*Patrycja Dąbrowska-Kłosińska**

Towards More Experimentalism in EU Governance of GMO Risks? Experience, Reforms and Remaining Problems

1. Introduction

The controversies surrounding the use and cultivation of genetically modified organisms (GMOs) in the European Union concern the uncertainty of their safety, possible risks to human health and the environment, and the potential lack of benefits to societies. Thus, it is already a truism that GMO risk regulation in the EU poses great challenges to legislators and policy-makers. Some of the problems arise from substantive disputes over the employment of potentially dangerous novel technologies of genetic engineering to the production of plants, foods, or medicines more generally, while others are of a procedural nature and concern the specificity of the EU and its constitutional structure. The regime has repeatedly instigated regulatory dilemmas for the EU and national authorities, in particular with regard to the introduction of new products on the market for cultivation purposes. It has remained one of the much-contested policy sectors since the launch of European regulation of biotechnology in the early 1990s.[1] In 2013, a decade after the last big reform and the

* **Patrycja Dąbrowska-Kłosińska**, Ph.D. – Assistant Professor, Centre for Europe, University of Warsaw. The text was prepared during the Author's Jean Monnet Fellowship 2012–2013 at the Robert Schuman Centre for Advanced Studies, Global Governance Programme, European University Institute in Florence. An earlier version of the paper was presented at the Annual Meeting of the American Political Science Association 2013, Chicago, 29.08.–01.09.2013.

introduction of the new regulatory system of 2001–2003, the EU GMO regime found itself once again in the process of transformation in response to implementation problems.[2]

The GMO regime in the EU also prompts contrasting theoretical interpretations and appraisals with respect to its current functioning and future prospects.[3] In other words, there have been divergent understandings of both the principal features of GMO governance in the EU, and what constitutes desirable changes to improve its effective (and therefore more democratic[4]) policy outcomes.[5] This pluralism of visions on GMO regulation and risks is also visible at the transnational level, where this field provides a prominent example of international law fragmentation, regime complexity and differing approaches to the precautionary principle.[6]

The interpretations of various scholars differ, especially on the issue of whether the EU Member States' inability to reach consensus on the scientific opinions and market authorisations of GMOs is producing disruptive effects in the EU's supranational, co-operative governance aimed at linking the potential benefits of modern biotechnology with food and environmental safety, or whether on the contrary the divergent positions of Member States are producing positive interactions between institutions, combining elements of learning and convergence with deliberative problem-solving.

---

[1] See: M. Lee, *EU Regulation of GMOs: Law and Decision-Making for a New Technology*, Cheltenham 2008; *What's the beef?: the contested governance of European food safety*, eds. C. Ansell, D. Vogel, Cambridge, Mass. 2006; *Biotechnology: the making of a global controversy*, eds. G. Gaskell, M.W. Bauer, Cambridge 2002.

[2] S. Poli, *The Member States' Long and Winding Road to Partial Regulatory Autonomy in Cultivating Genetically Modified Crops in the EU*, "European Journal of Risk Regulation" 2013, Vol. 2, pp. 143–157.

[3] P. Dąbrowska-Kłosińska, *EU Governance of GMOs: political struggles and experimentalist solutions?*, in: *EU Governance: Towards a New Architecture?*, eds. C. Sabel, J. Zeitlin, Oxford 2010, p. 182.

[4] S.S. Andersen, K.A. Eliassen, *The European Union: How Democratic Is It?*, London; Thousand Oaks, CA 1996, p. 9.

[5] See e.g. the various perceptions presented in: S. Poli, *Continuity and change in the EU regulatory framework on GMOs after the WTO dispute on "biotech products"*, "Legal Issues of Economic Integration" 2010, Vol. 37(2), pp. 133–148; M. Weimer, *Democratic legitimacy through European Conflicts-Law The Case of EU Administrative Governance of GMOs*, European University Institute doctoral thesis, Florence 2012; M. Kritikos, *Traditional risk analysis and releases of GMOs into the European Union: Space for non-scientific factors?*, "European Law Review" 2009, Vol. 34(3), pp. 405–432.

[6] N. Krisch, *Beyond constitutionalism: the pluralist structure of post-national law*, Oxford 2010, pp. 189–220; cf. also D. Vogel, *The Politics of Precaution Regulating Health, Safety, and Environmental Risks in Europe and the United States*, Princeton, NJ 2012.

In my previous work, I have argued that EU governance of GMOs, when analysed comprehensively as a policy-sector, has transformed into a regime embodying numerous experimentalist solutions typical of the new EU emerging architecture.[7] My earlier research in the field demonstrated that these experimentalist features are combined with regulatory measures that can be classified as a more traditional approach.[8] Firstly, while the GMO regulatory framework is based on EU regulations and directives, there has also been an expansion of soft measures and horizontal collaboration (e.g. OMC-type measures and guidelines, private and international standards, networked Internet tools (e.g. EFSAnet), and informal meetings between authorities. Regulation by information and networking are exemplary in ensuring post-market transparency of the GMO regime, which enables market regulation by consumers and private actors through traceability and labelling obligations, as well as effective crisis management and auditing through co-operative Internet-based networks (e.g. the RASFF system) and the operation of the Food and Veterinary Office. Secondly, the legal regime is characterised by several means of institutional and competence decentralisation, containing provisions that envisage co-operation through the networked administration of comitology committees, national authorities/bodies and EU agencies (EFSA). This is aimed at fostering horizontal collaboration and the networking of authorities on risk assessment and regulation within the GMO regime. Thirdly, the regulation of GMOs aims to expand, both in terms of rule making and rule application, the participation of civil society in policy-making, flexibility in implementation, and mechanisms aimed at fostering horizontal cooperation and learning from experience. In addition, there are measures which ensure policy revisability and the mutual accountability of the actors involved in the policy framework (e.g. through monitoring, reporting and peer-review). This paper builds on my earlier argumentation and expands my research to embrace the newest developments.

