Chapter 2
The Role of Risk Perception and Political Culture: A Comparative Study of Regulating Genetically Modified Food

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Abstract Policymakers in industrialized countries have responded differently to the perceived opportunities and threats regarding the genetic modification of agricultural food production. In particular, a biotechnology policy divide has emerged since the 1990s between North America and some countries in South America on the one hand and many countries in the European Union. This study asks whether national differences in political culture, as expressed through different levels of tolerance for uncertainty and risk affect the formulation of protective regulatory policy in the area of genetically modified food. To answer this question, the analysis applies elements of the cultural model developed by Hofstede and uses a modified version of the Margolis Risk Matrix to assess risk tolerance in regards to the regulation of genetically modified food in the United States, Canada, Brazil, and the European Union.

2.1 Introduction

The discovery of the molecular structure of deoxyribonucleic acid or DNA by James Watson and Francis Crick opened the door for the "direct, intentional alteration of the genetic materials of organisms [by] moving genes from one organism to another" [1]. The subsequent advances in and diversification of genetic modifications of agricultural food production through the technique of genetic engineering have paved the way for the expansion of biotechnology in agriculture across the globe. While industrialized countries like the United States and Canada dominate, developing nations like Argentina, India, and especially Brazil have also become major global players in agricultural biotechnology. This global expansion of genetic applications in agricultural has also sparked debate over the benefits and risks associated with them [2, 3]. Some argue that the predictability associated with

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genetic modifications in agriculture has the potential to strengthen the economies of industrialized countries, lower pesticide use, and combat hunger crises in developing countries. Others have resisted the spread and implementation of these biotechnology applications. Concerns have focused on the capacity of genetically modified foods to cross biological boundaries, causing harm to humans and the environment. However, resistance also stems from the post-material values movement of the 1960s and 1970s that highlighted negative sociological externalities of biotechnology, including the commodification of life and the increase of inequality [4].

Policymakers in industrialized countries have responded differently to these perceived opportunities and threats. A biotechnology policy divide has emerged since the 1990s between North America and the European Union (EU), while South American countries like Brazil have pursued an inconsistent policy trajectory [5–13]. The influences of socioeconomic conditions, political institutions, informal and formal participants in public policy decision-making, the media, and especially the contrasting policy implications of the "process" and "product" approaches to biotechnology regulations embraced by the US, Canada, Brazil, and EU are often cited to explain differences in policy design and implementation. This study, which highlights political culture and risk perceptions as special to understanding the complexity that characterizes this policy divide and policy inconsistencies, seeks to enhance our understanding of the remarkably different approaches taken by policymakers cross-nationally.

Do national differences in political culture, as expressed through different levels of tolerance for uncertainty and risk, affect the formulation of protective regulatory policy in the area of genetically modified food? Using consumer survey data and a detailed examination of the regulatory policies pursued in different national contexts, the study hypothesizes that varying levels of uncertainty tolerance coupled with prevailing risk perceptions either encourage the implementation of new protective policies or lead to the adjustment of existing regulations. This study applies elements of the cultural model developed by Hofstede [14] and uses a modified version of the *Margolis Risk Matrix* [15] to assess risk tolerance in different national contexts. Following a brief review of the literature about the influence of political culture and risk perceptions on policymaking, the paper compares the development of genetically modified food policy in the United States, Canada, Brazil, and European Union.

2.2 Political Culture, Risk Perceptions, and Policymaking

Discernible values and political cultures within and across countries shape citizen interactions with governments and influence policy processes. In the United States, researchers have identified a number of "major value orientations" and political cultures by region [16, 17]. Values such as individual freedom, equality, and progress, coupled with an individualistic, moralistic, and traditionalistic political

culture, have implications for policymaking. For several decades, the meaning and significance of political culture for the functioning of a democratic government has been an integral part of the scholarly discourse in political science [18–21]. Despite the volume of research that regards political culture as an important contextual variable, the intersection of political culture and policy processes has required researchers to go beyond the traditional political culture literature.

Work in the area of international management links different aspects of political culture within countries to both the operation of economic organizations and the unfolding of political processes [22, 23]. In line with Montesquieu's notion of the general spirit of a nation, Hofstede argues that the unique characteristics of political institutions, governmental arrangements, laws, and legal systems are the tangible manifestations of differences in the national identity or political culture of a given country or geopolitical region [24, 25]. Visible to the observer, these differences in political culture can be discerned, measured, and quantified into indexes applicable across different countries. Operationally, political culture may be assessed along a number of interrelated dimensions, including power distance, collectivism versus individualism, femininity versus masculinity, long- versus short-term orientation, and uncertainty avoidance.

As suggested by Hofstede, societies deal differently with ambiguities or uncertainties that are the result of advances in technology. Depending on how much uncertainty a society can tolerate, the degree of rejection or acceptance of new products by society and the corresponding legal and regulatory regime discussed and implemented by governments differ. Especially useful here is the uncertainty avoidance index developed by Hofstede, which is inversely related to the acceptance of new products [26]. The index reflects the extent to which members of a society attempt to cope with anxiety by minimizing uncertainty. The researchers provide a useful analytical tool to establish a link between political culture and policy processes. Considering several interrelated broadly conceived core cultural dimensions (e.g. power distance, collectivism, individualism, femininity, masculinity, and uncertainty avoidance) that can be reasonably generalized across countries and regions, the assessment tool developed by Hofstede offers a sound approach to understanding the influence of political culture on policy processes.

Along the lines of Charles-Louis de Montesquieu's notion of the general spirit of a nation, the researchers argue that the diversity of political institutions, government, laws, and legal systems, and so on are the manifestations of differences in the national identity or political culture of a given country. One of the critical aspects of political culture that influence policy processes is the way societies deal with ambiguities or uncertainties. While advances in technology can reduce uncertainties, the unknown health and environmental effects of new technologies, like the genetic engineering of food, can nourish uncertainties within societies. Depending on how much uncertainty a society can tolerate, governments discuss and implement different kinds of laws to deal with and reduce uncertainties. Within the broader context of different national identities in terms of their essential patterns of thinking and the subsequent emphasis of values, symbols, and rituals, Hofstede identifies five dimensions of political culture (i.e. power distance, collectivism vs.

individualism, femininity vs. masculinity, long vs. short term orientation, and uncertainty avoidance), and develops indices for each dimension usually ranging from 0 to 100 based on extensive survey research conducted in more than fifty countries.

The uncertainty avoidance index reflects the extent to which members of a society attempt to cope with anxiety by minimizing uncertainty, which is not to be confused with risk avoidance. Given the tensions between threats from the unknown and the need for predictability, the uncertainty avoidance index suggests that, in contrast to countries or regions characterized by high levels of uncertainty tolerance (e.g. Southern Europe and Latin America), societies characterized by low levels of uncertainty tolerance (e.g. Scandinavian countries and Northern America), are less confident in their ability to influence government and tend to prefer structured circumstances expressed by "more and more precise laws" [25].

In addition to the level of uncertainty tolerance among citizens of a given country, or countries across a region, different risk perceptions among policy stakeholders influence policy processes. The complexity of the policy environment in which considerations of risk arise as well as perennial confusion over how to use the concept of risk in practice compound the lack of clear information about risk. Risk is the "down side of a gamble … [which] implies a probability of outcome, and the gamble may be involuntary or voluntary, avoidable or unavoidable, controllable or uncontrollable. The total gamble in which the risk is embedded must be addressed if the risk is to be analyzed, both the upside (benefits) and down side" [27]. Thus, a risk is fairly straightforward, yet assessing its impact within a policy debate is difficult because of competing claims, issues and interests [28].

Perceptions of and predispositions toward risk are based on patterns of thinking, or mental models, [29] which can be defined as personal constructs that vary by individual and constitute a complex set of perceptions, opinions, attitudes, and beliefs used to make sense of reality [30–32]. Differences in these mental models can be noticeable, as they may affect both decision-making processes and their consequences [33, 15]. Non-expert lay observers outside the scientific community (i.e., the public) tend to rely on cognitive heuristics in their approach to assessing health and environmental risks more than experts within the scientific community [34–37]. Scholars have also considered the negative consequences that arise in the context of the expert-lay person dichotomy and have developed different models of risk perception. As a consequence, ethical concerns expressed by the public regarding major technological advances have been all but ignored by expert institutions [38]. Others argue that in addition to traditional factors like novelty and dread, concerns about "interference with nature" play a major role in accounting for the perceived risk of genetic engineering [33].

Margolis also provides a useful analytical framework for examining the influence of different risk perceptions on policymaking in the areas of health and the environment. The difference in attitude between experts and the lay public create rival mental models that affect both the choice of policy solutions and the solutions available. It is these different judgmental heuristics that create both consistencies and variation in risk evaluation. Thus, experts and the public may experience

different decisional dilemmas and varying risk perceptions. Perceptions concerning the dangers and opportunities of a given situation may lead to differences in the scope of regulatory approaches by government. To differentiate rival risk perceptions, the *Margolis Risk Matrix* suggests that an individual interprets a situation as: one that creates opportunities; one that presents threats; one that contains both opportunities and threats; or, as one that offers neither opportunity nor threat. Along the lines of any tangible costs and benefits (or dangers and opportunities), the *Margolis Risk Matrix* proposes distinct risk perceptions that can be applied to the general public and policymakers. These stakeholders often seek and rely on expert advice [15].

