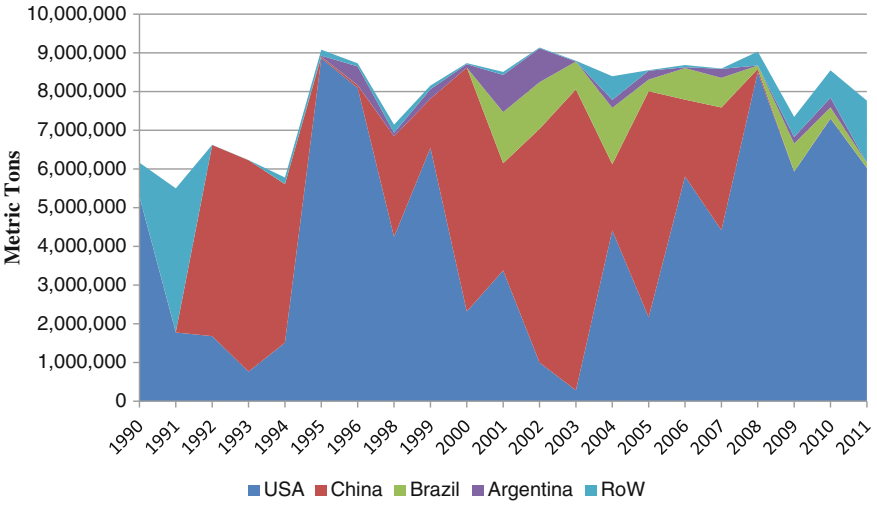

Fig. 1 South Korean maize and maize product imports. *Source: FAOSTAT*

moderate the price increases somewhat in the pork and poultry markets, but beef is another matter. Fully 96 % of beef herds in South Korea are made up of Korean native cattle, a breed different from American and European beef cattle (KOSIS 2013). Native beef is much preferred by South Korean consumers despite being more costly than imported beef (Wagyu Intl 2015). It is doubtful that imports would make large inroads into such a strongly segmented market.

Impacts of Asynchronous Approvals on Trade

Our premise in this analysis is that asynchronous approvals of new biotech crops among exporting and importing countries can lead to disruptions in bilateral trade flows. In such a case importers need to identify alternative suppliers and exporters need to find alternative markets for their products. The economic effects of the resulting trade distortions comprise changes in the volume of trade and changes in local prices. We will use a spatial equilibrium framework in analyzing the changes in trade flows resulting from asynchronous approvals. Spatial equilibrium models have certain advantages in analyzing the impact of trade disruptions, as they are specifically designed to compute optimal quantities flowing between pairs of trading partners. This type of model is thus uniquely suited to our analytical task.

Conceptual Model

For this analysis we develop a spatial equilibrium model representing the global maize sector based on the general approach for multi-region trade originally described by Takayama and Judge (1971). The objective of the spatial equilibrium model is to maximize net social welfare (consumer and producer surplus minus transportation costs and import and export tariffs) by choosing the bilateral trade flows subject to relevant behavioral constraints (i.e. non-negativity, market equilibrium, cross-price, and no-arbitrage constraints).

We calculate market equilibrium quantities and prices derived from the excess supply and demand functions for maize in each country using linear quantity-dependent supply and demand specifications

$$\text{Supply}: \; Q_i^S = \delta_{1i} + \delta_{2i} p_i^S \qquad \text{Demand}: Q_i^D = \gamma_{1i} - \gamma_{2i} p_i^D \tag{1}$$

where p_i^S is the supply price of maize in country i, p_i^D is the demand price in country i, Q_i^S is the quantity of maize supplied in country j, and Q_i^D is the quantity of maize demanded in county i. The equations are structured such that all of the model parameters are positive values. We allow the quantity demanded and quantity supplied to differ so individual countries can be net importers or exporters; market equilibrium is imposed by restricting the supply and demand prices to be equal ($p_i^S = p_i^D$). We can form the resulting linear aggregate excess demand function for country i as

$$Q_i^D - Q_i^S = (\gamma_{1i} - \delta_{1i}) - (\gamma_{2i} + \delta_{2i}) p_i = \beta_{1i} - \beta_{2i} p_i \tag{2}$$

We calibrate the excess demand function using observed price and import or export quantity data for each country to calculate market equilibrium values. For example, we compute the slope of the excess demand Eq. (2) from excess demand elasticity estimates taken from prior studies, and calculate the intercept from the observed price and quantity data.

Based on these linear excess demand equations, the net social welfare for country i is calculated as

$$\sum_i \beta_{1i} p_i - \sum_i \beta_{2i} p_i^2 / 2 \tag{3}$$

Our goal in this spatial equilibrium problem is to choose the trade flow volumes (imports or exports) that maximize the net social welfare expression in (3) subject to the behavioral constraints. The market equilibrium for each country is expressed in (2), and we also restrict international price differences to not be subject to arbitrage. As a result, the price differences between any two markets may not exceed the per-unit transport costs between those markets. The no-arbitrage condition also allows countries to impose import (t_{ij}^M) or export (t_{ij}^X) tariffs on their trade volumes. Any specific, per-unit tariff on maize is added to or subtracted from the associated

transportation rate for maize flowing to or from the country. The final form of the price constraint, representing a spatial equilibrium where no arbitrage between the countries is possible, is:

$$\left|p_i - p_j\right| \leq w_{ij} + \left(t_{ij}^X + t_{ij}^M\right)p_i \tag{4}$$

Thus the absolute price difference between countries i and j is less than or equal to the sum of the per-unit transportation costs plus all tariff rates. The solution to the spatial equilibrium model includes the excess supply and demand quantities and market clearing prices for maize in each country. These values are used as the baseline for our trade analysis.

To simulate an interruption of trade between countries h and k we increase the constraint bound in (4), which may be interpreted as imposing a prohibitively large per-unit cost of trade between the parties. In this case the no arbitrage constraint no longer holds at the spatial equilibrium; however, we maintain all other no-arbitrage constraints between h and k and all third parties. Thus the price difference between h and k cannot become implausibly large so long as other willing trading partners exist and have available stocks to exchange (i.e. an interior solution exists for each country). In this case the price changes in countries h and k largely are a result of the additional costs of reallocating the displaced quantities to other markets. The no-arbitrage constraints may no longer hold between countries h and k and all third parties when alternative trading partners do not have trading stocks equivalent to the displaced quantities. Here all pairs are forced into corner solutions. To deal with this we remove the no-arbitrage constraints for all interactions involving countries h or k, but retain them for all relationships among the third parties. In this case, the price changes resulting from the trade disruption may be large in countries h and k.

Data

A large amount of detailed data on production, consumption, trade flows, prices, freight rates, tariffs, and quotas for maize in selected countries and groups of countries is necessary in order to implement the spatial equilibrium model described above. We obtained detailed annual bilateral trade flow data for individual countries and some selected country groups from the Global Trade Atlas (GTIS 2012) as well as from FAO (FAOSTAT 2015). These data sets are based on national customs data collected by origin and and/or destination countries. In particular, the maize trade flows were collected for HS Code 1005. We collected data for all available trading partners; by using multiple, complementary data sources we ensured that trade flows between all relevant country pairs was included. The data was aggregated into 38 countries and country groupings yielding a symmetric 38×38 matrix of bilateral trade flows. Table 3 shows the countries and regions included in the analysis, and the abbreviations used in our tables for the rest of this paper. World

Table 3 Countries and country groupings

Acronym	Country/region	Acronym	Country/region
EU25	European Union 25	IND	India
BRA	Brazil	JPN	Japan
ARG	Argentina	THA	Thailand
USA	USA	KOR	South Korea
CHN	China	IDN	Indonesia
PAR	Paraguay	MYS	Malaysia
CAN	Canada	PHL	Philippines
MEX	Mexico	ANZ	Australia and New Zealand
BUR	Bulgaria and Romania	MAR	Morocco
WBA	Western Balkans	TUN	Tunisia
REU	Rest of Europe	DZA	Algeria
RUB	Russia and Belarus	EGY	Egypt
UKR	Ukraine	TUR	Turkey
CAM	Central America	ISR	Israel
VEN	Venezuela	LDC	Least Developed Countries
CHL	Chile	AFR	Non-LDC African Countries in the ACP
URY	Uruguay	C&P	Non-LDC Caribbean and Pacific Island countries in ACP
BOL	Bolivia	MIDE	Middle East (Syria, Iran, Iraq, Saudi Arabia, UAE)
RSA	Rest of South America	ROW	Rest of World

Bank standard country codes were used where applicable. When the data reported by the two partners of a trading pair did not match, the larger of the two values was used in the models. We gathered trade flow data in terms of both volume and value. Although the primary requirement of the analytical model was for volume data, value data allowed us to calculate implied per-unit costs for various trades which were then used in the validation of global trade prices, as discussed below.

We collected domestic supply and demand data from FAOSTAT, validated with USDA PS&D data. The composition of domestic demand (feed, food, and industrial demand) was taken into account in applying and weighting the appropriate elasticities to the trade model. Demand and supply elasticities were obtained from the FAPRI elasticity database (FAPRI 2012). Elasticities were validated and augmented with comparable elasticities taken from CAPRI (2012) and WATSIM (von Lampe 1998) where other data was unavailable.

A regression analysis was used to estimate freight rates for all possible routes between all trading pairs in the constructed 38 $\times$ 38 trade matrix based on actual reported freight rates for maize obtained from Maritime Research. The rates were

regressed against the distance covered in each individual trade as well as against selected capacity indices for panamax and handy size vessels typically used in dry bulk commodity trade. The resulting regression equation was then used to estimate freight rates for all routes and years in the analysis.

Global trade prices used in the model were based on cash port prices reported by USA, Brazil, Argentina, and the EU for the dominant trading ports. A weighted average FOB price for each port of origin and each country, based on each country's share of trade with these four countries. This FOB price was combined with transport costs calculated from the freight rates estimated above to derive a CIF price for each importer. In order to ensure consistency we validated these prices by comparing them with the implied per-unit import costs calculated from GTIS trade data. Annual data on each country's average applied tariff was collected from the WTO tariff database (WTO 2012). We validated this data with tariff rates maintained by FAPRI. All export tariffs used were from FAPRI. For country groups, calculated weighted average tariffs based on each country's volume of imports (or exports) and average tariff paid to each country.

Baseline Development and Model Validation

The baseline model was calibrated with GTIS trade data. The model generated estimates of supply, demand, imports, and exports for all 38 countries and country groups in the data base. We compared the baseline estimates with the observed data to evaluate the adequacy of the empirical model. The deviations of the model-derived baseline estimates from the actual excess demand and supply figures for maize, expressed as (baseline-actual)/actual, ranged from −29 to 12 % for all countries and years in the analysis. The average deviations were much smaller than the extreme values, typically under 5 %, with the overall average deviation for the world market at 3.6 %. Calculated baseline trade flows for all large importers and exporters also closely matched observed trade flows. As is typical, the spatial equilibrium model did not represent small volume trades as effectively as larger trade flows. Such trades typically represent opportunistic transactions within a year and are difficult to represent through annual averages. Overall, though, the baseline model runs were considered effective.

Empirical Results

In the last two decades South Korea has sourced the majority of its maize imports from China and the US. As China exported less maize, South Korea has come to rely more heavily on the US and to a lesser extent Argentina and Brazil. These dominant partners all have considerable biotech adoption. New partners have emerged recently, especially Europe (e.g. western Balkans, Ukraine), South Africa,

and India. Biotech maize production in most of these exporting countries is either not allowed or highly regulated.

It is possible to imagine potential scenarios in which maize imports of South Korea from the US or other exporters that grow biotech crops could be interrupted due to asynchronies in regulatory approvals. Export firms located in countries with plantings of newly approved biotech genetic events may find it risky or costly to deliver maize that could be rejected in South Korea and as such they may opt to forego exporting to that country. Alternatively, South Korean importing firms may opt to forego importing from exporting countries where unapproved events are present and LLP a chance.

Here we look at three scenarios where trade between South Korea and the major maize producers with high levels of biotech adoption—USA, Brazil, Argentina, and Paraguay—is disrupted. Accordingly no trades are allowed between these countries, forcing South Korea to import maize from other, non-traditional sources that do not have widespread biotech adoption. Likewise these four exporting countries must either consume domestically or export to new trading partners the maize that would have gone to South Korea.

Scenario 1: No Trade with ARG, BRA, USA, PAR

As maize from the US, Argentina, and Brazil becomes unavailable to South Korea, Ukraine picks up much of South Korea's demand facilitated by its relatively low transportation costs and its relatively large excess supply. In order to supply South Korea, though, Ukraine is forced to shift its export patterns. Much of the maize that would have been destined for the Mideast, North Africa, and the EU is diverted to South Korea. The EU internally changes its domestic supply and demand but also shifts more of its demand towards Argentina. The Mideast, with less ability to domestically produce maize, shifts its imports to the Americas, which now has an excess of maize. Likewise India, with its low transportation costs to South Korea, shifts exports away from some Less Developed Countries (LDCs) and towards South Korea. The Western Balkans also shift exports from the Mideast and Northern Africa in order to free exports for South Korea. The unfulfilled demand in the Mideast is filled by Brazil and Argentina. Internal consumption in exporting countries changes as depicted in the last nine rows of the table (Table 4).

The changes in trade flows necessitate a shift in global market conditions which are detailed in Table 5. In scenario 1 the unavailability of imports from traditional suppliers increases the price of maize in South Korea by 7.3 %. As expected, the maize price from alternative suppliers to South Korea (e.g. Ukraine, India, and the Western Balkans) increases, as does the price in most former customers of those countries, mainly the EU and North Africa. The price in the US declines by 0.5 % as a result of the trade disruption, and thus the price in countries that import maize from the US (e.g. Canada and Central America) declines as well. The price is less affected in Argentina and Brazil, where there was not a previously high level of trade with Korea.

Table 4 Scenario 1: Increase or (decrease) in trade volume from 2009 baseline (1000 MT)

Importers	BRA	ARG	USA	PAR	WBA	REU	RUB	UKR	IND
Selected exporters									
KOR	(638)	–	(6932)	–	1051	–	–	5153	1412
EU27	–	1533	–	–	–	(7)	–	(1297)	–
CHN	(1700)	(254)	1891	–	–	–	–	–	–
CAN	–	–	(21)	–	–	–	–	–	–
MEX	–	–	(42)	–	–	–	–	–	–
BUR	–	1	–	–	–	–	–	–	–
CAM	–	–	(6)	–	–	–	–	–	–
VEN	–	–	(3)	–	–	–	–	–	–
CHL	–	–	–	(2)	–	–	–	–	–
URY	–	–	–	(0)	–	–	–	–	–
BOL	–	–	–	(0)	–	–	–	–	–
RSA	–	–	(8)	–	–	–	–	–	–
JPN	–	–	(6)	–	–	–	–	–	–
THA	(304)	302	–	–	–	–	–	–	–
IDN	–	–	478	–	–	–	–	–	(481)
MYS	(8)	–	–	8	–	–	–	–	–
PHL	(945)	941	–	–	–	–	–	–	–
ANZ	–	(1)	–	–	–	–	–	–	–
MAR	(344)	–	347	–	–	–	–	–	–
TUN	–	–	–	–	717	–	–	(716)	–
DZA	–	–	1062	–	(589)	–	–	(472)	–
EGY	–	(2107)	2337	–	(217)	–	–	–	–
TUR	–	–	–	–	6	–	–	–	–
ISR	–	–	–	–	179	–	–	(179)	–
LDC	1208	–	–	–	–	–	–	–	(926)
AFR	39	–	–	–	–	–	–	–	–
C&P	–	–	(1)	–	–	–	–	–	–
MIDE	3309	412	–	–	(1164)	–	(59)	(2500)	–
ROW	(595)	(805)	1395	–	–	–	–	–	–
BRA	(12)	–	–	–	–	–	–	–	–
ARG	–	(5)	–	–	–	–	–	–	–
USA	–	–	(167)	–	–	–	–	–	–
PAR	–	–	–	(1)	–	–	–	–	–
WBA	–	–	–	–	7	–	–	–	–
REU	–	–	–	–	–	4	–	–	–
RUB	–	–	–	–	–	–	21	–	–
UKR	–	–	–	–	–	–	–	2	–
IND	–	–	–	–	–	–	–	–	(2)

Table 5 Scenario 1: Price, supply, and demand percentage change from 2009 baseline

	Price	Supply	Demand
KOR	7.3	1.1	(0.6)
EU27	0.8	0.2	(0.2)
CHN	(0.6)	(0.0)	0.0
BRA	(0.1)	(0.0)	0.0
ARG	(0.4)	(0.1)	0.1
USA	(0.5)	(0.1)	0.1
PAR	(0.5)	(0.2)	0.1
WBA	0.5	0.1	(0.1)
REU	1.2	0.2	(0.3)
RUB	2.0	0.6	(0.5)
UKR	1.0	0.3	(0.3)
IND	0.8	0.1	(0.1)
CAN	(0.5)	(0.1)	0.1
MEX	(0.5)	(0.1)	0.1
BUR	0.5	0.0	(0.0)
CAM	(0.5)	(0.0)	0.1
VEN	(0.5)	(0.0)	0.1
CHL	(0.5)	(0.0)	0.1
URY	(0.4)	(0.0)	0.1
BOL	(0.5)	(0.0)	0.0
RSA	(0.5)	(0.0)	0.1
JPN	(0.6)	(0.1)	0.0
THA	(0.2)	(0.0)	0.0
IDN	(0.1)	(0.0)	0.0
MYS	(0.1)	(0.0)	0.0
PHL	(0.2)	(0.0)	0.0
ANZ	(0.5)	(0.1)	0.0
MAR	0.9	0.2	(0.2)
TUN	0.5	0.1	(0.1)
DZA	0.9	0.1	(0.1)
EGY	0.3	0.1	(0.1)
TUR	0.3	0.1	(0.1)
ISR	0.3	0.1	(0.1)
LDC	3.5	0.2	(0.3)
AFR	0.8	0.0	(0.1)
C&P	(0.5)	(0.0)	0.0
MIDE	(0.1)	(0.0)	0.0
ROW	(0.2)	(0.0)	0.0

Scenario 2: No Trade with ARG, BGM, USA, PAR & 25 % Reduction in UKR

In 2009 there were a number of countries that were able to provide maize to South Korea at a reasonable price. Europe had a relatively large crop, and transport costs allowed them to be traded with South Korea at a competitive rate. Likewise India, with its relatively low transportation cost and excess supply of maize, was able to ship a considerable amount of maize to South Korea. There were no significant constraints on maize that needed to be overcome, such as in 2008 when global maize prices rose dramatically. The 2008 experience highlights how impacts can be a function of prevailing market conditions. Short crops in major producing nations, especially the US but also Brazil and Argentina, led to high prices around the globe.

As South Korea limits the breadth of countries from which it can source maize it increases its exposure to the production risk of those countries. As seen in scenario 1, without Argentina, Brazil, the US, and Paraguay, South Korea becomes highly dependent on Ukraine and India. Both of these countries have a high level of production risk. If a short crop were to occur in one country the impacts could be meaningful. Trade disruptions could also occur through other factors, such as financial crisis and associated credit constraints or the armed conflict that is currently present in the Ukraine. In scenario 2, we assume that Ukrainian exports are reduced by 25 % due to a short crop or other factors, in addition to the trade ban with Argentina, Brazil, Paraguay, and the US. Table 6 shows that the same general patterns persist as in scenario 1, but as there is less supply in Ukraine South Korea must turn more to India and the Western Balkans for its maize needs.

The reduction of maize production in Ukraine has the effect of increasing the global maize price and decreasing demand. As Table 7 shows, the price in South Korea rises by 8.4 % and demand for maize imports decreases by almost 1 %. The additive effects of higher global price and increased demand from South Korea raise prices in the Ukraine and WBA, as well as their trading partners. The impact of this scenario is more complex, as the effect of lower output in the Ukraine is higher global prices. These higher global prices appear to reverse some of the price impacts in countries that had lower prices in the previous scenario. Similarly countries with higher prices in scenario 1 experience still higher prices in scenario 2—especially Ukraine, the Western Balkans, and India. Interestingly, prices in India only increase by 1 % which is a minimal change from scenario 1.

Conversely, a 25 % increase in the maize exports in the Ukraine due to a bumper crop would have the effect of depressing maize prices across the globe. Despite the increase in production, the added demand from South Korea is sufficient to keep the maize price in Ukraine and the Western Balkans 1.2 % higher than the baseline, and their trading partners share these higher prices. The South Korean price rises 6.7 % over the baseline which is only one percentage point lower than in Scenario 1.

Table 6 Scenario 2: Increase or (decrease) in trade volume from 2009 baseline (1000 MT)

Importers	BRA	ARG	USA	PAR	WBA	REU	RUB	UKR	IND
Selected exporters									
KOR	(638)	–	(6932)	–	1962	–	–	4205	1445
EU27	–	1339	–	–	–	(4)	–	(1297)	–
CHN	(1700)	(254)	1672	–	–	–	–	–	–
CAN	–	–	(93)	–	–	–	–	–	–
MEX	–	–	(190)	–	–	–	–	–	–
BUR	–	3	–	–	–	–	–	–	–
CAM	–	–	(26)	–	–	–	–	–	–
VEN	–	–	(16)	–	–	–	–	–	–
CHL	–	–	–	(4)	–	–	–	–	–
URY	–	–	–	(1)	–	–	–	–	–
BOL	–	–	–	(0)	–	–	–	–	–
RSA	–	–	(37)	–	–	–	–	–	–
JPN	–	–	(26)	–	–	–	–	–	–
THA	(304)	296	–	–	–	–	–	–	–
IDN	–	–	454	–	–	–	–	–	(481)
MYS	(25)	–	–	19	–	–	–	–	–
PHL	(945)	923	–	–	–	–	–	–	–
ANZ	–	(2)	–	–	–	–	–	–	–
MAR	0	–	–	–	–	–	–	–	–
TUN	241	–	438	–	38	–	–	(716)	–
DZA	–	–	1061	–	(589)	–	–	(472)	–
EGY	–	(2107)	4560	–	(500)	–	–	(1900)	–
TUR	–	–	–	–	26	–	–	–	–
ISR	–	–	–	–	182	–	–	(179)	–
LDC	1163	–	–	–	–	–	–	–	(926)
AFR	4	–	–	–	–	–	–	–	–
C&P	–	–	(5)	–	–	–	–	–	–
MIDE	3024	669	–	–	(1164)	–	(44)	(2500)	–
ROW	(595)	(805)	1367	–	–	–	–	–	–
BRA	(117)	–	–	–	–	–	–	–	–
ARG	–	(12)	–	–	–	–	–	–	–
USA	–	–	(758)	–	–	–	–	–	–
PAR	–	–	–	(2)	–	–	–	–	–
WBA	–	–	–	–	19	–	–	–	–
REU	–	–	–	–	–	2	–	–	–
RUB	–	–	–	–	–	–	16	–	–
UKR	–	–	–	–	–	–	–	11	–
IND	–	–	–	–	–	–	–	–	(18)

Table 7 Scenario 2: Price, supply, and demand percentage change from 2009 baseline

	No US ARG BRA PAR, UKR production −25 %			No US ARG BRA PAR, UKR production +25 %		
	Price	Supply	Demand	Price	Supply	Demand
KOR	8.4	1.3	(0.7)	6.7	1.0	(0.5)
EU27	1.9	0.4	(0.5)	0.1	0.0	(0.0)
CHN	0.9	0.0	(0.0)	(2.8)	(0.1)	0.1
BRA	1.0	0.3	(0.4)	(0.7)	(0.2)	0.3
ARG	0.7	0.2	(0.1)	(1.1)	(0.3)	0.2
USA	0.7	0.1	(0.1)	(2.1)	(0.4)	0.3
PAR	0.7	0.3	(0.2)	(1.1)	(0.4)	0.3
WBA	1.3	0.2	(0.2)	1.2	0.2	(0.2)
REU	2.0	0.3	(0.4)	0.7	0.1	(0.2)
RUB	2.8	0.9	(0.7)	1.5	0.5	(0.4)
UKR	2.1	(24.6)	(0.6)	1.2	25.2	(0.3)
IND	1.1	0.2	(0.2)	0.7	0.1	(0.1)
CAN	0.7	0.1	(0.1)	(2.3)	(0.4)	0.4
MEX	0.7	0.1	(0.1)	(2.3)	(0.5)	0.3
BUR	1.5	0.1	(0.1)	1.4	0.1	(0.1)
CAM	0.8	0.1	(0.1)	(2.4)	(0.2)	0.3
VEN	0.8	0.1	(0.1)	(2.4)	(0.2)	0.3
CHL	0.8	0.1	(0.1)	(1.2)	(0.1)	0.1
URY	0.7	0.1	(0.1)	(1.2)	(0.1)	0.2
BOL	0.7	0.0	(0.0)	(1.6)	(0.0)	0.0
RSA	0.8	0.1	(0.1)	(2.4)	(0.2)	0.3
JPN	0.9	0.1	(0.1)	(2.8)	(0.3)	0.2
THA	1.3	0.1	(0.1)	(1.1)	(0.1)	0.1
IDN	1.3	0.1	(0.1)	(1.0)	(0.1)	0.1
MYS	1.3	0.2	(0.2)	(1.0)	(0.2)	0.2
PHL	1.2	0.2	(0.2)	(1.1)	(0.2)	0.2
ANZ	0.8	0.1	(0.1)	(1.3)	(0.2)	0.1
MAR	2.1	0.4	(0.5)	0.1	0.0	(0.0)
TUN	1.4	0.3	(0.4)	0.4	0.1	(0.1)
DZA	2.2	0.4	(0.2)	0.1	0.0	(0.0)
EGY	1.2	0.2	(0.2)	1.4	0.3	(0.2)
TUR	1.2	0.3	(0.3)	1.3	0.3	(0.3)
ISR	1.3	0.2	(0.3)	1.4	0.2	(0.3)
LDC	4.4	0.3	(0.4)	3.0	0.2	(0.3)
AFR	1.9	0.1	(0.2)	0.1	0.0	(0.0)
C&P	0.8	0.0	(0.1)	(2.4)	(0.1)	0.2
MIDE	1.3	0.1	(0.2)	(1.0)	(0.1)	0.1
ROW	1.2	0.1	(0.1)	(1.5)	(0.1)	0.2

Scenario 3: No Trade with ARG, BGM, USA, PAR & 25 % Increase in Freight Charges

Since 2008 the global economic slowdown has had the effect of depressing global freight prices. The two previous scenarios were modeled using these lower freight costs. To better understand the role that freight costs play, we investigate a third scenario where freight costs are allowed to increase from the baseline by 25 %. It is worth mentioning that even at a 25 % increase the freight costs are generally below historic levels.

Since trading costs are assumed to increase uniformly across the globe, trading patterns change only in minor ways. Perhaps the largest change is the decrease in demand and trade associated with the increase in global CIF maize prices (Table 8).

Global prices increase significantly, but the effect of those price changes is not distributed uniformly. Large importers with relatively high transportation costs or who are furthest from the suppliers of maize have the largest price impacts. Asian countries all have significantly higher prices as transportation costs are a large component of the maize price in those countries.

Countries whose transportation routes change dramatically from the baseline, such as South Korea, are the most affected. South Korea has a 15.6 % increase in maize price. New exporters to South Korea (i.e. WBU, UKR, IND) are similarly affected. They now have a higher export demand at a higher global price, which leads to higher prices for those countries. Interestingly, the major exporters experience a decrease in prices, as the global demand for maize is negatively affected by the increase in transportation costs. In this scenario the major American exporters are forced to increase domestic consumption.

A decrease in transportation costs has the opposite effect. Most major Asian importers have significant decreases in prices. Although South Korea does not enjoy as much of a price decrease as its neighbors, due to its shift in trading partners, it too has a small price decrease in this scenario (Table 9).

Impact on Korean Livestock Market

Consumer demand for animal-based food products has been changing in Korea. As incomes and the overall standard of living have steadily increased since 1960, consumption of animal products has increased as well; since 1990 animal products have made up a fairly constant 20 % of the average Korean's diet by weight. Total daily per capita food consumption has also increased by over 35 % in the last 15 years, from 1101 g in 1995 to 1505 g in 2010. The result has been a steadily increasing demand for meat, particularly beef and chicken. Total annual per capita meat consumption has increased from 27.4 kg in 1995 to 41.3 kg in 2011, a 50 % increase. Pork still holds the largest share of meat consumption, 46 % in 2011, even though its proportion has declined over the years. Beef and chicken make up 26 and 28 %, respectively, of Korean meat consumption (KMTA 2013).

Table 8 Scenario 3: Increase or (decrease) in trade volume from 2009 baseline (1000 MT)

Importers	BRA	ARG	USA	PAR	WBA	REU	RUB	UKR	IND
Selected exporters									
KOR	(638)	–	(6932)	–	1238	–	–	5143	1288
EU27	–	1371	–	–	–	(5)	–	(1297)	–
CHN	(1700)	(254)	2554	–	–	–	–	–	–
CAN	–	–	29	–	–	–	–	–	–
MEX	–	–	64	–	–	–	–	–	–
BUR	–	9	–	–	–	–	–	–	–
CAM	–	–	16	–	–	–	–	–	–
VEN	–	–	9	–	–	–	–	–	–
CHL	–	–	–	6	–	–	–	–	–
URY	–	–	–	0	–	–	–	–	–
BOL	–	–	–	(0)	–	–	–	–	–
RSA	–	–	21	–	–	–	–	–	–
JPN	–	–	53	–	–	–	–	–	–
THA	(304)	348	–	–	–	–	–	–	–
IDN	–	–	631	–	–	–	–	–	(481)
MYS	9	–	–	21	–	–	–	–	–
PHL	(945)	1062	–	–	–	–	–	–	–
ANZ	–	6	–	–	–	–	–	–	–
MAR	(84)	–	100	–	–	–	–	–	–
TUN	–	–	–	–	723	–	–	(716)	–
DZA	–	–	1068	–	(589)	–	–	(472)	–
EGY	–	(2107)	2766	–	(500)	–	–	(4)	–
TUR	–	–	–	–	68	–	–	–	–
ISR	–	–	–	–	190	–	–	(179)	–
LDC	1443	–	–	–	–	–	–	–	(926)
AFR	24	–	–	–	–	–	–	–	–
C&P	–	–	3	–	–	–	–	–	–
MIDE	3306	495	–	–	(1164)	–	(49)	(2500)	–
ROW	(595)	(805)	1533	–	–	–	–	–	–
BRA	(269)	–	–	–	–	–	–	–	–
ARG	–	(25)	–	–	–	–	–	–	–
USA	–	–	(652)	–	–	–	–	–	–
PAR	–	–	–	(4)	–	–	–	–	–
WBA	–	–	–	–	15	–	–	–	–
REU	–	–	–	–	–	3	–	–	–
RUB	–	–	–	–	–	–	17	–	–
UKR	–	–	–	–	–	–	–	6	–
IND	–	–	–	–	–	–	–	–	56

Table 9 Scenario 3: Price, supply, and demand percentage change from 2009 baseline

	No US ARG BRA PAR, transportation costs +25 %			No US ARG BRA PAR, transportation costs −25 %		
	Price	Supply	Demand	Price	Supply	Demand
KOR	15.6	2.4	(1.2)	(0.6)	(0.1)	0.1
EU27	0.2	0.1	(0.1)	1.5	0.3	(0.4)
CHN	6.0	0.2	(0.2)	(7.6)	(0.2)	0.2
BRA	(1.7)	(0.4)	0.6	1.8	0.5	(0.6)
ARG	(2.1)	(0.6)	0.4	1.6	0.4	(0.3)
USA	(1.8)	(0.4)	0.2	0.7	0.1	(0.1)
PAR	(2.3)	(0.9)	0.7	1.6	0.6	(0.5)
WBA	0.9	0.2	(0.2)	0.3	0.0	(0.0)
REU	1.0	0.1	(0.2)	1.7	0.3	(0.4)
RUB	1.7	0.5	(0.4)	2.6	0.8	(0.6)
UKR	1.2	0.4	(0.4)	1.2	0.4	(0.4)
IND	2.1	0.4	(0.4)	(1.9)	(0.4)	0.4
CAN	0.7	0.1	(0.1)	(2.0)	(0.3)	0.4
MEX	0.8	0.2	(0.1)	(2.1)	(0.4)	0.2
BUR	4.3	0.3	(0.4)	(2.9)	(0.2)	0.3
CAM	1.4	0.1	(0.2)	(2.8)	(0.2)	0.3
VEN	1.4	0.1	(0.2)	(2.7)	(0.2)	0.3
CHL	1.6	0.1	(0.2)	(2.3)	(0.2)	0.3
URY	0.5	0.0	(0.1)	(1.1)	(0.1)	0.1
BOL	(1.8)	(0.0)	0.0	0.7	0.0	(0.0)
RSA	1.4	0.1	(0.2)	(2.7)	(0.2)	0.3
JPN	5.6	0.6	(0.3)	(7.1)	(0.8)	0.4
THA	5.9	0.7	(0.5)	(5.9)	(0.7)	0.5
IDN	5.4	0.5	(0.4)	(5.3)	(0.5)	0.4
MYS	5.5	0.9	(1.0)	(5.3)	(0.9)	1.0
PHL	6.0	1.0	(0.8)	(6.1)	(1.0)	0.8
ANZ	3.4	0.6	(0.3)	(4.0)	(0.7)	0.4
MAR	3.7	0.8	(0.9)	(1.9)	(0.4)	0.4
TUN	4.0	0.9	(1.0)	(2.7)	(0.6)	0.7
DZA	4.1	0.7	(0.3)	(2.1)	(0.4)	0.2
EGY	4.0	0.8	(0.7)	(3.0)	(0.6)	0.5
TUR	3.5	0.7	(0.8)	(2.6)	(0.5)	0.6
ISR	4.0	0.7	(0.9)	(3.1)	(0.5)	0.7
LDC	6.4	0.4	(0.6)	0.9	0.1	(0.1)
AFR	0.5	0.0	(0.0)	1.2	0.1	(0.1)
C&P	1.5	0.1	(0.1)	(2.8)	(0.2)	0.2
MIDE	5.5	0.4	(0.7)	(5.4)	(0.3)	0.6
ROW	6.2	0.4	(0.6)	(6.4)	(0.5)	0.7

Table 10 Korean livestock industry structure

Item	2012 2/4	2012 3/4	2012 4/4	2013 1/4
Korean native cattle				
Number of farms	151,191	147,210	141,495	136,529
Total herd size	2,983,967	3,016,958	2,932,815	2,847,620
Average herd size	19.7	20.5	20.7	20.9
Other beef cattle				
Number of farms	5615	5672	5853	5697
Total herd size	125,089	125,798	125,786	118,764
Average herd size	22.3	22.2	21.5	20.8
Dairy cattle				
Number of farms	6114	6070	6007	5986
Total herd size	409,970	417,306	420,113	419,509
Average herd size	67.1	68.7	69.9	70.1
Swine				
Number of farms	6525	6404	6040	6130
Total herd size	9,433,059	9,936,587	9,915,935	10,106,531
Average herd size	1445.7	1551.6	1641.7	1648.7
Chicken				
Number of farms	3751	3198	3144	2955
Total herd size	170,026,012	139,442,340	146,835,639	139,732,482
Average flock size	45,328.2	43,603.0	46,703.4	47,286.8

Source KOSIS (http://kosis.kr)

Given this changing profile of demand, we see an interesting dichotomy in the Korean livestock industry. As Table 10 shows, swine and chicken production are characterized by large operations with sizable animal populations. Larger operations can be more resilient in the face of input price increases, and since Korean pork and poultry products are largely similar to those on world markets, imported meat products could mute consumer price effects of an increase in feed costs but also affect the demand for domestic production. Dairy and beef production, on the other hand, have much smaller average herd sizes which would indicate significant numbers of smaller, specialty producers. While we would expect smaller operations to be more sensitive to input price increases, the Korean beef industry may be less vulnerable to input price increases. Again referring to Table 10, Korean beef production is dominated by Korean native cattle, a distinctive breed. As noted earlier, consumers regard native beef as a separate and preferable product from beef from other breeds, including imported beef. As such, import substitution may be limited in this market. Consumer beef prices and consumption response to increases in feed prices would largely be mediated by the elasticity of consumer demand.

The Korean mixed feed market has been growing and changing in response to the livestock market. Table 11 shows how the feed use profile and total production have evolved over the past 12 years. In line with the changes in consumer demand

Table 11 Korean livestock feed production, metric tons

Year	Beef cattle	Dairy cattle	Swine	Chicken	Other	Total
2001	2,759,854	1,770,809	5,549,480	3,873,545	819,981	14,773,669
2002	2,752,883	1,764,410	5,949,977	4,053,177	1,081,232	15,601,679
2003	2,926,271	1,744,215	5,663,340	3,907,482	1,015,823	15,257,131
2004	3,044,571	1,632,431	5,419,107	3,836,210	818,743	14,751,062
2005	3,292,880	1,587,452	5,169,675	4,203,365	826,207	15,079,579
2006	3,573,731	1,539,243	5,175,067	4,267,345	919,595	15,474,981
2007	3,880,384	1,449,231	5,409,210	4,403,051	1,006,338	16,148,214
2008	4,164,606	1,370,319	5,306,987	4,285,756	1,003,272	16,130,940
2009	4,309,808	1,310,728	5,331,898	4,462,660	1,066,121	16,481,215
2010	4,761,372	1,291,589	5,534,948	4,658,257	1,287,463	17,533,629
2011	4,792,196	1,239,754	4,481,696	4,748,375	1,402,405	16,664,426
2012	5,142,859	1,336,115	5,685,466	4,822,358	1,545,478	18,532,276

Note For 2012, the statistics are accumulated totals for each category by mid-December
Source Food, Agriculture, Forestry, and Fisheries Statistical Yearbook 2012, Ministry for Food, Agriculture, Forestry and Fisheries, Republic of Korea, 2013

Table 12 Ingredients used by Korean mixed feed industry

Category	Major ingredients	Metric tons used	Percentage of each category
Grain	Maize	5,852,961	59.1
	Wheat	3,155,760	31.9
Bran	Wheat gluten	863,108	41.9
	Wheat bran	656,340	31.9
Animal protein	Meat meal	49,549	31.0
	Others	31,666	19.8
Vegetable protein	Soybean meal	2,028,501	44.7
	Coconut meal	489,303	10.7
Minerals	Limestone	467,256	53.2
	Additives	129,776	14.7
Other	Molasses	473,874	47.3
	Animal fat	330,806	33.0

Source KOFEED Association (http://www.kofeed.org)

and production, the beef sector has consumed a growing portion of feed production, until its share is now nearly equal to that of the pork sector, which has not changed appreciably. Feed consumption in the poultry sector has been growing slowly, while in the dairy sector it has declined steadily. Overall feed production has increased by 25 % over this time. This growth in production is heavily dependent on a reliable supply of maize, since maize is the major ingredient input in feed production, as shown in Table 12, closely followed by wheat and soybeans. An interruption in the supply, with its attendant price increase, of any of these three

major ingredients could have a major impact on both the availability and the price of livestock feed in Korea.

