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Risk Regulation and Deliberation in EU Administrative Governance—GMO Regulation and Its Reform

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Abstract: *The article analyses the problems of EU risk regulation of genetically modified organisms (GMOs) through the lens of deliberative theories of EU law and governance, such as deliberative supranationalism and experimentalist governance. Previous research had suggested that the GMO issue is not conductive to deliberation within EU institutions because of its high politicisation. This article argues that another equally salient factor is the scientification of the GMO authorisation process. Scientification stands for the Commission's overreliance on epistemic legitimacy as the basis for risk management. Given the deadlock of comitology in this field, scientification is exacerbated by a reversion to top-down regulation by the Commission. As a result, political responsibility for GMO authorisations gets lost. This article argues that both scientification and politicisation are mutually accelerative processes ultimately leading to a break down of dialogue at the EU level. This contradicts the assumption that deliberation is fostered by technocratic 'behind closed door' decision-making. In the GMO case, the top-down imposition of epistemic authority has only increased politicisation contributing to the de-legitimation of all EU institutions involved in GMO regulation. The recent EU reform on national opt-outs is not sufficient to address this problem. A successful reform should mitigate the negative effects of both politicisation and scientification.*

I Introduction

In January 2015 the European Parliament approved the amendment of Directive 2001/18 on the deliberate release into the environment of genetically modified organisms (GMOs)[1] with the aim of granting Member States the unprecedented right to restrict or ban GMO cultivation in their territory on grounds other than public health or environmental safety.[2] With this new reform of the EU legal framework for GMOs, the EU legislature hopes yet again to restore a functioning EU-wide process of GMO

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[1] Art 2, Dir 2001/18 defines GMOs as 'organism(s), with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.

[2] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory entered into force on 2 April 2015.

authorisation and to end the regulatory controversy surrounding this area for the last two decades. To evaluate the promise that this reform potentially holds requires an understanding of what makes this policy field one of the most gridlocked on the Union's agenda despite continuous reform efforts. In fact, GMO regulation constitutes one of the rare examples of the failure of deliberation in EU decision-making. This article, therefore, analyses EU regulation of GMOs as a test case for deliberative theories of EU law and governance, such as deliberative supranationalism and experimentalist governance.

Risk regulation is, in principle, considered as a domain favourable to the occurrence of deliberation, and a promising testing ground for deliberative theories in public regulation, especially in the transnational space.[3] The underlying assumption is that the scientific and technical questions arising in the regulation of risk-entailing products and technologies, including the accompanying scientific uncertainty, are likely to encourage a collective search for truth and for the best policy.[4] In the EU, the networked system of governance in comitology and in the Council has often been considered as fulfilling the special pre-conditions for successful deliberation.[5]

Back in 2001, Christian Joerges, in an article on the role of science within democratic risk management, stated that the regulation of transnational markets should be guided by 'transnational deliberative *fora*', which would become the basis of legitimate transnational governance:

> . . . among the three levels of governance—the nation-state, the EU, and the WTO—the EU comes closest to that ideal.[6]

This defence of deliberative supranationalism has become the basis for the successor theory of European Conflicts Law Constitutionalism (CLC): namely, the claim that European law in general, and European transnational governance in particular, can be re-interpreted as European 'conflicts-law', because they derive their legitimacy from existent deliberative practices, which are constitutionalised through procedural norms of transnational cooperation.[7] In a similar vein, other theorists of EU governance have identified the deliberative, self-transformative nature of European regulation as the core of EU's legal and regulatory architecture. According to Charles Sabel and Jonathan Zeitlin, the EU is a functioning novel polity without a state because of the fact that 'its decision-making is at least in part deliberative: actor's initial preferences are transformed through discussion by the force of the better argument'. The EU has developed a new architecture of experimentalist governance, which reconciles

[3] See P. Dabrowska, 'EU Governance of GMOs: political struggles and experimentalist solutions?', in C. Sabel and J. Zeitlin (eds), *EU Governance: towards a New Architecture?* (Oxford University Press, 2010); A. Spina, 'European Networks in the Regulation of Biotechnologies', (2010) 35 *European Law Review* 197; S. Murphy, 'Biotechnology and International Law', (2001) 42 *Harvard International Law Journal* 47.

[4] For a critical view, see M. Pollack and G. Shaffer, 'Risk Regulation, GMOs, and the Limits of Deliberation', in D. Naurin and H. Wallace (eds), *The European Union Council of Ministers* (Palgrave Macmillan, 2008).

[5] See T. Risse, 'Let's argue!: Communicative Action in World Politics', (2000) 54 *International Organization* 1, at 19–20; C. Joerges and J. Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology', (1997) 3 *European Law Journal* 273.

[6] C. Joerges, 'Law, Science, and the Management of Risks to Health at the National, European and International Level', (2001) 7 *Columbia Journal of European Law* 1, at 15–16.

[7] See C. Joerges, P.F. Kjaer and T. Ralli, 'A New Type of Conflicts Law as Constitutional Form in the Postnational Constellation', (2011) 2 *Transnational Legal Theory* 153.

centralised decision-making with local diversity by networking various types of decision-makers.[8]

European regulation of GMOs is a particularly instructive example of both the potential and the limits of deliberation as the legitimation basis for supranational regulation. Since Ulrich Beck's *Risk Society*,[9] it has been recognised that regulating technological risks has a strong political dimension, because it raises re-distributional conflicts. In other words, it raises essential political questions as to who should bear the economic, environmental, and social costs (the 'bads' rather than the 'goods') of globalisation, economic interdependence and technological progress. Over the last 20 years, the issue of GMO regulation in the EU has divided not only agricultural land (namely, into genetically modified (GM) and non-GM cultivation), but, with it, also the politics, societies and even identities in Europe.[10] Deliberation holds out the promise of legally enabling 'unity in diversity' in European governance via the creation of institutional frameworks within which comprehensive conflict resolutions become conceivable. In other words, deliberative transnational *fora* are seen as counteracting purely science-based technocratic governance, because they are able to balance various concerns (for example, trade, health, environment, socio-economic and ethical factors), thereby managing the political dimension of risk regulation. This article will show, however, that it is precisely this that EU institutions have been failing to do in the field of GMOs. The failure of European risk governance in this field presents itself as a challenge to deliberative theories such as CLC and experimentalist governance. At the same time, it also offers important insights into the pre-conditions of successful deliberation in European decision-making. Analysing the problems of EU governance of GMOs, as well as their causes, can enhance our understanding of the scope conditions of successful deliberation in EU administrative governance.

The article will proceed by reframing the problem of GMO regulation as one of a precarious co-production between scientification and politicisation (II). It will demonstrate this with an empirically informed analysis of the dynamics of GMO regulation between legislative ideals and institutional practices (III). Furthermore, it will address the question as to what extent the currently ongoing reform of the EU rules on GMO cultivation is able to reduce the dysfunctions of the current system of GMO authorisation (IV). Subsequently, the article will critically evaluate the promise of deliberation in EU administrative risk governance through the lens of the theories of deliberative supranationalism and experimentalist governance (V), before finally concluding (VI).