The specific types of risk perceptions that guide the decision-making process include: fungibility or balanced risk taking (seeing both dangers and opportunities); cautious or "better safe than sorry" risk aversion (seeing dangers but no opportunities); opportunistic or "waste not, want not" risk taking (seeing no dangers but opportunities); and, indifference or "move along, go along" risk indifference (seeing no dangers and no opportunities). The balanced risk position suggests that individuals who are aware of the dangers act to somehow trade off potential benefits. Persons who are guided in their assessment by the indifference risk position see neither dangers nor benefits and, as such, a given policy issue is off-screen and no response is to be expected. Finally, the cautious and opportunistic risk positions suggest that either dangers or benefits—but not both—guide a person's risk assessment and response to a policy issue. The combined use of the uncertainty avoidance index and the *Margolis Risk Matrix* as an analytical framework measures uncertainty tolerance across countries and regions and the prevailing risk perceptions among the relevant policy stakeholders [15].

2.3 Research Design

Relying on both the uncertainty avoidance index to understand the national or regional context and the *Margolis Risk Matrix* to assess the risk perceptions among the policymakers and the public, this study traces the policy trajectories of genetically modified food regulations in the United States, Canada, Brazil, and within the European Union between 1990 and 2006. The study hypothesizes that low levels of uncertainty tolerance and the prevalence of reasonable risk taking coupled with cautious risk perceptions encourages the formulation of stringent protective regulatory policies. On the other hand, high levels of uncertainty tolerance and the prevalence of indifference coupled with opportunistic risk perceptions among policy stakeholders encourages the continuation or adjustment of existing protective regulatory policies. Finally, regardless of low or high levels of uncertainty tolerance, the simultaneous and equally strong competition of cautious and opportunistic risk perception facilitate the development of an inconsistent protective regulatory framework.

In light of these research expectations, it is important to distinguish normal public policy from protective public policy. According to James Anderson, public policies consist of a "purposive course of action followed by an actor or set of actors in dealing with a matter of concerns." Public policies, he makes clear, are those laws and regulations "developed by governmental bodies and officials" [39]. Accordingly, protective regulatory policy, a type of policy output that is often associated with environmental regulations at the national level, is defined as a purposive action by government to enhance, protect, or maintain public health and safety in response to actual or potential hazards or threats that originate within the private sector [40–42].

In this study, the outcome of interest is the adoption of new or modification of existing protective regulatory policy in the area of genetically modified food. The uncertainty tolerance level and risk perceptions among policy stakeholders in a particular country or region are used to predict the appearance of new protective regulatory policies. Given the focus on genetically modified food, policy stakeholder representation is limited to the major regulatory policy institutions and scientific advisory committees dealing with genetically modified foods in the US, Canada, Brazil, and EU. They include the Food and Drug Administration and National Research Council in the United States, Health Canada, the Canadian National Biotechnology Advisory Committee, and the Royal Society of Canada. In regards to Brazil the focus rests on the National Biosafety Technical Commission, while the European Parliament, Commission, and Council of Ministers serve as the primary regulatory EU institutions.

The uncertainty tolerance level, defined as "the extent to which the members of a culture feel threatened by ambiguous or unknown situations," [25] is measured by the uncertainty avoidance index developed by Hofstede (see Table 2.1 for uncertainty avoidance index rankings and scores by country and region). Based on scores derived from survey research, the uncertainty avoidance index captures variations of risk avoidance attitudes across different countries and regions and provides the overall context for different policy related outcomes. It does not capture changes in uncertainty values over time nor negative attitudes towards a particular technology. For the present study, risk is defined as the assessment of the threats and opportunities presented by a potentially hazardous situation.

The uncertainty index is constructed using the country mean scores for the following three questions: (1) *Rule orientation*. Agreement with the statement: "Company rules should not be broken—even when the employee thinks it is in the company's best interest"; (2) *Employment stability*. Whether employed respondents intend to continue with their current employer either for 2 years or less, or from 2 to 5 years; and, (3) *Stress*. Expressed in the answer to the question: "How often do you feel nervous or tense at work?" The index normally has a value between 0 (weak uncertainty avoidance) and 100 (strong uncertainty avoidance).

The United States, which has an uncertainty avoidance index score of 46 out of 112 and is ranked 43 out of 50 countries and 3 regions, is characterized by high levels of uncertainty tolerance about new technologies (see Table 2.1). Canada ranks 41 with an uncertainty avoidance index score at 48. As such, Canada, which

Table 2.1 Uncertainty avoidance index (UAI) values for 50 countries and 3 regions

Score rank	Country or region	UAI score	Score rank	Country or region	UAI score
1	Greece	112	28	Equador	67
2	Portugal	104	29	Germany FR	65
3	Guatemala	101	30	Thailand	64
4	Uruguay	100	31/32	Iran	59
5/6	Belgium	94	31/32	Finland	59
5/6	Salvador	94	33	Switzerland	58
7	Japan	92	34	West Africa	54
8	Yugoslavia	88	35	Netherlands	53
9	Peru	87	36	East Africa	52
10/15	France	86	37	Australia	51
10/15	Chile	86	38	Norway	50
10/15	Spain	86	39/40	South Africa	49
10/15	Costa Rica	86	39/40	New Zealand	49
10/15	Panama	86	41/42	Indonesia	48
10/15	Argentina	86	41/42	Canada	48
16/17	Turkey	85	43	USA	46
16/17	South Korea	85	44	Philippines	44
18	Mexico	82	45	India	40
19	Israel	81	46	Malaysia	36
20	Colombia	80	47/48	Great Britain	35
21/22	Venezuela	76	47/48	Ireland (Republic of)	35
21/22	Brazil	76	49/50	Hong Kong	29
23	Italy	75	49/50	Sweden	29
24/25	Pakistan	70	51	Denmark	23
24/25	Austria	70	52	Jamaica	13
26	Taiwan	69	53	Singapore	8
27	Arab countries	68			

Source Hofstede [24], p. 113

serves as a control case in comparison to its southern neighbor, ranks slightly stronger in terms of uncertainty avoidance than the United States. In contrast to the United States and Canada, South American countries like Brazil are generally characterized by higher levels of uncertainty tolerance. Based on an index score of 76, Brazil ranks 21/22. Turning to Europe, an overwhelming majority of EU member states, including Germany, France, Italy, and Spain, with respective uncertainty avoidance index scores of 65, 86, 75, and 86, rank much higher on the uncertainty avoidance index. Similar to Brazil, this suggests low levels of uncertainty tolerance—and thus, presumably, a desire for more stringent regulatory policies compared to their North American counterparts. With the notable exception

of the United Kingdom, the low uncertainty tolerance countries include the dominant policy actors within the EU. Based on a combined average, Germany, France, Italy, and Spain rank 18 with an average uncertainty avoidance index score at 78.

For the analysis, the prevailing risk perceptions in a given country or region are identified along the balanced, cautious, opportunistic, and indifferent risk trajectories. Within the balanced risk position, stakeholders perceive risk in terms of high threat for the well being of society or the individual but also high opportunity for gaining tangible benefits. Public opinion and official policy statements or actions that present trade-offs between these threats to the well being of society and socioeconomic benefits illustrate the balanced risk perception.

From a cautious risk perspective, stakeholders perceive risk in terms of high threat to the well being of society or the individual and low opportunity for gaining tangible benefits. Public opinion and official policy statements or actions that strongly emphasize threats to the well being of society relative to socioeconomic benefits illustrate the cautious position. An opportunistic risk perception is characterized by low threat to the well being of society or the individual and high opportunity for gaining tangible benefits. Public opinion and official policy statements or actions that overemphasize socioeconomic benefits relative to threats illustrate the opportunistic risk assessment. Finally, stakeholders guided by indifference perceive risk in terms of low threat to the well being of society or the individual and low opportunity for gaining tangible benefits. Public opinion and official policy statements or actions that neither emphasize threats nor socioeconomic benefits to society illustrate the indifferent risk perception.

Poll results and document analysis of official policy statements, reports, and regulations were analyzed to assess the respective risk perceptions of policy stakeholders in the United States, Canada, Brazil, and European Union. Admittedly, data derived from document analysis alone has shortcomings. It is not possible, nor does this study claim, to trace regulators' thought processes. Rather, the evidence here examines the prevailing risk perceptions over time. Given the inconsistent availability of opinion polls regarding the genetic modification of food between 1990 and 2006, this study relies on different surveys and opinion polls conducted by research organizations and academic institutions. Similar question wording regarding the public's attitudes towards genetically modified food across different survey administrations allow for a comparison of risk perceptions across countries over time.