As described above, nearly all biotech maize imported by South Korea goes into the livestock feed market, so livestock producers could find themselves on the front lines of trade disruptions and price increases in the event of an asynchronous approval incident. In order to assess the impact on production costs and retail meat prices, we assumed a 7 % increase in the South Korean maize import price and tested its effect on beef, pork, and poultry markets. This is the price increase from our first scenario, and the smallest price increase we obtained from the three model scenarios, so it represents the smallest potential impact on feed markets. To model the effect of this price increase we use a partial equilibrium model that is substantially similar to the one described in Alston et al. (2014). We explicitly consider the relationship between biotech maize and substitute products, primarily conventional maize and wheat in this instance, and other feed ingredients that are complement products. The 7 % price increase initially occurs in 2015 and is maintained for the succeeding five years, through 2020. Again, this is not because we have reason to expect the price shock to last this long; the duration of the shock is entirely dependent on how quickly the regulatory environment adapts to the disruption of trade. Since the Korean beef market is so strongly differentiated, we assume no import substitution; market equilibration takes place via price changes local to the Korean market. We model the pork and broiler markets as open to world trade, so world prices pertain and markets adjust through changes in import quantities.

Table 13 Beef, pork, and broiler supply and use, difference from baseline

		2015	2016	2017	2018	2019	2020
Beef							
Production (%)	1000 MT	−0.16	−0.08	−0.25	−0.67	−1.00	−1.21
Retail price (%)	Won/kg	0.39	0.06	0.49	1.23	1.71	1.83
Producer income (%)	Won	−0.16	−0.23	−0.14	0.00	0.04	−0.04
Total consumption (%)	1000 MT	−0.07	−0.04	−0.10	−0.25	−0.36	−0.43
Pork							
Production (%)	1000 MT	0.00	−0.15	−0.23	−0.29	−0.31	−0.35
Imports (%)	1000 MT	0.00	0.27	0.47	0.70	0.84	0.97
Total consumption (%)	1000 MT	0.00	−0.01	0.00	0.02	0.05	0.07
Broilers							
Production (%)	1000 MT	−0.21	−0.33	−0.40	−0.43	−0.45	−0.46
Imports (%)	1000 MT	1.11	1.43	1.82	2.24	2.51	2.65
Total consumption (%)	1000 MT	0.00	−0.02	−0.01	0.05	0.09	0.12
Meat consumption (%)	kg/person	−0.02	−0.02	−0.03	−0.03	−0.03	−0.03

The results of our model are shown in Table 13. The beef market reacts most strongly, as the effects of the feed price increase are not mediated by imports. Wholesale and retail prices both increase as livestock farmers decrease production in the face of more expensive inputs. Due to the long production cycle for beef, the adjustment takes a considerable time. Producers see an initial drop in income relative to the baseline condition. By the end of the period farmer income has recovered to a level essentially equivalent to the baseline, implying that consumers are bearing the full cost of the maize price increase in this market segment, in the form of higher beef prices and reduced consumption.

Pork and broiler markets show similar patterns of response to the price shock. Domestic production decreases due to increased input costs and imports increase in order to clear the markets at world prices. Due to the relatively very short cycle of poultry production, the broiler market makes a large adjustment in the year of the shock, nearly half the change from the baseline that we see by the end of this period, in both domestic production and imports. Pork production adjusts more slowly, as its production cycle is similar in length to that of beef. In both cases total consumption increases slightly as consumers substitute less expensive pork and chicken for beef. Pork and poultry farmers unambiguously lose in this scenario, as they experience higher input prices and lower production volume yet still only receive the going world price for their products. The greater availability of pork and broilers at world prices ameliorates to some degree the losses experienced by consumers in the beef market, but not completely. Overall meat consumption decreases slightly due to higher prices and restricted supplies.

Conclusion

In this chapter we have explored some of the effects of trade disruptions due to asynchronous approvals of biotech crop varieties on grain and meat prices in South Korea. We find that feed grain price increases of up to 15 % are possible, seriously impacting production costs of grain users. The effects of the changes in trade patterns can be compounded by normal variation in other areas, such as seasonal changes in crop yield and production or shipping costs. Since most biotech crops, especially maize and soybeans, are used as livestock feed, pork and poultry producers bear the brunt of the price increases. In contrast, in the strongly segmented beef market, consumers end up bearing the increased costs.

We do not predict that current South Korean policy towards biotech crops will necessarily cause these conditions to occur. Rather, this has been a case study, using South Korea as an example, of what could happen in the case of any medium-sized country that might significantly lag behind the pace of change in agricultural biotechnology. Because of the interconnectedness of global agricultural markets, a disruption of trade with any one country will have worldwide effects. This is true not only of the major importing and exporting countries, but also smaller consumers such as South Korea. If that country is heavily dependent on imports of biotech

crops its internal markets will be impacted more profoundly than any other country's, but all countries will feel the effects. The results we have obtained here illustrate the importance of maintaining an efficient system for testing and approving new biotech crop varieties. The world's farmers are facing the twin tasks of feeding an ever growing population with limited resources and adapting to changes in climate, pests, and other environmental factors. A continuing flow of updated and improved agricultural biotechnology events is essential to successfully accomplishing those tasks.

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Low Level Presence and Asynchronous Authorizations of Genetically Modified Products in China

Jikun Huang and Jun Yang

Introduction

China developed a public sector dominated biotechnology program and commercialized several genetically modified (GM) plants beginning in the late 1990s. Plants that have been approved for commercialization prior to 2006 include biotech-derived varieties of cotton, petunia, tomato, sweet pepper, poplar trees, and papaya. Bt cotton is the most successful story of China's biotech program as it currently accounts for nearly 70 % of total cotton area. Huang et al. (2002) show that, when compared with conventional cotton, Bt cotton increases yield by 15 % and reduces pesticide use by 35.4 kg/ha (or nearly 60 % of pesticide use). In 2009 China issued production safety certificates to Bt rice and phytase maize, although to date they have not been approved for commercial production. Biotech soybean, wheat, and several other crops have also reached different stages of the biosafety regulation process.

While China has not produced GM soybeans or GM maize domestically, it has imported and consumed significant amounts of GM soybeans and is likely to import large amounts of GM maize in the near future. When it comes to importing GM crops from other countries, China has set up a case-by-case regulatory system to import GM food and feed. China has been importing GM soybeans and soybean oil for more than 10 years, resulting in China being the largest GM soybean importer. Recently, China has shifted from being a maize exporter to importer.

GM crop imports are subjected to China's agricultural biosafety regulations. According to China's regulatory framework, any request for import approval for

J. Huang (✉) · J. Yang
China Center for Agricultural Policy, School of Advanced Agricultural Sciences, Peking University, Beijing, China
e-mail: Jkhuang.ccap@igsnrr.ac.cn

J. Yang
e-mail: jyang03@sibs.ac.cn

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commodities with GM events can only be started after the event has been approved in the exporting countries. This delays the import of the GM event for as long as it takes the Chinese regulatory authority to undertake its assessment and make a decision. The lack of asynchrony of approvals between China and exporting countries, together with China's policy on zero tolerance levels for unapproved GM products, has raised many concerns by the exporters in GM crop exporting countries and major biotech companies in the rest of world.

The purpose of chapter is to document the regulations and approval processes for exporting GM products to China and their likely implications to international trade. To achieve this objective, we use GM soybean and maize as examples because these are the major GM products imported into China. This chapter is organized as follows: "China's Agricultural Biotech Rregulations and Authorization Procedures for Importing GM Products" section presents China's biosafety regulations and authorization and application procedure for biotech crop import. "GM Soybean and Maize Trade and Likely Impacts of Biosafety Regulations" section presents China's trade of soybean and maize and discusses the likely impacts of low level presence (LLP) from biotech crops to China's imports and that of its major trade partners. The last section concludes this study.

China's Agricultural Biotech Regulations and Authorization Procedures for Importing GM Products

Biosafety Regulation of Agricultural Biotechnology in China

China established its regulations for agricultural biosafety in the early 1990s and has periodically updated and amended the regulations over the past 20 years. The first biosafety regulation, The Measures for Safety Administration of Genetic Engineering, was issued by the Ministry of Science and Technology (MOST) in 1993. This regulation consisted of general principles, safety categories, risk evaluation, application and approval, safety control measures, and legal responsibilities. Following establishment of the MOST's guidelines, the Ministry of Agriculture (MOA) issued the Implementation Measures for Safety Control of Agricultural Organism Biological Engineering in 1996, which covers plants, animals, and microorganisms. The Implementation Measures provided detailed regulatory procedures needed to meet the necessary biosafety requirements in each stage of GM organism (GMO) development. These biosafety regulations have adopted a case-by-case procedure. However, labeling was not part of this regulation, nor were any restrictions imposed on import or export of GM products. The regulation also did not cover processed food products that use GMOs as ingredients. Under this regulation a Biosafety Committee was established in 1997 to provide MOA with expert advice on biosafety assessments.

In response to the increasing volume of GM imports and rising consumer concerns about GM food products, China amended its biosafety regulations in 2001 and 2002. In May 2001, the State Council issued a new regulation to replace the previous one issued by MOA in 1996. This amended regulation at the national level is titled Regulation on the Safety Administration of Agricultural Transgenic Organisms, and also includes trade regulations and labeling of GM products. This regulation came into effective on May 23, 2001. With the authority outlined in this new regulation, the Ministry of Agriculture issued three implementation regulations on biosafety management, trade, and labeling of GM products. These new implementations came into effect on March 20, 2002. The list of agricultural GMOs covered by labeling requirements includes 17 products from 5 different GM crops. They are soybean seeds, soybeans, soy flour, soy oil, soy meal, corn seeds, corn, corn oil, corn flour, rape seeds for planting, rape seed, rape seed oil, rape seed meal, cotton seeds for planting, tomato seeds, fresh tomatoes, and tomato sauce.

There are two important policies relating to GM product trade in the amended regulations. They are asynchronous authorization and zero tolerance. In accordance with China's biosafety regulation on GM imports, foreign institutions or companies that wish to export a GM product to China must submit the related certificate of biosafety approvals from the original country to China's Biosafety Management Office. The Chinese biosafety regulation process for import of any GM event can only be started after the event has been approved in the original country. This process normally takes about 2–3 years to get final permission. If a GM event is approved after undergoing regulatory review, the MOA then places the event on a list of products approved for import. For all approved GMOs, exporters (typically foreign trade firms that are selling food commodities into China) have to apply to the MOA for an export permit. At the same time importers (typically domestic firms inside China) must apply for import permits. In principle, export permits from foreign countries normally take a couple of months to be approved. Obviously, the asynchronous authorization between exporting countries and China is creating the risk of LLP and delaying commodity trade.

A zero tolerance policy further increases the risk for GM product trade. China has adopted regulations for a zero tolerance level for unapproved GM products. This means that any product imported would be refused if unapproved events were detected within that shipment. Combined with the asynchronous authorization of GM events between exporting countries and China, this zero tolerance policy is having significant trade implications.

When the tests prove the importer is in compliance, the shipment is released for unloading as long as the fees for the tests have been paid. According to China's regulations, for the first 10,000 tons, 20 samples are randomly chosen. After the first 10,000 tons, an additional sample is randomly chosen for each 1000 tons. Therefore, for a 60,000 ton vessel that is fully loaded, a total of 70 samples need to be tested. The tests are done in a local laboratory that is under contract to the port biosafety authority. The tests identify whether or not the shipment contains GM events and what types of GM events are present. Details of testing procedure are discussed in Huang et al. (2008).

Major GM Events of Soybean and Maize Approved in China

Based on China's biosafety regulations, the MOA has approved three GM soybean events. Although there are many more GM soybean events approved for production in the major soybean producing countries of Argentina, Brazil, and the USA, only three varieties are able to be exported to China. These export countries have successfully managed the risk of LLP of unapproved events, as there has not been any trade rejections occurring in the past 10 years. However, the difference in approved events between China and its main exporters represents a considerable risk for commodity traders who export soybeans to China.

China has also approved numerous GM maize events. According to Eurofins GeneScan (2012), 30 GM events of maize have been approved up to November 2012 in the USA, the largest maize exporting country in the world. However, of the 30 events approved in USA, only 13 events have been approved in China. There have been increasing concerns regarding asynchronous authorizations of GM maize events between the USA and China, given that China has become one of major maize importing countries in recent years. Different from soybean imports, China has rejected GM maize import shipments. For example, in November 2010, about 5.4 tons of GM maize imported from USA was refused entry by China because the unapproved GM event of MON89034 was found in the shipment. The GM event MON89034 was approved for import in 2011. More recently, the biotech industry is increasingly concerned about asynchronous authorizations of Syngenta's Agrisure Viptera variety that has been approved for production in the USA, but is still undergoing the Chinese approval process in 2013.

GM Soybean and Maize Trade and Likely Impacts of Biosafety Regulations

GM Soybean and Maize Trade

To estimate the amount of GM soybeans and maize imported into China, we classified soybean and maize imports by country regardless of whether a particular country produces GM soybeans or maize. Soybeans or maize is considered as GM if it is imported from a GM soybean or maize producing country; otherwise it is defined as non-GM. In the analysis, soybeans with codes of HS120100 and maize with codes of HS100590 and HS100510 are included. All trade data are from the UN Comtrade database from 1996 to 2010.

Base on trade data, China's soybean imports are dominated by exporting countries with GM production. As shown in Fig. 1, the three leading exporters of soybeans to China are the USA, Brazil, and Argentina. For example, China imported 58.4 million tons (or US$34.9 billion) of soybean in 2012, which was about 4.5 times domestic production. The import quantity shares from the USA,

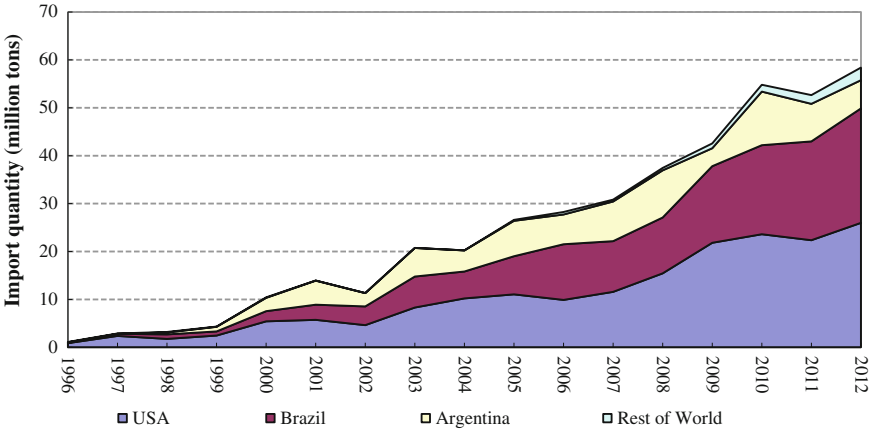

Fig. 1 Imports of soybeans to China, 1996–2012

Brazil and Argentina were 44.5 %, 40.9 %, and 10.1 %, respectively, in 2012. Because the USA, Brazil, and Argentina are the three largest GM soybean producing countries and based on the definition of GM and non-GM soybean in this study, we estimate that GM soybeans accounted for about 92 % of total soybean imports in 2012.

Similarly, China's maize imports are also dominated by GM varieties. China used to be a net exporter of maize from 2000 to 2009, with annual average net exports of 6.36 million tons (NBSC 2010). However, China's maize exports have declined rapidly in recent years because of rising demand for feed and processing uses. In 2010 China ceased to be a net exporter of maize and became a net importer. Imports have steadily risen from 1.57 million tons in 2010 to 5.2 million tons in 2012 (Fig. 2). Based on our estimate, it is expected that China's imports of maize

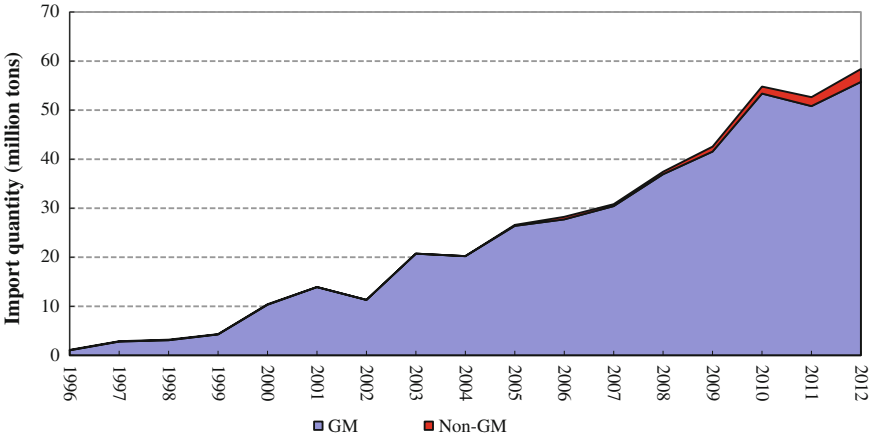

Fig. 2 Imports of GM and non-GM maize to China, 1996–2012

will further rise in the future (Huang et al. 2010). Meanwhile, the USA is the dominant maize exporter to China. As shown in Fig. 2, in 2012 there were 5.1 million tons of maize imported from the USA, which accounted for 98.2 % percent of total imports. Moreover, the USA is also the world's largest GM maize producing country, consequently it is not surprising that the majority of maize imported by China is GM.

Likely Economic Impacts of LLP of GM Soybean and Maize

Economic impacts from LLP of agricultural biotechnology products can be quite complicated. The impacts and costs over the long run are easier to analyze, while the short run impacts and costs can often be more challenging to quantify. For example, when a large volume shipment of a GM product is rejected at the point of border import inspection, the domestic market might not be capable of responding to the decrease in market supply, should there not be enough domestic supply or alternate import options in the short term. Under these circumstances, the rejection of a commodity shipment due to the detection of an unapproved GM product comingled into the imported commodity could result in significant food price increases in the short run (Gruere 2009). Other impacts that have received considerable attention include the disruption and difficulty of international commodity trade arrangements due to perceived risk of shipping non-GM crops that might contain LLP of GM crops to importing countries with zero-tolerance policies (Kalaitzandonakes 2011; Kiekebusch 2012; Stein 2009). When unauthorized shipments due to higher than accepted levels of LLP from GM crops have to be shipped back the original country or transferred to a third county the costs to exporters are high. Some commodity traders claim that the risks and costs associated with LLP of unauthorized GMOs are substantial, though little empirical analysis of this topic has been published so far.

To aid in the understanding of potential trade and economic implications of LLP and asynchronous authorizations of GM soybean and maize, Huang and Yang (2014) recently applied the Global Trade Analysis Program (GTAP) in an effort to quantify some of long term impacts for China and its major trading partners. These results show that "China's biosafety regulations on biotech crop import, which requires that import applications start after approval from the country of origin and the zero tolerance rule, will have important implications to major GM producing countries that export GM products to China in terms of trade, price and production and also to China itself in terms of food price and economic welfare." (p. 30, Huang and Yang 2014). The results also show that the impact on exporting countries and China's soybean production and price could be much large than those of maize. This is simply because soybean imports are substantially larger than maize imports. But with increasing maize imports in the future, it is expected that trade conflicts and impacts resulting from LLP and asynchronous authorizations of GM maize will also increase over time. Huang and Yang (2014) also show that while falling

imports of soybean and maize could increase domestic production, production expansion in China will be at the expense of other crops and livestock sectors. Social welfare in China would decline by US$191 million if 10 % of soybean imports were to be rejected due to LLP in 2015.

Conclusions

The world has witnessed a rapid increase in the number of countries adopting GM crops and in the cultivated area of GM crops. By 2012, 28 countries worldwide had planted GM crops, with the cultivated area reaching 170.3 million ha (James 2012) with soybeans, maize, cotton, and canola accounting for most of that area. Moreover, the adoption and cultivated area of the GM crops in the world are expected to continue this rapid growth (James 2012). China is one of the major countries undertaking research and development of GM technology and one of the first countries in the world to have commercialized GM crops (Huang et al. 2005). China has many GM crops in the pre-commercialization stage of production.

Reviews of China's biosafety regulations on biotech crops and their likely economic impacts in this chapter show that there are important implications from LLP and asynchronous authorizations of agricultural biotechnology on trade, food price, cost, and risk of trade. The disruption of trade in maize and soybeans caused by LLP will generate negative impacts on production, price, and trade with China's main trading partners, and in the meantime it will also have adverse effects on China's food prices and the nation's overall economic welfare. Although in some sense LLP regulations provide certain protections on those import commodities, there is a trade-off between food supply, food price, and social welfare induced by biosafety regulation on GM imports.

Less trade-distorting regulations on LLP can take advantage of comparative advantage of agricultural production, stabilize domestic food price, and increase total social welfare. Moreover, there could be a win-win scenario by finding pragmatic policy solutions that seek to ensure the health and safety of imported commodity shipments and to minimize disruptions to international trade without overly burdensome costs. Therefore, further global cooperation and multilateral information sharing mechanisms should be set up to enhance the safety management and also lower the multifarious and unnecessary costs of LLP.

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Asynchronous Approvals and the Low Level Presence of Unapproved GM Products in Imports: How "Tolerant" Should Small Countries Be?

Guillaume P. Gruère

Introduction

At the side of China and India, a number of small Asian countries are in the process of developing their biosafety regulatory frameworks. Most of them have continued to import genetically modified (GM) commodities or the products derived thereof with no or limited specific regulatory requirements, while developing guidelines and regulations on imports and use of GM commodities.

For these countries, implementing biosafety regulatory frameworks may create several trade related challenges that other countries do not face. First, introducing case-by-case regulatory authorization of GM events for use as food or feed, as they intend to do, will inevitably result in cascades of approvals that will be difficult to handle all at once. Second, given their relatively small market size, biotech companies may not have the economic incentive to submit an import approval dossier to the regulatory authority for each new GM event they introduce in foreign countries. Third, as price takers, they will not affect the world market for GM products if they reject GM imports.

Because of these specificities, small countries may be more likely to face the presence of new GM events in import shipments that have been approved by the exporting country but not subject to approval for import. In other words, asynchrony of approvals may have different implications for these countries than for large exporters or importers of GM products with pre-existing biosafety systems that have been the subject of other studies, such as members of the European Union, the United States, Latin American countries, or China (e.g., Kalaitzandonakes 2011). There is an increasing risk that these countries will be facing low level presence

G.P. Gruère (✉)
Formerly at the International Food Policy Research Institute (IFPRI), Washington, DC, USA
e-mail: ggruere@gmail.com

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(LLP) of GM products in imported shipments, leading to trade disruption if they enforce a zero tolerance policy.

This chapter aims to complement other studies by providing an economic analysis of asynchronous approval and applications of the Codex Annex (Codex Alimentarius Commission 2008)—a guideline that elicits a set of simplified risk assessment guidelines on the temporary approval for the low level presence of GM products approved by the exporter but not yet approved by importers—in small developing countries with an application to Vietnam. An analytical model is built to measure the trade-off between perceived safety and trade considerations. This model is used to simulate the cost of implementing regulations in the short run and of using different tolerance levels for LLP in the long run.[1]

The remaining part of the chapter is organized in two sections and a conclusion. The first section introduces the analytical model to identify the main policy constraints and variables. The second section applies the model to the case of Vietnam.

Economic Effects of Alternative LLP Policies in a Small Country

Let us assume, that at time t_0, a country A is importing product X from a GM producing country B. At time t_1, a new GM variety of X is approved in country B, but not yet in A. B is also a country where GM commodities are mixed in the system. In the absence of approval, until time t_2, and assuming a zero tolerance level, A has to find another version of the good, either in country B or another country to satisfy demand. For simplicity we assume that country A has to purchase a non-GM good at a higher price than the comingled GM commodity previously purchased from B, but in practice it could be a GM product coming from another country. Because A is a small country, it is assumed to be a price taker on the international market. Assume a linear inverse demand for X in country A, $p = aQ + b$, $(a < 0)$ and a linear supply $p = cQ + d\,(c > 0)$. Excess demand is derived as total demand minus production. It is also assumed that from the regulatory perspective of country A, knowing that the product has been approved in B, the probability of a food safety problem from the new GM event is well defined with a distribution $N(\sigma, v)$. This factor is taken from A's perspective, i.e., it is a perceived risk component that incorporates knowledge about potential real risk, uncertainty and confidence in the exporter's safety approval procedure. Lastly, we assume perfect enforcement as a benchmark and that the regulator is benevolent and independent in its decisions.

Country A makes its decision according to a social welfare function W that includes consumer and taxpayer welfare, taken within a production period:

$$W = w + (b - p)/Q + cQ^2/2 - \sigma DQ - CI(Q) \tag{1}$$

[1]The analysis draws on a longer analysis published by the International Agricultural Trade Policy Council. See Gruere (2011).

where w = basic welfare derived from good consumption; b = demand parameter; c = supply parameter; p = expected price under adopted policy; Q = quantity; σ = expected probability of potential damage per unit; D = damage per unit; and CI = cost of implementation.

Total welfare, as defined by this expression, can be allocated into three components: first, the Marshallian surplus; second, the expected damage from importing a possibly or perceived unsafe good; and third, the public costs of regulation. These three terms will be extended in more details below.

Most of the parameters depend on the regulatory choice. For simplicity, we will assume three possible regulatory scenarios for country A, that will be the main options of small developing country importers: (i) 0 % LLP; (ii) τ % tolerance to LLP (0 % < τ < 100 %); and (iii) let everything pass (τ = 100 %). We separate scenarios with zero or 100 % tolerance to single out the effect of implementing a LLP policy.

Total Surplus Effect

Total surplus can be divided into consumer and producer surplus. Consumer surplus is based on prices and quantities but will vary according to the regulations. In particular, for a given period, the variable (p) can be defined as the expected price, which depends on the proportion of non-GM products in imports (k_g) and the probability of rejection of shipments (π), and is defined as:

$$p = k_g p_0 + \left(1 - k_g\right)\left(\pi p_n + (1 - \pi) p_0\right) \tag{2}$$

where p_n is the price of non-GM counterpart and p_0 the price of the GM/mixed good (originally the price of the good). Assume $p_n = p_0(1 + \Delta)$, i.e. there is a proportional price premium Δ when one avoids the original undifferentiated mixed GM good, and Eq. (2) can be simplified to:

$$p = p_0\left(1 + \pi\left(1 - k_g\right)\Delta\right) \tag{3}$$

Note that this probability of rejection (π) can be interpreted as the probability of B traders not sending a shipment to country A because of the risk of rejection, and/or because the insurance cost would make their good noncompetitive. Thus the "rejection" rate may not mean an actual rejection; what matters is that the expected price is a weighted average of GM and its non-GM substitute.

This probability of rejection depends on the tolerance level τ, on the expected (average) concentration of non-approved GM events μ, and on the timing of approval at export and import. Indeed, there is a higher probability that a shipment will be rejected at a low tolerance level than at a high tolerance level for any shipment and that a shipment with a lower likelihood of presence of unapproved events will be accepted for any tolerance level. The timing of approval matters

significantly; the longer it takes to undertake a risk assessment, the longer shipments will be rejected. As time increases beyond a production season the concentration of the new GM event is likely to increase, so the probability of rejection should also increase. Figure 1 shows an illustrative schedule of rejection probabilities within a production season under different regulatory options for a shipment where the expected concentration original μ is close to a few percent. In this figure, the following notations are used to represent the timing of decisions:

- t_0: time of production approval in B,
- t_1: after production, export from B,
- t'_1: LLP approval,
- t_2: import approval.

Figure 1 also illustrates that timing is critical; the extent to which there is asynchrony in approval matters, and so does the delay to approve a new GM event for LLP. Furthermore, if the Codex Annex is applied a simplified procedure is used, but this procedure will only be effective if it is conducted quickly and if it is effectively faster than the full approval procedure. Taking this into consideration, there are three key timing related parameters:

$T_1 = t'_1 - t_1$ delay for LLP approval,
$T_2 = t_2 - t_1$ delay for full approval,
$T_3 = T_2 - T_1$ difference in speed between the LLP and full procedure.

Regarding surplus calculations, we use Marshallian welfare measurements. Higher prices due to trade restrictions will result in higher consumer price and lower consumer surplus. On the supply side, a higher domestic price, due to restrictions on GM imports can result in a supply response and higher producer surplus. However in an importing country, with linear and supply demand, this effect will not compensate for the loss in consumer surplus.

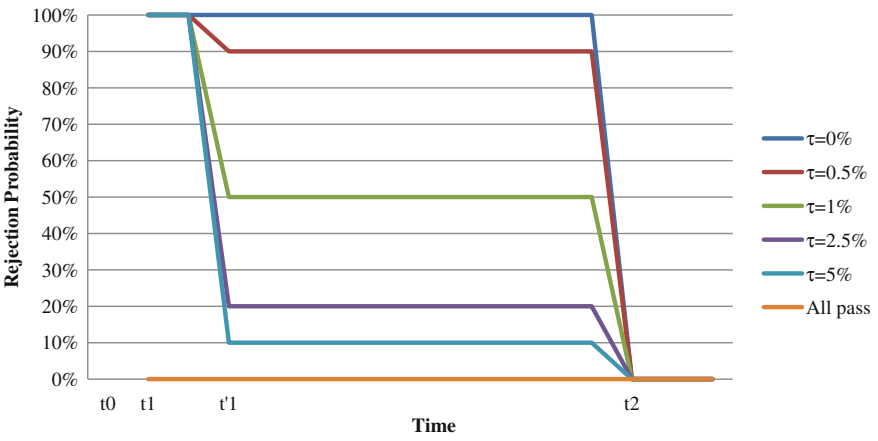

Fig. 1 Probability of rejection and regulatory options. *Source* Author

Risk and Perceived Safety

The second factor that affects welfare relates to safety and its proxy from the standpoint of the regulator, perceived safety. The goal of biosafety regulations for imported consumption goods for food, feed, or processing is to limit risks for consumers. In the presence of uncertainty and/or imperfect knowledge, the perspective of the regulator matters; this is why we use the term perceived safety.

In our analysis we model risk using an exposure and damage framework. Because of uncertainties we assume that the exposure is modeled as a probability distribution of potential damage per unit consumed. Figure 2 shows our interpretation of risk probabilities under different regulations. We assume that regulations affect both the mean and variance of the probability distribution of risks, but they do not completely eliminate risks. A zero percent LLP policy in the short run does provide some certainty as to food risks but does not eliminate risk. A nonzero percent tolerance level is modeled as a shift δ in mean probability of risks compared to zero percent, but we assume that the variance remains the same. This shift reflects the perceived possible risk associated with importing trace levels of a still unapproved GM product. Lastly, no import policy can both shift the mean and increase uncertainties about the perceived safety of imported products.

K is the crucial determinant of the perceived risk increase with a change in LLP tolerance levels for unapproved GM. K can be seen as the maximum expected risk increase from non-GM to 100 % GM. It depends on the type of product, the intended use of the product, and on the perceived value of the exporter's regulatory framework. If a country has a strong trust in the exporter's regulations, based on record or scientific expertise, it will not fear new unknown LLP risks in shipments. However, if the exporter's regulatory body is not considered credible, the importer will fear any possible intrusion of non-approved GM material.

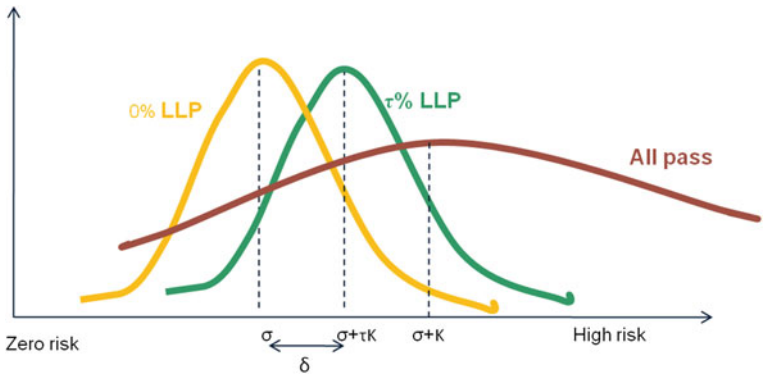

Fig. 2 Perceived risk probability distributions under different regulatory scenarios. *Source* Author

Cost of Implementation

The cost of implementation is defined as:

$$CI\,(Q) = (C_1(\tau)\,S(\tau) + C_2)\,Q \tag{4}$$

where $C_1(\tau)\,S(\tau)$ corresponds to the total testing costs, and C_2 the cost of equipment and inspectors. Both components are considered variable costs because they depend on total quantity imported. The first term depends on the tolerance level, as it is generally assumed that: $C_1(\tau < 1\ \%) > C_1\ (1\ \% < \tau < 5\ \%) > C_1(\tau > 5\ \%)$, given detection level requirements. $S(\tau)$, defined as the sampling factor, is directly dependent on the tolerance level. A high tolerance level does not require as large a sample for a given concentration level.

Identifying the Key Parameters

A rational and benevolent decision maker will choose the best regulatory options to maximize total welfare. The options are characterized by four choice variables: the tolerance level; the two timing variables T_1 and T_2; and the shift parameter K, representing the lack of confidence in a given exporter's regulations. Table 1 shows the basic price and welfare effects of an increase in each parameter by component and in total.

Simple derivations show that a higher tolerance level decreases the expected price of the imported good, which increases consumer surplus, but it maintains or decreases the risk avoidance factor/perceived safety of the regulation (depending on K) and decreases the cost of implementation. As a result, the effect on total welfare is ambiguous. In contrast, a rise in the LLP processing delay increases expected price except if the tolerance level is zero, and therefore either maintains or decreases consumer surplus. The risk avoidance effect is similar, and the cost of implementation may increase or remain unchanged. Thus the total welfare effect is either

Table 1 Effect of an increase in each key parameter on the total welfare of a LLP policy

Increase in	Price	Consumer surplus	Risk avoidance/perceived safety	Cost of implementation	Total welfare
τ	$\downarrow$	$\uparrow$	$\downarrow$ or $\rightarrow$	$\downarrow$	$\downarrow$ or $\uparrow$
T_1	$\uparrow$ or $\rightarrow$	$\downarrow$ or$\rightarrow$	$\rightarrow$	$\uparrow$ or $\rightarrow$	$\downarrow$ or $\rightarrow$
T_2	$\uparrow$	$\downarrow$	$\rightarrow$	$\uparrow$	$\downarrow$
K	$\rightarrow$	$\rightarrow$	$\downarrow$	$\rightarrow$	$\downarrow$

Source Author

negative or zero. Similarly, a longer delay in LLP approval will decrease consumer surplus and increase implementation costs with a resulting decrease in welfare. Lastly, increasing K, the lack of trust in the exporters' regulation, will only reduce the risk avoidance effect of any LLP policy and therefore reduce total welfare.

These results suggest that decision makers will always benefit from reducing approval delays and increasing confidence in exporters' regulation. In contrast, setting up the tolerance level involves balancing risk perceptions and economic considerations. The next section uses this framework to provide an empirical application of the model in the case of Vietnam.[2]

Application: Vietnam and the Low Level Presence of Unapproved GM Events

An Importer of GM Crops with Zero Percent Approval

There is no international database tracking movements of GM versus non-GM commodities and products, but one can use existing bilateral trade data as well as regulatory differences and GM adoption patterns to induce the share of trade that is likely GM. Here, we focus on imports of maize (HS classification code 100590), soybeans (HS 120100) and soymeal (HS 230400), using data from the UN Comtrade database from 1999 to 2010. To cope with asymmetries in trade reporting, and the fact that import and export data can be distorted by the reporters, we use two evaluation methods. The first method uses import data from Vietnam as a primary source and completes it with export data from partners (consistent with Feenstra et al. 2005). The second method focuses on reports from exporters to Vietnam and completes missing trade flows with import data. We also use adoption years for each GM commodity from the International Service for the Acquisition of Agri-biotech Applications (ISAAA) to ensure that annual exports only from GM adopting nations are considered likely GM. The results are presented graphically in terms of volumes and values in Figs. 3, 4, and 5 for the three commodities.

Overall, Vietnam has imported significant quantities of likely GM products, especially since 2004/05, and that the share of GM products is increasingly important. In average, at least 700,000 tons (worth USD 200 million) of GM products have been imported annually between 1999 and 2010. In 2010, this total reached 1.1 million tons (worth USD 374 million) and the share of GM import volume exceeded 80 % of total imports after 10 years of fluctuation between 18 and 54 %.

[2]The assessed regulatory options and data used for this application date from 2010 (or earlier), when this analysis was first developed.

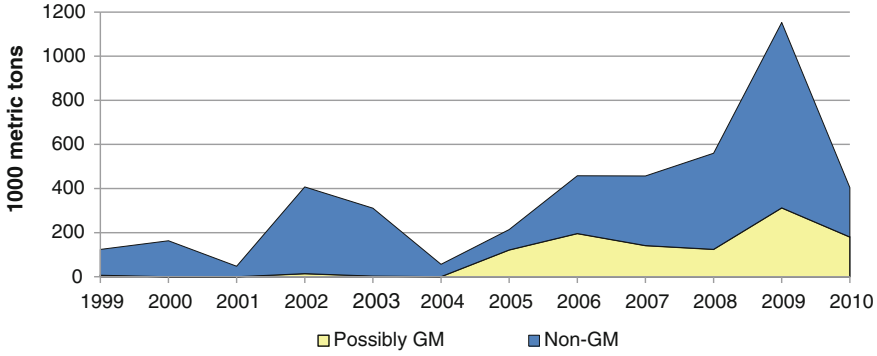

Fig. 3 Estimated volume of GM and non-GM maize imports in Vietnam

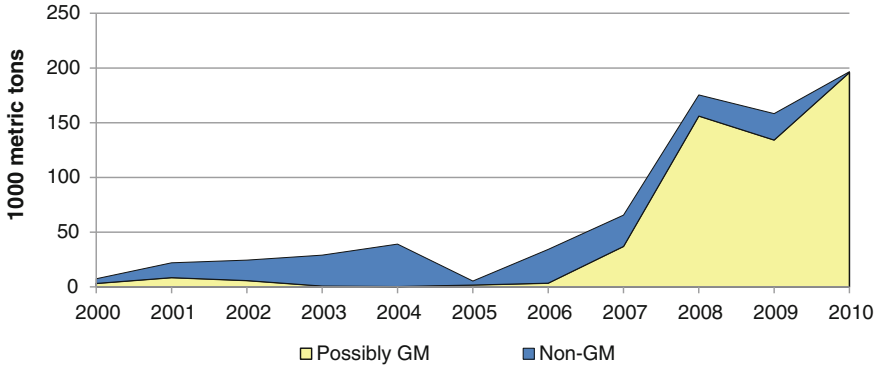

Fig. 4 Estimated volume of GM and non-GM soybean imports in Vietnam

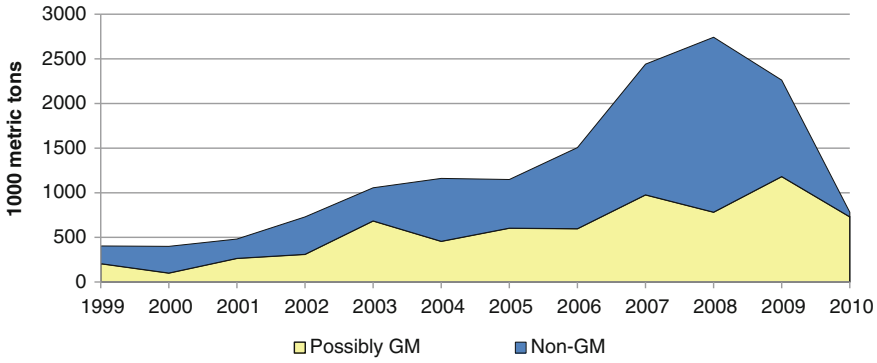

Fig. 5 Estimated volume of GM and non-GM soymeal imports in Vietnam

Biosafety legislation in Vietnam was built progressively in several iterations (Than Nan 2009). The 2010 biosafety regulation stipulates GM organisms used in food or feed can only be allowed if they have been the subject of an authorization—a certificate of eligibility for use as food or feed—by the relevant authority (Socialist Republic of Vietnam 2010). There are two alternatives to obtain this authorization. An applicant can:

(1) obtain a certificate from the GM food safety council, under a food safety application process similar to that in other countries, or
(2) demonstrate that the GM product has been permitted by at least five developed countries for use as food and no risk has been seen in these countries.