The experience of the first decade of the new GMO regime in the EU reveals that its experimentalist solutions have been effective, in the sense that the EU has successfully managed to modernise its outdated regulatory regime of the 1990s, control GMO risks, and avoid the mate-

[7] As characterised by C. Sabel, J. Zeitlin, *Learning from Difference: The New Architecture of Experimentalist Governance in the EU*, "European Law Journal" 2008, Vol. 14(3), pp. 271–327; see also: C. Sabel, J. Zeitlin, *Experimentalist Governance*, in: *The Oxford Handbook of Governance*, ed. D. Levi-Faur, Oxford 2012, pp. 169–183.

[8] P. Dąbrowska-Kłosińska, op.cit.

rialisation of any serious GMO hazard, which is the overall aim of the system.[9] The institutional structures, responsible actors and established regulatory solutions have operated efficiently to realise the GMO safety policy on the internal market, and it has been under constant evaluation, review and development.[10] Especially, in the cases of post-market control of risks and releases of unauthorised GM products, the EU's responses appear to have been prompt, effective and reflective of experimentalist features, including in the area of international co-operation.[11] At the same time, several aspects of the implementation of GMO governance in the EU provide a challenge to its positive assessment. The main problems concern the functioning of the authorisation procedures, which suffer from political, socio-economic and scientific disagreements on GMO approvals, in particular with regard to their cultivation, national opposition to the authoritative decisions taken by the Commission, and the inability of the EU and national authorities to engage fully in deliberative practices (which could be reflected in the voting configurations on individual products, indicating a consensus). This inevitably affects the democratic legitimacy of the regime, when assessed against the ideals of deliberative democracy.[12]

As a result, and in order to respond to the problems, the Commission tabled a proposal to re-nationalise GMO cultivation in 2010.[13] In parallel, the EU-wide reform of its comitology procedures, which was

[9] See e.g. Commission Decision 2010/315/EU of 8 June 2010 repealing Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products, and providing for random testing for the absence of that organism in rice products, OJ 2010 L 141/10.

[10] See e.g. Commission Regulation laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired, OJ 2011 L 166/9, the so-called Regulation on Low Level Presence (LLP).

[11] P. Dąbrowska-Kłosinska, *EU and Transnational Regulation of GMO Risks*, "GREEN Working Paper Series", Centre for the Study of Globalisation and Regionalisation, University of Warwick, June 2013, No. 36, pp. 1–34.

[12] Cf. P. Dąbrowska-Kłosińska, *The regulation of GMOs in the EU: conflicts, problems and reforms*, in: *Networks. In search of a model for European and global regulation*, ed. L. Ammannati, Torino 2012, pp. 99–126; M. Lee, *Multi-level Governance of Genetically Modifies Organisms in the European Union: Ambiguity and Hierarchy*, in: *The Regulation of Genetically Modified Organisms Comparative Approaches*, eds. L. Bodiguel-M. Cardwell, Oxford 2011; M.A. Pollack, G.C. Shaffer, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*, Oxford 2009.

[13] 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.

implemented in 2011, was aimed at addressing some of those regulatory difficulties.[14]

Bearing in mind the divergences in scholarly viewpoints assessing the experiences with implementation of the EU's GMO regime and the recent reformative developments in the policy-sector, this paper re-engages in the discussion on GMO governance and continues my earlier analyses through the lens of the experimentalist governance architecture.[15] It seeks to establish whether the processes leading to the GMO regulatory reforms, as well as their content, reveal experimentalist features, and whether the proposed modification of the principles of the GMO regulatory framework can be perceived to be a result of the 'recursive revision of objectives and goals in the light of results'[16] typically associated with experimentalist governance? If so, are any further modifications necessary to improve the democratic quality of the regime, which is allegedly suffering from profound political conflicts?

The paper proceeds in the following fashion. The following Section 2 presents the experience with the approvals and marketing of GMOs in the EU over the last decade, analyses the institutional responses to regulatory impasses and the monitoring exercises which revealed the need for revision of regime objectives, and finally offers an interpretation of experimentalist elements of the processes. Section 3 appraises the regulatory qualities of the GMO reforms against the premises of experimentalism, together with consideration of the possible obstacles to their effectiveness. Section 4 contains a summary and offers conclusions.

2. The Experience with GMO Approvals in the EU During the Last Decade

Before advancing to the main focus of this section, the internal EU regulatory regime on GMOs should be briefly explained. All GM products, including GM food and feed and GMOs for cultivation and industrial purposes, are subject to the pre-market approval system, incorporating the precautionary principle (i.e. an authorisation procedure with a case-by-case risk assessment for the marketing and release of GMOs) and post-market control, which includes labelling and traceability obligations. The

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

[15] See: C. Sabel, J. Zeitlin, *Learning from Difference…*, op.cit.

