Mol Breeding (2009) 23:99–112
DOI 10.1007/s11032-008-9217-z

Calling the tunes on transgenic crops: the case for regulatory harmony

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Received: 2 June 2008 / Accepted: 12 August 2008 / Published online: 30 August 2008

Abstract Genetically modified (GM) crops are now grown commercially in 23 countries, with another 29 granting approval for import and release into the environment. Despite the socio-economic and environmental benefits of the technology, further development is being hampered by differences in national regulatory frameworks relating to research, biosafety, and to the trade and use of GM crops. The biosafety regulations in different countries are based on five main international instruments that influence the development of national biosafety systems in terms of field trial permit requirements, risk assessment criteria, labeling, traceability, transparency, public awareness, post-monitoring and import regulations. The global harmonization of data collection, testing procedures and information exchange would help to remove artificial trade barriers, expedite the adoption of GM crops, foster technology transfer and protect developing countries from exploitation, instilling confidence and bringing the benefits of GM products to the consumer.

Keywords GM crops · Transgenic plants · Regulatory process · Precautionary approach · Risk assessment

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Introduction

In 2007 over 114 million ha (~282.4 million acres) of GM crops were grown in 23 countries, 11 in the industrial world and 12 in the developing world (James 2007). The USA headed the list, accounting for 50% of the total, while Poland, in last place, was the most recent addition to the 'GM club', reporting her first crop of Bt maize (see Box 1 for full ranking). The most prevalent traits among GM crops in 2007 were: herbicide tolerance, followed by stacked double and triple traits which for the first time, occupied a larger area than crops with pest resistance that ranked third (James 2007). Maize had the most events approved in 2006 (40) followed by cotton (18), canola (15) and soybean (8).

In the decade since GM crops were first adopted, it is estimated that farmers have earned $US 27 billion

Box 1 The 23 countries reporting commercial GM crops in 2007, in order of prevalence

1.	United States of America (57.7; soybean, maize, cotton, canola, squash, papaya, alfalfa)
2.	Argentina (19.1; soybean, maize, cotton)
3.	Brazil (15; soybean, cotton)
4.	Canada (7; canola, maize, soybean)
5.	India (6.2; cotton)
6.	China (3.8; cotton, tomato, poplar, petunia, papaya, sweet pepper)
7.	Paraguay (2.6; soybean)
8.	South Africa (1.8; maize, soybean, cotton)
9.	Uruguay (0.5; soybean, maize)
10.	The Philippines (0.3; maize)
11.	Australia (0.1; cotton)
12.	Spain (0.1; maize)
13.	Mexico (0.1; cotton, soybean)
14.	Colombia (low; cotton, carnation)
15.	Chile (low; maize, soybean, canola)
16.	France (low; maize)
17.	Honduras (low; maize)
18	Czech Republic (low; maize)
19.	Portugal (low; maize)
20.	Germany (low; maize)
21.	Slovakia (low; maize)
22.	Romania (low; maize)
23.	Poland (low; maize)

Data in parentheses show approximate area planted to GM crops (in millions of hectares) and principal crops for each country. Data from James (2007)

from the technology, split almost equally between developed and developing countries (Brookes and Barfoot 2006). As well as direct economic benefits, it has been reported that GM crops reduce pesticide use, reduce the use of fossil fuels in agriculture and (through the development of biofuel crops) could reduce the global consumption of fossil fuels by up to 65% (Brookes and Barfoot 2006). These benefits notwithstanding, many countries have strict regulatory frameworks governing the cultivation, trade and use of GM crops, some of which are not based on scientific principles and many of which erect unnecessary hurdles to the further development of the technology, especially in developing countries where the benefits are most needed (Christou and Twyman 2004).

Here we present the case for the global harmonization of biosafety regulations, in order to minimize potential risks and maximize the benefits of GM crops based on real science-based risk assessment procedures. We describe the five major international instruments that influence the development of national biosafety systems and use the *Bt* maize event MON810 developed by Monsanto (also known as YieldGard corn) to compare the strengths and weaknesses of regulatory systems in different countries.