A decision under option (1) is required to be taken within 180 days, while option (2) is required to lead to a determination within 2 months. In both cases, no product can be used or imported before getting approved, i.e., there is a zero tolerance level for unapproved products.

The Cost of Different LLP Policy Options

Using the general assumptions of the analytical framework, we evaluate the effects of the presence of unapproved events in the short and long run. Because of large uncertainties and the lack of reliable data on risk perceptions, we do not compute the risk avoidance term of the welfare function. Instead we compare the costs and economic surplus effects of different regulatory options to derive an estimate of what risk perception differences a particular option would imply for welfare maximization.

Table 2 provides a summary of the sources of the basic data used for computation. We focus on 2005–2009 because Vietnam has been importing increasing amounts of GM commodities since 2005. For alternatives to GM, we collect the trade values and volumes for all the GM producers of maize and soybeans between 2005 and 2009 on FAOSTAT. We identify for each year the GM producing countries, and differentiate the GM price and non-GM price for the three products. The difference between the two is computed as a market premium, of which we take the average value between 2005 and 2009. For instance we find average premia of 26.1 % for maize, 25.8 % for soybeans and 24 % for soymeal, accounting for all GM producers. These figures are consistent with data from the Tokyo Grain Exchange in the case of non-GM soybeans.[3] For the cost of testing CI(Q) we assign cost values between USD 0.10 and 2.50/ton, depending on the scenario based on the estimates used by Huang et al. (2008) in the case of China.

[3]The assumed rates may be on the higher range, but valid for a country like Vietnam, far from large producers, and with limited demand and bargaining power.

Table 2 Sources of data for the basic parameters

Parameter	Source
Production	FAOSTAT, average 2005–2009, zero for soymeal
Original price	Ratio of total trade value over total trade quantity, based on FAOSTAT data 2005–2009
Elasticities of supply and demand	IFPRI IMPACT model projection 2005–2009
Total imports	COMTRADE data used in section 1, for 2005–2009
Share of affected imports	Derived from COMTRADE data (used in section 1 for 2005–2009 evaluated under different scenarios)
Price premium	Derived from the difference between the trade value/quantity ratios for GM and non-GM producers, FAOSTAT data, for 2005–2009
Cost of testing/volume	Assumed to follow the following schedule per tolerance level: 5 %: USD 0.1/ton, 2.5 %: USD 0.5/ton, 1 % and 0.9 %: USD 1/ton, 0.5 %: USD 1.5/ton, and 0.1 %: USD 2.5/ton

Source as indicated

Short Run Considerations

When Vietnam introduces its regulatory approval procedures, it will face a cascade of approvals. This may create trade disruption in the short run if all commercial GM events are not approved. Still, the 2010 biosafety system set up in Vietnam allows for an accelerated approval process for GM events authorized and safely used in at least five developed countries. If this system works efficiently, is it likely that any GM will event remain unapproved during the transition?

To respond to this question, we looked at GM maize and soybean events approved in the United States and Canada as of 2010, two of the main exporters of GM crops where virtually all GM events currently used in these commodities have been approved first. We assume that the definition of developed countries includes nations with functioning regulatory systems, members of the OECD (e.g., Australia, Canada, European Union countries, Japan, Korea, Switzerland, and the United States). We further assume that GM crops only approved in USA and Canada are not traded on the international market. The GM events that are in use and not approved in five developed countries are the remaining ones. As shown in Table 3, eighteen of the thirty-eight GM events approved for planting in North America (as of 2010) would qualify for the rapid approval system under the Vietnamese regulation. In contrast, ten GM maize and soybean events would not qualify and yet be likely present in traded shipments arriving in Vietnam.

Assume that GM events under the short run clause are approved within 2 months, as stipulated in the regulation, while others are approved within 6 months. The 4 month difference extends the zero tolerance level on unapproved events especially in the US and Canada and thus results in changes in rejection probability and prices. We first calculate the annual economic effects of a zero tolerance level for rapidly

Table 3 GM event approvals passing the 5 developed country authorization threshold

Commodity	GM events approved in at least 5 developed countries	GM events approved in less than 5 developed countries		Total GM events planted in the USA or Canada
		Likely used in production	Probably not used or limited use	
Maize	14	7	8	29
Soybeans	4	3	2	9
Total	18	10	10	38

Source Authors, compiled from CERA (2010)

Table 4 Economic analysis of the two tier approval system for maize (in million USD)

	Crop	Rapid approval process for 18 GM events		Delay for US and Canada 10 GM events		Total effects
		Annualized	For 2 months	Annualized	For 4 months	
Consumer surplus effect	Maize	−65.0	−10.8	−9.1	−3.0	−13.8
	Soybean	−20.2	−3.4	−19.4	−6.5	−9.9
	Soymeal	−47.9	−8.0	−3.7	−1.2	−9.2
Producer surplus effect	Maize	+59.2	+9.9	+8.1	+2.7	+12.6
	Soybean	+16.0	+2.7	+15.3	+5.1	+7.8
	Soymeal	0	0	0	0	0
Total surplus effect	Maize	−5.8	−1.0	−1.1	−0.3	−1.3
	Soybean	−4.2	−0.7	−4.1	−1.4	−2.1
	Soymeal	−47.9	−8.0	−3.7	−1.2	−9.2
Cost of implementation	Maize	−1.3	−0.2	−2.6	−0.9	−1.1
	Soybean	−0.2	−0.04	−0.3	−0.09	−0.1
	Soymeal	−9.1	−1.5	−10.0	−3.3	−4.8
Total welfare change	Maize	−7.1	−1.2	−3.7	−1.2	−2.4
	Soybean	−4.5	−0.7	−4.3	−1.4	−2.1
	Soymeal	−57.0	−9.5	−13.8	−4.6	−14.1
Total three products		−68.6	−11.4	−21.8	−7.2	−18.6

Source Author's derivations

appraised products and then for those events from the US and Canada that are not qualifying for the 5 country clause. The results are shown in Table 4.

The total economic cost of the proposed system in the short run, not accounting for perceived safety increase, is estimated to be at USD 18.6 million for the three

products. Assuming all GM events could be processed within 2 months if eligible, we find that this total is reduced to USD 11.4 million. Therefore, the cost of having a five developed countries clause rather than three is estimated to be USD 7.2 million.

What Tolerance Level?

Given the absence of any reliable benchmark value, we set up a schedule of rejection probabilities, using a range of mathematical simulations. We assume that the observed concentration in a traded shipment is following one of seventeen normal distributions defined by distinct mean and standard deviations parameters between 0.01 and 2.5 % (truncated at zero to ensure that all concentrations are positive). Under each distribution we drew 1000 successive numbers and compared these numbers to six given tolerance levels: 0.1, 0.5, 0.9, 1, 2.5, and 5 %. Each time the concentration was above the tolerance level, the shipment was rejected. By counting the number of iterations where the shipments were rejected and dividing by 1000, we obtained probability of rejection for a given tolerance level and concentration distribution.

Figure 6 shows the results. On the horizontal axis, the seventeen distributions are presented with mean concentrations ranging from 0.01 to 2.5 % (from left to right), and variances within the same range. The results confirm that acceptance largely vary by tolerance level, but also help us determine the maximal mean and variance of concentration under which there will be no rejection for each tolerance level. This schedule is then used to set up probabilities of rejection under different tolerance levels for a given concentration as shown in Table 5 for four distributions of concentrations: N(0.1 %, 0.1 %), N(0.5 %, 0.5 %), N(1 %, 1 %) and N(2.5 %, 2.5 %).

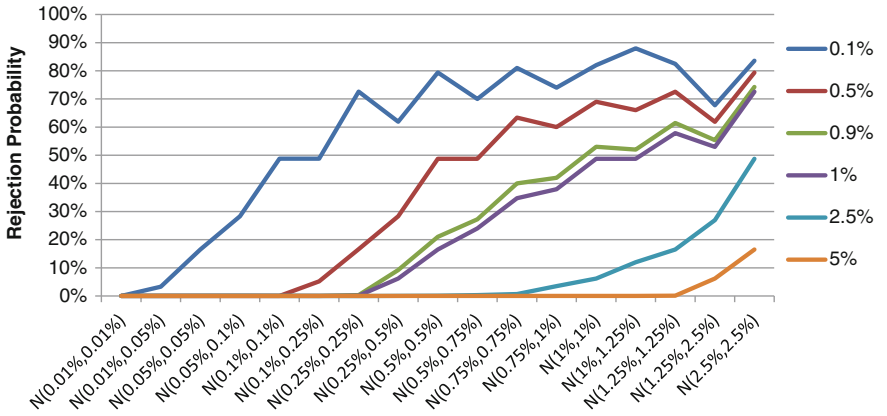

Fig. 6 Probability of rejection by concentration distribution and tolerance level. *Source* Author, based on simulations

Table 5 Probability of rejection by concentration and tolerance level

	N(0.1 %, 0.1 %)	N(0.5 %, 0.5 %)	N(1 %, 1 %)	N(2.5 %, 2.5 %)
τ = 0 %	1	1	1	1
τ = 0.1 %	0.488	0.79	0.82	0.84
τ = 0.5 %	0	0.49	0.69	0.79
τ = 0.9 %	0	0.21	0.53	0.74
τ = 1 %	0	0.17	0.49	0.73
τ = 2.5 %	0	0	0.06	0.49
τ = 5 %	0	0	0	0.17
All pass	0	0	0	0

Source: Author's derivations

Table 6 Scenarios of approval

	Maize	Soybeans	Soymeal
Scenario A	GM events from US + Canada affected	GM events from US + Canada affected	GM events from US + Canada affected
Scenario B	GM events from US + Canada + Argentina affected	GM events from US + Canada + Argentina affected	GM events from US + Argentina + Brazil affected
Scenario C	GM events from all countries affected	GM events from all countries affected	GM events from all countries affected

We then run the surplus computations under the three scenarios for each product as noted in Table 6. For simplification, we assume that there is no delay for LLP (T1 = 0) and that the approval takes the entire year. The results are presented in Tables 7, 8 and 9 in terms of total welfare effects, defined as change in total surplus and cost of implementation for maize, soybeans, and soymeal, respectively.

Welfare costs vary from USD 10,000 (soybeans, 5 % tolerance level) to over 57 million (soymeal, 0 % tolerance level). As expected, the effect of an unapproved soybean event, which would affect the soybean and soymeal markets together is much greater than that of a GM maize event. Furthermore, increasing the concentration or number of countries affected or decreasing the tolerance would increase the welfare costs as expected. Overall, the main lesson is that zero tolerance is quite costly; the costs found for maize range from USD 3.7 to 7 million (USD 7 to 28/ton); the cost for soybeans are around USD 4 million (over USD 80/ton), and they vary from USD 14 to 57 million per year (USD 7 to 31/ton) for soymeal.

Using these tables, one can look at individual cases and compare the effects of different tolerance levels. First, assume there is a new GM maize event that is rapidly adopted in the US, Canada and Argentina (scenario B see Fig. 7). The cost of maintaining a zero tolerance level would be around USD 6.5 million per year. Adopting a 1 % tolerance would reduce the cost significantly, but the difference

Table 7 Total welfare effects (USD million/year) in the case of maize under different scenarios

Scenario	Concentration	τ = 0 %	τ = 0.1 %	τ = 0.5 %	τ = 0.9 %	τ = 1 %	τ = 2.5 %	τ = 5 %
A	N(0.1, 0.1)	−3.69	−1.90	−0.85	−0.57	−0.57	−0.28	−0.06
	N(0.5, 0.5)	−3.69	−2.18	−1.35	−0.79	−0.74	−0.28	−0.06
	N(1, 1)	−3.69	−2.21	−1.55	−1.12	−1.07	−0.35	−0.06
	N(2.5, 2.5)	−3.69	−2.23	−1.64	−1.33	−1.32	−0.80	−0.24
B	N(0.1, 0.1)	−6.47	−3.80	−0.85	−0.57	−0.57	−0.28	−0.06
	N(0.5, 0.5)	−6.47	−4.98	−3.34	−1.74	−1.50	−0.28	−0.06
	N(1, 1)	−6.47	−5.07	−4.20	−3.31	−3.11	−0.65	−0.06
	N(2.5, 2.5)	−6.47	−5.13	−4.58	−4.20	−4.16	−2.90	−1.05
C	N(0.1, 0.1)	−7.10	−4.43	−0.85	−0.57	−0.57	−0.28	−0.06
	N(0.5, 0.5)	−7.10	−5.78	−4.01	−2.09	−1.78	−0.28	−0.06
	N(1, 1)	−7.10	−5.88	−5.02	−4.04	−3.80	−0.76	−0.06
	N(2.5, 2.5)	−7.10	−5.95	−5.44	−5.07	−5.02	−3.61	−1.35

Table 8 Total welfare effects (USD million/year) in the case of soybeans under different scenarios

Scenario	Concentration	τ = 0 %	τ = 0.1 %	τ = 0.5 %	τ = 0.9 %	τ = 1 %	τ = 2.5 %	τ = 5 %
A	N(0.1, 0.1)	−4.34	−2.42	−0.13	−0.09	−0.09	−0.04	−0.01
	N(0.5, 0.5)	−4.34	−3.55	−2.34	−1.10	−0.89	−0.04	−0.01
	N(1, 1)	−4.34	−3.64	−3.12	−2.48	−2.31	−0.35	−0.01
	N(2.5, 2.5)	−4.34	−3.70	−3.48	−3.27	−3.23	−2.28	−0.84
B	N(0.1, 0.1)	−4.46	−2.50	−0.13	−0.09	−0.09	−0.04	−0.01
	N(0.5, 0.5)	−4.46	−3.66	−2.43	−1.14	−0.93	−0.04	−0.01
	N(1, 1)	−4.46	−3.75	−3.23	−2.57	−2.39	−0.37	−0.01
	N(2.5, 2.5)	−4.46	−3.82	−3.59	−3.38	−3.34	−2.37	−0.88
C	N(0.1, 0.1)	−4.46	−2.50	−0.13	−0.09	−0.09	−0.04	−0.01
	N(0.5, 0.5)	−4.46	−3.66	−2.43	−1.15	−0.93	−0.04	−0.01
	N(1, 1)	−4.46	−3.75	−3.23	−2.57	−2.39	−0.37	−0.01
	N(2.5, 2.5)	−4.46	−3.82	−3.59	−3.38	−3.35	−2.37	−0.88

Table 9 Total welfare effects (USD million/year) in the case of soymeal under different scenarios

Scenario	Concentration	τ = 0 %	τ = 0.1 %	τ = 0.5 %	τ = 0.9 %	τ = 1 %	τ = 2.5 %	τ = 5 %
A	N(0.1, 0.1)	−13.80	−6.88	−3.03	−2.02	−2.02	−1.01	−0.20
	N(0.5, 0.5)	−13.80	−8.02	−4.86	−2.81	−2.64	−1.01	−0.20
	N(1, 1)	−13.80	−8.12	−5.62	−4.02	−3.86	−1.24	−0.20
	N(2.5, 2.5)	−13.80	−8.19	−6.00	−4.81	−4.77	−2.86	−0.85
B	N(0.1, 0.1)	−54.18	−27.30	−3.03	−2.02	−2.02	−1.01	−0.20
	N(0.5, 0.5)	−54.18	−40.74	−25.34	−11.78	−9.71	−1.01	−0.20
	N(1, 1)	−54.18	−41.87	−34.32	−26.28	−24.38	−3.92	−0.20
	N(2.5, 2.5)	−54.18	−42.73	−38.69	−35.57	−35.13	−23.52	−8.14
C	N(0.1, 0.1)	−57.05	−28.79	−3.03	−2.02	−2.02	−1.01	−0.20
	N(0.5, 0.5)	−57.05	−43.10	−26.84	−12.44	−10.23	−1.01	−0.20
	N(1, 1)	−57.05	−44.29	−36.40	−27.90	−25.88	−4.12	−0.20
	N(2.5, 2.5)	−57.05	−45.21	−41.04	−37.79	−37.32	−25.03	−8.68

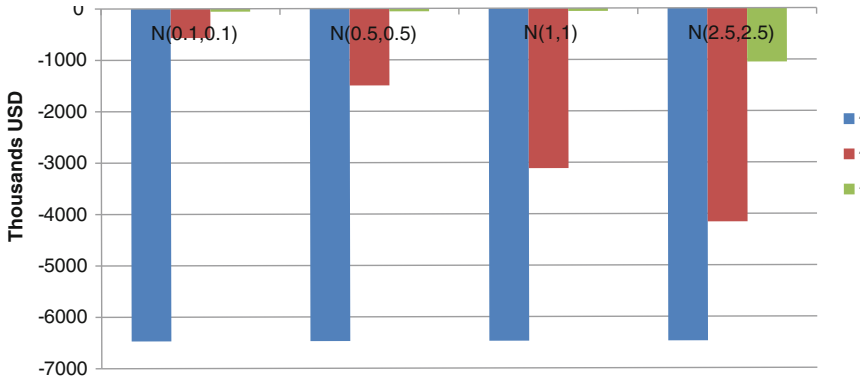

Fig. 7 Welfare effects for an unapproved GM maize event in US, Canada and Argentina. *Source* Author's derivations

would diminish as the presence of the GM event increases (between USD 568,000 and 4.1 million). In contrast, the use of a 5 % tolerance level low level presence would reduce the cost (USD 56,000—equal to the testing cost) for low concentrations, going to USD 1 million under the highest concentration.

As a second case study, assume that a new GM soybean event is being approved in the US and Canada, but not anywhere else. A very similar pattern is found but the values largely differ (Fig. 8). The cost of maintaining a zero tolerance level reaches USD 18 million per year. With a 1 % tolerance level this cost ranges only from USD 2 million to 8 million. With a 5 % tolerance level, the cost remains small

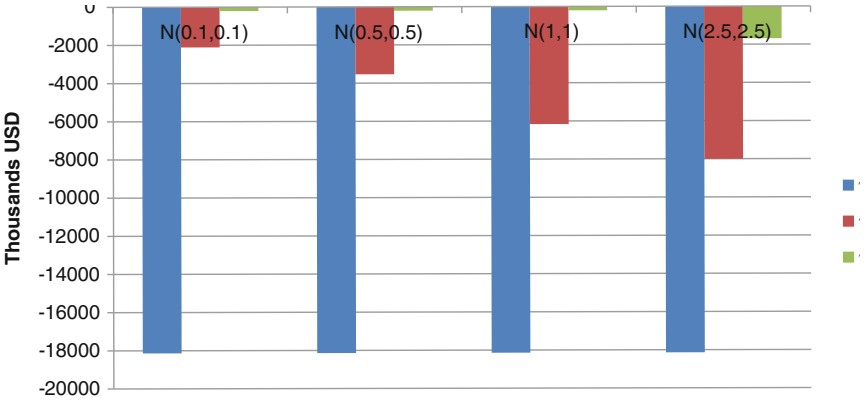

Fig. 8 Welfare effects of a single unapproved GM soybean event in the United States and Canada. *Source* Author's derivations

(approximately USD 200,000) with only under USD 2 million for the highest concentration. On average, a zero tolerance level costs USD 18 million, a 1 % tolerance USD 4.1 million, and a 5 % tolerance USD 580,000 per year.

A relevant question for a regulator could be the following: is maintaining a zero tolerance level that costs an average USD 14 million in order to address perceived safety concerns better than a 1 % presence of an unapproved event that has gone through safety authorization in the country of export? Similarly, one could ask: Is a zero tolerance level worth around USD 17 million more than a 5 % level? These questions may not be easy to answer, but they can provide a constructive benchmark for regulators considering different options.

Conclusions

This chapter analyzes the economic effects of different implementation options of LLP policies as proposed by the Codex Annex to cope with asynchronous approval of GM events in the case of small Asian countries. A simple analytical model is developed to identify factors for consideration in the design of regulations and apply it to Vietnam.

The tolerance level, the delay for LLP approval, the delay for full approval, and the degree of trust in exporter's regulations are found to be three determinant factors. In the case of Vietnam, the total cost of having a rapid approval for GM events approved in five developed countries, as proposed in the regulation, is estimated to amount to USD 18 million. In the longer term, tolerance levels matter; additional costs for zero tolerance level range from a few USD million to over 50 million per year. These costs need to be compared to the perceived benefits of implementing a zero tolerance policy.

Naturally, these simulation results remain imperfect and could be subject to improvement. Using improved estimates on costs of testing, concentration distributions, and price premia, among others, could help increase the confidence in the results. The methods could also try to account for nonmarket benefits derived by consumers with a lower tolerance level, or explore cases with non-benevolent regulators that could be bought out by special interests. Imperfect enforcement may also be considered a significant issue, given the lack of capacity of inspection services.

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Low Level Presence Under the WTO

William A. Kerr

Introduction

The issue of the management of a normally traded product which has become inadvertently mingled with another product that is not allowed to enter the customs territory of an importing country, albeit present in only trace amounts, has not historically been a concern of international trade law. As a result, the issue of low level presence (LLP) has not been specifically dealt with in international trade agreements. One interpretation of this gap in international trade law would be that the ability to set trade policy in this area falls exclusively in the jurisdiction of individual nation states. Another interpretation is that for Member States of the World Trade Organization (WTO), dispute settlement panels provide interpretations that act to complete agreements by filling in gaps. It is clear that dispute panels cannot extend trade agreements into areas where no negotiated agreement exists. For example, a dispute panel could not rule on a case involving trade barriers put in place due to a particular labour practice, say the use of child labour, because labour issues are not dealt with in the WTO but, rather, are dealt with by the International Labour Organization (Bakhshi and Kerr 2008).

On the other hand, dispute panels do make rulings that deal with issues that have not come up before within areas where trade agreements do apply. For example, a WTO Panel ruled on whether US legislation that extended extraterritorially to the international management of marine mammals could be used to justify trade restrictions—the well-known *Tuna-Dolphin* case (Isaac et al. 2002). The area of international trade law where a dispute is likely to arise over low level presence is in the areas of food safety or risks to the environment, which are covered under the WTO's Agreement on the Application of Sanitary and Phytosanitary Barriers

W.A. Kerr (✉)
University of Saskatchewan, Saskatoon, Canada
e-mail: william.kerr@usask.ca

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(SPS). Hence, while one would have to await the bringing forth of a formal dispute to the WTO to determine whether a panel would hear the case, the potential for a determination under the commitments undertaken in the SPS cannot be ruled out.

Comingling, Thresholds, and LLP

In modern international supply chains for bulk agricultural products, it is prohibitively expensive to ensure that no comingling takes place.[1] As a result, the optimum economic level for comingling is non-zero (Hobbs and Kerr 1999). Hence, in most cases, an agreement on tolerance levels is required. These agreed non-zero tolerances are normally determined through arrangements between private sector actors in international supply chains, who are interested in ensuring that the agreed tolerances are sufficiently lax to ensure the continued commercial viability of trade in the product that has been inadvertently comingled with a non-traded product, and governments that wish to protect their consumers from either health hazards or purchasing low quality products (e.g. the presence of insect fragments in processed meat lowers the quality of the meat). These tolerances are generally developed with commercial viability being an important part of the tolerance setting process. They are not included in trade agreements. For example, these types of tolerances exist for weed seeds, livestock antibiotics, insect fragments, chemical residues, manure and stones in various agri-food products.[2] Taking commercial considerations into account means that the tolerances are not considered trade barriers.

If tolerances are imposed—as opposed to negotiated—at such low levels that they do not consider concerns pertaining to international commercial viability, then they can be considered a trade barrier and recourse to trade agreements may be sought. Launching a trade dispute at the WTO, however, is a resource intensive effort that requires support from government and cannot provide a quick fix to a commercial disruption. The interest in low level presence as a potential issue in international trade in recent years has arisen in response to the European Union's policy of zero tolerance for imports of products comingled with genetically modified products that have not been approved for import into the EU. Taken literally, zero tolerance means a rejection of any import shipment where comingling is detected.

Under its zero tolerance policy, the EU has been routinely rejecting imports where comingling of unapproved GM material is detected. To date, however, these rejections have been one-offs rather than a continuing commercial problem

[1]It has become common practice in the literature to refer to mingled product as being comingled and I have chosen to follow this unofficial convention here.

[2]For a discussion of tolerance levels for common unwanted presences in agri-food trade see Olsen et al. (2001).

(e.g. Starlink maize, processed maize approved for animal feed but not for food in the US, 2000), Bt10 maize (comingling in maize gluten for feed, 2005), Liberty Link rice 601 and 604 (comingling in 2006), Herculex maize (comingling, 2006/2007), Roundup Ready II and Liberty Link (soya, 2008), BT 63 rice (comingling, 2008), MON88017, MON89034 and MIR 604 (maize in soya, 2009). While individual comingled shipments were rejected, the problems were fixed at their sources relatively easily so that future imports were not comingled—and, hence, not threatened with rejection. In these one-off cases, the launching of a dispute at the WTO could not be justified.

There has been one case where rejections of comingled product were not a one off. This was the case of EU rejections of non-GM flax from Canada comingled with an unapproved GM-flax known as Triffid. Comingling was found in multiple shipments and subsequently throughout the entire flax supply chain.[3] Given the widespread nature of the comingling, eliminating it was not technically feasible. The EU imposed an ongoing import ban on flax shipments from Canada with the result that considerable costs were borne by the Canadian flax sector (Dayananda 2011).[4] This ongoing disruption to trade could have justified the launching of a trade action at the WTO but, in the end, a commercially viable system for establishing tolerances was negotiated between the EU and representatives of the flax industry in Canada. Flax shipments to the EU resumed—albeit at reduced levels due to the cost of the ongoing testing and monitoring system that was put in place to ensure shipments were within the agreed tolerances.

The Canadian industry responded quickly to the closure of the EU flaxseed market by developing a Sample and Testing Protocol. The Protocol was developed by the Canadian Grain Commission (CGC)[5] and the Flax Council of Canada[6] together with the European Commission's Directorate-General for Health and Consumer Affairs (DG SANCO) and other EU stakeholders. Agriculture and Agri-Food Canada (AAFC), Foreign Affairs and International Trade Canada (DFAIT) and Canadian Food Inspection Agency (CFIA) were also involved in the development of the Protocol. Strictly speaking, however, the Protocol represents a private sector arrangement. The main goal of the Protocol is to meet the EU's strict import requirement of zero tolerance for unauthorized GM-flax and to assure a secure flaxseed supply. Thus, the Protocol establishes the sampling, testing and documentation measures that must be followed along the entire supply chain of Canadian flaxseed destined for the EU (CGC 2010). Two things are important to note. First, while the testing and monitoring regime established in the Protocol is both onerous and costly, it was accepted by the Canadian industry through

[3]See Viju et al. (2011) for discussion of the Triffid flax case.

[4]The import ban also imposed considerable costs on the import using industry in the EU.

[5]The quasi-government regulator of grain quality in Canada. It is important to note that it is not officially part of the Canadian government.

[6]The private sector representative of the Canadian flax industry.

negotiation, thus removing the potential for a trade dispute action against the EU at the WTO. Second, the tolerance level established through the Protocol is not zero, but rather above zero based on the results of a testing regime with non-zero parameters (Viju et al. 2011; Dayananda 2011). The question arises, however, what if a commercially acceptable (and hence viable) import regime could not be negotiated? What would the recourse be to the WTO? This question is important as more and more GM crops are approved in some parts of the world while approvals are denied or slower in other parts of the world; asynchronous approvals will increase. As a result, the potential for unintentional comingling and an increasing number of import bans under a strict policy of zero tolerance will increase.

The WTO and Low Level Presence

While there are other examples of zero tolerance in official policies,[7] it is the European Union's policy of zero tolerance for unapproved GM products that is currently creating international trade concerns. Thus, the remainder of this chapter will be framed within the context of the EU policy pertaining to imports of genetically modified agricultural products. Other examples of zero tolerance would have to be examined on a case-by-case basis.

The basis for the EU policy of rejecting imports of genetically modified products is that they pose a threat to human, animal or plant health or a risk to the environment.[8] Trade barriers justified on this basis come under the WTO's Agreement on the Application of Sanitary and Phytosanitary Barriers.

The SPS rules include nothing specific regarding low level presence. It is a country's fundamental right to protect its citizens, animals, plants and environment from threats arising from imports. Countries are allowed to erect trade barriers to achieve that end. There has been a long history, however, of countries using trade barriers justified on the basis of SPS concerns when the actual objective was to provide economic protection. For example, according to the World Organization for Animal Health[9]:

[7]Examples are various California laws banning the use of certain pesticides in agricultural production (Cash et al. 2003).

[8]It has been argued that the actual reason for the reticence of the EU in approving GM products is resistance from groups in civil society, both consumer groups and environmental groups. As the WTO has no direct mechanism to deal with governments wishing to put trade barriers in place due to consumer or environmentalist requests for protection, they have had to attempt to justify their trade restrictions on the basis of existing WTO rules, and in particular the SPS (see Kerr 2010 for an discussion of this issue).

[9]The World Organization for Animal Health is a long standing institution—the Office International des Epizootics that has been renamed. When the institution was renamed in 2003 it kept its historic and well known acronym, OIE.

> The ratification of the 1924 Agreement creating the OIE reflects a desire clearly expressed by the Secretary General of the League of Nations that year. He invited various governments to designate veterinary experts "to examine the health guarantees that could be provided by cattle-exporting countries, the facilities that importing countries could accord on the basis of these guarantees and, in general, to determine the most effective means of enabling statutory veterinary measures to be applied, taking into account the economic interests of exporting countries and without prejudicing the interests of countries wishing to protect themselves against animal diseases.
>
> …the Economic Committee of the League of Nations thus proposed to facilitate international trade in animals and animal products to try and reverse the *often highly overt tendency of numerous countries to use sanitary arguments purely for the purpose of economic protection* (emphasis added) (OIE 2000).

During the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiations that led to the establishment of the WTO, for the first time a serious attempt was made to bring trade in agricultural products under general GATT disciplines on the use of border measures and subsidies (Kerr 2000). There was considerable concern among those negotiating that, faced for the first time with serious constraints on the ability to extend economic protection from foreign competition to farmers, countries would begin to impose trade barriers on the basis of spurious SPS justifications (Kerr 2003). In an attempt to prevent the use of SPS justifications for nefarious purposes, the general GATT provisions regarding sanitary and phytosanitary measures were replaced by the much more specific SPS agreement (Isaac and Kerr 2003).

The SPS follows the general WTO principle of non-discrimination meaning that "like" products from all countries should be treated the same—Most Favoured Nation—and that foreign goods should not be regulated differently than "like" domestic products—National Treatment. Further, any trade barrier put in place should not be more onerous than is necessary to achieve its ends. If countries wish to put in place trade barriers justified on the basis of SPS concerns they must provide a scientific justification for the import ban (or other trade restriction) and they must undertake a risk assessment that shows a risk that is considered unacceptable arising from allowing imports.

The EU's system for approving new GM products allows for a scientific assessment of potential hazards and risks associated with new GM products by the European Food Safety Authority (EFSA) In addition, however, there is a layer of political approval that can override the scientific assessment. Thus, the EU's approval regime for GM products, including approvals for imports, may not be WTO compliant—but that will have to await a dispute challenge at the WTO.[10]

The reason, however, given by the EU regarding the ban on imports of products that are comingled is that the product unintentionally included in import shipments has not been approved in the EU. The threshold for comingled unapproved products is zero. As there is no specific provision for low level presence in the SPS, general

[10]See Viju et al. (2012) for a discussion of the EU regime for approval of GM products in the context of compliance with the WTO.

SPS provisions apply. According to the SPS, however, to put such a ban in place a Member State must provide a scientific justification and undertake a risk assessment. In the case of the import bans put in place for low level presence comingling, the EU provides neither. Instead, the unapproved GM products are assumed to pose a scientific threat and an unacceptable level of risk. This would seem to run directly contrary to the requirement of the SPS. In the case of the EU ban on imports of beef produced using growth hormones, the WTO Disputes panel ruled that the EU was in violation of its SPS commitments because, in part, it had not done a proper risk assessment (Roberts 1998; Kerr and Hobbs 2002).[11] Without a risk assessment, suggesting that countries should seek approval through the EU system for new GM products might be considered a trade barrier that is more onerous than required to achieve its objective. According to Article 5 (6) of the SPS:

> when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

The EU approval process is very long and costly (Viju et al. 2012). In some cases, approval for the unintentionally comingled product would never be sought in the EU—the product might not be agronomically suitable for cultivation in the EU, or the market might be perceived as too small to justify the expense of seeking approval or the GM product may be obsolete. Remember, it is not the primary export that needs approval, only the unintentionally comingled product that cannot be reduced to having a zero presence in the supply chain of imports. The case of Triffid flax is illustrative. GM Triffid flax was developed in Canada at the end of the 1990s and sought and received regulatory approval for cultivation in Canada and the US. The major market for Canadian flax is the EU, but Triffid was reaching the stage of commercialization at the point in time when biotechnology was becoming a major political issue in the EU. Concerned about losing the important EU market for flax, the developers of Triffid flax voluntarily withdrew the product and it was subsequently de-registered in North America. Triffid had never been grown commercially but seed companies were growing the variety in preparation for its commercialization. The stocks of Triffid flax were destroyed and, as far as anyone knew, it was no longer in the supply chain (Dayananda 2011). It was a decade later that traces of the Triffid variety were found initially in the EU and subsequently throughout the Canadian supply chain. In the intervening years, the Triffid variety had become agronomically obsolete, having been replaced by superior, non-GM varieties. Hence, approval for Triffid would never be sought in the EU. It was the market for Canadian non-GM flax that suffered from the import ban on comingled

[11]In the case of the import ban on beef produced using growth hormones the EU chose not the comply with the Panel's ruling and instead opted to accept retaliation, as is its right under the WTO. Failing to comply with a WTO Panel's ruling was an unprecedented decision by the EU and calls into question the credibility of international commitments. See Kerr and Hobbs (2005) for a discussion of the wider ramifications of the EU's decision to ignore the Panel's ruling.

GM flax. Hence, in the absence of a risk assessment, the alternative to the import ban provided by the EU—seeking approval to import—it could be argued as being an overly onerous barrier to trade. Of course, clarity on this issue will have to await a WTO dispute challenge and a Panel ruling.

The SPS does, however, allow the imposition of import barriers as a precaution if there is insufficient scientific information. According to Article 5 (7) of the SPS:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

The import bans on low level presence under the policy of zero tolerance put in place by the EU do not explicitly state that they are justified on the basis of precaution; that is, that insufficient scientific information exists. If challenged, however, this would seem to be an avenue that could be used to support the import bans. It is the other aspects of Article 5 (7) where it could be argued that the EU's existing system fails to comply. When imposing its import bans, the EU does not examine the sanitary and phytosanitary measures that other Members apply or the scientific evidence that underlies those measures. The EU's import bans are automatic for unapproved GM products. There is no process for examining the scientific evidence from other countries and considering such evidence sufficient to allow imports. The only recourse is to seek formal approval of the GM product in the EU.

The EU does make a distinction between two types of unapproved GM products. The first is commonly known as a low-level presence where the GM product is approved in the export market but not in the importing market. The second form of GM event is known as "adventitious presence", occurring when the GM product is not approved in any market (i.e. is an experimental product or is cultivated under confined field trials) (Viju et al. 2011). In the latter case, where sufficient scientific information does not yet exist, a precautionary ban may be accepted as a justification. In the first case, however, scientific evidence does exist because the products have received approvals by foreign authorities based on scientific evidence. For example, Triffid flax had received regulatory approval for cultivation in both Canada and the US. While an importing country may chose not to accept such evidence as being sufficient to approve imports, as in the case of the EU system, where import bans are automatic and such evidence is not taken into account, it could be argued that such a decision is not in compliance with SPS Article 5 (7).

Further, if the scientific evidence is not considered sufficient and an Import ban is imposed as a precaution, then it is incumbent upon the Member imposing the ban to proactively seek the additional information required to undertake a full scientific examination and a risk assessment. There is no evidence of the EU seeking such information. The EU regulatory approach is entirely passive, only allowing those wishing to import to use the processes established for formal approval of new

GM products. The case of a Member failing to "seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time" (SPS Article 5 (7)) has never been brought to a dispute panel; clarity would require a ruling from a panel.

Conclusions

In international trade law countries are allowed to put in place trade barriers and maintain them unless challenged by another country for being in violation of its international obligations. In the case of WTO members these obligations are set out in the WTO agreements. The WTO provides an opportunity for Member States to formally challenge trade barriers imposed by other Members if they believe the barrier does not comply with the provisions of the WTO agreement. As with any system of laws, there may be differences in interpretation. Dispute settlement mechanisms are the institutions put in place to adjudicate those differences in interpretation.

The WTO agreements make no specific reference to low level presence. Thus, trade barriers put in place to deal with the presence of unintentionally comingled products must be interpreted on the basis of general WTO rules. Automatic import bans on shipments comingled with unapproved GM products would appear not to comply with WTO obligations, but as with many differences in interpretation, clarity would have to await a challenge and a ruling from a dispute panel.

As approvals of new GM products increase both in the number of products and the number of countries, while at the same time approvals progress at a slower pace in other political jurisdictions, the probability of unintended comingling of unapproved GM products with products that could normally be imported will increase. As a result, international trade in agricultural products will be increasingly disrupted. Unless formally challenged, under international law countries can impose trade barriers and maintain them. Clarity on the issue of low level presence will have to await formal challenges and dispute panel rulings.

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Forging the Future of LLP: Building an International Coalition and Developing a National LLP Policy

Janice Tranberg and Sarah Lukie

Introduction

Since the first genetically modified (GM) crops were grown in 1996, agricultural biotechnology adoption has continued to increase around the world. From foundation traits like herbicide tolerance and insect resistance to more complex products with stacked and novel traits, research and adoption of GM crops is increasing, as are the number of products available on the market and the benefits to farmers, consumers, and the environment. Today, there are roughly 30 commercialized products on the market; it is estimated that there will be a three- to four-fold increase in the number of commercialized biotech products available to farmers in the coming years.

However, the adoption of GM crops has not occurred uniformly across the globe and regulatory approaches are diverse. Since biotech crops were first commercialized, global approvals and acceptance have varied, ranging from rapid adoption in countries such as the United States, Canada, and Argentina, to low adoption and even moratoria in some European, Asian, and African countries. Even though many countries have well-established regulatory systems for GM crops, approval timelines and duration of authorizations differ from country to country. These differences can lead to asynchronous authorizations among key trading countries and subsequently complicate or even disrupt international trade.