[16] C. Sabel, J. Zeitlin, *Experimentalist Governance…*, op.cit.

core of the EU normative system for GMOs is comprised of the Deliberate Release Directive 2001/18, the GM Food/ Feed Regulation 1829/03, and the Traceability Regulation 1830/03, which are accompanied by numerous implementing acts and soft laws.[17] This system conditions the market access of all products which are the result of a production process based on genetic modification on their general compliance with the level of risk, standards and procedures that are chosen by the EU. This means that the EU follows a process-based approach to GM products, which forms a part of the integrated food safety policy. Once a GM product is approved through the complex EU procedure, based on the Member States' and the Commission's participation in the comitology decision-making process and the obtainment of a scientific opinion from the European Food Safety Authority (EFSA), it can circulate freely on the internal market, unless national authorities invoke means of differentiation, in which case they must be science-based. Thus, as a general rule the EU exhaustively harmonises GMO marketing and commercial releases, which deepens integration and reassures the Member States that the standards applicable to the commercialisation of GMOs and the level of protection will be alike throughout the EU. Member States retain their autonomy through the possibility to introduce, based on socio-economic concerns, national and/ or regional measures to avoid the unintended presence of GMOs in other products (the so-called co-existence of GM and non-GM crops, through e.g. the declaration of GM-free zones), but this must be done within the limits of the Treaty provisions on the internal market.

1.1. The Complexity of and Problems with GMO Authorisations in the EU under the Original Objectives of the 2001–2003 Regime

The reform of the EU regime on GMOs in the years 2001–2003 brought hopes, if not promises, that decision-making on product approvals would become less controversial and politicised. However, when the Commission restarted GMO authorisations with a decision on GM maize NK603,[18] it became clear that this was not the case. Notwithstanding the modification of the old regulatory framework and the successful employment of

[17] T. Christoforou, *The Regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics*, "Common Market Law Review" 2004, Vol. 41, pp. 640–665.

[18] Commission Decision of 19 July 2004 concerning the placing on the market, in accordance with Directive 2001/18/EC of a maize product (NK603) genetically modified for glyphosate tolerance.

experimentalist solutions in many respects,[19] several problems continued to affect the functioning of the authorisation procedures and the GMO regulatory governance as a whole. In a somewhat simplified manner, the key difficulties concerned GMO approvals for marketing and cultivation, their scientific assessment and the resulting democratic legitimacy of the decision-making in the responsible committees (Standing Committee for Food Chain and Animal Health, Directive 2001/18 committee). These problems will be explained below in more detail.

A) Decision-making within comitology committees

During the past decade. since the re-start of approvals in 2004 (after termination of the *de facto* moratorium), there has never been a single vote either in the committee nor in the Council or the newly established appeal committee (after the comitology reform in 2010, described below) where Member States reached a qualified majority of votes either in favour of or against the Commission proposals.[20] Consequently, and in accordance with the strict procedural rules of comitology, final decisions were made by the Commission (which had three months to decide on a product after a vote took place).[21]

The next problem which appears to affect the functioning of approvals is a supposed lack of knowledge by the EU institutions on how to deal with the public participation in the process, the effect of which is that the EFSA scientific experts provide the sole justification for decisions.

B) Lack of adequate recognition of public comments expressed through institutionalised channels

The Commission seems to treat public comments as irrelevant, non-existent and solely the a result of a formal participatory democracy exercise (the public can comment, via an Internet tool, on EFSA opinions on a given product). At the same time, the EFSA opinions are considered as the ultimate source of authority.[22] In relation to the latter, in all cases of GMO approvals the Commission followed the EFSA's positive scientific

[19] P. Dąbrowska-Kłosińska, *EU Governance of GMOs…*, op.cit., pp. 191–198.

[20] Own empirical research based on the summary records of the SCFCAH meetings available at http://ec.europa.eu/food/plant/standing_committees/sc_modif_genet/index_en.htm. Unless indicated otherwise all the cited websites where last visited in May 2014.

[21] The QM was 255 out of 345 votes until the 2013 EU enlargement. Since the accession of Croatia on 1 July 2013, it has been 260 out of 352 votes.

[22] See also: D. Chalmers, *Risk, Anxiety and the European Mediation of the Politics of Life*, "European Law Review" 2005, Vol. 30(5), p. 666.

opinions, even though it could have reasonably departed from scientific grounds through the consideration of 'other legitimate factors'.[23] With respect to the exercise of participatory democracy, in none of the Commission decisions has there been a single reference to either the obligatory public consultation process or the public comments received opposing GMO approvals. Admittedly, the participation of the European public in the institutionalised consultation procedure has been very limited (submission of only a few to up to 20–30 comments per product), but at the same time this seems to be convenient for the institutions. The possible reasons lying behind the rather poor public participation are the lack of institutional interest, the fact that the public voice is not reflected in the final decisions, linguistic problems, and a possible procedural misalignment (people can comment on scientific opinions instead of draft decisions on products).[24]

Finally, the performance of the EFSA and its GMO Panel has often been subject to criticism, which has negatively affected its institutional reputation, the national attitudes towards its opinions, and consequently the functioning of GMO approval procedures.

C) EFSA's performance, scientific opinions and reputation

First, the opinions of the EFSA on GMOs have been criticised as insufficiently addressing national and public concerns on GM products, as well as framing many important safety concerns as non-scientific aspects. On the basis of their empirical research, some scholars maintain that the EFSA has been reluctant to outline uncertainties and define risks, and accordingly to expand its scientific expertise within the framework of its regulatory mandate under the General Food Law.[25] Secondly, the EFSA seems to accept the position of companies as risk assessors and agenda setters in approval procedures, and relatively rarely issues opinions on the inadequacy and insufficiency of scientific data which would stop it from reaching a positive conclusion on a product's safety.[26] Thirdly, the EFSA has long been facing accusations of non-independent behaviour towards

[23] See: Art. 7.1, Regulation 1829/03 on GM food and feed.