International instruments and national discord

Regulatory frameworks governing GM crops and their associated food products vary widely from country to country, but there are essentially only two ways in which legally binding regulations can be established—either they are developed specifically for GM crops, or they are adapted from existing legal instruments that apply to conventional agriculture and/or other GM organisms. In either case, regulatory development is influenced by five main international instruments, which are summarized in Table 1. Although the existence of these instruments ensures a certain level of international harmonization (Jaffe 2004; König et al. 2004) there remain major differences in how countries choose to interpret them, and therefore how they regulate the approval of GM crops. The most widely discussed example is the difference in approach between the EU and the USA regarding pre- and post-approval requirements. The EU follows the "precautionary approach" and the consumers' "right to know," with stringent approval, labeling and traceability standards on any food produced from or derived from GM ingredients (Gruère 2006a). In contrast, the US regulations are based on differences in the end product, and include a voluntary safety consultation and voluntary labeling guidelines for GM food. Most other developed countries, including Japan, Canada and Australia, have introduced regulations that share features of both the EU and US systems (Carter and Gruère 2006). The regulatory frameworks of selected countries are compared in Table 2.

Most countries have also developed guidelines for the use of experimental GM plants grown in containment. With the exception of Japan and Argentina (Flint et al. 2000; Suguru 2006) these guidelines are voluntary and no oversight or

Table 1 Key international agreements governing biosafety regulations

International biosafety agreements	Role in biotechnology
(i) World Trade Organization (WTO) agreements (www.wto.org)	Aims to control barriers to international trade
Agreement on the applications of sanitary and phytosanitary measures (SPS agreement) 1994	Provides for the enactment of laws, decrees, regulations, requirements and procedures relating to sanitary and phytosanitary concerns that may affect trade
Agreement on technical barrier to trade (TBT agreement) 1994	Provides for standards of ensuring the elimination of unfavorable treatment of trading member countries' products (biotechnological, industrial and agricultural products)
(ii) International treaty on plant genetic resources for food and agriculture by the UN FAO (http://www.fao.org/biodiversity/IPGR_en.asp)	Multilateral agreement relating to any genetic material of plant origin of value for food and agriculture
(iii) Codex alimentarius 2001 (www.codexalimentarius.net)	Set of international codes of practice, guidelines and recommendations pertaining to food safety. The WTO currently relies upon the Codex in making its adjudication
(iv) Cartagena protocol on biosafety under the convention on biological diversity (CBD) 2000 (http://www.cbd.int/biosafety/default.shtml)	Multilateral agreement covering the transboundary movement of living modified organisms (LMOs) that might have an adverse effect on biological diversity
(v) Organization for economic cooperation and development (OECD) 1961 (www.oecd.org)	Harmonization of international regulations, standards and policies

environmental assessment is required since environmental release is not anticipated. However, no food/feed use is allowed without approval by the appropriate agency and some countries may require permits for imported transgenic plant material. When it comes to field trials, the assessments and requirements depend on whether the release is confined or unconfined. For *confined* field trials, it is necessary to describe measures taken to ensure reproductive isolation, restrictions on post-harvest land use, site monitoring, and the control and disposition of plants and seed. Canada requires more detailed information (and no food/feed use is allowed without approval by Health Canada/CFIA) while Argentina requires the same data provided for contained use. For *unconfined release*, there are no requirements for reproductive isolation or restrictions on post-harvest land use but monitoring for adverse effects may be required. There are many similarities among the environmental safety requirements in different countries, including a description of the tissue and/or temporal specificity of the gene, its impact on reproductive and survival biology and adaptation to stress factors, the potential toxicity of gene products, breakdown products, by-products and their metabolic pathways, including effects on predators, grazers, parasites, pathogens, competitors and symbionts (including exposure levels), and the risk of gene flow and potential consequences of introgression.

