Cambridge Yearbook of European Legal Studies, 18 (2016), pp. 20–44
doi:10.1017/cel.2015.21

First published online 21 January 2016

Divided in Diversity: Reforming The EU's GMO Regime

Miranda GEELHOED*
School of Law, University of Edinburgh

Abstract
This article analyses the recent reform to the EU's genetically modified organisms (GMO) regime which allows Member States to restrict the cultivation of GMO on their territory for reasons that do not relate to issues of health and safety or the environment. By allowing for national differentiation – although on legally questionable grounds – new Article 26b of Directive 2001/18/EC has been presented as a solution to overcome the impasse in GMO decision-making. However, this article finds that the reform fails to provide a solution for the EU regime's most pressing problem, namely its disregard for scientific uncertainty and disagreement.

Keywords: GMO, cultivation, risk regulation, WTO, internal market, opt-outs, EFSA

I. INTRODUCTION

In early April 2015, an amendment to Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) entered into force, allowing Member States to restrict or prohibit the commercial cultivation of GMOs on their territory for reasons that do not relate to issues of safety for health and the environment.[1] The compromise in a second reading of the new Article 26b brought an end to five years of difficult negotiations on the division of competences in the regulation of GM crops, fuelled by the subsidiarity principle (Article 5(3) TEU). The Council and MEPs' sudden decisiveness may, however, be explained against the backdrop of the expected unilateral authorisation of the cultivation of genetically engineered Maize 1507 by the European Commission, despite rejections by 19 Member States and opposition in the European Parliament.[2] As an ultimate attempt by Member States to regain the final say on GMO cultivation, the recent adoption of Article 26b Directive 2001/18/EC has swiftly shifted the responsibilities and difficult political and legal discussions that are inherent to the GMO topic, from the EU to the national level. Whereas Austria narrowly beat Hungary in the first one-on-one implementation of

* I would like to thank Dr Apolline Roger for her thoughtful comments. All remaining errors are my own.

[1] Directive (EU) 2015/412 [2015] OJ L68/1.

[2] EP Resolution of 16 January 2014 on Placing on the Market for Cultivation of a Genetically Modified Maize Product (2013/2974) P7_TA(2014)0036.

the new rules,[3] Member States like Germany and the United Kingdom focused their efforts on the reconciliation of different internal positions regarding the question 'to ban or not to ban' and on the difficult task of drafting a legally watertight framework for restrictions.[4] Although Maize 1507 will only be the third crop to pass through the EU's regime,[5] Member States are compelled to exercise their new discretionary powers rapidly and effectively, with eight applications for GM crops pending in the authorisation machine and a Commission that is facing pressures from overseas to process GMO applications.[6]

Article 26b marks a new chapter in the EU's GMO dossier that has been shaped by external and internal, pro- and anti-GMO forces, which have either emphasised the technology's potential to increase agricultural productivity or its environmental and health risks.[7] The EU's initial, cautious steps in the 1990s to partly centralise the regulation of GMOs were meant to please both sides, by alleviating competitive distortions and providing for uniform protection through the mutual recognition of national risk assessments, only to be subjected to a central comitology risk-management procedure in case of reasoned objections.[8] Yet, public distrust in both foreign science and the EU's role in food safety issues resulted in a political impasse and a period of suspension of authorisations by the Commission that is known as the infamous 1999 *de facto moratorium*.[9] In the lead-up to the *EC Biotech Products* WTO complaint brought by the EU's biotech-minded trade partners, Canada, the USA and Argentina,[10] the EU therefore adopted an increasingly centralised – albeit still multilevel – legal framework consisting of Directive 2001/18/EC and

[3] Austrian National Council, *Rahmengesetz für Gentechnik-Anbauverbot*, 673 dB (July 2015) http://www.parlament.gv.at/PAKT/VHG/XXV/I/I_00673/index.shtml [last accessed 30 November 2015]; Hungarian Ministry of Agriculture, *Hungary could be first in EU to introduce new GMO regulations* (11 May 2015) http://www.kormany.hu/en/ministry-of-agriculture/news/hungary-could-be-first-in-eu-to-introduce-new-gmo-regulations [last accessed 30 November 2015].

[4] Whereas Germany seeks to opt – if legally feasible – for nationwide cultivation bans, (German Federal Ministry of Agriculture, *Anbauverbot von Gentechnikpflanzen in Deutschland* (1 September 2015) https://www.bmel.de/DE/Landwirtschaft/Pflanzenbau/Gentechnik/_Texte/NatRegelungAnbauverbote.html [last accessed 30 November 2015], the UK is likely to opt for more diversified, regional strategies as exemplified by its recent opt-out request under Art 26c(1) Directive 2015/412, '15 Member States Opt Out of GMO Culture' (*Euractiv,* 2 October 2015) http://www.euractiv.com/sections/agriculture-food/15-member-states-opt-out-gmo-culture-318181 [last accessed 30 November 2015].

[5] The other crops are the MON810 Maize, Commission Decision (EC) 98/294 [1998] OJ L 131/32, and the annulled authorisation for the Amflora Potato, Commission Decision (EU) 2010/135 [2010] OJ L53/11.

[6] Commission, *Fact Sheet: Questions and Answers on EU's policies on GMOs* (22 April 2015) MEMO/15/4778.

[7] On the risks and benefits of GMOs, see MA Pollack and GC Schaffer, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (Oxford University Press, 2009), ch 2.

[8] Art 13 Directive (EEC) 90/220 [1990] OJ L117/15.

[9] M Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar Publishing, 2008), p 66.

[10] WTO Dispute Settlement, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, Reports of the Panel (29 September 2006) WT/DS291/R, WT/DS292/R, WT/DS293/R;

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

the Regulation on genetically modified food and feed (1829/2003) that will be discussed hereafter.[11]

It may be understood from the strong opposition against Maize 1507 that the EU's regime, which has been in place for over a decade, has not been able to account for internal and external pressures. The recent reform shows that the Commission has again attributed the regulatory failure to a perceived imbalance in the division of EU and national competences. Contrary to earlier reforms, by allowing for national opt-outs, Article 26b seeks to solve the deficiencies through re-nationalisation or re-emphasis of national powers rather than centralisation. The amending Directive 2015/412 finds that cultivation 'is an issue with strong national, regional and local dimensions' and that the inability of the EU's decision-making process to take into account those national concerns that do not relate to GMO safety, calls for Member States themselves to be granted more flexibility to decide on such grounds.[12] The Commission, however, did not stop there. Seemingly encouraged by the entry into force of the amendment, it simultaneously proposed to add a mirror Article 34a to Regulation 1829/2003, allowing Member States to also restrict the use of GM food and feed products on non-safety grounds.[13] However, this re-nationalisation proposal was rejected by a large majority of European MEPs on 28 October 2015 and will thus not be the focus of this article, although analogies may be drawn and important differences may be emphasised where relevant.

Any form of re-establishment of national competences in the regulation of GMOs comes with political and practical issues that potentially undermine the regime's economic and environmental aims. As arguably the first case of de-harmonisation on the explicit basis provided by the Lisbon Treaty,[14] German Chancellor Angela Merkel has fearfully interpreted the amendment to be 'a first step at dismantling the EU's single market'.[15] Being more than just an ideological blow to the EU's vision of increased economic integration, decentralisation may undermine the GMO regime's objective to foster a competitive market. With regard to cultivation, the recent amendment may, moreover, by emphasising national

(F'note continued)

G Skogstad, 'Contested Accountability Claims and GMO Regulation in the European Union' (2011) 49 (4) *Journal of Common Market Studies* 895.

[11] Directive (EC) 2001/18 [2001] OJ L106/1; Regulation (EC) 1829/2003 [2003] OJ L268/1.

[12] Recs 6–7 Directive 2015/412.

[13] European Commission, Proposal for a Regulation 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; see also Commission, *Reviewing the decision-making process on genetically modified organisms (GMOs)* COM(2015) 176.

[14] Art 2(2) TFEU, last sentence. See however S Poli, 'The Member States' Long and Winding Road to Partial Regulatory Autonomy in Cultivating Genetically Modified Crops in the EU' (2013) 4 (2) *European Journal of Risk Regulation* 143, p 153 who argues that the provided conditional and partial re-nationalisation could not be based upon this.

[15] 'EU Governments Seen Opposing GM Crop Proposals' (*Euractiv*, 30 July 2010) http://www.euractiv.com/cap/eu-governments-seen-opposing-gm-news-496823 [last accessed August 2015].

