

GMOS IN THE INTERNAL MARKET: NEW LEGISLATION ON NATIONAL FLEXIBILITY

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Abstract

In an area where until now national autonomy has been tenaciously resisted, new EU legislation provides Member States with 'flexibility to decide whether or not they wish to cultivate GMOs on their territory'. This forces attention on to the subtle, and not so subtle, ways in which internal market law constrains political actors in the EU. But it is similarly suggestive of how political actors might contribute to the evolution of the internal market. As well as exploring this relationship between the new legislation and internal market law, this article reflects on the ways in which lessons from the past have been addressed by legislators. Whilst it takes somewhat seriously the politics of GMOs, the new legislation simultaneously reinforces some of the limitations of our dominant models for generating knowledge, including the EU's problematic dichotomy between facts and values, risk assessment and risk management.

Key words: internal market – GMOs – de-harmonisation – opt-out – flexibility – evidence – risk regulation

Introduction

The unfinished story of genetically modified organisms (GMOs) in the EU has been told many times, with many variations. And yet, there seems to be no end to the ways in which GMOs, and our responses to and understandings of them, expose features of legal and political phenomena that might otherwise go largely unremarked. The latest legislative chapter in the EU story is a 2015 Directive that claims 'to grant Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivate GMOs on their territory'.¹ This short (eight page, four article) piece of legislation deserves very careful attention. It is an important attempt at 'de-harmonisation',² the unpicking of harmonised legislation, and in an increasingly diverse and apparently

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¹ Directive 2015/412 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, Recital 8.

² I refer to 'de-harmonisation' in a fairly loose way, but whilst Article 26b allows for different outcomes in the Member States, a common process and approach applies. The language of 'opt out' is widely used, see M. Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance: GMO Regulation and Its Reform' (2015) ELJ forthcoming. De Sadeleer considers the new Directive to provide less than full harmonisation, N. de Sadeleer, 'The Uncertain Balance between Centrifugal and Centripetal Forces in the Marketing and Cultivation of GMOs in the EU', EJRR forthcoming. There has also been some debate as to whether non-health or -environmental issues were ever harmonised, see the discussion in M. Lee, *EU Environmental Law, Governance and Decision-Making* (Oxford: Hart Publishing, 2014), Chap 10.

increasingly sceptical Union, 'flexibility' in all of its many guises may become more important.³ That this turns out to be less straightforward than it sounds is not surprising, and perhaps the line between 'harmonisation and not' is more fuzzy than it seems.⁴

One of the reasons that GMOs have been compelling for EU lawyers is that they are tradeable products or 'goods', entitled to free movement under EU law. Internal market law is used in the new legislation as an explicit, if complicated and unpredictable, boundary on political action at the national level. And yet, EU level political action through that legislation may simultaneously influence our understanding of internal market law. We know that, broadly speaking, internal market law is socially constructed, effortfully maintained, and dynamic; if also highly developed and resistant to purposive change. Markets and their rules are not pre-formed and inevitable, but shaped by each other and by competing ideas of what they are and should be.⁵ And so as well as being shaped by the internal market, the political judgment reflected in the new legislation has the potential to shape the internal market in its turn.

As well as reflecting on the internal market, this article reflects on which lessons have been learned over at least twenty years of difficulties with GMOs. The legislation recognises, and attempts to respond to, certain insights about the fragility of particular approaches to knowledge generation and to politically legitimate decision-making in the EU,⁶ resonating also with broader questions about the space for democratic politics in 21st century governance. But the learning reflected in the new legislation is partial. The legislation if anything reinforces the EU's problematic dichotomy between facts and values, risk assessment and risk management. Whilst it takes somewhat seriously the politics of GMOs,

³ On the long history of differentiation, see AC.-G. Stubb, 'A Categorisation of Differentiated Integration' (1996) 34 JCMS 283, 291. From different perspectives, eg N. Walker, 'Sovereignty and Differentiated Integration in the European Union' (1998) 4 ELJ 355; J. Shaw, 'The Treaty of Amsterdam: Challenges of Flexibility and Legitimacy' (1998) 4 ELJ 63; R. Zbíral, 'Restoring tasks from the European Union to Member States: A Bumpy Road to an Unclear Destination' (2015) 52 CML Rev 51.

⁴ M. Lee, 'The Ambiguity of Multi-Level Governance and (De)-harmonisation in EU Environmental Law' (2014) CYELS 357; n 2 above.

⁵ There are lots different ways of thinking about this. See eg A. Lang, 'Reconstructing Embedded Liberalism: John Gerard Ruggie and Constructivist Approaches to the Study of the International Trade Regime' (2006) 9 *Journal of International Economic Law* 81; M. Callon, 'Civilising Markets: Carbon Trading Between *in vitro* and *in vivo* Experiments' (2009) 34 *Accounting, Organizations and Society* 535, S. Bogojevic, *Emissions Trading Schemes: Markets, States and Law*, especially Chap 3; S. Jasanoff (ed), *States of Knowledge: The Co-Production of Science and Social Order* (London: Routledge, 2004), in the context of 'facts' and 'politics', 'science' and 'social order'.

⁶ The EU is of course not monolithic, and nor are its institutions or the Member States. The regulatory process can however lead to entrenched positions, D. Chalmers, "'Food for Thought": Reconciling European Risks and Traditional Ways of Life' (2003) 66 MLR 532.

it simultaneously reinforces some of the limitations of our dominant models for generating knowledge, perhaps in a more subtle reflection of internal market values.

This article begins in the next section by briefly outlining the difficulties encountered in the regulation of GMOs so far. The precise character of disagreement on GMOs is complicated, but includes questions about the existence and acceptability of the risks posed to human health and the environment; about the nature and acceptability of the distributive impacts of GMOs; and about the existence and acceptability of other ethical questions, such as the extent to which GMOs interfere with and commodify 'nature'.⁷ Both 'too much' politics, and 'too much' science are blamed for the intractability of the disagreement over GMOs, but the two categories cannot be separated, and mutually reinforce each other.⁸ The 2015 legislation, and its permission to the Member States to restrict the cultivation of authorised GMOs in their territory, is then outlined, before turning to an exploration of the limits on Member State autonomy under the new legislation. Allowing more diverse national approaches to GMOs is in principle to be warmly welcomed. Nonetheless, the regulation of GMOs can only be understood in its broader legal context, and internal market rules will to a considerable extent determine what can and cannot be done with new found national freedom. GMOs have already demonstrated the limitations of legislative tweaks as a way to change engrained features of governance. But it is not implausible that the new legislation will shape the way internal market rules are applied: market rules are not natural phenomena that exist independently in the world. This article finally turns to consider the partial nature of the response of the new legislation to the dilemmas of risk regulation in the EU.

The path to the new legislation: Authorisation and contestation

The process for authorising GMOs broke down at the end of the 1990s, in the face of widespread public rejection of GM food and agriculture, and there were no authorisations between 1998 and 2004. The EU institutions and Member States ceased to apply the old legislation, and instead negotiated a new regulatory framework, composed of two key pieces

⁷ For discussion, see M. Lee, *EU Regulation of GMOs: Law and Decision-making for a New Technology* (Cheltenham: Edward Elgar, 2008).

⁸ M. Weimer, 'Risk Regulation, GMOs, and the Challenges to Deliberation in EU Governance – Politicization and Scientification as Co-Producing Trends' in C. Joerges and C. Glinski (eds), *The European Crisis and the Transformation of Transnational Governance – Authoritarian Managerialism versus Democratic Governance* (Oxford: Hart Publishing, 2014); more generally, E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Oxford: Hart Publishing, 2007).

of legislation, the Deliberate Release Directive and the Food and Feed Regulation.⁹ Deep divisions between the Member States, between the Member States and the EU institutions, and between and within the EU institutions mean that the legislation is still not working as envisaged. The first authorisation of a GM product in 2004 has been succeeded by relatively few further authorisations, and all of those in controversial circumstances.¹⁰

The authorisation process is complicated, varying according to the level of (dis)agreement between the Member States, and according to the uses for which the GMO is to be authorised, in particular, according to whether the GMO (including a seed or other plant propagating material) is ultimately for food or feed use or not. The key steps are a risk assessment by the European Food Safety Authority (EFSA), on the basis of information submitted by the applicant, and a decision on authorisation by the Commission and Member States through comitology (the examination procedure).¹¹ In no case between the end of 2004 and the agreement of the new legislation in 2015,¹² were the Member States able to reach a qualified majority in Comitology *either* to accept *or* to reject the Commission's draft decision. In these circumstances, the Commission is able to adopt its draft, and has thus had a controlling role, effectively freed from Member State supervision by the failure of comitology. As well as the EFSA opinion and 'any relevant provisions of Community law', the final decisions can rely on 'other legitimate factors relevant to the matter under consideration'.¹³ The Commission has relied in every case on the 'epistemic authority' provided by EFSA to justify its GMO decisions,¹⁴ and has never relied explicitly on other legitimate factors.¹⁵

An authorised GMO is supposed to enjoy free movement in the EU internal market, including for cultivation if that is covered by the authorisation. Before the introduction of the new legislation, independent Member State action was possible in very limited conditions. First, Article 114 of the Treaty on the Functioning of the European Union (TFEU) allows for a

⁹ Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms [2001] OJ L 106/1; Regulation 1829/2003/EC on genetically modified food and feed [2003] OJ L 268/1.

