Transboundary Trade in Genetically Modified Foods

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Abstract

This articles looks at the regulatory approach to GM foods at three levels: Codex Alimentarius, the WTO and the EU. The key issue is the latitude of the EU to have regional food safety measures that impose import restrictions on GM foods from third countries. This latitude is limited by the EU's commitment to the WTO Agreements, but the interpretation and application of the WTO Agreements are disputed by both the EU and other WTO Members. The objective of this article is to examine the impact of Codex Alimentarius measures on this conflict.
Keywords: GM foods, free trade, Codex Alimentarius, EU, WTO

1. Introduction

Genetically modified food products (hereafter referred to as GM foods) are a cause of conflict in international trade law. The main reason for this is the fundamental differences in the perception of the use of biotechnology in food production among the big players on the global market. This article will focus on specific issues, but the observations and conclusions regarding the different sources of international law will generally apply to most situations regarding transboundary movement of GM foods.

The aim of this article is to carry out a two-pronged analysis of the impact of Codex Alimentarius measures on regulation of international trade in GM foods. Firstly on the general legal force of the Codex Alimentarius measures within the framework of the WTO agreements and secondly on their influence on the assessment of specific EU rules on GM foods.

2. Codex Alimentarius

The Codex Alimentarius Commission was established in 1963. Regionally harmonised standards already existed in Europe (Codex Alimentarius Euroeaus) and Latin America (The Latin American Food Code), but the increasing globalisation of the food market created a need for broader harmonisation. To ensure the global perspective of the new institution it was established within the framework of the UN. More precisely Codex Alimentarius is placed under WHO and FAO, thus building a bridge between the two main UN operators in the field of food regulation and constitution a global reference point.

In the early years the work of the Codex Alimentarius Commission was surrounded with some legal academic interest, as this use of standards represented a novel approach to international regulation. But after some 10-15 years the interest seemed to decline most likely due to the fact that the Codex Alimentarius Standards are non-binding measures, which do not impose direct duties on the parties.

With the adoption of the WTO agreements in 1995 the Codex Alimentarius measures got a boost of interest. Both the TBT Agreement (The WTO Agreement on Technical Barriers to Trade) and the SPS Agreement (The WTO Agreement on the Application of Sanitary and Phytosanitary Measures), which are the main WTO sources of law regarding food products, have explicit reference to international standards and equivalent measures, thus injecting into the Codex Alimentarius measures a legal force beyond their immediate properties. An elaborate analysis of the interaction between Codex Alimentarius and WTO law follows in section V.

2.1. Codex Alimentarius measures in general

A general description of the scope of Codex Alimentarius in provided in Article 1 of the Statutes of the Codex Alimentarius Commission:

"The Codex Alimentarius Commission shall, subject to Article 5 below, be responsible for making proposals to, and shall be consulted by, the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:

a) protecting the health of the consumers and ensuring fair practices in the food trade;
b) promoting coordination of all food standards work undertaken by international governmental and nongovernmental organizations;
c) determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;
d) finalizing standards elaborated under (c) above and, after acceptance by governments, publishing them in a Codex Alimentarius either as regional or worldwide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable;
e) amending published standards, after appropriate survey in the light of developments."

As non-binding measures the Codex Alimentarius measures are meant to guide the regulatory behavior of the acceding States without taking the place of national legislation. This legal status follows from the articles 1 and 3 of the General Principles of the Codex Alimentarius:

Article 1: The Codex Alimentarius is a collection of internationally adopted food standards and related texts presented in a uniform manner. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

Article 3: Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.

A key purpose of the Codex Alimentarius is to protect the health of the consumers from risks related to the consumption of food (Masson-Matthee, 2007). In practice food safety is addressed in a variety of measures like general standards, commodity standards, recommendations, guidelines etc. But even if the main focus is on food safety and consumer protection it should be noticed that facilitation of international trade is also stated explicitly among the formal aims in the abovementioned Article 1 of the General Principles. This implies that trade interests should not only be considered 'external' interest, which must be balanced against the food safety interest of the Codex Alimentarius measures in the application of these measures. The trade interest is to be considered an integral aim of Codex Alimentarius; hence it shall be considered already in the drafting of Codex Alimentarius measures.

2.2. Measures concerning GM foods

At the 23rd meeting of the Codex Alimentarius Commission the Members agreed to establish an *ad hoc* intergovernmental task force on foods derived from biotechnology. The task force began mapping the need for Codex standards concerning GM foods. The progress of the task force was reported to the Codex Alimentarius Commission. At its 26th meeting in July 2003 the Codex Alimentarius Commission adopted the following four standards for risk assessment of GM foods:

1) The Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology;
2) The Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants;
3) The Draft Guideline for the Conduct of Food Safety Assessment of Recombinant-DNA Microorganisms; and
4) The Proposed Draft Annex on Possible Allergenicity Assessment.