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

autonomy and corresponding national borders, undervalue the boundary transgressing nature of pollen and seeds. Cross-boundary contamination risks of GM genetic material that can travel considerable distances by wind, insects and other animals, may have detrimental effects on the commercial and environmental interests of GMO-sceptical States. Article 26b's patchwork approach thus highlights the need for effective national measures to secure inter-Member State coexistence of farming practices and harmonised liability rules to channel commercial and environmental losses to the GMO's producer in the neighbouring, GMO-receptive Member State.[16]

Without forgetting these general difficulties associated with decentralised GMO regulations, this article argues that the redistribution of competences as prescribed by Article 26b is also unlikely to provide an adequate and sufficient solution to solve the impasse in GMO decision-making. Part II briefly describes the multilevel procedure for the authorisation of GMO cultivation that is still at the core of the regime and the problems it has encountered. It finds that the Commission has attributed the deadlock in EU decision-making to the regime's ignorance towards national, socioeconomic and natural particularities. Article 26b is thus presented as an answer to better 'take account of diversity in an EU of 28 Member States'.[17] Part III, however, argues that the artificial distinction that Article 26b draws between (EU) risk assessment and (partially national) risk management may make it very difficult for Member States to impose cultivation restrictions that stand up to legal scrutiny. The reform, by shifting powers in the protection of concerns that do not relate to environmental safety, has in fact shifted the focus away from the most critical point of ignorance that is troubling the EU's decision-making process, namely its disregard for scientific uncertainty and disagreement. Recognition of diversity in science and of the subjective choices that blur the fine lines between scientific risk assessment and political risk management is necessary to further decision-making, as well as a precondition for any lawful rejection by the EU of a GMO application or a national restriction on use. This article questions the Commission's assumption that issues of subsidiarity lie at the heart of the impasse, by identifying the underexplored and undervalued possibilities to improve the exercise of national authority within the EU's authorisation procedure to allow for more inclusive and democratic scientific opinions and political decisions. Taking better account of (notably scientific) diversity within the central GMO regime, rather than differentiation through re-nationalisation, should thus be the primary focus of future reforms.

[16] European Commission Recommendation (EU) [2010] OJ C200/1, providing guidelines for the development of national coexistence measures, is non-binding although the Amendment to Art 26a (Directive 2015/412) does require Member States to adopt measures in border areas as of 3 April 2017, following suggestions by European Parliament ENVI Committee, *Recommendations for Second Reading* A8-0038/2014, Amendments 9 and 34. Possibilities for redress depend on the applicable, national liability standards or on the application of Directive (EC) 2004/35 [2004] OJ L143/56 on environmental liability, which gives no financial guarantees (see contrarily ENVI Recommendations above: Amendment 44).

[17] European Commission, *Explanatory Memorandum* COM(2010) 375, p 2.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

II. DISREGARD FOR NATIONAL PARTICULARITIES IN THE CENTRAL REGIME

A. The EU authorisation procedure: risk assessment and risk management

Directive 2001/18/EC and Regulation 1829/2003 provide that no GMO shall be cultivated or marketed within the EU unless covered by an EU authorisation.[18] Whereas the authorisation procedure of Directive 2001/18/EC applies to the deliberate release of all GMOs 'as or in products', including non-foods like the Amflora Potato for industrial application,[19] Regulation 1829/2003 only applies to GMOs intended for animal feed and human food use.[20] Yet, a single application for authorisation under the latter suffices in case of overlap between both pieces of legislation, which then incorporates Directive 2001/18/EC's environmental risk assessment (ERA).[21] Under Directive 2001/18/EC the first assessment report on the health and environmental risks is prepared by the national authority to which the person seeking placement of the GMO on the market (the applicant) directs its application, only to be forwarded to the European Food Safety Authority (EFSA) central GMO Panel if inter-Member State agreement on the risks cannot be reached.[22] Under Regulation 1829/2003 the national authority only acts as a portal, which directly forwards the application to the EFSA.[23] Yet, Member States do provide assistance through the EFSA's Advisory Forum and have to be consulted when an ERA is a mandatory part of the evaluation, before the EFSA forwards its – so far systematically positive – assessments on the safety risks of the GMO to the first actor in the risk-management phase: the European Commission.

Although the Commission may adopt a different opinion on motivated grounds,[24] it has thus far always confirmed the EFSA's stance, by submitting a draft authorisation to the Standing Committee on the Food Chain and Animal Health (SCFAH),[25] whose members are expert Member State representatives.[26] The SCFAH is supposed to adopt or reject the decision by qualified majority. However, it has so far failed to do so and the current comitology rules thus provide that the draft is then forwarded to an appeal committee, whose members are selected by Member States to de-politicise and facilitate risk management.[27] Like its predecessor, the

[18] Rec 32 and Art 4(1) Directive 2001/18/EC; Art 4(2) Regulation 1829/2003.

[19] Art 1 Directive 2001/18/EC; note 5 above (Amflora Decision).

[20] Art 3 Regulation 1829/2003.

[21] Art 17(5) Regulation 1829/2003 and Annexes II and VII Directive 2001/18/EC.

[22] Art 28 Directive 2001/18/EC and Regulation (EC) 178/2002 [2002] OJ L 31/1 establishing EFSA.

[23] Art 5(1)(2) and 17(1)(2) Regulation 1829/2003; Lee note 9 above, p 66.

[24] Arts 18(6) and 19(1) Regulation 1829/2003; Art 28 Directive 2001/18/EC.

[25] Arts 3 and 5 Regulation (EU) 182/2011 [2011] OJ L55/13 and Art 35(1) Regulation 1829/2003. Under Directive 2001/18/EC the Commission is assisted by a Regulatory Committee (Art 30).

[26] On the voting behaviour of SCFAH members C Klika et al, 'Why Science Cannot Tame Politics: The New EU Comitology Rules and the Centralised Authorisation Procedure of GMOs' (2013) 4(3) *European Journal of Risk Regulation* 327, p 330.

[27] Art 6 Regulation 182/2011.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

Council, the appeal committee has, however, equally struggled to reject or adopt the draft by qualified majority, which means it is then returned to the Commission.[28] Whereas the Old Comitology Decision, which still applies to the Maize 1507 application, obliges the Commission to adopt its initial (favourable) decision, the current rules give the possibility for a change of heart.[29] However, the Commission is yet to make use of this legal leeway.

B. Neglect of diverse political considerations and environmental conditions

The GMO deadlock provides an exception to the overall smooth functioning of comitology procedures for food safety, which intend to allow for more time and cost-efficient decision-making. The inability of Member States to reach a qualified majority has meant that the Commission has been the sole force behind *post-moratorium* authorisations. The Commission has attributed the political impasse in the authorisation of both GM crops and products to the fact that national positions are usually not based on science, but on other considerations, which the centralised regime has failed to take into account.[30]

These include societal concerns of a socioeconomic and an ethical character, linked to the divergent views on the intrinsic, cultural and economic value of particular agricultural practices.[31] The local nature of these political pressures would complicate centralisation in the perceived 'absence of a European demos',[32] although the authorisation process does provide for some possibilities for consideration through public involvement.[33] However, neither the EFSA nor the Commission, as the regime's *de facto* regulators, have taken the responsibility to account for expressed public concerns in their opinions and draft decisions. Despite the absence of a definition of risk, which would allow for broad interpretations, the EFSA has held that it is not empowered to integrate ethical and social considerations into its work.[34] It has held that such integration would make its evaluations more

[28] For empirical evidence see Klika et al note 26 above, p 332; for a theoretical perspective see V Paskalev, 'Can Science Tame Politics: The Collapse of the New GMO Regime in the EU' (2011) 3 (2) *European Journal of Risk Regulation* 190.

[29] Compare Art 5(6) Commission Decision (EC) 1999/468 [1999] OJ L184/23 and Art 6(3) Regulation 182/2011.

[30] Recs 6, 14–15 Directive 2015/412 and COM(2015) 177, p 3; see also the original proposal: COM(2010) 375.

[31] M Kritikos, 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?' (2009) 34 (3) *European Law Review* 405, p 431; V Hristova, 'Between Politics and Science. Accommodating National Diversity in GMO Regulation' in MBA van Asselt et al (eds), *Balancing Between Trade and Risk Integrating Legal and Social Science Perspectives* (Routledge, 2013), p 115.

[32] Kritikos ibid, p 431; also D Chalmers, '"Food for Thought": Reconciling European Risks and Traditional Ways of Life' (2003) 66 (4) *The Modern Law Review* 532, p 547.

[33] Art 24 Directive 2001/18/EC and Art 6(7) Regulation 1829/2003 provide for public participation in risk assessment and the Commission has the (so far unexplored) possibility to consult an ethical committee.

[34] Kritikos see note 31 above, p 419; Poli see note 14 above, p 149.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

inefficient, because 'the issues are exclusively technical and the European public is not appropriately trained on risk technologies'.[35] Accordingly, the EFSA has not only framed the issue in such a way as to render lay expertise irrelevant, but also denies that some socioeconomic factors like the anticipated scale of cultivation are intrinsically linked to an evaluation of the likelihood of harm, which complicates a strict policy/science divide.[36]

The Commission is, moreover, explicitly empowered to take 'other legitimate factors' than science into account (Article 19(1) Regulation 1829/2003). The regime's preference for a scientific foundation is, however, reflected in the Commission's obligation to 'provide an explanation' in case it departs from the EFSA's opinion.[37] The hierarchy established by the current legislation is also reflected in general European case-law regarding the regulation of uncertain risks. In *Pfizer*, a case concerning the use of antibiotics in feed, the Court of First Instance (now the General Court) held that science must in principle be fought with science of a 'level that at least be commensurate with that of the opinion in question', thus marginalising – although not nullifying – secondary political reasons.[38] These thresholds may explain the Commission's reluctance to look beyond the EFSA's opinions. As a result, any meaningful distinction between risk assessment and risk management on a central level has been lost.[39]

In addition to diverse social and public perceptions, the regime's sound science approach supposes a universality that neglects the diverse environmental conditions in Member States and the fact that a risk assessment's outcome depends on the territorial and ecological context in which it is conducted. The natural particularities of European regions may prescribe and justify a stricter evaluation of a GMO than one carried out under general circumstances. Although the Commission and the EFSA risk-assessment Guidelines recognise the possibility to integrate natural diversity on the basis of information provided by national expert authorities, substantial efforts seem to be lacking.[40]

---

[35] Interviews with EFSA Members by Kritikos see note 31 above, p 419.