¹⁰ Decisions authorising GMOs can be found on the GMO register, http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

¹¹ Regulation 182/2011/EU laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [2011] OJ L 55/13.

¹² European Commission, *Communication Reviewing the Decision-making Process on Genetically Modified Organisms* COM (2015) 176.

¹³ This applies *only* to GMOs (including seeds) intended for food and feed.

¹⁴ Weimer, n 2 above.

¹⁵ Some reasons for that are found in administrative law and the grounds for authorisation in the legislation, see J. Scott, 'European Regulation of GMOs and the WTO' (2003) 9 *Columbia Journal of European Law* 213; Lee n 7 above, Chap 3. The Commission provides other reasons, n 12.

national measure in order to protect ‘the environment or the working environment’, provided it is based on ‘new scientific evidence’ and a problem ‘specific to the member state’, criteria interpreted narrowly.¹⁶ The safeguard clauses in the legislation are even more limited, and according to the Court not really about national freedom of action at all, but about enabling emergency action at EU level.¹⁷ Co-existence under Article 26a of the Deliberate Release Directive, which provides that ‘Member States may take appropriate measures to avoid the unintended presence of GMOs in other products’, has been more practical.¹⁸ However, Article 26a has a relatively specific purpose, the co-existence of GM, conventional and organic agriculture, and the Member States are also subject to the internal market disciplines discussed below. Notwithstanding the narrow scope of the legal provisions, a large number of national or sub-national¹⁹ bans on GMOs are in place, and many are not easily supportable in law. It has however apparently been impossible for the Commission to force the issue; in particular, Member States have not been willing in Council to impose the cultivation of GMOs on their reluctant peers. There has also been fairly limited action by the industry, who at least until recently seemed wary of provoking public opinion.

The new legislation applies to cultivation only, which ‘experience has shown ... is an issue which is more thoroughly addressed at Member State level.’²⁰ Cultivation has indeed been especially sensitive. However, Member State concern about GMOs is not limited to cultivation. Article 26b seems to have no relevance to the consistent comitology stalemate on applications that exclude cultivation from their scope. The Commission has proposed the extension of similar measures to food and feed GMOs not intended for cultivation. If this proposal is passed, only non-cultivated, non-food, non-feed GMOs, such as flowers or GMOs for industrial use, will be unaffected by the new approach to national measures.²¹

¹⁶ See the discussion in Lee, n 2 above, Chap 10.

¹⁷ Case C-58/10 to 68/10 *Monsanto v Ministre de l’Agriculture et de la Peche* [2011] ECR I-7763; see Lee, *ibid*.

¹⁸ N 9 above. The new legislation also amends existing Article 26a, adding the following words: ‘Member States in which GMOs are cultivated shall take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited...’; the obligation to take cross-border action could be contrasted with the voluntary nature of co-existence measures generally.

¹⁹ Whilst it is not the focus of this article, the sub-national level is significant for GMOs, see J. Hunt, ‘Ploughing Their Own Furrow: Subnational Regions and the Regulation of GM Crop Cultivation’ (2012) 13 *CYELS* 135.

²⁰ Recital 6.

²¹ European Commission, *Proposal for a Regulation amending Regulation 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. Non-living non-food or feed GM material, such as cotton in clothes, is unregulated in the EU, neither authorised nor labelled.

The authorisation process remains slow and contested, with no guarantees of a final decision, and the legitimacy of those decisions that are made is highly sensitive. GMOs follow the EU's standard structure for risk regulation: expert risk assessment (EFSA) followed by political risk management (comitology). For GMOs, the combination of 'sound science' and political deliberation have not enabled a workable harmonised solution. This exposes the broader fragility of decision-making in areas of high technological complexity, in respect of both risk assessment as the provider of universal, objective and decisive facts, and 'Commission plus comitology' as the provider of politically legitimate decisions. Disagreement over GMOs also highlights the impossibility of making a clean separation between the categories of risk assessment and risk management, given both the normative commitments implicit in risk assessment, and the way in which the political risk manager seeks legitimacy from the 'facts', as well as the mutual dependence between the two sets of institutions and two modes of reasoning.²² The post-authorisation disorder raises still further questions about the ability of the EU institutions to comply with the law. Whilst Member States frequently challenge the boundaries of free movement, such persistent and widespread disobedience is striking.

The 2015 Legislation

The 2015 legislation, citing Article 2(2) TFEU,²³ introduces a new Article 26b to the Deliberate Release Directive. This allows a Member State 'during the authorisation procedure of a given GMO'²⁴ to 'demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is to be excluded from cultivation'.²⁵ The applicant 'may adjust or confirm the geographical scope of its initial notification/application'. If the applicant adjusts the geographical scope, the authorisation will be restricted geographically. The opportunity for agreement may take some of the legal risk out of the de-harmonisation, since the applicant may be content with the limitation, perhaps because it had not intended to cultivate in the concerned Member State, or because it accepts the hoped for quid pro quo of easier authorisation in less resistant Member States.²⁶ But the Treaty applies even if the geographical restriction is included in the terms of the authorisation, and future legal challenge from disappointed applicants, perhaps

²² Weimer and Fisher, n 8 above.

²³ '... The Member States shall again exercise their competence to the extent that the Union has decided to cease exercising its competence.'

²⁴ Or during renewal of authorisation.

²⁵ Art 26(b)(1).

²⁶ The recitals suggest that most restrictions will take place at the authorisation stage.

arguing that their ‘consent’ during the authorisation process is not genuine, or from the Commission, is certainly conceivable. The ‘demand’ is made between EFSA’s opinion and the Commission putting a draft to comitology. In the absence of adjustment by the applicant, the decision is left to Commission and comitology, ‘in the light of the environmental risk assessment carried out by the Authority’.²⁷

If a GMO has been authorised without geographical restriction (because no demand was made or because it was rejected), Article 26b(3) allows a Member State to ‘adopt measures restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by crop or trait’. Any such measures must be ‘in conformity with Union law, reasoned, proportional and non-discriminatory’. They must also be ‘based on compelling grounds’. A non-exhaustive (‘such as those related to’) list of possible compelling grounds is included in the final legislation:

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

The compelling grounds

may be invoked individually or in combination, with the exception of the ground set out in point (g) which cannot be used individually, depending on the particular circumstances of the Member State, region or area in which those measures will apply, but shall, in no case, conflict with [EFSA’s] environmental risk assessment.²⁸

I return to the environmental risk assessment below. Presumably public policy can be invoked only in combination in order to rule out any argument that GMOs are simply ‘wrong’. The Member State will need to argue around the public policy of something, land use for example. The Court takes a strict approach to public policy under Article 36 TFEU, requiring ‘a genuine and sufficiently serious threat to a fundamental interest of society’.²⁹ Quite when ‘circumstances’ will be deemed to be locally or nationally ‘particular’ may lead to some debate. For example, in response to a notification of national action under Article 114(5)

²⁷ Recital 12.

²⁸ Article 26b(5) allows for the reintegration of excluded areas into the authorisation of a GMO.

²⁹ Case C-3602 *Omega* [2004] I 9609, [30]. The public policy justification in Article 36 is rarely used, and the Court resists its use to expand Article 36 by including independent concerns (such as environmental protection), P. Craig and G. de Búrca, *EU Law: Text, Cases and Materials* (Oxford: OUP, 2011), 670. In *Omega*, *ibid*, the protection of human dignity was a legitimate public policy concern.

TFEU, the Commission described Austria's small farms as 'a common characteristic, to be found in all the Member States'.³⁰ The requirement for 'particular circumstances' is indeed reminiscent of the requirement under Article 114(5) that the problem addressed be 'specific' to the Member State, 'somewhere between [a problem] which is unique and one which is common, generalised or widespread'.³¹ Under Article 114, 'the aptness or inaptness' of harmonisation, whether the problem is so widespread that it demands a harmonised response, is crucial.³² Given that the context of the new legislation is precisely the decision to allow national flexibility, we might expect a more generous interpretation, so that national and sub-national authorities are free to respond to their 'particular circumstances' in diverse ways, even if *physical* circumstances are widely shared.

