

DIFFERENT REGULATORY APPROACHES TO RISK MANAGEMENT OF GMOs IN THE EU AND THE US

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Abstract

Trade in genetically modified organisms (GMOs) is being discussed under the negotiated draft of the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the US due to different regulatory approaches to the risk management of GMOs on both sides of the Atlantic. The aim of this paper is to examine whether the EU's precautionary principle can be reconciled with the US science-based approach in such a way as to avoid future trade disputes between the EU and the US within the World Trade Organization (WTO), where the reluctant approach of the EU with respect to GMOs was challenged by the US in the past before the Dispute Settlement Body. Even though the EU has authorized some GMOs to be marketed, they have to be labelled properly unless they are contained in foodstuffs as trace elements only. In the US, on the contrary, the labelling of GMOs is not mandatory and proceeds on a voluntary basis. Since the EU aims at maintaining a high level of consumer protection, it believes that consumers are entitled to be informed about the origin of the foodstuffs they are buying, thus shifting the precautionary decision from supranational to individual level.

Key words: GMOs, precautionary principle, EU, US, WTO

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Introduction

So far, scholarly literature has mainly focused on individual elements of risk regulation related to producing and distributing genetically modified organisms (GMOs), such as patenting GMOs, marketing GMOs, labelling GMOs, trade disputes concerning GMOs, class actions in the US as opposed to the lack of collective dispute resolution in the European Union, differences between the United States' science-based approach and the European Union's precautionary principle. However, the risk management of GMOs has not been treated holistically, intertwining the distinct elements of its risk regulation and focusing the on

future regulation of GMOs in the Transatlantic Trade and Investment Partnership (TTIP) Agreement between the US and the EU which is currently being negotiated. Looking at the recently concluded negotiations of CETA (Comprehensive Economic and Trade Agreement) between Canada and the EU (European Commission, 2014), we can anticipate the manner in which GMOs are going to be regulated in the TTIP Agreement. Prior to addressing the risk regulation of GMOs in CETA, let us have a brief look at the diverging risk regulation concepts applied to authorizing and marketing GMOs on the two sides of the Atlantic, where the Canadian approach largely echoes the American one.

1. The European Union's precautionary principle versus the United States' science-based approach

The precautionary principle has its origins in the German concept of "Vorsorgeprinzip", which inspired its introduction into the legal rules of the European Union (EU). The founding treaty of the European Union (formerly referred to as the European Communities) incorporated the precautionary principle in its wording by means of its 1993 Maastricht revision, which appears to restrict the precautionary principle to the field of environmental protection. However, later, the Court of Justice of the European Union (CJEU) declared the precautionary principle a general principle of law, thus extending its application to other regulatory areas, such as the consumer protection and the protection of human health.

The precautionary principle is not precisely defined in the Treaty on the Functioning of the European Union.¹ Therefore, its interpretation relies either on the recommendation issued by the European Commission² which does not have a binding nature or on the judgments delivered by the CJEU in specific cases, which serve as a precedent. In case Monsanto, the Court of Justice explains the meaning of the precautionary principle in the following terms:

«It follows from the precautionary principle that where there is uncertainty as to the existence or extent of risk to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent.» (CJEU, 2003)

This reasoning provided by the Court of Justice of the European Union gives a clear priority to protecting human health over protecting economic interests of business operators. Also, more judgments delivered by the Court of Justice suggest that a high level of health protection may have a negative impact on economic activities of businesses (see for instance CJEU, 2000).

The trouble of the precautionary principle stems from a concept which is too vague to be predicable. The CJEU interprets this principle in a way that can hardly be justified on a scientific level, thus giving rise to international trade disputes, such as the GMOs differences between the EU and the US within the World Trade Organization (WTO) (Gruszczynski and Werner, 2014). In this trade dispute the EU's precautionary principle created a non-tariff barrier to trade under the Sanitary and Phytosanitary (SPS) Agreement since under EU law protective measures are justified as long as "it is impossible to carry out a full scientific risk assessment because of inadequacy or incompleteness of available scientific data" (CJEU, 2010). Yet, this did not help the EU to win the case before the WTO Dispute Settlement Body (DSB) which did not recognize the precautionary principle invoked by the EU. The WTO DSB concluded that the EU failed to provide any scientific evidence of health risk assessment whatsoever so as to justify the ban on US imports of GMOs to the EU (Vogel, 2012).