II Politicisation and Scientification as Co-producing Trends in GMO Regulation

Over the last 20 years, the controversy surrounding GMO authorisations has divided the EU not only politically, but also geographically. At the moment, there are over 100 voluntary 'GMO-free regions' in the EU.[11] Preferences (and as their basis, beliefs,

[8] C. Sabel and J. Zeitlin (eds), *Experimentalist Governance in the European Union* (Oxford University Press, 2010), at 2.

[9] U. Beck, *Risk Society: Towards a New Modernity* (SAGE Publications, 1992).

[10] For example, regional identities that are either 'GMO-free' or not. See http://www.gmo-free-regions.org.

[11] Not counting GMO-free provinces, departments or municipalities. See a map of GMO regions in 2012 at http://www.gmo-free-regions.org/fileadmin/pics/gmo-free-regions/conference_2012/map/EU_map_0912.png.

risk perceptions and socio-economic interests) with regard to GMO cultivation differ greatly among the Member States. Moreover, several Eurobarometer surveys have indicated that the majority of European citizens opposes the use of GMOs as food and in agriculture.[12] All these factors make EU agreement on common authorisations difficult, if not impossible, as evidenced by the year-long deadlock in both comitology and the Council of Ministers.

Legal and political disagreement is perpetuated in the post-authorisation phase. Several Member States have banned GMO cultivation on their territory in response to strong anti-GM movements at home. Although the Commission considers these bans to be unlawful, it is powerless to lift them against a qualified majority of national representatives in the Council and comitology. Until recently, the only issue Member States were able to agree upon since the enactment of the reformed GMO framework in 2001–2003 was that the Commission should not be entitled to lift national bans against the will of the Member States and their citizens.[13] This is a profound contestation of the Commission's authority to decide on GMO cultivation for the Union as a whole.

All these seem to suggest that the high politicisation of decision-making on GMO cultivation is the main factor preventing successful deliberation in the Council and comitology. Mark Pollack and Greg Shaffer, indeed, have argued that the GMO issue is not conductive to the sort of deliberative decision-making in the comitology process advocated by Joerges due to the intense politicisation of the issue in public opinion. According to them, politicisation:

> . . . has severely limited the ability of member-state representatives to engage in the sort of deliberative search for better policy depicted in the Habermasian literature. In this sense, our analysis lends further support to the view that transparency and politicization *decrease* the prospect for deliberation in transnational bodies, which appears to function most effectively in closed, *in-camera* settings. If confirmed by other studies, this finding suggests *a stark normative trade-off between transparency and openness, on the one hand, and deliberative decision-making on the other* (last emphasis added).

While politicisation certainly hampers a deliberative problem-oriented type of decision-making, how appropriate is it to draw a causal link from transparency to politicisation and, further, to the failure of deliberation? Are we, in this way, not omitting a part of the problem analysis? This article submits that the problems of GMO regulation in the EU are rooted not just in the politicisation and decisional deadlock within comitology. This is accompanied by another equally salient dimension of the GMO governance failure: namely, the *de facto* shift from de-centralised to unilateral top-down decision-making combined with the scientification[14] of the authorisation process.

This other dimension points us to a sort of 'parallel reality' of GMO regulation. The two main EU institutions responsible for authorisations—the European Commission and its expert agency, the European Food Safety Authority (EFSA)—

[12] The last survey indicated 58% opposing GMOs, see Eurobarometer (2008), *Attitudes of European citizens towards the environment*, at 65.

[13] The Council, on several occasions, voted with qualified majority against Commission proposals to lift national safeguard measures on GMOs. See M. Weimer, 'Applying Precaution in EU Authorisation of Genetically Modified Products—Challenges and Suggestions for Reform', (2010) 16 *European Law Journal* 624.

[14] On the notions of politicisation and scientification, although in a slightly different form, see M. Everson and E. Vos (eds), 'The Scientification of Politics and the Politicisation of Science', in *Uncertain Risks Regulated*, (Routledge-Cavendish, 2009), at 1.

continue to approve GMOs. Despite strong opposition from several Member States and the public,[15] under the current legal framework, the Commission has authorised every GMO application submitted to it, following, in each case, a positive EFSA opinion, finding no risks to human or animal health or to the environment. Moreover, high-ranking EU officials have publicly taken a pro-GMO stance in an attempt to end what some perceive to be a 'GMO psychosis'.[16] Anne Glover, the former EU chief scientific advisor, has publicly criticised opposition to GMOs on the grounds of health protection and environmental safety as lacking robust scientific evidence and declaring the precautionary principle as being no longer relevant with regard to GMO foods or crops.[17] Hence, this parallel reality is one in which regulatory science[18] constitutes a powerful basis for Commission decisions on GMOs.

It follows that Pollack and Shaffer's analysis does not consider the very important role that top-down decision-making combined with scientification plays in contributing to the increased politicisation of GMO regulation. In fact, the EU experience with GMOs is strongly marked by the clash between these two above-described trends. To date, no settled view exists on how to define the actual problem with regulating GMOs. While some blame the polarised public debate calling for more science-based regulation, others see the over-reliance on science as the root of the problem. To understand the problems of GMO regulation in Europe (and, importantly, also to draw lessons for other fields of risk regulation) it is, therefore, of crucial importance to analyse the interconnection between both politicisation and scientification as dynamic processes. The following section analyses the ways in which both processes are inter-related and are potentially co-producing each other.[19]

III GMO Regulation between Legislative Rules and Administrative Practices[20]

The current EU legal framework for GMOs[21] has been shaped in the aftermath of the BSE crisis. The rules, first, respond to the institutional failures of EU food safety regulation uncovered by the BSE and other food-safety crises, which occurred during the 1990s. Second, reforming the authorisation procedure for GMOs was an essential

[15] See F. Seifert, 'Synchronised National Publics as a Functional Equivalent of an Integrated European Public. The Case of Biotechnology', (2006) 10 *European Integration Online Papers*.

[16] See a statement by former Commissioner for Health and Consumer Protection David Byrne in 'Risk versus Benefit', European Voice Conference 'Farm to Fork', SPEECH/01/565, Brussels, 22 November 2001.

[17] See interview with EurActiv, *EU science advisor: 'Lots of policies are not based on evidence*', 24 July 2012, available at: http://www.euractiv.com/innovation-enterprise/chief-scientifc-adviser-policy-p-interview-514074.

[18] On this term, see S. Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press, 1990).

[19] The notion is being adapted from S. Jasanoff (ed.), *States of Knowledge: The Co-production of Science and Social Order* (Routledge, 2004), at 1.

[20] For a more detailed account see M. Weimer, 'Risk Regulation, GMOs, and the challenges to deliberation in EU governance: politicisation and scientification as co-producing trends', in C. Joerges and C. Glinski (eds) *The European Crisis and the Transformation of Transnational Governance* (Hart Publishing, 2014).