[36] Paskalev see note 28 above, pp 203–204 with reference to the dissenting opinions of two EFSA Members regarding the positive opinion for the Amflora Potato; also F Wickson and B Wynne, 'The Anglerfish Deception' (2012) 13 (2) *EMBO Reports* 100, p 102.

[37] Similarly Hristova see note 31 above, p 114 and Skogstad see note 10 above, p 903.

[38] *Pfizer Animal Health SA v Council of the European Union,* T-13/99, EU:T:2002:209, para 199; discussed by A Janssen and MBA van Asselt, 'The Precautionary Principle in Court. An Analysis of Post-Pfizer Case Law' in MBA van Asselt et al (eds), *Balancing between Trade and Risk Integrating Legal and Social Science Perspectives* (Routledge, 2013) 197.

[39] Similarly Kritikos see note 31 above, p 425; W Weimer, 'Legitimacy Through Precaution in European Regulation of GMOs?' in C Joerges et al (eds), *Transnational Standards of Social Protection Contrasting European and International Governance* (Arena Reports, 2008) 159, pp 188–189 finds that Member States have been unable to compensate for this.

[40] Commission, *Communication to COM(2010) 375* COM(2010) 380, p 5; EPEC, *Evaluation of the EU Legislative Framework in the Field of Cultivation of GMOs – Final Report to DG Sanco* (March 2011) para 5.2.2; see also Part III.C below.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

C. The solution provided for by Article 26b: diversification through decentralisation

The EU regime's ignorance towards national particularities prior to authorisation, has led Member States to resort to restrictive post-authorisation measures. However, their possibilities have been restricted by the fact that Directive 2001/18/EC and Regulation 1829/2003 were generally agreed to provide for exhaustive harmonisation of laws concerning the commercial release of GMOs.[41] Both are adopted on the basis of the *a priori* shared competence *ex* Article 95 EC (Article 114 TFEU) with a view to approximate laws to ensure the effective functioning of the internal market. Harmonisation, however, only precludes national derogations to the extent that they pursue the same specific (primary) objectives.[42] Explicitly recognised to be falling outside the scope of the centralised regime are the economic risks of GMO cultivation, which can still be regulated on a Member State level through coexistence measures (Article 26a Directive 2001/18/EC). While the Commission has acknowledged that securing coexistence could require small GM-free areas, in most cases isolation distances would be a sufficient and thus more proportionate measure.[43] Further-reaching bans could only be justified by the safeguard clauses of Directive 2001/18/EC (Article 23) and Regulation 1829/2003 (Article 34) or Article 114(5) TFEU.[44] Although both routes for derogation are subject to strict requirements, like the presentation of new scientific evidence that would invalidate the EFSA's opinion, this has not prevented Member States from relying on the provisions to justify bans.[45] Particularly, their role in comitology has enabled Member States to reject the Commission's draft decisions to lift safeguard restrictions, even if, arguably, scientifically unfounded.[46]

In the wake of the cultivation approval for the Amflora Potato, the Commission submitted a solution to better account for Member State diversity in the GMO debate, which would diminish their (mis)use of derogation clauses, while simultaneously – so the Commission expects – reducing the national stakes and thus political disagreement in comitology.[47] Article 26b and the many drafts that preceded it, seek to facilitate differentiation through decentralisation or, if one takes the view that the protection of non-safety related objections was never exercised by

---

[41] T Christoforou, 'The Regulation of Genetically Modified Organisms in the European Union: the Interplay of Science, Law and Politics' (2004) 41 (3) *Common Market Law Review* 637, p 672; J Scott, 'European Regulation of GMOs and the WTO' (2003) 9 *Columbia Journal of European Law* 213, p 226.

[42] Scott ibid, pp 226–227; P Dabrowska-Klosinska, *Hybrid solutions for hybrid products?: EU Governance of GMOs* (PhD Thesis, European University Institute, 2006) p 139; *Compassion in World Farming Ltd,* C-1/96, EU:C:1998:113, paras 47, 53.

[43] Commission Recommendation on coexistence, see note 16 above, para 2.4.

[44] *Pioneer Hi-Bred Italia v Italian Ministry of Agriculture,* C-36/11, EU:C:2012:534, paras 72–76.

[45] Eg *Monsanto SAS v French Ministry of Agriculture and Fisheries,* C-58/10 to C-68/10, EU:C:2011:553; *Land of Upper Austria and Republic of Austria v Commission,* EU:T:2005:347.

[46] Hristova see note 31 above, p 116; Skogstad see note 10 above, pp 901–902.

[47] Rec 7 Directive 2015/412; Commission, *Explanatory Memorandum* COM(2010) 375, p 8.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

the EU regime, by re-emphasising national competences.[48] Inspired by the Biocidal Products Regulation, Article 26b provides for two phases in which territorial restrictions may be adopted.[49] Pre-authorisation, Member States may ask the applicant *via* the Commission to adjust the geographical scope of its application.[50] If the applicant does not consent, post-authorisation restrictions may be adopted for that GMO, or for a group of GMOs defined by crop or trait. Article 26b(3) provides that measures must be based on compelling grounds such as those related to:

(a) Environmental policy objectives
(b) Town and country planning
(c) Land use
(d) Socioeconomic impacts
(e) Avoidance of GMO presence in other products without prejudice to Article 26a
(f) Agricultural policy objectives
(g) Public policy.

Article 26b thus aims to provide Member States with more flexibility to restrict GMO cultivation 'in the light of the expression of national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment'.[51] Article 26b's indicative list of grounds for restrictions reflects years of negotiations on the possibilities for national opt-outs. Whereas the Commission's original proposal and its subsequent communications had focused on the socioeconomic and public policy implications of GMO cultivation,[52] the European Parliament had emphasised the environmental impacts of GMO cultivation, including, but not limited to, the impacts on specific regional biodiversity.[53] The next part of this article finds that the possibilities that Article 26b aims to provide for differentiation on socioeconomic and public policy grounds (b–g), could be undermined by the possibly unlawful nature of such national bans under internal market and WTO law. Although trade laws and notably the principle of proportionality may also impact the legality of restrictions based on 'environmental policy objectives' (a), this ambiguous addition that followed parliamentary amendments gives rise to more pertinent issues due to the requirement in Article 26b that bans shall, in no case, conflict with the EU's environmental risk assessment.

[48] European Parliament ENVI Committee, *Opinion on Legal Basis of COM(2010) 375* PE462.539v01-00 (29 March 2011) which questions the proposal's 'added value'.

[49] Art 37 Regulation (EU) 582/2011 [2012] OJ L167/1.

[50] Art 26(1) and (2) Directive 2001/18/EC.

[51] Rec 7 Directive 2015/412.

[52] Eg COM(2010) 380.

[53] European Parliament, *Report on proposal COM(2010) 375/2010/0208(COD)* A7-0170/2011.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

III. LEGAL OBSTACLES TO NATIONAL RESTRICTIONS BASED UPON THE GROUNDS LISTED IN ARTICLE 26B

A. The internal market barrier: socioeconomic reasons and public policy

The two-phased procedure of Article 26b, that allows applicants to consider the adjustments of the geographical scope of their applications upon requests, has given rise to questions regarding the involvement and authority of the biotech industry.[54] The fundamental issue of letting the regulatee decide on its own regulation first, may be more acute considering that possibilities for Member States to impose bans unilaterally in the second opt-out phase may be limited by the requirements that legally sound derogations have to meet. It may be understood from the above that in an occupied field 'any national measure must be assessed in the light of the provisions of the harmonising measure' as *lex specialis*.[55] Article 26b(3) is, however, distinct from derogation provisions in secondary law like the safeguard clauses, as it holds that measures must still be 'in conformity with Union Law'. The effect of the reform is thus only to redefine or even just to clarify the extent of harmonisation: to narrow or elucidate the regime's objectives.[56] Article 26b does not provide Member States with an enforceable right to ban GMOs, but only reallocates competences, the exercise of which is still subject to EU law on the free movement of goods: Articles 34–36 TFEU.[57] Although single market concerns may be more evident with regard to direct restrictions on 'use' of GM products under the proposed Article 34a Regulation 1829/2003 that was rejected on this ground, cultivation bans that prohibit the use of GM seeds adopted under Article 26b are equally likely to be 'capable of hindering, directly or indirectly, actually or potentially intra-[EU] trade'.[58] Such restrictions will therefore qualify as a measure having equivalent effect to a quantitative import restriction (MEE).[59] Although bans take immediate effect, they may be subject to infringement procedures or national proceedings

[54] Amendments 35–36 ENVI Recommendations note 16 above.

[55] *Radlberger Getränkegesellschaft v Land Baden-Württemberg,* C-309/02, EU:C:2004:799, para 53.

[56] Similarly KPE Lasok and R Haynes, 'Advice: In the Matter of the Proposed Regulation to Amend Directive 2001/18/EC' (*GM Freeze,* 23 June 2010), paras 14–29 http://www.gmfreeze.org/site_media/uploads/publications/lasok_and_haynes-GMO_cultivation_ADVICE.pdf [last accessed 1 December 2015]; M Weimer, 'What Price Flexibility? The Recent Commission Proposal to Allow for National "Opts-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon' (2010) 1 (4) *European Journal of Risk Regulation* 345, p 355.

