Review

A review of regulatory issues raised by genetically modified organisms in agriculture†

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Abstract

The use of genetically modified organisms (GMOs) in agriculture has been controversial since the late 1990s, and the question of how to regulate the products of modern agricultural biotechnology is central to that debate. Aside from potential impacts on human health and the environment, regulators must consider and are influenced by a range of issues that go beyond scientific evidence. This paper reviews these regulatory issues, using the case studies of GMO regulation in the USA and the European Union for illustration. It first discusses approaches to technology and nature as fundamental choices associated with the use of GMOs in agriculture. It then moves on to socio-economic issues, which form the context in which regulatory decisions are made. On the basis of these two first sections, the review turns to a discussion of ways in which regulators frame GM crop and food policies. Finally, it addresses possible challenges to regulation, in particular critical public opinion or trade clashes resulting from conflicting regulatory approaches. This paper concludes that, when there is perceived scientific uncertainty concerning the potential impacts of a new technology on the part of certain stakeholders and actors in the debate, non-scientific regulatory considerations, for example relating to ethical, social and economic issues, are of crucial importance in shaping regulation.

Keywords: Genetically modified foods and plants, Regulation, Public policy, USA, European Union

Review Methodology: This paper draws on research conducted in the context of the author's doctoral dissertation completed at the University of Zürich in 2007 [1]. As such, it is based on extensive searches for primary and secondary literature over several years, as well as on a series of qualitative interviews with decision-makers and stakeholders involved in the regulation of GMOs in agriculture in Europe and the USA. In addition, CAB Abstracts was searched.

Introduction

The use of genetically modified organisms (GMOs) in agriculture has been controversial since the late 1990s. Genetically modified (GM) crops were commercialized in the early 1990s by a handful of multinational corporations headquartered in the USA. The year 1996 saw the first planting and harvesting of GM maize and soybeans, the two most widespread GM crops (The first GM food to be commercialized was the Flavr Savr tomato in 1994), and processed foods containing GMOs found their way onto US supermarket shelves shortly afterwards. GMOs in agriculture became a contentious issue when first shipments of GM maize and soybeans travelled from North America to Europe. Although the acronym 'GMO' was largely unknown to consumers worldwide in 1996, today it is a mainstream term and a hotly debated topic, especially in the European Union (EU). At the same time, the global use of agricultural biotechnology has increased steadily and dramatically since the 1990s, with a rise in value of GM crops from US$115 million in 1996 to US$6.9 billion in 2007 [2]. Since the 1990s, a subject of intense

†The views expressed in this paper are those of the author and may not under any circumstances be regarded as stating an official position of her current employer, the European Commission.

debate between proponents and critics has been whether GM crops and foods are safe for human health and for the environment (Representative works supporting GM foods and crops are [3, 4]. Works criticizing the use of GMOs in agriculture include [5–8]). GM food proponents stress that, so far, no health problems have emerged that can clearly be attributed to GM crops and foods, and believe that such problems are unlikely to arise. They also foresee a 'second generation' of GM food products that should bring a range of advantages including health benefits for consumers, such as improved nutritional value, taste, longer shelf-life and wider product choice. Critics, on the other hand, are of the opinion that agricultural biotechnology brings no tangible benefits to consumers and that it will not do so in the foreseeable future. Instead, they emphasize the potential health hazards that GM crops and food might pose, in particular food allergies and resistance to antibiotics through the insertion of antibiotic resistance marker genes during genetic engineering of GM foods.

With regard to environmental issues, GM food supporters maintain that GM crops enable the effective control of pests and weeds while at the same time reducing the need for tillage and therefore soil damage and erosion. Another argument for proponents is that GM crops reduce the use of pesticides, especially herbicides and insecticides. Insect-resistant crops are specifically modified to resist pests and therefore no longer require as much conventional insecticide. Herbicide-tolerant plants, one of the main types of GM crops, are modified to resist the use of glyphosate-based herbicide (e.g. RoundUp). Some studies have shown that the amount of glyphosate-based herbicide needed in combination with GM crops resistant to this type of herbicide is lower than the amount of herbicide (containing other active ingredients than glyphosate) needed in combination with non-GM crops. GM food and crop critics call these claims into question, arguing that results are ambiguous regarding reduced pesticide use. In addition, opponents of GMOs in agriculture fear the development of weeds ('superweeds') and insects that are resistant to pesticides. They also warn against 'genetic contamination' or 'genetic pollution' of other species if GM plants spread through pollen and seeds in an uncontrolled manner. This in turn might threaten the ecosystem and biodiversity, a point played down by proponents by the possibility of isolating GM crops to a certain extent.