The Commission's proposal for national flexibility in respect of GM food or feed not destined for cultivation³³ is a little simpler in its structure than the 2015 Directive, although there is plenty of opportunity for evolution during the legislative process.³⁴ The authorisation regime remains unchanged (so there is no opportunity to 'demand' a restricted geographical scope to the authorisation), and there is no indicative list of 'compelling grounds'. A proposed new Article 34a of the Food and Feed Regulation provides for national measures that must be '(a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the risk assessment carried out pursuant this Regulation; (b) proportional and non-discriminatory.'

The controversy that surrounds the new, 2015, legislation exposes, not for the first time, the contested and dynamic understandings of the internal market in the EU. It took five years for the new legislation to be passed into law, and that outcome looked dubious at times. Some are concerned that Article 26b is simply incompatible with internal market law. For example, the initial response of the British government to the Commission's proposal was hostile,³⁵ concerned 'that the proposals run completely counter to the principle of the Single Market

³⁰ Case T-366/03 and 235/04 *Land Oberösterreich and Austria v Commission* [2005] ECR II-4005, [65].

³¹ Case C-439 and 454/05 *Land Oberösterreich and Austria v Commission* [2007] ECR I-7141, [110] (Sharpston AG).

³² Case T-182/06 *Netherlands v Commission* [2007] ECR II-1983, [64].

³³ European Commission, n 21 above.

³⁴ The European Parliament Committee on the Environment, Public Health and Food Safety has recommended rejection of the proposal (25 June 2015). The main concerns seem to be that it represents a reneging on Commission promises to revisit the authorisation process, questions of practicality in terms of imposing border controls on agricultural commodities, and whether there is sufficient legal certainty and 'adequate tools' for the Member States in the context of internal market and WTO compliance.

³⁵ European Commission, *Proposal for a Regulation 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.

per se. By allowing national discretion, we clearly lose the opportunity to have a free trade in the market'.³⁶ On the narrow legal point, the new legislation is fairly clearly *capable* of being implemented compatibly with internal market disciplines, as discussed in the next section. But the initial UK government response reveals a particular narrow understanding of the internal market, as well as the central place of that narrow internal market to, in turn, understandings of the proper role of the EU. *This* internal market prioritises the economic over the social and has limited tolerance for social regulation that limits 'freedom' to trade,³⁷ in turn, and possibly paradoxically in this case, that leads to limited tolerance for national or sub-national diversity. By contrast, other visions of the internal market will pay more attention to the social, and would be more welcoming of collective decisions about the world we live in, even if those collective decisions are taken in the historical national or local space. As Weiler puts it, a choice of 'the market' is itself 'a highly politicized choice of ethos, ideology, and political culture'.³⁸ But, as he recognises, the choice does not end there: 'markets' are human constructions, of infinite variety.³⁹ The relationship between the economic and the social, and where authority should be exercised on those matters, has been the subject of long standing debates in the EU.⁴⁰ This is precisely one of the issues at stake in the contested governance of GMOs.

The concern for trade was not the only line of resistance to the proposal that eventually turned into the new legislation. The new legislation is presented as a way to increase authorisations, and hence increase the role of GMOs in EU agriculture. Those who sought to keep GMOs out of the EU may fear that the legislation will work precisely as planned, and when coupled with concern that the legislation grants only a very narrow space for national action in the internal market, the whole thing may look like a ruse.⁴¹ As should become clear, I have some sympathy with this view. But in truth it is often a little simplistic to present decisions as belonging to *either* the national *or* the EU level. Authority is rarely monolithic. In

³⁶ House of Commons European Scrutiny Committee, 14 June 2011, James Paice, Minister of State for Defra, who also referred to science and the WTO. The UK government had reversed its position by the time of the *Review of the Balance of Competences between the United Kingdom and the European Union: Agriculture* (London: Crown Copyright, 2014): 'the Government hopes there will be agreement on this as soon as possible', [2.134]. (Although generally, the balance of competence review saw no grounds for 'repatriation' of powers.)

³⁷ This simplifies, since there is not likely to be one single vision of the market even by those contributing to this particular debate. See P. Craig, 'The United Kingdom, the European Union, and Sovereignty' in R. Rawlings, P. Leyland and A.L. Young (eds), *Sovereignty and the Law: Domestic, European and International Perspectives* (Oxford: OUP, 2013) for one particular Tory Eurosceptic approach to the internal market versus social regulation, especially from 175.

³⁸ J.H.H. Weiler, 'The Transformation of Europe' (1991) 100 *Yale Law Journal* 2403, 2477.

³⁹ See n 5 above.

⁴⁰ The literature is vast, but the discussion can be seen in both Weiler, n 38 above, and Craig, n 37 above.

⁴¹ F. Wickson and B. Wynne, 'The Anglerfish Deception' (2012) 13 *EMBO Reports: Science and Society* 100.

the authorisation process, the Member States are obviously central to comitology, and they should also be involved in risk assessment, both in EFSA's constitution and in various levels of consultation.⁴² The problem is that this sharing of authority has essentially broken down in the case of GMOs. Even if it does not provide straightforward *autonomy* for the national or sub-national level, the new legislation should still be taken seriously as representing a particular, shifting, vision of the internal market.

Trade, the internal market and national 'flexibility'

The governance of GMOs has been stymied by resistance to mutual recognition,⁴³ followed by resistance to harmonised decisions, and this is recognised by the new legislation. Internal market law, however, places significant constraints on a Member State wishing to restrict the cultivation of authorised GMOs under the new legislation. This is a self-conscious factor in the new legislation: the recitals provide that the measures must 'be in conformity with the Treaties, in particular as regards the principle of non-discrimination between national and non-national products, [and] the principle of proportionality', citing Articles 34 and 36 TFEU,⁴⁴ and as set out above, Article 26b(3) requires national measures to be 'in conformity with Union law, reasoned, proportional and non-discriminatory'. Of course, compliance with the Treaties would be necessary even in the absence of such provisions, and secondary legislation must itself comply with primary law. It is not my intention to attempt to predict the future, either the extent to which Article 26b will be called on, or how subtly and effectively.⁴⁵ And national restrictions on cultivation may or may not go to Court. If they do, as discussed below, the case law leaves the Court significant interpretive flexibility. If they do not, internal market law continues to exert influence, and Member States will need to explain their decisions to industry, the Commission and other Member States.

⁴² M. Lee, 'EU Multi-level Governance of GMOs: Ambiguity and Hierarchy' in M. Cardwell and L. Bodiguel, *Regulation of GMOs* (Oxford: OUP, 2010). EFSA has been criticised for failure to collaborate, see eg EPEC Report to DG Sanco, *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 on or in products Under Directive 2001/18/EC; Final Report* (2011), [5.2], and the Commission has on occasion intervened to require further consideration of national views.

⁴³ Under the Deliberate Release Directive, n 9 above, the first step is an attempt at mutual recognition: the Member State to whom the application is made is able to make the decision in the absence of intervention from any other Member State, in which case (and every time in fact) we turn to the EU process.

⁴⁴ And Article 216(2) TFEU, Recital 16.

⁴⁵ Nineteen Member States have demanded geographical restrictions in respect of the GMOs that have been subject to decision so far, see http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en.htm .

Goods (including GMOs) are prima facie entitled to free movement in the internal market, and Article 34 TFEU is the basic provision prohibiting '[q]uantitative restrictions on imports and all measures having equivalent effect'. There is of course a daunting literature and case law on the internal market, on the doctrinal shifts and complexities, on its strengths and limitations, on its relationship with ideas of democracy, identity and constitution, and these tell their own stories about the ways in which the EU internal market is seen. For current purposes, it seems to be reasonably straightforward that a complete ban on the cultivation of GMOs (even in a small part of a Member State's territory) would fall within Article 34,⁴⁶ and so would need to be justified, either under Article 36 TFEU,⁴⁷ or under the Court's 'mandatory requirements' doctrine, which allows for the pursuit of other categories of public interest.⁴⁸ Article 36 and the mandatory requirements doctrine are available only in the absence of exhaustive EU level harmonisation. The precise character of the new legislation is open to question,⁴⁹ and a range of options may be available to the Court. But the freedom of action allowed to the Member States and the explicitly non-exhaustive list of 'compelling grounds', coupled with the reference in the legislation to internal market law, suggests that these provisions should be applied. They are certainly worth exploring for what they tell us about the governance of GMOs.