[24] Cf. M.P. Ferreti, *Participatory Strategies in the Regulation of GMO Products in the EU*, in: *Civil Society Participation in European and Global Governance: A Cure for the Democratic Deficit?*, eds. J. Steffek, C. Kissling, P. Nanz, Basingstoke; New York 2008, pp. 166–184; P. Dabrowska, *Civil Society Involvement in the EU Regulations on GMOs: From the Design of a Participatory Garden to Growing Trees of European Public Debate?*, "Journal of Civil Society" 2007, Vol. 3(3), pp. 287–304.

[25] M.B.A. van Asselt, E. Vos, *Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox*, "Journal of Risk Research" 2008, Vol. 11(1–2), pp. 281–300.

[26] http://www.efsa.europa.eu/en/press/news/130416.htm.

industry and tolerance of conflicts-of-interest in its top management.[27] The express recognition of the agency's wrongdoing culminated in the beginning of 2012, when the European Parliament refused to grant a discharge to the agency's budget for 2010, following scrutiny of several past years of EFSA practice.[28]

As a result of the above, the impossibility of building a consensus among the Member States, either for or against Commission proposals on GM products, has been linked to many factors. Furthermore the political stalemate, the end result of which left the Commission as the sole decision-maker, raised doubts about the democratic legitimacy of decisions, especially in view of the premises of deliberative democracy.[29] Yet it is also important to realise in this context that the behaviour of the Commission has been linked clearly to the WTO Biotech case against the EU.[30] In other words, the WTO dispute prompted the resumption of GMO authorisations in the EU and offered a legitimising argument for the Commission to strictly apply the procedural steps in GMO approvals (in line with rules of comitology), but it also reinforced a strict scientific discipline in the authorisations. In this sense procedural formalism, positivist legalism and legal efficiency have overtaken claims for more deliberation, a consensual approach, and mitigation of the anti-democratic effects of the decision-making processes.

1.2. Attempts to Enhance EU-National Co-operation in Procedures for Products' Approvals

The experience with authorisation procedures on GMOs provoked Member States to express their dissatisfaction with approvals as early as 2005–2006, mostly at the forum of the Environmental Council.[31] There was a growing awareness in the Commission units working on biotechnology at that time that the lack of qualified majority votes on the GMO

[27] K. Kanska, *Wolves in the clothing of sheep? The case of the European Food Safety Authority*, "European Law Review" 2004, Vol. 29(5), pp. 711–27.

[28] *Three EU agencies fail MEPs' ethics test*, EUobserver, 28.03.2012, *Resignation at EU drugs agency highlights ethics issues*, EUobserver, 05.04.2012, *MEPs divided on whether to punish EU agencies*, EUobserver, 09.05.2012.

[29] M. Navah, *The Politics of Risk Decision-Making: The Voting Behaviour of the EU Member States on GMOs*, in: *Balancing between Trade and Risk Integrating Legal and Social Science Perspectives*, eds. M.B.A., van Asselt, E. Versluis, E. Vos, Abingdon, Oxon; New York 2013.

[30] J. Scott, *European Regulation of GMOs: thinking about "judicial review" in the WTO* in: *Uncertain Risks Regulated*, eds. E. Vos, M. Everson, London 2009, pp. 295–321.

[31] Information note from Mrs M. Kyprianou and S. Dimas, Orientation debate on possible improvements to the authorisation procedure of GMOs, 12.04.2006.

proposals, and the continuation of approvals in the face of national concerns (and sometimes even the opposition of a majority of Member States) would result in a lack of democratic legitimacy of the decisions.[32] The experience with approvals also indicated clearly that there was a need for more co-operation with national authorities to build any consensus on GMO policy-making. Therefore, in January 2004, March 2005 and April 2006, the Commission held three 'orientation debates' on GMOs to seek possible solutions.[33] These debates led to recommendations for a continuation of authorisations, a high intensification of efforts to facilitate national co-operation, and an improvement of consultations through scientific networking in the activities of EFSA.[34]

The internal reflection process of the Commission coincided with its attempts to effectively implement the WTO 2006 ruling (the WTO Panel report of 29 September 2006 decided that the EU de facto moratorium on product approvals, and national bans on GMOs, were unlawful under the SPS Agreement). Apart from the strict proceduralism, this process has also brought about some experimentalist practices.[35] In particular, between 2006-2010 (as compared to 2001–2004) there was a tendency to increase co-operation and reciprocal understanding in decision-making processes, as well as the transparency of the Commission's GMO websites.[36] For example, informal EU-MS co-operation, outside normatively prescribed steps and with the aim of building a wider consensus, took place through the Commission's referral of questions back to the EFSA, and direct meetings between EFSA officials and national authorities in SCFCAH to address national concerns on GMO applications. EFSA also attempted to improve on several issues which included networking and consultation with Member States: it has been slowly evolving from a solely Internet-based networking system to a policy of regular meetings and personal contacts (since 2008).[37]

---

[32] Interview with a Commission official, February 2005.

[33] Cf. M.A. Pollack, G.C. Shaffer, *The EU Regulatory System on GMOs* in: *Uncertain Risks Regulated: National, EU and International Regulatory Models Compared*, eds. E. Vos, M. Everson, London 2009, pp. 285–286.