[57] Council Legal Service, *Opinion COM(2010) 375* 15696/10 (5 November 2010) and ENVI Legal Opinion (n 48), p 8. See contrarily G Winter, *Nationale Anbaubeschränkungen und -verbote für gentechnisch veränderte Pflanzen und ihre Vereinbarkeit mit Verfassungs-, Unions- und Völkerrecht* (German Federal Agency for Nature Conservation, May 2015) and H Gaßner et al, *Rechtsfragen einer nationalen Umsetzung der Opt-out-Änderungsrichtlinie* (German Federal Agency for Nature Conservation, May 2015) who argue that despite the explicit references to Arts 34–36 (Rec 16 Directive 2015/412) and Union Law, Art 26b should be treated as a self-standing provision of secondary law that exhaustively determines both the possibilities and the limitations for national opt-outs.

[58] *Dassonville,* 8/74, EU:C:1974:82, p 852.

[59] M Lee, 'The Ambiguity of Multi- Level Governance and (De-)Harmonisation in EU Environmental Law' (2013) 15 *Cambridge Yearbook of European Legal Studies* 357, p 374.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

brought by the GMO producer or even disadvantaged domestic farmers.[60] Member States would then have to prove that their restrictions are justified and would have to be proportionate to the aim pursued.

Whereas Article 26b's recognition of social and public considerations that shape positions on GMOs may be welcomed, it may not provide for legally solid grounds to justify a MEE under Article 36 TFEU or the *Cassis de Dijon* doctrine.[61] For example, Article 26b aims to complement Article 26a Directive 2001/18/EC to provide for an all-encompassing system to avoid GM presence above the 0.9% labelling threshold in conventional or organic crops, as a response to voiced concerns by Poland and Austria that they cannot enact effective coexistence measures.[62] However, the Commission itself has treated coexistence as merely a way to protect farmers from economic losses.[63] Whereas *Cassis de Dijon* allows for indistinctly applicable laws to be justified on broad grounds of mandatory requirements of public interest, the Court of Justice of the European Union (Court) has systematically held that purely economic aims cannot be considered as such.[64] Regarding coexistence acts, which have thus far not been subject to judicial review, the Commission has put the issue aside, finding that their size prevents them from hindering trade, thus arguably inventing a *de minimis*-type exception to Article 34 TFEU.[65] Likewise, the recent report by the European GMO Socio-Economics Bureau, that was installed to facilitate the exchange of information on socioeconomic impacts, has quantified all the effects of GMO cultivation on national agricultural practices in economic terms, making it very doubtful whether it can be used as evidence to support legally sound socioeconomic

[60] Proceedings brought under Art 258 TFEU or in national courts, which, considering the ambiguities in Art 26b, are likely also to involve the Court through preliminary questions of interpretation, Art 267 TFEU. See also M Moore, *Directive 2015/412 - judicial review of restrictions of cultivation of GMOs based on socioeconomic grounds* (Conference Paper Budapest, 17 April 2015) http://www.nakvi.hu/app/gmo/doc/mmeu.pdf [last accessed August 2015].

[61] *Rewe-Zentral v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon),* C-120/78, EU:C:1979:42.

[62] It was rejected as a basis for derogation under Art 114(5) TFEU as an economic, rather than an environmental ground, *Land Oberösterreich and Austria v Commission,* T-366/03 and T-235/04, EU:T:2005:347 as discussed by FM Fleurke, 'What Use for Art 95(5) EC? An Analysis of Land Oberösterreich and Republic of Austria v Commission' (2008) 20 (2) *Journal of Environmental Law* 267.

[63] Eg Rec 4 and para 2.3 Commission Recommendation on coexistence, see note 16 above; M Lee, 'The Governance of Coexistence Between GMOs and Other Forms of Agriculture: A Purely Economic Issue?' (2008) 20 (2) *Journal of Environmental Law* 193.

[64] *Decker v Caisse de Maladie des Employés Privés,* C-120/95, EU:C:1998:167, para 39; *Chemische Afvalstoffen Dusseldorp v Dutch Ministry for Housing and the Environment,* C-203/96, EU:C:1998:316, para 44.

[65] European Commission, *Considerations on Legal Issues on GMO Cultivation Raised in the Opinion of the Legal Service of the Council of the European Union of 5 November 2010* COM(2010) 1454, p 11; the Court has rejected such an exception in the context of the free movement of goods, eg *Criminal Proceeding against Ditlev Bluhme,* C-67/97, EU:C:1998:584. J Hojnik, 'De Minimis Rule within the EU Internal Market Freedoms: Towards a More Mature and Legitimate Market?' (2013) 6 (1) *European Journal of Legal Studies* 25.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

justifications.[66] To justify their bans the Member States could, however, argue that the pursuit of economic objectives can contribute to the achievement of underlying, compelling non-economic aims.[67] Accordingly they must, as the Commission has failed to do, emphasise the social value of sustaining particular agricultural practices and consumer choice, and the importance of preventing deterioration of cultural heritage and landscape impoverishment through spatial planning and land use policies. They may in this regard rely on the *Ospelt* case regarding Austrian land ownership restrictions in which aims like 'preserving agricultural communities, ... the sympathetic management of the countryside as well as encouraging the reasonable use of land' were recognised as legitimate aims to restrict free movement.[68] In addition to the listed socioeconomic considerations, Member States may also invoke public policy or morality concerns. However, public policy, that according to Article 26b(3) can only be used in combination with another justification ground, has been interpreted and permitted restrictively as derogation by the Court.[69] In *Centre Leclerc* it held that a danger of civil disturbances could justify national measures, although the French government had failed to show a threat which it would be unable to meet with the means at its disposal.[70] Similar judicial restraint can be observed regarding public morality or ethics as justifications. Although not included in Article 26b(3), the Court has already accepted these objectives to fall outside the scope of harmonisation provided for by Directive 2001/18/EC, which explicitly recognises these national competences.[71] Only in 'exceptional cases' regarding, for example, indecent, obscene or violent products, has the public morality defence thus far been upheld.[72]

Moreover, in any of the situations above, the main difficulty will be establishing the facts to prove impacts of a qualitative nature in order to substantiate a justification for national restrictions.[73] Empirical evidence and general data are lacking due to limited experience with GMO cultivation in Europe and the absence of an obligation on applicants to provide information on socioeconomic impacts.[74] Conflicting perspectives

---

[66] J Kathage et al, *Framework for the Socio-Economic Analysis of the Cultivation of Genetically Modified Crops* (Publications Office of the European Union, 2015) doi:10.2791/060437.

[67] *Openbaar Ministerie v Nertsvoerderfabriek Nederland BV,* C-118/86, EU:C:1987:424, paras 14–15.

[68] *Margarethe Ospelt and Schlössle Weissenberg Familienstiftung,* C-452/01, EU:C:2003:493, para 39; for discussion of the relevance of this case in the GMO context see Lee note 9 above, p 111.

[69] C Barnard, 'Derogations, Justifications and the Four Freedoms: Is State Interest Really Protected?' in C Barnard and P Odudu, *The Outer Limits of European Union Law* (Hart Publishing, 2009), p 278.

[70] *Cullet v Leclerc,* C-231/83, EU:C:1985:29; P Craig and G de Burca, *EU Law. Text, Cases and Materials* (Oxford University Press, 2011), p 670.

[71] *Commission v Poland,* C-165/08, EU:C:2009:473, para 50; Rec 57 and Art 29 Directive 2001/18/EC.

[72] Eg *Regina v Henn and Darby,* C-34/79, EU:C:1979:295 regarding pornographic materials and *Omega,* C-36/02, EU:C:2004:614 regarding violent videogames.

[73] COGEM, *Building Blocks for an Assessment Framework for the Cultivation of Genetically Modified Crops* COGEM Report CGM/141222-01 (December 2014), p 35; Moore see note 60 above, p 2.

[74] A Roger, 'In the public interest? A Comparative Analysis of Norway and the EU GMO Regulations' (2015) 24 (3) *Review of European, Comparative & International Environmental Law* 264, p 276.

and interests within Member States and the EU may also complicate the imposition of universal restrictions based on socioeconomic considerations, which may explain why the Commission itself has held that it has not been in a position to justify an EU-wide ban on GM crops or products on overriding reasons of public interest.[75]

Whereas research has shown that the Court has been increasingly reluctant to accept justifications for internal market derogations under Article 36 TFEU and *Cassis de Dijon*,[76] only time will tell if the judiciary will show leniency in light of apparent explicit approval by EU lawmakers. However, Member States' burdens to justify bans may be lessened by the fact that Article 26b(3) allows them to invoke multiple grounds. The highest hurdle for legal restrictions may thus be imposed by proportionality as a general principle of EU law – explicit in Article 26b. Proportionality holds that the means used must be suitable (effective) and necessary to achieve the aim, which means that there may not be less onerous measures available to achieve the same result and that the disadvantages may not be disproportionate to the interests of producers and potential farmers and consumers.[77] The necessity test has been applied restrictively in general Court case-law and Advocate General Bot has held within the context of coexistence that cultivation prohibitions are 'subject to the provision of strict proof' that technical measures would not suffice.[78] The restraint prescribed by proportionality is at odds with the broad autonomy sought by Member States, as reflected in the bans that have been adopted prior to the Article 26b reform and which for the greater part cover entire States. Very broad restrictions may be necessary to achieve social objectives in nations that are dominated by small-scale or organic farming practices like Austria and Poland. But they may be difficult to defend in Germany and Hungary, where landscapes have been shaped by industrialisation and efficiency-based agricultural policies, unless their GMO prohibitions are a first step in a larger move towards a more sustainable agricultural system.[79] Consumer interests and ethical concerns may, moreover, be adequately protected by labelling requirements.[80] In its current form Article 26b may, therefore, be more likely to legalise local free-zones in predominantly pro-GMO States, than territory

[75] COM(2015) 176 see note 13 above, p 6 and fn 23.