This section will discuss, first, the notion of 'compelling grounds' in the legislation, aligned with what counts as a good reason for national measures in internal market law. I will then turn to 'proportionality', under which rubric much of the policing of national measures is likely to take place. This discussion has two objectives. The first is to illustrate that the limits of GMO governance will be set by its interactions with internal market law; political and democratic choices have to fit into this space.⁵⁰ The second is to explore the ways in which internal market law may be shaped in turn by tenacious resistance to GMOs, as manifested in this hard-won legislation.⁵¹ This does have worrying aspects, since a court that obediently

⁴⁶ If we see restrictions on cultivation as a restriction on use, it would have 'a considerable influence on the behaviour of consumers', and 'greatly restrict' the use of GM seeds, Case C-142/05 *Åklagaren v Mickelsson and Roos* [2009] ECR I-4273, [26] and [28].

⁴⁷ Article 34 'shall not preclude' Member State restrictions that protect 'public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property'.

⁴⁸ Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)* [1979] ECR 649. Any debate about the application of the latter to discriminatory measures is side-stepped by the bar on discrimination in the Directive.

⁴⁹ N 2 above.

⁵⁰ De-harmonisation takes us back to a negative integration model, see F.W. Scharpf, 'The Assymetry of European Integration, or Why the EU cannot be a "Social Market Economy"' (2009) *Socio-Economic Review* 1.

⁵¹ We might think about the ways in which choices made in 'non-binding' guidance, opinions and advice might shape legal interpretation, eg E. Korkea-Aho, 'Laws in Progress? Reconceptualizing

follows political signals in every case is barely worthy of the name. However, arguably the most criticised and contentious Court of Justice decisions over recent years are cases in which it has rejected not only national collective social values, but also what had been thought to be EU collective agreement to respect and protect those values.⁵² Whilst secondary legislation cannot amend the Treaty, Treaty interpretation is not a natural and static phenomenon. Some visions of EU internal market law are able at least to consider the intensity and nature of national concerns and distinctive political views around Europe.

Good reasons for national measures

The Member State will need to justify its measures in terms of public interest. The Directive lists some 'compelling grounds', as set out above: town and country planning; land use; socio-economic impacts; avoidance of GMO presence in other products (without prejudice to Article 26a); agricultural policy objectives; and public policy. As well as being fairly unspecific, the list is non-exhaustive, suggesting that we may turn to the Court's general case law on the objectives that a Member State may pursue compatibly with the internal market. The case law suggests that the Court would be reluctant to find that an objective genuinely believed by a government to be in the public interest is simply illegitimate.⁵³

In an effort to present their measures in the terms that fit most readily into the pre-2015 legislative framework, governments have so far justified most national bans on cultivation on the basis of risk to environment and human health. The persistent and ongoing questioning of the adequacy of risk assessment of GMOs is certainly real, and is indeed acknowledged in the new legislation's promise to update the rules on risk assessment.⁵⁴ The place of 'risk' in the new legislation is, however, tricky. In the original Commission proposal on Article 26b, human health and environmental protection were explicitly not permissible grounds for national measures.⁵⁵ Risks to the environment and human health were deemed to have been satisfactorily addressed by the authorisation procedure, and remained harmonised. In the final version of the legislation, health is not excluded, and environmental policy is

Accountability Strategies in the Era of Framework Norms' (2013) 2 *Transnational Environmental Law* 363; T. Hervey, "Adjudicating in the Shadow of the Informal Settlement?": The Court of Justice of the European Union, "New Governance" and Social Welfare' (2010) 63 *Current Legal Problems* 92.

⁵² C-438/05 *International Transport Workers' Federation and Finnish Seamen's Union v Viking Line* [2007] ECR I-10779; Case C-341/05 *Laval v Svenska Byggnadsarbetareförbundet* [2007] ECR I-11767. Response to Case C-370/12 *Pringle v Ireland* nyr might tend in the other directions. On both perspectives, see P. Syrpis, 'The Relationship between Primary and Secondary Law in the EU' (2015) 52 *CML Rev* 461.

⁵³ Discussed in Lee, n 2 above, Chap 10.

⁵⁴ Recital 3. Risk assessment is the issue on which views are 'most diverse' according to EPEC, above n 42, [5.1].

⁵⁵ Commission, n 35 above.

explicitly listed as a legitimate concern.⁵⁶ The ‘uniform scientific assessment throughout the Union’ remains,⁵⁷ however, and Article 26b prohibits national measures that ‘conflict with the environmental risk assessment’ carried out by EFSA. So Member States are not able to rely on *competing* risk assessments that simply reach a different conclusion from EFSA, or on scepticism as to the adequacy of EFSA’s risk assessment. The Recitals envisage ‘grounds distinct from and complementary to those assessed according to the harmonised set of Union rules’.⁵⁸ Socio-economic grounds, for example, would presumably be ‘distinct’ and not ‘conflict’ with a positive risk assessment. A justification based on ‘environmental policy’ grounds is to be based on ‘*impacts* which are distinct from and complementary to [EFSA’s] assessment of risks to health and the environment’.⁵⁹ The only example of such an impact in the recitals refers to environmentally beneficial farming:

the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability, or maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features, as well as specific ecosystem functions and services.⁶⁰

A Member State might also seek to establish that the EU risk assessment has not taken into consideration its domestic environmental conditions.⁶¹ A more challenging argument would be to use Article 26b to accommodate political or cultural differences as to the acceptability of risk:⁶² the argument would be, not that the GMO is after all ‘unsafe’, but that when, for example, remaining uncertainties are coupled with particular concerns about distributional effects, risks deemed acceptable at EU level are no longer acceptable at the national or sub-national level. The Member State will need to avoid aspiring to a different level of protection, since that too is harmonised.⁶³

The expectation seems to be that the new legislation will primarily be used to pursue objectives *other* than environmental and health protection. Quite how the Member States will explain these objectives, beyond the non-specific terms of the legislation, is not easy to

⁵⁶ Although the Commission still refers to grounds ‘other than those related to risks to health and the environment’, n 12 above, 6-7.

⁵⁷ Recital 14.

⁵⁸ Recital 13. This may raise questions as to exactly what is taken into account at the EU level, and points to the concerns discussed in the final section below.

⁵⁹ Recital 14, emphasis added

⁶⁰ Recital 14.

⁶¹ EFSA purports to take diverse environmental conditions into account, but some Member States are concerned about whether regional variability is adequately considered by EFSA, EPEC, n 42 above, [5.2]. The requirement for ‘new evidence’ under Article 114 probably makes that a more challenging route for this sort of argument.

⁶² This is not possible under Article 114.

⁶³ By implication, but also Recital 14.

predict.⁶⁴ Poland famously attempted to defend its ban on the cultivation of GM seeds as ‘inspired by the Christian and Humanist ethical principles adhered to by the majority of the Polish people’,⁶⁵ linking those principles to an objection to acquiring intellectual property rights in living organisms, to a ‘quest for harmony between Man and Nature’ and to an argument that the ‘reduction of living organisms to the level of products for purely commercial ends’ is likely ‘to undermine the foundation of society’.⁶⁶ The Court did not comment on the legitimacy of those objectives, but it seems unlikely that they would be ruled out of bounds in principle, although they will be scrutinised carefully.⁶⁷

The Recitals to the Directive provide some assistance in filling out the compelling ‘socio-economic’ grounds found in Article 26b. Recital 15 suggests that the ‘high cost, impracticability or impossibility of implementing co-existence measures due to specific geographical conditions, such as small islands or mountain zones’⁶⁸ allows the Member State to turn to the new Article 26b. Countries including Austria and Hungary are indeed concerned about the impossibility of co-existence, albeit more on the basis of the structure of their farming systems than the geographical conditions referred to in the recital.⁶⁹ Hungary is concerned that the small scale of farming in some of its regions will increase the costs of co-existence to the point that maintaining different forms of agriculture is economically unviable; Austria that its high proportion of small farms and organic agriculture makes co-existence impossible. The recitals also provide that ‘[g]rounds relating to agricultural policy objectives may include the need to protect the diversity of agricultural production and the need to ensure seed and plant propagating material purity’.⁷⁰ Austria is concerned that widespread GM agriculture ‘would at first interfere with and then, in the long-term, displace organic and conventional genetically modified-free production’.⁷¹ In a different context, Austria has been allowed to pursue the ‘social objectives’ of ‘preserving agricultural communities, maintaining a distribution of land ownership which allows the development of viable farms and sympathetic management of green spaces and the countryside’.⁷² The distributive effects of GMOs, who will reap the benefits and bear their costs, including concern that GMOs could be more compatible with large farms and monocultures than with smaller and mixed farming,

⁶⁴ Although see de Sadeleer’s discussion of the list in the Directive, n 2 above.