For the United States, the sampling period extends from 1990 to 2006. Relevant opinion surveys include the 2001–2006 Pew Initiative on Food and Biotechnology, a 1999–2000 Gallup Poll, and a wide variety of other studies conducted by research organizations and policy institutes such as the Food Policy Institute at Rutgers University [43–55]. For the EU, the 1991–2005 Eurobarometer surveys capture the attitudes regarding the risk perceptions associated with genetically modified foods, while public opinion polls conducted by a number of Canadian academics and research organizations (e.g., Decima Research and Pollara Research) illustrate the relevant Canadian attitudes between 1997 and 2006 [56–59]. While there is an extensive array of opinion polls available for the United States and the EU, the

range of surveys to understand the attitudes towards genetically modified foods in Brazil remains somewhat limited. Nevertheless, the scientifically-based public opinion polls sponsored by the Brazilian Institute of Public and Statistical Opinion (IBOPE) as well as those conducted by scholars in regards to specific segments of society allow for accurately capturing the relevant attitudes between 2001 and 2006 [60–64].

2.4 Risk Perceptions and Policy Trajectories

2.4.1 The United States

The existence of genetically modified (GM) food in the United States became widely known with the approval of recombinant bovine growth hormones in 1993, the commercialization of the first genetically engineered tomato in 1994, and the approval of other genetically engineered products like cotton, soybeans, and squash by 1996. Based on a pro-business and anti-regulatory consensus pursued in tandem by the United States government and the influential biotechnology industry, the relevant regulatory framework was well established by the 1980s and reflected the "optimism about progress in the natural sciences and related technological innovations on the conviction that society would benefit more from GM technology if governments would interfere as little as possible and avoid the introduction of specific legislation" [65]. Following the regulatory adjustments proposed by the President's Office of Science and Technology Policy and enshrined in the 1986 *Coordinated Framework for Regulation of Biotechnology,* the Food and Drug Administration in its 1992 statement of policy, *Foods Derived from New Plant Varieties,* reiterated the product-based approach of the regulatory regime. Accordingly, genetically modified foods are held to pose no safety concerns because "many of the food crops currently being developed with gene splicing techniques do not contain substances that are significantly different from substances already in the diet" [66].

Within the context of emphasizing the safety or minimal dangers to human health and the environment of these modified foods, minimize regulatory burden, and facilitate the development and commercialization of such products, public opinion and especially official statements associated with the Food and Drug Administration highlighted the tangible spillover benefits of genetically modified food for society. The public, largely unaware of the major technological changes in agricultural food production, uninformed regarding the potential negative environmental effects of genetically modified food, and largely excluded from the relevant decision-making processes that ultimately determined the commercial marketing of genetically modified food, had little basis for assessing the potential dangers of engineered food. Within this broader context of low awareness and a regulatory approach that limited public input, concerns regarding genetically

modified food among the public were not well organized or given much credence. While the public knew little about biotechnology applications in general, perception of genetically modified food in the context of biotechnology applications was generally positive and emphasized consumer benefits of such applications [51, 55, 67, 54]. Support rates consistently hovered around 70 % during the 1990s, illustrating both considerable support and "remarkable stability of people's opinions on biotechnology in the US" [68].

This positive public opinion embedded within a utilitarian worldview of technological advances and coupled with the government's strong support for scientific research on food genetics as well as the courts' positive assessment of biotechnology regulations framed the oversight functions at the agency level [69]. Staffed with many former employees of major agribusiness corporations, the Food and Drug Administration cooperated closely with entities like Monsanto and touted the benefits of GM food, as illustrated by the approval of the recombinant bovine growth hormone in 1993 [70–74]. As a consequence of this mutually opportunistic risk perception among regulators and agribusiness representatives, public statements by officials within the agency emphasized that genetic engineering of food would contribute to "enhanced resistance to disease, pests and herbicide in major field crops. For biotechnology techniques applied to feed grain and forage crop production, consumer effects will almost exclusively be cost reduction" [75].

In light of these favorable claims, and the concerted lobbying efforts by agribusiness, [76] the Food and Drug Administration's Center for Food Safety and Applied Nutrition generally opposed labeling requirements for genetically modified food unless their nutritional content was substantially modified. The implementation of a mandatory labeling requirement would "increase the cost of these foods to consumers and would disrupt our complex food distribution system" [77]. Although the Food and Drug Administration provided guidance to the industry as to how they may voluntarily label genetically modified foods, the agency also maintained that "bioengineered foods [do not] differ from other foods in any meaningful or uniform manner, and that GM foods as a category of food products do not present any different or greater safety concern than foods developed by traditional plant breeding" [69].

That genetically modified food was considered unlikely to pose any hazardous risk to the public health became apparent during the Food and Drug Administration's approval of numerous genetically modified products between 1994 and 2007 [78]. The Flavr-Savr tomato offers a case in point. Developed by Calgene, a small company based in California that in 1996 was taken over by Monsanto, [79] the Flavr-Savr was subjected to a comprehensive approval process by the Food and Drug Administration. In its document on *Foods Derived From New Plant Varieties* and other public statements, the agency viewed the genetically modified tomato as beneficial to the consumer and deemed it to pose no environmental risks [66, 80, 81]. Genetically modified foods like the Flavr-Savr were characterized by "improved shelf-life, processing characteristics, flavor, nutritional properties, and agronomic characteristics, such as tolerance to chemical herbicides and resistance to pests and disease" [76].

Although the genetically modified tomato was eventually taken off the market in 1997 due to poor yield in the unsuitable sandy soil and humid climate of Florida, the Food and Drug Administration stated during the initial approval process that "the intended effect of the altered RNA of the new PG (polygalacturonase) gene that suppresses the breakdown of pectin in Flavr-Savr tomatoes does not raise safety questions. Pectin is a part of many fruits and is generally recognized as safe (GRAS) substance" [80].

As the approval process of genetically modified food developed between 1994 and 2007, the public continued to associate genetically modified food with mostly low threats to human health and saw the possibility of gaining benefits from it. Poll results from the mid- to late-1990s seemed to confirm the public's positive attitudes towards genetically modified food. Assuming that engineered food would improve the quality of life and benefit society, a majority of the public continued to believe that tangible gains could be derived from genetically modified food [46, 82]. However, the formation of the Organic Consumer Association in the late 1990s, the anti-GM food campaigns organized by voters to require mandatory labeling during the early 2000s, and surveys conducted by the Pew Initiative on Food and Biotechnology between 2001 and 2006 also illustrate a shift in public opinion characterized by the emergence of a visibly cautious risk perception mixed with elements of an opportunistic risk position.

In contrast to the 1990s, when public attitudes were generally supportive of genetically modified food and few consumer interest groups considered potential biotechnology threats to be a high priority, a much more skeptical public has emerged over the past decade. Survey results from the Pew Initiative on Food and Biotechnology have since 2001 indicated that a relatively small segment of society, around 25 %, expresses outright "support for genetically modified foods" [83]. Parallel to this mixture of opportunistic and cautious risk perceptions, low knowledge and awareness about food biotechnology applications continued to play a major role in public opinion polls, which through 2006 showed that a majority of the public had not heard much about biotechnology or knew very little about the various biotechnology applications [46, 49, 51, 84, 85]. According to Mark Winston, a close observer of the biotechnology debate, the public "has been besieged by sound bites and public relations hype rather than exposed to comprehensive and informed debate and dialogue" [86].

Within this broader context, Americans remained confident in the ability of the appropriate regulatory agencies to guarantee the introduction of safe biotechnology products and ensure the maintenance of public health [87]. As these public perceptions evolved, the Food and Drug Administration continued to emphasize the low threats and benefits of genetically modified food by referring to the "substantial equivalence" principle (i.e., the undistinguishable nature of genetically modified food from conventional food). Accordingly, a 1995 policy statement by the Food and Drug Administration stipulated that no formal review was needed for engineered food:

> Based upon the extensive history of safety of plant varieties developed through agricultural research, the Food and Drug Administration has not found it necessary to review the safety of food derived from new plant varieties. [Moreover] the Food and Drug Administration is not aware of information that would distinguish genetically engineered food as a class from food developed through other methods of plant breeding [88].

The belief that biotechnology "greatly expands the pool of potentially useful traits available" and the minimal concerns regarding allergic reaction and antibiotic resistance characterized the agency's fundamental perspectives on genetically modified food as both beneficial and safe [89].

The StarLink corn saga that played out between 1997 and 2001 shook public confidence in the food manufacturing industry but this crisis "did not lead to a visible consumer reaction, like the shoppers panic that would surely have occurred in Europe" [71]. Press reports and public statements from Friends of the Earth suggested a widespread "commingling" of StarLink, a genetically engineered corn plant with the ability to encode the Bt protein Cry9c that was not approved for human consumption, with non-genetically modified corn destined for human consumption. Tests confirmed by the Food and Drug Administration in 2000 found StarLink traces in taco shells [90]. Despite these events and the recall of various foods by producers in response to the Food and Drug Administration's continued StarLink investigation, the agency's approach to regulating genetically modified food did not change during this period. Not only did the agency maintain its 1994 policy of voluntary consultation with the biotechnology industry to assist in the safety assessment of genetically modified products entering the food chain, the Food and Drug Administration also continued to stress that genetically engineered food was safe and beneficial.