The persistent lack of consensus with respect to the impact of GM crops and foods on health and the environment faces regulators with a difficult task. Under these circumstances, regulatory issues, in particular ethical, legal, economic and societal questions, have gained visibility and have become crucial ingredients in the policy-making process. In the existing literature, these non-scientific regulatory issues are typically addressed in the context of empirical case studies whose main focus is to describe and/or explain the cases(s) at hand. Structured reviews of non-scientific regulatory issues, however, are uncommon. This paper aims to fill this gap by providing a structured overview of regulatory issues associated with GMOs in agriculture that do not focus on the scientific issues of health and the environment. It attempts to go beyond description by offering an analytical framework to understand and categorize regulatory issues relating to GM foods and crops.

In order to illustrate the regulatory issues discussed, examples will be drawn from case studies of GMO regulation in the USA and the EU, two key contrasting players in the GMO debate. Regulators in the USA and the EU have taken very different approaches to the regulation of GMOs in agriculture although they are regulating the same technology and products. This underscores the view taken in this paper that, in some countries and societies, non-scientific regulatory issues may be central when it comes to regulating GMOs in agriculture.

Regulatory issues associated with GMOs in agriculture can be discussed in a variety of ways, as they are intricately linked. This paper reviews these issues under the following headings: approaches to technology and nature (as the fundamental questions underlying regulation), socio-economic issues (as the context in which regulatory decisions are taken) and issues that potentially challenge regulation (such as lack of public acceptance and trade conflicts).

Approaches to Technology and Nature: Foundations of Regulation

The regulation of a new technology is, as a general rule, based on a risk assessment of that technology. If a technology leads to public controversy and debate, however, other aspects may come into play. In a broad sense, regulatory decisions on how to regulate any new technology are based on societies' approaches towards technology and nature. The most fundamental question to be answered is whether and to what extent a given society believes that a certain technology, in this case the use of genetic engineering in agriculture, is a useful and appropriate way forward. For over half a century, there has been a mainstream notion among most scientists, regulators and the public-at-large that the discovery of the structure of deoxyribonucleic acid (DNA) in 1953 and the ensuing development of genetics and of genetic engineering techniques are the key to understanding and designing life itself [9]. It should not be forgotten, however, that this conviction, which forms the foundation for the acceptance of GMOs in agriculture, is fairly recent, and that it might change in the future. As the history of science shows, mainstream scientific convictions can and do change over time (e.g. climate change). Even today, some scientists and GMO sceptics underline that the current focus on DNA and the genetic make-up is strongly reductionist. The argument here is that an organism can never only be

understood as being the result of the expression of its genes, but also as the result of its environment, and that the focus on DNA as the basis of life has become a cultural phenomenon as well as a scientific one [10–12]. Current regulations of GMOs in agriculture are all based on the assumption that genetics is a very important if not *the* way forward for science and society.

Beyond the issue of what scientific approach is appropriate to move society forward, a further key question that societies must ask when deciding to use a new technology is whether it is morally right or wrong to use that technology [13]. Regulators translate this fundamental decision into regulation by banning or allowing a technology to be used under certain conditions [14]. For GMOs in agriculture, and genetic engineering generally speaking, the most fundamental question discussed is whether genetic engineering is compatible with nature, i.e. whether GMOs could develop in nature without the help of technology. For proponents of GM foods and crops as well as for regulators who choose a relatively tolerant and market-oriented regulation, agriculture, with or without genetic engineering, means tampering with nature. In this view, genetic engineering is nothing more than an extension of traditional selective plant breeding, which is a form of genetic manipulation within one species. In addition, proponents emphasize that genetic engineering is very precise and that it can introduce desirable traits into useful organisms more efficiently than traditional breeding methods (This approach is powerfully illustrated by the US Food and Drug Administration's 1992 policy statement on GMOs in agriculture [15]). For critics and more cautious societies, on the other hand, scientists have gone beyond their remit with modern agricultural biotechnology: they are 'playing God' and manipulating life. While traditional biotechnology (excluding genetic engineering techniques) is applied in appropriate environments adapted to the organisms it uses (e.g. a specific ecosystem), modern biotechnology (i.e. genetic engineering) is conducted in isolation and can cross species barriers and thus create new genetic make-ups that could not be developed within nature, and which might therefore be hazardous for biodiversity (This approach is taken by the European Parliament/ Council of the European Union [16]).