[34] Communication to the Commission for an orientation debate on genetically modified organisms SEC(2005) 396; Information note from Mrs M. Kyprianou and S. Dimas, op.cit.

[35] P. Dąbrowska-Kłosińska, *EU and Transnational Regulation of GMO Risks*, op.cit.

[36] S. Poli, *The EC's implementation of the WTO ruling in the biotech dispute*, "European Law Review" 2007, No. 32, pp. 725–726.

[37] Summary Report of the SCFCAH meeting, GMO Section, 10.09.2012; Summary Report of the SCFCAH meeting, GMO Section, 24.09.2010, p. 4. The list

At the same time, the attempts to enhance EU-national co-operation and facilitate deliberation in the decision-making processes has surely been negatively affected by the instability of the institutional practice of the EU bodies and the scandals over EFSA independence. These factors gave rise to further frustration and disappointment in the Member States. While the feedback of EFSA scientists participating in bilateral meetings with Member States' representatives has been generally positive,[38] there have also been rumours circulating between national authorities that EFSA experts are 'arrogant' and 'over formally treating scientific criteria in case of cultivation'.[39] National authorities also claim that EFSA has never accepted their scientific arguments, objections and doubts. There have only been several meetings so far, but they have not visibly transformed voting configurations in the political procedures into more 'consensual' ones. With respect to the Commission's behaviour, the example of authorisation for cultivation of the so-called Amflora potato is revealing. The approval of the product was originally proposed in 2007, but it faced firm opposition from many national authorities because of the *nptII* gene used in the product as a selectable marker conferring kanamycin (antibiotic) resistance. The opposition of the Member States was founded on, *inter alia,* the statutory provisions of Directive 2001/18, which declares the phasing out of these types of markers in GM products. After the consultations and exchanges of scientific and political opinions took place, national authorities were expecting to continue co-operation on the issue (in the meantime it seems that the process was 'suspended'). However, in 2010 one of the first decisions of the new Commissioner Dalli was to authorise the product without any further notice to the Member States, many of which received the news with great surprise.[40]

As a result, as more decisions were taken by the Commission authorising GMOs in light of the lack of qualified majority votes, the Member States became ever more dissatisfied and the pertinent national objections to individual authorisations became ever more firm. Interestingly, the fact

of bilateral and multilateral meetings of the EFSA GMO Panel with Member States authorities, at http://www.efsa.europa.eu/en/gmo/gmomsmeetings.htm and EFSA Scientific Network for Risk Assessment of GMOs, at: http://www.efsa.europa.eu/en/gmonetworks/docs/gmonetworkstor.pdf.

[38] http://www.efsa.europa.eu/en/gmo/gmomsmeetings.htm.

[39] Polish official citing Austrian and French opinions, interview, May 2010.

[40] Interview with a Polish official, May 2010. See also: judgment of 13 December 2013 in case T-240/10 *Hungary v. Commission* where the Court invalidated the authorisation decision in question, nyr.

that the Commission was proceeding with approvals and imposing its hierarchical power in light of the lack of a Member State consensus seemed to intensify the solidity and firmness of national positions rather than foster more deliberation in the shadow of hierarchy.[41]

There is also arguably another – political – explanation of the current institutional practice.[42] That is, the Commission authorises GM products if the EFSA gives a positive opinion because it is convinced that this is a pragmatic approach *vis-à-vis* the WTO and the Member States. The Commission is also generally aware of the fact that it can more or less decisively proceed with authorisations for import and processing, because what is really unacceptable to the EU public are approvals for cultivation. On their part, Member States appear to be relatively happy with the Commission 'officially' approving products in view of their divided positions, because otherwise they would have to explain their voting behaviour to their national constituents. So possibly there has been some tacit acceptance by the Member States of the 'formal non-consensus' on approvals as long as the regime is not reformed, since it allows them to shift the official responsibility for decisions to the Commission. Otherwise national authorities would probably more actively protest against the Commission's behaviour, and in addition probably use the Court as a remedy. As one official puts it: 'The Commission became a bad guy and Member States can say in front of their public that they have not approved the products'.[43] It seems that at the same time, and especially around 2008-2010, the Member States' inability to come to any consensus on the GMO proposals reached a certain level of stagnation, reflected by an unwillingness to engage in any process of re-shaping voting positions in view of the unstable practices of the EU institutions involved. This also reflects the argument that the interpretation of the process of GMO authorisations in the EU is much more complex than simply being a battle-field of state-interests wishing to exercise their powers over GMO approvals. In this light it would seem that the presentation of the GMO approval regime as a significant conflict over the exercise of powers to approve or reject GMOs may be overstated and/or oversimplified.

[41] Interview with a Polish official, May 2010. Cf. also T. Boerzel, *Experimentalist governance in the EU: The emperor's new clothes?*, "Regulation and Governance" 2012, Vol. 6(3), pp. 378–384.

[42] Interview with a Commission official, July 2013.

[43] Ibidem.