[21] Dir. 2001/18 on the deliberate release into the environment of genetically modified organisms, OJ 2001 L 106/1; Reg 1829/2003 on genetically modified food and feed, OJ 2003, L 268/1 and 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, OJ 2003, L 268/24.

pre-condition to ending the then EU *de facto* moratorium on the authorisation of GMOs, and thereby the transatlantic conflict over GMO trade.[22]

On the one hand, the legal rules seem to recognise the complexity both in societal and in scientific terms of decision-making on GMOs. They respond with a procedural solution that structures the process of authorisation as a cooperative effort of various actors, thereby aiming to reconcile two potentially conflicting rationalities: a scientific and a political rationality.[23] The former underlies the process of scientific evaluation of GMO risks, thereby providing the overall administrative process with cognitive or functional legitimacy.[24] The latter should govern the process of risk management as 'weighing policy alternatives in consultation with interested parties', and which not only takes into account the outcome of risk assessment, but also other non-scientific legitimate factors,[25] as well as the precautionary principle and scientific uncertainty.[26] Political rationality can, therefore, be seen as securing both the normative and democratic legitimacy of GMO authorisations in the EU.[27]

Moreover, the implementation process is structured as de-centralised administrative cooperation.[28] A dense procedural framework orchestrates the input of the various actors in the authorisation process. Both the Commission as the risk manager and EFSA as the risk assessor are embedded in a de-centralised transnational network, which essentially aims at preventing unilateral action on the part of the EU institutions. On the one hand, when authorising GMOs, the Commission is obliged to follow the comitology examination procedure, which should compensate for the loss of national regulatory competences by serving as a forum for the Member States to express their concerns. The new comitology rules adopted in 2010 explicitly stress the deliberative element of this administrative process.[29] On the other hand, EFSA has not been designed as a superior authority to national scientific authorities, but as a

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[22] The *de facto* moratorium lasted between 1998 and 2004; See, also, M. Pollack and G. Shaffer, *When Cooperation Fails: the International Law and Politics of Genetically Modified Foods* (Oxford University Press, 2009).

[23] See, also, T. Christoforou, 'The Precautionary Principle and Democratizing Expertise: A European Legal Perspective', (2003) 30(3) *Science and Public Policy* 205. In the Pfizer case, Case T-13/99, *Pfizer Animal Health SA v. Council* [2002] ECR II-3305, the EU General Court has confirmed this interpretation of the precautionary principle stating that the latter is based on the idea that scientific legitimacy is not sufficient to underpin regulatory decisions on risk, but must be complemented by a political legitimacy provided for by the risk manager who is democratically accountable and has the discretion to take into consideration other factors than the results of the scientific risk assessment.

[24] See J. Black, 'Constructing and contesting legitimacy and accountability in polycentric regulatory regimes', (2008) 2 *Regulation & Governance* 137, at 146: 'functional legitimacy claims focus on the outcomes and consequences of the organization (for example efficiency, expertise or effectiveness) and the extent to which it operates in conformance with professional or scientific norms.'

[25] Following Preamble 19 of Reg 178/2003 laying down the general principles and requirements of food law and establishing EFSA such factors can include societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

[26] See Art 6 (2) and (3), Reg 178/2003 and Art 3 (12), Reg 178/2003 defining risk management.

[27] According to Black, n 25 above, regulators often aim at satisfying various legitimacy claims. Normative legitimacy is achieved when the goals and/or procedures of a regulatory activity are perceived as morally appropriate, at 144. Democratic legitimacy is achieved when the regulatory activity complies with certain models of democratic governance, for example, representative, participatory or deliberative, at 146.

[28] On administrative cooperation, see E. Schmidt-Assmann, *Der europäische Verwaltungsverbund Formen und Verfahren der Verwaltungszusammenarbeit in der EU* (Tübingen, Mohr Siebeck, 2005); see also D. Chalmers, '"Food for Thought": Reconciling European Risks and Traditional Ways of Life', (2003) 66 *Modern Law Review* 538.

[29] Art 3 (4) and a corresponding provision in Art 6 (2), Reg 182/2011.

networked agency that promotes networking and scientific co-operation between national authorities while mediating divergent scientific risk assessments.[30] Hence, shared responsibility and, in fact, shared authority for GMO authorisations is therefore a key feature of this regulatory regime.[31]

On the other hand, the idea of a cooperative and de-centralised management of GMO risks is far from being realised in practice. The latter is characterised by the failure to achieve a balanced deliberative form of decision-making able to reconcile scientific and political legitimacy. Instead, the institutional practice is caught in between the scientification of the Commission's risk management, on the one hand, and the politicisation of comitology decision-making, on the other. Moreover, the following analysis shows problematical shifts of authority, which go beyond the system of shared responsibility envisaged by the EU legislature. Instead of administrative cooperation between national and supranational actors during risk management, top-down decision-making by the Commission dominates the process.

A EFSA's Insertion of Epistemic Authority

Since the establishment of EFSA, cooperation with national scientific authorities on GMO risk assessments has been hampered by a lack of trust and conflicting views over GMO safety. An external evaluation report of 2011 on the EU legislative framework in the field of GMO cultivation (the European Policy Evaluation Consortium (EPEC) report) found the need to improve communication and dialogue between EFSA and the Member State authorities in order to increase the rate of learning in the system.[32] The majority of national authorities perceive that EFSA does not sufficiently consider their comments.[33] One particular problem is that most applications for cultivation are now being submitted via Regulation 1829/2003, which means that applications are being sent to EFSA directly, bypassing the national evaluation stage.[34]

Moreover, empirical studies of EFSA's work[35] indicate that although legally EFSA has not been granted a superior authority over national scientific authorities, in practice EFSA's GMO panel asserts scientific authority by overriding national safety concerns. In this field, EFSA therefore fails to fulfil its legally envisaged function as a mediator between different national risk assessors and as a networked agency.

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[30] See Art 22 (7), 23, 30 and 36, Reg 178/2003.

[31] Similar M. Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar Publishing, 2008), at 102; D. Chalmers, 'Risk, Anxiety and the European Mediation of the Politics of Life', (2005) 30 *European Law Review* 649, at 669; Dabrowska, n 3 above.

[32] European Policy Evaluation Consortium (EPEC), Evaluation of the EU legislative framework in the field of cultivation of GMOs under Dir 2001/18/EC and Reg (EC) No 1829/2003, and the placing on the market of GMOs as or in products under Dir 2001/18/EC, Final Report, March 2011, at 75.

[33] *Ibid*., at 20 and 74.

[34] *Ibid*., at 17.

[35] See M. van Asselt and E. Vos, 'Wrestling with Uncertain risks: EU Regulation of GMOs and the Uncertainty Paradox', (2008) 11 *Journal of Risk Research* 281 with further references; M. van Asselt, E. Vos and B. Rooijackers, 'Science, Knowledge and Uncertainty in EU Risk Regulation', in E. Vos and M. Everson (eds), *Uncertain Risks Regulated*, (Routledge-Cavendish, 2009); D. Chalmers, 'Risk, Anxiety and the European Mediation of the Politics of Life', (2005) 30 *European Law Review* 649; For a view that cooperation problems between EFSA and the Member States are overstated, see S. Poli, 'Scientific advice in the GMO area', in A. Alemanno and S. Gabbi (eds), *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority* (Ashgate Publishing, 2014), at 111.