Pre-approval considerations

Different countries follow different roads to the commercialization of GM crops and their products, but all involve thorough and rigorous pre-approval safety and risk assessment studies, as exemplified by the MON810 event, which has been approved in 14 countries in addition to the EU (AGBIOS 2008a, b) (Tables 3 and 4). A risk assessment typically involves hazard identification, hazard characterization, exposure assessment and risk characterization (The European Parliament the Council of the European Union 2002; Codex Alimentarius Commission 2003), and generally occurs in two steps—the identification of differences between a GM product and its conventional counterpart, followed by an assessment of the safety impact of such differences. As stated above, one of the most significant examples of international discord in GM regulation is in pre-approval risk assessment, with the USA favoring a comparative analysis approach based on *substantial equivalence*, which seeks to determine whether a GM product is as safe as its conventional counterpart, and

Table 2 Current biosafety regulations for selected countries worldwide

Country	Governing bodies/agencies	Regulations/laws	Product/process based	Transparency	Labeling and traceability	Tolerance levels
USA	US Department of Agriculture	Federal Plant Protection Act	Product	Yes	Voluntary[a]	5%
	Environmental Protection Agency	Federal Insecticide, Fungicide and Rodenticide Act, Federal Food Drug and Cosmetic Act, Toxic Substances Control Act				
	Food and Drug Administration	Federal Food Drug and Cosmetic Act				
Canada	Canadian Food Inspection Agency	Consumer Packaging & Labeling Act, Feeds Act, Fertilizers Act, Food & Drugs Act, Health of Animals Act, Seeds Act, Plant Protection Act	Product	Yes	Voluntary[a]	5%
	Health Canada	Food & Drugs Act, Canadian Environmental Protection Act, Pest Control Products Act				
	Environment Canada	Canadian Environmental Protection Act				
EU	Member states' competent authorities and European Commission	EU Directive 2001/18/EC (2001), EC Regulation 258/97 (1997)	Process	Yes	Mandatory[b]	0.9%; 0.5% food and feed
UK	Health and Safety Executive, Department for Environment, Food, and Rural Affairs	Directive 2001/18/EC	Process	Yes	Mandatory	c
	Food Standards Agency, Advisory Committee on Releases to the Environment	Regulation (EC) No 1829/2003				
Australia	Office of the Gene Technology Regulator, Food Standards Australia New Zealand	Gene Technology Act 2000 Standard 1.5.2—Food Produced Using Gene Technology	Process	Yes	Mandatory	1%
New Zealand	Environmental Risk Management Authority, New Zealand Food Safety Authority, Food Standards Australia New Zealand, Ministry of Agriculture and Forestry	The Hazardous Substances & New Organisms Act 1996 (HSNO Act)	Process	Yes	Mandatory	1%

Table 2 continued

Country	Governing bodies/agencies	Regulations/laws	Product/process based	Transparency	Labeling and traceability	Tolerance levels
China	Administration for Quality Supervision, Inspection and Quarantine State Environmental Protection Administration, Ministry of Science and Technology, Ministry of Commerce, Ministry of Health	Under discussion	Process	n.i.	Mandatory	1%
Japan	Ministry of Agriculture, Forestry and Fisheries, Ministry of Health, Labor and Welfare, Ministry of the Environment, Ministry of Education, Culture, Sports, Science & Technology	Law Concerning the Conservation & Sustainable Use of Biological Diversity through Regulations on the Use of LMOs, Food Sanitation Law, Feed Safety Law	Process	Yes	Mandatory for selected products	5%
Taiwan	Taiwan Department of Health, Council of Agriculture	Article 14 of the Law Governing Food Sanitation	Product	Yes	Mandatory	5%
Bangladesh	Ministry of Agriculture, Ministry of Science and Information & Communication Technology, Ministry of Environment & Forest	Draft Biosafety Guidelines	Product	n.i.	No labeling regulation	n.i.
India	Ministry of Environment & Forests, Department of Biotechnology	EPA 1986 & 1989 Rules	Process	Yes	Proposed legislation for mandatory labeling	n.i.
The Philippines	National Committee on Biosafety of the Philippines (Departments of Agriculture, Science & Technology, Health, and Environment & Natural Resources), Institutional Biosafety Committee	E.O. 430 (1990), DA-A.O. No. 8 (2002)	Product	Yes	Voluntary	5%
Argentina	Comisión Nacional Asesora de Biotecnología Agropecuaria, Servicio Nacional de Sanidad y Calidad Agroalimentaria, Instituto Nacional de Semillas, Direccion Nacional de Mercados Agroalimentarios	Law 18284 on Argentine Food Codex, Decree 1585/96, Decree 4238, Decree 815/99, Resolution 289/97, Resolution 511/98, Resolution 1265/99	Product	Yes	Voluntary	n.i.

