'False pretense of unity' – A comment on the EU speaking with 'one voice' in trade negotiations in the field of biotechnology

Sophia Paulini[*]

1. *Introduction*

The negotiations of Comprehensive Economic and Trade Agreement between the EU and Canada (CETA) has caused some to fear that EU standards of genetic modified organisms (GMO) regulation in the agri-food field will be watered down following the entry into force of the agreement.[1] In Alessandra Arcuri's article 'Is CETA keeping up with the promise?', provisions addressing biotechnology were interpreted in the light of the rules on treaty interpretation to conclude that those provisions should be read as being largely 'respectful of stringent regulatory standards and of the precautionary principle.'[2]

As a side note in the latter article, Arcuri points out that 'the European regulatory framework [in the field of GMOs] is presented as monolithic in the context of CETA', whereas 'the reality is more complex.'[3] This comment aims to draw attention to and expand on this side note by analysing the paradoxical situation that in the field of GMO regulation the EU speaks with 'one voice' in trade negotiations despite

[*] PhD Candidate at Erasmus University Rotterdam.

[1] K Kodde, 'CETA trade deal puts EU food and agriculture standards at risk' (2017) <www.greenpeace.org/international/en/news/Blogs/makingwaves/ceta-trade-canada-eu-food-and-agriculture-leaks/blog/60271/>; B Thomsen, 'CETA's threat to agricultural markets and food quality' in H Mertins-Kirkwood et al (eds), *Making Sense of CETA* (2nd edn, PowerShift 2016); C Then, 'Freihandel – Einfallstor für die Agro-Gentechnik' (2015) Study on behalf of the Green Party in the German Federal Parliament.

[2] A Arcuri, 'Is CETA keeping up with the promise? Interpreting certain provisions relation to Biotechnology' (2017) 41 QIL 58.

[3] ibid 38.

there being no consensus among Member States in this policy field. This lack of internal consensus has been a subject of major regulatory struggle in the EU for many years now and has caused the policy field of GMO regulation to become the 'most gridlocked on the Union's agenda despite continuous reform efforts.'[4] The most recent reform strategy has been to give up on finding a common ground and on taking decisions on the desirability of GMOs as a community by rolling competences back to the Member States. In the field of GMO cultivation this has been done by providing Member States with the possibility to single-handedly restrict or prohibit the cultivation of GMOs in their territory. Despite the foregoing, the EU still speaks *unisono* in trade negotiations on this topic, as it did in the negotiations leading up to CETA. This is a paradox that has so far been discussed – at most – tangentially, even though a closer look reveals that it is seriously problematic.

2. *Complex and everything but monolithic – The EU regulatory framework for GMOs*

The regulatory framework for the authorisation of the cultivation of GMOs under Directive 2001/18/EC[5] and of GM food/feed under Regulation 1829/2003[6] requires a case-by-case evaluation of the risk of each GMO that is intended to be place on the market. The authorisation process constitutes a so-called 'risk analysis',[7] which is divided into a 'risk assessment' and 'risk management' phase. In the risk assessment phase, the European Food Safety Authority (EFSA) issues a scientific opinion

[4] M Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance – GMO Regulation and Its Reform' (2015) 21 Eur L J 623.

[5] 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 and repealing Council Directive 90/220/EEC – Commission Declaration [2001] OJ L 106/1 (Deliberate Release) art 4(3).

[6] Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] OJ L 268/1 (GMO Food and Feed) art 4(2).

[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] L 31/1 (General Food Law Regulation) art 6.

defining the risk of the GMO in question. In the risk management phase, the European Commission is tasked to consider the results of EFSA's risk assessment as well as 'other factors legitimate to the matter under consideration'[8] in order to issue a draft decision that grants or refuses the authorisation of the GMO in question. Member States then take a vote on this decision in the comitology committee. On paper, the authorisation system was regarded 'as a promising example of precautionary transnational governance' as it attempts to 'reconcile two potentially conflicting notions of legitimacy, namely the scientific and the political legitimacy of GMO authorizations.'[9] It is, however, no secret that the EU authorisation system for GMOs turned out to be a failure and has been at a breaking point for many years now.

The main shortcoming of the EU regulatory framework for GMOs is the failure of the authorisation process to take into account a wider range of more individualised factors that go beyond the scientific assessment and that member states consider relevant. . The time and place for this to be done is the risk management stage. However, while Member States are incapable of bringing non-scientific factors that they deem relevant into the comitology forum, the Commission is adamantly ignoring factors beyond science when issuing its draft decision. As pointed out by Arcuri, since the creation of the centralised authorisation system for GMOs, Member States have never achieved the necessary majority in the comitology forum to make a decision (for or against a particular GMO).[10] If no necessary majority is achieved, the European Commission alone is authorised to take the final decision on the matter, which renders Member States unable to bring more individualised factors and considerations beyond science into the authorisation process. The Commission, for its part, does not include factors beyond science in its draft decision. According to the Commission, 'other legitimate factors' can be taken into consideration in addition to EFSA's risk assessment but

[8] ibid art 6(3).