The quality of scientific risk assessment, which constitutes a meta-review by EFSA of the data and analyses provided by the applicant company, has also been strongly criticised by several stakeholders including national authorities, non-government organisations and independent scientific institutes. In 2008, the European Environmental Council has called upon EFSA to improve its assessment of the long-term risks of GMOs, and, for example, to revise its guidelines for environmental risk assessment.[36] Furthermore, empirical research indicates that EFSA's risk assessment is being characterised by the so-called 'uncertainty paradox'.[37] The latter is described as a situation in which scientific uncertainty is acknowledged, in principle, but the role of science is actually framed as one of providing certainty and definitive answers about the absence or presence of risk despite uncertainty precluding both conclusiveness and definitiveness. The uncertainty-intolerant attitude on the part of EFSA is characterised by the reluctance to acknowledge the existence of uncertainty in GMO risk assessments, or, at least, to deem it as relevant, instead of genuinely and systematically investigating it.

There have been, however, some recent developments in EFSA's GMO risk assessment, which indicate a potential shift toward more uncertainty-tolerant assessment practices. Two controversial cases concerning applications for GMO cultivation are indicative in this respect, namely EFSA's assessments of Pioneer's maize 1507 and of the BASF's Amflora potato.[38] These cases are characterised by scientific contestation on the part of both Member States and independent institutes over potential risks to human health and the environment; strong objections to the quality of EFSA risk assessment; and consequently, a recurrent referral back to EFSA by the Commission, which resulted in a high number of EFSA opinion updates on the same GMO.

An analysis of EFSA risk assessments of both GMOs shows an interesting development in two respects. First, the pressure exerted by national authorities and independent research studies as well as the recurrent referral back to EFSA by the Commission seems to have forced the agency to engage more seriously with competing views and uncertainty information.[39] It moved from providing definite answers on the safety of the GMO in question to more nuanced answers while indicating knowledge gaps and remaining uncertainties. Second, however, this ultimately did not alter the substantial outcome of EFSA risk assessments, namely, the finding of safety. Potential risks and uncertainties arising from the cultivation of both GMOs were treated as manageable through post-authorisation measures such as monitoring and mitigation.

B Politicisation, Deadlock and Reversion to Hierarchy in Comitology

EFSA's constructed scientific authority has strong *de facto* influence on the outcome of authorisation decisions taken by the Commission within comitology. In practice, the Commission ultimately followed every EFSA opinion, all of which were in favour of authorisation. In no case did the Commission exercise its discretion to depart from EFSA's advice, for example, upon the basis of socio-economic concerns or with reference to scientific uncertainty and the need for a precautionary

[36] European Council conclusions adopted on 4 December 2008, available at: http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/envir/104509.pdf.

[37] Van Asselt and Vos, n 35 above, at 283.

[38] The following account is based upon a forthcoming paper by M. Weimer and G. Pisani (on file with the authors).

[39] On this term, see van Asselt and Vos, n 35 above.

approach.[40] However, in view of the new Commission practice developed over the last couple of years to delay authorisations while referring opinions back to EFSA for an update, it may no longer be adequate to compare the Commission with a blind driver receiving directions from a passenger (EFSA) in the back seat.[41] The Commission does not follow EFSA blindly, but, to date, it has always followed its advice in the end, albeit with considerable delay. This indicates that the Commission is often, especially in controversial cases, paralysed between EFSA's opinion and national as well as public opposition to GMO cultivation. Above all, it is not able, or does not see itself as being entitled,[42] to exercise political discretion, and to depart from EFSA's advice even where there are indications of scientific uncertainty or strong socio-economic objections. It should be emphasised that from the Commission's point of view, EFSA's epistemic authority seems to be the only legitimate basis for the authorisation decision, which ultimately contributes to the loss of political responsibility for GMO authorisations in the EU. Importantly, the comitology process, due to its malfunctioning in this field, fails to mitigate this problem.[43]

This leads to the de facto ineffectiveness of the national input into the authorisation process. Instead of shared authority and cooperation, the Commission appears as the most powerful institution in the authorisation process.[44] Through the, by now, common practice of adopting the final decision by default following the reversed majority voting rule—a mechanism that was originally created for exceptional cases—the Commission re-installs top-down unilateral decision-making *vis-à-vis* the Member States in this process. The weakness of national representation in comitology is even more precarious as comitology networks are not able to mitigate effectively the strong influence of EFSA on the Commission. This, in turn, re-inforces the scientification of the authorisation process.[45]

IV Seeking Escape Routes through Reform—The New EU Approach to GMO Cultivation

In response to the protracted problems of GMO regulation described above in July 2010, the European Commission presented a reform proposal for the GMO legal framework. It adopted a legislative proposal[46] to amend Directive 2001/18 on the deliberate release of GMOs into the environment in order to grant Member States

[40] See, for example, Mihail Kritikos, 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?', (2009) 34 *European Law Review* 405.

[41] This metaphor was originally expressed by a Commission official and cited in E. Vos and F. Wendler, *Food Safety Regulation in Europe: A Comparative Institutional Analysis* (Intersentia, 2006), at 122.

[42] The problem seems to be one of legal entitlement. The legal grounds for authorisation under Reg 1829/2003 (Art 4 (1) and (5)) are framed in narrower terms than its regulatory objectives, and stand in contrast with Art 7 of the Regulation which requires the Commission to take into account 'other legitimate factors'. See, on this, J. Scott, 'European Regulation of GMOs: Thinking about Judicial Review in the WTO', (2004) 57 *Current Legal Problems* 117, at 118–119.

[43] See M. Weimer, n 20 above.

[44] This power is, of course, very contingent as the Commission is not able to enforce compliance with its decisions post-authorisation in several of the Member States.

[45] The authorisation process for Pioneer maize 1507 epitomises these problems, see M. Weimer, n 20 above and Weimer and Pisani, n 38 above.