1.3. Monitoring of Implementation, Revision of Strategies and Peer-review Exercises

Following up on the early attempts to unblock the political deadlock, both the EU institutions and Member States continued the search for new solutions for GMO policy. In particular, several reflexive exercises were undertaken at various levels of governance, with a view towards assessing existing solutions and the need for further reforms. They were realised in parallel to the regular monitoring and reporting activities prescribed in the statutory provisions.[44] These processes were evolving when it became clear that the regulatory impasse on GMO approvals had already led to a regulatory crisis.[45]

In 2008, both the President of the Commission, Manuel Barosso, and the French Council Presidency independently proposed initiatives to find solutions in view of the national and public reservations to the GMO regime.[46] The French Presidency established the Ad hoc Council Working Party on GMOs in the second half of 2008, which resulted in unanimous Council conclusions on 4 December 2008[47] (national authorities claim that the Commission tried to impede this process).[48] The document called for, *inter alia,* a strengthening of environmental risk assessment, more freedom for Member States to decide upon GMO-free zones on their national territory, and appraisal of the socio-economic benefits and risks of GMOs. Especially the latter two elements were a clear indication of a change of approach in the GMO regime and the modification of the original objec-

[44] See e.g. Commission mid-term review of the Strategy on Life Sciences and Biotechnology COM (2007) 175 final; and Commission Staff Working Document – Document accompanying the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the mid-term review of the Strategy on Life Sciences and Biotechnology SEC/2007/0441 final.

[45] See: Summary Record of the SCFCAH meeting, GMO Section, 16.06.2008 describing the Commission orientation debate on GMOs which took place on 07.05.2008, Minutes of the 2874th meeting of the Environment Council, 05.06.2008, doc. ref. 10385/08, pp. 6–7, written question by MEP Friedrich-Wilhelm Graefe zu Baringdorf (Verts/ALE) to the Commission and the reply by the President J. Barroso, doc. ref. P-7065/08, and written question by MEP Emmanouil Angelakas (PPE-DE) to the Commission and the reply by the President J. Barroso, doc. ref. E-6248/08, OJ 2009 C 316.

[46] J.G. Carrau, *Lack of Sherpas for a GMO Escape Route in the EU*, "German Law Journal" 2009, Vol. 10, pp. 1169–1200.

[47] Council Conclusions on Genetically Modified Organisms (GMOs), 05.12.2008, doc. ref. 16882/08.

[48] Interview with a Polish official, May 2010.

tives, which were premised on EU-wide market approvals and vested the authority on products' safety and risk assessment primarily in the hands of scientific experts. Furthermore, in the environmental Council meeting in June 2009, thirteen Member States expressly called for revision of the existing regulatory framework.[49]

The new national proposal was rather radical and marked an explicit departure from the original premises of the GMO regulatory system, especially with respect to the socio-economic conditions of approvals and national autonomy to regulate the cultivation of GMOs. As a response, the Commission prepared a proposal for reform which included the renationalisation of competence for GMO cultivation (i.e. backing off by the EU from the already harmonised field) and more national autonomy (see below). These were definitely new objectives and framework goals for the GMO regime.[50] Simultaneously, the much-needed reform of comitology was already in the pipeline, set to come into effect in 2011.

In addition, as a part of the continuous process of reviewing the existing legislation and improving its implementation, the Commission arranged an evaluation of the GMO regime between 2009 and early 2011. Two separate and independent consultancies addressed aspects of the implementation of the GMO cultivation and GM food and feed legislation respectively.[51] The main goal was to collect facts and opinions, particularly from stakeholders and competent authorities.[52] The evaluations assessed the effectiveness and efficiency of the regulatory process and formulated options for its improvement and adjustment. The results were published in 2011 and 2012, and broadly outlined the problems associated with the functioning of GMO approval procedures in the EU, concluding that:

'The legislative framework as it operates today is not meeting needs or expectations, or its own objectives. The system is not working as envisaged and is not, in aggregate, meeting its objectives. Dissatisfaction and frustration are widespread. The 'dysfunction' in the system arises as a consequence of a complex set of factors, both external and internal to

[49] Note from the Secretariat General of the Council to the MS Delegations, 24 June 2009, doc ref. 11226/2/09 REV 2. The supporting MS: BG, IE, EL, CY, LV, LT, HU, LU, MT, NL, PL and SI.

[50] See also: S. Poli, *The Member States'*…, op.cit., p. 148 ff.

[51] See on details the relevant website of the Commission: http://ec.europa.eu/food/plant/gmo/evaluation/index_en.htmandhttp://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm.

[52] The consultees were: national authorities, EFSA, environmental and industry NGOs (institutionalised civil society), private companies and the research institutes.

the authorisation process. The external socio-political environment undoubtedly affects the way actors engage with and use the process. The EU operates an approval system based on a science-based safety assessment for products that many in Europe, including Member State governments, object to on socio-economic and ethical grounds. And while extensive efforts have been made to ensure that the appraisal systems are rigorous, they struggle to accommodate the particular assumptions, perceptions of risk and local concerns of different actors The resulting frustration triggers objections, which result in requests for further analysis, which increases the workload on the system, which in a world of finite resource leads to more delays, which further increases frustration'.[53]

Finally, the EFSA also participated in the process of institutional revision of strategies. This was accompanied by an internal process of competence simplification within the Commission (transfer of the GMO powers from DG AGRI and ENV to the competence of DG SANCO). A new EFSA policy on independence and transparency towards the public was proposed following the European Parliament's heavy censure, together with a modification of approach towards direct meetings between scientists and the public.[54] Moreover, after ten years of hesitation the EFSA finally decided to open Panel meetings to the public, something which it had long had the competence to do but had refrained from implementing.[55]

The described initiatives, analysing options for policy modification, can be systematised as follows. They were either (i) to be routinely prescribed by legislation to be carried out both by the EU institutions and the Member States based on their implementing experience (acting as lower-level units); or (ii) political in nature, leading to the revision of institutional strategies; or (iii) to be carried out by independent peers, who would present the evaluation of the regime based on broad consultation processes involving all stakeholders and their experience.