The cornerstone of the Codex standards is the Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, which sets out the general requirements to risk assessment, risk management, risk communication, information exchange and a review process.

The guidelines for foods derived from GM plants and microorganism complement the general principles (Ostrovsky, 2004). The Codex guidelines does not set any level for acceptable risk nor do they attempt to define the concept of 'risk'. Instead the guidelines focus on the procedure for risk assessment.

An awareness of the impact on international trade law is detectable in the design of the Codex principles and guidelines. Safety assessments carried out in accordance with the guidelines should not be seen as an assessment of the absolute risk. A *substantial equivalence* method is integrated in the risk assessment, and consequently the risk of a GM food product should be assessed in comparison with its conventional counterpart.

What we have seen so far is Codex Alimentarius providing non-binding procedural guidelines for risk assessment of GM foods. Does that have any legal significance? Compliance with the material requirements to the risk assessment mainly relies on the political loyality of the Codex Alimentarius members. There are no international enforcement measures – which would also be meaningless regarding non-binding measures. The main legal significance lies in the methodical approach to GM foods. First of all the Codex guidelines acknowledge the use of GMO's as a special feature that calls for special risk assessment. But on the other hand the application of the *substantial equivalence* method indicates that GM foods are considered comparable to their conventional counterparts. And as it will be discussed later in this article this may have a direct impact on the application of the legally binding WTO agreements.

2.3. Labelling of GM foods

Not every aspect concerning GM foods became subject to Codex Alimentarius measures in 2003. The most notable absence was measures regarding labelling. The Codex Ethics Code points out labelling as a key mechanism for ensuring consumer protection, and several sets of labelling standards have been adopted (MacMaoláin, 2007). Both general standards like the General Standard for the Labelling of Pre-packaged Foods (Codex Standard 1/1985) and product specific standards i.a. the Codex Standard for Chocolate (Codex Standard 87/1981). But initially nothing specifically regarding the presence or use of GMOs.

But why this absence of Codex Alimentarius labelling standards and other harmonisation measures regarding labelling of GM foods? Other aspects regarding these products had already been subject to harmonisation and adoption of labelling standards is acknowledged as a general aim of Codex Alimentarius. The answer, again, lies in the different perceptions of biotechnology in food production. From the perspective of *e.g.* an American food company it is obvious that a label stating the content or use of GMOs in a food product would be treated as a warning label by the average European consumer. The issue of GM labelling measures was debated in the Codex Commission for Food Labelling over two decades without the efforts resulting in any kind of consensus regarding the wording of such recommendations. At one meeting of the Codex Commission for Food Labelling the disagreements between Members proved to be so exhaustive that the chairman of the meeting suggested a three-year time-out on the matter. However, several Members objected to this, so the matter was still on the agenda for the upcoming meetings of the Commission.

Finally, at its 39th session in 2011 the Codex Committee on Food Labelling (CCFL) was able to adopt guidelines for labelling of GM foods. As the last of the opposing countries the United States yielded and accepted the adoption of formal guidelines (Compilation of Codex texts relevant to the labelling of foods derived from modern biotechnology (CAC/GL 76-2011). As with the risk assessment guidelines, the labelling guidelines per se are not binding and consequently they do not prescribe any kind of mandatory labelling. But as it will be discussed later in the article, the existence of Codex guidelines may influence the application of binding WTO Law.

3. Interaction with WTO Law

The Codex Alimentarius measures are non-binding by nature, which leaves the question: how do they have any significance in relations to the legally binding WTO agreements? The WTO agreements themselves do not carry out harmonisation of specific areas like food safety, environmental protection etc. nor do they prescribe positive requirements for the parties in these areas. WTO law generally keeps a relatively narrow focus on removal of trade barriers. However, WTO law acknowledges the value of international harmonisation, also for the purposes pursued by the WTO, hence the WTO agreements contains encouragements and even binding requirements for the parties to comply with harmonised international measures when such measures exist. And this is where the legal force is injected into the Codex Alimentarius measures.

Even if they are non-binding in their own right, their general acceptance under WTO law means that one party is bound to accept national/regional measures adopted by another party, even if this has a trade restricting side-effect, as long as the given measures corresponds with a Codex Alimentarius measure.

3.1. The SPS Agreement

When dealing with aspects of food law regarding safety and health in a WTO setting the SPS Agreement is the key source. One aspect of the formal definition of sanitary and phytosanitary measures is: "Any measure applied to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs"(Annex A, Provision 1, litra b).