[76] Barnard see note 69 above, p 280; Lee see note 59 above, p 377 with reference to *International Transport Workers' Federation and Finnish Seamen's Union v Viking Line,* C-438/05, EU:C:2007:772.

[77] *Fedesa,* C-331/88, EU:C:1990:391, para 13; about proportionality in the context of the proposal see also Lee note 59 above, p 377 and M Dobbs, 'Legalising General Prohibitions on Cultivation of Genetically Modified Organisms' (2010) 11(12*) German Law Journal* 1347, p 1363.

[78] Opinion of Advocate General Bot in *Pioneer Hi-Bred Italia v Italian Ministry of Agriculture,* C-36/11, EU:C:2012:250, point 61; see more generally also Barnard note 69 above, p 282.

[79] Winter see note 57 above, pp 30–32 on the discretion the proportionality principle would leave Member States to partially intervene to protect certain objectives by restricting GMO cultivation, while still permitting activities that may similarly threaten these objectives, like industrial agricultural practices, that may need regulation in the (near) future. However, about the difficulties in invoking a move towards a more sustainable agricultural system as a legitimate objective under Art 26b, see hereafter Part III.C.

[80] Drawing an analogy with case law regarding proportionality in the context of consumer protection, eg *Commission v Germany*, C-178/84, EU:C:1987:126 and *Cassis de Dijon,* EU:C:1979:42 discussed by Barnard see note 69 above, p 283.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

wide bans in the States that the Commission seeks to appease to further central decision-making.

B. The WTO barrier: the protection of public morals

The exercise of national autonomy granted by Article 26b may be further impeded by Member States' external obligations under international trade law.[81] While the reform, as a means to facilitate central decision-making, may be an attempt to comply with the WTO's *EC Biotech Report* that condemned the EU's 'undue delays', it leaves Member States on their own to defend their bans.[82] An assessment of WTO law reveals that it poses obstacles similar to those under internal market law.[83] A restriction based on the autonomous grounds of Article 26b that are not linked to issues of safety for health or the environment would be likely to be governed by the GATT[84] rather than the SPS Agreement. The latter, as *lex specialis* to Article XX(b) GATT, only concerns measures that 'protect human, animal and plant health'.[85] Article III.4 GATT, in principle, prohibits restrictions to the extent that they treat GMOs less favourably than 'like' products of national origin. Whether GMOs are like their conventional counterparts shall be assessed according to the *Asbestos* criteria, which compare their properties, nature, end-use and notably consumers' tastes and habits.[86] Contrarily to the EU's process-based regulation, which emphasises the different technologies used, the GATT's focus on product characteristics may complicate the denial of substantial equivalence, due to the evolvement of conventional breeding techniques that can sometimes create GMO-like traits in crops, and the fact that research has shown that stark differences in stated consumer preferences may not be supported by empirical evidence that analyses European consumers' 'willingness to pay'.[87]

In the likely event that the WTO Panel establishes regulatory discrimination, Member States' restrictions would need to be exempted from the GATT under Article XX. However, its exhaustive list of justifications is more restrictive than the EU's mandatory requirements doctrine and the only viable objective to legitimise bans seems to be the protection of public morals (Article XX(a) GATT). In *US Gamble* the Panel did recognise that public morals, as 'standards of right and wrong' may vary depending on national social, cultural and religious values and that Parties

[81] Rec 6 explicitly refers to Art 216(2) TFEU.

[82] WTO Dispute Settlement, *EC Biotech Products,* WT/DS291–293/R, paras 7.1567–1568; 8.6–8.7.

[83] For a more elaborate analysis see Dobbs note 77 above, p 1366; Opinion Council Legal Service see note 57 above, p 13; European Parliament Legal Service, *Opinion COM(2010) 375* SJ-0630/10, p 6.

[84] General Agreement on Tariffs and Trade (15 April 1994) 33 ILM 1153.

[85] Annex A WTO Agreement on the Application of Sanitary and Phytosanitary Measures (15 April 1994) 1867 UNTS 493.

[86] WTO Dispute Settlement, *European Communities — Measures Affecting Asbestos and Products Containing Asbestos* (12 March 2001), WT/DS135/AB/R, para 101.

[87] M Lusser et al, *Report International Workshop on Socioeconomic Impacts of Genetically Modified Crops* (JRC-IPTS and FAO, 2012) pp 12–13; Kathage et al see note 66 above, p 17; COGEM see note 73 above, p 39.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

have some discretion in defining the concept.[88] However, if Member States are able to prove 'an important value of interest' in their territory that requires protection, they would still have to substantiate why the restriction is a necessary tool to safeguard their public concerns.[89] The test that was developed in *Chinese Audiovisual Products* closely resembles the proportionality test under EU law, weighing and balancing the contribution of the measure to the achievement of the objective and its restrictive impact on trade.[90] The recent case brought by Canada and Norway regarding the EU's ban on seal products confirms that WTO law is similarly likely to require complete prohibitions on the use of products to be lifted when less-trade restrictive alternative measures, like labelling requirements, are reasonably available.[91]

C. *Ambiguous (im)possibilities for differentiation on environmental grounds*

The Achilles' heel of Article 26b is the limited room for manoeuvre it seems to leave Member States to justify cultivation restrictions with reference to the scientifically substantiated risks GM crops pose to their environments. Member States have continuously invoked the impacts of GMO cultivation on their natural surroundings to justify national regulations, as illustrated by the reference in German restrictions on the cultivation of MON 810 to the '*Gefahr für die Umwelt*', and the emphasis on the '*risques environnementaux*' by the complete French ban on GM corn.[92] Their strong sympathy towards environmental objectives may explain why national restrictions have mainly targeted crops, while the consideration of environmental impacts in the context of imported GMOs is limited to those felt on EU territory due to unintended releases.[93] This is confirmed by the fact that even the most GMO-sceptical States expressed their disapproval towards the Commission's envisaged, but now abandoned, extension of the decentralisation solution to GM products, which raise moral and public policy concerns similar to those reiterated in

[88] WTO Dispute Settlement, *United States — Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (16 January 2004), WT/DS285/R, par 6.465, 6.461; for discussion see P van den Bossche, *The Law and Policy of the World Trade Organisation* (Cambridge University Press, 2013), p 570.

[89] WTO Dispute Settlement *European Communities — Measures Prohibiting the Importation and Marketing of Seal Products* (25 November 2013) WT/DS400/R, para 7.632.

[90] WTO Dispute Settlement, *China – Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products* (12 August 2009), WT/DS363/R para 7.788; van den Bossche see note 88 above, p 570.

[91] WTO Appellate Body Report, *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products* (22 May 2014), WT/DS400/AB/R, par 5.3.2.5.

[92] '"Gefahr für die Umwelt" Aigner verbietet Genmais-Anbau' (*Stern,* 14 April 2009) http://www.stern.de/wissen/ernaehrung/gefahr-fuer-die-umwelt-aigner-verbietet-genmais-anbau-660801.html [last accessed August 2015]; *LOI No 2014-567 du 2 juin 2014 relative à l'interdiction de la mise en culture du des variétés de maïs génétiquement modifié,* JORF (3 June 2014) No 0127, p 9208.

[93] Eg the Environmental Monitoring Plan for Maize Bt11(non-cultivation), drafted in accordance with Annex VII Directive 2001/18/EC: http://ec.europa.eu/food/dyna/gm_register/100222-monitoringplan-Bt11.pdf [last accessed August 2015].

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

the context of GM crops.[94] It may be argued that Member States' hesitance to look beyond the environmental impact of GMO cultivation is to be explained by the fact that prior to Article 26b, they were not (or did not feel) empowered to appeal to other justifications. However, not forgetting the obstacles imposed by trade law discussed above, their task to legitimise bans with reference to socioeconomic considerations may be further complicated by the fact that the Court has emphasised Member States' evidentiary burden to prove that the non-scientific concern is invoked 'as a separate justification, [not] as an aspect of the justification relating to protection of human health and the environment'.[95] A recent report drafted to advise the German government on their possibilities for restriction under Article 26b has rightly called into question whether it is at all possible to completely isolate the listed socioeconomic reasons from environmental concerns, arguing that Germany should avoid discussions on artificial distinctions by primarily basing its future (nationwide) restriction on environmental aims.[96] The report derives Member States' power to do so from the fact that Article 26b(3)(a) does list 'environmental policy objectives' as a legitimate national goal for protection.[97]

The value of the inclusion of 'environmental policy objectives' is, however, limited by the requirement in Article 26b(3) that the grounds invoked by Member States 'shall, in no case, conflict with the environmental risk assessment carried out' pursuant to Directive 2001/18/EC or Regulation 1829/2003. Which powers the provision does confer on Member States is unclear and this will likely be subject to divergent interpretations that will require judicial valuation of their legal merit. Directive 2015/412 seems to aim to grant possibilities for national protection of local landscapes, biodiversity and specific ecosystem functions and services as a solution for the EFSA's failure to assess risks under specific, rather than general, circumstances.[98] However, the disregard for environmental specificities and particularities is only an implementation problem, while the EFSA's Guidance Document on the ERA of GM Plants – to be incorporated by the Commission in the Annexes to Directive 2001/18/EC – explicitly recognises that the EU's environmental heterogeneity is a cross-cutting consideration that influences every step of the case-by-case risk-assessment process.[99] Accordingly, it finds that 'there may be a broad range of environmental characteristics (regional-specific) to be taken into account' and that applicants, who are under obligation to explain why their studies in certain areas are considered representative for other receiving environments, should always consider the

[94] See Part I above and the recording of the Council (Agriculture and Fisheries) negotiations on 13 July 2015 at http://video.consilium.europa.eu/webcast.aspx?ticket=775-979-16166 [last accessed August 2015].