Agricultural research has shown that "most of the substances that are being introduced into food by genetic modification have been safely consumed as food [already] or are substantially similar to such substances" [88]. The Food and Drug Administration continued to emphasize the safety of genetically modified food, as illustrated by James Maryanski's testimony before the Senate Committee on Agriculture, Nutrition and Forestry in the fall of 1999. Maryanski, the agency's biotechnology coordinator, stated that, "In most cases, these genes [recombinant DNA] produce proteins, or proteins that modify fatty acids or carbohydrates in the plant, in other words, common food substances" [91]. Before a Senate hearing a year later, Joseph A Levitt, the Food and Drug Administration's director of Food Safety and Applied Nutrition, echoed these sentiments of no known dangers [92]. The agency continued to stress the benefits associated with food biotechnology, including the reduction of chemical pesticides and herbicides and the possible improvement of food's nutritional properties [93].

The regulatory changes proposed since 2000 by the Food and Drug Administration, coupled with the agency's long-standing awareness that the introduction of genetically modified proteins into food may cause allergic or toxic reactions in consumers, did not challenge the prevailing opportunistic risk perception within the agency. In response to public concerns, the Food and Drug Administration in May 2000 proposed changing the voluntary evaluation or consultation procedures that

guided the pre-market notification program for genetically modified food. Until then, food companies were not required to seek pre-market consultation on new genetically modified products.

Officially announced on January 18, 2001 in conjunction with a proposal for voluntary labeling of genetically engineered food, the adjusted consultation rule required genetically modified food developers to submit data regarding plant-derived genetically engineered food at least 120 days before releasing an engineered food product into the market [94]. This mandatory pre-market notification proposal, later complemented by guidance on the evaluation of genetically modified plants intended for food use and posting of the consultation results on the Food and Drug Administration website, appeared to represent a fundamental change in the agency's risk perception [95]. However, while the Food and Drug Administration has continued to make the consultation results available online, it dropped the mandatory pre-market notification and voluntary consultation plan in 2003 and reiterated that transferred genetic materials do not pose any significant safety concerns [94–98].

Guided by an opportunistic risk perception, the Food and Drug Administration remained firm on the issue of mandatory genetically modified food labeling. The agency strongly believed that food created through biotechnology was identical to food developed using conventional plant breeding methods. Thus, while the Food and Drug Administration agreed to voluntary labeling, as suggested by the 2001 document, *Draft Guidance for Industry*: *Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*, [99] it did not require any special labeling to distinguish GM food from non-GM food [96]. Policymakers have not changed their views on labeling or their risk assessment of genetically modified food despite mounting pressures, namely: consumer concerns and demands for the right to know which foods have been genetically engineered; repeated introduction of a bill in Congress to require genetically modified labeling, known as the *Genetically Engineered Food Right-to-Know* Act (H.R. 5269 2006); the enactment or serious consideration of food labeling regulations at the state level; and, recent food scares such as the ProdiGene affair.

The ProdiGene affair, which involved field trials of pharmaceutical maize conducted by Texas-based ProdiGene to produce a vaccine that prevents diarrhea in pigs influenced but did not change prevailing risk perceptions within the Food and Drug Administration. Ultimately, the agency decided to order the destruction of fields in Nebraska and Iowa that were contaminated with genetically modified corn. Since the end of 2002, the agency has proposed strategies to minimize the inadvertent introduction of genetically modified materials into agriculture, the environment, and the food supply. Despite other incidents (e.g., the Ventria affair, in which California-based Ventria Bioscience developed transgenic rice varieties to be openly grown in trial plots located in the rice growing area of California's Central Valley), the Food and Drug Administration's emphasis on the minimal dangers and discussion of the tangible benefits of food biotechnology suggest the opportunistic risk perception within the agency continues to prevail [100–102].

2.4.2 Canada

The U.S. proposal to release engineered organisms for field testing sparked a debate in Canada about biotechnology application in the early 1980s. Policymakers and national advisory committees showed strong support for biotechnology. Published by the Canadian Ministry of State for Science and Technology in 1980, *Biotechnology in Canada* laid the policy groundwork for the "promotion and development of biotechnology" and the establishment of a private-sector task force on biotechnology [103]. With the aim of accelerating commercial progress and maintaining competitiveness relative to other countries in biotechnology research, the Canadian government invested millions of dollars to institutionalize the 1983 *National Biotechnology Strategy* and fund national biotechnology research centers. This in turn led to the establishment of the National Biotechnology Advisory Committee, whose members—drawn from academia, the private sector, and government—were charged with providing advice to the Science and Technology ministry on a national biotechnology strategy.

In 1984, the first report published by the National Biotechnology Advisory Committee foresaw an active role for the federal government in shaping biotechnology policing and used the government to "take advantage of the current window of opportunity in biotechnology" [103]. Sensitive to domestic and international pressures to develop biotechnology, senior officials within the Canadian agriculture bureaucracy also emphasized the benefits of new biotechnologies and stressed the need to develop relevant regulations that would protect human and animal health while safeguarding the environment and promoting a competitive advantage for industry [103, 104].

Although the potential hazards of genetically modified organisms were actively debated in response to a 1989 report by the Ecological Society of America, the Canadian government did not reconsider its favorable stance on biotechnology and continued with the formulation of a relevant regulatory framework. Driven by the consensus to achieve progress through biotechnology and the increasing conviction that engineered food products were as safe as conventional products, policymakers began to lay the foundation for the 1993 *Regulatory Framework for Biotechnology*. While the document disregards most social, economic, and ethical issues raised by the new technologies, the regulatory framework coupled science-based risk assessment with other internationally recognized and established risk assessment concepts. By then the notions of *familiarity* and *substantial equivalence*, advocated by various national and international organizations, including the OECD, National Academy of Sciences in the US, United Nations' Food and Agriculture Organization, and World Health Organization, became the main regulatory principles guiding Canadian policymakers in crafting the regulation of biotechnology applications [105–107].

Guided by these principles and relying on "information and advice from scientific networks and advisory committees in developing the genetically modified policy and regulatory framework" [108]. Within a regulatory environment where

participation in decision-making is exclusionary and judicious, the Canadian government avoided public and parliamentary debates and decided to divide regulatory responsibilities among Environment Canada, Health Canada, and the Canadian Food Inspection Agency. Environment Canada assumed responsibility for assessing the environmental risks of biotechnology products and Health Canada, the Canadian counterpart to the U.S. Food and Drug Administration, was charged with the regulation of genetically modified food based on B.28.001, B.28.002, and B.28.003 of the 1920 Food and Drugs Act.

Yet, despite these regulatory adjustments, there are important differences between Canada and the United States. Under Division 28 of the Food and Drug Regulations (Novel Foods), Health Canada considers any genetically modified food a *novel* food by definition and follows a formal pre-market notification policy that requires manufacturers and importers of genetically modified food to submit data to Health Canada for a pre-market assessment. Furthermore, Canada's consolidation of the food inspection service during the 1990s culminated in the establishment of the Canadian Food Inspection Agency, which is responsible for monitoring and implementing the policies of Environmental Canada and Health Canada [107, 109, 110].

That the assessment of novel food by Health Canada made use of the substantial equivalence principle became apparent with Health Canada's approval of genetically modified food based on the *Guidelines for the Safety Assessment of Novel Foods* [111]. Operating under these guidelines and in some cases hastened by major international agribusinesses like Monsanto, Health Canada has approved more than 90 novel foods since the mid-1990s, ranging from novel varieties of corn and potatoes to soybeans and tomatoes [72, 112]. As in the United States, the Flavr-Savr™ tomato made its debut in the mid-1990s and like its southern neighbor, the Canadian government did not require any labeling. Comparing the Flavr-Savr™ tomatoes to other non-genetically engineered counterparts, Health Canada "found no difference in composition or nutritional characteristics. Based on Calgene's information, the Department found the Flavr Savr to be as safe and nutritious as other tomato varieties" [113]. By acknowledging that this genetically modified product is engineered to "ripen longer on the vine than other tomatoes in order to more fully develop its flavor," Health Canada also acknowledged the benefits of the novel tomato.

As the approval of genetically modified food continued to rely on the assessment of scientists working for the government and a regulatory framework that did not provide for independent scientific review and public involvement in product assessment, no major public controversies regarding the regulatory framework and genetically modified foods emerged [105]. In fact, poll results illustrate that the public was scarcely aware of these applications. A national survey conducted in 1997 by Einsiedel and Medlock asked: "What comes to mind when you think about biotechnology in a broad sense, that is, including genetic engineering?" Only one third of respondents answered this open-ended question [59]. A second national opinion poll conducted in 1999 confirmed public unfamiliarity with biotechnology applications [58].

However, as nongovernmental organizations became increasingly visible in opposition to biotechnology applications and the news media began paying more attention to covering biotechnology events, awareness increased. A national survey conducted in 2000 revealed a significant change in the level of public awareness. In response to the same open-ended question concerning biotechnology and genetic engineering, more than 75 % of respondents ventured an answer [59]. Since 2001, overall familiarity with and support of biotechnology has steadily grown [56, 114]. At the same time, "there remains continued and widespread wariness about GM food," according to Pollara Research [114].