Creating new crops and foods further raises the issue of intellectual property ownership, which is a legal, economic and ethical issue (recent reviews include [17–19]). Most commercially successful GM crops and foods are the result of investments by private companies. GM crops and food supporters strongly believe that developers of agricultural biotechnology should hold intellectual property rights and be able to patent GM products. They set forth that successful investment should lead to profit, even if existing plants are involved. From this perspective, it is right for biotechnology companies to make profits from the applications they develop since they have invested heavily in them. The logic here is that buyers of the seed featuring this technology will quickly receive compensation through higher yields and less expensive farming needs. The current practice is that these companies own the intellectual property related to these GM crops and recoup their investment by charging relatively high fees on every bag of seed sold to farmers. In this connection, the saving of seeds after one GM crop harvest and the replanting of this seed are not permitted. The enforcement of intellectual property rights is usually handled in court, but can also be addressed through technological means; in the 1990s, agricultural biotechnology companies initiated research on the so-called 'terminator' technology, which made seed sterile in the second generation [20]. This technology was met by such negative public reaction that it was not further developed. Critics of agricultural biotechnology heavily criticize agricultural biotechnology companies' practices with regard to intellectual property. They view exclusive property rights with regard to living organisms as an exploitation of nature and life that should not be permitted (It should be noted that patents on plants have been granted for many decades, and that this practice is by no means restricted to GM plants). From this perspective, the fact that farmers are required to agree to conditions by which they cannot replant seed is unethical. Critics believed that the terminator technology was contrary to nature's inherent cycle of reproduction and that it undermined traditional agricultural practice. Regarding the GM seed market generally, anti-GM food voices denounce agricultural biotechnology companies for introducing products that promote agribusiness and monoculture, thus threatening traditional farming methods. They stress that the GM seed market is controlled by a few multinationals, which can set prices as they wish.

A final important issue in the context of approaches towards technology is that of the supposed and actual impact of this technology on the situation of agriculture in developing countries [21–24]. While this in many cases does not have a direct impact on GMO regulation, it forms an important part of the debate on this issue. GM food proponents suggest that genetic engineering could help increase the food supply in developing countries, if varieties were developed that could make more efficient use of land and combat local pests, etc. A frequently cited example is that of drought-resistant crops. To the suggestion that GM crops can solve world hunger, critics counter that the developing world needs different kinds of help than agricultural biotechnology, leading to sustainable solutions that would not make them dependent on industrialized countries. They contend that GM food proponents exploit the idea of helping nations in need of food aid for the sake of publicity. They argue that GM foods in the developing world create dependence on technologies, which these countries cannot afford and will not help them develop.

The issues discussed in this section are the more prominent ones that are raised within the GM food and crop debate and considered by regulators. Choices on

these fundamental questions form the foundations of regulations of GMOs in agriculture, and fundamentally steer more technical and scientific regulatory considerations.

Socio-economic Issues: The Regulatory Context

Regulatory decisions on GMOs in agriculture are taken within specific socio-economic contexts, which greatly influence regulation and its implementation. A series of well-written narrative and chronological accounts of developments surrounding agricultural biotechnology address these issues in a comprehensive manner (outstanding works are [25–27]).

A first fundamental issue is the place that industry in general, and the agricultural biotechnology industry specifically, occupy within a society. There is a general assumption within industrialized societies that modern biotechnology is a driver of economic growth that should be promoted, and also that citizens should be protected from any potential hazards. However, regulatory choices do often underline one goal more than another. Some regulators, in particular the EU and individual European countries, have developed regulation that focuses both on controlling industry and on protecting the citizen from potential environmental and health hazards. EU regulation of GMOs basically supports biotechnology with the objective of growth and competitiveness, but also underlines the need for protection from any hazards that agricultural biotechnology might bring with it (cf., for example, [28]). Other regulators, in particular the United States, have developed rules that focus primarily on creating a stable context in which industry can benefit from low regulatory costs and focus on investing in the commercialization of new crop varieties. Industry in general and the biotechnology industry in particular are seen as engines of the US economy, and the main role of policy is, hence, to create a secure and predictable regulatory environment that will make it possible for industry to operate efficiently and productively. US policy on GM food and other applications of biotechnology have therefore primarily been devised against the backdrop of the larger goal of achieving and maintaining economic growth and international competitiveness (Useful descriptions of US regulation are [29, 30]; contributions to the comparison of EU and US regulations include [31–35]).