[95] *Commission v Poland,* EU:C:2009:473, paras 52–55.

[96] Gaßner et al see note 57 above, p 26.

[97] Note that to the extent that environmental aims are brought outside the harmonisation scope, they may require protection as 'mandatory requirements' as accepted in, eg, Case C-2/90 *Commission v Belgium* [1992] ECR I-4431 (*Walloon Waste*).

[98] Rec 14 Directive 2015/412 and Part II.B above.

[99] Art 3 Directive 2015/412; EFSA Panel on Genetically Modified Organisms, 'Guidance on the Environmental Risk Assessment of Genetically Modified Plants' (2010) 8 (11) *EFSA Journal* 1879, sec 2.3.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

'worst-case scenario' in which exposure and impact are expected to be the highest.[100] The question is whether or not Article 26b(3) allows Member States to refer to those local or regional impacts that they hold to be overlooked by the ERA, despite the EFSA's formal commitment to consider all receiving environments. It has been argued that it follows from Article 23b's reference to the ERA 'carried out' that Member States are only prevented from relying on impacts that were in fact examined.[101] However, the requirement in Recitals 13–14 of Directive 2015/412 (mirroring earlier versions of Article 23b) that environmental grounds must still be 'distinct' from those assessed under the EU's safety regime, may be interpreted to mean that national powers in this regard are restricted by the hypothetical, rather than the concrete assessment of environmental risks by the EFSA.[102] Moreover, if Member States could rely on grounds that were not part of the ERA, it may not be enough to support a reclaim of discretion to assess and manage the risks for local landscapes and ecosystems by relying on the absence of explicit references to these impacts in the EFSA's scientific opinions. The EFSA's consideration of regional particularities (or the absence thereof) may be implied through its acceptance or rejection of studies by applicants as being representative of other regions. This can be illustrated by the EFSA's dismissive response to a request by Austria in the assessment procedure for the MON88017 maize to present additional information to support the representativeness of the studies in Germany and Spain, finding that the field trials 'allow for conclusions for other European environments'.[103] Not a lack of reflection on Austria's particular environments, but the EFSA's unwillingness to qualify local conditions as sufficiently distinct to demand a separate (stricter) assessment, thus seems to be the main problem. It is unlikely that Article 26b will be accepted to provide a way for Member States to challenge the EFSA's (political) choices in this regard. If it would, it may not increase possibilities compared to the already existing option under Article 114(5) TFEU for derogations in light of a specific, national problem that requires evidence 'of unusual or unique ecosystems'.[104] Moreover, a proportionality problem would still arise with respect to the wide bans in the obstructing States, which are unlikely to be entirely characterised by unique elements that demand preferential treatment.[105]

---

[100] Ibid, pp 24–25.

[101] Winter see note 57 above, p 14; also Lee see note 59 above, fn 77. Compare the text of Art 26b(3)(a) following the ENVI Recommendations see note 16 above: 'environmental policy objectives ... which are complementary to the impacts *concretely* examined during the scientific risk assessment' [emphasis added].

[102] This defendable conclusion would also restrict Member States' possibilities to rely on other grounds listed by Winter in note 57 above, p 14 (apparently inspired by the amendments proposed by MEPs Staes and Boylan that were only partly reflected in the ENVI Recommendations in note 16 above, Amendment 17) that are not concretely assessed by EFSA, although such considerations are formally a part of the central ERA. In the context of COM(2010) 375 see Lasok and Haynes see note 56 above, paras 30–35.

[103] *Application EFSA-GMO-CZ-2008-54 (MON88017 maize CULTIVATION) – Scientific comments and opinions submitted by EU Member States*, Annex G, pp 3–4, EFSA Register of Questions EFSA-Q-2011-01117.

[104] *Land Oberösterreich and Austria v Commission*, C-439/05 P and C-454/05, EU:C:2007:510, paras 54–55.

[105] Similarly Poli see note 14 above, p 150.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

The 'maintenance and development of agricultural practices which offer a *better* potential to reconcile production with ecosystem sustainability' (emphasis added) is given by Directive 2015/412 as another example of a 'distinct' environmental policy objective.[106] Possibilities for the justification of bans may, however, be similarly restricted by the prohibition of conflicting ERAs. According to the EFSA's guidelines the ERA is not limited to the direct environmental impacts of the GM crop, but also assesses the indirect impacts of the associated 'specific cultivation, management and harvesting techniques', eg, linked to herbicide regimes, crop rotation schemes and tillage rates for GM crops.[107] The ERA, however, assesses the comparative or relative safety of the impacts of the GMO and the related production systems.[108] The results of the EFSA's scientific opinions are therefore inevitably politicised by its choices regarding the relevant baseline of receiving environments, including different production systems as point of reference against which changes can be assessed.[109] Although the EFSA's guidelines acknowledge the EU's diverse landscape of intense, integrated and organic farming, its opinions seem to mainly draw comparisons with conventional systems.[110] Member States would effectively be allowed to challenge the EFSA's choice of comparator if they could justify restrictions in order to maintain or develop more sustainable agricultural practices, where the EFSA has found that the GMO related production system has no adverse effects compared to representative management techniques.[111] Furthermore, the relevant baselines are normally determined by the level of harm caused by current farming practices, making it questionable whether bans could be justified as a step in the development (rather than the maintenance) of agroecological farming practices.[112]

The EFSA has, moreover, already recognised the unsustainable changes in product systems and farming management related to GMO cultivation in some of its opinions. Regarding several of Monsanto's herbicide tolerant GMOs, it found the use of glyphosate, the active substance in the herbicide Roundup, 'over the top of the crop' to be a substantial change in crop management that may have adverse environmental impacts.[113] Yet, rather than providing a negative opinion on the

---

[106] Rec 14 Directive 2015/412.

[107] EFSA Guidance see note 99 above, sec 3.5, examples p 71.

[108] Eg ibid, pp 3, 11.

[109] Similarly Wickson and Wynne see note 36 above.

[110] EFSA Guidance see note 99 above, p 70; eg EFSA Panel on Genetically Modified Organisms, 'Scientific Opinion on Application (EFSA-GMO-NL-2005-24) for the Placing on the Market of the Herbicide Tolerant Genetically Modified Soybean 40-3-2 for Cultivation under Regulation (EC) 1829/2003 from Monsanto' (2012) 10 (6) *EFSA Journal* 2753, in which GMO related cultivation practices (spraying of glyphosate on the crop) is compared to conventional practices (pre-sowing use of glyphosate), rather than agroecological farming practices which do not use glyphosate at all.

[111] EFSA Guidance see note 99 above, p 21, recognises that 'whereas in general parlance the term "comparator" applies to the plant, ERA must account for the production system as a whole'.

[112] Ibid, pp 24 and 21 which note that comparisons should be made with (current) representative management techniques 'rather than "untreated" regimes which may be agronomically less realistic'; also Roger see note 74 above, part IV.

[113] Eg EFSA Panel on GMO see note 110 above, pp 35–36.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

safety of the GMO soya beans and corn, the EFSA recommended the adoption of risk mitigation measures to manage the use of the herbicide.[114] Indeed, the regulation of the related cultivation techniques that are the direct cause of environmental harm – and the only cause if the GMO is considered to be 'as safe as its conventional counterparts'[115] – may be a more proportionate, alternative measure than a cultivation ban. However, within the context of Roundup Ready GMOs, it is unlikely that these measures could amount to a complete prohibition of glyphosate – that would diminish the added value of the particular GMO crops and may thus be regarded as a *de facto* restriction on cultivation – while a recent German risk assessment has reaffirmed its general safety.[116] Member States on both sides of the GMO debate that have raised concerns regarding Roundup, will thus again find their hands to be tied, this time by the EU's likely re-approval of glyphosate under Regulation 1107/2009 for the placing on the market of plant protection products.[117]

Overall, the two examples of environmental policy objectives listed by Directive 2015/412 are unlikely to provide for solid grounds for spacious cultivation restrictions. The aforementioned German report has, however, inventively interpreted Article 26b(3)(a) to, at least in theory, grant for extensive possibilities for environmental differentiation by highlighting the artificial distinction between risk assessment and risk management in the EU's authorisation procedure.[118] Whereas Article 23b(3) only refers to the former, a textual reading would allow Member States to adopt restrictions based on a divergent perspective on the politically accepted level of risk. However, such decentralisation of all (safety and non-safety) risk-management decisions seems to conflict with a teleological understanding of Directive 2015/412, that explicitly aims to maintain a uniform level of environmental protection.[119] More importantly, Member States would not be able to adopt restrictions to manage risks which have not been acknowledged by the ERA. Their powers are thus greatly limited by the fact that positive opinions were adopted by unanimity regarding all but one application, with the EFSA stating that the GMOs were 'unlikely to raise safety concerns for the environment'.[120] Accordingly, and similarly to the examples of 'environmental objectives' discussed above, even this rather permissive understanding of Article 26b does not provide an answer to, and actually highlights, the

[114] Ibid, pp 76–77; EFSA Panel on Genetically Modified Organisms, 'Scientific Opinion on application (EFSA-GMO-UK-2008-60) for the Placing on the Market of Herbicide Tolerant Genetically Modified Maize 98140 for Food and Feed Uses, Import and Processing Under Regulation (EC) 1829/2003 from Pioneer Overseas Corporation' (2011) 10 (6) *EFSA Journal* 3139, pp 76–77.