Stressing that genetically modified products are not inherently different from their naturally grown counterparts, the Canadian government has continued to emphasize the safety and benefits of genetically modified food as economically beneficial and innovative. The approval guidelines for novel foods, released in 1994, the *Canadian Biotechnology Strategy* published in 1998, and a report titled *Biotechnology Transforming Society* published by the Canadian Department of Foreign Affairs and International Trade in 2003 all emphasized the benefits associated with the new technology [115–117]. Similar to the United States, a scientifically rational focus embedded within an opportunistic risk perception remained the hallmark of the regulatory food biotechnology framework in Canada, despite increasing international attention to genetically modified food and domestic skepticism regarding the Canadian genetically modified food regulatory framework at the dawn of the twenty-first century. In 2000, the Codex Alimentarius Commission, formed jointly by the World Health Organization and the Food and Agriculture Organization, enumerated several universal principles regarding the safety of genetically modified food and called for explicit labeling of such food products [118].

In light of the increasing controversies around genetically modified food in Canada, the Royal Society of Canada, an independent panel of scientists, published *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology* in 2001. This report pointed to significant shortcomings in the existing risk assessment procedures used by the Canadian government and concluded that the Canadian regulatory framework failed to conform to scientific standards.

Filled with more than 50 recommendations, including a call to make public experimental protocols and data, *Elements of Precaution* urged the Canadian government to broaden and strengthen the biotechnology regulatory system. The government had already begun to move in this direction, reconsidering the 1983 *Canadian Biotechnology Strategy* and establishing a new advisory body, the Canadian Biotechnology Advisory Committee, in the late 1990s. In response to the Royal Society of Canada, the government announced that it would make changes to its risk assessment procedures. However, the government's *Action Plan*, a series of progress reports published in 2001, does not indicate any fundamental regulatory changes—nor does the government's assessment of labeling as expensive and impractical [107, 119].

Though the regulatory approach remains fundamentally unchanged, public acceptance of biotechnology applications changed considerably between 1997 and

2006—a trend that has softened the opportunistic risk perception of genetically modified food among the Canadian public in favor of a more cautious approach. Although survey results show a decrease in approval regarding the acceptability of various biotechnology applications, including genetically modified food, public opinion remained generally favorable into the mid-2000s. In 1997, 67 % of the public *definitely agreed/agreed* that genetically modified food was useful; by 2000 the equivalent figures dropped to 57 for the combined categories. For the same time period, risk perceptions about genetically modified food remained high, while a decreasing but still substantial percentage of respondents remained supportive of encouraging genetically modified food applications in 2001. As indicated by focus group studies that were conducted since 2001, Canadians have become increasingly skeptical of genetically modified food with a substantial segment of society expressing the belief that specific biotechnology applications, such as engineered fish and agricultural products, will have more negative than positive effects [56, 114].

2.4.3 Brazil

A relatively orderly policy process and consistent risk perceptions underpinned the regulation of genetically modified foods in the United States and Canada. In contrast, the regulatory policy trajectory in Brazil was one characterized by paradoxes and mutually exclusive and competing risk perceptions within and at different levels of government. Brazil's food biotechnology regulatory framework can be traced to 1986. In that year, a state-owned research enterprise associated with the Ministry of Agriculture, Livestock, and Supply, the Empresa Brasileira de Pesquisa Agropecuária or Brazilian Agricultural Research Enterprise, successfully created the country's first genetically modified plant [120]. At this time, an overarching regulatory framework governing biotechnology applications did not exist. The beginnings of such a framework, profoundly influenced by Brazil's strong consumer protection movement in the wake of Brazil's democratic transition in the mid 1980s, were included in Article 225 of the 1988 Federal Constitution. It required the national government to "preserve the diversity and the integrity of the genetic patrimony of the country" and "control the production, commercialization and use of techniques, methods and substances that pose a risk to life, the quality of life and the environment" [121, 122].

Convinced by the appropriateness of the precautionary principle, the regulatory framework continued to evolve with Brazil signing the Convention on Biological Diversity at the United Nations Conference on Environment and Development in Rio de Janeiro in 1992. This Convention, designed as a practical guideline to realize the principles of Agenda 21 and signed by more than 150 governments including Canada and the EU, but not the United States, sparked Brazil's initial policy response under the Presidency of Fernando Henrique Cardoso (1995–2002). Particularly, the policy aimed at restricting both the release of genetically modified organisms into the environment and commercialization of food derived from

transgenic crops. The Cardoso government, known for its implementation of market-oriented and modernizing reforms, envisioned a protective regulatory framework whereby the federal government would regulate approved biotechnology research through the Comissão Técnica Nacional de Biossegurança or National Biosafety Technical Commission. Furthermore, the administration favored a moratorium of planting of transgenic seeds for commercial purposes between 1995 and 1998; and, based on proper labeling, the commercialization of genetically modified products [13].

A major clarification of Brazil's legal and regulatory framework occurred with the passage of the 1995 Law of Biosecurity, number 8,974, which continued to rely on the EU's established norm of the precautionary principle. The law authorized the government to form a new regulatory institution, the Comissão Técnica Nacional de Biossegurança, charged with overseeing the "experimentation, registration, use, transportation, storage, commercialization, liberations, and waste removal of genetically modified materials" [13]. In order to pursue these regulatory goals within the broader institutional authority of the Ministry of Science and Technology, the 18 commission members, appointed for 2 years on a rotating basis by the Minister of Science and Technology, include representatives from the federal government, scientists, experts with scientific and technical knowledge in animal, plant, environment, and health sciences as well as civil society specialists in consumer defense and family farming. In addition to developing standards and norms in the areas of biosafety hazards and risks associated with genetically modified organisms, the actual approval process of transgenic foods requires the Comissão Técnica Nacional de Biossegurança to submit documentation to the Ministries of Agriculture, Livestock and Food Supply, Health, and Environment. Despite its diverse membership and regulatory scope, the commission has also served as a tool for policymakers in the department of agriculture to emphasize the economic and technical aspects of transgenic crops, while excluding environmental, health, and other social concerns [123, 124].

A complex web of legal and regulatory controversies unfolded following the passage of the biosecurity law. It began with the commercialization of Monsanto's roundup ready soybeans, which in reference to famous Argentine footballer Diego Armando Maradona are also known as Maradona soybeans in Brazil. In 1998, the Comissão Técnica Nacional de Biossegurança (13 votes in favor, one against, and one abstention) permitted the commercialization of Maradona soybeans. With no strings attached, this decision did neither require an environmental impact statement or labeling of the genetically modified product. Deliberating within the context of mounting pressure by Monsanto and its strategic partnership with Empresa Brasileira de Pesquisa Agropecária, the commission's technical report emphasized that "genetically modified foods do not offer risks to the environment or to health" [125]. However, this regulatory stance ignored a previous court order that ordered the pro-transgenic Ministry of Agriculture, led by agriculture minister Marcus Vincius Pratini de Moraes, to deny Monsanto the registration of roundup ready soybeans in Brazil [74, 126, 127].

A series of intense legal wrangling followed. In September 1998, a non-governmental organization and the country's most prominent consumer protection association opposed to genetic modified foods, the Instituto Brasileiro de Defesa do Consumidor or Brazilian Institute in Defense of the Consumer, argued that Maradona soybeans are substantially different than conventional soybeans. In protest to the Comissão Técnica Nacional de Biossegurança's decision, the consumer defense organization also withdrew its civil society representative from the commission and filed a lawsuit before the 6th Civil Law Circuit in Brasilia arguing that the decision ignored possible adverse effects of biotechnology on human health. Moreover, Comissão Técnica Nacional de Biossegurança's approval process violated the Federal Constitution, which required an environmental impact statement to plant genetically modified soybeans and the labeling of such products. Drawing on an international anti-genetics network and relying on banners that stated *Fankensoya: don't swallow it*, Greenpeace joined the Instituto Brasileiro de Defesa do Consumidor to challenge Comissão Técnica Nacional de Biossegurança's decision. On June 28, 2000, the Federal Court agreed with the plaintiffs and upheld the precautionary principle incorporated into the environmental provision of the Brazilian Constitution. Accordingly, the court reversed the decision handed down by the commission and required an environmental impact statement, crop segregation, and labeling [128–131].