[46] See Proposal for a Regulation of the European Parliament and of the Council amending Dir 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 of 13.7.2010.

more freedom to restrict or ban the cultivation of GMOs on their territory. The new EU approach of the so-called 'opt-out' measures is following the principles of flexibility and subsidiarity. It represents not only a substantial policy turn when compared with the EU policy toward national restrictions of GMO cultivation to date, but is also the first time that the Commission has proposed to give back decision rights previously exercised at the EU level.[47]

Not surprisingly, the EU institutions have been struggling to find a common position on the reform proposal. At its first reading in 2011, the European Parliament has introduced several amendments.[48] Between 2011 and 2014, the proposal has been blocked at the stage of first Council reading, because of Member States' disagreement. Some Member States feared that national opt-outs on GMOs would be incompatible with the EU internal market and/or World Trade Organisation rules, whereas others demanded a more far-reaching reform of the EU authorisation procedure.[49] After 3 years of deadlock in the Council, in June 2014, under the outgoing Greek presidency, the Member States finally agreed on a common position. In January 2015, finally, the European Parliament adopted the proposal.[50]

According to the latest amendment of Directive 2001/18, a new Article 26b titled 'Cultivation' has been inserted into the Directive laying down the procedure for the adoption by a Member State of measures restricting or prohibiting the cultivation of a GMO previously authorised at EU level in all or part of its territory. This procedure consists of two different pathways toward the national opt-out. The first pathway, the so-called 'restriction of scope' request, is consensual in nature as it involves an agreement between the applicant and a Member State. During the authorisation of a given GMO, a Member State may request the applicant via the Commission to adjust the geographical scope of its application so as to exclude the territory of that Member State from cultivation of the GMO in question.[51] Where the applicant agrees, the authorisation for the GMO in question shall be granted only with the adjusted geographical scope.[52] However, and this is the second pathway, where the applicant opposes the adjustment or where no demand for a restriction of scope was made in the first place, a Member State may still adopt the so-called 'post-authorisation opt-out'.[53] In other words, a Member State may adopt measures restricting or prohibiting the cultivation of the GMO irrespective of the applicant's consent, provided that certain substantive[54] and procedural[55] conditions are fulfilled.

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[47] See below. For an exploration of why the Commission made this proposal, see M. Weimer, 'What price flexibility?—The Recent Commission Proposal to Allow for National "Opt-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Post-Lisbon', (2010) 4 *European Journal of Risk Regulation* 345.

[48] See European Parliament legislative resolution of 5 July 2011, 2010/0208 (COD) available at: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2011-314, last accessed 29 September 2014.

[49] See in more detail Weimer, n 20 above.

[50] Position of the European Parliament adopted at second reading on 13 January 2015 with a view to the adoption of Dir (EU) 2015/. . . of the European Parliament and of the Council amending Dir 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.

[51] Art 26b (1).

[52] Art 26b (2).

[53] Art 26b (3).

[54] Art 26b (3).

[55] Art 26b (4).

Mainly, two legal issues make this amendment particularly controversial, and are in turn intertwined with its political promise, namely to end the GMO regulatory deadlock. The first issue concerns the grounds and substantive conditions for the invocation of national 'post-authorisation opt-outs', whereas the second issue concerns the legal basis for the legislative amendment.

A Legal Issues

a) The Grounds for 'Opting-Out'

According to the amendment, Member States have to base their opt-outs on compelling grounds, which do not conflict with the scientific risk assessment conducted by EFSA. The new Article 26b (3) states that Member States may adopt opt-out measures:

> . . . provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on compelling grounds such as those related to: (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.

At the same time, the amendment emphasises that the assessment of potential risks on human and animal health and on the environment of the deliberate release of GMOs is fully harmonised. Therefore, the Member States should only use grounds related to environmental policy objectives, which do not conflict with the EU assessment of risks.[56]

The insulation of EFSA risk assessment from the proposed changes, however, is controversial. Critics of the current EU authorisation process are concerned that the reform would be used to divert attention from the problems of environmental risk assessment by EFSA. After all, opposition to GMOs is not only based on socio-economic interests and conflicts, but also on conflicting views on how to deal with the scientific uncertainty surrounding the long-term impact of GMOs on public health and the environment (see above). Demands for greater national flexibility in handling GMOs therefore also extend to aspects related to risk assessment especially given the currently narrow interpretation of existing safeguard and opt-out clauses by the EU Courts and the Commission.[57]

Moreover, it is doubtful as to whether a clear-cut legal differentiation between 'environmental policy objectives' invoked by the Member States under the new Article 26 b and environmental protection as covered by the EU-wide authorisation process (and therein EFSA's risk assessment) will be feasible in practice. In other words, given the contestation surrounding EFSA's risk assessments, will it really be possible to grant Member States more flexibility to decide on GMO cultivation 'without affecting the risk assessment provided in the system of Union authorisations of GMOs'?[58] It seems realistic to expect that some Member States generally opposed to GMO cultivation will be tempted to invoke the new opt-out legal basis on the ground, for example, of potential long-term environmental risks or other safety concerns, thereby trying to undermine EFSA's assessments. The legal wording of the amendment is indeterminate enough to allow for this possibility. Following recital (14):

[56] See recitals (6) and (14) of the amendment as adopted by the European Parliament.

[57] Namely, under Reg 1829/2003 and Dir 2001/18, as well as the opt-out clause in Art 114 (4) and (5) TFEU. See for a discussion Lee, n 31 above.

[58] See recital (14) and Art 26 b (3) of the amendment as adopted by the European Parliament.

> a Member State should only use grounds with respect to environmental policy objectives relating to impacts which are *distinct from and complementary* to the assessment of risks to health and the environment which are assessed in the context of the authorisation procedures (. . .), such as 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. (emphasis added).

Despite of the (non-exclusive) list of possible examples of environmental policy objectives, the formulation 'distinct from and complementary' seems ambiguous, making the practical distinction between issues of environmental protection covered by EFSA and other 'complementary' issues of environmental policy a blurry one. It arguably opens up room for different interpretations.

The adopted formulation reflects the political struggle between the European Parliament on the one hand and the Council and Commission on the other. While the latter were originally in favour of excluding environmental policy objectives or at least choosing a more restrictive language,[59] the Parliament insisted on a broader formulation[60] as well as on the term 'complementary to the assessment of risks (by EFSA)'. According to the Parliament, the risk assessment conducted at EU level cannot be exhaustive. Through the Parliament position shines a particular understanding of opt-out measures as also giving expression to the precautionary principle.[61] Both the Commission and the Council, however, have rejected this understanding. In their view, it would threaten the uniformity of the scientific assessment throughout the Union, and interfere with the competences that are granted to the risk assessors and risk managers under the current legal framework. It is clear that this position is motivated by the concern over the unity of the internal market given that the main objective of the new EU approach is to facilitate the smooth functioning of the internal market. Granting Member States the right to opt-out shall ultimately facilitate the decision-making process on GMOs at EU level.[62]

This shows that the adopted amendment is characterised by a tension between the unity of EU risk assessment and national flexibility based on other (but inter-related) grounds. This tension constitutes yet another manifestation of a dominant, but problematic linear model of risk regulation. According to this model, risk regulation is a process that can be neatly divided into a technical risk assessment and a political risk management. By insisting that the EU scientific risk assessment can be separated from the more messy sphere of GMO politics at national level, which represent values, socio-economic concerns and broader environmental policy, the amendment seems to suggest that the role of the Commission in GMO authorisations is one of a neutral

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[59] The Council suggested the formulation 'environmental policy objectives distinct from the elements assessed according to Dir 2001/18 and Reg 1829/2003.'