Table 2 continued

Country	Governing bodies/agencies	Regulations/laws	Product/process based	Transparency	Labeling and traceability	Tolerance levels
Chile	Advisory Committee for the Release of Transgenics (Ministry of Agriculture, Agricultural & Livestock Service, National Agricultural Research Institute, National Commission on Scientific & Technical Research)	Resolution of exemption 1927/93, Decree-Law 3554/81	n.i.	n.i.	Mandatory	n.i.
Brazil	Conselho Nacional de Biosegurança, Comissão Técnica Nacional de Biossegurança	Biosafety Law Number 11.105	Process	n.i.	Mandatory	1%
Mexico	Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentacion, Secretaría de medio ambiente y recursos naturales,Secretaria de Salud, Comision Federal para la Proteccion contra Riesgos Sanitarios, Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados	Biosafety Law of Genetically Modified Organisms (2005)	Process	Yes	Mandatory	n.i.
South Africa	Executive Council of Genetically Modified Organisms, Department of Agriculture, Department of Environment & Tourism, Department of Health	GMO Act, 1997 (Act No. 15 of 1997) amended 2007, National Biodiversity Act	Product	Yes	Voluntary	1%
Burkina Faso	National Biosafety Agency	Decree 2003–208-/PRES/PM/ MAECR/MFB/MECV	Process	No	n.i.	n.i.
Egypt	National Biosafety Committee	No proper biosafety regulation but Ministerial decree No. 1648 (1998) is for commercialization of imported products; National Biosafety Committee guidelines occur however not legally binding	Process	n.i.	No labeling required (no framework)	Not established

Table 2 continued

Country	Governing bodies/agencies	Regulations/laws	Product/process based	Transparency	Labeling and traceability	Tolerance levels
Kenya	National Biosafety Committee, National Environmental Management Authority, Kenya Bureau of Standards, Kenya Animal Plant Health Inspectorate Services, Kenya Standing Committee on Imports & Exports, Public Health Department, Department of Veterinary Services, Pest Control Products Board	Kenyan Draft Biosafety Bill of 2003, EMCA Act	Process	Yes	No labeling addressed in draft bill	Not established
Zambia	National Biosafety Authority, Scientific Advisory Committee[d]	National Biotechnology & Biosafety Bill	Process	Yes	n.i.	n.i.
Nigeria	Federal Ministry of Environment, National Biosafety Committee	Nigeria Biosafety Guidelines, Draft biosafety bill	Process	Yes (planned in draft bill)	Mandatory as planned in draft	n.i.

[a] Labeling required if safety concerns (allergenic, change in nutritional composition) exist (Alexander et al. 2007)

[b] Labeling required at a 0.9% threshold for approved GM organisms or 0.5% for GM organisms given a favorable risk assessment but not yet approved (called 'adventitious presence') and 0% for unapproved GMOs

[c] To be established by the biosafety bill, however the Parliamentary Committee on Education, Science and Technology currently is in rule

[d] Labeling is required of seeds used for planting—the characteristics of the acquired genetic combination, implications with regard to special conditions and growing requirements, and changes in reproductive and productive characteristics should be stated. n.i. = not indicated

Table 3 Summary of the data required (from regulatory frameworks of different countries) for approval of MON810 (data from AGBIOS 2008a)