The court decision and the justification provided by the Federal Judge, Antinio Souza Prudente, caused further controversies among the business and scientific communities. Stating that the "irresponsible spread of progress in genetic engineering would lead to damaging de-regulation of the global economy, that may at the beginning of the new millennium lead to a civilization bearing alien creatures …," [132] this ruling, unsuccessfully appealed by the federal government and Monsanto, paved the way for a judicial moratorium on genetically modified field trials that effectively lasted until 2003. As businesses and scientists, supportive of genetically modified products, reacted strongly to the judge's anti-science word choice, the government defended transgenic foods and lauded the work of the Comissão Técnica Nacional de Biossegurança. Signed by the President's Chief of Staff and six ministers, including the Ministers of Science and Technology, the Environment, Agriculture, Justice, and Health, the government released a communiqué defending the use of genetically modified foods. It stated that the commission considered "possible risks to human and animal health and to the environment" [133] and claimed that "the government understands that Brazil cannot be outside this technology (of transgenics) or any other which might bring benefits to the country and its citizens" [134]. The Minister of Agriculture, Marcus Vincius Pratini de Moraes, accusing the non-governmental organizations of being sponsored by multi-national corporations, favored the cultivation of genetically modified foods [135]. In alliance with the Empresa Brasileira de Pesquisa Agropecária, which controlled more than 50 % of the national soybean seed production, Pratini added that "the sales of agrotoxins in Brazil could drop by 50 % with the dissemination of glyphosate-resistant GM soybeans [and] that Brazilian agriculture would be less competitive if farmers did not plant transgenic crops" [126].

Opposition to the use of genetically modified foods formed at the state level of Brazil, thereby adding another layer of competing risk perceptions. With the goal to strengthen the competitive advantage in the production of non-genetically modified crops exported to the European Union and based on a political platform that emphasized environmental protection, public health, and humans before profit, the newly elected Worker's Party government under the leadership of Olivio Dutra declared the southern state of Rio Grande do Sul free of genetically modified seeds (zona livre dos transgenicos) in 1999. Following this declaration, the State Secretary Office of Agriculture supported a ban on genetically modified crops to both strengthen soybean exports to Europe and protect public health.

These actions by a state that grew the most soy prompted 25 non-governmental organizations to form *For a Brazil Free of Transgenics*. It opposed the cultivation and commercialization of genetically altered agricultural products and argued that the effects of these products pose health risks. The efforts of *For a Brazil Free of Transgenics* resulted in legislation that outlawed the cultivation of transgenic seeds in the states of Santa Catarina, Mato Grosso do Sul, Pará, and Rio de Janeiro [136, 74].

Despite opposition at the state level and court rulings banning the commercialization of genetically modified crops, roundup ready soybeans spread rapidly across the country. Brazil's neighbor, Argentina, authorized the sale of these genetically modified soybeans in 1996. Ironically, farmers in the north of Rio Grande do Sul had been smuggling the transgenic seeds into Brazil from Argentina and illegally planting them for years. Perceived as easier to manage compared to their conventional counterpart, estimates suggested that the planting of such crops in this state increased from 15 % in 1999 to 80 % in 2004. As a result, the federal government, under its new president, Luis Inácio Lula da Silva (2003–2010), intervened to resolve the emerging legal conflicts. Officials, like federal deputy Darcisio Perondi, called for the immediate release of genetically modified soybeans arguing that "51 % of the worldwide soybean harvest is transgenic, and growing by around 20 % every year … Transgenic crops benefit the economy and the environment as they do not require the use of agrotoxins and therefore more is produced in a smaller space and thus biodiversity is protected" [126]. By early 2003, it was also clear that over 10 % of the national 49 million tons harvest were transgenic. These facts and the government's early launch of the nationwide *Zero Hunger Program* made the destruction of such a large amount of foodstuff economically and politically unfeasible [137, 138].

In the face of these challenges and confronted by a legal environment that can be described as regulatory anarchy, the Lula administration maneuvered to take a policy stance on genetically modified foods—a difficult undertaking due to divisions and competing risk perceptions among government officials. Initially opposed to genetically modified crops, Lula acknowledged that there was "a very serious debate [about transgenic crops] within the government, because at some point we will have to say whether we are in favor or opposed. I have been strongly opposed politically today scientifically, I have doubts" [131]. Ambiguous at best, others took a much clearer stance. The Minister of Agriculture, Roberto Rodrigues, was a strong supporter of biotechnology, the Minister of the Environment, Maria Silva, an

environmental activist, was opposed to transgenic food, while the head of the Brazilian Agricultural Research Enterprise, Clayton Campanhola, argued that genetically modified crops "will only be released when there is sufficient information to guarantee that there is no threat to biosecurity" [131]. Within this environment of competing and sometime ambiguous risk perceptions and faced with increasing pressure projected by organized farmers like the Federation of Farmers of Rio Grande do Sul, President Lula, despite the opposition from within government and environmental advocates, sent provisional measure 113 to Congress. Approved by Congress as law 10688 in April 2003, the measure permitted the sale of genetically modified soybeans until January 2004 and required these crops to be segregated and labeled [139–141].

Another wave of presidential decrees and provisional measures followed in order to address the legal conflicts created by the illegal planting and sale of genetically modified soybeans. Although they ultimately legalized the planting and sale of Maradona soybeans, these ad hoc and often temporary measures did not address the structural underpinnings of the existing biotechnology regulatory framework. In an attempt to do so, the new Law of Biosecurity (number 11,105), passed by Congress on March 2, 2005, revoked the 1995 Law of Biosecurity and all of the previous provisional measures. The law authorized the newly created National Council on Biosecurity under the Office of the President to formulate and implement a national biosafety policy as well as question decisions made by the Comissão Técnica Nacional de Biossegurança.

In contrast to the 1995 law, however, the reworked commission, which operates independently from the National Council on Biosecurity and whose membership increased from 18 to 27, served as the sole decision maker to approve the commercial release of transgenic organisms. More powerful than ever, the Comissão Técnica Nacional de Biossegurança became an object for both pro- and anti-transgenic camps. While tensions and polarization characterized the decision making process, the Comissão Técnica Nacional de Biossegurança, continued to weigh the risks of transgenic foods and, as of July 2011, has approved 31 such products [126, 142–144].

Parallel to the wide range of inconsistencies that surrounded the initial implementation and subsequent reorganization of the regulatory framework of genetically modified organisms, public opinion revealed consistent patterns. National surveys conducted by the Brazilian Institute of Public and Statistical Opinion in 2001, 2002, and 2003 showed that a clear majority preferred non-transgenic food over their conventionally grown counterparts. More than 70 % preferred the former, while about 15 % favored genetically modified crops. As the public became considerably more aware of such crops between 2001 and 2003, Brazilians remained skeptical about them. In fact, a substantial majority associated specific risks with genetically modified food or rejected the planting of transgenic crops until the potential risks associated with them are better understood. Accordingly, more than half were concerned that genetically modified food could damage the environment and nearly two-thirds thought that such food could pose a threat to human health. Consistent with this highly skeptical assessment, more than 70 % opposed planting of

genetically modified crops [60–62]. Some of these patterns have also been confirmed by other studies. Focusing on the attitudes of young Brazilians between the ages of 16 and 24, Massarani and de Castro Moreira found that 66 % perceived biotechnology in food as socially useful. At the same time, 78 % expressed a strong sense of risks associated with this technology [63, 64].

2.4.4 The European Union

As government agencies, agribusinesses, and biotechnology firms in the United States and Canada proceeded with the commercialization of genetically engineered food and the regulatory framework for food biotechnology took different turns in Brazil, the policymakers within the EU, viewing biotechnology applications as a novel process, responded very differently. The establishment of the European Parliament's Committee on Energy, Research and Technology, and the subsequent release of the 1987 *Viehoff Report* concerning the risks of biotechnology, signaled a landmark regulatory decision. In an effort to establish a uniform regulatory approach across the member states regarding the anticipated release of genetically modified organisms, the report recommended a risk assessment of genetically engineered microorganisms and demanded a moratorium on the environmental release of such organisms "until binding Community safety directives have been drawn up" [8].

In response, the primary policy organs responsible for establishing the appropriate framework for the EU, including the European Commission and the Council of Ministers, turned their attention to the benefits and risks of biotechnology applications. In contrast to the 1976 U.S. National Institutes of Health guidelines and the favorable OECD's report on *Recombinant DNA Safety Considerations*, [145] many European policymakers, who associated genetically modified organisms with social, environmental, and economic threats, adopted an increasingly skeptical standpoint towards the unregulated application of biotechnology. They advocated the precautionary principle—a principle whose regulatory origin or gradual incorporation into the EU environmental regulatory framework can be traced to the 1969 *Swedish Environmental Protection Act* and Germany's advocacy of the *Vorsorgungsprinzip*, or cautionary principle [146–148].

Concerned about the potential risks of biotechnology and the need to safeguard the environment, the European Commission pointed to the biotechnology industries' "lack of candor … about the potential environmental risks from their products …" [71] and emphasized that "the widespread use and release of novel GMOs [genetically modified organisms] could upset the delicate balance existing in nature or even have evolutionary impacts" [146]. To avoid potentially irreversible and adverse effects of genetically modified organisms on human health and the environment, and to harmonize the national rules on the marketing of genetically modified products, a series of directives were proposed in 1994, including Council Directives 90/219/EEC and 90/220/EEC (both implemented by the Director-General for Environment

and later revised by the Council Directives 94/51/EC and 94/15/EC). These directives, which were composed of more than 20 articles and were concerned with the contained use and deliberate release of GM microorganisms into the environment, reaffirmed the Commission's precautionary principle [149, 150].