[60] In the first reading, the Parliament suggested to include 'grounds relating to environmental impacts which might arise from the deliberate release or the placing on the market of GMOs, and which are complementary to the environmental impacts examined during the assessment of the negative impacts on the environment' under the Directive; and grounds relating to the 'absence or lack of data on the potential negative impacts of the release of GMOs on the territory or biodiversity of the Member State.' See EP resolution, n 48 above.

[61] The Commission, however, has a different understanding of the precautionary principle in that it does not accept that the principle can justify a 'zero-risk' approach to the marketing of GMOs, see M. Weimer, n 13 above.

[62] See recital (8) of the amendment as adopted by the European Parliament.

apolitical regulator guided by facts. As expressed by Heyvaert, the separation between risk assessment and risk management:

> . . . performs a vital function in amplifying the effect of the necessity of regulatory outcomes, and allowing the Commission as decision-maker to project the image of dispassionate, neutral arbiter of a exogenously generated information rather than an unconstrained regulatory force.[63]

Such an understanding, however, omits that fact that the practice of risk regulation is an iterative process constantly involving scientific, socio-political, and other inputs.[64] Moreover, the amendment raises the question of how we should understand the role of the Commission as risk manager during the EU authorisation process particularly in view of Article 7 of Regulation 1829/2003. According to the latter, next to EFSA opinion, the Commission shall also take into account other legitimate factors. And yet, the agreed reform confirms the view that the Commission has never felt at ease with the political discretion granted to it in this provision. The Commission sees itself as an evidence-based administrative body relying exclusively on EFSA's advice. The amendment seems to release the Commission from the burden of exercising political discretion during the process of authorisation by shifting it to the national level.

Further issues with regard to the 'post-authorisation' opt-outs are legal certainty and the substantive conditions that the Member States will have to fulfil to justify their measures against judicial challenge.[65] According to the new Article 26b (3), the national measures have to be 'in conformity with Union law, reasoned, proportional and non-discriminatory'. In the assessment of the legality of future national 'opt-outs' by EU courts especially the proportionality of as well as the level of proof required to sustain the reasoning behind national measures will be decisive. Given the considerable impact on the freedom of movement of goods and on other individual rights of the companies and farmers supporting GMO cultivation, EU courts are likely to scrutinise proportionality and reason giving closely.

b) The Choice of the Legal Basis

Next to the issues discussed above, the choice of the appropriate legal basis for the legislative amendment of Directive 2001/18 has also been controversial. The amendment is based on Article 114 of Treaty on the Functioning of the European Union (TFEU), which reflects the position of both the Commission and the Council. Both institutions see Article 114 as the appropriate legal basis, because, first, Directive 2001/18 itself is based on Article 114, and second, the main purpose of the amendment is to ensure the smooth functioning of the internal market. 'To the extent that other considerations are involved, such as those relating to the environment, these are secondary in relation to the main purpose'.[66] The Parliament initially insisted on Article 192 (1) of TFEU (the legal basis for measures of environmental policy), but dropped this demand in the final amendment.[67]

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[63] V. Heyvaert, 'Governing Climate Change: Towards a New Paradigm for Risk Regulation', (2011) 74 *Modern Law Review* 817, at 826.

[64] See E. Fisher, 'Framing Risk Regulation: A Critical Reflection', (2013) 2 *European Journal of Risk Regulation* 125.

[65] At EU level. However, legal challenge at the WTO would also be possible.

[66] See Statement of the Council's reasons, Interinstitutional File 2010/0208 (COD), at 3.

[67] Likely in exchange for a wider formulation with regard to 'environmental policy objectives' as grounds for opt-outs, see above.

However, the choice of Article 114 of TFEU for the GMO amendment also raises a novel EU legal issue. As mentioned above, the amendment could be seen as a precedent for rolling back harmonisation in an area of shared competences, in which the EU previously exercised its competence, namely by harmonising rules on GMO authorisation. An indication thereof is the reference in the amendment (recital 6) to the new Lisbon Article 2 (2), third sentence TFEU, according to which Member States 'shall again exercise their competence to the extent that the Union has decided to cease exercising its competence'. The Council legal service, as well as some commentators have raised doubts as to whether Article 114 of TFEU in combination with Article 2 (2) third sentence could be used as the legal basis for this amendment. After all, it seems odd that a measure granting the Member States the freedom to ban or restrict the free circulation of GMOs is based on a provision aiming at the improved functioning of the internal market. This reform, however, should be seen as an atypical measure, which, in the view of the EU legislature, is necessary to restore the internal market for GMOs given the year-long stalemate in this policy field (see above). Accordingly, the amendment emphasises that by granting more national flexibility, it ultimately aims at facilitating the smooth functioning of the internal market.[68]

In addition, some commentators have argued that Article 2 (2) of TFEU could only be used if the EU completely ceases exercising its powers in an area of shared competence, with the consequence that the Member States regain their sovereignty in this area. In the GMO case, however, the EU risk assessment remains fully harmonised.[69] It should be noted that Article 2 (2) does not specify the conditions for the EU to cease exercising its competences, which speaks in favour of certain legislative discretion also with regard to the choice of the legal basis.[70] Moreover, the wording of the third sentence of Article 2 (2) speaks against an interpretation, which would require a complete seizure of EU exercise of competence, because the Member States regain their competence 'to the extent' that the Union ceases to exercise its competence. Thus, a partial de-harmonisation seems, in principle, possible under this provision.[71]

Nevertheless, the amendment should arguably not be considered as a proper example of a (first time) invocation of Article 2 (2) of TFEU (and therefore as partial de-harmonisation). The reason for that is that the legal framework laying down both the possibility and conditions of national opt-outs is being determined at EU level. Member States do not regain their competence to set their own rules regarding GMO cultivation. They merely require a new EU legal basis to deviate similar to other

[68] E.g. in recital (8). Whether such economic framing of the issues at stake with national flexibility is an adequate one is a separate question that merits further analysis.

[69] S. Poli, 'The Member States' Long and Winding Road to Partial Regulatory Autonomy in Cultivating Genetically Modified Crops in the EU', (2013) 2 *European Journal of Risk Regulation* 143, at 144.

[70] One could also argue that the competence to harmonise on the basis of Art 114 also includes the competence to adapt already adopted measures to changing circumstances, either by increasing or by lowering the degree of harmonisation already achieved. In Case C-58/08 *Vodafone and Ohters* [2010] I-04999, para 34 the Court stated that, 'Where an act based on Article 95 EC has already removed any obstacle to trade in the area that it harmonises, the Community legislature cannot be denied the possibility of adapting that act to any change in circumstances or development of knowledge having regard to its task of safeguarding the general interests recognised by the Treaty'.

[71] This corresponds to the understanding that the scope of the exercise of the EU competence only covers those elements governed by the Union act in question, and does not cover the whole area, see Protocol No 25 on the exercise of shared competence.

compatible legal bases known in EU law (e.g. the so-called 'safeguard clauses' or Article 115 (4) and (5) of TFEU). When doing so, Member States still have to comply with EU rules as defined in this amendment. What is arguably new in this amendment is the far-reaching nature of the opt-outs, namely being granted for other reasons than environmental and public health safety.