Requirement	Information to be provided
Summary of introduced genetic elements	Gene, promoter, terminator, copy number and form of gene (full or truncated)
Characteristics of host plant	Region of origin, reproduction, known toxins or allergens
Characteristics of donor organism	Organism name, pathogenicity, gene of interest
Modification method	Procedure used for genetic modification
Characteristics of the modification	Introduced DNA (including selectable marker if used), genetic stability of the introduced trait, expressed protein
Environmental Safety considerations	Outcrossing potential, weediness potential, secondary and non-target adverse effects, impact on biodiversity
Food and/or Feed safety considerations	Dietary exposure, nutritional composition, toxicity, allergenicity, digestibility

Table 4 Summary of Regulatory approvals for MON810 (data from AGBIOS 2008b)

Country	Environment	Food and/or feed	Food	Feed	Marketing	Modification process or GM product based regulatory approval
Argentina	1998		1998	1998		Process
Australia			2000			Process
Brazil	2008					Process
Canada	1997		1997	1997		Product
China		2004				Process
European Union[a]	1998	1998			1998	Process
Japan	1996		1997	1997		Process
Korea			2002	2004		Process
Mexico		2002				Process
Philippines	2002		2002	2002		Process
South Africa	1997		1997	1997		Process
Switzerland			2000	2000		Process
Taiwan			2002			Process
United States	1995	1996				Product
Uruguay	2003	2003				Process

[a] Notified as an existing product on 12 July 2004

the EU favoring the *precautionary approach*, which in essence considers GM products inherently unsafe (Box 2).

Specific national differences in risk assessment requirements often reflect the way words are interpreted, and this can result not only in disharmony but also seemingly illogical rules that conflict with scientific principles. For example, a fundamental flaw in many regulatory frameworks is the assumption that a 'genetically modified organism' created through 'modern biotechnology' methods has characteristics that make it inherently more risky than one created through conventional breeding. Genetic modification accomplished through conventional breeding is assumed to be risk free and is therefore absolved from regulatory scrutiny. In Taiwan, for example, the Law Governing Food Sanitation (Article 14, Paragraph 1) states: *Genetic modification means techniques that apply genetic engineering or modern biotechnology to transfer or insert genetic material into a living cell or organism resulting in genetic modification of the cell or organism. The technique does not include conventional breeding, cell fusion, protoplast fusion, hybridization, induced mutagenesis,*

Box 2 Substantial equivalence vs. the precautionary approach—a tale of transatlantic regulatory discord

The USA and EU use fundamentally distinct approaches to determine the risk of GM products. Basically, the US *comparative approach* seeks to determine whether a GM product has the same risk as its non-GM contemporary, whereas the EU precautionary approach assumes that a GM product is inherently hazardous and requires tests to be carried out to demonstrate safety.

The *comparative approach* is based on comparisons between GM products and their closest conventional counterparts, usually common foods already regarded as safe (World Health Organization 1995, 2000). If a GM food is found to be *substantially equivalent* in composition and nutritional characteristics to an existing food, it is also considered to be equally safe (FDA 1992; Organization for Economic Cooperation and Development 1993; Maryanski 1995; Kuiper et al. 2001). If there are characteristics that are not substantially equivalent, risk assessment focuses on those differences. This approach acknowledges there is no such thing as absolute safety or zero risk, but proposes that a safety evaluated as equivalent to common foods is an acceptable risk. The OECD Task Force on the Safety of Novel Foods and Feed is developing guidance documents to show what tests and tolerance limits are required to demonstrate substantial equivalence.