J. Tranberg (✉)
CropLife Canada, Ottawa, Canada
e-mail: tranbergj@croplife.ca

S. Lukie
CropLife International, Brussels, Belgium
e-mail: Sarah.Lukie@croplife.org

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One of the most significant trade issues today is the increasing instances of low level presence (LLP) of biotech products. In the context of agricultural biotechnology and for the purposes of this chapter, LLP is defined as the unintentional presence of biotechnology-derived plant material in imported commodities that have undergone a full safety assessment and have been authorized for use in food, feed, grain, and derived products by the competent government authority in one or more countries, including the country of cultivation. These events in question have been through rigorous risk assessments and have been found to be safe—and they are in the marketplace today.

LLP differs from adventitious presence (AP) in that AP in this context refers to an instance of a biotech event, detected in a grain shipment, that is not yet approved in any market, whereas an LLP event has already received approval and comprehensive safety assessment.

No matter how sophisticated our grain trading systems nor how carefully shipments are stewarded from field to shelf, LLP occurs. While there is an enormous infrastructure dedicated to the bulk handling and movement of grain and seed from farms to consumers around the world, even the most sophisticated infrastructure cannot prevent different crops or crop varieties from potentially coming into contact with one another. When this occurs in a country where either no LLP policy dealing with GM crops exists, or where there is a "zero tolerance" policy, this has the potential to have negative consequences on the global trade of grain.

Resolution of the concerns around the LLP issue has been slow in coming, but is critical to enable global bulk commodity supply chains to function effectively and efficiently. This chapter explores the efforts of the plant biotechnology and grain trade industries, governments, and the international trade community in addressing this important issue.

How Instances of LLP Can Impact Trade

Governments around the world are only just beginning to identify mechanisms to address LLP at the national level, and many still have de facto zero tolerance policies. This means that within those markets, it is illegal to sell or distribute a product known to contain a product not approved for food, feed, or processing (FFP) use in that country. Should a shipment of commodity grain arrive at a port of entry and, during the inspection process, traces of an unapproved biotech event be found, experience has shown that the shipment can be rejected, turned away, quarantined, or even destroyed.

When commodity shipments are stopped, consequences can be significant. Millions of dollars can be lost in time and grain quality as the shipment is diverted to other markets, repurposed, or destroyed. Trade in the commodity usually grinds to a halt as importers and exporters deal with inspectors, trade officials, and nervous buyers. Grain supplies and ingredient pipelines can be disrupted and shortages can occur. This can have a significant impact in areas of food insecurity.

The ripple effect of an LLP incident extends beyond the particular shipment in question to the entire food chain and even the consuming public. The environment and attitude toward biotech commodities can change quickly and may become negative. Anti-biotech activism typically spikes as organizers take advantage of the opportunity and point to the unapproved event as evidence of unsafe science and government capacity concerns. As a result, governments become overly cautious and consider more onerous regulatory regimes, technology providers begin to see delays and set-backs for technology, and farmers lose markets for crops already planted.

Trade experts and economists have analyzed the potential economic impact of LLP on the agri-food sector in order to quantify the cost and losses in trade, especially in its impact on the European agri-food industry where there is a zero tolerance policy. One study (Landmark Europe 2009) estimates the potential cost of an LLP incident involving EU-unauthorized biotech maize from the United States could cost between 5 and 46 million Euros, not including potential indirect costs such as supply shortages or plant shutdowns.

As an example, in 2009 a shipment of soybeans from the United States was placed in quarantine before it could enter Europe, where there is a zero-tolerance policy for traces of unapproved biotech products. Dust particles of a biotech corn (MON88017), which received a full safety approval by both Canadian and United States regulatory authorities and was given full commercial release for production and consumption in both countries, accidentally made it into the shipment of soybeans somewhere in the transportation process. These traces of fully approved corn dust caused the soybean shipment to be quarantined, triggering significant economic losses and market upheaval that is felt even today.

Efforts to Address and Resolve the LLP Dilemma

In the mid-2000s, it became clear that LLP was increasingly becoming more of a trade issue, causing national governments, international organizations, and the private sector to mobilize and identify a solution to LLP-related challenges. All sides seemed to agree on the same basic premise that the implications of LLP instances were too significant and detrimental to long-term trade, technology development, and innovation to be ignored, and that policies must be developed at the national and international levels to address the issue.

Industry Engagement

On the industry side, biotech companies, producer groups, processed food companies, and the grain trade industry were increasingly recognizing the urgent need for international coordination around LLP. Not only were all parties dealing with

the looming threat of trade disruptions, they were increasingly concerned about the long-term effects of LLP on commodity agriculture and in particular the impact of de facto embargoes, delays in commercialization of technology, and delays in farmer access to technologies.

Convinced that industry had an important role to play in shaping developments on LLP at an international level, several groups began to coalesce around the issue. Interested parties throughout the value chain began coming together to discuss their various positions on LLP, sketch out possibilities for international solutions, and identify potential paths forward. Ultimately, CropLife International took on a more formal coalition-building role, bringing together a host of organizations with shared interests to unite in one common goal: to proactively place pressure on the international community, increase awareness of the issue, and drive international policy developments on LLP.

The resulting coalition became known as the Global Adventitious Presence Coalition (GAPC). The GAPC was unique in that spanned the full supply chain from seed to shelf, and was a truly international effort with members across all grain producing continents. The original members of the GAPC included representatives from the grain and feed industry, processed food products industry, seed industry, and technology providers.

In 2005 the GAPC began its work. The first tasks addressed by the group were primarily building blocks: coordinating members' global positions; identifying those elements required to frame an ideal global safety assessment; and determining the primary advocacy targets—in this case, the *Codex Alimentarius* and its member countries. Additionally, the GAPC created a global team to ensure that industry members in countries represented in the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology were coordinated and engaging in advocacy with like-minded governments to obtain their support for taking on the project in this Codex Task Force and framing it in a way that was consistent with the coalition's position.

In 2006, the Codex Task Force on Foods Derived from Biotechnology[1] agreed to draft international guidance for food safety assessment of low-level presence of biotech products authorized as safe for use in food, feed, and processed products. Over the course of 2 years, a small group of Codex members worked to develop a draft guidance document that would address the most pressing issue—the development of acceptable risk assessment standards that could be widely agreed upon. During this time, GAPC advocacy efforts focused on three priorities:

[1] http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList=24.

(1) To separate the issues of LLP and AP and focus the international discussion of LLP on LLP only;
(2) To get the international community to recognize LLP as a trade reality and one that is a LEGAL issue as opposed to a SAFETY issue; and
(3) To have the outcome of Codex negotiations be the establishment of internationally agreed-upon risk assessment standards for LLP.

In 2008, the Codex Task Force on Foods Derived from Biotechnology approved and adopted The Annex on Food Safety Assessment in Situations of Low-level Presence (LLP) of Recombinant-DNA Plant Material in Food. The final guidance document outlined the international consensus that there is a fundamental difference with respect to food safety requirements for instances of LLP, when a product has been approved for planting and consumption in at least one country, versus a product that has not yet been issued an authorization anywhere in the world. It was the hope of the Codex Commission that the LLP Annex would enable importing countries to consider an abbreviated risk assessment in a manner aligned with Codex guidelines in instances of LLP of products that are considered safe and fully authorized in the country of export. In a perfect world, many Codex members believed that this would begin to address and mitigate the problematic impacts of LLP experienced to date.

For the GAPC, the adoption of the Codex LLP Annex signaled an important turning point in the LLP debate for several reasons. First, it gave the issue of LLP legitimacy, recognizing it as a unique issue in and of itself, separate and distinct from AP. By agreeing to the Annex, Codex countries recognized that LLP should be treated differently than AP.

Secondly, it firmly established that LLP is not a *safety* issue. Rather, the LLP Annex acknowledged that while LLP is an important trade issue, it should be treated as a *legal* issue, since the LLP products in question would already have undergone a rigorous risk assessment process by a competent authority and declared safe.

While a significant milestone, the GAPC realized that finalization of the Codex LLP Annex was not an end to the LLP issue but rather a beginning, and that the implementation of the LLP Annex guidance would be at the discretion of individual governments. However, GAPC firmly believed that the successful outcome of the Codex LLP Annex would set the framework for constructive national approaches to LLP which would naturally extend the Codex work. The GAPC's ultimate goal was the creation and implementation of a coordinated set of national standards based on practical, technically feasible, and cost-effective LLP standards for shipments of grain and grain products which would maximize the value of the product in question while minimizing trade disruptions and their associated costs.

The GAPC believed that the Codex Annex would help accomplish two key objectives:

- It would allow governments to declare the low level presence of an event not approved in the importing country as safe for food and feed use at low levels.
- It would support the development of *de minimus* or marketing thresholds for LLP to be established based on what thresholds are technically feasible, cost effective, and practical for shipment of FFP grain.

With this in mind, the GAPC's work turned towards proactively supporting the adoption and implementation of the Codex LLP Annex at the national level.

Numerous countries were interested in implementing the Annex into national law following completion of the Codex process, and discussions began with coalition members and governments both regionally and nationally. Canada is a good example of a country which recognized the trade implications of LLP and has become a leader in the global LLP debate.

The Canadian Experience

Canada, recognizing the challenge of effectively managing the international trade of biotech-derived products and minimizing the trade impacts caused by LLP has been working on a domestic LLP policy for some time. As a country with a significant agricultural economy highly dependent on international trade, Canada has become a leader in addressing LLP and a model for the international community on pragmatic approaches to this important issue.

Canada has first-hand experience with the devastating effects of LLP on international trade. In 2009, a GM flax variety, Triffid, was found in shipments bound for European ports. Following a red alert, trade of all Canadian flax with the European Union was halted. Triffid flax represents a prime example of LLP in that the variety, while never commercially grown and then de-registered in 2001, had received a full food, feed and environmental approval in both Canada and the United States. But with Europe's zero threshold for unauthorized biotech events, all flax shipments were stopped.

The impact on Canadian flax producers was significant, estimated at approximately $30 million (Ryan and Smyth 2012). This situation, while causing substantial economic harm, had a positive effect by raising the political awareness of the importance of LLP and its impact on international trade. Canada's Minister of Agriculture at the time, the Honourable Gerry Ritz, acknowledged the importance of the flax trade to Canadian producers, understood the concept of LLP, and recognized how a regulatory policy to deal with LLP could assist the trade of biotech products internationally.

The Canadian Government, after discussions with importing countries, realized that its own LLP system was inadequate to manage shipments entering Canada

which may contain traces of biotech crops which have not had a full approval in Canada. Driven by senior political support, Canada began work on a domestic LLP policy.

Early in 2007, the agriculture industry in Canada recognized that LLP was going to be a key issue with respect to the international trade of products of plant biotechnology. The agricultural value chain came together, under the Canada Grains Council and supported financially by Agriculture and Agri-Food Canada (AAFC), to produce the report, Creating an Environment for the Successful Commercialization of Canadian Crop Innovation.[2] This report, endorsed by over 50 Canadian organizations, highlighted 26 recommendations to increase agricultural innovation aimed at both industry and governments. The recommendations in the report encompass innovation from "mind to plate" and LLP was identified as a key limiting factor.

As a result of the collaborative approach to the development of the report and to facilitate the implementation of the report's recommendations, the Grains Innovation Roundtable (GIRT) was formed in 2009 with the assistance of AAFC. The strength of this roundtable process was the cross-sectoral involvement of the industries sitting alongside senior officials from the Canadian government regulatory departments. Together participants delved deeper into the issues and strategized on methods to create solutions that would be acceptable to both government and the industry.

The 26 recommendations identified in the original report were divided and covered by five working groups, with one of the groups, the Trade Policy Working Group (TPWG), tasked with responding to recommendations involving the removal of trade barriers associated with the approval and commercial production of innovative crops and products in Canada and importing countries, including LLP.

The TPWG consisted of approximately 20 members representing a range of sectors and organizations experienced with regulatory and political challenges affecting international trade of innovative crops and products, along with regulatory experts from the Canadian Food Inspection Agency (CFIA), AAFC, Health Canada and the Market Access Secretariat (MAS).

The TPWG undertook a comprehensive review of the current Canadian regulatory system, including the acts and regulations which govern biotech crops, in order to fully understand its benefits and limitations and to determine if and where regulatory changes might be required. As part of this analysis, a LLP scenarios subgroup was formed to test several specific examples and their implications for current regulations and guidelines. Following an extensive review, the TPWG drafted a proposed framework for a LLP policy in Canada.

The key objective of the proposed approach included increasing predictability for grains and seed exporters/importers, minimizing trade disputes, and reducing "emergency-like" responses. The new approach was intended to increase public confidence in the system and minimize potential negative impacts on trade.

[2] http://www.canadagrainscouncil.ca/uploads/innovation_report_English.pdf.

The TPWG agreed that a 'one-size fits all' approach would not work. Instead a tool-kit approach was envisioned, which would be flexible enough to fit both current and new innovative technologies and crops in the ag-biotech industry. The recommendations are laid out below.

Proposed framework for Canada's future LLP policy[a]	
Scope	• Grains for direct use in food, feed or processing • LLP only (events approved in at least one country); not AP (events that have not been approved for commercial use in any country)
Objectives	• Increase predictability for grain and seed exporters and importers • Minimize trade disruption • Inspire the adoption of trade-friendly LLP policies in other importing countries • Reduce "emergency-like" responses • Ensure food, feed and environmental safety • Increase public confidence in Canadian system
Principles	Canada's future LLP management approach should: • Replace "zero tolerance" policies with reasonable, risk-based thresholds • Be science-based • Be consistent with international trade rules and obligations and aligned with applicable international standards • Consider and minimize potential for unwanted impacts on export markets • Be flexible—provide the tools to respond to a variety of circumstances • Be proactive, where possible • Be operationally practicable for industry and government
Approach	A tool-kit approach is envisioned, in which Canada could employ strategies specific to the particular LLP situation: • Promote increased synchronization of approvals among countries • Consider and, to the extent possible, recognize the conclusions of risk assessments completed in other countries when formulating a risk management decision and/or establishing administrative tolerances • *Proactively* initiate research or risk assessments to enable development of a risk management policy *before* the event appears in international shipments • Risk management procedures should reflect the level of risk as determined by CODEX-based LLP risk assessments and complimentary feed and environment assessments, and • When a risk management decision is made, it should be communicated publicly along with any identified threshold and/or testing requirements

[a]Table adapted from the GIRT TPWG final report

At the same time, and in response to the Government of Canada's commitment to develop a domestic LLP policy, an Interdepartmental Assistant Deputy Ministers (ADMs) Committee on Trade in GMOs was initiated in 2010. Comprising ADMs from AAFC, Health Canada, Department of Foreign Affairs and International Trade (DFAIT), the Canadian Grain Commission, and Environment Canada, this high level committee was mandated to address market access issues involving biotech crops while ensuring the continued protection of human and animal health and the environment in Canada.

The committee's work plan consisted of several complementary activities to the TPWG including the development of an issues paper analyzing domestic and

international LLP management approaches, an assessment process identifying priority sectors and countries involved, an international engagement strategy for advocating trade-friendly approaches for managing LLP, and the development of a domestic LLP policy. To facilitate appropriate information exchange between the TPWG and the Interdepartmental ADM Committee, representatives from the multi-department secretariat supporting the ADM Committee participated in the TPWG.

The value of the government-industry roundtable approach is that it provided a forum for the open exchange of ideas working towards a mutual goal. It helped increase communication and understanding from all perspectives, reduced the chances of misunderstanding through a "ping-pong" approach, saved time and improved efficiency.

Recognizing the value of this approach, the AAFC organized a permanent Grains Roundtable (GRT) and formed a biotech sub-working group to continue to focus on biotech specific issues including LLP.

Canadian Domestic LLP Policy Development

As of this writing, the Government of Canada, proactively looking to enhance its regulatory system to manage LLP while protecting human and animal health and the environment and minimizing the impact on innovation and trade, is in the process of developing its domestic LLP policy.

Through the Interdepartmental ADM Committee, several versions of a draft LLP policy for grains have been developed and circulated for consultation. The first version of a series of options for the creation of a domestic LLP policy was drafted and sent out for consultation in September 2011. Approximately 180 invitations were sent to stakeholders, including developers, grower groups, grain handlers, and organic and food industries, asking for input. Stakeholders were able to provide feedback in two ways: written and in-person consultations. As a result of the consultations, the Government heard from stakeholders with over 60 detailed written submissions.

Taking the information gathered from the consultations, the Government of Canada's Interdepartmental working group was tasked with looking at the domestic LLP policy directions and implementation considerations to refine the policy. Work continues with the industry through the GRT MAWG Biotech sub-working group on specific issues, including refining a potential action level and identifying a measurement of uncertainty associated with this level. This measurement is based on science and assures consistent results.

Regarding the threshold-related part of the proposal, the Canadian Government recognizes that the establishment of a risk management (RM) decision threshold is separate from the risk assessment (RA) process and takes into account separate factors. Officials are considering the establishment of an expert committee to make

recommendations on the threshold, using information from the risk assessment which will be conducted within the Canadian government regulatory system. The government is also considering a threshold approach based on crop type as opposed to GM event-by-event, realizing that event specific thresholds would create significant cost implications if different thresholds were introduced for different events that could be within the same commodity.

A second draft of Canada's domestic policy for LLP, modified using information captured in the first consultation, was made available for consultation from November 6, 2012, to January 19, 2013. This draft was open to consultation to all Canadians and international governments and interested organizations through the World Trade Organization. Details of the consultation document are available through the Government of Canada website.[3]

In summary, this draft policy outlines a stepwise risk-based approach to manage LLP in grain consisting of two levels:

(1) A low, uniform Action Level will be set for LLP in grain of all crop types. When LLP is detected at concentrations below the Action Level, no enforcement action would be triggered. This risk management element will address potential trace amounts of LLP resulting from dust or other sources. Since the food safety assessment that the GM crop has passed is consistent with the Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, below the Action Level, LLP is unlikely to pose a risk. The Government of Canada will publicly consult on the specific numerical value that should apply to the Action Level. An Action Level of 0.1 or 0.2 % is proposed.
(2) Crop-specific Threshold Levels will be set for individual crop types and will be higher than the Action Level. The Threshold Levels will be set to reflect achievable levels for unintentional presence based on best management grain handling practices for each crop type while respecting the realities of the grain handling and transportation systems in place around the world. These Threshold Levels will only be applicable for an individual GM crop after a Canadian LLP risk assessment has determined that the presence of the GM crop at the proposed level is unlikely to pose a risk to food, feed or environmental safety.

When levels exceed the Action or Threshold Levels, a risk assessment for the specific situation will be conducted to determine the appropriate enforcement actions to return the situation to compliance with regulatory requirements. When there is reason to believe that a specific LLP occurrence may pose a risk, enforcement action will be taken to return the situation to compliance with regulatory requirements.

[3] http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1348076201400&lang=eng.

At the time of this writing, the Government of Canada is in the process of reviewing all the comments collected from the consultation process and making necessary adjustments to the draft policy.

The State of Play in 2013

Based on the Canadian example, it is clear that there has been positive national and international progress on the issue of LLP. However, all parties admit that there is a still a long way to go.

Today the work of the GAPC continues, but its name and focus has shifted. In recognition of developments on the global stage, the GAPC has evolved into the Global Alliance for Ag Biotech Trade (GAABT). GAABT has largely the same membership as GAPC, with the addition of several producer and commodity groups present in multiple countries.

Like the GAPC, the GAABT has a broad scope: supporting major import market approvals, reducing asynchronous approvals, and encouraging development of trade-facilitative LLP policies at the national and international level. It works closely with national teams to accomplish its work. Today, GAABT has three strategic goals:

First, to ensure that targeted countries progress in adoption of authorization policies that minimize the gap between approvals in importing and cultivating countries, thereby minimizing the potential for LLP trade disruptions. To accomplish this goal, GAABT is taking a three-pronged approach, advocating for (1) synchronized approvals, (2) recognition of other country approvals, and (3) use of the Codex LLP Annex. Priority countries for these efforts include Canada, China, Colombia, Korea, Philippines, Taiwan, and the United States.

A second strategic goal of GAABT is for the Global LLP Initiative to maintain momentum and progress towards establishing a harmonized approach to handling of LLP and minimizing asynchronous approvals among participating governments. The Global LLP Initiative grew out of a meeting hosted by the Government of Canada to which like-minded, interested countries were invited to work collaboratively on the issue of LLP, with the understanding that finding global solutions to facilitate the management of LLP will reduce the likelihood of trade disruptions and increase transparency and predictability of trade. As of 2013, 15 governments are participating in the initiative, including Argentina, Australia, Brazil, Canada, Chile, Costa Rica, the European Union, Indonesia, Mexico, Paraguay, Philippines, Russia, South Africa, the United States, Uruguay, and Vietnam.

A third goal of GAABT is the establishment of international and regional guidance to address LLP in seed to minimize commerce disruptions within the seed trade.

Conclusion

The world of agricultural biotechnology is changing at a rapid pace. Where there were once just a few products on the market in just a few countries a little over 15 years ago, today the product pipeline is full, with new products and new traits and farmer benefits moving through the regulatory process and towards the market at a steady rate. Many of the new traits on the horizon have never been seen before, including crop composition and tolerances to environmental stressors such as drought, extreme temperature, and saline soils. In the future, plant biotechnology will improve new crops such as rice and potatoes.

We are seeing new players involved in technology development, and more countries as well. For example, countries such as China and India are close to commercializing new domestically-developed biotech crops which, although intended for domestic use, could find their way beyond their borders.

Exciting times are ahead for technology developers as well as farmers and consumers. But with these exciting times there will be new challenges, as regulatory systems deal with the onslaught of new plant biotech innovations and applications for their commercialization and use, and countries and traders alike deal with more asynchronous and potentially isolated approvals. In this environment, LLP will become a larger and more challenging issue as these new products enter the marketplace and LLP incidents increase accordingly.

The global biotechnology industry continues to believe it has an important role in shaping policies at the international and domestic country levels to help manage and reduce disruptions to trade caused by LLP. Through strong commitment and leadership on an international scale, it will continue to push for adoption of practical, pragmatic frameworks and policies on LLP to facilitate trade in agricultural commodities that feed, clothe, and fuel the world.

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Market Solutions to Coexistence and Regulatory Asynchrony

Peter W.B. Phillips

Introduction

It looks increasingly likely that the future of biotechnology will be determined as much in the marketplace as in the capitals of key nation states. Regardless of what governments now do about regulating biotechnology in the agri-food sector, the technology seems to be irreversibly present in parts of the global marketplace. How the market is able to respond to diverging and incommensurate demands about the provenance of food will influence the scale and scope of benefits and costs generated, and ultimately will determine how investors (both public and private) allocate resources to this area. Coexistence will either be part of the solution or part of the problem.

This chapter examines this issue from both the theoretical and practical perspectives and offers insights into the areas of greatest opportunity or threat. The chapter first reviews the background to our current coexistence conundrum then examines the range of theoretical perspectives brought to bear on coexistence, assesses the practical impacts and the pathways of decision making that will affect coexistence practices and offers some concluding comments on the way ahead.

Background

Since 1998, the US, Canada, Argentina and a number of other major food producers and exporters have expeditiously developed, adapted, and adopted genetically modified traits in a range of large area crops while the EU and a number of other

P.W.B. Phillips (✉)
University of Saskatchewan, Saskatoon, Canada
e-mail: peter.phillips@usask.ca

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food importing countries signalled to suppliers their unwillingness to approve new varieties for domestic use or undifferentiated imported supplies. One result of the divergent regulatory decisions is that asynchronous approvals have emerged.

The gap between markets remains large, partly because a de facto EU moratorium was in force for over a decade. It is important to note that no single country has reviewed and recorded positive approvals for all of the 144 events recorded as of 2014. The highest rates of positive review was in the Canada and US, two of the largest producers and exporters, and Japan, a key importer. In 19 countries examined, the average country undertook reviews on only about 5 of the 16 species under investigation, completing 12 % of the possible environmental reviews and 27 % of the food safety audits (Table 1). The low level of successful review for environmental release reflects the politics of the adopting countries while the somewhat higher percentage of completed food reviews reflects the reality that much of the international trade is now likely to include GM elements. At the crop level, we see more divergence. For example, all 19 countries in our sample have approved at least one variety of soybeans for food use and nine have approved at

Table 1 Regulatory decisions related to GM events, 1995–2011

	# recorded decisions			% of maximum possible decisions		
	# species	Environmental approval	Food approval	# species (%)	Environmental approval (%)	Food approval (%)
Argentina	2	11	11	13	11	10
Australia	6	6	35	38	6	32
Brazil	2	14	14	13	14	13
Canada	13	71	74	81	70	67
China	3	0	21	19	0	19
Columbia	5	1	8	31	1	7
EU	5	4	25	31	4	23
Japan	6	50	61	38	50	55
Korea	5	2	48	31	2	44
Mexico	7	2	46	44	2	42
Paraguay	1	1	1	6	1	1
Philippines	5	5	45	31	5	41
Russia	2	0	5	13	0	5
S. Africa	3	4	15	19	4	14
Switzerland	2	0	4	13	0	4
Taiwan	2	0	20	13	0	18
Uruguay	2	3	3	13	3	3
US	14	68	67	88	67	61
Average	4.6	12.0	26.5	29	12	24
Maximum	16	101	110	–	–	–

Source Author's calculation of tabulations from GM Crops Database (http://cera-gmc.org/index.php?action=gm_crop_database)

least one variety for cultivation. For maize, 17 have approved at least one event for food use and 9 have approved at least one variety for cultivation.

A practical outcome of the diverging regulatory processes is a new set of rules to define and differentiate different product streams. In the context of GM foods, 49 countries or regions (75 countries if you count all the EU member states) have developed or considered labeling rules that firms must abide by if they seek to market foods in those countries. Gruère and Rao (2007) offer the most recent summary of status of consumer labeling regulations as they relate to GM foods. They note that as of 2007, a range of countries had voluntary labeling guidelines (e.g., US, Canada, Hong Kong and South Africa), while more had mandatory labeling requirements (e.g., Australia, the EU, Japan, Brazil and China). Voluntary labeling guidelines dictate rules that define what foods can be called GM or non-GM, and let the food companies decide if they want to use such signals on their products. In contrast, mandatory labeling requires food companies (processors, retailers and sometimes food producers) to display whether the targeted products or ingredients are derived from genetically modified materials. A number of countries with mandatory labeling for GM ingredients also have voluntary guidelines for the labeling of non-GM food (e.g., Japan and the EU). This mixed mandatory/voluntary system is in place in countries with mandatory labeling to facilitate firms marketing to consumers who are willing to pay a premium to completely avoid GM ingredients. One practical challenge is that the specifics for product differentiation vary between countries. Some countries have either adopted or debated requiring labeling for: specific lists of particular food ingredients or all ingredients in packaged food products that include detectable transgenic protein or DNA; highly processed products derived from GM ingredients (even without a quantifiable presence of GM elements), animal feed, additives, and flavorings; meat and other products from animals fed with GM feed; food sold by caterers and restaurants; and unpackaged food. Meanwhile, there is no consensus on the appropriate threshold to trigger labelling of GM ingredients; some have applied a standard to each ingredient or only to three or five main ingredients, while others have set thresholds ranging from 0.9 to 5 % of volume (Phillips and McNeill 2000).

Pathways to Decision Making

Four key decisions made by actors are critical for understanding the underlying pathways of technological diffusion and value generation. While the decisions are linked, one could look at them as: the decision to invest in discovery, research, and development in the context of GM foods (by multinational firms, governments and seed consortia); the decision to adapt that technology to the marketplace (which involves both the commercial supply chain and the regulators); the decision of individual farmers to adopt the technology in their operations; and finally the decision of a consumer to purchase and consume the product of the technology.

Generally economists treat those as separate decision points, with upstream decisions creating downstream opportunities.

Profit optimizing firms are posited to seek economic profits from developing and commercializing new technologies. They are generally assumed to make investments in opportunities offering risk adjusted, internal rates of return above their cost of capital, which means they tend to ignore value generated but not appropriated by them. The other supply chain actors are believed to undertake similar analyses; unfortunately, we tend to presume that they are effectively docile "takers" of new technologies. Farmers at times are singled out for further analysis which generally assumes they undertake implicit cost-benefit calculations to assess new technology opportunities. Finally, we usually model consumers as rational, all-knowing beings who purchase without emotion.

None of these assumptions fit the circumstances of GM foods. Companies are continually testing their choices and recalibrating their net present value calculations in response to changes in market circumstances, changes in expected costs and benefits, alterations in their discount rate, and the timing of their activities. This can at times lead to significant mid-course corrections in their R&D pipeline budgets as their expectations change. In short, small changes in expectations can lead to large shifts in effort. There is also some evidence that competing and complementary supply chain participants are willing to exploit whatever market power they have. They no longer automatically accept what flows downstream—wholesalers want assurances of the quality of products they handle, branded food processors have very explicit moral or corporate strategies that dictate what they will accept, and retailers are increasingly moving upstream to exploit their market power to develop differentiated products (often under own-label brands) to enhance their profits. Moving downstream, farmers are similarly canny when it comes to new technologies. They are looking at how innovations might fit in their production system (e.g. fit with complementary technologies or competing crops in rotations) and what risks they might impose in terms of market access. Signals coming from local and global consumers have at times influenced farmer attitudes to adopting new crops (e.g. GM wheat). One way of handling this conceptually is to add supply chain and consumer attitudes as variables in the decision matrix, which may work to either block options or alternatively to depress a farmer's specific cost-benefit calculations (e.g. Haggui et al. 2006). Finally, consumers are far from certain about how to assess and value these items, and their opinions have the possibility of feeding back into the biotechnology research cost-benefit analyses, into considerations of firms in the supply chain, and, as just noted, into farmer decisions about adoption. In short, it is increasingly risky to treat each decision point as an isolated choice that can be made independently of others, or that can ignore the role of expectations and preferences.

Beyond the pathways of influence and their effect on the micro-level decision making, there are a range of methods of aggregating the impacts and estimating the effects on groups, the market and the economy. Welfare analysis (e.g. Alston et al. 1995), 'meta-analysis' (e.g. Lusk et al. 2005) and applied general equilibrium (AGE) modeling (e.g. Anderson 2010) all offer estimates of the impacts of new

technology and the potential to infer the opportunity costs of delayed, truncated or cancelled adoptions. Opportunity costs can show how large the gap is between the actual and the optimum, focus attention on where unrealized benefits may be located and identify potential win-win solutions to hold-ups in the market.

Practical Effects

While more nimble, efficient, and synchronous regulatory action by proponents, national regulators, and the supply chain is the ideal, in the interim uncertainties and risks have created a chill on trade in GM commodities, delayed and truncated uptake by farmers and the supply chain, lowered investment in new GM crops, and ultimately brought about higher consumer prices and lower benefits than would otherwise prevail.

The first evidence of this mismatch of supply and demand has been observed in the trade system. If one takes the number of countries actually producing GM crops (based on ISAAA reports), one can estimate market shares of GM producing nations. The data shows that GM producers account for the lion's share of the three largest food crops that have GM varieties available. Somewhat worrying is that those key producers export to between 108 and 193 countries, many of which have specific rules about labeling and marketing GM foods (Table 2). In this context, firms are challenged to seek ways to sustain both production and trade. In the absence of domestic differentiation strategies, any produce coming from an exporting country has the risk of being comingled and triggering regulatory oversight in the international marketplace or an array of commercial responses.

Against this backdrop, new, specific, timely, and cost effective scientific tests have revealed the low-level presence of GM traits in canola, maize, rice, and flax, and fears of similar events in wheat, soybeans, and other staple crops have generated significant concern. In the first instance, these events have destroyed economic value—market losses arise as accidental blends need to be tracked down and

Table 2 Global GM production and trade (2010)

Crop	# states approved and producing	% production from GM states (%)	% exports from producing states (%)	Total # importers
Maize	16	55	68.7	193
Soybeans	11	85.3	97.1	170
Canola	4	23.5	53.3	117
Potato	3	4.0	17.0	200
Papaya	2	1.3	11.8	129
Sugar beet	2	5.3	5.3	108

Sources Author's calculations using data from ISAAA and FAOStat

diverted to second-best markets. Beyond the events themselves, exporters report increasing marketing costs for securing quality-assured supplies, elongated and more expensive regulatory processes, and costly and often destructive litigation (other chapters in this book examine these issues). In most cases, the end result is lower uptake and use of what is almost universally judged by scientists and regulators to be safe and efficacious technologies and depressed prices in commodity markets faced with managing differentiated demands from the global supply chain.

There is also some evidence that supply chains that receive and handle the key GM products are struggling to adapt. In the largest sense, there are 340 million metric tons of grains and oilseeds in the international trading system involving 195 countries. Each core crop has upwards of 20 different grades or differentiations (in some cases more than 100), each with its own specifications. Underlying those shipments is a research and development system which turns over the seed stock in some crops every 3–5 years with new varieties, new traits, and new attributes, some of which enhance value and some of which simply create differentiable attributes. In Canada, for instance, there are more than a dozen centres of public-private research effort involving hundreds of actors, more than 3000 seed growers who multiply the foundation seed for commercial sale, and about 200,000 farmers who plant an array of crops and varieties in sophisticated rotations on more than 50 million acres. The grains and oilseeds in Western Canada are then harvested and largely stored on-farm and called forward by public and private market aggregators through about 375 delivery points. The average commodity shipments then involve a minimum of three domestic transfers, in unit sizes ranging from 300 bushels to 6000 metric tons, ultimately being aggregated in unit trains for shipment to the US or FOB at export position in cargo holds of ocean freighters. Beyond our borders, shipments usually involve at least a further two transfers before they reach the specific buyer who contracted for that product.

In response to these uncertainties and challenges, there are a rising number of examples where supply chain actors have interceded in the market and refused to handle crops that might be difficult to trade. In the late 1990s many food processors worked to remove or differentiate GM crops from their supply chains in order to meet the pending rules of EC Reg 258/97 which laid out new labeling provisions (Phillips and McNeill 2000). Seven large European supermarket chains joined forces to eliminate GM ingredients in their own-label products. These included Carrefour (France), Delaize (Belgium), Marks and Spenser (UK), Migros (Switzerland), Sainsbury's (UK), SuperQuinn (Ireland), and Tesco (UK). A range of other retailers in Europe (e.g. Effelunga, Edeka, Somerfield, Waitrose, Iceland Foods, and Northern Foods) and elsewhere (e.g. Woolworth's in South Africa and Park N'Shop in China and Hong Kong) responded by claiming their own-label products were free of GM materials (ibid.). In response, aggregators offered to meet these new requirements by either replacing inescapably comingled ingredients with alternate non-GM ingredients or developed parallel supply chains to serve this differentiated market. The leadership was largely in the hands of the retailer or branded foods processer.

In the intervening period a number of wholesale aggregators have also threatened to refuse to trade in GM crops (e.g. when GM wheat was proposed in North America). One of the few documented cases where a firm rejected legally approved GM crops was recently litigated in the US. A federal district court ruled in 2011 that St. Louis-based grain handler Bunge North America does not have to accept GM maize produced by Syngenta AG. Syngenta sued Bunge after it rejected Syngenta's Agrisure Viptera maize. Bunge, which runs grain elevators and receiving stations, said it was "unable to accept" delivery of the maize because the GM maize is not cleared for approval in export markets. The federal court ruled that, "Bunge's decision to reject Viptera maize at all of its locations was a legitimate and reasonable business decision. The injunction would impose prodigious costs on Bunge for a situation that Bunge did not create" (http://www.bloomberg.com/news/articles/2011-09-27/syngenta-loses-court-ruling-against-bunge-unit-over-modified-corn-lawsuit). There are no estimates of the costs of this decision, but there surely are both real economic costs, as producers have to seek other venues for sale, and some negative signalling to producers, seed suppliers, and biotechnology companies that business is getting more uncertain.

Adoption can be assessed at two levels. In the first instance, the number of countries that produce a crop represents one type of maximum market penetration. As shown in Table 3, soybeans and maize have the highest penetration rates, averaging around 10 % of the total countries producing those crops. While one might interpret this low penetration as reflecting the unwillingness of countries to accept GM technologies, in many cases it is simply a business decision based on the expectation that there would not be adequate revenues for the technology owners to justify the investments in acquiring regulatory compliance and developing a domestic supply system. A number of tentative estimates of the costs of regulatory compliance in developing countries suggest the upfront cost per country has ranged from US$500,000 to US$5 million for the first GM event in a species and initial approval has taken from 2 to 7 years, with subsequent GM traits in the same crop

Table 3 Global adoption of GM technologies by crop

	# countries producing crop 2009	# countries producing GM crops	2010 GM area (million ha)	2009 global area planted (million ha)	GM area as % world crop area (%)
Soybean	91	11	73.3	99.5	73.7
Maize	163	16	46.8	158.6	29.5
Rapeseed/canola	61	4	7.0	31.1	22.5
Potato	157	3	Trace	18.7	~0
Papaya	62	2	Trace	0.4	~0
Sugar beet	53	2	Trace	4.3	~0
Squash	Na	1	Trace	Na	Na
Tomato	172	1	trace	4.4	~0

Source Author's calculations using data from ISAAA and FAOStat

being less expensive and more timely (Kalaitzandonakes et al. 2006; Pray et al. 2005, 2006; Bayer et al. 2010). Assuming a biotechnology company could generate free cash flow of $10/hectare planted and they got above-average farmer adoption, there are at least 40 countries producing maize where they would not likely be able to recoup even the lowest likely regulatory costs within 10 years of starting the process. Few companies are willing to take that risk.

A second way to look at adoption is the share of the global area planted to GM crops. Using ISAAA numbers, we are able to estimate that in 2009 while only about 12 % of the total countries producing soybeans adopted GM varieties, the GM area in those countries accounted for an estimated 73 % of global soybean area. GM maize accounted for about 30 % of global area while GM canola represented about 22 %. In countries which approved and adopted the technology, adoption rates were much higher. HT canola accounted more than 90 % of Canada's canola area and GM soybeans accounted for a similar share in the US and Argentine markets.

There are a number of studies that can help us to estimate the effect of the adoption to date and provide insights into the opportunity cost of incomplete adoption. Brookes and Barfoot (2010) used an array of economic studies of GM crops and an economic model to calculate the economic effects of GM technologies both on the crops that have been targeted for introduction of GM traits and for competing or complementary crops. They estimate that soybean prices are 9.6 % lower than they would otherwise be, while maize prices are 5.8 % lower and canola prices are 3.8 % lower. Given that these crops are also substitutes for other foodstuffs, such as wheat, barley, sunflower, and sorghum, the greater competition from these three core foodstuffs has caused price pressures in those markets, ranging from a drop in wheat prices of 2.7 % from what otherwise might have prevailed, to as large as a 4.2 % drop for sorghum.