As mentioned WTO law does not prescribe any positive requirements for the parties on this matter. On the other hand, WTO law to a large extent constitutes a negative delimitation of the latitude of the parties to adopt or maintain national or regional (in the case of the EU) measures. The SPS Agreement is imperial since it regulates the range of legal defences of the parties to adopt measures, which – as a starting point – are in conflict with the WTO duties of the given party.

It is argued by Jackson (2006) that leaving WTO members 'sovereign' rights as regards acceptable levels of risk in various products works against the trade liberalization intended by the WTO. *Jackson* contends that the SPS Agreement contains 'tortured negotiated language' as a result of the efforts to pursue the combined goals of liberalizing trade and allowing members latitude to decide their own levels of tolerable risk. When looking at the SPS Agreement and its application in practice, this does, however, not appear generally disturbing. The SPS Agreement openly (forced language or not) acknowledges both the international trade interests and the access to national/regional risk management and it is designed to strike a balance between the interests.

The preamble of the agreement mentions harmonisation as a way of minimising the negative impact of national measures on international trade, and this emphasis on harmonisation is followed by an explicit reference to international standards, guidelines and recommendations as such harmonisation measures. In Annex A of the SPS Agreement Codex Alimentarius measures are specifically pointed out as part of this category (Annex A, Provision 3, litra a).

The formal impact of Codex Alimentarius measures under the SPS Agreement is regulated by Article 3:

Article 3.1: To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this agreement, and in particular in paragraph 3.

Article 3.2: Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

The implication of Article 3.2 is clear. If a national/regional measure conforms to a Codex Alimentarius measure it is by definition lawful under WTO law. No further justification should be required from the Member, as the conformity with the given Codex Alimentarius measure is a sufficient defence. Article 3.1 is close to having the shape of a positive requirement to the WTO members to comply with existing international measures. However, it should be noticed that Article 3.1 only requires conformity with international measures *if* national/regional measures are adopted. In a trade perspective the implication of Article 3.1 is presumption that sanitary and phytosanitary measures, which do not conform to existing international measures, are inconsistent with WTO law.

3.2. The TBT Agreement

When dealing with trade aspects of food regulation the TBT Agreement needs to be considered, since it covers all products including agricultural products (Article 1.3). Like the SPS Agreements, the TBT Agreement mentions international standards in its preamble as an instrument to improve the production efficiency as well as facilitate international trade. As opposed the SPS Agreement, the TBT Agreement has no direct reference to Codex Alimentarius. It is, however, stated by the Appellate Body in *EC – Sardines* (WT/DS 231, *EC – Sardines*) that Codex Alimentarius falls under the definition of international standardisation bodies referred to in the agreement. A key issue in *EC – Sardines* was whether Codex Standard 94/1981 constituted a relevant international standard.

The deciding factor for the Panel was whether the product coverage of Codex Standard 94/1981 was similar to that of the disputed EU technical regulation, hence the Panel examined if the Codex Standard '[...] bears upon, relate[s] to or [is] pertinent to' the EU technical regulation. The Panel found that since the two measures were aimed at the same overall product category and since they included the same types of requirements, the Codex Standard was a relevant international standard, thus restricting the EU when adopting regional legislation (Para. 7.68 of the Panel Report). This was upheld by the Appellate Body (Para. 233 of the Appellate Body Report). The next question was then whether the EU technical regulation could be considered to be *based* on the international standard. The opinion of the Panel as stated in *EC – Sardines* is that the criteria 'based on' is not satisfied merely by the disputed measure not contradicting the given international measure.

According to the Panel there is a duty to apply the relevant international standards as '[...] the principal constituent or fundamental principle for the purpose of enacting the technical regulation' (Para. 7.110 of the Panel Report). This position seems to be modified by the Appellate Body as it is stated in the Appellate Body Report that the satisfaction of the criteria *based on* depends on whether there is a contradiction between the international standard and the national/regional technical regulation (Para. 249 of the Appellate Body Report). In conclusion it appears to be sufficient that a national/regional measures does not contradict relevant international standards in order to consider it to be *based on* these standards (van den Bossche, 2008). This may seem like a somewhat lax attitude the international standards, but it is consistent with the fact that WTO Law aims at negative integration of national/regional markets. The pursuit of that goal does not require the exhaustive efforts concerning international standards claimed by the Panel in *EC – Sardines*.