A further crucial element that regulators take into account both implicitly and explicitly is the social, cultural and economic importance of agriculture in a given society (Good discussions of this area can be found in [36–38]). Some societies apply the principles of 'agribusiness', a model of agricultural growth based on industrial methods. Others are trying to move away from agribusiness in order to move towards an environmentally sustainable agricultural farming model, which focuses on compatibility with the environment and biodiversity, avoids monocultures and may include organic farming. The choice of using GMOs in agriculture on a large scale is connected with the choice of using agribusiness as a predominant agricultural model. Indeed, the use of GMOs in agriculture can substantially reduce the costs of agricultural production on a large scale, mainly through a reduction of the costs of labour. In contrast, avoiding or minimizing the use of GMOs in agriculture is more coherent with the sustainable farming model. Societies that are trying to make the transition from heavily industrial methods to this kind of farming are often sceptical of the use of GMOs in agriculture.

In this context, regulatory choices also depend on the economic importance of agriculture for trade in a given society. In 2007, over 20 countries cultivated GM crops, with the USA accounting for roughly 50% of the 114.3 million ha of GM crops planted. Other main producers are Argentina (17% of production), Brazil (13%), Canada (6%) and India (5%). In Europe, the largest GM crop producer is Spain, with a production accounting for less than 0.1% of global production [2]. The United States and other large GM crop producers not only produce but also export large amounts of GM (and non-GM) maize and soybeans, the largest GM crops, than other countries. Consequently, revenue from maize and soybean trade is much more important for North American and South American countries than for European countries. In 2006, the USA produced roughly 267 million metric tonnes of maize and 88 million metric tonnes of soybeans, while the EU produced 56 million metric tonnes and 1.2 million tonnes, respectively [39]. On average, over the past decade, the USA has exported one-quarter to one-third of its maize and 30–40% of its soybeans [40]. Its revenue from export of bulk commodities such as maize and soybeans to the EU is considerable. Within this context, and given the geographical features of the American Midwest that are conducive to large-scale farming, it makes sense economically for the USA to use GM crop varieties.

The issues described lead to different distributions of influence and power when it comes to lobbying structures. Actors with stakes in the regulation of GMOs in agriculture have different levels of influence and access to regulators. In countries where GM crops are already grown and distributed, such as the USA, industry, large farmers' associations, food processors and retailers have a strong interest and considerable success in maintaining a relatively tolerant and market-oriented regulatory situation. In these societies, critics (e.g. environmental organizations, small and family farms and some consumer groups) find it difficult to get access to policy-makers and to stimulate public interest in change. In contrast, in societies (e.g. many European countries) where farmers are less strongly oriented towards the large-scale production of maize and soybeans, and where public scepticism towards GM products makes retailers reluctant to stock GM products, the biotechnology industry finds it

more difficult to get its views across to regulators, and it is easier for GM food critics (environmental non-governmental organizations and consumer groups) to have a strong impact on policy.

Framing GM Crop and Food Policies: Making Regulatory Choices

On the basis of the ethical and socio-economic considerations discussed above, policy-makers make key decisions on how to regulate GMOs in agriculture. One fundamental issue is how to 'frame' modern agricultural biotechnology and its products, i.e. in what light to cast GMO crops and foods through regulation and what assumptions to attach to them both consciously and unconsciously [41, 42]. Depending on whether societies believe that modern agricultural biotechnology is a fundamentally new and different technology or not, they create completely new regulations or use an existing regulatory framework.