These price effects translate into significant welfare effects. Anderson (2010) used the GTAP AGE model to estimate that the introduction of the crops as of 2010 raised global GDP by US$2.3 billion (1997$), with about 41 % of the benefit accruing to producers and consumers in the adopting countries and the rest to consumers in non-adopting importing countries. They also estimated the opportunity cost of the truncated diffusion of GM soybeans, maize, and canola and the delayed adoption of GM rice and wheat. If adoption of those crops is limited to the USA, Canada, and Argentina, they estimated that annual global welfare from those core crops could still rise by $4.3 billion (1997$), with about 25 % of the benefits captured in the three leading adopting countries and the rest in consuming countries (mostly in the developing world, but some in the EU). They then estimated that if all countries (except the EU) adopt the technology, annual global welfare could jump by more than $7.5 billion (1997$), with almost all the incremental benefits flowing to producers and consumers in developing nations. The extended EU moratorium on both production and consumption inflicted a range of economic costs on both EU producers and consumers and on the rest of the world. While the EU bears the lion's share of the losses from the moratorium, the annual gains in the three key adopting nations are estimated to be cut by $250 million per year,

Table 4 Estimated impact of truncated diffusion on GM technology revenues

	2010 GM area (million ha)[a]	2009 total area (million ha)[b]	GM as % world[c] (%)	Estimated price impact[d] (%)	Extrapolated price with full adoption[e] (%)	Annual technology revenue (US $ billion)	
						Actual[f]	Full Adoption[g]
Soybean	73.3	99.5	73.7	−9.6	−13.0	$1.1	$1.4
Maize	46.8	158.6	29.5	−5.8	−19.7	$1.6	$5.4
Canola	7.0	31.1	22.5	−3.8	−16.7	$0.1	$0.4
Total	127.1	289.2	43.9	–	–	$2.8	$7.2

Sources Authors calculations using [a] ISAAA; [b] FAO Stat; [c] Calculated; [d] Brookes and Barfoot; [e] calculated; [f] Brookes and Barfoot; [g] calculated

undoubtedly reducing the incentives for biotech companies to sustain their investments in new traits and varieties and farmers to adapt and adopt the technology.

Using Brookes and Barfoot (2010) data, we can put the effect of limited adoption into context in two important ways. First, if the technology diffused fully, there would be both greater economic benefits for consumers, with prices down by at least 13 % for the three crops, compared with actual drops of only 3.8–9.6 % (Table 4). More importantly from the perspective of sustained innovation in the agri-food sector, greater adoption would generate greater technology revenues which would provide more of an incentive for the leading biotechnology companies to sustain or expand their research efforts. With adoption rates in 2010, technology revenues for the three key GM food crops were estimated to be about $2.8 billion. If adoption was to rise, those revenues would rise. Scaling the Brookes and Barfoot estimates, one could anticipate that at maximum adoption gross annual technology revenues on these crops could rise to as high as $7.2 billion, more than $4.4 billion higher than estimated.

The big question is what the agro-biotechnology industry would do with $4.4 billion more in annual revenues, possibly more if the technology was able to be adapted and adopted in rice, wheat, and other major commodity food crops. There is limited evidence. James (2003) summed up the research effort in 2001, concluding that there was about $4.4 billion in crop biotechnology investment, 70 % by private firms and 30 % in the public domain. He further concluded that 96 % of the investment was in industrial countries. Put in context, the private biotechnology sector was probably investing about $3 billion annually in anticipation of generating gross annual revenues somewhere in the $3–7 billion range, relative to an annual global seed trade then estimated to be about $25 billion.

A review of the financial statements and publicly revealed research plans in 2014 showed that the then top five private investors invested about six percent of gross revenues on research and developmentt. Monsanto was at the high end, investing about 11.5 %; at the other end, Dow invested about 3.1 % of gross revenues (this lower rate may be due to Dow's more diversified portfolio of activities). Taking the average of the sector, the absence of up to $4.4 billion in revenues in 2011 would

translate into a drop of $264 million in annual investments. Given the Phillips McDougall (2011) estimate that it takes about US$130 million to bring a major new trait/crop combination to market, this translates into about 2 fewer major innovations per year. If we used Monsanto's R&D rate, which is mainly an agro-biotechnology play, then 11.5 % of the missing $4.4 billion would translate into more than $530 million of lost investment, or about an average of four new traits per year. We have seen some evidence of the narrowed research effort. A review in 2013 of the publicly stated research pipelines of the five key multinationals (Monsanto, Bayer, Pioneer Hi-Bred, Syngenta and Dow Agrosciences) showed that the bulk of their effort was focused on maize, soybeans, canola, and cotton, with what appeared to be only tentative efforts related to other large area field crops or vegetables. In Canada, for example, in 2010 all but 15 of the 979 field trials were conducted on canola, maize, and soybeans—one single alfalfa trial (by Monsanto) was the exception that made the rule.

Conclusions

Asynchronous approvals for GM crops—whether due to different regulatory decisions or varying effort by proponents to gain approvals—are significant in the key product categories for GM grains and oilseeds. This is creating a number of immediate challenges for the global agri-food system that, if unresolved, could have long-term effects on prices, trade, investment, innovation, and ultimately the global capacity to produce sufficient volumes of food to adequately feed the growing world population.

Asynchronous approvals are a systemic concern for the global agri-food system. They are caused by disconnects between consumers (with varying expectations and preferences), between regulators (due to their inability and unwillingness to seek harmonization of regulations or the synchronous assessments of specific products), and between proponents and regulators (as proponents selectively prosecute their products rather than seeking universal market approval). Asynchronous approvals would be a minor issue if the price premiums were large enough to encourage global supply chains to adequately differentiate those systems to deliver quality assured products with different provenance. But they are not.

Identifying the sources of asynchrony is only half the challenge. The solution will only come if the opportunity costs identified in this chapter can be monetized and mobilized to incent one or more of the actors to close the gaps. This is not as easy as it might seem. While all of the economic studies suggest that the opportunity costs of the current situation are large and have real and significant effects on trade, prices, and investment, mobilizing those interests is not straightforward.

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Coexistence of Genetically Modified, Conventional, and Organic Food Products: A Framework and Analysis

Konstantinos Giannakas

Introduction

The coexistence of genetically modified (GM) products with their conventional and organic counterparts has been one of the most scrutinized issues surrounding the introduction of products of agricultural biotechnology into the agri-food marketing system. Fears that the widespread adoption of GM products would drive their conventional (and, perhaps, organic) counterparts out of the market have been countered by arguments that their presence enhances the equilibrium product variety in the market (GMO Compass; EarthOpenSource). Central to the argument is, of course, the possibility of coexistence of GM, conventional, and organic products with the main focus having been on farm production systems and the prospect of coexistence of GM, conventional, and organic crops (Devos et al. 2009; Bertheau 2013).

While the coexistence of the three different cropping systems is certainly necessary for the existence of GM, conventional, and organic food products in the final consumer markets, the availability of GM, conventional, and organic crops is not sufficient for ensuring the coexistence of food products utilizing these crops. The coexistence of GM, conventional, and organic food products will be determined, instead, by consumer attitudes towards these products, food companies, and their interaction in the relevant food product markets. The possibility of coexistence of the three different types of food is at the heart of this chapter.

Specifically, this chapter develops an empirically relevant, integrated, multi-market framework of analysis of the coexistence of conventional, GM, and organic food products. The framework builds upon the Giannakas and Fulton vertical product differentiation framework [presented formally in Giannakas (2011) and used in several studies of the markets for GM, conventional, and organic

K. Giannakas (✉)
University of Nebraska-Lincoln, Lincoln, USA
e-mail: kgiannakas@unl.edu

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products cited therein] and explicitly accounts for the well-documented (a) heterogeneity in consumer preferences for GM, conventional, and organic food products and (b) imperfect competition among the suppliers of these products (who can procure the necessary agricultural crop either domestically or from the world market).

Once developed, the framework is used to identify (i) the *determinants* of coexistence of GM, conventional, and organic food products and (ii) the *exact conditions* under which this coexistence will occur. In addition to enabling the analysis of coexistence of these important food product categories, the proposed framework allows us to effectively capture the impacts of coexistence-affecting strategies and policies [like various regulatory requirements for GM food, low-level presence (LLP) thresholds for conventional food, information campaigns for GM and/or organic food, etc.] on equilibrium prices and quantities, the welfare of different consumers, and the profits of the suppliers of these products. While most of the analysis focuses on the case where the GM, conventional, and organic food products are segregated and marketed separately, the issue of coexistence under a no GM labeling regime (where the GM and conventional products are marketed together as a non-labeled good) is also considered and analyzed within this framework.

The rest of the chapter is structured as follows. The next section focuses on consumer decisions and derives the demands for GM, conventional, and organic food products as well as the consumer welfare associated with the consumption of these products. The analysis then identifies the key determinants of the coexistence of the three products as well as the exact conditions under which this coexistence will occur. The section following derives the equilibrium prices of the GM, conventional, and organic food products, which are shown to be among the key determinants of their coexistence, and discusses how strategy- and policy-induced changes in consumer preferences, cost, and/or market structure in the three supply channels affect equilibrium prices, quantities/market shares, and consumer and supplier welfare. The possibility of coexistence when GM and conventional food products are marketed together as a non-labeled good is also discussed before the final section summarizes and concludes.

Consumers

Product and Consumer Characteristics—Utility Function

To capture the consumer attitudes towards GM, conventional, and organic food products reflected in numerous stated and revealed consumer preference studies around the world (Noussair et al. 2004; Yiridoe et al. 2005; Lusk et al. 2005), these close but imperfect substitute products are modeled as vertically differentiated goods. Consumers rank qualities uniformly so that if the GM, conventional, and

organic food products were offered at the same price, all consumers would prefer the organic version of the product, while if only the GM and conventional versions were available and offered at the same price, all consumers would prefer the conventional version of the food product. However, it should be noted that even though the three food products are uniformly quality-ranked, consumers differ in their valuation of (and their willingness-to-pay for) the perceived quality differences between the three products. To capture these elements, this chapter employs a variant of the Giannakas and Fulton framework of vertical product differentiation (on the specifics of the Giannakas and Fulton framework, its suitability for the analysis of food products, and its relationship with the classical models of vertical product differentiation, see Giannakas 2011).

To begin, consider a consumer with differentiating characteristic $\alpha \in [0, 1]$ who has the choice between GM, conventional, and organic versions of a food product. The products share the same physical characteristics (product attributes) but differ in the process through which they have been produced (process attributes). Assuming that the unit consumption of the product in question represents a small share of the total budget, the consumer utility can be expressed as:

$$\begin{array}{ll} U_{gm} = U - p_{gm} - \lambda\alpha & \text{if a unit of GM product is consumed} \\ U_{c} = U - p_{c} - \kappa\alpha & \text{if a unit of conventional product is consumed} \\ U_{o} = U - p_{o} + \mu\alpha & \text{if a unit of organic product is consumed} \end{array} \quad (1)$$

where U_{gm}, U_c, and U_o are the utilities associated with the unit consumption of the GM, conventional, and organic food product, respectively; U is a base level of utility associated with the consumption of the physical characteristics of this product (product attributes); p_{gm}, p_c, and p_o are the consumer prices of the GM, conventional, and organic food products, respectively; α captures the differences in the consumer valuation of the product differentiating attribute (i.e., the process through which these products have been produced); λ and κ are utility discount factors associated with the consumption of the GM and conventional versions of the food product, respectively; and μ is a utility enhancement factor associated with the consumption of the organic version of the product.

In this context, $U - \lambda\alpha$, $U - \kappa\alpha$, and $U + \mu\alpha$ capture the valuation of (and the maximum willingness-to-pay for) a unit of GM, conventional, and organic food product, respectively, for the consumer with differentiating attribute α. Subtracting the equilibrium prices from these willingness-to-pay values provides direct measures of the consumer surplus associated with the consumption of the three products. For simplicity and without loss of generality, κ is normalized to zero, in which case $\lambda\alpha$ and $\mu\alpha$ capture, respectively, the aversion to GM products and preference for organic products (relative to their conventional counterparts) of the consumer with differentiating attribute α. The greater the value of α, the greater the consumer aversion to interventions in the production process, and the greater the preference for "more natural" ways of production.

Consumer Decisions and Welfare

Individual consumer choice depends on the relationship between the utilities associated with the consumption of different products. In this context, the consumer with differentiating attribute

$$\alpha_{gm} : U_{gm} = U_c \Rightarrow \alpha_{gm} = \frac{p_c - p_{gm}}{\lambda} \tag{2}$$

is indifferent between consuming a unit of the GM and a unit of the conventional product as the utility associated with the consumption of these products is the same. Similarly, the consumer with differentiating characteristic:

$$\alpha_c : U_c = U_o \Rightarrow \alpha_c = \frac{p_o - p_c}{\mu} \tag{3}$$

is indifferent between consuming a unit of the conventional product and a unit of its organic counterpart.

Consumers with strong aversion to interventions in the production process/strong preference for "natural" production methods (i.e., consumers with $\alpha \in (\alpha_c, 1]$) prefer the organic version of the product. Consumers with $\alpha \in (\alpha_{gm}, \alpha_c]$ prefer the conventional version of the product, while consumers with $\alpha \in [0, \alpha_{gm}]$ consume the GM version of the food product. Figure 1 graphs the utilities associated with the consumption of the GM, conventional, and organic food products and the decisions made by the different consumers when the three products coexist in the market.

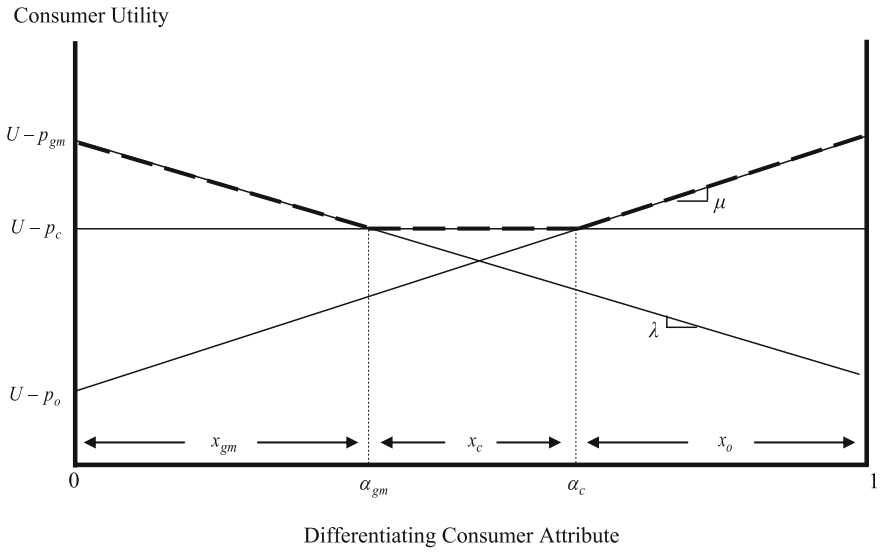

Fig. 1 Consumer decisions and welfare when GM, conventional, and organic products coexist

When consumers are uniformly distributed between the polar values of α, α_{gm} determines the share of the GM product in total consumption, x_{gm}. The consumption share of the conventional product, x_c, is given by $\alpha_c - \alpha_{gm}$, while the consumption share of the organic food product, x_o, is given by $1 - \alpha_c$. Normalizing the mass of consumers at unity, x_{gm}, x_c, and x_o give the consumer demands for the GM, conventional, and organic versions of the food product, respectively. Mathematically, x_{gm}, x_c, and x_o can be written as:

$$x_{gm} = \frac{p_c - p_{gm}}{\lambda} \tag{4}$$

$$x_c = \frac{\lambda p_o + \mu p_{gm} - (\mu + \lambda) p_c}{\mu\lambda} \tag{5}$$

$$x_o = \frac{\mu - p_o + p_c}{\mu} \tag{6}$$

It is important to note that in addition to enabling the derivation of the market shares and consumer demands for the different products, the framework of analysis outlined above also enables the derivation of theory-consistent measures of consumer welfare. In particular, since the expressions in (1) are direct measures of the surplus associated with the consumption of the different products for the consumer with differentiating attribute α, the area under the effective (bold dashed kinked) utility curve in Fig. 1 shows the welfare of the different consumers. Specifically, the surplus of consumers of the GM product (CS_{gm}), the conventional product (CS_c), and the organic product (CS_o) is given by

$$CS_{gm} = \int_0^{\alpha_{gm}} U_{gm} d\alpha = \left[U - \frac{p_c + p_{gm}}{2}\right] \frac{p_c - p_{gm}}{\lambda} \tag{7}$$

$$CS_c = \int_{\alpha_{gm}}^{\alpha_c} U_c d\alpha = (U - p_c) \frac{\lambda p_o + \mu p_{gm} - (\mu + \lambda) p_c}{\mu\lambda} \tag{8}$$

$$CS_o = \int_{\alpha_c}^{1} U_o d\alpha = \left[U + \frac{\mu - p_o - p_c}{2}\right] \frac{\mu - p_o + p_c}{\mu} \tag{9}$$

while the total consumer surplus is given by the summation of CS_{gm}, CS_c and CS_o above.

Conditions for the Absence/Exit of a Product from the Market

From Eqs. (4)–(6) it follows that the demand for a product falls with an increase in its price and/or a reduction in the utility associated with its consumption (captured by the relevant preference parameter—i.e., λ for the GM product and μ for its organic counterpart), and rises as the price of its substitute(s) increases. If p_{gm} were greater than p_c, the utility curve U_{gm} in Fig. 1 would lie underneath U_c for all consumers ($\forall\alpha$), the GM product would be driven out of the market, and the demand for the conventional and organic versions of the product would be, respectively:

$$x_c = \alpha_c = \frac{p_o - p_c}{\mu} \tag{10}$$

$$x_o = \frac{\mu - p_o + p_c}{\mu} \tag{11}$$

On the other hand, if the price premium enjoyed by the organic product, $p_o - p_c$, exceeded the valuation of the quality difference between the organic and conventional products for all consumers, μ, the utility curve U_o would lie underneath U_c $\forall\alpha$, and it would be the organic version of the product priced out of the market. In such a case, if the GM product were priced below its conventional counterpart, the demand for the conventional and GM versions of the product would be, respectively:

$$x_c = 1 - \alpha_{gm} = \frac{\lambda - p_c + p_{gm}}{\lambda} \tag{12}$$

$$x_{gm} = \frac{p_c - p_{gm}}{\lambda} \tag{13}$$

while, if p_{gm} exceeded p_c, the utility curve U_c would lie above the U_{gm} and U_o curves for all consumers, and the conventional version of the product would dominate the market.

Finally, if the price of the conventional product exceeded a critical level $p_c^+ = \frac{\lambda p_o + \mu p_{gm}}{\mu + \lambda}$, the utility curve U_c would lie underneath the U_{gm} and U_o curves for all consumers, and the conventional product would be driven out of the market. The demands for the GM and organic products would then be:

$$x_{gm} = \alpha'_{gm} = \frac{p_o - p_{gm}}{\mu + \lambda} \quad \text{where: } \alpha'_{gm} : U_{gm} = U_o \tag{14}$$

$$x_o = \frac{\mu + \lambda - p_o + p_{gm}}{\mu + \lambda} \tag{15}$$

Conditions for the Coexistence of GM, Conventional, and Organic Food Products

Based on the above analysis, for GM, conventional, and organic versions of the product to coexist in the market (i.e., for x_{gm}, x_c, and x_o to all be positive), the GM product should be priced below the conventional product, which, in turn, should be priced below the organic version of the product, i.e.,

$$p_{gm} < p_c < p_o \tag{16a}$$

with the relationship between the price premiums being:

$$\frac{\mu}{\lambda}(p_c - p_{gm}) < p_o - p_c < \mu \tag{16b}$$

With consumer prices of GM, conventional, and organic products being key determinants of the coexistence of the three products in the market, the next section focuses on the determination of these prices and the factors affecting their level.

Food Suppliers and Equilibrium Prices of GM, Conventional, and Organic Products

This section considers the determination of equilibrium prices in the markets for GM, conventional, and organic food products. The analysis will allow for imperfect competition among suppliers of the three products that seek to maximize their profits. The next part presents the demands faced by suppliers of GM, conventional, and organic food products followed by the derivation of the equilibrium prices and quantities of these products.

Consumer Demands for GM, Conventional, and Organic Food Products

Figure 2 graphs the inverse demand curves for GM, conventional, and organic products (shown as D_{gm}, D_c, and D_o, respectively) in the familiar price-quantity space when prices and preference parameters are such that the three products coexist in the market. These demands are derived from the expressions for x_{gm}, x_c, and x_o in Eqs. (4)–(6), can be written as:

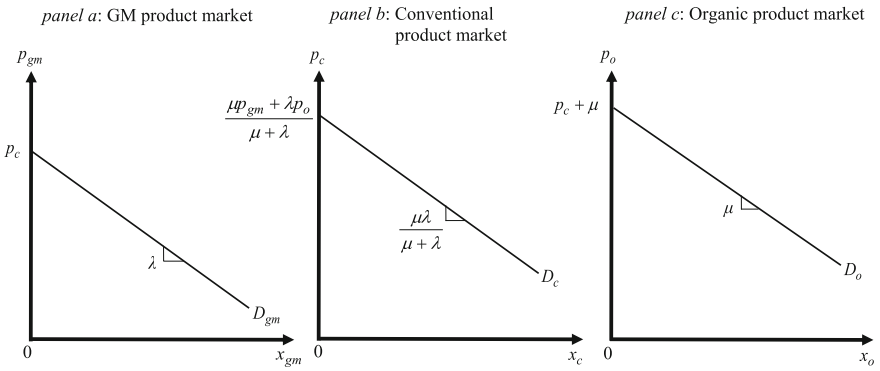

Fig. 2 Consumer demands when different products coexist in the market

$$p_{gm} = p_c - \lambda x_{gm} \tag{17}$$

$$p_c = \frac{\lambda p_o + \mu p_{gm}}{(\mu + \lambda)} - \frac{\mu\lambda}{(\mu + \lambda)} x_c \tag{18}$$

$$p_o = p_c + \mu - \mu x_o \tag{19}$$

and further illustrate the interdependence between the markets of the three products —the price and/or preference parameter associated with the consumption of a product are direct arguments in the demand for its closest substitute(s).

Equilibrium Conditions

Facing the demand schedules derived in Eqs. (17)–(19) and depicted in Fig. 2, the profit-maximizing suppliers of GM, conventional, and organic food products will find it optimal to produce the quantities determined by the equality of the relevant marginal revenues ("MR") and marginal costs and charge the maximum price consumers are willing to pay for these quantities (determined by the points on the demand curves that correspond to the optimal output levels).

Figure 3 graphs the equilibrium prices and quantities in the markets for GM, conventional, and organic food products, while Eqs. (20)–(25) show these equilibria mathematically.

$$p_{gm} = \frac{\theta_{gm} p_c + c_{gm}}{1 + \theta_{gm}} \tag{20}$$

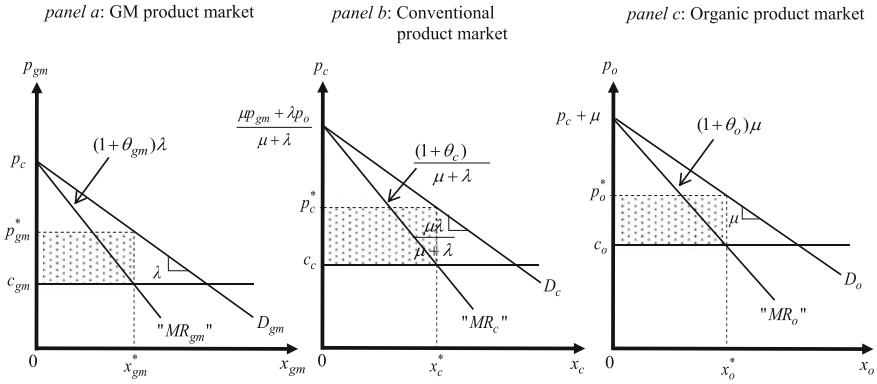

Fig. 3 Equilibrium conditions when different products coexist in the market

$$p_c = \frac{\theta_c\left(\lambda p_o + \mu p_{gm}\right) + (\mu+\lambda)c_c}{(1+\theta_c)(\mu+\lambda)} \tag{21}$$

$$p_o = \frac{\theta_o(p_c+\mu) + c_o}{1+\theta_o} \tag{22}$$

$$x_{gm} = \frac{p_c - c_{gm}}{\left(1+\theta_{gm}\right)\lambda} \tag{23}$$

$$x_c = \frac{\lambda p_o + \mu p_{gm} - (\mu+\lambda)c_c}{(1+\theta_c)\mu\lambda} \tag{24}$$

$$x_o = \frac{p_c + \mu - c_o}{(1+\theta_o)\mu} \tag{25}$$

The parameters θ_{gm}, θ_c, and θ_o are conjectural variation elasticities for the markets of GM, conventional, and organic food products, respectively. These parameters take values between zero and one and capture the degree of market power exercised by suppliers of these products. Specifically, the θ parameter takes value of one in the monopoly case, zero under perfect competition and Bertrand oligopolistic price competition, and $\theta \in (0, 1)$ under alternative oligopolistic market structures—the greater is the conjectural variation elasticity in a food product market, the greater the market power exercised by the suppliers of this product. The parameters c_{gm}, c_c, and c_o, represent the costs faced by suppliers of GM, conventional, and organic food products, respectively. These costs capture (i) the production, processing, and marketing costs along the three supply channels; (ii) the costs associated with the segregation and labeling, where relevant, of these products; and (iii) the market power at previous stages of the supply chain (i.e., the market power of input suppliers, wholesalers, etc.). The greater the production, processing and/or marketing costs, and/or the greater the labeling and segregation

costs, and/or the greater the market power upstream in a supply channel, the greater the costs of a product.

The expression of equilibrium prices and quantities of GM, conventional, and organic products as function of the equilibrium prices of their substitutes in Eqs. (20)–(25) captures the exact nature of interaction/interdependence among the markets for the three products and it enables the tracking of the effects of changes in the price of a product (due to changes in costs, consumer preferences, and/or market power of the suppliers of this product—see Section on "Changes in the Determinants of Coexistence", below) on the markets for its substitute products. Of course, by solving the expressions for the equilibrium prices in Eqs. (20)–(22) simultaneously and substituting into the expressions for the equilibrium quantities in Eqs. (23)–(25), we can express the equilibrium prices and quantities of GM, conventional, and organic food products as functions of the exogenous variables of our model (i.e., preference parameters, market power, and costs in the different supply channels) as:

$$p_{gm} = \frac{\theta_{gm}A + Bc_{gm}}{(1+\theta_{gm})B} \tag{26}$$

$$p_c = \frac{A}{B} \tag{27}$$

$$p_o = \frac{\theta_o(A+\mu B) + Bc_o}{(1+\theta_o)B} \tag{28}$$

$$x_{gm} = \frac{A - Bc_{gm}}{(1+\theta_{gm})\lambda B} \tag{29}$$

$$x_c = \frac{[\lambda\theta_o(1+\theta_{gm}) + \mu\theta_{gm}(1+\theta_o)]A + [\mu\lambda\theta_o(1+\theta_{gm}) + \lambda(1+\theta_{gm})c_o + \mu(1+\theta_o)c_{gm} - (\mu+\lambda)(1+\theta_o)(1+\theta_{gm})c_c]B}{\mu\lambda(1+\theta_c)(1+\theta_o)(1+\theta_{gm})B} \tag{30}$$

$$x_o = \frac{A + B(\mu - c_o)}{(1+\theta_o)\mu B} \tag{31}$$

where $A = \lambda\theta_c(1+\theta_{gm})(\mu\theta_o + c_o) + \mu\theta_c(1+\theta_o)c_{gm} + (\mu+\lambda)(1+\theta_{gm})(1+\theta_o)c_c$ and $B = \mu(1+\theta_o)(1+\theta_c+\theta_{gm}) + \lambda(1+\theta_{gm})(1+\theta_c+\theta_o)$.

Finally, the profits of the suppliers of GM, conventional, and organic food products are given by:

$$\Pi_i = (p_i - c_i)x_i \quad \text{with } i \in \{gm, c, o\} \tag{32}$$

and are depicted by the dotted areas in Fig. 3.

Changes in the Determinants of Coexistence

In addition to enabling the identification of (i) the key factors affecting the coexistence of GM, conventional, and organic food products and (ii) the exact conditions under which such coexistence will take place, the framework presented above can be used to analyze how different policies and strategies affecting the cost structure, market power, and/or consumer preferences for the different products (like changes in regulatory requirements for GM food or adventitious presence thresholds for conventional food, the provision of new information on GM or organic food, etc.) affect the equilibrium quantities and prices of these products, and the welfare of the groups involved.

For instance, an increase in the costs associated with the production of GM products (due to stricter regulatory requirements governing this supply channel, for instance) will increase the price and reduce the equilibrium quantity of this product (i.e., $\frac{\partial p_{gm}}{\partial c_{gm}} > 0$ and $\frac{\partial q_{gm}}{\partial c_{gm}} < 0$). The increased p_{gm} increases the demand for conventional products [recall the expression for D_c in Eq. (18)], which increases, in turn, the price, quantity, and profits in the conventional supply channel (i.e., $\frac{\partial p_c}{\partial p_{gm}} > 0$, $\frac{\partial q_c}{\partial p_{gm}} > 0$, and $\frac{\partial \Pi_c}{\partial p_{gm}} > 0$). The increased p_c increases demand for organic products [recall the expression for D_o in Eq. (19)], and the price, quantity, and profits in the organic food product market (i.e., $\frac{\partial p_o}{\partial p_c} > 0$, $\frac{\partial q_o}{\partial p_c} > 0$, and $\frac{\partial \Pi_o}{\partial p_c} > 0$). While suppliers of conventional and organic products gain from an increase in the costs associated with the production of the GM product, suppliers of GM products lose and so do the consumers of all three products considered here (i.e., $\frac{\partial \Pi_{gm}}{\partial p_{gm}} < 0$, $\frac{\partial CS_i}{\partial p_{gm}} < 0$). Figure 4 depicts the market and welfare effects of increased c_{gm} both in the price-quantity and the consumer utility spaces.

Similarly, an increase in the market power of, say, conventional product suppliers, increases the price and reduces the quantity of this product (while increasing, of course, the profits of these imperfectly competitive suppliers—i.e., $\frac{\partial p_c}{\partial \theta_c} > 0$, $\frac{\partial q_c}{\partial \theta_c} < 0$, and $\frac{\partial \Pi_c}{\partial \theta_c} > 0$). The increased p_c increases demand for GM and organic products and also equilibrium prices, quantities, and profits in the markets for GM and organic products (i.e., $\frac{\partial p_j}{\partial p_c} > 0$, $\frac{\partial q_j}{\partial p_c} > 0$, and $\frac{\partial \Pi_j}{\partial p_c} > 0$ with $j \in \{gm, o\}$). While all suppliers gain in this case, consumers lose as the increased market power in the market for conventional food products results in increased prices of all three substitutes (i.e., $\frac{\partial CS_i}{\partial \theta_c} < 0$).

The results regarding changes in costs and market power in other markets are similar. In general, an increase in cost or/and degree of market power in the supply channel of a product increases the price and reduces the quantity of this product while causing equilibrium prices and quantities of substitutes to increase. While suppliers of substitute products gain, the increased food prices hurt all consumers. The effect on suppliers of the product in question depends on whether costs or

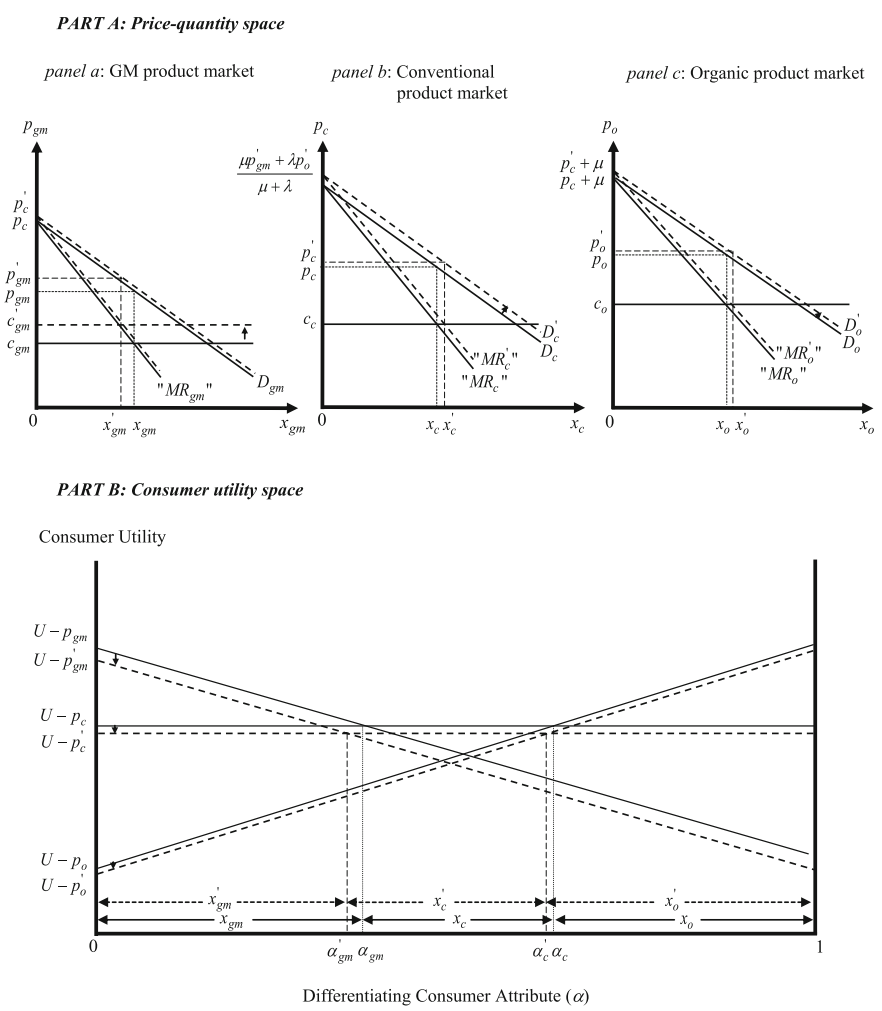

Fig. 4 Market and welfare effects of an increase in c_{gm}

market power increased—i.e., while an increase in the cost of a product causes supplier profits to fall, an increase in market power makes these suppliers better off.

Regarding consumer preferences, an increase in the level of consumer aversion to GM products (captured by an increase in the utility discount factor associated with the consumption of GM products, λ), reduces the demand for GM products while increasing consumer demands for the conventional and organic counterparts. Equilibrium quantity and supplier profits fall in the GM market while increasing in the markets for conventional and organic food products (i.e., $\frac{\partial q_{gm}}{\partial \lambda} < 0$ and $\frac{\partial \Pi_{gm}}{\partial \lambda} < 0$, while $\frac{\partial q_k}{\partial \lambda} > 0$ and $\frac{\partial \Pi_k}{\partial \lambda} > 0$ with $k \in \{c, o\}$). All prices increase in this case resulting

in welfare losses for all consumers involved (i.e., $\frac{\partial p_i}{\partial \lambda} > 0$ and $\frac{\partial CS_i}{\partial \lambda} < 0$).[1] Figure 5 graphs the market and welfare impacts of increased consumer aversion to GM products both in price-quantity and consumer utility spaces.

Finally, an increase in consumer valuation of organic food products, μ, increases the demand for organic products and reduces demand for GM and conventional counterparts. Price, quantity, and profits increase in the organic market and fall in the markets for GM and conventional food products (i.e., $\frac{\partial p_o}{\partial \mu} > 0$, $\frac{\partial q_o}{\partial \mu} > 0$, and $\frac{\partial \Pi_o}{\partial \mu} > 0$, while $\frac{\partial p_l}{\partial \mu} < 0$, $\frac{\partial q_l}{\partial \lambda} < 0$, and $\frac{\partial \Pi_l}{\partial \lambda} < 0$ with $l \in \{gm, c\}$. All consumers gain in this case (i.e., $\frac{\partial CS_i}{\partial \mu} > 0$)—consumers of GM and conventional food products benefit as prices of these products fall, while consumers of organic food products benefit as the welfare gains associated with their increased valuation of the organic product outweigh the welfare loss caused by the increased price of this product.

Extension of the Framework—Coexistence Under a No Labeling Regime

Given the credence nature of the process attribute differentiating GM and conventional food products, in the absence of a labeling regime the two products are marketed together as an undifferentiated, non-labeled good. Consumers cannot distinguish between non-labeled GM and conventional products and their utility becomes:

$$\begin{array}{ll} U_{nl} = U - p_{nl} - v\alpha & \text{if a unit of non-labeled product is consumed} \\ U_o = U - p_o + \mu\alpha & \text{if a unit of organic product is consumed} \end{array} \tag{33}$$

where p_{nl} is the price of the non-labeled food product and v is the utility discount factor associated with consumption of this product. Assuming rational expectations, $v = \psi\lambda$, where ψ is the share of the GM product in the total supply of the non-labeled good, capturing the probability that the non-labeled product is, in fact, genetically modified (see Giannakas and Fulton 2002).

[1]It should be noted that the increase in p_{gm} under increased λ is the outcome of the imperfectly competitive GM suppliers facing constant marginal costs (in which case the shift in D_{gm} due to the higher p_c results in increased p_{gm}). If GM suppliers were facing increasing marginal costs, the increased λ could result in reduced p_{gm} and benefits for consumers with low or no aversion to interventions in food production. Consumers with relatively low or no aversion to GM products would gain in this case as their welfare benefits from the reduced p_{gm} would outweigh the welfare losses associated with the increased λ. While at least some of the consumers of the GM product would benefit in this case, the rest of the results on the market and welfare effects of an increase in consumer aversion to GM products remain unaffected.

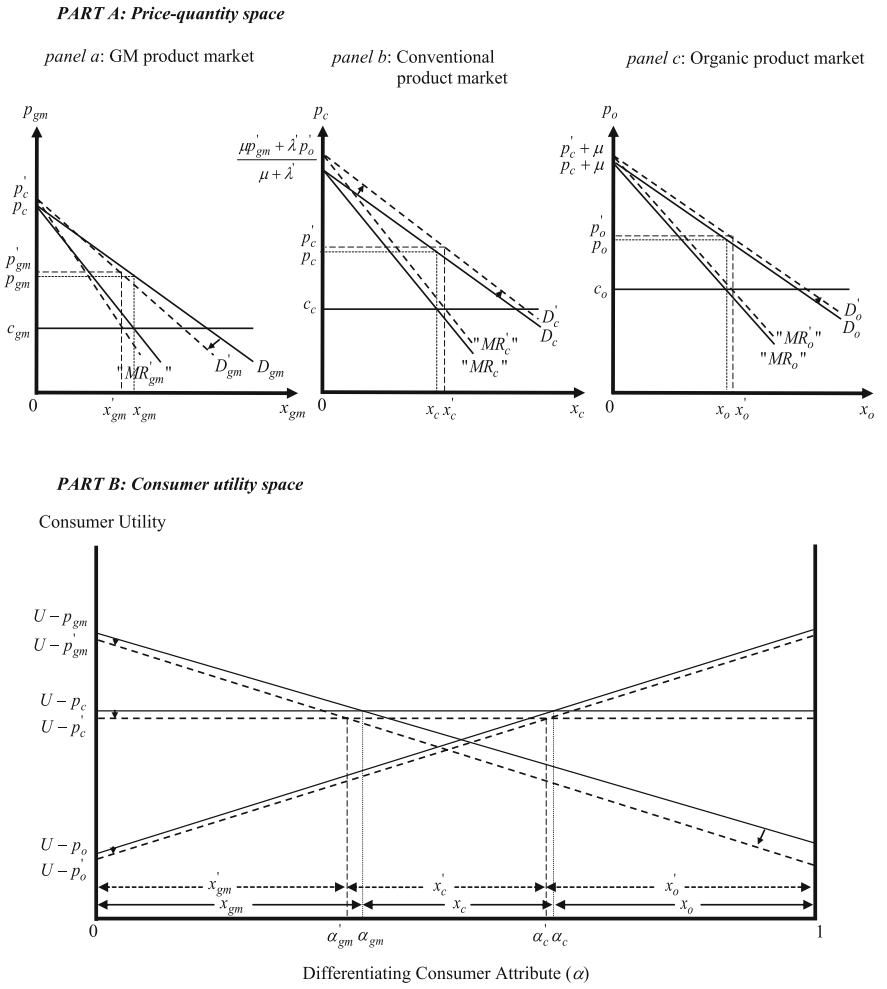

Fig. 5 Market and welfare effects of an increase in consumer aversion to GM products, λ

Following the process established earlier, we can identify the level of the differentiating attribute corresponding to the consumer who is indifferent between the non-labeled food product and its organic counterpart as:

$$\alpha_{nl} : U_{nl} = U_o \Rightarrow \alpha_{nl} = \frac{p_o - p_{nl}}{v + \mu} \tag{34}$$

and consumer demands for the non-labeled and organic food products as:

$$x_{nl} = \alpha_{nl} = \frac{p_o - p_{nl}}{v + \mu} \tag{35}$$

$$x_o = 1 - \alpha_{nl} = \frac{v + \mu + p_{nl} - p_o}{v + \mu} \tag{36}$$

It follows that, for non-labeled and organic food products to coexist in the market, the non-labeled product should be priced below its organic counterpart with the price premium enjoyed by the organic product being less than the maximum consumer valuation of the perceived quality difference between the two products, i.e.,

$$0 < p_o - p_{nl} < v + \mu \tag{37}$$

The inverse demands for non-labeled and organic products faced by their suppliers when this coexistence condition is satisfied are given by

$$p_{nl} = p_o - (v + \mu)x_{nl} \tag{38}$$

$$p_o = (p_{nl} + v + \mu) - (v + \mu)x_o \tag{39}$$

and are graphed in Fig. 6. Figure 6 also graphs the costs faced by suppliers of organic and non-labeled GM and conventional food products for the case in which the agronomic benefits associated with production of GM products result in $c_{gm} < c_c$ (Qaim 2009; Mannion and Morse 2012).