The TBT Agreement has a dual approach to international standards quite similar to that of the SPS Agreement. The articles 2.4 and 5.4 address the positive requirement to the Members, as they state that technical regulations should be based on international standards where such standards exist or where there completion is imminent. Article 2.5 addresses the impact of international standards in relations with the justification of technical regulation on national or regional level. It is stated that when such a technical regulation is prepared, adopted or applied in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade. So, if a national or regional technical regulation conforms to relevant Codex Alimentarius standards it is presumed to correspond with the TBT Agreement.

The adoption of the abovementioned Codex Guidelines for labelling of GM foods may prove to have significant impact on the application of the TBT Agreement on national and regional labelling requirements for GM foods. The EU labelling rules, which are addressed below, are connected to a strict approval scheme. Thus, it may be argued that the labelling requirements serve no sanitary or phytosanitary purpose, in which case the SPS Agreement is not applicable. But since it may now be claimed that labelling of GM foods is based on international guidelines it may be in compliance with the TBT Agreement.

4. The EU Perspective

Having explored the scope of the Codex Alimentarius measures regarding GM foods and their impact on WTO law, the next step is to assess how the Codex Alimentarius measures affects EU Law by virtue of this impact on WTO Law. Even if the efforts of Codex Alimentarius is to carry out global harmonisation there is little doubt that regulation of food safety is a permanent battle field in international trade law. With the fundamental differences in the approach to food safety in the EU and the US as well as other GMO producing countries the application of Codex Alimentarius measures can be the best way to create a common playing field (Lindner, 2008).

The EU rules on GM foods have travelled between different regulatory systems since the first piece of legislation was adopted in 1990. At that time GM foods was regulated by the Directive on Deliberate Release of GMOs into the Environment (Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms). Later (in 1997), GM foods was moved from the directive and into the Novel Foods Regulation (Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients). With the latest change in 2003 the regulation of GM foods was separated into two EU Regulations:

The Food and Feed Regulation (Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed) and the Regulation on Labelling and Traceability of GM Food and Feed (Regulation (EC) No 1830/2003 of the Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms).

With the adoption of these two Regulations the EU to the step from harmonized legislation into full centralisation of the area. When assessing the impact of the Codex Alimentarius Guidelines on EU countries, we can focus solely on the EU legislation. The Regulations do not contain any safety clauses providing Member States latitude to adopt or maintain national legislation and no national transposition of the EU measures is required – or even allowed. Since the two Regulations are adopted pursuant to *i.a.* Article 114 TFEU the general safety clause prescribed by Article 114(4-5) applies. This, however, provides the Member States only very limited latitude to adopt or maintain national rules, and it will be difficult for Member States to justify a need for special legislation in this area.

4.1. The Food and Feed Regulation

The centrepiece of the regulation of GM foods in EU Law is the Food and Feed Regulation. The Regulation establishes the centralised approval scheme for both GM food and feed products to be placed on the Internal Market of the EU. The reason for describing the approval mechanism as centralised is that the risk assessment is carried out by EFSA and the approval is decided at EU level by a comitology (Anker, 2006). Thus, the national legislators and food safety authorities have no formal role in the approval procedure.

Since approval is required to place GM foods on the EU market, the approval scheme is potentially a trade restriction on food products from third countries. And since such third countries to a very large extent will be WTO members this may be a cause of conflict. One of the motivations for the adoption of the new approval and labelling rules in 2003 was to persuade Member States to abolish their national restrictions on import of GM foods, thus avoiding an EU defeat in the then pending *GMO Case* (WT/DS 291, 292 and 293, *EC – Biotech Products*) at the WTO Dispute Settlement Body (Baetens, 2007). The mission was to a certain extent accomplished as the Member States lifted their national bans and permanent blocks of the then approval mechanism (the so-called *de facto-moratorium*). But this is not necessarily the end of all conflict. Many of the GMO producing countries (prominently the United States) have been far from impressed with the EU rules from 2003. From these countries it has consistently been argued that GM foods and their conventional counterparts are to be considered *like products* in a WTO context. And from that point of view special requirements to GM foods constitute differential treatment, which is a violation of WTO Law.

There is no clear decision of this matter within WTO Law, but the reference to international standards in WTO Law could potentially guide the interpretation. However, no clear answers are found here either. It can be argued that the *substantial equivalence* method of the Codex Guidelines indicates that GM foods and conventional foods are indeed 'like products'. On the other, the basic idea of the Codex Guidelines is to provide harmonised procedures for assessing risks particular to GM foods, which can be seen as an indication that international standards distinguish between GM foods and conventional foods. GMO sceptic countries will argue that this speaks against the two being 'like products'. In the abovementioned *GMO Case* the Panel avoided deciding on this matter even if it had been raised by the parties. A clarification of the matter requires it being raised as an unavoidable question in a future case.