Directive 90/220/EEC, for instance, cites the potential *irreversible* environmental effects of food biotechnology applications and establishes an elaborate regulatory system of placing GM products on the market. The evaluation and authorization of such biotechnology applications rely on a complex system of assessment reports and interstate information exchanges in the forms of dossiers and opinions circulated to all EU member states by the member state's appropriate Competent Authority, which is responsible for transposing directives into national law on behalf of the member state. Moreover, in case of justifiable risk, the safeguard clause under Article 16 of Directive 90/220/EEC authorizes member states to unilaterally prohibit the distribution of biotechnology products within their respective territories. The safeguard clause has been invoked on several occasions by several countries with relatively high uncertainty avoidance index scores, including Austria (three times), France (two times), and once by Germany, Luxembourg, and Greece [151].

The European Parliament in particular followed a precautionary policy approach regarding food biotechnology that reflects Europeans' strong social and cultural connection to food and their subsequent view of genetically engineered food as artificial and unnatural [152–154]. Given the logical implications of this connection within an overall environment of low uncertainty tolerance levels and the extensive publicity given in many European countries to the potential risks of genetically modified foods, the cautious risk perception of the European public has emphasized the dangers and mostly dismissed the potential benefits associated with genetically modified products. Eurobarometer surveys from 1991 and 1993 provide insight into the public's general attitudes toward genetic engineering and its different applications. Based on averages ranging from +2 (maximal support) to −2 (minimal support), no country in the EU was highly supportive of genetically modified food. In fact, support for genetically modified food remained weak at +0.47 in 1991 and +0.40 in 1993.

Within this context, and faced with public pressure throughout the early 1990s, the EU continued to closely regulate genetically modified food. Initially, the European Commission, charged with proposing legislation and overseeing the implementation of policy, favored a simple notification procedure for authorizing genetically engineered food. The Environment Committee of the European Parliament disagreed and proposed a series of amendments, requiring the labeling of genetically modified food products in 1993. While the Council of Ministers, responsible for passing EU laws, did not fully support the idea of labeling, the full plenary of the European Parliament and several member states did. The policy debate on labeling reached its regulatory apex shortly before the BSE (Bovine Spongiform Encephalopathy) or mad cow disease outbreak in the UK in January 1992, which sent shock waves throughout Europe. On March 12, 1996 the European Parliament mandated genetically modified food labeling requirements and was

supported by the European Commissioner for Health and Consumer Protection [155, 156].

The controversy over genetically modified food intensified in several European countries in 1996, which was a watershed year in Europe [157]. In that year, the EU granted Monsanto to market its herbicide-tolerant soybeans and a year later Syngenta (then known as Ciba-Geigy) received permission to commercialize its insect tolerant Bt 176 maize. As the first genetically modified seeds were imported from the United States, the debate surrounding Bt maize intensified. Moreover, the mad cow disease crisis became a major issue on both the policy and public agendas. As noted by Toke and others, this crisis was not the principal reason for Europeans rejecting genetically modified food [71]. Nevertheless, the possible spread of BSE shook Europeans' belief in the trustworthiness of the policy institutions responsible for ensuring the public health, deepened their suspicion of genetically modified foods, and influenced policy decision making in many European countries. Advances in and controversies over biotechnology applications did not translate into increased knowledge about genetic engineering. In fact, the knowledge of biotechnology techniques among Europeans remained relatively low and varied by country, as illustrated by Eurobarometer surveys throughout the 1990s.

While the introduction of biotechnology products continued in the US, most members of the Regulatory Committee of the EU and European Parliament objected to the authorization of genetically modified maize. Although the European Commission eventually allowed the import and cultivation of GM maize in 1997, Austria prohibited its import by invoking the safeguard clause of Directive 90/220, which allows member states to restrict products believed to pose a danger to the health and safety of citizens. Despite the intensity associated with these issues and the emergence of a well organized opposition to fight genetically modified products, as illustrated by the anti-genetically modified product movement of NGOs and other interest groups in France, most of the public within the EU had demonstrated low levels of knowledge concerning genetic engineering [158–161]. Based on a nine-item quiz to measure biotechnology knowledge, the Eurobarometer surveys between 1996 and 2002 indicate a slight overall upward trend in knowledge. However, only three countries, Sweden, Denmark, and the Netherlands, consistently passed the quiz by answering even 60 % of the items correctly, or, as in the case of Sweden in 2002, 70 % [162]. While these trends have not changed significantly, a 2005 Eurobarometer poll showed that 80 % of Europeans were familiar with genetically modified food [163].

Regardless of low biotechnology knowledge among the European public, the EU continued its active policy engagement in the regulation of genetically modified food. In response to North American genetically modified soybeans reaching Europe, the EU, with considerable support from the European Council and Parliament, established specific labeling rules and mandated labeling requirements for most genetically modified food under the Novel Foods Regulation (EC) No. 258/97, Council Directive 97/35/EC, and IP/97/1044. Fully introduced by September 1998, the labeling requirements specified in Directive 97/35/EC and IP/97/1044 not only amended Directive 90/220/EEC but also coincided with the disappearance of

genetically modified products throughout Europe. Despite having authorized 18 genetically modified products for commercial use since Directive 90/220/EEC, increasing doubts about the safety of food biotechnology applications convinced 12 of the then-15 member states to oppose the authorization of new genetically modified organisms. Faced with this broad-based opposition, the European Commission, rather than challenging strong anti-GM sentiment, agreed to halt the authorization of genetically modified organisms, paving the way for a de facto GM product moratorium that started in 1998 and lasted until 2004 [164, 165].

Pending reform of Directive 90/220/EC, the Council of Environmental Ministers halted any approval of new GM organisms and began to revamp its regulatory system "to better address the challenges of modern biotechnology" [107]. Countries characterized by low levels of uncertainty tolerance, including Greece, France, Italy, Austria, and Germany, either invoked the safeguard clause to ban GM organisms that had already been approved at the EU level or refused approval of new GM products until the development of stricter risk assessment procedures and the implementation of traceability, liability, and labeling rules. Consumers' unions across Europe echoed these sentiments of opposition. Accordingly, the International Consumer's Organization urged "governments … [to] require full pre-market evaluation and social and safety impact assessment of GM foods" [158].

These events convinced the EU to expand and revamp the regulatory food safety framework. The 1999 *White Paper on Food Safety* proposed the establishment of an independent European food safety agency modeled after the Food and Drug Administration. Aimed at ensuring consumer health protection in the area of food safety and enabling the agency to draw on independent scientific opinions, this proposal became a functional reality in 2002 with the establishment of the European Food Safety Authority and subsequent formation of the Scientific Committee and Scientific Panels a year later [166]. Furthermore, the EU deemed the procedures that govern the deliberate release of GM organisms into the environment under the Directive 90/220/EEC as environmentally unsound and replaced it with Directive 2001/18/EC (the *Deliberate Release Directive*), which reiterated the safeguard clause, reaffirmed the *precautionary* principle, emphasized *preventive* actions, and introduced an *ethical* dimension to assess GM products. As part of the officially sanctioned notification process, this directive required genetically modified food producers to provide a full environmental risk assessment detailing the foreseeable risks of such products to human health and the environment. Member states were authorized to conduct their own investigation and take into account the ethical implications of marketing genetically modified food [167]. Finally, based on guidelines adopted by the European Commission in 2003, 15 of the 27 EU member states have implemented national strategies for the coexistence of genetically modified crops with their organic counterparts [165].

As determined by advanced search engine results on governmental websites for Health Canada and the European Union, there are currently about 600 EU documents dealing with food biotechnology in contrast to about 200 for Canada. While the U.S. Food and Drug Administration does not allow for tailored online searches

regarding the regulations of genetically modified food, there are significantly fewer regulations in the United States compared to Europe [168]. As pointed out by Carter and Gruère, "globally, the EU has the most comprehensive regulations on GM food" [169]. The new, more extensive regulatory framework is a continuation of the EU's latest effort to regulate GM food. The *Food and Feed Regulation*, (EC) 1829/2003, clarified a series of previous regulations and directives that directly or indirectly dealt with genetically modified food, including Regulation (EC) No. 258/97 and Directives 82/47/EEC, 2002/53/EC, 2002/55/EC, 68/19/EEC, and 2001/18/EC. Consisting of 49 articles and one annex, the primary objective of Regulation (EC) 1829/2003 is 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" [170]. As a number of countries including Austria, Greece, Germany, Luxembourg, and Germany maintained a ban on certain genetically modified foods, the latest additions to the regulatory framework focus on the traceability of novel foods throughout the production and distribution process [171, 172].