It should be noted that while satisfying the conditions in Eq. (37) guarantees the coexistence of non-labeled and organic products, it does not tell us much about the coexistence of GM and conventional products in the market for non-labeled goods. Put a different way, while the condition in Eq. (37) is necessary for the coexistence of non-labeled and organic food products, it is not sufficient for coexistence of GM, conventional, and organic food products when GM and conventional products are marketed together as a non-labeled good.

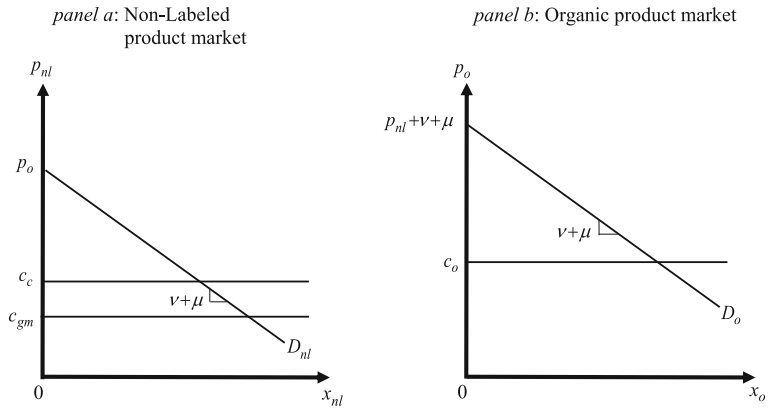

Fig. 6 Demand and cost conditions in markets for non-labeled and organic food products

The coexistence of GM and conventional products in the market for non-labeled goods will depend instead on (a) the structure of the market for non-labeled products and the nature of the strategic interaction among the suppliers of GM and conventional products, (b) the relative costs faced by suppliers of GM and conventional products, and (c) the endogeneity of costs and ability of suppliers to switch to production of a cheaper substitute. In particular, if suppliers of non-labeled products were perfectly competitive, then the product with the higher production costs (conventional food product in Fig. 6) would be driven out of the market and the non-labeled product would be priced at the lower marginal cost of the product remaining in the market (GM product in Fig. 6). For GM and conventional products to coexist under perfect competition among suppliers of non-labeled food products, these products should have the same costs of production. This is quite unlikely, however, due to both the agronomic benefits associated with the production of GM products and the fact that costs are continuous variables and the probability that c_c and c_{gm} will take the same value is zero.

Similarly, if suppliers of non-labeled products were imperfectly competitive and involved in Betrand price competition, the lower cost firm(s) would drive their higher cost rival(s) out of the market by pricing the non-labeled produce either marginally below their rivals' costs (i.e., $p_{nl} = c_c - \varepsilon$ in Fig. 6 where $\varepsilon \approx 0$), or at the pure monopoly price corresponding to their production cost (i.e., price corresponding to output determined by the equality of marginal revenues and marginal costs, when this pure monopoly price is below the production cost of the higher-cost non-labeled product suppliers). Similar to the perfectly competitive case, for GM and conventional products to coexist in the market, the costs associated with the production of the GM and conventional food products should be the same.

For different cost suppliers of GM and conventional products to coexist in the market, they would have to compete in quantities (making their decisions either simultaneously, *à la* Cournot, or sequentially, *à la* Stackelberg) and be unable (or find it unprofitable) to alter the type of product they produce. In such a case, the lower cost firms (GM suppliers in Fig. 6) would enjoy greater market share than their higher costs rivals, unless the cost differences are relatively small and the lower cost firms are followers in a Stackelberg-type competition.

Obviously, if food product suppliers could switch their production between GM and conventional food products (i.e., if switching costs were less than the efficiency gains associated with such a change), they would always do so since changing their production would enable the high cost firms to increase their profitability by producing undifferentiated non-labeled products at reduced costs. Consistent with Akerlof's *lemons theorem*, the marketing of GM and conventional products as a non-labeled good would result, in this case, in the low quality product driving the high quality product out of the market, jeopardizing the potential for coexistence of GM, conventional, and organic products in this market.

Conclusion

This chapter developed an empirically relevant, integrated, multi-market framework of heterogeneous consumers and imperfectly competitive food product suppliers to (i) identify the determinants of coexistence of genetically modified, conventional, and organic food products and (ii) specify the exact conditions under which such coexistence will occur. Coexistence of GM, conventional, and organic food products was shown to depend on the market structure of and nature of the strategic interactions among participants in different supply channels; the costs associated with the supply of the three products; the consumer attitudes towards GM, conventional, and organic food products; and the segregation and labeling regime governing the products of agricultural biotechnology.

In addition to enabling the analysis of the coexistence of GM, conventional, and organic food products, the methodological framework presented in this chapter allows us to effectively capture the impacts of coexistence-affecting strategies and policies on equilibrium prices and quantities, the welfare of different consumers, and supplier profits. Our framework could also provide a valuable theoretical grounding to empirical analyses of coexistence of these increasingly important types of food products.

Finally, it is important to note that while our analysis focused on the decisions and welfare of heterogeneous consumers and imperfectly competitive suppliers of GM, conventional, and organic food products, our framework can be easily extended to analyze the decisions and welfare of producers of GM, conventional, and organic crops used in the production of the relevant food products as well as the decisions and welfare of the suppliers of inputs (e.g., seeds, chemicals, fertilizers etc.) used in the production of these crops. The models of heterogeneous agricultural producers and imperfectly competitive input suppliers developed in Giannakas (2002), Fulton and Giannakas (2004), Giannakas and Yiannaka (2008), and Plastina et al. (2011) are consistent with the framework presented here and can form the basis for such an endeavor.

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The Cost of a GMO-Free Market Basket of Food in the US

Barry K. Goodwin, Michele Marra and Nicholas Piggott

Introduction

Technological progress in the production of foods and fiber has led to unprecedented growth in the productivity of agriculture. The USDA reports that total US agricultural output grew at an average annual rate of 1.49 % between 1948 and 2011 while input use only grew at 0.07 % per year.[1] There are many reasons for this impressive growth, including improvements in cropping practices, input qualities, resource management, selective breeding, and other widespread innovations in production practices. One important innovation that many believe has increased productivity is the genetic modification of crops in order to achieve increased output, higher quality, or lower production costs. According to the USDA, 90 % of corn, 93 % of soybeans, and 90 % of cotton planted in 2013 in the US was genetically modified.[2]

[1]Economic Research Service, USDA, "Agricultural Productivity in the U.S.," http://www.ers.usda.gov/data-products/agricultural-productivity-in-the-us.aspx#28247 (accessed May 11, 2014).
[2]Economic Research Service, USDA, "Recent Trends in GE Adoption," http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx#.U2-igPldXK0 (accessed May 11, 2014).

B.K. Goodwin (✉) · M. Marra · N. Piggott
North Carolina State University, Raleigh, NC, USA
e-mail: barry_goodwin@ncsu.edu

M. Marra
e-mail: michele_marra@ncsu.edu

N. Piggott
e-mail: nick_piggott@ncsu.edu

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Technological improvements have increased the overall quality and variety of the US food supply while, at the same time, lowering overall food costs. The share of disposable personal income spent on food at home fell from 21.2 % in 1930 to 5.7 % in 2012.[3] However, these technological advances have not been viewed as positive by all consumers. In particular, despite scientific evidence to the contrary, skepticism and suspicion regarding the safety and quality of genetically modified organisms (GMOs) exists among many consumers. This has led to efforts to legislate labeling of any foods containing GMOs (e.g., Proposition 37, which was defeated by California voters in 2012 and Vermont H.112 which was signed into law on May 8, 2014). Similar labeling laws have existed in the European Union for many years.

While there seems to be little lingering doubt about the yield increases brought about by GM crops, much less is known about the extent to which consumer concern about GMOs translate into price and food expenditure effects. A number of studies have evaluated consumers' willingness to pay for non-GMO food. Studies by Huffman (2010), Bukenya and Wright (2007), and Tegene et al. (2003) find that US consumers are willing to pay premiums ranging from 14 to 21 % for food certified to be GMO-free. Lusk et al. (2003) found that US consumers were willing to pay an additional $2.83–$3.31 per pound for beef that was not fed GMO ingredients. They also found that analogous premiums in Europe ranged from $4.86 to $11.01. Research has also documented that the information that consumers' have about GMO foods heavily influences their willingness to pay. For example, Lusk et al. (2003) found that a lack of knowledge about GMOs significantly increased a consumers' stated willingness to pay for GMO-free foods. Such willingness to pay studies are also widely recognized to have a number of biases that result in stated values far exceeding what consumers actually pay. The segregation and identity preservation needed to ensure food ingredients remain GMO-free from the farm gate to the retail store are also likely to be substantial. Such costs depend upon tolerance levels and the degree of regulation entailed.

Many retail outlets already offer foods that are certified to be GMO-free. The market share of GMO-free foods is modest but some retailers are identifying such products in their in-house brands. For example, the Whole Foods supermarket chain recently announced a commitment to label all foods containing GMO ingredients. Fernandez-Cornejo et al. (2014) report that of the 7637 new food products introduced between February 12, 2010 and February 11, 2011, 2.6 % advertise that they are GMO-free and 8 % advertise that they are organic.

[3]Economic Research Service, USDA, "Food Expenditures," http://www.ers.usda.gov/data-products/food-expenditures.aspx#.U2-tR_ldXK0 (accessed May 11, 2014).

Data

To our knowledge, no existing research has considered the cost implications of adopting a totally GMO-free diet for a typical family. We attempt to fill this void by considering the composition of the typical US household's food bill and the prominence of GMO ingredients across the diet. To this end, we utilize data from the Bureau of Labor Statistics (BLS) on the market basket weights used in calculating the consumer price index (CPI) and the composition of the average household's annual food bill that is reported in the Consumer Expenditure Survey. The CPI uses expenditure weights calculated from surveys of about 7000 families per year and collects detailed purchase data for over 200 item categories. We use the latest market basket weights (2007–2008) and Consumer Expenditure Survey (2011) reported by the BLS.

We also consider consumption of the various food items that are likely to contain GMO ingredients, either directly or as an animal feed. This is made possible by the EPA's Food Commodity Intake Database (FCID), which is comprised of data taken from the National Health and Nutrition Examination Survey (NHANES) of the CDC and USDA and the FCID recipe database, which derives the consumption of raw crop and livestock commodities from the dietary patterns reported in the NHANES. While the principal goal of the FCID is to monitor dietary exposure to pesticides, it also provides a detailed measure of the daily consumption of the base commodities (e.g., corn, beef, etc.) that are ingredients in the US food supply.

As we have noted, a variety of empirical studies have attempted to infer the price differences of existing GM commodities and GMO-free alternatives. Nearly all of this research has been done for broad commodity categories. For example, Barrows et al. (2014) find that the adoption of GM corn lowered corn prices by 13 % while adoption of GM soybeans lowered prices by 2–65 %. It is difficult to extend these aggregate price impacts through the marketing chain to infer how the cost of the typical grocery basket was impacted by GM crops. To reinforce these aggregate estimates, we adopt a unique approach that is empirical but largely anecdotal. We use proprietary grocery item pricing for conventional and certified GMO-free food items. In particular, we utilize market research data collected by Mintel from retail outlets over the preceding 12-month period for bakery, dairy, and snack food items. The Mintel data contain unit prices and detailed product descriptions. From this extensive database, we use a text matching algorithm to identify comparable GM-containing food items for each GMO-free certified item.[4] We utilize text mining algorithms applied to detailed product descriptions to identify GMO-free items as well as the unit size (in ounces) of the item.

[4]We utilize a generalization of the Levenshtein (1966) edit distance, which is a measure of dissimilarity between two text strings.

Analysis and Results

Table 1 presents detailed price comparisons for food items certified to be GMO-free and comparable food items that do not have such a certification. The price comparisons are made on a per-unit (i.e., package) basis as well as on a price per ounce of product. The product descriptions do not contain unit sizes in every case and thus the per-ounce comparisons are missing in some cases. It is important to note that although our matching algorithms derive the closest product matches possible, the products being compared may nevertheless differ in ways that we do not observe and thus that are not accounted for in the price differences. By comparing a large number of similar products, we hope to diminish any biases that would reflect product differences other than the GMO-free certification. That said, we also evaluate price differences that are based upon the relevant literature surveyed above.

Over all of the product matches, a GMO-free certification raises prices by an average of 34 %. This is quite similar to the commodity price differences identified in the empirical literature. An interesting observation is that, for those products for which we are able to define unit size, GMO-free certified products seem to be packaged in smaller units. If one considers pricing on a per-ounce basis, the GMO-free certification adds 69 % to price. The fact that unit sizes are absent in many cases may suggest that the 34 % price difference is more reliable.

Before proceeding to an evaluation of how these price differences translate into household expenditure differences, it is interesting to consider the prevalence of GMO containing food items in the typical consumer's diet. We utilized the EPA's FCID database to determine the typical US consumer's intake of commodities in processed and prepared food items. Table 2 contains the results of this survey of consumption patterns.

We report both mean and median daily intakes, since it is not uncommon for certain segments of the population to avoid a specific commodity altogether (e.g., vegetarians will have no meat consumption). In the case of field corn, which is overwhelmingly comprised of GM corn, the typical individual consumes 76.5 grams of corn across a wide range of processed commodities. These commodities include ingredients such as corn flour, corn meal, corn syrup, and so forth. In the case of soybean products, a commodity that is nearly entirely GM, the average consumer has a daily intake of about 30.4 g. The gram intake totals are of interest, but perhaps more enlightening is the broad range of food ingredients that contain the relevant agricultural commodities. In the case of meats, which use GM products as feed inputs, poultry is consumed the most, followed by beef products, and finally by pork. The median consumption of pork is quite low, reflecting the fact that a significant share of the US population does not consume pork products.

Though the quantitative measures of daily consumption of raw commodities is difficult to interpret in terms of the costs of a typical food basket, the FCID data do provide a detailed illustration of exactly how GM commodities are used in the US food supply. The breadth of food ingredients that contain GM commodities is

Table 1 Price differences between comparable GMO-free certified and non-certified food products

Non-GMO certified product	Comparable product without non-GMO certification	Non-GMO unit price	Comparable unit price	Non-GMO price/oz.	Comparable price/oz.	Percentage Unit price Difference (%)[a]	Percentage Price/oz. Difference (%)
Sugar Cookie Mix	Sugar Cookie Mix	3.99	1.89	0.27	0.01	75	320
Chocolate Chip Cookie Mix	Chocolate Chip Cookie Mix	2.99	3.49	0.16	0.18	−15	−15
All Purpose Flour	All Purpose Flour	3.99	1.49	0.25	0.05	99	168
Peanut Butter Cookies	Peanut Butter Cookies	6.99	2.79	0.58	0.17	92	121
Lemon Cookies	Lemon Cookies	6.99	1.99	0.58	0.15	126	134
Vanilla Animal Cookies	Vanilla Animal Cookies	2.49	3.49	0.42	0.39	−34	7
Oatmeal Animal Cookies	Oatmeal Animal Cookies	2.49	4.49	0.42	0.06	−59	194
Blueberry Pastry Crisps	Blueberry Pastry Crisps	1.99	1.99	0.05	0.00	0	248
Buttermilk Biscuits	Buttermilk Biscuits	1.98	2.79	0.12	0.11	−34	10
Cinnamon Rolls with Icing	Cinnamon Rolls with Icing	3.98	2.19	0.02	0.02	60	25
Chocolate Chip Cookies	Chocolate Chip Cookies	4.99	3.29	0.08	0.00	42	283
Blueberry Waffles	Blueberry Waffles	2.69	2.54	0.03	0.02	6	43
Half & Half	Half & Half	3.99	2.48	–	–	48	–
Eggnog	Eggnog	2.69	2.59	–	–	4	–
Whole Milk	Whole Milk	2.69	3.56	–	–	−28	–
Fat Free Milk	Fat Free Milk	2.69	1.99	–	–	30	–
Vanilla Almond Milk	Vanilla Almond Milk	3.00	2.99	–	–	0	–
Organic Whole Milk	Organic Whole Milk	6.99	3.59	–	–	67	–
Nonfat Yogurt with Blueberry on the Bottom	Nonfat Yogurt with Blueberry on the Bottom	1.00	1.79	0.02	0.03	−58	−58
Double Gloucester Cheese	Double Gloucester Cheese	8.99	7.99	–	1.14	12	–
Plain Soymilk	Plain Soymilk	2.00	2.69	–	–	−30	–
Whole Milk	Whole Milk	4.99	3.56	–	–	34	–

(continued)

Table 1 (continued)

Non-GMO certified product	Comparable product without non-GMO certification	Non-GMO unit price	Comparable unit price	Non-GMO price/oz.	Comparable price/oz.	Percentage Unit price Difference (%)[a]	Percentage Price/oz. Difference (%)
Vanilla Almond Drink	Vanilla Almond Drink	6.49	3.39	–	–	65	–
Chocolate Peanut Butter Protein Bar	Chocolate Peanut Butter Protein Bar	15.19	11.99	0.13	–	24	–
Raz-Mataz Berry Fruit Chews	Raz-Mataz Berry Fruit Chews	2.98	1.00	0.01	0.01	109	−52
Oats & Honey Crunchy Granola Bars	Oats & Honey Crunchy Granola Bars	2.94	2.24	0.04	0.03	27	50
Chocolate Peanut Butter Protein Bar	Chocolate Peanut Butter Protein Bar	15.19	11.99	0.13	–	24	–
Original Almond milk	Original Almond milk	2.59	2.99	–	–	−14	–
Low Fat Milk	Low Fat Milk	1.69	1.00	–	–	52	–
Original Almond Milk	Original Almond milk	3.00	2.99	–	–	0	–
Nonfat Yogurt with Super Fruits on the Bottom	Nonfat Yogurt with Superfruits on the Bottom	1.00	1.79	0.02	0.03	−58	−58
Non-Fat Yogurt with Blueberry on the Bottom	Nonfat Yogurt with Blueberry on the Bottom	1.39	1.79	0.03	0.03	−25	−25
Chocolate Brownie	Chocolate Brownies	7.99	7.99	0.67	0.67	0	0
Panettone Cake	Panettone	5.99	9.99	–	0.06	−51	.
Provolone Cheese Slices	Provolone Cheese	3.99	4.99	0.67	0.62	−22	6
Lowfat Vanilla Yogurt	Low Fat Vanilla Yogurt	4.49	1.99	0.14	0.40	81	−104
Peanut Butter Chocolate Chip Bars	Peanut Butter & Chocolate Chip	5.00	17.99	0.63	0.14	−128	152
Nonfat Yogurt with Caramel on the Bottom	Nonfat Yogurt	1.00	1.00	0.02	0.02	0	−19

(continued)

Table 1 (continued)

Non-GMO certified product	Comparable product without non-GMO certification	Non-GMO unit price	Comparable unit price	Non-GMO price/oz.	Comparable price/oz.	Percentage Unit price Difference (%)[a]	Percentage Price/oz. Difference (%)
Crescent Rolls	Crescent Roll Dough	2.98	3.48	0.37	0.22	−16	54
Non-Fat Yogurt with Pineapple on the Bottom	Nonfat Yogurt	1.39	1.00	0.03	0.02	33	14
Plain Non-Fat Yogurt	Peach Nonfat Yogurt	1.39	0.80	0.03	0.13	55	−163
Non-Fat Yogurt with Strawberry on the Bottom	Nonfat Yogurt	1.39	1.00	0.03	0.02	33	14
Peanut Butter Chocolate Chip Real Whole Food Bar	Peanut Butter & Chocolate Chip	3.29	17.99	1.10	0.14	−170	209
Reduced Fat Milk	2 % Reduced Fat Milk	4.99	1.99	–	–	92	–
Reduced Fat Milk	2 % Reduced Fat Milk	3.58	1.99	–	–	59	–
Peanut Butter Chocolate Chip Protein Pleasure Bar	Peanut Butter & Chocolate Chip	2.99	17.99	0.12	0.14	−179	−13
Peanut Butter Cookie Bar	Peanut Bar	2.99	0.68	0.19	0.00	148	366
Peanut Butter Cookie Bar	Peanut Bar	22.95	0.68	0.08	0.00	352	280
MMM… Chocolate Chip Cookie Mix	Mint Chocolate Chip Cookie Mix	5.69	1.89	0.04	0.14	110	−119
Non-Fat Yogurt with Black Cherry on the Bottom	Nonfat Yogurt	1.39	1.00	0.03	0.02	33	14
Peanut Butter Cookie Bars	Peanut Bar	5.00	0.68	0.06	0.00	200	251
Chocolate Peanut Butter Blast Nutrition Bars	Chocolate Peanut Butter Bars	23.31	6.98	0.11	0.08	121	29
Non-Fat Yogurt with Salted Caramel on the Bottom	Nonfat Yogurt	1.39	1.00	0.03	0.02	33	14
Peanut Sea Salt Bar	Peanut Bar	2.49	0.68	0.17	0.00	130	355

(continued)

Table 1 (continued)

Non-GMO certified product	Comparable product without non-GMO certification	Non-GMO unit price	Comparable unit price	Non-GMO price/oz.	Comparable price/oz.	Percentage Unit price Difference (%)[a]	Percentage Price/oz. Difference (%)
Peanut Butter Animal Cookies	Peanut Butter Oatmeal Cookies	2.49	2.18	0.42	0.02	13	287
0 % Fat Plain Greek Yogurt	Nonfat Plain Greek Yogurt	3.99	3.72	–	0.16	7	–
Organic Buttery Spread	Original Buttery Spread	2.99	2.98	0.23	0.20	0	15
Mint Chocolate Chip Protein Bar	Mint Chocolate 20 g Protein Bar	21.50	2.99	0.07	0.01	197	175
Organic White Corn Tortilla Chips	Organic Blue Corn Tortilla Chips	3.99	2.99	0.05	0.25	29	−154
Choco Moko Cookies	Chocolate Cookies	8.99	2.88	0.82	0.29	114	104
Nonfat Yogurt with Chocolate Fudge Sauce on the Bottom	Nonfat Yogurt	3.50	1.00	0.08	0.02	125	125
Vanilla Pure Almond Milk	Vanilla Almond Milk	3.39	2.99	–	–	13	–
White Tortilla Chips	White Corn Tortilla Chips	5.19	2.99	0.32	0.23	55	34
Yellow Tortilla Chips	Yellow Corn Tortilla Chips	5.19	2.29	0.32	0.18	82	61
Pumpkin Tortilla Chips	Pumpkin Seed Tortilla Chips	3.69	2.50	0.62	0.42	39	39
American Flavor Rice Vegan Slices	American Flavor Slices	3.18	3.27	0.05	0.04	−3	6
Cheddar Flavor Rice Vegan Slices	Cheddar Flavor Slices	3.18	3.99	0.05	0.05	−23	−14
					Average:	34	69

[a]Percentage differences given by *ln (Non-GMO Price/Comparable Price)*

Table 2 Average and median daily intake (grams) for selected food commodities

Product category	Products	Average daily intake (g)	Median daily intake (g)
Field Corn Products	Field corn flour, field corn flour-baby food, field corn meal, field corn meal-baby food, field corn bran, field corn starch, field corn starch-baby food, field corn syrup, field corn syrup-baby food, field corn oil, field corn oil-baby food	76.5	52.0
Soybean Products	Soybean seed, soybean soy milk, soybean soy milk-baby food, infant formula, soybean oil, soybean oil- baby foods, soybean vegetable or soybean flour, soybean flour-baby food	30.4	21.2
Cotton Products	Cottonseed oil or cottonseed oil-baby food	1.5	1.1
Canola Products	Rapeseed oil or rapeseed oil-baby food	1.6	0.6
Beef Products	Beef meat or beef meat-baby food, beef meat dried, beef meat byproducts, beef meat byproducts-baby food, beef fat or beef fat-baby food, beef, kidney or beef, liver or beef, liver-baby food	48.1	12.4
Poultry Products	Chicken meat or chicken meat-baby food, chicken liver, chicken meat byproducts or chicken meat byproducts-baby food, chicken fat or chicken fat-baby food, or chicken skin or chicken skin baby food turkey meat or turkey, meat-baby food, turkey liver or turkey liver-baby food, turkey meat byproducts or turkey meat byproducts-baby food, or turkey fat or turkey fat-baby food, turkey skin or turkey skin-baby food, or poultry other meat, poultry other liver or poultry other meat byproducts, or poultry other fat, poultry other skin, egg whole or egg whole-baby food, or egg white or egg white (solids)-baby food, egg yolk or egg yolk-baby food	71.8	47.8
Pork Products	Pork, meat or Pork, meat-baby food or Pork, skin or Pork, meat byproducts or Pork, meat byproducts-baby food or Pork, fat or Pork, fat-baby food or Pork, kidney or Pork, liver	24.6	3.0

Based upon the food commodity intake database, the NHANES/what we eat in America survey data, and the US-EPA office of pesticide programs

impressive and serves to highlight the significant dietary changes that would be necessary to avoid consumption of GM commodities in the US diet.

Table 3 presents the latest average annual expenditures on food by US households. This is based on the 2011 Consumer Expenditure Survey of the BLS.[5] The data are comprised of a survey of the population of 60.14 million US households. The average household consisted of 3.2 persons, 0.9 children, and had an annual

[5]Bureau of Labor Statistics, US Department of Labor, "Expenditure Tables," http://www.bls.gov/cex/csxstnd.htm (accessed May 12, 2014).

Table 3 Expenditures on broad food categories for average household in 2011

Average annual $ expenditures (2011 CES)	63,972
Food	8315
Food at home	4944
Cereals and bakery products	687
Cereals and cereal products	225
Bakery products	462
Meats, poultry, fish, and eggs	1084
Beef	298
Pork	209
Other meats	166
Poultry	197
Fish and seafood	153
Eggs	62
Dairy products	533
Fresh milk and cream	194
Other dairy products	339
Fruits and vegetables	926
Fresh fruits	325
Fresh vegetables	294
Processed fruits	144
Processed vegetables	164
Other food at home	1714
Sugar and other sweets	188
Fats and oils	142
Miscellaneous foods	866
Nonalcoholic beverages	445
Food prepared by consumer unit on out-of-town trips	72
Food away from home	3370
Alcoholic beverages	515

Taken from the 2011 Consumer Expenditure Survey

gross income of $86,700. Total annual expenditures averaged $63,972, of which $8315 went toward food. Of that amount, $4944 was spent on food at home and $3370 was spent on food away from home. Spending on broad categories of food items is included in Table 3.

In order to decompose the total expenditures of $63,972 into specific food categories, we applied the 2007/08 CPI market basket weights to the total expenditures.[6] Table 4 presents the detailed CPI weights and total expenditures on

[6]Note that modest differences in expenditures in broad categories arise from applying the CPI weights to the 2011 expenditures. For example, the weights imply total food expenditures of $8791 as compared to the CES total of $8315. We utilize the CPI weights because of the significantly greater detail that they provide.

Table 4 Simulated impacts of a 34 % price increase in foods containing GMOs on average household expenditures (Based on 2011 Consumer Expenditure Survey)

Category	Food items	2007/08 CPI weights	2011 CES expenditures	Farm value as % of retail	Contains GMO ingredients	Expenditures with no GMOs
Total expenditures from CES			63,972.00			
Food and beverages		14.792	9462.74			
Food		13.742	8791.03			
Food at home		7.816	5000.05			
Cereals and cereal products	Flour and prepared flour mixes	0.039	24.95	7 %	*	33.43
	Breakfast cereal	0.194	124.11		*	166.30
	Rice, pasta, cornmeal	0.118	75.49		*	101.15
Bakery products	Bread	0.212	135.62		*	181.73
	Fresh biscuits, rolls, muffins	0.109	69.73		*	93.44
	Cakes, cupcakes, and cookies	0.197	126.02		*	168.87
	Other bakery products	0.220	140.74		*	188.59
Beef and veal	Uncooked ground beef	0.202	129.22	56 %	#	173.16
	Uncooked beef roasts	0.081	51.82		#	69.44
	Uncooked beef steaks	0.173	110.67		#	148.30
	Uncooked other beef and veal	0.047	30.07		#	40.29
Pork	Bacon, breakfast sausage, and related products	0.124	79.33	38 %	#	106.30
	Ham	0.071	45.42		#	60.86
	Pork chops	0.066	42.22		#	56.58
	Other pork including roasts and picnics	0.080	51.18		#	68.58

(continued)

Table 4 (continued)

Category	Food items	2007/08 CPI weights	2011 CES expenditures	Farm value as % of retail	Contains GMO ingredients	Expenditures with no GMOs
Other meats		0.236	150.97		#	202.31
Poultry	Chicken	0.269	172.08	38 %	#	230.59
	Other poultry including turkey	0.067	42.86		#	57.43
Fish and seafood	Fresh fish and seafood	0.159	101.72			101.72
	Processed fish and seafood	0.138	88.28			88.28
Eggs		0.099	63.33		#	84.87
Dairy and related products	Milk	0.281	179.76	31 %	#	240.88
	Cheese and related products	0.269	172.08		#	230.59
	Ice cream and related products	0.130	83.16		#	111.44
	Other dairy and related products	0.159	101.72		#	136.30
Fresh fruits	Apples	0.071	45.42	33 %		45.42
	Bananas	0.066	42.22			42.22
	Citrus fruits	0.084	53.74			53.74
	Other fresh fruits	0.228	145.86			145.86
Fresh vegetables	Potatoes	0.070	44.78	23 %		44.78
	Lettuce	0.057	36.46			36.46
	Tomatoes	0.076	48.62			48.62
	Other fresh vegetables	0.233	149.05			149.05
Processed fruits and vegetables	Canned fruits and vegetables	0.138	88.28			88.28
	Frozen fruits and vegetables	0.081	51.82			51.82
	Other processed fruits and vegetables including dried	0.048	30.71			30.71

(continued)

Table 4 (continued)

Category	Food items	2007/08 CPI weights	2011 CES expenditures	Farm value as % of retail	Contains GMO ingredients	Expenditures with no GMOs
Juices and nonalcoholic drinks	Carbonated drinks	0.285	182.32		*	244.31
	Frozen noncarbonated juices and drinks	0.013	8.32		*	11.14
	Nonfrozen noncarbonated juices and drinks	0.397	253.97		*	340.32
	Coffee	0.112	71.65			71.65
	Other beverage materials including tea	0.119	76.13			76.13
Other food at home	Sugar and artificial sweeteners	0.055	35.18		*	47.15
	Candy and chewing gum	0.188	120.27		*	161.16
	Other sweets	0.054	34.54		*	46.29
	Butter and margarine	0.067	42.86		*	57.43
	Salad dressing	0.063	40.30		*	54.01
	Other fats and oils including peanut butter	0.102	65.25		*	87.44
	Soups	0.090	57.57		*	77.15
	Frozen and freeze dried prepared foods	0.301	192.56		*	258.02
	Snacks	0.314	200.87		*	269.17
	Spices, seasonings, condiments, sauces	0.250	159.93		*	214.31
	Baby food	0.079	50.54		*	67.72
	Other miscellaneous foods	0.432	276.36		*	370.32

(continued)

Table 4 (continued)

Category	Food items	2007/08 CPI weights	2011 CES expenditures	Farm value as % of retail	Contains GMO ingredients	Expenditures with no GMOs
Food away from home	Full service meals and snacks	2.870	1836.00		*	2460.24
	Limited service meals and snacks	2.347	1501.42		*	2011.91
	Food at employee sites and schools	0.269	172.08		*	230.59
	Food from vending machines and mobile vendors	0.112	71.65		*	96.01
	Other food away from home	0.329	210.47		*	282.03
Alcoholic beverages at home	Beer, ale, and other malt beverages at home	0.303	193.84		*	259.74
	Distilled spirits at home	0.079	50.54		*	67.72
	Wine at home	0.232	148.42			148.42
Alcoholic beverages away from home		0.437	279.56		*	374.61
TOTAL (at +34 % Price Impact)		14.79	9462.10			12,263.34
ALTERNATE PRICE IMPACTS:						
+10 %						10,285.99
+13 % (Average of studies surveyed by Sexton and Zilberman (2014))						10,533.99
+20 %						11,109.89
+40 %						12,757.68
+69 % ($/oz. Change from Mintel)						15,146.98

A '*' indicates the commodities contain GMO ingredients and a "#" indicates that GMO feed is used in production. We assume a baseline 34 % price increase in all goods for which GMOs are used as direct ingredients or feedstuffs

specific food categories. We have also included (where possible) the farm to retail value proportions. These are not used directly in our calculations but they do allow informal inferences regarding the degree to which farm price shocks might be reflected in retail prices. These data were collected from unpublished USDA

sources.[7] We identify each food item category that is likely to have GMO ingredients. This includes cereal and bakery products, meat and poultry, dairy, beverages, prepared foods, and food away from home.

Of the total expenditures of $9462 on food and beverages, $8239 is spent on food items likely to contain GMO ingredients. We consider the impacts on the typical family's food budget of a GMO-free diet. First, we consider the 34 % price premium implied by our comparison of specific GMO-free certified food products and comparable conventional foods. In that case, the typical family's food budget would increase from $9462 to $12,263 each year. Of course, depending on household composition and consumption patterns, the price impacts could differ widely across households. We next consider the impacts of a modest 10 % price premium for GMO-free food items. In that case, total expenditures would rise to $10,286 per year. In the case of a 20 % price premium, which is the midpoint of the estimates reviewed by Barrows, Sexton, and Zilberman (2014), total food expenditures would increase to $11,110. A 40 % price premium would increase food expenditures to $12,758. Finally, if we apply the 69 % price premium implied by our $/ounce price comparisons, total food expenditures would rise to $15,147.

Conclusion

Overall, our calculations suggest that the cost of a typical US family's market basket of food would rise from 8 to 50 % annually, depending on the impacts on retail prices from going to a GMO-free diet. To put this in perspective, consider a comparison of food spending in developed countries that regulate GMO ingredients to that of the US. According to calculations presented by "Civil Eats," the typical US family spends approximately 6.9 % of its household budget on food at home as compared to 13.9 % in France and 11.1 % in Germany.[8] Dietary differences beyond GMO regulation are likely reflected in these statistics, but it is likely that at least part of the budget differences reflect the higher costs associated with GMO-free foods.

In short, the budgetary implications of a GMO-free diet are substantial. GMO-free food items are shown to be more expensive than conventional alternatives. GMO ingredients play an important and ubiquitous role in the US food supply. Even small increases in the costs of these ingredients translate into significant impacts on the typical US household. Increased food costs would not only impact food consumption patterns but would also affect all classes of expenditures as limited income is redistributed across alternative consumption items.

[7]Economic Research Service, USDA, "Price Spreads from Farm to Consumer," http://ers.usda.gov/data-products/price-spreads-from-farm-to-consumer.aspx#.U3DoM_ldXK0 (accessed May 12, 2014).

[8]Civil Eats, "How Much of Our Spending Goes Toward Food?" http://civileats.com/2011/03/29/mapping-global-food-spending-infographic/ (accessed May 12, 2014).

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Lessons from EU Voluntary Labeling Schemes for GM-Free Processed Food Products

Thomas J. Venus, Nicholas Kalaitzandonakes and Justus Wesseler

Introduction: GM-Free Labeling in the EU Versus US

In the European Union, a mandatory GMO labeling law for food and feed products that contain more than 0.9 % EU-approved GMOs has been in place since the early 2000s. This law does not include animal products derived from animals that were fed with GM feed. To enable consumers to also choose animal products derived from animals that were fed with non-GM feed only, some EU Member States have chosen to adopt national GM-free schemes. The labeling scheme in the EU results in three potential product categories: products labeled as GM following the mandatory labeling standard; products labeled as GM-free, following voluntary labeling standards; and non-labeled food products. The presence of positive and negative GM labels can be confusing for consumers. A European Commission report shows that consumers often believe that the unlabeled products are GM (European Commission 2015).

In the United States, so far, only guidelines (or non-binding recommendations) exist on how labeling should be applied (FDA 2001). The independent Non-GMO Project provides a "Non-GMO Project Verified" seal for labels of conforming products (AMS/USDA 2015) but other voluntary labeling schemes also exist. The US Food and Drug Administration (FDA) guideline states that GM-free labeling shall not be misleading (i.e., no products should be labeled when there are

T.J. Venus (✉) · J. Wesseler
Wageningen University, Wageningen, The Netherlands
e-mail: thomas.venus@wur.nl

J. Wesseler
e-mail: justus.wesseler@wur.nl

N. Kalaitzandonakes
University of Missouri, Columbia, MO, USA
e-mail: KalaitzandonakesN@missouri.edu

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no marketed GMO varieties of that product) and only be used for products that can contain GM components (Gruére and Rao 2007).