B The Reform's Potential to End the GMO Regulatory Deadlock

The question that this article set out to address is to what extent this new reform is able to reduce the dysfunctions of the current system of GMO authorisation. In other words, will this amendment help escape the vicious cycle of scientification and politicisation as described in this article, thereby improving the system's potential for deliberation about both the risks and benefits of agricultural biotechnology? The answer to this question is not straightforward.

On the one hand, it could be argued that this latest reform is the first genuine attempt to accommodate the diversity of national preferences toward GMOs in the Union. The amendment recognises what many critical commentators have been arguing for a long time, namely that GMO cultivation requires a more flexible approach because it 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'.[72] The reform is certainly a compromise that ultimately aims to remedy the impasse in comitology, thereby safeguarding the EU authorisation procedure, including the central position of EFSA within it. Yet, the far-reaching nature of the new legal basis for opt-outs is a precedent in the history of EU legal integration. It can be seen as a recognition of the contestation surrounding the Commission's political authority to decide on GMO cultivation for the Union as a whole. The reform seems to acknowledge that an EU authorisation regime, if enforced against the will of the majority of the Member States, is not sustainable in the long term.

Coming back to the theoretical framework of both CLC and experimentalist governance, the reform could also be seen as fulfilling an important normative requirement raised by both theories. Regulatory outcomes of transnational governance must remain revisable by, for example, providing for the possibility of national opt-outs for those Member States whose legitimate regulatory concerns demand a deviation from the common European solution. It seems therefore adequate to complement the 'trivial insight'[73] of deliberative supranationalism, namely, that 'crises which can no longer be managed at the national level require transnational responses' with a similarly trivial insight that where transnational responses fail to produce legitimate solutions for the whole of the Union, a differentiated approach allowing for national derogations should be adopted.

The currently attempted reform is the result of a long and painful process of institutional failure and learning in this field. It embraces an idea that is fundamental to the overall EU legal framework on GMOs, but which so far could not be realised in the authorisation practice (see above), namely of de-centralised multilevel governance. Rather than being a perfect solution to the complex problems of GMO authorisation, the reform should be seen as an important intermediate step, which will allow

[72] Recital (6) of the amendment as adopted by the European Parliament.
[73] According to Joerges, n 6 above.

Member States to experiment with different solutions to GMO cultivation, and will hopefully enable further deliberation about the future EU approach to GMOs.

Finally, allowing Member States to decide on national opt-outs will assign more responsibility to the national governments and their societies, which in turn might foster democratic deliberation about the pros and cons of agricultural biotechnology at the national level. A statement in the Commission's explanatory memorandum for the reform proposal is insightful in this regard:

> Given the more national or regional approach towards GMO cultivation, it is also expected that the level of public involvement in the national and regional decision-making will increase and Member States will allocate more resources and time to involve their public with regard to their decisions.[74]

In other words, shifting political responsibility for GMO cultivation back to the national level could bring about more political and democratic accountability for GMO decisions in the EU as national governments would no longer be able to shift the blame for unpopular authorisations onto the Commission and EFSA.

On the other hand, the legal and political difficulties surrounding this reform, as well as the underlying tension between uniformity and flexibility, make it at best a partial solution to the problems previously identified in this article. Most notably, the reform does not address the problem of the scientification of risk management in the EU authorisation procedure, and might even exacerbate it further. The reason for that is the underlying flawed understanding of risk regulation as a linear model able to separate scientific assessment from the messy sphere of national GMO politics. The amendment puts too much emphasis on the uniformity of the EU risk assessment, the need to facilitate the EU authorisation process, as well as to protect the prerogatives of both the Commission and EFSA. It seems likely that the trade-off for national opt-outs for GMO cultivation will be the strengthening of the top-down approach to authorisation as criticised in this article. In other words, the problem of over-reliance on EFSA as the main scientific authority on GMOs (rather than a networked cooperative agency) as well as the Commission's dependency on epistemic legitimacy as the sole basis for risk management are likely to remain unresolved. In this way, both contestation and politicisation of EU risk evaluation of GMOs are likely to continue after this reform.

V The Promise of Deliberation in European Administrative Risk Governance

What does the present analysis of the 'GMO conundrum' teach us about deliberative theories of EU law and governance? It is sometimes suggested that EU regulation of GMOs is a unique, exceptional case, which makes generalisation difficult. The extent to which the GMO case is unique stands, in fact, in direct negative proportion to the extent to which the insights gained from the GMO case can be generalised. In other words, the more uniqueness we see, the less generalisation is possible.

There is, arguably, something exceptional about the regulatory conundrum in the field of the EU regulation of GMOs. This exceptionality, however, is not intrinsic to the subject of agricultural biotechnology as such. Instead, the exceptional nature of the EU regulation in this field refers to the high degree of institutional path dependence, as well as to how deeply entrenched and irreconcilable positions toward GMOs in the EU have become overtime. Yet, agricultural biotechnology, as a policy field,

[74] See Commission proposal, n 46 above, at 6.

shares several features with other areas of risk and technology regulation. Such features include, for example, the unavailability of conclusive scientific evidence of absence of harm, scientific uncertainty, the potential for long-term impact on the environment and public health, high media visibility, strong economic incentives and market pressure, and the relevance of consumer risk perceptions and other non-risk-related ethical and socio-economic concerns. In the risk governance literature, GMO risks have been characterised as the so-called uncertain risks.[75] Regulating such risks is especially challenging, but it is not exceptional. Other examples of policy fields that are highly controversial or have the potential to become cases of regulatory controversy can easily be found, such as animal cloning, nanotechnology or chemicals.[76] In other words, the problems of regulating GMOs in Europe are problems inherent to risk regulation, as well as to the broader task of integrating technological innovations into society in a democratic and socially sustainable way. If this is true, then the experience of regulating GMOs in the EU is an extremely important source for learning about risk governance, in general, and the potential of deliberation to contribute to its legitimacy, in particular.

Having said that, the GMO case challenges the sociological basis of both CLC and its predecessor theory of deliberative supranationalism, namely, that the EU comes closest to the ideal of transnational deliberation in networks as the basis for legitimate transnational governance.[77] Although the EU legal structures of GMO regulation embody the idea of proceduralised cooperation and the balancing of different risk and non-risk concerns, rule implementation has, in practice, failed to manage the political dimension of GMO authorisation. In both deliberative *fora* of the authorisation procedure, EFSA and comitology, de-centralised multilevel governance reverted to *de facto* assertion of authority and top-down regulation, overriding national concerns. Ultimately, the failure of cooperation and deliberation within these *fora* strengthened the Commission's reliance on scientific experts within the regime. As a result, in practice, although not foreseen as such, EU authorisation of GMOs reverts to a purely technocratic process.