[115] Ibid.

[116] A Neslen and T Levitt, 'Weedkiller suspected of causing cancer deemed "safe"' (*The Guardian,* 15 July 2015) http://www.theguardian.com/environment/2015/jul/15/weedkiller-suspected-of-causing-cancer-deemed-safe [last accessed August 2015].

[117] Regulation (EC) 1107/2009 [2009] OJ L309/1.

[118] Gaßner et al see note 57 above, pp 33–43, 51–54.

[119] Recs 2 and 14 Directive 2015/412.

[120] Eg EFSA Panel on Genetically Modified Organisms, 'Scientific Opinion Updating the Evaluation of the Environmental Risk Assessment and Risk Management Recommendations on Insect Resistant Genetically Modified Maize 1507 for Cultivation' (2011) 9 (11) *EFSA Journal* 2429; see also Klika et al see note 26 above, p 330; Gaßner et al see note 57, pp 48–49.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

most pressing problem troubling the EU GMO's regime: its lack of recognition of scientific uncertainty and diversity.

IV. REFORMING THE GMO REGIME: CENTRAL ACCOMODATION OF (SCIENTIFIC) DIVERSITY

A. Risk assessment: better acknowledgement of scientific uncertainty and diversity

The strict division between risk assessment and risk management envisioned by the current regime relies on a presumed possibility to quantify the likelihood of harm caused by the cultivation of GMOs on the basis of scientific evidence. This presumption is, however, undermined by the uncertainties that trouble debates on GMOs.[121] The EFSA's ERA guidelines affirm that 'any uncertainty inherent to the different steps of the ERA should be highlighted and quantified as much as possible'.[122] However, only regarding the authorisation of the Amflora Potato did two dissenting panellists accept for the first time the limits of 'the current state of knowledge'.[123] Furthermore, it follows from the above that the EFSA's objective opinions disguise subjective choices that allow for multiple scientific truths.[124] To provide a solution for the EFSA's failure to acknowledge scientific uncertainty and subjectivity, Winter has argued that statements of facts in the ERA should be separated from general environmental evaluations that lack unequivocal evidence.[125] He seems to be inspired by the Parliament's ENVI Committee, which recommended for scientific uncertainties regarding the protection of environmental objectives or a lack of data on regional impacts, to be legitimate grounds for Member States' derogations.[126] Winter thus holds that Article 26b would allow Member States to rely on *Ganzheitliche Gesichtspunkte*: holistic, trans-scientific aspects that bridge risk assessment and risk management, to justify their bans.[127] Accordingly, any statement that conceals political choices, eg, due to hidden uncertainties, should only be considered as an expression of opinion. National derogations would thus not only be possible on the grounds related to different receiving environments and risk management valuations, but also on diverse assessments that are based on different scientific methodologies, estimations and longer-term perspectives on the emergence of adverse effects.[128] In effect, this interpretation could mark a shift away from the GMO regime's exhaustive approximation, to minimum harmonisation (resembling Article 193 TFEU), that allows Member States to introduce or maintain more stringent environmental protection

[121] Klika et al see note 26 above, p 330; Hristova see note 31 above, p 109.

[122] EFSA Guidance above note 99, p 13.

[123] See Paskalev note 28 above, p 203; *Hungary v Commission,* T-240/10, EU:T:2013:645, para 37.

[124] Similarly Wickson and Wynne see note 36 above and Part III.C above.

[125] Winter see note 57 above, p 14.

[126] Amendment 17 ENVI Recommendations see note 16 above.

[127] Winter see note 57 above, pp 15–16.

[128] For various examples see Winter note 57 above, p 15. However, Rec 3 Directive 2015/412 explicitly recognises these considerations to be part of the (harmonised) EU's risk-assessment that needs to be 'regularly updated'.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

measures. Indeed, this understanding of Article 26b and its reallocation of competences may be the only way in which the reform provides an adequate and sufficient solution for the diversity problems of the EU's GMO regime.[129] However, this overly extensive interpretation is unlikely to survive judicial review, since it greatly undermines the very essence of the EU's centralised safety assessment that is reflected in the regime's and Directive 2015/412's internal market legal bases.[130] Moreover, giving Member States the final say on GMO cultivation seems to address their current national resistance as a symptom of the regime's diversity problems, rather than the underlying causes. The Council Conclusions of 2008 had, contrarily, urged for better accommodation of scientific, geographical and social diversity within the centralised authorisation procedure.[131]

The EFSA's disregard for scientific uncertainty and diversity is, again, an implementation problem rather than one of law. Whereas the EFSA does not perform its own tests, a network of public and private, scientific and lay experts is established on paper with the EFSA at its nexus, which would allow for broad-scale collection of data and multilevel cooperation and debate.[132] However, in practice, Regulation 1829/2003's one-door-one-key structure has taken a more hierarchical shape with the EFSA at the top. The scientific body has been accused of 'aggressive treatment of national work',[133] although some efforts have been made through information sharing and cooperation with national authorities.[134] Furthermore, the EFSA has depended heavily on the applicant as its primary source of knowledge, as exemplified by recent studies regarding the Maize 1507 assessment which showed great reliance on research conducted by Pioneer or scientists with industry ties.[135] This may in the first place be explained by the lack of scientific data from impartial studies on the risks of GMOs. Directive 2015/412 recognises that an increase in independent studies does not only require funding to be made available, but also 'access to all relevant material' – which is complicated by intellectual property hurdles that might need to be flattened through

[129] See more extensively on minimum environmental harmonisation as the only adequate solution, based on the redistribution of competences, for all the regime's diversity problems: M Geelhoed, 'A Growing Impasse: the Future of the EU's GMO Regime' (*University of Edinburgh, Europa Working Paper 2014/08*, 14 November 2014), sec 3.4, although placing the discussion in the context of the (possibly wrong) legal basis of the GMO regime.

[130] Ibid, Art 114 TFEU and Part II.C above. See also Rec 2 Directive 2015/412.

[131] EU Council, *Council Conclusions on Genetically Modified Organisms* [2008] 16882/08, notably paras 1–4 and 7–10.

[132] Paskalev see note 28 above, p 7 and Art 30(4) Regulation 178/2002.

[133] D Chalmers, 'Risk, Anxiety and the European Mediation of the Politics of Life' (2005) 30 (5) *European Law Review* 649, p 661.

[134] P Dabrowska-Klosinska, 'Towards More Experimentalism in the EU Governance on GMO Risks? Regulatory Experience, Responsive Reforms and Remaining Problems' (2013) *APSA 2013 Annual Meeting Paper*, p 14; J N Perry et al, 'Response to "The anglerfish deception"' (2012) 13 (6) *EMBO Reports* 481.

[135] A Bauer-Panskus and C Then, 'Case study: Industry Influence in the Risk Assessment of Genetically Engineered Maize 1507' (*TestBiotech*, 10 April 2014) https://www.testbiotech.org/node/1030 [last accessed August 2015].

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

legal provisions.[136] Yet, even when evidence is available and submitted by Member States, it has often been rejected with simple reference to the very information provided by the applicant that it aims to contradict.[137] Improving the implementation and functioning of the EU's centralised risk-assessment procedure to allow for scientific opinions that are more inclusive of pluralist views, may not be the quick fix that the Commission desired, but there seems to be ample scope for improvement. However, the EFSA's third opinion regarding Maize 1507 shows some willingness to better acknowledge counterevidence of possible and regional-specific risks, thereby repealing its initial firm conclusion that the corn would 'not have an adverse effect'.[138] It is then up to the Commission and Member States to enact effective risk-management measures.

B. Risk management: potential for precaution under WTO law

A pressing question is namely whether, once the EFSA acknowledges the uncertainties and diversities in the assessment of GMO safety, risk-managers could reject GMO cultivation based upon unfavourable scientific evidence and related socioeconomic concerns. The fact that the Commission has relied on the EFSA's opinions as a solid and single basis for its draft authorisations, despite the fact that even the EFSA recognised them only to be 'scientific information to inform the decision-making process',[139] has been explained as 'a pragmatic approach *vis-à-vis* the WTO'.[140] Although a detailed analysis of the EU's international obligations is beyond the scope of this article, some preliminary observations may indicate that the Commission's attitude is based upon a too restrictive reading of the *EC Biotech* ruling.[141] The rejection of a GMO application (or a cultivation restriction) as a means to protect health or the environment is to be qualified as a Sanitary and Phytosanitary (SPS) measure.[142] Although the requirement that such measures need to be 'based on an assessment' (Article 5.1 SPS Agreement) affirms the WTO's scientific focus, the Agreement leaves open the possibility that the assessment will identify uncertain risks that could justify

[136] Rec 19 Directive 2015/412; about the overprotection of commercial interests at the expense of transparency regarding safety risks: K M Nielsen, 'Biosafety Data as Confidential Business Information' (2013) 11 (3) *PLOS Biology* e1001499.