A telling example for illustrating different ways of framing modern agricultural biotechnology and its applications is the comparison between the United States and the EU. In the United States, regulatory emphasis is on the end product. GM food policy is based on the premise that GM products should be regulated like any other food, irrespective of their method of production. This is often referred to as a 'product-based approach'. In the United States, GM products are regulated by existing statutes. In 1984, the US Office of Science and Technology Policy devised a regulatory matrix of existing federal agencies and laws to regulate biotechnology, which was confirmed by the Coordinated Framework in 1986 and reiterated in 1992 [43–45]. Accordingly, the legal basis for GM food and crop regulation in the USA consists of three statutes, which are implemented by three federal agencies. Firstly, the Animal and Plant Health Inspection Service is responsible for protecting US agriculture from pests and diseases under the Plant Protection Act of 2000 [46]. Secondly, the Food and Drug Administration ensures that food, feed and food additives are properly labelled and safe to eat for humans and animals under the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA) [47]. Finally, the Environmental Protection Agency (EPA) ensures that pesticides used in plants are safe for the environment under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 [48]. EPA also defines pesticide residue tolerances in food under FFDCA. The statutes applied by EPA are found both under the Agriculture and Food/Drugs Titles of the US Code.

In contrast, EU policy takes a 'process-oriented approach', which posits that the process of production is what should trigger a specific regulatory process. It follows that GM foods and crops should be regulated as such because they are produced through genetic engineering, a specific production process. Within this framework, EU rules relevant to GM foods and crops cover two main types of authorization: deliberate release of GMOs into the environment and use in GM food and feed. EU legislation and regulation on GMOs can thus be divided into 'horizontal' legislation, which deals with the environmental release of GMOs in a broad sense, and 'vertical' or 'sector-related' legislation or regulation, which covers specific products made with GMOs (e.g. food, feed, seed and medicine) and individual issues related to them (labelling and traceability). EP and Council Directive 2001/18/EC of 2001 [16] is the horizontal piece of legislation covering the deliberate release into the environment of GMOs, both for experimental purposes and for placing on the market. It came into force in October 2002, replacing its predecessor, Council Directive 90/220/EEC [49]. Main 'vertical' instruments within the EU are EP and Council Regulation 1829/2003 on GM food and feed, which replaced EP and Council Regulation 258/97 on Novel Foods in 2004, and EP and Council Regulation 1830/2003 on traceability and labelling [50–52].

The 'product versus process' distinction illustrated with the US and EU cases [53, 54] is connected with dissimilar perceptions of modern biotechnology. US documents convey the notion that genetic engineering is nothing radically new, but merely a natural extension of traditional agricultural breeding. The EU, on the other hand, views genetic engineering as a stark departure from conventional technologies. It views GMOs as not occurring in nature, and therefore as fundamentally new and different. This is why, in the EU, the introduction of GMOs into the environment is strictly regulated. The consequence of these different assessments of GM food technology is that the USA makes use of existing laws and adapts them to GM foods and crops, whereas the EU has a regulatory regime specific to agricultural biotechnology and biotechnology in general.

A further fundamental regulatory choice connected with ethical views and the socio-economic context is the question of how precautionary and restrictive regulation should be. This choice is linked to question, discussed above, of creating a new set of regulations or not. Creating new regulations may mean a more restrictive regulatory regime than using existing rules. The choice of a more or less tolerant regulation is also connected with societies' perceptions of the capacity of science to deal with uncertainty, and of how to define and address potential risks connected with GM products. While science can never guarantee that anything is 100%, industrialized societies generally tend to rely heavily on science to seek solutions for society's problems. At the same time, European countries generally appear to be more reluctant than the USA and Canada to fully trust science [55–59]. Once again, the USA and EU examples are helpful for illustration. The USA bases its GM food policy on the 'sound science principle', also called a 'science-based approach', a strong and unwavering faith in science's

capacity to furnish unequivocal information and establish clear answers. This in turn supposes that science and scientific expertise can and do deliver the incontestable evidence necessary to make sound policy decisions. In the case of agricultural biotechnology, this principle has led to regulators' perceived certainty that GM foods do not pose significant risks, and that a narrow definition of risks connected with GM foods is acceptable. It is supposed that GM foods pose no significant risk until proved otherwise, for example by consumers or by a demonstrated impact on the environment. This approach makes a relatively tolerant GM food policy possible. Labelling of GM foods is voluntary, and there are no rules on traceability [60]. While the EU also abides by the sound science principle, it introduces an important caveat by also basing its GM food policy on the precautionary principle. The idea behind this is that sound science as a principle alone may not always suffice. The precautionary principle states that lack of scientific information and certainty shall not stop measures from being taken to prevent potential hazards. The EU views the area of GM foods as one of scientific uncertainty, and therefore assumes that GM products may be hazardous until proved safe. In this context, the EU has also put in place strict labelling and traceability rules for GM products, including GM feed [53, 55]. These were primarily put in place to ensure that consumers are informed and free to choose. In practice, they have meant that very few labelled GM products are available in the EU.