The *precautionary approach* is incorporated into the decision procedures of the Cartagena Protocol by which a country may refuse the import of a particular GM product even when there is no evidence that it is harmful. This approach was introduced into European environmental policies in the late 1970s, and has emerged as one of the principal tenets of international environmental law (Barrett 1999; Shipworth and Kenley 1999). While few would argue that caution is entirely unnecessary, debate continues over the level of precaution that is required, particularly in terms of the required level of scientific evidence for the absence of risk, and the relationship between risk assessment and cost-benefit analysis. Those pushing for more comprehensive safety procedures and a separation of trade and environmental interests tend to favor a strong precautionary approach in some cases taking the form of a complete ban on GM products.

ex vivo fertilization, somatic mutation, and polyploidy induction. Therefore, the focus of safety and risk assessment is placed on the process of genetic modification and not the product. A plant created through mutagenesis would be treated differently to an identical transgenic plant, a phenomenon described by McHughen 2007 as scientifically invalid. McHughen correctly emphasizes that *pragmatic and scientifically sound regulatory regimes prioritize according to degree of risk: products with higher risk attract greater regulatory scrutiny*. All current regulatory frameworks are erroneous in this respect except those of the US Food and Drug Administration (FDA) and Canadian Food Inspection Agency (CFIA).

All countries considering the commercial release of GM crops require a summary of the introduced genes, their genetic stability and expression through subsequent generations. However, some regulators place extraordinary concern on the presence of selectable marker genes, which results in major differences between countries (Ramessar et al. 2007). For example, the EU have adopted a precautionary approach to the presence of an ampicillin resistance gene in Bt crops, resulting in approvals being refused, whereas in the US and Canada the Bt genes are the principal concern even though the ampicillin resistance marker was also evaluated. In the latter case, the products were approved based on a proper risk/benefit assessment. YieldGard corn avoids the need to demonstrate selectable marker safety because the marker gene was lost by segregation in the progeny of the MON810 event. Therefore, regulatory concerns over MON810 focused on three categories of risk: toxicity of the Bt protein itself, the harm that the Bt protein might cause to non-target organisms (including those that prey on the target insect) and the selection pressure that widespread use of the Bt crop would exert in favor of insects that are resistant to the toxin, thus jeopardizing the benefits of the product. Research on the effects of Bt on non-target organisms suggest an overall minimal risk (Sanvido et al. 2007), but some have nevertheless argued that the safety studies are invalid because the toxin was derived from microbial sources and not the actual Bt crop (Cummins 2004). However, this ignores the fact that most regulatory frameworks have adopted the comparative approach to risk assessment (Conner et al. 2003; Nap et al. 2003) and require data to show that the bacterial products have, among other things, retained their active domains as toxins and possess similar immune profiles to the proteins produced in Bt crops, making them "substantially equivalent", a view that was accepted in the USA (EPA/BPPD 1995). Research on the environmental impact of Bt maize has shown that the GM crops have no impact on the environment and may even be beneficial by reducing insecticide use (Eizaguirre et al. 2006; Marvier et al. 2007).

As well as their environmental impact, risk assessments must also evaluate the hazards posed by GM crops intended for human and animal consumption, particularly the toxicity and allergenicity of the recombinant protein. For animal feed, additional risks are considered by some regulatory agencies, such as the relatively larger proportion of the diet represented by GM feed (Aumaitre et al. 2002) and the possibility of humans being exposed to risk indirectly through the consumption of meat and dairy products from GM-fed animals (MacKenzie and McLean 2002). In the case of MON810, acute toxicity testing was performed on rodents using toxin produced in microbes, since insufficient levels of the protein were present in plant material (OECD 2007). As with the environmental tests, some argued for a precautionary approach because the actual plants were not used, despite proof of equivalence (Cummins 2004) (see Box 2 for further discussion). Since no internationally accepted animal allergenicity model is available to test the Bt toxin, a screening model has been developed to compare the toxin to known food allergens (Aumaitre et al. 2002; Codex Alimentarius Commission 2003). In the case of MON810, the Cry1Ab endotoxin was found to degrade rapidly in acidic gastric fluids, and the amino acid sequence data showed no similarities to known allergens. This, combined with the fact that the *cry1Ab* gene has a long history of safe use on food crops as a biopesticide, was sufficient to convince regulators of the product's safety (AGBIOS 2008b). Food safety assessments also consider the potential for any change in nutritional composition or bioavailability, especially in key elements that have a significant impact on the diet. Data on fatty acid profiles, protein content, crude fibre, ash, phytate and moisture content provided for MON810 samples from various field trials in the US and EU revealed no significant differences (AGBIOS 2008b).