As discussed earlier in this article labelling is an issue of particular interest in the area of GM Foods. In addition to the approval scheme, the Food and Feed Regulation prescribes mandatory labelling of GM Foods. Within EU Law this is considered a relatively peaceful measure. When performing proportionality assessments of national trade restricting measures, the EU Court of Justice has traditionally considered labelling requirements the lesser evil among trade restricting measures. But from the point of view of the GMO producing third countries, the labelling requirement may be a considerable restriction on their access to the EU market. Due to the prevailing consumer perception of GM foods in the EU Member States any emphasis of the use of GMO's in the production chain may *de facto* serve as a warning label, which will discourage consumers from buying the product (Andersen, 2010).

Economists have even argued that mandatory labelling on a market with a predominantly negative consumer perception of the subject of the labelling may create a corner outcome, thus curtailing the diversity on the market to the detriment of the consumers (Gruère, Carter & Farzin, 2008). As mentioned earlier in this article the labelling requirement could earlier have been claimed to be a violation of WTO Law. As the labelling is subsequent to the strict approval procedure it would be difficult to argue, that it is a sanitary or phytosanitary measures. Consequently, it cannot be defended under the SPS Agreement. But with the adoption of the abovementioned Codex Guidelines for labelling of GM Foods, it may now be possible to defend the EU labelling requirements under the TBT Agreement.

Pursuant to Article 2(4) of the TBT Agreement the WTO Members must base their 'technical regulations' on international standards, *in casu* the Codex Guidelines. This also implies that when WTO Members base trade restricting measures on international standards, they will be considered consistent with WTO Law.

4.2. The Regulation on Labelling and Traceability

The Food and Feed Regulation is supplemented by the Regulation on Labelling and Traceability. The separation of the rules into the two Regulations is not quite consistent. As seen above the majority of the labelling rules relevant to the consumer are found in the Food and Feed Regulation. The Regulation on Labelling and Traceability also contains certain rules concerning consumer oriented labelling of GM foods, but these rules are clearly *lex generalis* to the labelling rules in the Food and Feed Regulation, which was adopted at the same time. It is difficult to see the general rules serving any regulatory purpose.

The legal significance of the Regulation on Labelling and Traceability lies mainly in the traceability rules. Ensuring traceability of GM foods serves two main purposes: First, facilitation of the labelling rules. Effective enforcement of the labelling rules requires reliable traceability. And second, traceability enables withdrawal of GM foods if new knowledge of adverse effects on health or environment becomes available after the approval and marketing of a given product.

In the context of this article the Regulation on Labelling and Traceability is not likely to cause problems. If the labelling requirements should become an issue under WTO Law, the focus will be on the *lex specialis* rules of the Food and Feed Regulation. And since both risk assessment and labelling are subject to international standardisation in the shape of the Codex Guidelines, the traceability rules, which might be considered restrictive by a third country exporter, will most likely be found compatible with the TBT Agreement, as the rules on traceability are closely linked to either the labelling or to the possibility to react on a renewed risk assessment.

5. Conclusions

The objective of this article has been to examine the role of Codex Alimentarius in the tension field between EU Law and WTO Law in the regulation of GM foods. The regulatory approach of EU Law is based on a perception of GM foods, which is not shared by a group of other WTO Members. The international harmonisation provided by Codex Alimentarius clarifies some but not all of the regulatory uncertainty.

The most prominent effect of the non-binding Codex Guidelines is the acknowledgement of labelling requirements for GM foods. Before the adoption of the Codex Guidelines it was expected that the EU rules on labelling of GM foods could cause a second GMO case at the WTO Dispute Settlement Body. But with the adoption of the Codex Guidelines all of the GMO producing countries appear to accept this.

The impact of the Codex Guidelines on risk assessment is less clear. They clearly imply that the fundamental requirement of a risk assessment is in accordance with international standards and consequently also compliant with WTO Law. But when it comes to the application of the risk assessment in a subsequent approval procedure the Codex Guidelines does not provide clear answers. Since the Codex Guidelines does not address the issue of acceptable level of risk, this is still open for very different opinions. The same with the in WTO Law crucial question whether or not GM foods and their conventional counterparts are to be considered 'like products'. In the *GMO Case* the WTO Dispute Settlement Body missed its first opportunity to decide on the matter, hence leaving it unresolved.

In conclusion, GM foods still have the potential to be a cause of conflict in international trade. Some issues have been resolved through the adoption of Codex Alimentarius measures, but notable problems are still unresolved.

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