[53] European Policy Evaluation Consortium, *Evaluation of the EU legislative Framework in the Field of Cultivation of GMOs*, Final report, March 2011, http://ec.europa.eu/food/plant/gmo/reports_studies/docs/gmo_cultivation_ report_en.pdf.

[54] EFSA press release, *European Court of Auditors recognises EFSA's advanced independence policy, makes recommendations*, 11.10.2012; EFSA's Policy on Independence and Scientific Decision-Making Processes at http://www.efsa.europa.eu/en/aboutefsa/keydocs.htm.

[55] EFSA Pilot Project Observers 2012, see: http://www.efsa.europa.eu/en/stakeholders/observers.htm and EFSA Guidelines for Observers, 01.10.2012, available at: http://www.efsa.europa.eu/en/stakeholders/docs/observersguidelines.pdf.

1.4. Recursive Revision of Objectives in the Light of Results

This paper has shown that an understanding of the controversy over GMO governance in the EU as solely as a regulatory conflict over the exercise of anti- and pro-GMO powers is probably over-simplified. The section below interprets the dynamics of revision of the GMO regime as an example of a process that can be characterised as 'recursive revision of objectives in the light of results'.[56]

In view of the functioning of the governance system over the last decade, it seems incontrovertible that the originally-set framework goals and objectives of the 2001–2003 GMO regime require revision. The lower-level units (private actors, consumers and the general public, national authorities), which were given broad discretion to advance these goals (as described above), have demonstrated varied experience and different degrees of autonomy in their implementation. For example, several national governments invoked safeguard clauses to ban GM products which were legally authorised by the Commission and backed by the scientific expertise of the EFSA. The legality of these clauses was exposed to the 'correction procedure', where they were easily accepted by the Council (the majority of the remaining Member States), even though the EFSA has not found them to be scientifically justified. In effect the safeguard clauses, originally designed as emergency measures, have recently become additional mechanisms for the revision and contestation of GMO approvals, sharing of experience with marketing between Member States, and a means for additional deliberation on scientific issues. Some of the clauses were challenged by private companies, and the ECJ expressly 'corrected' the Polish legislative measures as inadequate.[57]

In the further exercise of their discretion, some of the national authorities, who represent 28 Member States with diverse local, environmental and geographical conditions, accurately transposed the EU GMO legislation into different national contexts, while others have failed to do so. Some of them have also been brought before the Court to correct their performance.[58]

[56] C. Sabel, J. Zeitlin, *Experimentalist Governance*, op.cit.

[57] PL has adopted a general legislation prohibiting the marketing of GM seeds which was not based on the safeguard clauses set out in EU legislation. The Court of Justice of the EU issued a judgement whereby it considered that legislation contrary to EU law and condemned Poland for failure to fulfil its obligations, see: case C-165/08 Commission v. Poland, ECR [2009] I-06843. See also judgement in case C-36/11 Pioneer Hi Bred Italia Srl, nyr.

[58] E.g. judgment in case C-121/07 Commission v. France, ECR [2008] I-09159. See also judgment of the Court of 26 September 2013 in case T-164/10 Pioneer Hi-Bred International, Inc. v. Commission, nyr.

Moreover, following the enlargements in 2004, 2007 and 2013, the circle of national authorities sharing their information was considerably broadened. The experience and input of the new actors in implementation has definitely influenced the regulatory changes, as seven out of the thirteen States calling for revision of the GMO regime were new EU Members, who did not participate in the adoption of the original objectives. The call for legislative revision also indicates that the positions of different states are aimed at different impacts, inasmuch as some of them who supported the revision are not usually considered as anti-GMO (e.g. the Netherlands, which has separately proposed the re-nationalisation of national powers on GMOs).

In addition, the monthly meetings of national authorities and EFSA and Commission officials in the relevant comitology committees have been significantly transformed into forums of regular reporting on national performance, sharing of information and experiences in national contexts and markets, and constant discussions and interaction, where all the decision-making actors are exposed to each other and have to explain their behaviour.

These committees have the potential to be an institutional setting where the dynamic accountability between the actors can be observed. It is true that during GMO approvals Member States are divided and the voting configurations reached do not reflect deliberations, but at the same time, this divergence can also be viewed as inspiring. That is, the committees witness a constant articulation of problems and disagreements (political, scientific, etc.), as well as argument-based exchanges of national experience and various proposals, which are verified and debated on a regular basis. The meetings are also relatively transparent to the public – the summary record of their content is published.

In addition, the independent peer-review evaluation is evidence of an experimentalist dynamic accountability in the regime.[59] The reports have offered independent assessments based on the broad participation of lower-level units, their knowledge and opinions. The reports have also openly acknowledged the 'complexity and ambiguity' of problems and the need for policy revision.[60]

The current reform has brought about change in the original objectives of the legislation, inasmuch as it has proposed further flexibility in the decision-making procedures, re-nationalisation of GMO cultivation, and the introduction of non-scientific grounds as a possible basis for re-

[59] P. Dąbrowska-Kłosinska, *EU and Transnational Regulation of GMO Risks…*, op.cit.