The American science-based approach, on the other hand, seems much more precise and predictable in its application while adopting a very different stance to precaution. Unless the existence of a risk has been scientifically proved, the new product can be certified and marketed as safe. This concept is also applied to GMO products which are considered as essentially identical to conventional produce. If a consumer wishes to avoid GMOs, he or she is bound to purchase organic produce which prohibits the use of genetically engineered seeds. Unlike in the US, GMOs require a special case-by-case safety assessment to be allowed on the EU market. The procedure to obtain the permit to grow or import GMOs is burdensome and time-consuming. In the US, the procedure to introduce GMO products is much more flexible and straightforward than in the EU, which takes into account consumer preferences¹ and is much more careful about the marketing of genetically engineered products within the territory of the Member States. Also, EU Member States retain certain safeguard clauses which enable them to ban GMO from their markets if certain safety concerns arise.

If consumers suffer damage, the US legal system provides for a special manner of conflict resolution by means of a class action. In Europe, no EU wide collective redress is available to date. The US class action has been mentioned as a useful tool for obtaining justice by consumers by many commentators of the currently negotiated Transatlantic Trade and Investment Partnership (TTIP) Agreement between the US and the EU which aims at creating a vast free trade area in the world, covering 850 million consumers. The following paragraphs

¹ An EU funded study concluded that «by and large, consumers continue to display a negative attitude towards genetically modified ingredients in food products and gene technology, in particular.» European Commission (2010). A decade of EU-funded GMO Research (2001-2010). EU, Brussels.

shall briefly discuss the American class action which is intended as an *ex-post* risk management tool if a marketed product triggers safety or health issues to consumers.

2. The American class action

The class action has been devised to achieve procedural economy, so that individuals would not flood law courts with separate claims concerning very similar issues. At the same time, class action avoids contradictory judgments on analogical law suits. Businesses often fear class actions since these can result in high punitive damages (also referred to as exemplary damages). That is why businesses try to find different manners of avoiding class action, for instance by incorporating class action waivers into their contracts with consumers, or by imposing arbitration to avoid possible class actions before a law court. In this context, many scholars argue that even though class actions are not dead, their “utility as a prosecution tool has been compromised” (Vairo, 2015). Others maintain that “businesses will eventually be able to eliminate virtually all class actions that are brought against them” stressing that businesses are afraid of the unpredictable constitution of lay juries before law courts and prefer arbitration performed by professionals (Fitzpatrick, 2015).

There is a general belief that class actions in the US amount to a considerable proportion of litigation. However, compared to the general volume of litigation, the number of class actions remains rather low. This is often due to the fact that class actions need to be certified before they can proceed and only a small proportion of class actions manage to obtain the necessary court certification. Sometimes, judges fail to certify a planned class action because the interests of class members are not sufficiently identical or because the defendant’s assets are insufficient to obtain damages (Hodges, 2015). Also, even if a class action succeeds, the sum obtained by individual class members may very low, compared to the overall settlement, as most of the settlement is paid out as costs of legal representation and agency costs which may be rather high. In the end, legal representatives often earn much more money on class action than the class members whose interests were supposed to be protected by class action. This is the case because there is no public funding of legal representatives pursuing class action. Hodges believes that private funding of class action always “raises issues of conflict of interest and increases the potential for abuse” (Hodges 2015).

Also, Zajc and Cepec (Zajc and Cepec, 2015) share the view that representation and agency costs constitute the main reason for inefficiency of the American style class action and

try to propose alternatives for their European counterpart, should the EU decide to proceed with the idea of introducing collective redress for consumer law suits.

3. Reconciling regulatory divergences across the Atlantic in the CETA Agreement?

The European Union's precautionary principle is not compatible with the American science-based approach as a tool for risk management decisions. Whereas the European Union's approach is holistic, taking into account science as well as consumer preferences, the American approach relies entirely on science, yet in legal terms, it is inconsistent. This inconsistency can be demonstrated on the US regulatory approach to GMOs. On the one hand, the US regulatory body, Food and Drug Agency (FDA) considers GMOs as essentially equivalent to conventional produce (with no mandatory labelling of GMOs), however, on the other hand, the corresponding federal authorities recognize the novelty of GMOs in terms of their patentability (without taking into account that novel technologies are likely to generate novel risks). Indeed, scientists and scholars from both sides of the Atlantic agree that independent research on the risks and benefits of GMOs is underfunded and hence insufficient to adopt well-informed policy decisions as to the (un)safety of authorizing GMOs (Wolfenbarger, 2000; Rajan, 2012).

Similarly to the US, Canada is an exporter of GMOs. Also, it joined the US in its GMO trade dispute against the EU before the WTO. Hence, the CETA between Canada and the EU shall address the issues of GMOs in an unambiguous way if trade disputes between these two entities are to be avoided in the future.