[9] M Weimer, 'Risk Regulation, GMOs, and the changes to the deliberation in EU governance, Politicisation and scientification as co-producing trends' (2014) Amsterdam L School Legal Studies Research Paper No 2014-21 10.

[10] Arcuri (n 2) 38.

could not be used as a justification to deny EU authorisation if GMO has been deemed safe by EFSA.[11]

The ignorance of factors beyond EFSA's risk assessment necessitates the EU to fall back on the pretence that EFSA possesses 'super-scientific powers'[12] on which Member States should exclusively rely. Member States are not willing to do that, as becomes apparent in the post-authorisation stage. Here, numerous Member States have illegally banned GMO cultivation in their territory based on, among others, ethical and socio-economic grounds that they felt were not taken into account in the centralized authorisation process. The Commission's efforts to overturn Member States' illegal bans of GM crops have been consistently rejected in the Council.[13]

3. *Range of Member States views*

It is worth taking a look at just how different policy stances of Member States are vis-à-vis GMOs. Member States have been classified on the basis of their (non-)acceptance of plant biotechnology into 'adopters', 'conflicted', and 'opposed'.[14] 'Adopters' are Member States that grow GM plants (eg Spain, Portugal, Czech Republic and Slovakia) and Member States that would be principally willing to cultivate GM plants under the right climatic and agricultural circumstances (eg Denmark, Flanders, the Netherlands, Sweden and the United Kingdom). Among the 'adopters' particular note should be taken of the 'GMO champion' Spain. The latter is the only Member State that grows significant volumes of Bt maize, the sole GM plant authorised in EU. In fact, 30% of the total

[11] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM(2015) 177 final, 3-4.

[12] ibid 41.

[13] 'Evaluation of the EU Legislative Framework in the Field of Cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003, and the Placing on the Market of GMOs as or in Products under Directive 2001/18/EC' Final Report to DG SANCO (European Policy Evaluation Consortium 2011) 89.

[14] JM Lucht, 'Public Acceptance of Plant Biotechnology and GM Crops' (2015) 7 Viruses 4265.

Spanish maize area is planted with Bt maize.[15] 'Conflicted' Member States include countries where certain stakeholder groups would support the adoption of GM crops, but there is significant political pressure opposing GM technology, for example, from consumers and NGOs (eg France, Germany and Poland). In 'opposed' Member States, located mainly in Central and South Europe (eg Austria, Croatia, Greece, Hungary and Italy), most stakeholders and politicians oppose the cultivation of GMOs.[16]

It is by no means an exaggeration to claim that the issue of GMO regulation has divided regions, politics, societies and identities in Europe.[17] A closer look at this 'complex reality' therefore inevitably brings up the question whose standards and whose policy stance the EU is actually representing when it speaks about agri-food biotechnology in trade negotiations.

4. *The general trend of competences being rolled back to Member States*

The new Directive 2015/412[18] amending Directive 2001/18/EC constitutes an attempt to find a way out of the gridlocked authorisation system. Article 26(b) of Directive 2015/412 provides Member States the option to restrict or prohibit the cultivation of GMOs that have been centrally authorised to be placed on the market. According to Article 26(b), Member States may restrict or prohibit the cultivation of a specific GMO on the basis of 'compelling grounds', such as environmental policy objectives, socio-economic impacts or public policy. The diversity among Member States in this policy area is demonstrated again in the different reactions of Member States following the introduction of Article 26(b). For example, whereas Germany is opting for nationwide cultivation

[15] OECD, 'Farm Management Practices to Foster Green Growth' (2016) OECD Green Growth Studies 107.

[16] JM Lucht (n 14) 4265.

[17] M Weimer, 'Risk Regulation and Deliberation' (n 4) 624.

[18] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory [2015] OJ L 68/1.

bans, the UK indicated its intention to come up with regional strategies and to create a more diversified opt-out system.[19]

One way to understand Directive 2015/412 is the European Commission compromising and giving up on the vision of a centralised authorisation system by legitimising the formerly illegal prohibitions and restrictions that have been applied by Member States to EU-wide authorised GMO seeds. However, it is important to note that Directive 2015/412 also entails a shift of legal and political accountability from the EU to Member States, who do not only have the right to prohibit the cultivation of GMOs but will also have to ensure that measures taken comply with 'international obligations of the EU, and in particular with the ones established under the World Trade Organisation (WTO).'[20]

Illegal bans restricting GM food and feed have not been as widely used by Member States as in the field of GMO cultivation.[21] Nevertheless, following a review of the decision-making process on GMOs, the Commission also deemed the authorisation system set out in Regulation 1829/2003 on genetically modified food and feed as dysfunctional. This finding is based on the high number of Member States voting against the authorisation of GM food and feed and on the fact that Member States have never achieved the necessary majority in the comitology procedure. According to the Commission, it is apparent that Member States do not feel that the process allows them to fully address their individual concerns and fails to take into account factors which do not only relate to issues associated with the safety of GMOs for health or the environment.[22]

[19] M Geelhoed, 'Divided in Diversity: Reforming The EU's GMO Regime' (2016) 18 Cambridge YB Eur L Studies 21.