⁶⁵ Case C-165/08 *Commission v Poland* [2009] ECR I-6843, [30].

⁶⁶ *Ibid.*, [31].

⁶⁷ As indeed they were in this case, discussed below.

⁶⁸ Recital 15. Recall that co-existence measures can be implemented under Article 26a, n above.

⁶⁹ In their national responses to the Commission’s socio-economic questionnaire, available at http://ec.europa.eu/food/plant/gmo/new/socio-economic_considerations/index_en.htm. Note Austria’s concern with geography in its Article 114 TFEU litigation, n 30 and 31 above.

⁷⁰ Recital 15.

⁷¹ N 69 above.

⁷² Case 452/01 *Ospelt v Schlössle Weissenberg Familienstiftung* [2003] ECR I-9743, [39].

seem to be implicit in some of this discussion. Hungary raises distribution more directly, claiming that the advantages are all with the 'giant' companies selling GMOs, and that agricultural biotechnology may 'totally [transform]' agriculture's 'social characteristics and traditions' affecting 'ownership structures, market relationships, ... and biodiversity'.

The case law suggests that the Court is likely to be content to accept claims that a particular interest is a legitimate objective or 'compelling ground' for the (sub)-national authority to pursue (subject to proportionality and evidence, discussed below). It draws the line, however, at the pursuit of economic objectives,⁷³ even when it is argued that offering economic protection to a national industry allows that industry to provide other public, for example environmental, benefits.⁷⁴ Efforts to protect existing forms of farming or food production may in some cases have economic aspects. This could include for example protection from the costs of GM 'contamination', as above, but becomes particularly acute if the aim is to protect agriculture from economic competition from the large companies and farms which it is claimed will benefit most from agricultural biotechnology.

This bar on economic objectives, however, is neither completely without flexibility nor easy to predict. The most obvious area of flexibility is in the way the Court has applied internal market provisions to state services. Whilst this case law has been enormously controversial,⁷⁵ it is clear that efforts to protect state resources are a legitimate feature of, for example, measures aiming to protect public health or education systems.⁷⁶ The Court has also, perhaps more pertinently for current purposes, accepted the necessity of ensuring the profitability of domestic waste treatment centres 'where the objective of an economic nature necessarily enables the objective relating to health to be attained.'⁷⁷ A number of cases on national support of renewable energy also imply a little flexibility towards economic objectives. The Renewable Energy Directive 2009 states that Member States 'have the right to decide ... to which extent they support energy from renewable sources which is produced in a different Member State',⁷⁸ at least in part because '[f]or the proper functioning of national

⁷³ Case C-120/95 *Decker* [1998] ECR I-1831, [39].

⁷⁴ Case C-203/96 *Chemische Afvalstoffen Dusseldorp BV v Minister Van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer* [1998] ECR I-4075, [44].

⁷⁵ Eg C. Newdick, 'Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity' (2006) CML Rev 1645; N. Nic Shuibhne and M. Maci, 'Proving Public Interest: The Growing Impact of Evidence in Free Movement Case Law' (2013) 504 CML Rev 965

⁷⁶ Nic Shuibhne and Maci, *ibid*.

⁷⁷ In one case. J. Jans and H. Vedder, *European Environmental Law: After Lisbon* (Groningen: Europa Law Publishing, 2012), 280-83, see less flexibility than N. de Sadeleer, *EU Environmental Law and the Internal Market* (Oxford: OUP, 2014). The quotation is from the most open case, Case 118/86 *Nertsvoederfabriek* [1987] ECR 3883, [15].

⁷⁸ Directive 2009/28/EC on the promotion of the use of energy from renewable sources [2009] OJ L 140/16, Article 3.

support schemes it is vital that Member States can control the effect and costs of their national support schemes'.⁷⁹ *Ålands Vindkraft* involves a Swedish system under which electricity suppliers are required to surrender a quota of 'renewable energy certificates', which are issued only in respect of energy generated in Sweden. The argument that this discriminatory measure was pursued for climate change mitigation (when in the absence of financial considerations, it does not matter where renewable energy is produced), as well as public health reasons, was accepted by the Court, suggesting the importance of the Member State's economic concerns.⁸⁰

Member States will need to establish clearly the underlying values at stake in any economic protection of particular forms of farming. Although the Court is not consistent,⁸¹ we might expect the 2015 legislation to influence assessment of the legitimacy of national measures.⁸² The legislation refers explicitly to socio-economic objectives, which are not easily distinguishable from economic objectives. The link between a concern for the economic viability of particular ways of organising farming and underlying policy objectives is anticipated by Recital 14, which, as quoted above, raises the possibility that some agricultural practices can support 'ecosystem sustainability', the 'maintenance of local biodiversity', 'certain types of natural and landscape features', as well as 'specific ecosystem functions and services'.

Proportionality

The previous sub-section considered the sorts of objectives that might legitimately be pursued by a Member State under Article 26b. Although that will need to be carefully argued, much of the internal market policing of national measures will in fact take place under the rubric of 'proportionality'. The approach to proportionality in internal market cases is not straightforward, or consistent.⁸³ Proportionality 'proper', a substantive balancing of the importance of the objective being pursued against the degree of interference with the internal market, is unusual,⁸⁴ and reliance on listed 'compelling grounds' should help in that case to establish the importance of the objective pursued.

⁷⁹ Recital 25.

⁸⁰ C-573/12 *Ålands vindkraft AB v Energimyndigheten* nyr. See also C-204/12 *Essent Belgium v Vlaamse Reguleringsinstantie voor de Elektriciteits-en Gasmarkt* nyr. The flexible approach to proportionality is discussed below.

⁸¹ Syrpis, n 52 above.

⁸² The legislation is clearly significant in the renewable energy cases, and indeed in the peculiar shape of the waste cases.

⁸³ P. Craig, *EU Administrative Law* (Oxford: OUP, 2012); F. Jacobs, 'The Role of the European Court of Justice in the Protection of the Environment' (2006) 18 JEL 185; de Sadeleer, n 77 above.

⁸⁴ But see Craig, *ibid.*

A Member State will have to establish that its measure is suitable (that is, capable of being effective) and necessary (that is, less restrictive measures are not available). How stringently these issues are assessed is not entirely clear.⁸⁵ De Witte discusses the dramatically different policing of ‘moral’ issues by the Court, from a purportedly ‘objective, legal’ EU approach that leaves no space for nationally autonomous approaches, to effectively abandoning any consideration of proportionality in favour of national moral judgment.⁸⁶ In some cases, the Court emphasises an especially strong role for *national* value judgments, for example in some of the cases addressing fundamental rights,⁸⁷ and when ‘there are significant moral, religious and cultural differences between the Member States’.⁸⁸ New Article 26b demonstrates a shared EU political understanding of the significance of distinctive national and sub-national interests and values. We might expect this shared understanding of a persistently difficult issue to shape proportionality at the flexible end of the Court’s range of approaches.

The role of legislation in interpreting the Treaties is also however unclear,⁸⁹ and given the different approaches, any selection from the case law has to be read with caution. But the renewable energy cases make a useful example. In its not terribly searching examination of proportionality, the Court cites the legislation: ‘it is essential, in order to ensure the proper functioning of the national support schemes, that Member States be able to “control the effect and costs of their national support schemes according to their different potentials”’.⁹⁰ The existence of nationally differentiated targets for renewable energy was also significant, another shared recognition of diverse situations.⁹¹ The picture is, of course, complicated, and there is surely no room for complacency.⁹²

Conclusions on the internal market

⁸⁵ I return to questions of evidence below.

⁸⁶ F. de Witte, ‘Sex, Drugs and EU Law: The Recognition of Moral and Ethical Diversity in EU Law’ (2013) 50 CML Rev 1545, criticising both Case C-34/10 *Brüstle v Greenpeace* [2011] ECR I-09821 and Case C-137/09 *Josemans v Burgemeester van Maastricht* [2010] ECR I-13019.

⁸⁷ *Omega* n 29 above, [37].

⁸⁸ Case C-447 and 448/08 *Sjöberg* [2010] ECR I-6921, [37] (of gambling).

⁸⁹ Syrpis n 52 above, also including cases where the legislative context hardens the proportionality inquiry, eg C-639/11 *Commission v Poland* nyr.