In Europe, the precautionary principle found its expression in a *de facto* moratorium lasting between 1999 and 2004. Proclaimed by several Member States in 1999, this moratorium was described as '*de facto*' because it had no legal basis within EU law. Certain Member States requested an extensive revision of Directive 2001/18, for example broadening the scope of the environmental risk assessment and foreseeing public consultation, as well as the adoption of rules on labelling and traceability of GMOs and GMO-derived products before any new products were approved. Such rules were adopted in 2003, and approval of GMO products started again in 2004.

Regulating GMOs in agriculture is also intimately connected with the definition of their potential risks. It is striking that regulators can arrive at very different answers on this issue depending on ethical and socio-economic considerations. In the USA, the potential risks posed by GM foods are precisely defined in terms of their specific characteristics and immediate impacts on human health and the environment. The definition of risk used by US agencies is therefore relatively narrow, specific, direct and short-term [15]. The EU defines potential risks more broadly than the USA, and includes delayed effects on health and the environment, as well as social and ethical issues. In contrast with the USA, in the EU it is accepted that defining the level of acceptable risk is a normative decision, not only a scientific one [61].

Public Opinion and Trade Conflicts: Challenges to Regulation

Since GM foods and crops were first commercialized in the mid-1990s, a series of events have called the use of modern agricultural biotechnology into question.

A particularly noteworthy episode was the spread of bovine spongiform encephalopathy (BSE) or 'mad cow disease' in Europe, which was transmitted to human beings in the form of the Creutzfeldt–Jakob disease. BSE has nothing to do with genetic engineering, but, because of the timing of this crisis, it had profound repercussions for public acceptance of GMOs. Around the time that the first GM crops were being planted and harvested in the United States, the BSE crisis was reaching its peak. In 1995, the first case of a new variant of Creutzfeldt–Jakob disease (vCJD), a disease in humans resembling BSE, was diagnosed in the UK, and in 1996, the UK government announced that there appeared to be a link between BSE and vCJD. The EU reacted by imposing a worldwide ban on UK cattle and beef exports. The probable causes of BSE are completely unrelated to genetic engineering and GM food, but they determined a general climate of lack of trust in industry and regulators, which only strengthened by the arrival of GM crops to Europe. For both BSE and GMOs, intensive farming and industrialization of the farming and food industries were seen as the culprits. In both cases, regulators were perceived as having failed in their responsibilities, and concealing important information from the public. In the late 1990s, BSE appeared to be the leading cause for scepticism over GM food in Europe [32, 35, 62]. As a result of BSE and other crises, many Europeans tend to mistrust not only industry, but also their regulators. Indeed, they trusted consumer and environmental organizations rather than governments, industry or academia [63].

The US experience with events that could potentially lead to crisis and public rejection has been very different. Indeed, in 2000, an event took place in the United States that, in contrast with the BSE crisis, was explicitly linked to GMOs in agriculture, but did not result in a full-blown crisis. In 2000, traces of StarLink maize, a GM maize variety approved for use in feed but not in food, were discovered in Kraft taco shells. After this discovery, 51 consumers reported allergic reactions as a result of consuming taco shells. Roughly half of these qualified for testing, and 17 were willing to give blood samples to be analysed. In a report released in 2001, the Centers for Disease Control and Prevention found no evidence that the reactions that the affected people experienced were associated with an allergic reaction to StarLink maize [64]. This evidence, together with the fact that there were no casualties and that StarLink producer Aventis agreed to compensate farmers for financial losses due to StarLink, resulted in the issue dying down relatively quickly. In order to prevent future problems of this nature, regulation was adopted to prohibit split approvals for animal and

human consumption. Since the reactions of industry and regulators were swift and efficient and displayed an 'in control' situation to American consumers, public trust in the regulation of GMOs in agriculture did not suffer a major blow.