Current State of GM-Free Schemes and Their Evolution in the EU

In 1997, NGOs in Austria campaigned for retailers to ban GM food as well as livestock products derived from GM fed animals. The same year 1.2 million people signed a referendum against GMO use in food and feed (Seifert 2002). Austria implemented a directive for defining GM-free production in 1998 (Federal Ministry of Austria 2010). Germany also introduced GM-free standards in 1998 under the regulation for novel food products (NLV). In 2008, the German Genetic Engineering Act of 1990 was revised (Federal Ministry of Germany 2004) and it now includes GM-free standards, which are less restrictive than the previous ones under the NLV. In 2012, France adopted new legislation on GM-free production with GM thresholds for GM-free labels. The threshold is either 0.1 or 0.9 % adventitious presence of GMOs in animal feed, depending on the type of label (Répubique Francaise 2012). Labeling schemes in Finland and the Netherlands require a zero tolerance level of GMOs in feed. Labeling schemes in Austria, France and Germany allow adventitious presence of GMOs up to a threshold and farmers can feed GMOs for a certain time period without losing their GM-free certification. The non-GM feeding times vary by country. Poultry must be fed with non-GM feed beginning 3 days after birth in Austria and France, while it is sufficient in Germany to feed non-GM feed starting 10 weeks before slaughter. The non-GM feeding period is 6 weeks before laying eggs in all three countries. Pigs are required to be fed non-GM feed for the total fattening period in Austria and 4 or 4.5 months before slaughtering in Germany or France, respectively. The minimum non-GM feeding before milking is 2 weeks in Austria, 3 months in Germany, and 6 months in France. GM feed additives like vitamins, amino acids, or enzymes are allowed. Additionally, GM medicinal products or vaccines can be used to treat animals (European Commission 2015). However, some of the country- and animal-specific thresholds substantially contradict what consumers expect from the label (Henseleit et al. 2009).

While Austria, France, Germany, and the Netherlands specify the wording that must be used for labeling, Austria and Germany also provide a non-prescriptive logo. The minimum requirement a firm has to comply with, independently of the logo, is the national regulation or guideline (European Commission 2015).

In countries that do not have GM-free labeling schemes (e.g., the UK, Slovenia, the Czech Republic, Poland, Spain), some retailers have developed their own private standard (Moses and Brookes 2013). Belgium and Sweden prohibit “GM-free” labels.

GM-free schemes of some countries allow GM-free labeling of non-animal food products. The German scheme allows GM-free labeling of non-animal food, if adventitious presence of GMOs is below 0.1 %. Additionally, labels must comply with the regulation on self-evident advertising, which prohibits the use of a GM-free label when consumers can expect the product to be naturally GM-free. The governmental food inspection agency in Germany, for example, decided that Oettinger, the brewery of the most consumed German beer brand, is allowed to label their beer as GM-free, if all ingredients contain <0.1 % adventitious presence of GMOs (Spelsberg 2013). The German brewers' association heavily criticized the decision by Oettinger, claiming that GM-free labeling of beer deceives consumers (Spelsberg 2013). Table 1 provides an overview of the evolution of GM-free schemes in the EU.

GM-Free Label Implementation of Retailers

Over the last decade, several retailers have adopted GM-free labels for their retail brands (Wesseler 2014). In Austria, according to ARGE (2013), almost all milk and eggs are produced GM-free, but not necessarily labeled. In Germany, more than 50 % of eggs and somewhat <10 % of milk is produced according to the GM-free standard (VLOG 2015). In France, as of 2010–2011 Carrefour is the major GM-free producer with about 70 % GM-free labeled pork (Lebensmittelzeitung 2010). In a survey, Passuello et al. (2013) show that the largest Italian retailer sells about 100 % of its own brands of poultry, eggs, and milk as well as 50 % of cold cut meat, cheese, and ham as GM-free.

The major retailers in the UK agreed to sell GM-free poultry products and eggs until all retailers (except Waitrose) abandoned the GM-free policy in 2012–2013 (GM Freeze 2013). A similar situation occurred in Germany, when the German association of poultry producers announced they would exit the GM-free market in 2014 (ZDG 2014). However, the environmental NGO Greenpeace strongly attacked the largest producer of the association, Wiesenhof, making them to convert back to GM-free production.

Two German discounters (ALDI and LIDL) started GM-free agreements with their suppliers without labeling the final product. Venus and Wesseler (2015) argue that the non-labeling GM-free production can be viewed as a two stage investment, where the supplier agreement reduces the probability of anti-GMO group attacks as well as the risk of liability issues, but allows firms to implement the label quickly if demand for labeled products increases. By the end of 2015 and beginning of 2016, ALDI (Süd) and LIDL started GM-free labeling of milk products.

Table 1 Evolution of GM-free schemes in the EU

1997	Austria founds the association ARGE Gentechnikfrei to promote GM-free food in Austria
1998	Austria implements the first directive for defining GMO-free production as Codex Alimentarius Austriacus Guideline (Federal Ministry of Austria 2010)
2000	The major supermarkets in the UK committed "…to phase out GM feed for the animals used to produce their meat and dairy products … Fresh poultry was the most reliable for being GM-free" whereas other products probably are less reliable (GM Freeze 2013)
2000/01	COOP Italia, the largest food retailer in Italy, includes GM-free-labeled chicken and turkey in 2000 and GM-free cattle, pork, and fish in 2001 in its retail brand assortment (Mazzini 2009)
2003	The first egg producer in Austria (Toni's Freilandeier) offered conventional GM-free labeled eggs (Faißner 2005)
2003	The first European dairy from Austria (Tirol Milch) offers GM-free labeled whole and low-fat milk (Tirolmilch Online 2012)
2003	Co-op, a British company that owns farms and supermarkets, announces they will ban GMOs throughout the entire food supply chain, which includes GM-fed animal products (BBC News 2003)
2004	The largest Swiss milk processor, Emmi, starts to use entirely GMO-free milk
2004	Greenpeace pressures the Austrian dairy NÖM to stop using GM feed derived milk. The dairy answers 1 day later with the promise to abandon milk from cows fed with GM feed and the promise not to charge an extra premium to consumers (Greenpeace 2006)
2004	France legally defines GM-free labeling.
2004–2007	COOP Italia adds GM-free eggs (2004), milk, some cheese products, and salami to its GM-free assortment (Mazzini 2009)
2005	Brazil, the largest (GM and non-GM) soy supplier to the European Union, legalizes GM soybean production
2005	The first German dairy (Upländer Bauernmolkerei) starts to offer GMO-free milk, following the model of the Austrian dairy Tirol Milch. The dairy emphasizes the difficulties in fulfilling all requirements under the strict regulations during that time, which entailed high costs and contained many uncertainties about legal requirements (Gen-ethisches-Netzwerk 2006)
2008	German Genetic engineering Act of 1990 is revised. GM-free labeling is no longer based on the regulation for novel food products (NLV) of 1998 (Federal Ministry of Germany 1998). The new regulation is less strict and less uncertain; it allows firms to use some GMOs in feed (a certain time period and certain threshold), GM additives, vaccines, and medicines
2008	The first large German dairy (Landliebe) produces GM-free labeled products with about 1000 GM-free suppliers after being pressured by NGOs. Another dairy (Weihenstephan) did not give up resistance to the NGO pressure (Greenpeace 2008)
2009	The German Federal Ministry for Food, Agriculture and Consumer Protection (BMELV) introduces a uniform national GM-free label (BMELV 2012)
2010	The German agricultural ministry founds the association "VLOG" which issues the license for the public, uniform GM-free label (BMELV 2012)
2010	The largest French retailer chain Carrefour Group adopts a GM-free label (Lebensmittelzeitung 2010)

(continued)

Table 1 (continued)

2012	France adopts new legislation on GM-free production with different GM-thresholds for GM-free labels (0.1 or 0.9 % GMOs in animal feed) (Répubique Francaise 2012)
2012	Genetic ID (Europe) AG becomes a member of the German VLOG to uniformly control and certify firms of the GM-free supply chain
2012	The two largest German retailers, EDEKA and REWE, and a smaller one called TEGUT, announce they will adopt a GM-free label for some of their retail brand products: EDEKA and TEGUT for dairy products and eggs and REWE for dairy products (VLOG 2012)
2012/2013	The major retailers in the UK abandon their policies that poultry and egg suppliers use only non-GM feed. ASDA and Morrisons in 2012, Tesco, Cooperative, Marks & Spencer and Sainsbury's in April 2013
2013	Agricultural ministers of nine European countries/regions sign the Danube Soya declaration to support a new GM-free domestic protein policy for agriculture (Szocs 2013)
2013	Representatives of industries and food retailing from five European countries release the "Brussels Soy Declaration" to support a non-GM soybean production system (ProTerra Foundation 2013)
2014	The central association for poultry production in Germany decides to abandon GM-free policy after 14 years due to bottlenecks in non-GM feed supply and higher GM-free production costs (ZDG 2014)
2015	The German retailer REWE and discounter PENNY offer GM-free poultry. German discounter ALDI Süd start GM-free labeling and LIDL follows labeling in 2016

The Production Side: Example of the German GM-Free Milk Market

Figure 1 shows that in 2011, more than twice as much GM-free milk than organic milk was produced in Germany. Of the 91,550 German dairy farms 6.6 % produce GM-free milk that makes up 5.2 % of all milk production, and 3.4 % of the dairy farms produce organic milk that makes up 2.0 % of all milk production.

Since 2011, the share of GM-free milk has increased. In the German state Bavaria, a survey shows that about 20.5 % of the milk is GM-free (Hein et al. 2014). Most dairies are small self-marketing farm shops with fewer than 10 suppliers (farmers). Many dairies have between 10 and 100 suppliers. However, more dairies are expected to switch to GM-free production; several dairies stated in a recent survey that the retailer they supply their milk to requires them to produce GM-free, or has announced that it will do so soon (Punt et al. 2016). Liability issues and reputation effects might be more important drivers to switch to GM-free production than short term benefits such as higher profits (Punt et al. 2016). The importance of long-term effects has implications for the coexistence of GM and GM-free products. The probability of adventitious presence of GMOs within the non-GM supply chain increases not only the costs of coexistence, but also the probability of mislabeling.

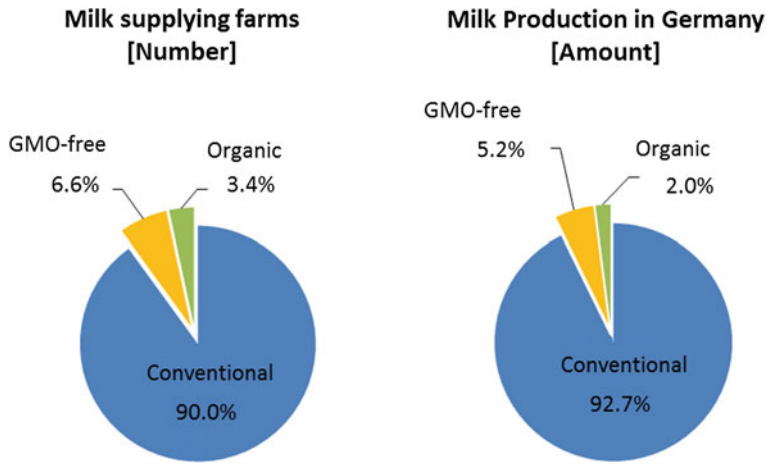

Fig. 1 Percentage distribution of milk supplying farms and amount of milk production in Germany in 2011 (Venus and Wesseler 2012)

Lessons Learned

1. The concept of having several labeling schemes (i.e., positive mandatory and negative voluntary) in place may create misperception or confusion of consumers.
2. The adoption of GM-free labels is often a result of anti-GMO activism—a similarity to the quasi-ban of GM-labeled products.
3. GM-free production without labeling may reduce vulnerability to anti-GMO activism as well as liability risks while at the same time leaving the option for implementing a label in case of increasing GM-free demand.
4. Some retailers demand GM-free production by their suppliers.
5. Long-term effects such as liability issues and reputation effects have to be considered in the evaluation of coexistence of GM and non-GM markets.

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Welfare and Co-existence

David Zilberman and Justus Wesseler

The backlash against the introduction of genetically modified (GM) crops and the concern about contamination of non-GM crops by genetic material originating from GM crops has resulted in a complex and costly legal and physical arrangement for coexistence of GM and non-GM agricultural product systems. It has also led to a new broad body of research on various aspects of co-existence. This chapter aims to understand some of the economic forces that lead to the need for co-existence, and to develop welfare economics-based mechanisms to solve it.

The desire for co-existence is an indicator of a divide between the different groups of individuals that are behind these systems. In the first section of this chapter, we will try to identify the areas of consensus among all the parties that are concerned about co-existence and then identify the sources of disagreement. In the next section, we will summarize what we know about the benefits and the challenges of both GMO and organic systems. That will lead us to a discussion of some criteria for efficient regulation, both in terms of labeling as well as purity standards. Finally, we will discuss future challenges and issues.

D. Zilberman (✉)
University of California-Berkeley, Berkeley, CA, USA
e-mail: zilber11@berkeley.edu

J. Wesseler
Department of Agriculture and Food,
Technical University - Munich, Munich, Germany
e-mail: justus.wesseler@wzw.tum.de

J. Wesseler
Wageningen University, Wageningen, The Netherlands

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Common Ground and Disagreements Surrounding the Co-existence Debate

The participants in the debate about food agree that our food and natural resources are facing several challenges. First, to increase food production by 30–50 % by 2040 to meet population growth, as well as growth of food demand associated with increasing income. Second, to address the challenges of climate change. And third, to sustain or even reduce the resource footprint of agriculture. There is also an agreement of the desirability of reducing food waste, pollution, poverty, hunger, and the gap between the rich and poor. There is also consensus about the desirability of increasing opportunity for rural development and use of more renewable resources.

At the same time, there are several sources of disagreement:

1. Agricultural technology. For example, since the publication of *Silent Spring* in 1962, there has been a strong desire to eliminate pesticides.
2. Agricultural biotechnology. Another source of disagreement is the utilization of technologies originating from molecular biology methods to manipulate crops.
3. The structure of agriculture. This includes the role of agribusiness; the size, distribution, and relative merits of production of small and large farms; and the distribution of market power throughout the agricultural and food system.
4. The merit of free trade in agricultural goods.
5. The role of the government on agriculture.

Rausser et al. (2015) suggested that much of the debate on the future of agriculture is between two paradigms: the industrialized food and agriculture paradigm versus the naturalization paradigm. Generally, the people who tend to oppose GMOs are also for small farms, limiting trade, and support of organic agriculture. There is a perception that GMOs are associated with industrial and corporate agriculture (Winston and Winston 2009) but, as we will argue later, GM technologies can be and have been utilized by small producers; therefore, some of the conflict associated with the notion of co-existence can be resolved.

The basic argument that we would like to advance is that solving the problems and concerns mentioned earlier requires an "all of the above" strategy, and molecular biology and chemical tools are essential and complementary to ecological knowledge in the quest to produce efficient and environmentally sustainable agriculture. There is a place for different forms of agriculture, but they can operate in a complementary and harmonious manner.

Addressing the Challenges Facing Agriculture

In order for the agriculture industry to meet its future challenges, producers must improve performance and efficiency in several areas. One is higher yield, both in terms of per area as well as per unit of natural resource used. There is also a need to

increase input efficiency, in particular the conservation of water and chemicals. Finally, reducing agricultural pollution will be necessary in the future. As we will show later, agricultural biotechnology can contribute to meeting these objectives. Furthermore, the literature on sustainable development (Zilberman 2014) suggests that the ultimate source of increased input use efficiency and reduced waste is replacement of physical inputs with certain elements of human and social capital, including increased reliance on advanced knowledge of biology, ecology, and agriculture as well as advanced social science that results in an improved organizational structure from the perspectives of efficiency and distribution.

Climate Change

To address the challenges of climate change, we need to identify its main implications. First, there is a concern of increased weather instability, as measured by increased likelihood of extreme weather events like droughts and floods. Second, there is a concern about migrating weather, through which some areas, such as Mexico and Spain, will become too hot to farm, while other areas, like Canada and Scandinavia, will become more hospitable for agriculture practices. Similarly, some regions with already hot and dry climate conditions, such as in Africa and India, will lose much productive capacity while other currently wet and cooler regions, such as Siberia and Iceland, will gain. The migration of warmer climate from the equator towards the poles is compounded with the problem of migrating pests, which can generate major challenges, as plants are unable to migrate at the same speed (Porter et al. 1991). The third problem is the increasing rate of snow pack melting, which will result in an increase in variability and severity of floods and a decline in the availability of water storage for the dry season. Finally, there is a problem of rising sea levels, which may lead to the loss of high value agricultural land as well as damage to coastal infrastructure.

These changes may result in several responses (Zilberman et al. 2012). Migration of weather may lead to migration of people, unless individuals can adapt to the changes in environmental conditions where they are currently living. The recent events in the Middle East are an indicator of humanity's difficulties in dealing with migration, and there are already some suggestions that some of the turmoil in the Middle East was the result of migration caused by climate change (Kelley et al. 2015). Adaptation that would allow people to stay where they are include innovation of new technologies, adoption of new or existing technologies, increase and changes in patterns of trade, development of insurance schemes that will allow financial resilience during extreme events, as well as building new infrastructure and creating incentives for increased productivity.

In particular, adaptating to climate change will require changes in crop production practices, development of seed varieties and production practices that are more resilient to changes in weather patterns and to pests, as well as improved water conservation and storage measures. These adaptation measures suggest that a much

faster turnaround time in crop breeding systems would expand the range of problems that can be addressed by development of new seed varieties. In some situations, addressing increased instability in water availability by developing varieties that are more resilient to water stress may be more economical and environmentally friendly than investing in new water infrastructure. Similarly, developing new varieties that are resistant to emerging pest pressures may be more cost effective and less environmentally harmful than the development of new pesticides or the increased rate of human migration. Agricultural biotechnology will be especially important in developing new varieties that would enhance farmers' ability to continue production in varying climatic conditions. Constructing new supply chains and trade networks would allow for increased resilience of agricultural systems under changing conditions.

Transitioning to a Renewable Economy

Reliance on non-renewable resources, like petroleum, is not part of long-term sustainable development; rather, development must transition to the use of renewable resources and recycling of already transformed natural resources as key inputs whenever possible to meet industrial and consumer needs. A key element of the emerging bioeconomy (Zilberman et al. 2013a, b; McCormick and Kautto 2013) is the use of agricultural activities to produce, for example, biofuels, fine chemicals like beta carotene, natural food coloring, and cosmetics. This expansion of agricultural outputs requires resources like land and water, and requires establishing new supply chains, policies, and institutions. The introduction of biofuel resulted in concerns about future increases in the price and availability of food (Wright 2014; De Gorter et al. 2015), and about the expansion of the foot print of agriculture (Khanna and Crago 2012). These concerns can be met through increased agricultural productivity that can be achieved, in large part, through the intensive use of GM crops (Zilberman et al. 2013a, b).

Increasing Farm Income

One of the major challenges of agricultural policies is to enhance farm income. As Cochrane (1979) observed, the low elasticity of demand for agricultural products has resulted in significant decline in agricultural incomes once supply is increasing, which in turn leads to low farm-level incomes. This phenomenon has led to the creation of agricultural support programs in developed countries but to increased rural poverty in developing ones. The income and well-being of people with a significant reliance on the agricultural sector improves with production oriented towards goods with higher elasticity of demand and income (Gardner 1992). That may occur through a transition from agricultural commodities to differentiated

products that in turn can increase and stabilize agricultural incomes. This process is embodied in the vision of the bioeconomy (McCormick and Kautto 2013) that emphasizes value-added activities, which may include ecotourism, exotic fruits and vegetables, improving product quality, and enhancing product characteristics. Gil et al. (2000) found that there is a significant segment of high income consumers who are willing to pay significantly more for organic products. Thus a diversified food system including both organic and non-organic agricultural product system makes economic sense from the perspective of rural income enhancement and of satisfying consumer demand. This is consistent with Levenstein's (1988) historical analysis of food consumption, especially in the United States. Food systems have been bifurcated, wherein a minority of consumers were buying luxury and specialized food items, and the majority were buying affordable food commodities. This phenomenon suggests that there is a strong case for co-existence of organic and non-GMO products that target special groups alongside affordable products that may need to be produced using GM traits.

U.S. President Obama's "all of the above" approach to energy can apply to agricultural production as well.[1] GMO, organic, and agro-ecological perspectives on farming can and should mix to produce an integrated agricultural and food system that meets major social concerns. However, GMO crop cultivation has been practically banned in European countries and many African countries. The next section analyzes the state of knowledge about GMOs and some of the implications of their restricted usage.

About GMOs and Their Impacts

Most food products consumed today have been modified in one way or another. In the past, humans improved plant quality by trial and error, selective breeding, and manipulation of seeds through means such as irradiation aimed to induce beneficial mutations. The term GMO, as most commonly used, refers to crops that were produced by transgenic breeding and other methods that take advantage of modern knowledge in molecular biology. This practice allows the developer of the new variety to understand the modification of the organism, in this case a seed, and control it at the molecular level. As knowledge expands, new techniques for crop breeding emerge [such as CRISPR, a new gene editing method (Sternberg et al. 2014)] and thus pose new challenges to the regulatory process because the outcomes of applying the technology are less easy to identify. But increased understanding of these methods through further investigation may make them more reliable.

[1] https://www.whitehouse.gov/sites/default/files/docs/aota_energy_strategy_as_a_path_to_sustainable_economic_growth.pdf.

Further, the term "GMO" is a political construct, namely an idea that is constructed through the political process (Herring 2008). The EU definition of GMO in its biosafety directive[2] as "*an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*". This is a broad definition, which may apply to various approaches that have different degrees of complexity and accuracy. In the current debate the term GMO applies most often to transgenic approaches, and the legal system may need to determine to what extent it will apply to other approaches of modification. A key question is whether these transgenic techniques could result in dangerous outcomes. According to Paarlberg (2013) most leading regulatory agencies and national academies of science have found that GMO traits approved thus far pose no new risks to human health and the environment. Furthermore, the leading organismal biologist E.O Wilson stated "*I'll probably get it in the neck from my conservationist colleagues, but we've got to go all out on genetically modified crops. There doesn't seem to be any other way of creating the next green revolution without GMOs"*.[3] Thus, it is quite apparent that current science does not provide a basis for not pursuing GMOs.

At the same time, even with the limited use of GMOs in agricultural production, researchers have shown significant improvement in certain human welfare indicators. Klümper and Qaim (2014), in a meta-analysis of empirical studies estimating the impacts of GMOs, found that on average, adoption of GMOs has reduced chemical pesticide use by 37 %, increased crop yields by 22 %, and increased farmer profits by 68 %. Barrows et al. (2014) used aggregate data and estimated that GMOs increased the supply of corn by 5–12 %, cotton by 5–20 % and soybeans by 2–40 %, while also reducing their prices by 4–16 % (corn), 16–28 % (cotton) and 2–49 % (soybeans). A reduction of 10 % in the price of corn or 25 % in the price of soybeans has significant impacts especially for the low- and middle-classes and the poor in developing countries because it enables individuals in these classes to consume more protein from chicken and pork that are produced with the extra grain supplies.

The claims that GMOs favor large farmers are not supported by evidence on the ground: with close to a 90 % adoption rate of Bt cotton in India and 58 % in Burkina Faso it is clear that this seed technology is adopted by small farmers. The simplicity of the technology and the fact that, unlike pesticides, it does not requires extra capital, makes it actually beneficial for the poor. As the NRC (2010) report suggests the benefits from the adoption of GMOs did not accrue to Monsanto and the other seed companies but rather were distributed among the innovators, retailers, farmers, and consumers. As the adoption of GMOs increases, the share of gains going to the consumers is also likely to increase (Zilberman et al. 2015).

[2]See article 2, directive 2001/18 http://www.biosafety.be/GB/Dir.Eur.GB/Del.Rel./2001_18/2001_18_TC.htmlartciale.

[3]http://www.theguardian.com/science/2001/feb/17/books.guardianreview57.

Research also shows some of the beneficial environmental and health implications. The 2010 NRC report suggests that adoption of GMOs has improved water quality, reduced damage from pesticides, and reduced greenhouse gas (GHG) emissions. It cites evidence of saved lives through reduced exposure to pesticides; avoidance of exposure to chemicals was a major cause for adoption of GMOs in the United States. According to Barrows et al. (2014) the adoption of GMOs in 2010 reduced GHG annually by an amount equivalent to 16 % of the annual U.S. GHG emissions emitted by automobiles. Further, adoption of GMO varieties does not necessarily lead to declines in crop biodiversity. Krishna et al. (2016) found that with the 90 % adoption of Bt cotton, crop biodiversity is now at the same level that it was before the introduction of transgenic seed varieties. Furthermore GMOs may assist with the reintroduction of certain varieties that were eliminated because of vulnerability to pest that may now be controlled for by GM varieties.

Thus, despite consumers' perceptions (Grunert 2005) the introduction of GMOs can be advantageous from the perspective of productivity as well as environmental and human health indicators. It is quite important to assess to what extent the perception that organic food is superior to other foods in terms of sustainability (Grunert 2005; Aschemann-Witzel and Zielke 2015) is supported by facts on the ground.

Demystifying Organic Farming

Organic farming, like GMOs, is a political construct. The USDA has established the criteria for organic food after a major public debate. The suggestion by Ronald Adamchak (2007) of marrying GMO farming with organic farming is an appropriate approach. It will improve the efficiency of organic products and will defend an effective regime that does not rely on chemical pesticides, which are reviled by many people. It seems that the appeal of organic is that it is a "natural system" which do not use synthetic inputs. But it relies on many biological pesticides like Bt and uses metals such as zinc and copper to carry out various activities. Furthermore, the construct of "natural" can be misleading—what is natural about growing organic vegetables in a greenhouse near a Whole Earth center? The definitions used to label a product "organic" are open to debate—one that will be ongoing for many years and decades to come.

In a recent study, Smith-Spangler et al. (2012) found that "[t]he published literature lacks strong evidence that organic foods are significantly more nutritious than conventional foods. Consumption of organic foods may reduce exposure to pesticide residues and antibiotic resistant bacteria." Seufert et al. (2012) conducted a meta-analysis and found that yield differences between organic and conventional farming vary across locations and by crop. The yield of organic farming may be 5–34 % lower compared to convention methods. Their analysis does include situations where the use of organic is not feasible because of pest problems that can be

solved by conventional agriculture, so the productivity losses from banning pesticides and other chemicals that are part of conventional farming may be much higher. Organic farming tends to be concentrated in regions where the conditions for its success are especially appealing, like the central valley of California which is an irrigated desert with dry conditions that are not amenable to large pest populations. While organic farming can prosper in that region with its highly educated farmers, it is less likely to succeed in regions with humid weather. While organic is perceived as especially appropriate to small farmers, the higher risk and professionalism it may require may lead to a structure with more and larger farms with better capacity to absorb risks than conventional farming. A study by Serra et al. (2008) finds that organic wheat farms are in fact larger than conventional farms to allow better capacity to address risk considerations. Organic farming may demand higher level of human capital and education. On the other hand, studies find organic food earns much higher prices per unit. Aschemann-Witzel and Zielke (2015) find that the willingness to pay premium for organics varies from 5 to 100 % and on average it is 30 %. Thus targeting the markets where the supply loss of organics is low and willingness to pay is high (like Northern California) is a viable strategy to enhance earning. But organic farming alone cannot provide a large scale solution for agriculture; the social and environmental costs associated with requiring its introduction and banning synthetic chemicals and GMOs are enormous.[4]

The bottom line is that organic, GMO and conventional agriculture should co-exist to attain social targets of increased farmer income and improved social welfare and control of environmental problems like climate change.

The Case for Efficient Regulation

One obstacle in meeting the challenges facing agriculture and natural resources is the concern over regulation. Adaptation to climate change requires a high degree of innovation. Innovations in turn introduce new procedures that are objectively risky due to their novelty and are a source of concern.

Efficient regulatory systems are essential both for achieving desirable outcomes as well as to overcome political objections stemming from concerns. Welfare economics suggests that efficient regulation enables maximizing the expected discounted net benefits from the introduction of a new technology, taking into account the cost of implementation of the regulation (Arrow et al. 1996).

The challenge in the regulatory process is the identification of random factors that affect the outcomes of technology. These factors are associated with the performance of the technology, both by itself and in interactions with other systems,

[4]This is outside the scope of this paper. Zilberman et al. (1991) documented the large social welfare loss associated with a ban of pesticides in the US and California.

and its implementation. Government control of the regulatory process is important because innovators and implementers may not take into account some costs to consumers, and thus self-regulation may be suboptimal (Wesseler and Smart 2014). There is also the issue of public perception—greater trust in government often results in increased support and acceptance of regulatory regimes and the technology itself (Kikulwe et al. 2014). To accommodate concerns about safety, especially when it is difficult to quantify the cost of social and environmental side effects of the adoption of a new technology, Lichtenberg and Zilberman (1986) suggest the use of the cost effectiveness approach in establishing regulations. Namely, this approach seeks to establish regulations that maximize net expected discounted social benefits subject to stochastic upper bound constraints of environmental and health risks (e.g. number of accidents). The probability that these risk constraints are exceeded must be below a pre-defined reliability factor. Both the upper bound on risk associated with a new technology and the reliability factor are mechanisms to express public concern about the safety of a technology. But a lower acceptable risk threshold and a higher mandated degree of reliability tend to increase the cost of adoption of technology. This has been further advanced by taking irreversible effects into account (Demont et al. 2004; Wesseler et al. 2007). Using this approach, one can develop benefit-risk tradeoffs that recognize that stricter risk targets and reliability factors are costly in terms of benefits lost. Thus policymakers need to balance safety considerations with risk. Clearly, excessively strict regulations may prevent the implementation of worthy innovations and the benefits thereof (Wesseler and Zilberman 2014). A strong interpretation of the "Precautionary Principle" (van den Belt 2003) is one example of an approach in which the desire to prevent all foreseeable risks stops the adoption of new technologies. van den Belt (2003) has shown this kind of reasoning has serious flaws. Furthermore, the applications in Lichtenberg (2002), Demont et al. (2004), and Wesseler et al. (2007) also emphasize heterogeneity, in particular that new technologies may have multiple applications with different benefit-risk considerations. Frequently, optimum regulation may eliminate the applications of a technology (e.g. a chemical or GM crop) that have a benefit-risk ratio below a threshold level while allowing applications with a benefit-risk ratio above the threshold. They suggest that a complete ban of a particular technology, except in extreme cases, is suboptimal.

The works of Arrow and Fisher (1974) as well as Dixit and Pindyck (1994) suggest that for environmental regulation, and especially the approval of new projects, timing matters. If the decisions are perceived to be reversible and the outcome is uncertain, it may be worthwhile to delay the regulatory decision until more information is available. In particular, a delay is justified if the expected gains from additional information are greater than the additional gain of earlier implementation of the technology as well as the extra learning associated with early introduction. This gain must also be greater than the loss of benefits during the period of the delay. For example, if the introduction of a certain trait of GMO, for instance Golden Rice, is delayed to know more of the implications of using the trait,

then the policy maker was rational only if the benefits from the delay are greater than the costs such as loss of eyesight and other factors during the delay (Wesseler and Zilberman 2014).

The Cost of Over-Regulating of GMOs

There have been several studies that suggest that GMOs have been over-regulated (see Just et al. 2006). Over-regulation includes banning the use of GMOs in agriculture in certain countries and requiring additional testing. Sometimes small countries that are in the same region develop their own regulatory system rather than relying on a regional regulatory system that would reduce redundancy. The Cartagena Protocol on Biosafety[5] developed regulations that are quite expensive and required many developing countries to create additional, expensive analytical research capacity (Paarlberg 2009). Graff et al. (2009) suggest that the practical ban and heavy restrictions imposed on GMO use in Europe in 1999 not only drastically slowed the growth of the agricultural biotechnology industry but in fact contributed to a contraction of it. If investors face uncertain and tough regulation of some industry over time, they will reduce their investment. Other studies, including Bradford et al. (2005), have shown that a reluctance to invest in traits and specialty crops may lead to a situation in which many socially valuable traits in relatively small crops (measured by combined producer and consumer benefit) will not be developed by the private sector due to the high cost of regulation that reduces the incentive to develop them. There are many other examples wherein delay and regulation are likely to have substantial effects on measures of welfare (Wesseler 2009).

Wesseler and Zilberman (2014) use the real option approach to assess the cost of delaying the introduction of golden rice in India. Golden rice has a trait that introduces vitamin A into the rice and can prevent blindness among poor farmers in South Asia that rely mostly on rice for their livelihood. Five hundred thousand people are blinded every year; the authorities have slowed the development of golden rice and delayed its approval for more than ten years. The accumulated cost of delay is in millions of eyesight years and in billions of dollars.

Golden rice is not the only lost opportunity. Bennett et al. (2013) identify more than 100 GM traits that are commercially viable but have not been brought into production due to regulations. Regulatory constraints prevented the adoption of new GM traits that can address the maize streak virus, which is endemic to Africa and causes $\sim$30 % or more in crop losses. In addition, they prevented the adoption of corn varieties that combine drought-tolerant and insect-resistant traits for use by smallholder farmers in sub-Saharan Africa. Regulation prevented the adoption of a

[5]See https://bch.cbd.int/protocol.

transgenic regular- and plantain-banana variety that addresses a major disease and nematode problems that lead to a 20–30 % reduction in yield. Tens of millions of people depend on these varieties yet they are still not approved. The real option approach was also used by Zilberman, Kaplan, and Wesseler (forthcoming) to assess the impact of banning the use of GM traits in wheat, rice, and corn. They present several scenarios assuming different levels of elasticities of supply and demand and find that the net present value due to a 30 year delay of GM traits can be between $500 billion to $1200 billion in lost welfare to consumers and producers. Most of the welfare loss is to consumers as the prices of basic foods are higher than they would otherwise be. The main losers from the banning of GM traits are predominately poor and low-income people while much of the objection to GM, and the support to the organizations that oppose GM in agriculture, are among the middle- and upper-classes. It seems that the poor are paying for the anxieties of the rich.

Towards Sound Regulation of GM

As we showed, excessive regulation of GM in agriculture stems from concerns over environmental consequences and political economic considerations (Herring and Paarlberg forthcoming). Attitudes towards biotechnology vary across groups and nations. The strongest support of the technology come from its manufacturers and some farmers' groups. While consumers are suspicious of GM technology, there are differences in attitudes among different groups—and it is likely to change if products that seem more valuable will be introduced. Manufacturers of alternative products (e.g. pesticides) have opposed the use of GM technology but environmental groups have been the strongest source of opposition. However, it seems that environmental groups have resistance to changes and position themselves in a defensive stance[6] while the reality is evolving. As we stated earlier, responsible and effective use of new varieties that can take advantage of the latest in GM technology may be crucial in enhancing adaptation to and mitigation of climate change. It seems that the interests of the environment may support these technologies and they can be paired well with organic farming. Similarly, much of the objection to the introduction of GM varieties is in European countries, including Germany and Austria, which gave up their capacity for developing products based on modern biology. Due to political reasons, they instead emphasized organic farming. While it may serve their interest in the present and may be politically expedient in the short-term, the exporting of restrictive regulation from Europe to Africa has negative global effects.

[6]For example, we see the Environmental Defense Fund and National Resource Defense Council.

Furthermore, the restrictive regulation of biotechnology may become more difficult to maintain in the long-run as technologies are evolving. Now there are early applications of the latest in gene editing. The detection of the use of these technologies is more difficult than the detection of GMO and these technologies are relatively easy to adopt and may have widespread use (Shan et al. 2013). Thus countries that continue to ban biotechnology will find themselves at a relative disadvantage—and if this attitude spreads internationally, it will inflict negative externalities on poorer nations.

Thus changes in the regulatory environment are necessary in order to take advantage of the new tools we have and address global threats like climate change. Our analysis suggests several principles for decision making. First, emphasize science-based regulation because science is a major objective tool, even with all its limitations. Second, aim to avoid bans and other extreme measures and to encourage choice and innovation. Countries and regions may restrict the use of GM in agriculture, but this restriction should not eliminate its use entirely. Since the net benefits of technologies vary across applications, their use should be allowed when the net benefits outweigh the risks. Third, enhance access to information and develop mechanisms to monitor the benefits, costs, and negative effects of new technologies in order to improve them. Active learning will allow for the ongoing refinement of technologies and policies and take advantage of new knowledge as we move forward. Fourth, reduce unnecessary barriers to trade and enable regions to import products for which they do not have relative advantage, while emphasizing their areas of strength. Finally, in assessing new policies, emphasize a global perspective recognizing that what is good for the developed countries in the North is not always good from a global perspective.

This perspective will allow us to deal with some specific policy issues. The first is the use of labels. While "the right to know" has been a major reason asking for mandatory labeling, property rights issues (Rothbard 1982) and the extra cost of labeling that may be passed down to people who oppose it (Huffman and McCluskey 2014) make the case for voluntary labeling.

Zilberman et al. (2014) develop welfare criteria that determines under what conditions each system is desirable, but the political process may not reach this social optimum because votes may not necessarily reflect the opposition to GM and voters' participation in elections is partial. But it is also clear that the design of labels is important, especially those used as a warning system when there is no scientific justification for warnings about GMOs in the same way that warnings about other hazards are merited. Thus, there is a case for "matter-of-fact" labeling[7] whereby the barcode will allow the consumer to access information about the product, including farming techniques, presence of GM traits, and more. This approach can become more practical with the increasing social capability of our society.

[7]See article: http://grist.org/food/heres-how-to-do-gmo-labeling-so-everyone-wins/?utm_source=syndication&utm_medium=rss&utm_campaign=feed.

Secondly, one of the most difficult problems is establishing purity standards for non-GM products. The higher the purity standard, the greater the cost of separating GM from non-GM. Conceptually, if one could know how the demand for non-GM is affected by purity, then one could maximize expected benefit gained from consumption of GM and of non-GM minus the cost and thus create optimal purity standards.[8] Given the difficulty of assessing the cost of purity, governments consider several commonsense standards, assess their costs (purity standards and the enforcement mechanism have implications about land allocation and distance between GM and non-GM facilities (see Beckmann et al. 2010), and establish one standard based on understanding the trade-off between cost and purity. With this standard created, other groups can establish more strict standards, but then must pay for monitoring them. The increase in private sector standards for GM-free food serves as an example (Wesseler 2014). It is quite clear that very strict purity standards and heavy-handed enforcement mechanisms will suppress the evolution of GMOs and will be costly to the direct economy involved and to the global community (Falck-Zepeda et al. 2013). Furthermore, Moschini (2015) developed a rigorous welfare analysis on the economic impact on mandatory isolation standards and buffer zones between GM and non-GM crops. The study shows that imposing the cost of separation on the GM producers exclusively is inefficient if parties do not negotiate, and rather that efficient allocation occurs if the cost of implementing co-existence is shared between GM and non-GM farms.

A third and related issue is that of a minimum separation standard, which establishes the spatial distance required between GM and non-GM crops. This issue is also related to the purity standard of non-GM crops. The land allocation and separation standard can be established through the use of expected benefit-cost analysis taking into account the different values of GM and non-GM crops as well as various advantageous presence considerations. The separation standard can vary by crops and location—for example, areas may have different standards based on average prevailing winds (Angevin et al. 2015). One approach to implement land allocation between transgenic and non-GM crops is through assignment of property rights in the spirit of the Coase Theorem (Beckmann and Wesseler 2007). In reality, many European countries have developed separation standards that prevented the use of GM varieties in many regions. The minimum distance requirements implemented in many EU member states also discriminate against smaller farms and reduce their competitiveness (Schenkelaars and Wesseler 2015) but the economic implications also largely depend on the spatial setting and the flexibility of coexistence policies (Groeneveld et al. 2013).

[8]A conceptual model to address this information gap may rely on hedonic pricing models (Bewley 1969; Hamilton and Zilberman 2006; Lichtenberg and Zilberman 1988).