⁹⁰ *Ålands Vindkraft* n 80 above, citing recital 25 of the Renewable Energy Directive, n 78 above.

⁹¹ There are no national targets beyond 2020.

⁹² The legislation in *Laval* and *Viking*, n 52 above, did not lead to sensitive treatment of national policy by the Court. But the legislation did feed into the interpretation of the Treaty, at the same time as the Treaty was used to support a narrow interpretation of the legislation, S. Deakin, ‘Regulatory Competition after *Laval*’ (2007) 10 CYELS 581.

The new legislation claims that it is 'likely to improve the process for authorisations of GMOs' and 'facilitate the smooth functioning of the internal market'.⁹³ It is not then simply about enhancing national autonomy on the grounds that diversity is thought to be preferable to uniformity; it is also to fix a failing system, when one of the reasons the failures matter so much is that they challenge the internal market core of the EU.⁹⁴ This raises questions of how deeply into the system the fix is prepared to go, and how much flexibility the legislation really provides in the context of the internal market.

The space left to the Member States by the new legislation is not easily predictable. It is certainly limited, but has the potential to be significant. Equally, the space for the legislation to shape the internal market is unpredictable, but again, could be significant. However things progress, the framing of the debate is revealing. The cultivation of GMOs is positioned as the European common interest, the norm, and their prohibition an anomaly that needs to be justified.⁹⁵ Although the 'compelling grounds' are not exhaustive, the question of whether any particular modification is needed, or provides a social benefit – essentially a justification for placing the product on the market - is notable for its absence from the new legislation.⁹⁶ Howse describes the 'myth of "trade and ..."' as being 'that there is a trading system with a secure sense of self-identity facing "critics" who want to get in the door on the basis of some concern of dubious or complex relevance or relation to the system'.⁹⁷ The modesty of the legislation is clear: as much a reinforcement of access (of new technology) to the market, as a re-conceptualisation of the market.

Lessons learned and ignored: the political and technical in the new legislation

This new legislation responds to many years of criticism of both the narrow grounds for assessing GMOs and the overly rigorous centralisation of decision-making. But it is

⁹³ Recital 8. Note though the Article 114 legal basis, Weimer, n 2 above.

⁹⁴ The challenges are internal and external, see also F. Randour, C. Janssens and T. Delreux, 'The Cultivation of Genetically Modified Organisms in the European Union: A Necessary Trade-Off?' (2014) 52 JCMS 1307, 1308; G. Skogstad, 'Contested Accountability Claims and GMO Regulation in the European Union' (2011) 49 JCMS 895.

⁹⁵ Lang, n 5 above. By striking contrast with the discussion in A. Roger, 'In the Public Interest? A Comparative Analysis of Norway and EU GMO Regulations' RECIEL forthcoming.

⁹⁶ Also Roger, *ibid.* In Case T-240/10 *Hungary v European Commission* nyr, Hungary refers explicitly to the question of social benefit. Most GMOs at the moment are designed to protect crops from a pest, or allow the application of herbicide, but there is no explicit reference even to narrow agricultural benefit. Regulation 528/2012 concerning the making available on the market and use of biocidal products [2012] OJ L 167/1 allows for restrictions when the organism that the product targets is 'not present in harmful quantities' (only with respect to mutual recognition, *not* EU authorisation).

⁹⁷ R. Howse, 'From Politics to Technocracy - and Back Again: The Fate of the Multilateral Trading Regime' (2002) 96 *American Journal of International Law* 94, 109.

ambiguous in its structure. On the one hand, the legislation does indeed seem to recognise both broad grounds and national political authority. On the other hand, however, it may even reinforce the centrality and authority of a highly technocratic approach to decision-making at the EU level. In this section I try to explore the ambiguity of the legislation, first by thinking about the ways in which it may reinforce the contested approach to risk assessment at EU level, and secondly by speculating on the nature of the evidence that may be required from Member States seeking to make use of the new legislation.

The acknowledgement in the new legislation of a broad range of possible reasons for decisions may be a partial response to alleged de-politicisation of EU decision-making. Critiques of de-politicisation take many forms, at all levels of governance.⁹⁸ For current purposes, the concern is about a preference for universalising expert discourse, an assumption that everything that is interesting about GMOs can be captured by expert risk assessment,⁹⁹ reinforced by the way in which administrative and internal market law creates a narrow 'managerial space'¹⁰⁰ for risk regulation. The framing of the debate by this expert discourse can make it difficult for other perspectives to have a voice within the institutions of power; and the obscurity of the place where the 'real' decision is taken can make it difficult to identify a forum for democratic engagement, or indeed for any engagement with the normative questions. This de-politicisation matters because the choices being made in these technical spaces are in fact deeply political, 'choices by well placed men and women at various spots where power happens',¹⁰¹ but are not open to contestation as such. Of course this is not to suggest that expertise and law 'successfully' sidesteps politics, so that politics disappears: not only would that be simplistic, but also paradoxical given the argument here about the potential of mutual influence between political actors and the internal market. Moreover, GMOs demonstrate an extraordinarily resilient line of political contestation. But there is a question of dominance, and indeed the very peculiar politics and failures of GMOs

⁹⁸ Again, the literature is daunting. From an EU perspective, see eg M. Dawson, 'Transforming into What? New Governance in the EU and the "Managerial Sensibility" in Modern Law' [2010] *Wisconsin Law Review* 389; de Witte, n 86 above; also G. Davies, 'Democracy and Legitimacy in the Shadow of Purposive Competence' (2015) 21 *ELJ* 2. At the global level, see eg M. Koskenniemi, 'The Fate of Public International Law: Between technique and Politics' (2007) 70 *MLR* 1; Howse n 97 above; Lang, n 5 above.

⁹⁹ So that social questions are reframed in terms of risk, eg B. Wynne, 'Public Engagement as a means of Restoring Public Trust in Science – Hitting the Notes, But Missing the Music?' (2006) 9 *Community Genetics* 211; M. Kritikos, 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?' (2009) 34 *EL Rev* 405.

¹⁰⁰ Dawson, n 98 above.

¹⁰¹ Koskenniemi, n 98 above, 29.

have shone a light on the ways in which a largely technocratic process fails to engage properly with centrality of substantive normative concerns.¹⁰²

In its recognition of an open-ended range of ‘compelling grounds’ for decisions on GMOs, and its recognition that different cultures and societies may think differently on these issues, the new legislation allows the difficult political questions about GMOs to be openly addressed. This is to be welcomed, recognising many years of insight from the social sciences that GMOs (and other areas of socio-technological innovation) are about more than technically assessed ‘risk’. This has long been rhetorically accepted,¹⁰³ and is even institutionalised. In the GMO regulation, that institutionalisation takes place in a number of ways, including through legal guarantees of public consultation,¹⁰⁴ explicit ‘respect for ethical principles recognised in a Member State’¹⁰⁵ and permission to consider a full range of ‘other legitimate factors’ in decisions on food and feed.¹⁰⁶ The Member States have also, in principle, always been fully integrated into the process.¹⁰⁷ The institutionalisation has been weak however. Public views are difficult to feed into the process, the space for national ethical principles is uncertain, ‘other legitimate factors’ has never been applied, and in fact, EFSA and the Commission dominate the process.

So the new legislation is a fresh attempt to institutionalise the politics of GMOs, to embed politics in the regulatory process. But this is one side of the coin. We might equally be concerned that the new legislation will in fact reinforce the centrality of (EU) technical, expert authority. The legislation takes seriously the notion that there are concerns about GMOs that go beyond questions of risk, but does not engage with the equally significant, and equally well-recognised, difficulty of *separating* the political and the scientific (the risk and the other). Values infuse risk assessment, and political decisions properly demand knowledge on facts about the world; neither is prior to or independent of the other. In practice this might mean for example that the level of risk or uncertainty one is prepared to tolerate is intimately connected with the distribution of benefit and burden; and that the normative commitments of individuals and institutions contribute to the choice of methodologies and comparators in the

¹⁰² Comitology at its best provides only a forum for closed deliberation rather than public politics, but the *failure* of comitology in the case of GMOs means that even in its own terms it cannot introduce normative criteria to the process.

¹⁰³ A. Stirling, ‘Power, Truth and Progress: Towards Knowledge Democracies in Europe’ in J. Wilsdon and R. Doubleday (eds), *Future Directions for Scientific Advice in Europe* (Centre for Science and Policy, 2015). M. Lee, ‘Beyond Safety? The Broadening Scope of Risk Regulation’ (2009) 62 *Current Legal Problems* 242.

¹⁰⁴ Deliberate Release Directive, n 9 above, Article 24.