Regulators' different ways of dealing with challenges are also reflected in the distinct ways in which the state can choose to intervene in the case of market failure. In the USA, the philosophy underlying GM food policy is that the federal government should remain as disengaged as possible and not intervene as long as the market performs well. If a market failure does occur, as in the case of the StarLink episode, the US jury-based judicial system intervenes afterwards. In this system, a civil court may award both compensation and punitive damages (fines), which can be very high. For example, the biotechnology company Aventis paid millions of dollars to US farmers and grain elevator owners to compensate for financial losses resulting from the StarLink affair (25 cents per bushel of StarLink or contaminated maize). Moreover, the US jury-based system allows class action suits, i.e. lawsuits brought by one or more plaintiffs on behalf of a larger group of individuals who have a common interest. It is easier for individuals to bring a claim in the USA than in Europe, as lawyers are allowed to take on cases on a contingency fee basis. This means that the individual is not required to finance the case him or herself. Instead, his or her lawyers are paid a percentage of the damages if they win a case. The result is that US lawyers have an incentive to sue for very high maximum damages as their compensation depends on it. This type of agreement is generally not allowed in the EU. These features of the US legal system encourage biotechnology companies to fully comply with all existing obligatory and voluntary regulatory procedures in order to discourage damage claims, especially since agricultural biotechnology developers have had trouble finding companies to insure GM food liability. Indeed, both in the United States and Europe, existing insurance connected with GM foods is usually limited both in terms of scope and financial coverage [65]. In contrast, the EU regulatory system is a model in which the state regulates GM food in order to prevent market failures such as environment or health-related problems before they can occur. The focus is on protecting health and the environment even if growth is hampered in the process. There is less reliance on the judicial system to correct problems after a failure, a fact that is connected with the above-mentioned lack of a class action tradition based on contingency fees, as well as comparatively high court fees [66]. The judicial system also provides less of a deterrent for industry since judges (not juries) merely award compensation to victims of product defects in a civil court. Additional fines can be levied only after a successful criminal prosecution. Potential plaintiffs therefore have lowered expectations as to the money they might expect to obtain from a defendant and, in most cases, bear a substantial personal financial risk. Most court cases involving GM food in Europe have so far been connected with the destruction of field test plots [67].

A further way in which regulations can be challenged is when they clash with one another. In the area of GMOs in agriculture, this happened through a World Trade Organization (WTO) dispute that lasted from 2003 to 2006 [68–73]. In May 2003, the USA, Canada and Argentina brought a WTO complaint against the EU for hindering trade with GM food and crops [74]. It charged that the EU's *de facto* moratorium, in place from 1999 to 2004, as well as individual EU Member States' national bans (It is important to underline that EU Member States' views on GMOs in agriculture are not by any means homogeneous. While certain EU Member States are quite supportive of agricultural biotechnology, others are more critical. This is usually connected with national public opinion and interest structures. As a result, individual Member States implement EU Directives in different ways, and sometimes even find themselves at odds with European policies) were inconsistent with provisions of several WTO agreements: the 1994 General Agreement on Tariffs and Trade (GATT), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, and the WTO Agreement on Technical Barriers to Trade. While the EU invoked the precautionary principle to justify its policy, the United States viewed EU policies as protectionist measures incompatible with international trade agreements. In 2006, the WTO announced in a final ruling that the *de facto* moratorium on GM crops and foods had been illegal [75]. The verdict also condemned a series of Member States for applying own bans on certain GMO products previously approved by the European Commission. However, the decision did not touch on the sensitive issue of whether GMOs are safe or whether they can be considered comparable with conventional products, and did not challenge the EU's regulatory framework on GMOs.

Conclusion

This review has given an overview over the regulatory issues associated with GMOs in agriculture. It has discussed approaches to technology and nature as foundations of regulatory choices, socio-economic issues as an influential context that shapes regulations, the framing of regulations on the basis of ethical and socio-economic considerations, and finally situations in which regulation is challenged. This paper shows that when conclusive scientific information is perceived as lacking by certain actors in the debate, non-scientific regulatory issues can become central ingredients of decision-making. It further suggests that regulation and regulatory decisions are shaped by regulatory cultures that can differ widely. These regulatory cultures are also shaped by special interests and different distributions of power. The example of GMO regulation in the United States shows a clear-cut science-based

approach within a society in which agribusiness and industry are major driving forces. In the case of the USA, regulators have come to the conclusion that scientific evidence warrants a product-based and relatively tolerant regulation of GMOs in agriculture. In the EU, on the other hand, the view that scientific evidence is lacking prevails. EU GM crop and food regulation is therefore based on a cultural context of precaution and public scepticism towards science and technology, as well as only moderately developed socio-economic interests in GMOs in agriculture and a strong anti-GMO lobby.

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