Conclusion

The development of principles for co-existence between GMO and organic agriculture is a major challenge because coexistence of both sectors is very important for the economic viability of agriculture and for global prosperity. GMOs and the transgenic revolution can increase the supply of food, contribute to the mitigation of and adaptation to climate change, and will significantly benefit the poor. Organic is a differentiated market that can increase the income of farmers. In an ideal world, the two methods of production can be integrated to some extent, which could result in reduced reliance on chemical pesticides and reduced conflict.

In the current situation, when the likelihood of integration is minimal, it is important to develop standards and policies that will improve social welfare and allow these two sectors to flourish. In particular, the regulatory framework in Europe and the US of GMOs in agriculture is burdensome. It slows the introduction of new and exciting GM traits into the supply chain and increases the price of food. Because of different political economic situations, the regulatory approach in Europe is spilling over globally and the net effect is that the poor frequently pay for the anxieties of the rich.

Given that the biotechnology revolution is in its infancy, developing mechanisms to accommodate and utilize it safely, rather than rejecting it, is in the interest of humanity and of individual countries. In particular the EU's policies towards GM and other technologies in agriculture may slow the further introduction of these technologies, but may end up harming Europe in the long-run. But we observe similar developments in other regions, including the US. Improving regulation by relying more strongly on science, principles of efficiency, and considerations of equity should be introduced to take advantage of new knowledge and to help strive towards sustainable development.

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GM Maize in Mexico: The Challenge of Coexistence in a Centre of Origin

Peter W.B. Phillips

Introduction

One of the sub-texts to the debate about coexistence is whether and how modern improved varieties embodying GM traits can coexist with landrace varieties and traditional knowledge, especially in centres of origin and biological diversity. This issue came to a head in 2001 when David Quist and Ignacio Chapela, two University of California Berkeley plant biologists, published in *Nature* that they had found transgenes introgressed in local maize landraces in the mountains of Oaxaca, Mexico (Quist and Chapela 2001). A pressing concern for many was that none of the transgenes found had been approved for deliberate environmental release in Mexico. The resulting flurry of activity engaged local campesinos, a host of environmental NGOs, the main biotechnology companies that had developed the disputed traits, a range of scientists around the world, various state authorities and the federal government in Mexico and, ultimately, a reference to the North American Commission for Environmental Cooperation.

This case highlights the challenges of defining coexistence and of managing effective coexistence of GM and other crops, especially landraces, in developing nations.

The author was a member of the CEC Advisory Panel 2003–2004.

P.W.B. Phillips (✉)
University of Saskatchewan, Saskatoon, Canada
e-mail: peter.phillips@usask.ca

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History

Mexico is regarded as the birthplace of cultivated maize. The leading hypothesis is that maize descended from teosinte, a grassy plant common in the highlands in Mexico (Mangelsdorf and Reeves 1939). Dozens of local landraces of maize have emerged and been cultivated for between 5000 and 8000 years; the genetic base of these landraces has varied widely by location and over time. Wild teosinte populations persist, often as part of the agro-ecosystem where maize is grown, and because they are the same species, gene flow among the two crops is possible.

Maize in Mexico is the most important crop cultivar, with 7.9 million hectares of production in 2001. Most domestic production is white maize varieties for human consumption; the country imports more than 5 million tonnes annually, largely yellow maize for animal feed. The maize areas include modern improved hybrid varieties developed by multinational seed companies, open-pollinated improved varieties developed by national public research institutions and small companies and landraces conserved and cultivated by campesinos. Carpentier and Herrmann (2003) note that although there is evidence that new hybrids of maize introduced into Mexico have contributed genes to local races, the idea of introducing transgenes from unrelated phylogenetic groups into the land races and wild relatives of maize, possibly changing the nature of agriculture and contributing to the loss of biological and cultural diversity, was a matter of deep concern both in Mexico and internationally.

Maize has been the target of aggressive genetic transformation since the beginning of GM crops. By 1988 transgenic maize crops were in confined field trials in the US and a range of other countries. The first commercial GM maize varieties were approved for unconfined production in the US and Canada in 1995 and entered the export market in 1996. Since then 70 transgenic traits have been proposed (21 between 1995 and 2001), mostly involving insect resistance and herbicide tolerance (CERA 2016). While some of these candidate traits were introduced into confined field trials in Mexico, none of the varieties had been approved for unconfined cultivation by 2001, at least partly because of concerns about the effect of these crops on landraces and the indigenous agro-ecological system operating in many regions of the country.

Controversy erupted in 2001 when two plant biologists reported in *Nature* that in 2000 they had detected transgenes in local maize landrace varieties in the mountains of Oaxaca, Mexico. They reported that they had used PCR-based methods and a dot-blot DNA hybridization technique on a pooled-kernel sample of Mexican landrace maize from the Oaxaca region and that their tests detected the presence of the 35S cauliflower mosaic virus promoter sequence, the promoter used in all GM maize varieties commercially then available in the US. They also used PCR-based methods to test for the nopaline synthase (NOS) terminator sequence, also used in the GM maize varieties in the commercial trade.

Once the results were released in Nature, a host of critics emerged to challenge or debate the findings. In the first instance, a broad section of the scientific

community commented on and wrote to Nature and other journals disputing the technical results. They argued that inverse PCR analysis, as undertaken by Quist and Chapela, was especially prone to artifacts and false positives. *Nature* received numerous communications about the article and its findings and the editors corresponded with the authors in search of further evidence, but in the end the editor took the unusual step of publicly reporting that "the evidence available is not sufficient to justify the publication of the original paper" (Nature 2002).

Many in the scientific and industrial community hoped that the declaration of the Nature editor would be the end of the matter. But the underlying issue remained unanswered. There were early warnings of a high probability of transgenic maize entering Mexico as early as 1995 (Turrent and Serratos 2004). Moreover, the environmental group Greenpeace reported in March 1999 that they had found evidence of transgenic maize in commodity shipments imported from the US at the port of Veracruz (Rowell 2003). Quist and Chapela simply added to an already simmering debate. In response, the government commissioned a larger study involving the Center for Research and Advanced Studies of the National Polytechnic Institute (CINVESTAV-IPN), a Mexican non-governmental scientific research and the Institute of Ecology at the National Autonomous University of Mexico (UNAM). Tests conducted in 2001 in 188 communes in the Oaxaca region revealed that 7.6 % of the maize plants examined contained genes from GM maize; in subsequent investigations in 2002 the reported incidence fell to 0.11 %. A number of other field studies were undertaken in an effort to confirm or refute the results, but none was successfully peer reviewed until 2005; that study found no evidence of any transgenes in the crop or in government storage facilities in either the 2003 or 2004 crop years (Ortiz-Garcia et al. 2005). Over time a range of scholars and practitioners came to a somewhat unsatisfactory scientific judgment that introgression was both likely and inevitable given the context for the traditional agro-economy in Mexico but that the biological impact on both farmer production and biodiversity would be minimal or undetectable in the long-term:

> [N]ovel alleles introduced by gene flow may or may not persist in recipient populations depending on: (1) whether gene flow is a one time or recurrent event, (2) the rate of gene flow, and (3) whether the novel allele is locally detrimental, beneficial, or neutral and depending on the size of the recipient population. These principles apply to both conventional genes and transgenes… Transgenes that are beneficial or selectively neutral have the potential to persist indefinitely in llandraces of maize… There is no reason to expect that a transgene would have any greater or lesser effect on the genetic diversity of landraces or teosinte than other genes from similarly used modern cultivars. The scientific definition of genetic diversity is the sum of all of the variants of each gene in the gene pool of a given population, variety, or species. The maize gene pool represents tens of thousands of genes, many of which vary within and among populations. Transgenes are unlikely to displace more than a tiny fraction of the native gene pool, if any, because maize is an outcrossing plant with very high rates of genetic recombination. Instead, transgenes would be added to the dynamic mix of genes that are already present in landraces, including conventional genes from modern cultivars. Thus, the introgression of a few individual transgenes is unlikely to have any major biological effect on genetic diversity in maize landraces. (CEC 2004: 17)

Meanwhile, the public controversy continued to build both in Mexico and throughout the global NGO community. In April 2002, the Commission for Environmental Cooperation (CEC), a creation of the NAFTA side deals in 1994, was petitioned by 21 indigenous communities of Oaxaca and three Mexican environmental groups, Greenpeace México, the Mexican Center for Environmental Law (Centro Mexicano de Derecho Ambiental) and the Union of Mexican Environmental Groups, eventually supported by more than 90 letters from organizations and institutions throughout the three NAFTA countries, to undertake an investigation under Chapter 13 of the Agreement. This issue was considered of great potential environmental importance, given that Mexico is a center of origin and diversity for maize and that maize is so intrinsically linked to Mexican culture, especially that of Mexican indigenous groups. An Advisory Group on Maize and Biodiversity, involving 16 participants from industry, academia and NGOs in Canada, the US, Mexico and the UK, was commissioned to use objective science and the participation of stakeholders to transparently develop an advisory report. The Advisory Group, in collaboration with the CEC Secretariat, commissioned a set of background chapters from a range of academics and practitioners about specific topics related to maize. The papers were assessed by the group, peer reviewed and published in a compendium to the final report. The Secretariat and the Advisory Group also convened an open public symposium in Oaxaca where summaries of the chapters were presented and discussed. The Advisory Group then met and formulated a set of key findings and recommendations based on the background chapters and the peer reviews, the professional expertise of the members themselves, comments received at the public symposium and, subsequently, the comments of the Parties to the North American Agreement on Environmental Cooperation (NAAEC).

The Advisory Group accepted that "maize has significant cultural, symbolic, and spiritual values for most Mexicans… Many campesinos and the community organizers who are most vocal and concerned with transgenic gene flow perceive GM maize as a direct threat to political autonomy, cultural identity, personal safety and biodiversity" (CEC 2004: 23). High levels of poverty and dependence upon agriculture for income and food security, a significant indigenous population and recent migration and dislocation distinguishes rural Mexico. The issue of transgenic maize has become entwined with historical issues and grievances affecting rural Mexicans that are not directly associated with either improved maize or traditional landraces: indigenous peoples have a history of perceived inequity and injustice at the hands of Mexicans of Spanish origin, Americans and powerful elites. In that context, the CEC Advisory Group sought to understand how the genes may have introgressed into Mexico and what policies and strategies might be used to eliminate the introgressed traits from landraces and to reduce the potential for further introgression.

The Advisory Group reviewed the technical evidence to identify possible pathways of introgression and strategies to handle further difficulties. In the first instance, they looked at maize itself, which is an open-pollinated crop. For centuries, peasants have taken advantage of this, hybridizing cultivated maize and weedy or wild relatives to develop new races of maize that fit their needs,

preferences and local environments. Ethnic groups practicing traditional agriculture have maintained these selection processes with domesticated maize, which is judged by many as an important form of in situ conservation of germplasm. An estimated 84 ethnic groups in Mexico contributed to the domestication of maize and have been long-term stewards of the 59 identified Mexican maize landraces. In pre-Columbian times these ethnic groups occupied the whole country, but they retreated to the sierras during the European conquest. Geographic isolation preserved ecological diversity and generated a range of productive ecosystems. Experimental planting and breeding of maize was identified as a millennia-long tradition at the core of the generation of the many native landraces of maize. Mexican landraces are neither genetically static nor genetically homogenous: they are constantly being changed by those who use them. As part of this process, genes from improved/modern varieties are sometimes deliberately or inadvertently introduced into the landraces.

The CEC Advisory Group learned that a de facto moratorium on the field release of transgenic maize in Mexico existed after 1998, with a set of strict biosafety regulations embodied in an official standard set by the Ministry of Agriculture (NOM-056-FITO-1995) limiting cultivation of transgenic maize to confined research plots. Almost all reported instances of transgenic maize grown in Mexico before the de facto moratorium (1998) covered less than one hectare. One challenge identified is that the official standard did not make any specific provisions for the grain trade. An estimated 5 million metric tons of unprocessed maize grain was imported annually from the US between 1997 and 2003; given the extensive blending and pooling common in the US trade, an estimated 30 % admixture of GM maize would have been imported over that period. The feed industry and food processors used the bulk of imported maize but an estimated 600,000 tonnes of maize grain was distributed as food aid to poorly developed rural areas. About 70 % of maize grain samples collected from some of the 22,000 stores the Mexican government owns and operates throughout Mexico under the brand Diconsa in 2003 was identified as imported grain (Turrent and Serratos 2004). The CEC Advisory Group heard evidence that campesinos regularly test different sources of improved materials drawn from government food aid channels or from the commercial seed trade; moreover, sometimes maize from government distribution stores is the only seed available after a bad harvest. The evidence strongly suggested that campesinos may have inadvertently planted transgenic maize and crossed those traits into land races, at least partly because there was no visible way of differentiating transgenic from non-transgenic seed.

The advisory group went on to recommend a range of scientific, regulatory, industrial and social responses to the presence of transgenes in landraces in Mexico. In the first instance, the Advisory Group offered a range of recommendations to address the introgression of unapproved traits in the Mexican maize industry. They recommended that, because the persistence and spread of new genes depends so much on the gene flow rate, the Mexican government should strengthen the moratorium on commercial planting of transgenic maize by minimizing the import of living modified maize from countries that commercially grow and comingle

transgenic maize with conventional varieties. A range of complementary measures were proposed. Mexico could, for example, require that unprocessed maize imported from the United States (or any other country that comingles and exports GM and conventional maize seed to Mexico) be directed to mills for immediate processing; a system of 'end-use certificates' could be used to ensure all imported GM maize is handled appropriately. Additionally, the Mexican government was advised to directly notify local campesinos that maize grain distributed through Diconsa is likely to contain transgenic materials and should not be planted or comingled with traditional seeds. This effort should include both clear labeling of Diconsa grain bags, containers, and grain silos and programs to educate farmers to avoid planting seeds that may contain GM maize (including seed brought from the United States or other countries where transgenic maize is grown).

Over the longer term, there remains a question of how to preserve the separation of both landraces and transgenic crops if and when GM varieties are approved for unconfined release and cultivation in Mexico. While that was not in the immediate future when the Advisory Group produced its report in 2004 a number of the measures proposed would go a long way to sustaining mutual coexistence between landrace and commercial maize. In the first instance, the CEC Advisory Group recommended increased public support for in situ conservation of landrace diversity by providing support for community seed banks, farmer training and extension services, registration and codification of local and traditional knowledge, and greater scientific research into landrace character and identity. This might involve subsidies for campesinos willing to sustain traditional farming operations and to pursue breeding practices that preserve landraces in a way that prevents or minimizes the introgression of genes from other sources and localities. A quality-assured landrace seed program might be needed. This could involve ex situ seed banks, provision of a service for campesino farmers to submit seed or other materials they intend to use for breeding to labs for investigation of the presence of any GM traits, regional registration of campesino breeders and development of a more formal set of regional and sectoral organizations. If effective, this would both limit introgression of new transgenes and detect and facilitate removal of any transgenes currently in campesino seeds.

Finally, the CEC Advisory Group recommended that the governments of Canada, Mexico and US use the North American Biotechnology Initiative to harmonize the assessment and management of biosafety risks through greater coordination of research and regulatory policies. This was perhaps the most controversial recommendation from the perspective of the biotechnology industry and the governments of Canada and the US. The CEC Advisory group recommended that in addition to sharing more information and knowledge on the attributes and risks of any new crop cultivated in any of the three countries *before* such a crop is commercialized, this could also involve proponents making coordinated applications for regulatory review in all three markets and possibly even coordinating approvals in the three markets. The challenge is that in many cases it may not be commercially appropriate to release a new product simultaneously in all markets.

In the end this report had little practical impact on coexistence policy at tshe North American level. The draft final report was submitted to the NAAEC member states and substantive formal responses from the three governments were received and incorporated into the final report. The release of the report was significantly delayed; it was finally unceremoniously released on the Friday after the US Presidential Election in 2004 without further comment or public discussion by the member countries.

In 2005, the Mexican Biosafety Law (LBOGM 2005) was enacted, effectively removing the moratorium and formalizing a pathway for the approval of large-scale commercial cultivation of GM crops in Mexico. Between 2009 and 2012, the Mexican biosafety commission, CIBIOGEM, approved 177 small GM maize field trials to four transnational companies: Dow AgroSciences, DuPont/Pioneer Hi-Bred, Monsanto and Syngenta. Five applications for commercial-scale cultivation of GM maize were pending at the end of 2012 (Sewell 2012). Monsanto, Pioneer Hi-Bred (owned by DuPont) and Dow Agrosciences de Mexico have applications that, if approved, could lead to 2.5 Mha of GM maize in the states of Sinaloa and Tamaulipas. A government decision was expected in time for the 2013 crop but this was delayed until after the Presidential election and a change of government in spring 2013; as of early 2016 no commercial releases have been approved.

Conclusions

This case offers a few critical lessons about coexistence of modern improved varieties embodying GM traits with landraces and traditional agriculture, especially in countries of origin or biodiversity.

The first lesson is that coexistence in these contexts has little to do with market risk. Rather, it is about a fundamentally different world view. While the CEC Advisory Group noted that campesinos did not perceive any value from transgenics, and advised that the NAAEC member states should direct some effort to remedying that situation, in the end the Advisory Group recommendations tacitly accept that the campesinos and their champions in the environmental movement are not concerned about utility but about different world views. Greater awareness will not narrow the demands for effective coexistence of the two forms of farming.

Second, the CEC Chapter 13 Panel investigation into the Mexican maize case highlighted that some of the knowledge needed to design and manage a coexistence system is neither in the scientific domain nor readily accessible to industry proponents or governments. The Panel concluded that the campesinos (i.e. small, indigenous landholders and farmers) had significant knowledge of both the in situ properties of landraces and the agronomic and social practices of farming, which were significant for scientists undertaking field studies and for regulators assessing risks of open cultivation. This knowledge does not conform to the norms of scientific and regulatory discourse, but remains real and potentially important in many contexts.

Third, indigenous peoples are unlikely to be able to manage coexistence programs without help. The CEC Advisory Group offered a number of practical and relatively inexpensive actions that would go a long way to defining, organizing, managing and enforcing a separate and parallel existence of GM and landrace varieties in Mexico. Nevertheless, given that none of the recommendations was implemented fully, there is no practical experience to show that the system would work as proposed.

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Conclusions and Synthesis

Nicholas Kalaitzandonakes, Peter W.B. Phillips and Stuart J. Smyth

The works in this volume affirm that coexistence is a complex, multifaceted issue. The need for coexistence in agricultural markets affects the decisions and behavior of individual farmers and multinational grain trading firms alike. It is relevant to local grain elevators and international agriculture markets. It is discussed between neighbors and at meetings of world political leaders. As innovation continues in world food markets, coexistence will continue to be an important consideration for all market participants.

As contentious as coexistence may be in the present day, it is far from a new issue. From the perspective of agricultural and food markets, coexistence is about delivering a specific product of a specific quality to a consumer that values it. This is true regardless of whether the product in question is a specific grade of wheat delivered to a specialty mill producing pasta flour, organic produce delivered to a high-end grocery store, or ordinary number two yellow maize delivered to the local elevator. In all cases the customer values the particular quality traits embodied in the product, and comingling with other varieties dilutes those traits and reduces the value of the product. To the extent that the comingling is unintentional it may represent an externality and a lapse in coexistence. Inasmuch as effective segregation must be maintained throughout the supply chain in order to ensure coexistence, coordination among the various supply chain elements is necessary. Accurate information about relevant attributes must accompany each lot of produce as it moves through the supply chain. The key question addressed by this volume, then,

N. Kalaitzandonakes (✉)
University of Missouri, Columbia, MO, USA
e-mail: KalaitzandonakesN@missouri.edu

P.W.B. Phillips · S.J. Smyth
University of Saskatchewan, Saskatoon, Canada
e-mail: peter.phillips@usask.ca

S.J. Smyth
e-mail: stuart.smyth@usask.ca

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is twofold. First, what failures, if any, can we identify in the existing market efforts to manage the necessary coordination and ensure coexistence? A range of mechanisms are available in the context of market relationships, chief among them relative prices, the apportionment of property rights and effective contractss. Still, markets are not perfect and we must be alert to the possibility of market failure. Second, even if market failures exist, can government do better than markets? It is generally not certain that efficiency gains are always possible through government intervention, even in the case of demonstrated market failure. If such gains are in fact possible, we must still compare the benefits and costs of different forms of interventions and their mode of employment.

Such questions are fundamental to this debate and are of great and continuing importance. As Dillen, Rizov, and Rodriguez-Cerezo (Chap. "Developing Solutions for Coexistence in The EU—Legal, Technical, and Economic Issues") report, loss of value through comingling is the type of market failure coexistence regulations in the EU are aimed at preventing. Several contributors touched on this aspect of the coexistence question. In the opening chapter, van Deynze, et al., discuss in some depth gene flow, a primary source of a potential externality in agricultural production. Essentially the transfer of pollen from one crop variety to another, gene flow is an inseparable part of the natural environment in which agriculture takes place, and a primary mechanism for comingling in all production systems, including between GM and non-GM varieties. But there are technical measures that can assist growers to limiting gene flow when necessary; van Deynze et al. review such measures and draw conclusions about their effectiveness. Indeed, maintaining the genetic purity of seed strains has been a top priority of the certified seed industry for the entirety of its roughly century-long existence. Over that time seed production professionals have developed effective methods for dealing with the natural process of gene flow by segregating fields to assure seed purity. Gumina (Chap. "The Science of Gene Flow in Agriculture and Its Role in Coexistence") reviewed seed industry practices, and described time-tested procedures for ensuring seed purity. Clarkson (Chap. "Economic and Legal Principles of Coexistence Policy in North America") addressed coexistence from the point of view of a grain trading firm that does a significant volume of business in organic produce. He related how, in storage and transportation systems, current industry practices ensure a high degree of product purity at a reasonable cost. These authors present a consistent picture of a successful coexistence regime with two important dimensions. First, technical segregation measures ranging from barriers and isolation in field production to equipment and facility use rules in transportation, storage, and processing serve to keep different products separate as they travel through the supply chain. Biotechnology may offer new, even more effective segregation techniques, such as pollen incompatibility. Second, it is important to recognize that in the natural environment where agriculture takes place perfect segregation is impossible. Realistic tolerance thresholds are thus an important aspect of any coexistence regime. Thresholds represent a balance between the amount of comingling a buyer is willing to accept before the value of the product is significantly degraded, and the degree of purity a supplier can guarantee at a reasonable

cost. The authors were unanimous in emphasizing that zero tolerance policies for comingling are unworkable and impossible to meet in any line of production.

As in any production process, costs are a significant influence on supplier decision making. Giroux (Chap. "Developing Market Driven Standards for Coexistence: Tolerances, Thresholds, and Other Technical Standards Used by the Seed Industry") described at some length the need for a price premium in order to pay for the costs of segregation in a diversified product stream. Generally, it is the higher-value specialty products (e.g., organic or non-GM crops) that carry the higher price that covers the added cost of coexistence. Giroux pointed out that the essential elements of market driven coexistence systems are consumer willingness to pay (WTP) for the higher value products and effective contracts that ensure both understanding among supply chain participants and effective identity preservation of the specialty products. These elements are critical in that they foster accurate price signals that create an appropriate incentive structure. This drives the participation of producers, supply chain intermediaries, and others in a coexistence system that requires costly resources of production, storage, and transport. Kalaitzandonakes and Magnier (Chap. "What Can We Learn About Coexistence from Commercial Non-GM Programs in the US?") found that in the real-world setting of non-GM producers in the US these incentives work well to entice producer participation in specialty IP production. Further, they found that while explicit prices and costs were important decision points, farmers in fact took into consideration a range of factors, including the suitability of their individual farm structure and their capacity to segregate as well as the potential pecuniary and non-pecuniary gains associated with non-GM production. Overall they portrayed a well-functioning market that provided a range of commodity and specialty goods according to consumer market valuations, as expressed in prices, where coexistence issues are often settled through coordination with neighboring growers, with no significant market failures. In a discussion of canola production in Canada, Smyth and Phillips (Chap. "Commercialization Strategies and Market Opportunities for GM Canola") describe a similar situation where, while organic, non-GM, and GM canola are all available, GM has largely out-competed the other two based on price and cost considerations. In their words, "The capacity to coexist exists, but the economics does not support it."

Of course, the institutional environment and other factors can vary among markets. Thus some markets may not provide adequate incentives or be able to sufficiently prevent externalities. In addition, distributional issues may impede the development of a workable coexistence system. In cases such as these, government regulation may be necessary to allocate property rights, establish responsibilities, or otherwise ensure that proper incentives operate. Coelho (Chap. "Coexistence in Brazil") gives one example of how government regulation facilitated coexistence. He describes the process through which Brazil formulated and passed its Biosafety Law in 2005. Here the government worked closely with the maize industry to facilitate the development of workable, effective coexistence measures, codified those measure into law, and then communicated them to growers all over the country. Initial assessments suggest that the system is successful in achieving

coexistence of GM and non-GM maize markets. In contrast, Purnhagen and Wesseler (Chap. "The Principle(s) of Co-existence in the Market for GMOs in Europe: Social, Economic and Legal Avenues") describe how a different regulatory design, this in the EU, can lead to policies that may not improve efficiency. Here the responsibility, and thus cost, of securing coexistence is mandated to fall on the producer that introduces a new crop into the environment (usually GM), regardless of whether it will support a sufficient price premium. As commodity crops, GM varieties enjoy no price premium, so the rules discourage their production. EU regulations also place severe penalties on farmers whose production contains unacceptable levels of GM content. This further raises the cost of comingling and strengthens the implied disincentives for GM growers. These regulatory outcomes are in fact consistent with the EU definition of coexistence, described in the introduction, as the prevention of the presence of GM material in non-GM production. The EU regulatory regime achieves its stated objective, albeit at some cost. Whether the cost is commensurate with the perceived benefits of regulation is not strictly an economic question and it must be answered by citizens and policy makers in the EU. Purnhagen and Wesseler contribute to such considerations by delineating the costs of the regulatory design.

The different characteristics of national regulatory systems are also reflected in the court cases examined here. In general, courts function to clarify the application of regulations by resolving disputes that arise between individuals. Their decisions are constrained, however, by the system of laws and legal principles under which they operate. The cases from Australia, Canada, and the US reported by Bryson (Chap. "Lessons from the Legal Cases of GM Alfalfa and Sugar Beet Deregulation in the United States") and Blakeney (Chap. "Organic Versus GM Agriculture in the Courtroom in Australia and the USA") make some progress toward a clearer statement of property rights and grower responsibilities, even though technical aspects of the cases prevented the courts from ruling on some potentially important questions. There are still significant questions and considerations that have not yet been taken up, as Kershen (Chap. "Coexistence—Under-Explored Facets for a USDA Policy") described. A case from Germany, analyzed by Purnhagen and Wesseler (Chap. "The "Honey" Judgment of Bablok and Others Versus Freistaat Bayern in the Court of Justice of the European Union: Implications for Coexistence") had a substantially different effect due to the different legal environment in which it occurred. This judgement made GM field trials substantially more risky and expensive in Europe, and may provide a justification for using GMO approvals as a barrier to international trade. Thus we see again that a different basic concept of coexistence can lead to very different regulatory and legal outcomes.

Many of the above considerations pertain to the challenges of managing segmented supply chains in order to serve diverse consumer demand in certain markets. Such needs will always be present in the market, and will likely increase in the future. There will always be a demand for organic and non-GM food and feed products, and the market for specialty conventional and GM products will continue to grow. Actors throughout the agricultural supply chain have been able to manage such segregated production systems and supply chains at a cost, and are positioned

to continue to do so in the future. In this context both producers and consumers have strong incentives to arrive at mutually agreeable quality standards for the products involved. When we enter the realm of international trade, however, institutional arrangements can differ significantly across borders and can significantly complicate market functions. In this context, some market actors must coordinate the movement of large volume and high value shipments from one market region to another. In doing so, they have to take into account the workings of regulatory systems in those different regions. As these systems tend to operate on their own timetable and by their own rules, asynchronous regulatory approvals for new GM products become a significant factor in market decision making. Other policies, such as zero tolerance of unapproved GM material, are also important.

Gumina (Chap. "Developing Market Driven Standards for Coexistence: Tolerances, Thresholds, and Other Technical Standards Used by the Seed Industry") and Clarkson (Chap. "Organic Label Rules and Market Tensions: The Challenge of Satisfying Buyers") emphasized that a zero tolerance threshold for GM material cannot be met in normal agricultural production and Giroux (Chap. "Economic and Legal Principles of Coexistence Policy in North America") went on to show that extremely low thresholds are not much better. At very low thresholds compliance costs begin to increase exponentially, quickly becoming prohibitive. The cost of noncompliance increases at low thresholds as well, as Babuscio et al. (Chap. "The Canadian and European Union Impacts from the Detection of GM Flax ") pointed out. In the Triffid flax case, the unintentional presence, at concentrations of 0.01 % or less, of a deregistered GM flax variety had profound effects on international flax trade. Flax processors in Europe experienced higher costs and smaller margins and world trade patterns changed permanently, with Canadian producers losing market share to producers in other regions. Similarly, Wree and Wesseler (Chap. "Consequences of Adventitious Presence of Non-approved GMOs in Seeds: The Case of Maize Seeds in Germany") showed how zero tolerance coupled with a lack of clear legal standards assigning liabilities in case of violations results in excess costs and risk, especially for farmers.

Importantly, zero tolerance policies and the multitude of national regulatory approval systems come together to produce significant distortions in international agricultural markets. Beyond the consequences on various national agricultural production systems, the global regulatory system has created a new class of coexistence issues related to asynchronous approvals. Each producing, exporting, or importing nation maintains its own process for approving market entry of new biotech crops. Each nation's approval system operates by its own criteria and on its own time schedule. The structure of the international system virtually guarantees some degree of asynchrony in national approvals of new varieties. Until a new GM variety is approved in a particular import market, it cannot legally enter the country. Phillips (Chap. "Market Solutions to Coexistence and Regulatory Asynchrony") discussed how asynchronous approvals are a major concern with a seeming divide between regulators and consumers. If a GM crop variety in production is not approved in some significant import market, then the market must distinguish the supplies and incur costs for their technical separation, even if consumers regard

them as equivalent. Since there are often no market price premiums for commodity goods, producers and exporters must find other ways to coordinate the supply chain and direct commodities to the proper market area. If exporters are not successful in keeping the supply chain segregated, the cost can be prodigious, and include the cost of fines, redirecting shipments, or perhaps having a shipment destroyed. Ultimately, these costs will be paid by all consumers in the asynchronous importing countries in the form of reduced supplies, inefficient trade arrangements and higher prices. Not surprisingly, many actors in international agricultural markets have decided that their best option is to work to prevent the possibility of trade disruptions. For this reason, most biotech development firms have instituted stewardship policies, whereby new GM varieties are not commercialized until they are approved in all relevant markets.

The effects of asynchronous approvals and zero tolerance policies go much further than the costs they impose on the supply side of the market. As Sachs (Chap. "Regulatory Approval Asynchrony, LLP, and Implications for Biotech R&D and Innovation") points out, compliance costs are only a small part of the costs generated by the current regulatory regime. The demand side of the market, from downstream producers to everyday consumers, bears significantly greater costs. Kalaitzandonakes et al. (Chap. "Potential Economic Impacts of Asynchronous Approvals of Biotech Crops on South Korea") modeled the potential effects of a trade disruption due to the presence of unapproved varieties in export shipments. Feed prices increased significantly, with amplified downstream effects in livestock and consumer meat markets. As discussed by Huang and Yang (Chap. "Low Level Presence and Asynchronous Authorizations of Genetically Modified Products in China"), China's approval system is more asynchronous than most and thus can produce significant trade disruptions that cause increased food costs throughout the Chinese economy. The loss of societal benefits from innovations that are delayed or never developed due to uncertain, uncoordinated, or stifling regulatory regimes are at least as great if not more so. When suppliers make stewardship policies their standard procedure to avoid the cost of trade disruptions, the entire cycle of innovation is delayed, and varieties that might not generate the income to justify the expense of pursuing multiple approvals are never developed. The resulting delay in adoption of new varieties has its own costs; as models by Kalaitzandonakes, Zahringer, and Kruse (Chap. "The Economic Impacts of Regulatory Delays: the Case of HT Soybeans") demonstrated, the path by which benefits from innovation accrue to market actors is permanently changed by any delay. Not only are the prices of commodities and follow-on goods like meat and poultry temporarily higher during the delay than they would have been, surplus is irretrievably transferred from consumers to producers. Such costs may at some point be much greater in the wheat market, which has yet to have any significant GM varieties released. Wilson and Dahl (Chap. "Potential Economic Impacts of Low Level Presence (LLP) in the Global Wheat Market") pointed out that since wheat production is already strongly differentiated, with many varieties on the market, the supply chain is already well positioned to maintain coexistence in the production and trade of GM varieties. However, the large number of extant wheat

varieties means that as future GM events are commercialized the potential for asynchronous approvals will be compounded relative to other crops. It is also important to realize that, as Gruere (Chap. "Asynchronous Approvals and the Low Level Presence of Unapproved GM Products in Imports: How "Tolerant" Should Small Countries be?") demonstrated, the costs of zero tolerance are not restricted to the major producer and importer nations. Smaller countries, by virtue of their position in the marketplace, are more likely to experience LLP incidents and face correspondingly higher potential costs.

While the costs of asynchronous approvals, zero tolerance policies, and the resulting delays in innovation are substantial, those costs for the most part seem to be diffused among market actors. Regulators often have limited incentive to minimize the distortions that result from their decisions when the effects are so diffused. Thus any solution here will only come when some market actors are sufficiently impacted by the costs to have an incentive to push for a resolution through the political process. It is unclear exactly what it would take for this to happen. Authors in three chapters offer some possibilities for workable resolution frameworks. Phillipson and Smyth (Chap. "Regulatory Lags for Genetically Modified Crops: Legal and Political Perspectives"), in noting the effects of regulatory lags, showed how the Patent Cooperation Treaty could serve as a model for a coordinated international approval system. This is admittedly not a perfect solution. They note that a variety of non-scientific and political factors influence regulatory asynchrony; command economies in particular have both the incentive and the ability to use GM approvals as a tool in international political relations. Kerr (Chap. "Low Level Presence Under the WTO") offered the possibility that the WTO may be a potential forum for international cooperation. Even though WTO rules do not make specific mention of LLP, the effects of LLP incidents on trade relations may make this a relevant option. While international efforts are necessary to address asynchronous approvals, individual countries may make progress on establishing realistic thresholds and decreasing LLP incidents, as Tranberg and Lukie (Chap. "Forging the Future of LLP: Building an International Coalition and Developing a National LLP Policy") described in the case of Canada. There may be no perfect system, but there is general agreement on a principled point among the authors. While changing current zero tolerance policies to enabling thresholds is necessary and would be a significant improvement, the full solution does not lie there. The LLP issue is fundamentally the result of uncoordinated regulatory systems that produce asynchronous approvals. The sustainable solution is to correct the discoordination and implement a more science-based and less politically-based system. Until that happens, the LLP issue and its attendant trade disruptions will continue to generate significant market inefficiencies and costs.

Of course, all coexistence measures entail costs, since they involve the use of scarce resources. To the extent that the most important market participants, consumers, are willing to pay those costs to maintain choice and diversity in food products, coexistence is a positive economic benefit for all. This outcome is not inevitable, however with Giannakas (Chap. "Coexistence of Genetically Modified, Conventional, and Organic Food Products: A Framework and Analysis") offered a

model for understanding the conditions necessary for sustainable coexistence. As long as market prices accurately reflect consumer preferences market outcomes have the potential to be optimal. Higher valued specialty products will carry a higher price, and it is that price differential that covers the cost of coexistence. He goes on to investigate how market structure, specifically oligopoly and the degree of market power it confers, can influence equilibrium prices and quantities. In short, the greater the market power of a supplier, the more of the total economic surplus they can appropriate. Market structure can also influence decision making in other ways. Venus, Wesseler, and Kalaitzandonakes (Chap. "Lessons from EU Voluntary Labeling Schemes for GM-free Processed Food Products") described how retailers and processors may have different interests and incentives regarding GM labeling. Voluntary labeling regimes may differ based on whether they are driven by retailers or processors, and whether there are a few large firms or many small ones in the relevant market sector. Market structure can influence how costs are apportioned among market participants, but a large portion of coexistence costs will unavoidably fall on consumers. Goodwin, Marra, and Piggot (Chap. "The Cost of a GMO-Free Market Basket of Food in the US") quantified the relative costs of coexistence with a real world example. They showed that families in Europe spend up to twice the proportion of their household budget on food as families in the US. The costs involved in maintaining a completely GM-free food supply in Europe are not the sole reason for this, but they play their part.

Overall then, it might be concluded that when governments define the purpose of their regulatory systems as facilitating communication among all supply chain stakeholders (including seed companies, growers, traders, processors, retailers, and consumers), codifying industry best practices and thresholds and facilitating market interactions, it may be possible to decrease transaction costs, enhance efficiency and improve both consumer and producer welfare. When, however, governments attempt to drive the market to particular outcomes motivated by considerations of allocation of specific rights, the task is more difficult and market inefficiencies can emerge. These can increase costs for all, but as such costs might be distributed widely and unevenly across many actors, corrective mechanisms can prove difficult to organize and finance.

It may also be concluded from the contributions of various authors that the task of bringing all sides to a workable agreement on coexistence will remain challenging. In the conclusion to his discussion of coexistence between GM and landrace maize strains in Mexico (Chap. "GM Maize in Mexico: The Challenge of Coexistence in a Centre of Origin"), Phillips noted that coexistence in this instance is in fact a matter of "fundamentally different world views", not about market risk or economic value. Those who are most committed to maintaining complete segregation between GM and landrace maize, unlike commercial farmers in developed countries, are not trying to deliver a specific, desired product to consumers. Rather, they are attempting to prevent what they see as an inappropriate influence from impinging on their traditional lifestyle. Additional information about the safety and utility of GM maize is not likely to change their views or decisions; those considerations are not relevant to such calculus. This lesson may be more widely

applicable than just the case of small Mexican maize farmers. Zilberman and Wesseler (Chap. "Welfare and Co-existence") drew a similar conclusion when they placed the coexistence issue in the larger context of the debate over the future of agriculture. From this perspective, coexistence is just one part of a clash of paradigms, each with its own preferred view of what agriculture, and possibly life in general, ought to look like. As in the Mexican case, a discussion based on concerns of promoting economic efficiency and avoiding trade disruptions may not find a great deal of common ground. Zilberman and Wesseler note that many who oppose GM crops ascribe to a "naturalization" paradigm and favor "small farms, limiting trade, and support of organic agriculture." A discussion of how GM varieties might in fact fit with such a paradigm might be more fruitful, if all participants can maintain credibility in each other's eyes.

The paradigm clash, insofar as it is an accurate portrayal of the situation, is naturally reflected in the political process surrounding GM crops in general and coexistence in particular. It was not the purpose of this book to determine which of these paradigms is 'more correct'. That is not an economic question. It is, however, useful to note that it seems to be the core reason why GM coexistence can, in some instances, become an apparently intractable issue. Taking that as the starting point, the contributions here explored some of the economic consequences of that conflict and identify some potential strategies and policies that could trigger more fruitful and meaningful discussion in the future. It is our hope that the chapters contained in this volume will contribute to a better understanding of the full scope of coexistence and serve as a springboard for further scholarship and greater policy clarity on this critical issue.

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