¹⁰⁵ Ibid, Recital 9.

¹⁰⁶ Food and Feed Regulation, n 9 above, Articles 7 and 19.

¹⁰⁷ Text at n 42 above.

risk assessment. The new legislation attempts to leave the EU level risk assessment intact as a single definition of safety, universally applicable.¹⁰⁸ So even whilst implicitly acknowledging its failures so far, the new legislation reinforces the elusive boundaries between fact and value.

The broadly shared perception that the WTO privileges technocratic risk assessment as a resource for decision-making is palpable in the new legislation's insistence on the continued validity of the EFSA risk assessment.¹⁰⁹ The focus of this article is on the EU sphere,¹¹⁰ and a full discussion of the WTO position is not possible.¹¹¹ But it would be remiss not to pause for a moment, in particular given the argument in this article that internal market rules are in part constituted by context; that context includes the international sphere. Criticism of the WTO's approach to risk assessment is certainly valid,¹¹² but the WTO's approach is complicated,¹¹³ and not straightforwardly averse to flexible justifications for action, or different forms of evidence.¹¹⁴ The Commission will strongly resist any allegation that the GATT's non-discrimination provisions have been breached at all,¹¹⁵ but if necessary, the EU may need to turn to the argument that national bans are 'necessary to protect public morals' under Article XX(a). 'Public morals' denote 'standards of right and wrong conduct maintained by or on behalf of a community or nation',¹¹⁶ which 'can vary in time and space, depending

¹⁰⁸ Wickson and Wynne, n 41 above.

¹⁰⁹ There was quite some to-ing and fro-ing between the institutions on WTO compatibility, with legal opinions from Commission, Council and Parliament, see the discussion in European Commission, *Complementary considerations on legal issues on GMO cultivation raised in the Opinions of the Legal Service of the Council of the European Union of 5 November 2010 and of the Legal Service of the European Parliament of 17 November 2010 – WTO Compatibility* SEC (2011) 551 final. Note the reference to Article 216(2) TFEU, Recital 16.

¹¹⁰ See M.A. Pollack and G.C. Shaffer, *When Cooperation Fails: International Law and Politics of Genetically Modified Foods* (Oxford: OUP, 2009); Scott, n 15 above; R. Howse and P.C. Mavroidis, 'Europe's Evolving Regulatory Strategy for GMOs: The Issue of Consistency with WTO Law: of Kine and Brine' (2000) 24 *Fordham International Law Journal* 317.

¹¹¹ Further, whether the WTO can still be confidently placed at the centre of the international trading system is increasingly open to question, and the relationship between the WTO and the EU's bilateral agreements will no doubt provoke a literature and a jurisprudence all of its own.

¹¹² Criticism of the WTO's science is strongest under the Sanitary and Phytosanitary Agreement, but most of the national measures will not be sanitary or phytosanitary measures, eg J. Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (Oxford: OUP, 2007). On the Agreement's broad scope of application, however, 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 *EJIL* 1009.

¹¹³ Eg A. Lang, 'New Legal Realism, Empiricism and Scientism: The Relative Objectivity of Law and Social Science' (2015) 28 *LJIL* 231; C. Bonneuil and L. Levidow, 'How Does the World Trade Organization Know? The Mobilization and Staging of Scientific Expertise in the GMO Trade Dispute' (2011) 42 *Social Studies of Science* 75.

¹¹⁴ Eg Scott, n 15 above; Howse, n 97 above.

¹¹⁵ Commission, n 109 above. If the Agreement on Technical Barriers to Trade applies, the pursuit of 'legitimate objectives' is permitted, subject of course to conditions.

¹¹⁶ *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (DS 285/AB/R, 7 April 2005), [296].

upon a range of factors, including prevailing social, cultural, ethical and religious values'.¹¹⁷ Although the inclusion of animal rights within the 'public morals' rubric suggests a broad interpretation,¹¹⁸ it is unlikely that 'public morals' will be allowed to expand indefinitely, and this space for the pursuit of social values is also limited by the 'chapeau' to Article XX.¹¹⁹ So it will require careful arguing. But the EU and its Member States retain authority to regulate GMOs, and the same sorts of questions, about the scope and shape of that authority, will need to be asked in the WTO as are asked in the EU.¹²⁰

The partial relocation of decisions on cultivation to the national or local level is also ambiguous in its effect on EU decisions. On the one hand the new legislation demonstrates an important recognition that EFSA has not provided stable 'facts' about the world, and that Commission plus comitology has not provided a broadly legitimate forum for politically significant decisions. It also accepts the need for *collective* decisions (at the national or sub-national level), an important advance on the earlier assumption that labelling and individual choice in the market can sweep up all of the issues left after 'risk'.¹²¹ But there is a danger that putting these questions into the hands of the Member States further marginalises the expression of the 'political' at EU level. Allowing authorisation decisions at EU level to take account of 'other legitimate factors' was a potentially significant and positive development for EU risk regulation. There is considerable space in EU law for EFSA and the Commission to recognise and engage with scientific uncertainty and disagreement. If Article 26b further downgrades the status of uncertainty, and of broad social and political values, in EU authorisation, especially if coupled with a very narrow freedom of action for the Member States, we take a step backwards.¹²² Which is not to say that enhanced room for diversity in this area is not a very good thing, or that this geographical and political space is inappropriate. GMOs raise fundamental questions about the sort of world we wish to live in, and these questions are likely to be understood differently in different cultures and contexts.¹²³ But it is crucial to continue to seek out space for normative assessment at *both*

¹¹⁷ *Gambling*, Panel Report (WT/DS285/R, 10 November, 2007), [6.461].

¹¹⁸ *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products* (DS400/AB/R, 22 May 2014).

¹¹⁹ The 'chapeau' prohibits the application of measures 'in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade'.

¹²⁰ *EC - Measures Affecting the Approval and Marketing of Biotech Products*, (DS 291, 292, 293, 29 September 2006) addressed the breakdown of the legal process during the moratorium, rather than the application of regulation.

¹²¹ Lee, n 7 above, Chap 4.

¹²² Lee, n 2 above, Chap 10; Weimer, n 2 above.

¹²³ S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Oxford: Princeton University Press, 2005).

EU and (sub-)national level, including normative assessment within and about questions of harm to human health and the environment.

I do not want to suggest that finding this space is straightforward. But the operation of the new legislation is still to be argued for, and could feasibly make a positive contribution. Member States taking restrictive measures will need to collaborate with industry, other Member States and the EU institutions, during and after the authorisation process.¹²⁴ The failure of collaboration and deliberation on GMOs so far is discouraging. But the fresh terms for discussion and the potential for divergent approaches could conceivably reinvigorate the debate at EU as well as national level; the utilisation by the Member States of the dichotomy between risk assessment and risk management, when they argue, as suggested above, that risks acceptable at the EU level are not acceptable nationally, could even destabilize that dichotomy.

There is a further element to the concern that the new legislation, far from expanding the space for political debate on GMOs, actually reinforces a technocratic approach. The new legislation may privilege a turn to methodologies that, whilst alternative to risk assessment, are equally prone to reductionism, and continue to exclude non-experts. Member States need to convince their interlocutors (courts, peers, industry and the EU institutions) of the validity and rationality of their approach. Nic Shuibhne and Maci's insightful review of the Court's approach to the role of evidence in internal market law indicates the difficulty (again) of predicting exactly what the Court will demand of a Member State seeking to establish genuine motivations and proportionate measures.¹²⁵ The new legislation simply requires the restriction to be 'reasoned', which suggests that a convincing articulation of the political, economic, social or ethical choices, suffices – the reasons for taking the decision. But the Court clearly can demand evidence, and is willing to condemn a measure in the absence of evidence that it pursues a particular public interest in a proportionate manner. The UK Supreme Court may go a little far in saying that 'moral or political considerations' or 'intuitive common sense' may be incapable of being established by 'evidence'¹²⁶ (and it depends precisely on what we mean by evidence), but a demand for hard empirical data in every

¹²⁴ This is required by the process following the 'demand' for geographical restrictions during authorisation, which is communicated to the applicant, and arises before comitology. If the restriction is imposed after authorisation, the Commission receives 75 days notice (no GMOs may be planted in the meantime), and 'may make any comments it considers appropriate'; the Member State can adopt its measures as originally proposed, or 'amended to take account of any non-binding comments received from the Commission', Art 26b(4).

¹²⁵ N 75 above.