It may well be that learning is easier to achieve in theory than in practice. In response to the GMO and other case studies of EU governance, especially in the field of Europe's economic crisis management, Joerges and Weimer has recently suggested the need to re-conceive CLC as a critical, rather than a re-constructive, theory.[78] Moreover, the recent efforts to reform the EU legal framework for GMO cultivation seems to respond to the normative demand of CLC to keep regulatory outcomes of transnational governance open and revisable (see above).

Moreover, the GMO case also challenges related accounts of GMO regulation as an experimentalist governance regime. Also here, although the regulatory design can be characterised as building in elements of experimentalism, namely, through its procedural structure of the cooperation and bottom-up input of the various actors, the account of implementation failure in this article suggests a less optimistic view of

[75] Van O. Renn and M. van Asselt, 'Risk Governance', (2011) 14 *Journal of Risk Research* 431; Vos and Everson (eds), n 14 above.

[76] See M. van Asselt, E. Vos and E. Versluis (eds), *Balancing between Trade and Risk* (Routledge Taylor & Francis, 2013).

[77] See Joerges, n 6 above.

[78] See C. Joerges and M. Weimer, 'A Crisis of Executive Managerialism in the European Union—No Alternative?', in G. de Búrca, C. Kilpatrick and J. Scott (eds), *Critical Legal Perspectives on Global Governance: Liber Amicorum for David M Trubek* (Hart Publishing, 2013).

the governance practice in this field, at least with regard to the EU authorisation process. As explained above, the input of lower level actors from the national level is *de facto* precluded in both EFSA and the comitology procedure. This stands in the way of mutual learning. The latter pre-supposes an open mindset of all the actors, in the sense of their willingness to revise both their knowledge about, and their attitudes toward, GMOs in the light of the contributions and experience made by other actors. This, however, is difficult to perceive in the current institutional deadlock, in which positions are both entrenched and politicised.

The opt-out reform, however, demonstrates that institutional learning on a larger scale is occurring. As explained above, although the reform is at best a partial solution to the problems of GMO authorisation described in this article, it nevertheless allows for national experimentation with different solutions to GMO cultivation and will hopefully help in improving democratic deliberation about the risks and benefits of agricultural biotechnology at the national level.

VI Conclusions

The findings of this article indicate that a response to the failure of deliberation and cooperation at EU level cannot be a return to top-down regulation with 'behind closed doors' technocratic deliberation.[79] It also contradicts the assumption that deliberation is fostered by technocratic 'behind closed doors' decision-making. In the GMO case, the top-down imposition of epistemic authority has only served to increase the politicisation. Arguably, in cases of high political contestation and disagreement, especially in multilevel systems, deliberation remains the only way forward, because it manages to keep decisions open, where no legitimate final authority is available. The EU's authority as a legal and political system is based upon an ongoing contestation and resettlement of legal and political authority,[80] of which the current GMO reform serves as a vivid example. As one experimentalist scholar has aptly noted, such cases call for the 'no-final-decider principle'[81] according to which the EU might well not be the appropriate locus of authority to decide on GMO cultivation at present, although dialogue must nonetheless go on.

What this article has shown, however, is that blaming politicisation for the failure of deliberation in GMO regulation does not take the full regulatory complexity of this field into account, nor, in particular, the problematical effects of scientification, *i.e.*, the over-reliance on regulatory science and epistemic legitimacy as the basis for GMO authorisations. The two trends of politicisation and scientification are not only conflicting, they are actually, to some extent, mutually accelerative. On the one hand, instances of uncertainty intolerance on the part of EFSA and the Commission serve to contribute to the distrust and the ever more fierce responses of the anti-GM movement, and therefore to the resistance of several of the Member States. On the other hand, this, in turn, infuriates the GMO proponents, which call for science-based decisions. The conclusions of the EPEC external evaluation report of the GMO framework are insightful in this regard:

[79] Nor is the 'stark normative trade-off between transparency and openness, on the one hand, and deliberative decision-making on the other', as suggested by Pollack and Shaffer, n 4 above, unavoidable.
[80] See Joerges and Weimer, n 78 above.
[81] C. Sabel in the Workshop on 'Experimentalism in Transnational Governance' at the University of Amsterdam, 1–2 November 2013, the Netherlands.

> Despite the best efforts of many hard-working individuals and the/0 ongoing efforts to improve it, the system is not working as envisaged and is not, in aggregate, meeting its objectives. As the analysis in this report and earlier outputs from this evaluation have suggested, the "dysfunction" arises as a consequence of a complex set of factors, both external and internal to the authorisation process.[82]

The report further notes that the frustrations with the legislative framework among the consulted parties concentrate on the risk management phase. However, it goes on to state that 'many of the causal factors behind the blockages in decision-making lie "upstream" in the risk assessment process'.[83] This shows that the currently ongoing opt-out reform of GMO cultivation is at best a partial solution to the problems of GMO authorisation in the EU. As shown in this article, on the one hand, it represents a genuine and long-awaited attempt to accommodate the diversity of national preferences toward GMOs in the Union. On the other hand, it does not address the problems of EU risk assessment, nor the scientification of risk management in the EU authorisation procedure. Therefore, the trade-off for national opt-outs for GMO cultivation is likely the strengthening of the top-down approach to authorisation as criticised in this article.

This, however, would be deeply problematic given the complex intertwinement or co-production between the scientification of risk management and the politicisation of comitology as analysed in this article. Such co-production is a major challenge to the EU regulation of GMOs, and, potentially, to other controversial cases of EU risk regulation. The unfortunate results of it are entrenched positions, polarisation and a breakdown of dialogue. Importantly, the analysis confirms the insight that calling upon scientific experts to resolve political conflicts can ultimately backfire. Over-reliance on expert advice leads to the politicisation of science and to the consequent de-legitimation of political institutions. As noted by Stuart Shapiro and David Guston in the context of the US public administration:

> Just as judicial oversight of regulatory affairs has encouraged the politicization of the courts, regulatory peer review [by scientific experts] will likely result in the increased politicization of science. Rather than providing more certainty and leading to closure, the addition of more knowledge can lead to more conflict. Regulatory peer review [by scientific experts] may thus perversely contribute to the de-legitimation of political institutions by politicizing the science that such institutions are supposed to rely on for conflict resolution.

In the case of EU GMO regulation, we are facing the problem of the de-legitimation of the EU public administration. Over-reliance on EFSA to produce authoritative scientific advice, the Commission's dependency on epistemic legitimacy as the sole basis for risk management, together with the failure of the comitology system to exercise political responsibility, increasingly contributes to the sense that the EU institutions involved have disqualified themselves as legitimate decision-makers in this field. To address this problem, a reform should go beyond the current efforts, which, if not followed up by more far-reaching structural change at EU level, might exacerbate the scientification of the EU authorisation process. A successful reform, however, must be able to mitigate the negative effects of both processes, namely, of politicisation and of scientification.

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[82] EPEC Report, n 32 above, at 73.

[83] *Ibid*., at 76; see, also, at 14–32: 'the effective functioning of the institutional decision-making phase of the legislative process critically depends on confidence in the risk assessment.'