[20] Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, COM(2010) 375 final, 7.

[21] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Reviewing the decision-making process on genetically modified organisms (GMOs)' COM(2015) 176 final, 5. One Member State has measures relating to three products in place.

[22] ibid 6.

The Commission therefore proposed an amendment to Regulation 1829/2003 that mirrors Article 26(b) in Directive 2015/412.[23] The proposal suggests the inclusion of Article 34(a), which permits Member States to adopt measures restricting or prohibiting the use of GM food and feed. According to Article 34(a), such measures must be based on compelling grounds and cannot conflict with the risk assessment that was carried out. Measures adopted under Article 34(a) must also be reasoned, proportional and non-discriminatory and have to comply with EU law. This proposal was rejected by the European Parliament, among other things, based on concerns that the Commission proposal may be incompatible with internal market as well as WTO rules. The European Parliament therefore asked the Commission to withdraw its proposal and to submit a new one.[24]

Despite the rejection of this proposal by the European Parliament, the point remains that, as a result of a review it undertook of the current legislation on the authorisation of GMOs, the Commission regards reform of the current system as absolutely necessary. Instead of reforming the centralized authorisation procedure, the Commission opts for the rolling back of competences to Member States and thereby confirms the reform strategy adopted for the cultivation of GMOs as the general reform strategy in the field of GMO regulation. The latter shows that the Commission understands the GMO policies of Member States are too diverse to maintain a centralised authorisation process and the main reason for the dysfunctionality of the authorisation process is that factors and more individual considerations that go beyond the scientific assessment are practically ignored.

[23] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM(2015) 177 final.

[24] European Parliament, 'Report on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory' (2015) A8-0305/2015, 6.

5. *The consequences of the 'false pretense of unity'*

Based on the foregoing explanations, it is clear that there is no uniform policy stance among Member States in the field of GMO regulation. The centralised authorisation system failed as it was incapable of dealing with this diversity, which caused the Commission to start handing competences back to Member States. Nevertheless, the EU still speaks with 'one voice' in trade negotiations on the topic of biotechnology. The consequence of this false pretense of unity is that, as can be seen in CETA, the text agreed upon in the negotiations does not reflect the policy situation in the EU. Provisions on biotechnology in CETA do neither acknowledge that in the area of cultivation competences have been partly passed back to Member State level, nor does it reflect the recent policy change of Member States being able to restrict the use of GMOs on the basis of factors beyond science.

To provide an example, in Article 25 CETA, the importance of 'shared objectives' is noted, one of which is 'to promote efficient science-based approval processes for biotechnology product' (Article 25.2 (2) (b)). Arcuri pointed out that there is room for interpretation of the term 'science-based' as a nuanced vision of science compatible with the precautionary principle.[25] What is still problematic, however, is that it does not reflect at all the recent policy change, codified in Directive 2015/412, to restrict or even prohibit GMOs on the basis of factors that go beyond science. As elaborated above, this policy change is based on the acknowledgment of the European Commission that the authorisation system is flawed since considerations beyond EFSA's scientific assessment are not taken into account within the authorisation process. Despite this, the Commission has apparently not insisted on including factors in the text of CETA that are relevant to Member States in the approval of biotechnologies, besides scientific factors.

What are the repercussions of the above-discussed inconsistencies for Member States? Pursuant to Directive 2015/412, Member States can now restrict or prohibit the cultivation of GMOs on the basis of factors other than scientific considerations. The same may be possible for GM food and feed in the future. However, according to several commentators such restrictions and prohibitions possibly constitute a violation of WTO

[25] Arcuri (n 2) 52.

law or may be inconsistent with provisions of trade agreements between the EU and third countries,[26] such as CETA. Whereas it seems reasonable that Member States have to take legal responsibility for their own individual restrictive or prohibitive measures, the discrepancies between internal and external GMO policy is likely to prove problematic. This is because Member States are granted – under EU law – the means to impose restrictions or prohibitions that may be deemed illegal on the basis of international trade rules, which the EU negotiated on behalf of all Member States. The fact that Member States have not been raising this issue can only be due to the vast number of concerns about CETA's legal effects, of which some more intricate and complex ones are bound to get lost in the shuffle. However, it has to be expected that the consequences of the above-elaborated 'false pretense of unity' will become apparent sooner or later.

[26] Geelhoed (n 19) 33-34; H-G Dederer, 'The Challenge of Regulating Genetically Modified Organisms in the European Union: Trends and Issues' in Yumiko Nakanishi (ed), *Contemporary Issues in Environmental Law, The EU and Japan* (Springer 2016) 164.