A major problem with current regulatory frameworks is that the approval process is unrealistically long, certainly much longer than originally envisaged. In the early 1990s it was believed that it would only take 3–5 years for developing countries to carry out the GM transformation research phase and gain biosafety approval (Brenner 2004) but this has recently been revised to 10–15 years (Baumüller 2004). This increases the costs, resulting in immense financial burdens for developing countries that already lag behind with their national framework strategies.

Post-approval considerations

After commercial approval, many countries continue to monitor GM crops for potential negative environmental impact, or to manage the risk of resistant insect populations evolving through the over-use of Bt crops. In the US, Canada and Argentina, an insect resistance management plan is required by regulatory agencies and has been developed and implemented by the industry. Grower compliance is addressed through a detailed communications strategy and a non-binding acknowledgement document (MacKenzie 2006).

Several countries have also introduced voluntary or mandatory labeling regulations for GM foods, often as a response to political pressure (Table 2). Labeling and traceability standards are controversial, with proponents arguing for consumer choice and opponents criticizing the additional costs passed on to consumers and the tacit implication that GM labels are equivalent to health warnings on tobacco products. In the EU, food and feed containing more than 0.9% GM product must be labeled, although meat and dairy products derived from GM-fed livestock are currently exempt. The labeling regulations in Australia and New Zealand also apply to food additives and processing aids that have been produced using gene technology (Brent et al. 2003). In contrast, the USA and Canada have not imposed labeling regulations for GM foods. Their position is that since substantial equivalence has been demonstrated between a GM product and its traditional counterpart, labeling is not required (Gruère 2006b).

Public participation and transparency are essential components of a good regulatory system and both help to ensure consumer trust and approval (Australian Government 2007). Public participation includes the opportunity to provide information and comment on regulations, guidance and product applications. Transparency ensures that the public has access to information about the regulatory process, ongoing applications, a clearly written decision document and information about when and where applications can be reviewed. A good regulatory system should also respond to comments in decision-making documents

to assure that public concerns are considered seriously (Jaffe 2004). Almost all countries with established regulatory systems offer transparency, but the FSANZ system in Australia and New Zealand is unique in that it provides all application data (except commercial-in-confidence) including the assessment and decision-making processes, and undertakes two rounds of public consultation (Brent et al. 2003; Australian Government 2007; Office of Gene Technology Regulator 2007).

Socio-economic considerations

Modern agricultural biotechnology raises a number of socio-economic issues, and GM technology has had both positive and negative impacts (Cuite et al. 2005). Although farmers have profited from GM crops, political tensions over transatlantic differences in biosafety regulations have had a negative effect. For example, US food exporters and biotechnology companies have complained about the EU's slow and obscure approval process, and bans by individual EU countries on GM products approved by the EU as a whole (Fransen et al. 2005). This ongoing dispute has been intensified by EU's introduction of mandatory labeling. The role of the World Trade Organization's legal framework regarding trade in GM products [the Sanitary and Phytosanitary (SPS) Agreement and the Agreement on Technical Barriers to Trade (TBT), see Table 1] has played a significant role in stifling the opportunities offered by GM products.

Strict labeling, identity preservation and import requirements impose additional costs and reduce public confidence, which in turn affects trade. The decline in US corn exports to the EU has been blamed on the EU's strict approval and labeling requirements, with some EU countries banning GM products all together (Bernauer 2003). Developing countries have also been drawn into this dispute as both sides try to win their support. Many developing countries have banned GM products due to consumer and environmental concerns, only to find themselves excluded from markets and refused financial support from industrialized nations to conduct research and build human capital for biotechnology activities.

Several policy tools have been used to accommodate, reduce or eliminate international regulatory diversity (Bernauer 2005). One realistic approach is *mutual recognition*, where countries agree to recognize each other's regulations, e.g. the US and EU could agree to allow imports of each other's products (GM and conventional) produced and marketed under home regulations, giving consumers on both sides of the Atlantic the choice.