As the regulatory scope has expanded, statements by the European Commission have begun to address the potential benefits of genetically engineered products [173]. However, this more welcoming stance contrasts with the fact that the European Food Safety Authority has approved only one genetically modified product since 2004 [174]. Moreover, public perception of genetically modified food has remained negative. Eurobarometer surveys show that national attitudes toward genetically modified food have been mostly characterized by negative undertones, judging such products as not being useful and a risk to society at large. Large segments of the public in Belgium, Sweden, Denmark, Germany, Italy, the Netherlands, Austria, and Greece were particularly unsupportive of genetically modified food. Except for Denmark, Sweden, and Austria, support for GM food has declined considerably since 1996. EU averages between 1996 and 2005 derived from the Eurobarometer studies confirm the overall decline in and low support for genetically modified food between 1996 and 2005. To some extent, these patterns are also visible in the United States and Canada (see Fig. 2.1). Studies that highlight the Europeans cautious approach to, and the perceived threat associated with,

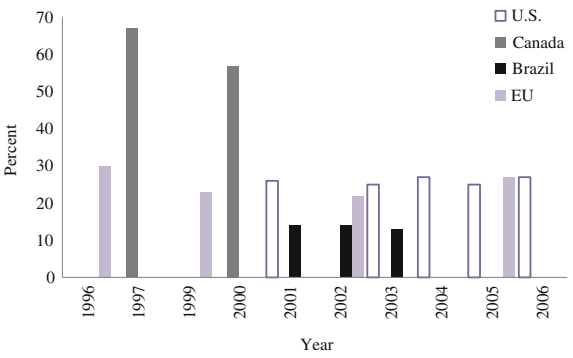

Fig. 2.1 Public support for GM food in the US, Canada, Brazil, and EU

genetically engineered food reiterate the low support for genetically modified food within the EU—a pattern firmly established since the first half of the 1990s [175, 176].

Notes For the U.S., the survey asked: Do you favor the introduction of genetically modified foods into the US food supply? For Canada, the survey asked: Is using biotechnology in the production of food and drinks useful? For Brazil, the survey asked about the preference of genetically modified foods. For the EU, the results for 1996–2002 are based on *decided* Europeans in support of GM food, while the 2005 polling results are based on a combination of those who "agree" and "totally agree" with GM Food [176].

2.5 Conclusion

This study asked whether different uncertainty tolerance levels and risk perceptions provide another explanatory dimension to the formulation of policies regarding genetically engineered food in the United States, Canada, Brazil, and EU. Different uncertainty tolerance levels and risk perceptions among policy stakeholders, defined here as the public and policymakers in relevant regulatory agencies, are linked to distinctive protective policies in the area of food biotechnology. The formulation of stringent regulatory policies occurs within an environment of low uncertainty tolerance levels and prevalent cautious risk perceptions. On the other hand, high uncertainty tolerance levels and the initial prevalence of opportunistic risk perceptions among policy stakeholders encourage the continuation or adjustment of existing protective regulatory policies. The competition of different risk perceptions facilitates the emergence of an inconsistent regulatory framework. While risk perceptions among policy stakeholders can change and remain ambiguous, the findings of this analysis illustrate that country or region-specific differences in political culture—and the prevailing risk perceptions among policy stakeholders associated with them—can add another explanatory dimension to understand policy outcomes (see Table 2.2).

On both sides of the Atlantic, public knowledge about biotechnology applications, including genetically modified food, remained relatively low in the United States, Canada, and the EU throughout the 1990s. However, as skepticism and controversies surrounding genetically modified food deepened and press coverage intensified, familiarity with genetically modified food increased, especially among Europeans and, as indicated by polls conducted in the early 2000s, among Brazilians. Surveys at the state, regional, and international levels also showed that the publics in the United States and Canada were more supportive of food biotechnology applications compared to their European and especially Brazilian counterparts. Because of the perceived benefits and presumed low danger levels of genetically modified foods, a substantial segment of the public in the United States and Canada mostly supported genetically modified food, especially during the first half of the 1990s.

Table 2.2 Genetically modified food policy and policy risk perception timeline

Year	United States	Canada	Brazil	EU
1980	–	MOSST: Biotechnology in Canada	–	–
1983	–	National Biotechnology strategy	–	–
1986	*Coordinated framework for regulation of biotechnology*	–	–	–
1987	–	–	–	Viehoff report
1990	–	–	–	Council directive 90/220/EEC on the deliberate release into the environment of GMOs
1992	FDA: *Foods derived from new plant varieties*	–	–	–
1994	FDA approval of the Flavr-Savr™ tomato	HC: *Guidelines for the safety assessment of novel foods*	–	–
1995	FDA: *Safety assurance of foods derived by modern biotechnology in the United States*	–	Law of biosecurity establishes the National Biosafety Technical Commission (CTNBio)	
1996	–	–	–	European parliament mandates GM food labeling requirements
1997	EPA: Allows limited registration of a new btcorn called star link	Creation of CFIA	–	–
1998	–	Canadian biotechnology strategy secretariat: *Canadian biotechnology strategy: An ongoing renewal process*	Federal court prohibits the commercialization of genetically modified soybeans	–
2000	FDA: Confirms traces of Star link in taco shells	–	–	Commission of the European communities: White paper on food safety

(continued)

Table 2.2 (continued)

Year	United States	Canada	Brazil	EU
2001	–	–	–	Council directive 2001/18/EC on the deliberate release of GMOs
2005	–	–	New Law of Biosecurity strengthens the power of the CTN Bio	–
2006	–	–	–	FDA: *Guidance for industry. Recommendations for the early food safety evaluation of new non-pesticidal proteins produced by new plant intended for food use*
Policymaker/Public risk perceptions		1990s		2000s
United States		Opportunistic/opportunistic		Opportunistic/ cautious elements
Canada		Opportunistic/opportunistic		Opportunistic/ cautious elements
Brazil		Competing risk Perceptions/unknown		Competing risk perceptions/cautious
EU		Cautious/cautious		Cautious/cautious

However, by the late 1990s and early 2000s, a public increasingly skeptical and uncertain about such products developed an unfavorable assessment of genetically modified food in the United States, Canada, and the EU, suggesting an opportunistic risk perception mixed with visible signs of caution. While the level of public skepticism changed in the United States, Canada, and the EU, the Brazilian public acknowledged some benefits associated with food biotechnology but was consistently and strongly opposed to it, suggesting a mostly cautious risk perception.

While regulatory adjustments have been proposed in the United States and Canada to reflect the increasing skepticism regarding genetically modified food, policymakers within the Food and Drug Administration and Health Canada have continued to encourage the advancement of genetically engineered food, mostly praising its safety and benefits. In contrast, the consistent suspicion of genetically modified food as something unnatural coincided with the Europeans' less favorable assessment of engineered food products. While exceptions exist, policymakers

within the major regulatory bodies of the EU generally downplayed the benefits of genetically modified food and instead emphasized the risks associated with them. Consistent policy trajectories are much more difficult to pinpoint in the case of Brazil. Divisions and competing risk perceptions within government and at the sub-national level dominated the development of Brazil's food biotechnology regulatory framework. Accordingly, the simultaneous and sometimes ambiguous advocacy of risks and benefits in regards to genetically modified food at the federal and state level of government as well as the subsequent legal battles that challenged the Comissão Técnica Nacional de Biossegurança's opportunistic risk perception paved the way for the development of an inconsistent regulatory framework.

Stakeholders in the United States and Canada tended to perceive risks associated with genetically modified food in terms of low threats and high opportunity. Since the late 1990s there has been an increasing and clearly visible cautious risk perception growing among the North American public similar to (although not as severe as) the European and Brazilian outlook. This trend, however, also indicated a widening risk perception gap between the public and policymakers in the United States and Canada. Following a mostly opportunistic risk perception, especially among regulators, within an environment of high tolerance for uncertainty, the United States and Canada adjusted and expanded the responsibilities of the existing protective regulatory frameworks into the area of genetically modified food. Accordingly, the Food and Drug Administration and Health Canada, responsible for the regulation of conventionally produced food, took on the regulatory responsibility for food biotechnology. Within the context of low uncertainty tolerance, the European public and policymakers tended to perceive genetically modified food in terms of high threat and low opportunity. When combined with the fear of the unknown, this mostly cautious risk perception among EU policy stakeholders contributed to the creation of elaborate and stringent protective regulatory policies throughout the EU. Brazil, similar to many European countries characterized by low levels of uncertainty tolerance, initially pursued a precautionary policy approach vis-à-vis food biotechnology. However, as divisions along competing risk perceptions within both the Cardoso and Lula administrations crystallized, partially in response to external and internal pressures, the regulatory framework became increasingly inconsistent.

In addition to conventional explanations that focus on socioeconomic conditions, the role of political institutions, or a process versus product outlook on policy formation, the influence of political culture and risk perceptions provide another useful analytical perspective to understand the genetically modified food policy divide between North America and the EU and, to some extent, the inconsistent policy trajectory of food biotechnology in Brazil. The uncertainty avoidance index and *Margolis Risk Matrix* assists researchers in assessing the influence of differences in political culture and risk perceptions on policymaking. By drawing attention to core values across societies in terms of differences in risk tolerance, these analytical approaches can be reasonably generalized and add to traditional perspectives on policymaking. Nevertheless, conceptual and methodological

weaknesses remain regarding the operationalization of the risk perception framework in modeling the dynamic relationship between risk perceptions and other sociopolitical variables. Relying on regulatory policies other than those related to genetically modified food, future studies in this area should refine the political culture/risk perception framework, consider the influence of the media on agenda-setting in the selected policy area, and take into account different policy dynamics as a result of differences in economic and political development.

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