[137] See, eg Member States' comments to the MON88017 maize opinion, note 103 above.

[138] EFSA Panel on Genetically Modified Organisms, 'Scientific Opinion Supplementing the Conclusions of the Environmental Risk Assessment and Management Recommendations on the Genetically Modified Insect Resistant Maize 1507 for Cultivation' (2012) 10 (11) *EFSA Journal* 2934.

[139] Ibid, p 3.

[140] Dabrowska-Klosinska see note 134 above, p 9.

[141] WTO Dispute Settlement, *EC Biotech,* WT/DS291–293/R, condemned the EU's 'undue delays' in its approvals and Member States safeguard measures for not being based on 'an assessment' (Art 5.1 and Annex A(4) SPS Agreement).

[142] Art 1.1–1.2 and Annex 1 SPS Agreement; for discussion of the WTO Panel's extensive interpretation of the scope of the SPS Agreement see: J Peel, 'A GMO by Any Other Name ... Might Be an SPS Risk!: Implications of Expanding the Scope of the WTO Sanitary and Phytosanitary Measures Agreement' (2006) 17 (5) *European Journal of International Law* 1009.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

restrictions.[143] Such scientific uncertainty may not only arise in absence of sufficient evidence, but also when evidence is contradictory.[144] In the latter instance the Appellate Body has explicitly allowed measures to be adopted on the basis of divergent (minority) opinions, thus permitting precaution.[145] In fact, *EC Biotech* only condemned measures that were based on evidence of risks that were not acknowledged by the EU's assessment. This supports the view that the EFSA's opinions should be more inclusive of different scientific perspectives to give risk-managers room for manoeuvre.[146] A precautionary approach based on independent research would also be in accordance with Article 114(3) TFEU that requires internal market legislation to seek a high level of environmental protection', to compensate for Member States' loss of autonomy in this field.

Moreover, once the EU's safety-assessment recognises the existence of (uncertain) risks, trade law seems to grant risk-managers some discretion to decide whether they fall within society's acceptable level of risk.[147] It follows from the above that risk assessment is not free of subjective choices and it has been argued that public perception could be a legitimate factor to be taken into account when choosing between contradictory scientific evidence in support of a cautious or permissive approach to a risky product.[148] Various SPS provisions that required normative judgements to establish the appropriate level of protection have also been interpreted to possibly allow for choices by risk-managers motivated by social concerns.[149] Emphasising, yet again, the close relation between environmental and societal impacts, the WTO's insensitivity towards the latter can be attributed to the reluctance of the EU's own risk-assessor to acknowledge their potential (although inherently uncertain) scientific merit.[150] Whereas the EU may again restrict its

[143] Art 2.2 SPS Agreement; I Cheyne, 'Case Notes – Life After the Biotech Products Dispute' (2008) 10 (1) *Environmental Law Review* 52, p 61.

[144] In the former case, Art 5(7) SPS Agreement explicitly permits precaution.

[145] WTO Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)* (16 January 1998) WT/DS26/AB/R, WT/DS48/AB/R, para 194; J Zander, *The Application of the Precautionary Principle in Practice* (Cambridge University Press, 2010), p 73; L Gruszczynski, *Regulating Health and Environmental Risks Under WTO Law* (Oxford University Press, 2010), p 136.

[146] Likewise B Ivanova and MBA van Asselt, 'Pre-Empting Precaution – GMO Trade Conflicts, Uncertainty Intolerant Risk-Assessment and Precaution-based Risk Management' in MBA van Asselt et al (eds), *Balancing Between Trade and Risk Integrating Legal and Social Science Perspectives* (Routledge, 2013), p 94.

[147] A Alemanno, 'Public Perception of Food Safety Risks Under WTO Law: A Normative Perspective' in G Van Calster and D Prévost (eds), *Research Handbook on Environment, Health and the WTO* (Edward Elgar Publishing, 2013).

[148] T Epps, 'Reconciling Public Opinion and WTO Rules Under the SPS Agreement' (2008) 7 (2) *World Trade Review* 359, p 384 and (albeit more cautiously) Alemanno ibid, p 288, referencing *EC Hormones,* WT/DS26/AB/R and its follow-up *United States — Continued Suspension of Obligations in the EC — Hormones Dispute* (16 October 2008), WT/DS320/AB/R.

[149] Epps ibid, p 373 and Alemanno see note 147 above, p 281, with reference to Arts 5.4–5.7 SPS Agreement.

[150] In both *EC Hormones,* WT/DS26/AB/R and *EC Biotech,* WT/DS291–293/R the SPS measures were not supported at all by the assessment carried out.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

breathing space in the future through the expected transatlantic trade agreement, the multilateral regime in place does not necessarily prevent it from rejecting GMOs on the basis of contradictory scientific data and other concerns. Only once the vital step of recognising scientific uncertainty and disagreement is taken, thereby re-empowering Member States to decide on a broad diversity of information and not only the facts that the EFSA and the Commission deem to be relevant and of merit,[151] can the real problems within comitology be identified and addressed. Increased transparency and inclusiveness may reveal that a different understanding and valuation of environmental risks lie at the heart of the GMO impasse. Although there is a lot to be said for the uniform protection against the safety of GMOs,[152] the German recommendation for decentralisation of risk management (although possibly requiring reforms beyond Article 26b), may then provide inspiration to better appreciate divergent national views on whether the identified risks are worth taking. In essence, this solution may have similar effects to the first-phase option under Article 26b that allows for differentiation between pro-GMO and anti-GMO States through the request to adjust the scope of application. However, giving Member States the final and legally enforceable say on GMO cultivation (within or outside the EU's authorisation procedure), rather than leaving such choices to the whims of the industry, seems highly preferable and allows for more democratic decision-making: one of the objectives of the Juncker Commission.[153]

V. CONCLUSION

The recent breakthrough in the lengthy negotiations on the option for national cultivation restrictions has been welcomed by the Health & Food Safety Commissioner as a significant move beyond Member States' divergences.[154] This article has, however, found that the reform is unlikely to break the impasse in the EU's regime, while the new Article 26b fails to provide an adequate solution for the central system's neglect towards national diversity in debates on GMOs. By primarily bringing non-safety, socioeconomic objectives outside the scope of total harmonisation, the proposal disregards Member States' internal and external obligations under EU and WTO law. The opportunities for national bans based on environmental concerns are obscure. Article 26b is not likely to grant Member States full autonomy to protect themselves against the (uncertain) risks for their natural surroundings, and intrinsically related socioeconomic risks, if the EFSA's ERA has not at all acknowledged the possibility that

[151] Whose legitimacy has been challenged due to conflicts of interest and democratic deficits, see, eg *Decision of the European Ombudsman Closing the Inquiry Into Complaint 346/2013/SID Against the European Food and Safety Authority ('EFSA')* http://www.ombudsman.europa.eu/cases/decision.faces/en/58868/html.bookmark [last accessed 2 December 2015].

[152] See Part I above.

[153] J Juncker, *A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change* (Strasbourg, 15 July 2014) http://www.eesc.europa.eu/resources/docs/jean-claude-juncker—political-guidelines.pdf [last accessed August 2015], p 11.

[154] European Commission, *Commissioner Andriukaitis welcomes provisional political agreement on GMO cultivation* STATEMENT/14/2363.

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press

they could materialise. The reform therefore does not account for the fact that Member States have reasonably felt that their scientific findings and national interests have been neglected by the EFSA's risk-assessment procedure. Furthermore, by attributing the GMO regime's problems to an imbalance in the crude division of shared competences between the EU and Member States only, Article 26b fails to consider and explore the subtle roles that Member States play in the central authorisation procedure. Recognition of national positions and the continuous developments in science to allow for EU opinions and decisions that are more inclusive of diversity, through improved implementation of the legal framework in place, must remain the primary focus of future reforms.

Progress and improvements in this regard may, however, be hampered by the adoption of Article 26b. The reform has, at least for the moment, moved the centre of the discussions on GMOs and thereby also the responsibilities for further action, from the EU level to national and regional governmental bodies. Moreover, re-nationalisation also means multiplication of debates, possibly exponentially due to the many ambiguities that surround Article 26b, that could further undermine legal certainty in a field of regulation where legality and political reality have more often than not been at odds. Illustrative in this regard are the current discussions within the UK that have widened the divide between GMO-sympathetic England and the GMO-reluctant Scottish and Welsh nations. Simultaneously, it emphasises the difficulties in imposing a ban that would stand up to legal challenges, with Scotland's Environment Secretary arguably incorrectly interpreting the reform to allow Scotland to now unilaterally 'uphold the precautionary principle'.[155] The coming few months and years will be crucial for the future of the EU's multi-level GMO regime, for only time will tell how Member States' will implement their discretionary powers, how the exercise of competences may be further restricted through judicial review of national legislation and how the Commission will use its dominance in the EU's risk-management procedure to push for approvals against the backdrop of the questionable possibilities for national opt-outs. It may be difficult, in the midst of all this uproar, to refocus the EU's attention on the shortcomings within its central authorisation procedure and to address these problems to prevent the EU's GMO regime from becoming further divided in diversity.

[155] S Carrell, 'Scotland to Issue Formal Ban on Genetically Modified Crops' (*Guardian,* 9 August 2015) http://www.theguardian.com/environment/2015/aug/09/scotland-to-issue-formal-ban-on-genetically-modified-crops [last accessed August 2015].

https://doi.org/10.1017/cel.2015.21 Published online by Cambridge University Press