A harmonious future?

GM products around the world are subject to diverse regulatory frameworks, some stringent but fair, others unduly restrictive and illogical. None of these systems is ideal, and what is needed is a global, harmonized regulatory system that is flexible enough to adapt to regional differences and different types of platform and product, while showing due respect for science-based risk assessment and sensible concerns of all legitimate stakeholders. In the EU, there is an oppressive and restrictive regulatory framework dominated by potential risks, while positive economic, environmental, and health aspects of GM technology have been largely ignored. Although organizations such as EFSA are doing their best to improve on the situation, the EU still faces deterioration of its research and development base, the loss of markets for European agricultural products and an increased dependence on food and feed imports (Mitchell 2003).

Harmonization means that regulatory requirements are streamlined and that assessments carried out in different countries are made compatible. This does not necessarily imply that all countries should have identical policies, priorities or strategies. However, countries should be able to work together at a regional level to develop and implement sustainable strategic frameworks for the development, handling and use of modern biotechnology. The discussion on regional harmonization of biosafety issues can be clustered into three categories (AU Biosafety Project 2007):

(i) *Harmonization of technical and scientific matters*. The aim is uniformity in requirements for data collection, development of norms and standards for sampling, and testing procedures. Sharing of information at national and international level is needed, for example by the creation of a database for risk assessment and risk management which will be valuable for

participating countries in their monitoring and creation of public awareness. This will also promote inter-country exchange of information and expertise.

(ii) *Harmonization of GMO-related legislation and decision-making*. This can be achieved by the creation of regional bodies, networks or laws to take GMO-related decisions thus breaking down possible oppressive trade barriers. An example is the African Model Law on Safety in Biotechnology developed by the African Union (AU) to guide member states in their development of their own national biosafety laws. This law might aim to benefit trade related areas in Africa however it embraces the *precautionary approach*, and may actually inadvertently strengthen trade barriers if African countries pay increasing attention to the international trade conflicts before setting up their national legislations. Therefore when developing such networks or laws, caution needs to be taken in order to maximize the benefits while minimizing any possible risks of GM crops.

(iii) *Harmonization of policies and recommendations*. Reaching an agreement on harmonization of regulations requires consultation, negotiation and consensus-building. National sovereignty must be acknowledged, and individual countries' priorities met. For this initiative, effective networking and communication is important: facilitating effective collaboration among policy makers, researchers, farmers, service providers, civil society organizations, government leaders and society is thus imperative. The high costs of regulation and testing of GM products also needs to be considered: many African countries lack the infrastructure, resources or capacity to implement them. Therefore, projects aiming to harmonize biosafety regulations should consider using centralized resources: an example would be where each member state contributes to a biosafety fund to form regional centers of excellence and a central biosafety clearing house. These would allow countries with weak or underdeveloped capacities to access cutting-edge research and development facilities, boosting the exchange of scientific and technical information on GMOs.

Harmonization therefore, would have many advantages: (1) regulatory authorities would benefit from experiences in other countries, both on the organizational level and on the content of risk analyses; (2) it would foster technology transfer by instilling confidence and simplifying the preparation of field trial applications; and (3) it would prevent developing countries from being used as a testing ground for field trials that would not be permitted in other countries (Bijman 1994).

The way forward is for the regulators to identify common themes and apply appropriate regulations that will lead to the development of GM crops with the long-term potential to ensure food security. The claims of critics should be considered in the context of demonstrated safety and benefits rather than unsubstantiated risks. Despite harmony at the scientific level, general agreement among the scientific community as to what constitutes a 'safe' GM product, and approvals by bodies such as EFSA, many EU national governments nevertheless illegally overrule such approvals. Misinterpretations and misunderstandings of the regulatory process and of GM crops in general must not be allowed to impede a technology that is already delivering real benefits today and promises important, sustainable benefits in the future.

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