The CETA between Canada and the EU contains no express reference to GMOs. Instead, the treatment of GMOs has been concealed under a less visible subtitle of "biotechnology". Chapter 29 of the CETA established bilateral cooperation in the area of biotechnology (EU-Canada Biotechnology Dialogue), which raises concern about the maintenance of stricter EU rules on the authorization of GMOs. Although the European Commission as the negotiator of the CETA explained that this trade agreement shall not affect EU's restrictions on GMOs, some "critical voices fear that the precautionary principle prevailing in the EU might be watered down in the future under the influence of the different regulatory cooperation fora initiated by the CETA" (Schöllmann, 2016). However, to become applicable, the CETA requires the consent by the Council of the EU which represents the

interests of the Member States as well as an approval by the European Parliament which appears to be more cautious about the possible risks resulting from the trade agreement.

The legal nature of the CETA, however, is not quite clear. In case it exceeds EU's exclusive powers on common commercial policy, which is most likely, the draft CETA agreement will fall within the category of the so-called mixed agreements (having the EU and all its Member States as one contractual party and the third country, in case of the CETA, Canada, as the other contractual party) and it will have to pass through a ratification process in all EU Member States, which is rather cumbersome. The legal nature of the post-Lisbon generation of free trade agreements will be clarified by the Court of Justice of the EU in its opinion on the EU-Singapore Free Trade Agreement which is expected to be delivered either in late 2016 or in early 2017.

The constitutional rules of all EU Member States (except for Malta and the UK) require international treaties to be ratified by their respective national parliaments. Some EU Member States' constitutions even leave room for referenda to be organized with respect to the approval of international treaties (Eschbach, 2016). As a result, a single national parliament or a single national referendum can prevent the CETA from becoming effective if the vote is negative. The national parliaments' opinions on the CETA as a whole may or may not coincide with the national parliaments' standpoint with respect to GMOs, which will be discussed in the following paragraph.

By October 2015 nineteen EU Member States (or some of the parts of their territory in case of Belgium and the UK) have decided to ban the cultivation of GMOs within their own territory based on an "opt out" option available under EU law. The remaining EU Member States in favor of growing GM plants within their territory include in alphabetical order: Belgian Flanders, Czech Republic, Estonia, Finland, the UK (except for Scotland, Wales and Northern Ireland), Ireland, Portugal, Rumania, Slovakia, Spain, and Sweden (Chow, 2015). The unwillingness of most EU Member States to authorize the cultivation of GMOs within their territory can imply their lack of support for increased imports of (possibly unlabeled) GMOs from across the Atlantic under the CETA.

At present, the EU is negotiating another free trade agreement with the US (the so-called TTIP), where the GMOs could raise a serious issue of concern in terms of deregulation, ignoring the precautionary principle applied to GMOs in the EU so far. The official Commission sources state that biotechnology will not be covered by the TTIP agreement, however, unofficial information published by an NGO suggests otherwise (Corporate Europe

Observatory, 2015). If GMOs are included in the final wording of the TTIP agreement and the Court of Justice rules on a mixed nature of this type of free trade agreements, the opinions of national parliaments and/or public opinion of citizens of those EU Member States that will hold referenda on (dis)approving the TTIP agreement will play a crucial part in preserving or relaxing the current level of precaution with respect to GMOs in Europe.

Also, the CETA mentions WTO's Technical Barriers to Trade Agreement that can be relevant to GMO labelling. Strict rules on GMO labelling can be considered technical barriers to trade as they increase exporters' costs (no labelling implies no extra costs whereas extra labelling of GMO origin of products implies higher costs) and require exporters to separate GMO produce from GMO free goods when packing the products to be dispatched.

The unprecise wording of the CETA concerning the risk management of GMOs is likely to generate more trade disputes between Canada and the EU. To resolve trade disputes based on the CETA, a special dispute settlement body composed of permanent judges should be set up (European Commission, 2016). If the TTIP agreement which is still under negotiation echoes the same wording on biotechnology, trade disputes on GMOs between the two entities across the Atlantic are even more likely.

Conclusion

Different approaches to risk management of GMOs across both sides of the Atlantic are difficult, if not impossible to reconcile. Scientists and scholars agree that independent research on risks and benefits of GMOs is insufficient to take well informed policy decisions. In this context, the European Union's approach is more favorable to not authoring GMOs if scientific uncertainty as to the safety of GMOs prevails. On the contrary, the US approach echoed by Canada is in favor of authorizing GMOs as long as the risks resulting from their cultivation and consumption have not been scientifically proved.

The EU has completed the negotiations of the CETA with Canada where biotechnology has been addressed in a manner which has voiced criticism by those who fear that the EU's precautionary principle might be abandoned in a future if preference is given to free trade in GMOs. In order for the CETA to become effective it still needs to be translated to all EU official languages, approved by the Council of the EU and by the European Parliament, at the very least. Should the Court of Justice of the EU arrive at the conclusion that the post-Lisbon free trade agreements fall within the category of mixed agreements, also the ratification of the CETA by all EU Member States at national level will be mandatory.

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