¹²⁶ *R (on the application of Lumsdon) v Legal Services Board* [2015] UKSC 41, [56] per Lords Reed and Toulson.

case would make it more difficult to speak to some issues, and it may prefer the ‘economic, concrete, quantifiable and direct’ over the ‘complex, indirect, qualitative and social’.¹²⁷ Further, gathering evidence could be costly, particularly since whilst the applicant for authorisation is required to provide data and information for the purposes of risk assessment, there is no such requirement in respect of other objectives.

Poland failed to justify its ban on the cultivation of GM seeds because it had ‘failed ... to establish that the true purpose of the contested national provisions was in fact to pursue the religious and ethical objectives’.¹²⁸ This may have been an extreme case. Poland raised its claimed religious and ethical motivations at the last moment, and did not seem to take very serious steps to convince the Court that these were indeed the reasons for its actions. In another GMO case, Advocate General Bot seemed sceptical that a restriction on cultivation could ever be ‘necessary’ to ensure co-existence,¹²⁹ and emphasised the need for ‘strict proof that other measures would not be sufficient’.¹³⁰ But he did not volunteer what sort of evidence is needed. To take advantage of the freedoms offered by the new legislation, the Member State in principle needs to establish that the cultivation of GMOs would indeed threaten the underlying values it seeks to protect, and that nothing short of a ban at the particular geographical scale will do. Italy would have needed to provide technical evidence of the amount of space needed to maintain ‘GM-free’¹³¹ agriculture, for example the behaviour of GM pollen in the environment, and the way and rate at which it spreads into other crops and wild relatives.

If the new legislation is to open up decision-making on GMOs, demands for evidence should not be too rigid and diverse evidence should be acceptable. As well as economic and technical agronomic evidence, qualitative explanations of likely effects should be possible, evidence from the social sciences, evidence of public views on GMOs specifically, and on distributional issues more broadly, even the ways in which literature and art connect forms of agriculture with culture and identity. Questions of coherence or consistency may underpin

¹²⁷ Davies, n 98 above, 20, of internal market thinking rather than evidence.

¹²⁸ N 65 above, [52].

¹²⁹ Under Article 26a. Other measures to ensure the co-existence of different forms of agriculture include staggered sowing, weed management and careful cleaning and maintenance of equipment.

¹³⁰ Case C-36/11 *Pioneer Hi Bred Italia Srl v Ministero delle Politiche Agricole Alimentari e Forestali* nyr, [61] (Bot AG). The Advocate General had the new legislation (then in draft) in mind, [1]. The Italian measure would have been difficult to defend in any circumstances.

¹³¹ Raising questions about what we mean by ‘GM free’, compare the approach in European Commission, *Recommendation on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified (GM) crops with conventional and organic farming* C (2003) with European Commission, *Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops* [2010] OJ C 200/1.

questions of evidence,¹³² such that a consistent approach towards, for example, the support of a particular farming structure (small, family farms), also goes to both the genuineness and the effectiveness of the Member State's motivations. Even in this respect, a counsel of perfection must be resisted, since the factors that affect whether or not to take action will vary in every case.¹³³ We might also call on the precautionary principle, as a general principle of EU law,¹³⁴ for example where there is inadequate or competing evidence on the impact of GMOs on small or organic farming: 'where there is scientific uncertainty as to the existence or extent of risks', protective measures can be taken 'without having to wait until the reality and seriousness of those risks become fully apparent'.¹³⁵

The Commission has hinted at the evidence that *it* will be looking for, and it does seem to point in a worrying direction for anyone concerned to open up decision-making. Its socio-economic report on GMOs (which predates the new legislation, but not its proposal) emphasised the importance of gathering 'statistically relevant data on socio-economic impacts', urging a move 'from polarised perceptions to more tangible and objective results'.¹³⁶ The Commission has established a 'European GMO Socio-Economics Bureau' to develop Reference Documents to 'enable a science-based assessment' of the socio-economic implications of the cultivation and use of GMOs.¹³⁷ This sort of joint evidence gathering could be a useful resource for a Member State seeking to understand the vulnerability of its national farming structure. But an insistence on a particular sort of evidence could make certain types of justification difficult; and insistence on an 'EU' version of that evidence could significantly restrict diversity.

More encouragingly, although neither easy nor inexpensive,¹³⁸ the Commission anticipates that the Member States will devote 'more resources and time' to public participation following the introduction of Article 26b: 'Social, economic and ethical aspects are expected to be put

¹³² G. Mathisen, 'Consistency and Coherence as Conditions for Justification of Member State Measures Restricting Free Movement' (2010) 47 CML Rev 1021.

¹³³ See the discussion of animal welfare in other forms of hunting and slaughterhouses in *Seals*, n 118 above, [5.200]. Note also Recital 19 which emphasises that restrictions on cultivation should not prevent biotechnology research.

¹³⁴ Cases T-74/00, T-76/00 and T141/00 *Artegoda v Commission* [2002] ECR II-4945, [184].

¹³⁵ Eg Case C-41/02 *Commission v Netherlands (Fortified Foodstuffs)* [2004] ECR I-11375, [52].

¹³⁶ European Commission, *Report on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, as Requested by the Conclusions of the Environment Council of December 2008* COM (2011) no number, 8.

¹³⁷ <https://ec.europa.eu/jrc/en/eseb>. In a presentation on the negotiation of Article 26b, a Commission representative pointed out that 'the work of ESEB could become valuable', Minutes to meeting of 25-26 March 2014.

¹³⁸ Public engagement exercises will probably need to be ongoing – by analogy with the argument that national rules must not 'crystallize given consumer habits so as to consolidate an advantage acquired by national industries', eg Case 170/78 *Commission v United Kingdom* [1980] ECR 417.

on the table and provide the platform for the respective decisions at national, regional or local level'.¹³⁹ Participation might help to establish the moral weight of a particular issue within the Member State, as well as allowing the underlying *reasons* for public views on GMOs to be explored. The absence of any reference to public or consumer rejection of GMOs in Article 26b or the recitals is striking.¹⁴⁰ A simple response to popular rejection of GMOs would be problematic. Poland's argument that it would be 'unethical' to impose legal requirements 'to which most of the Polish people were opposed' was rejected by the Court: 'a Member State cannot rely ... on the views of a section of public opinion in order unilaterally to challenge a harmonising measure'.¹⁴¹ But the legislation may support a more generous approach: *national* action under the new legislation is not unilateral, but consensual.

The 'unlearned' lessons apparent in the structure of the new legislation may simply be more subtle reflections of the constraints of internal market law than those discussed in the previous section. The internal market intensifies the need to demonstrate the coherence and rationality of Member State action, encouraging a search for apparently manageable knowledge and quantification, for 'strategies of communication' that appear to speak to diverse audiences.¹⁴² Again, political actors are not powerless. Improved articulation and explanation of *other* sorts of reasons and *other* sorts of evidence may contribute to a shift in what counts as a plausible reason and basis for action.

Conclusions

Long after we might have expected objectors to GMOs to have lost their sense of agency and initiative, GMOs show us that people and nations are not powerless. Having told us so much about EU administration, this new legislation shows how GMOs continue to demand that light be shone on core areas of EU law. It reveals contested visions of the internal market, and engages self-consciously with what the internal market is and could be. GMOs have already taught us that small technical legislative changes do not straightforwardly change deeply rooted assumptions and legal contexts. De-harmonisation is no simple task, and we should not expect Article 26b to revolutionise Member State autonomy over GMOs.

¹³⁹ Commission, n 35 above, [2.2.2].

¹⁴⁰ Whilst a significant issue for some Member States, see the responses at n 69 above.

¹⁴¹ N 65 above, [56]. T. Novitz, 'A Human Rights Analysis of the *Viking* and *Laval* Judgments' (2007) 10 CYELS 541 notes that *Viking* n 52 above protects collective action only in pursuit of another recognised interest (worker protection).

¹⁴² T.M. Porter, *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life* (Princeton University Press, 1995), viii.

But there is considerable scope, in particular relying on the political agreement manifest in the legislative language, to shape internal market disciplines in a reasonably flexible way.

The legislation deserves careful attention as representing a particular, shifting vision of the internal market. The change of philosophy in the new legislation is however partial. The tension is clear throughout the recitals, for example in the recognition that cultivation has 'strong national, regional and local dimensions, given its link to land use, to local agricultural structures and to the protection or maintenance of habitats, ecosystems and landscapes', but that simultaneously 'the common authorisation procedure, in particular the evaluation process conducted primarily by [EFSA] should not be adversely affected'.¹⁴³ Whilst the new legislation takes somewhat seriously the *politics* of GMOs, it fails to take seriously the limitations of dominant EU models for generating knowledge.

¹⁴³ Recital 6.