[60] C. Sabel, J. Zeitlin, *Experimentalist Governance…*, op.cit., p. 173.

striction of GMOs on national territories. This was carried out in view of the experience with approvals and national implementation. Moreover, it has tried to reflect, at least in part, the reality of the GMO market. The European Citizens Initiative has also certainly influenced the Commission's proposal, although recognition of the public voice was not expressly acknowledged by the institutions.[61]

In sum, the above interpretation indicates that the deeply contentious policy field still allows for the search for new solutions based on the input of the many and various actors and stakeholders involved. In view of the above, we could say that while the functioning of the GMO governance has not been perfect, it has nonetheless also produced some evidence of democratising effects. Yet at the same time it is clear that the ideals of deliberative democracy are much more demanding. We would like to witness the Member States engaged in a more visible deliberation during approval procedures, with the assistance of stable institutional practices of the Commission and EFSA. Before trying to assess what the remaining obstacles are to reach these ideals, below we present the regulatory features of the present reforms.

2. The Current Regulatory Reforms

The preceding section analysed the genesis and processes leading to the present reforms in the GMO sector. It showed how the problematic experience with GMO approvals and marketing led to a pragmatic need for redefinition of policy objectives. Now we examine the regulatory solutions contained in the reforms, both those implemented and those proposed.

2.1. Reform of Comitology

The EU constitutional reform of comitology did not result solely from the problems of the GMO governance, but the complexities of the GMO approvals certainly influenced the current shape of the reform.[62] The new Regulation of comitology contains several provisions which are highly relevant to the decision-making processes in the Standing Committee for Food Chain and Animal Health, which debates and determines GMO authorisations.[63]

[61] Cf. S. Poli, *The Member States'*..., op.cit., p. 151.
[62] Cf. recital 11 and 13-14 of the Preamble, Regulation 182/2011.
[63] See art. 2, 5–6 of the Regulation 182/2011.

First, the regulation introduces a new procedure for decision-making (an examination procedure), which replaces the previous regulatory procedure. Although it is still based on qualified majority voting of the Member States,[64] the new procedure is much more flexible than the old one, and it acknowledges the experiences with GMO votes.

In particular, when no opinion is delivered in the committee, the Commission will not adopt a measure either if it concerns the protection of the health or safety of humans, animals or plants (here: a decision for a GMO approval), or if a simple majority of the committee members (15 out of 28 Member States) oppose it (unless it is deemed *necessary*). This is a significant change as compared to old rules, where the procedural structure of the regulatory comitology procedure did not allow the Commission to not adopt a proposed measure (art. 5 of Council Decision 1999/468 as amended in 2006). This means that now the Commission can refrain from taking a decision in the event the requisite number of votes are not attained in GMO cases. However, it remains an unsettled question whether the Commission will actually use its new competence to abstain from adopting controversial decisions on the basis of, e.g., minority scientific views included in EFSA opinions.[65] Article 5 stipulates the procedural steps in question:

'2. Where the committee delivers a positive opinion, the Commission shall adopt the draft implementing act.

3. Without prejudice to Article 7, if the committee delivers a negative opinion, the Commission shall not adopt the draft implementing act. Where an implementing act is deemed to be necessary, the chair may either submit an amended version of the draft implementing act to the same committee within 2 months of delivery of the negative opinion, or submit the draft implementing act within 1 month of such delivery to the appeal committee for further deliberation.

4. Where no opinion is delivered, the Commission may adopt the draft implementing act, except in the cases provided for in the second subparagraph. Where the Commission does not adopt the draft implementing act, the chair may submit to the committee an amended version thereof.

Without prejudice to Article 7, the Commission shall not adopt the draft implementing act where:

[64] M. Weimer, op.cit., pp. 160–162.

[65] S. Poli, *The Commission's New Approach to the Cultivation of Genetically Modified Organisms*, "European Journal of Risk Regulation" 2010, Vol. 1(4), pp. 339–344.

(a) that act concerns taxation, financial services, the protection of the health or safety of humans, animals or plants, [emphasis added] or definitive multilateral safeguard measures;
(b) the basic act provides that the draft implementing act may not be adopted where no opinion is delivered; or
(c) a simple majority of the component members of the committee opposes it.

In any of the cases referred to in the second subparagraph, where an implementing act is deemed to be necessary, the chair may either submit an amended version of that act to the same committee within 2 months of the vote, or submit the draft implementing act within 1 month of the vote to the appeal committee for further deliberation.'

Second, there is a new appeal committee, which replaces the Council meetings within the comitology structure. This allows for a second discussion of a matter at a higher level, but without a necessity of levering the case to the Council, a solution for decision-making which is hoped to become more effective and less politicised. The applicable procedure is again more flexible and emphasises the need for co-operation on proposed decisions. The role of the appeal committee is to deliberate and resolve contentious issues under the leadership of the chair. It is composed of higher-level national officials and chaired by the Commission (Deputy Director of the DG instead of the Head of Unit who chairs committees' meetings). Art. 6 specifies the applicable procedure:

'Article 6
Referral to the appeal committee
1. The appeal committee shall deliver its opinion by the majority provided for in Article 5(1).
2. Until an opinion is delivered, any member of the appeal committee may suggest amendments to the draft implementing act and the chair may decide whether or not to modify it.

The chair shall endeavour to find solutions which command the widest possible support within the appeal committee.

The chair shall inform the appeal committee of the manner in which the discussions and suggestions for amendments have been taken into account, in particular as regards suggestions for amendments which have been largely supported within the appeal committee.

3. Where the appeal committee delivers a positive opinion, the Commission shall adopt the draft implementing act.

Where no opinion is delivered, the Commission may adopt the draft implementing act.

Where the appeal committee delivers a negative opinion, the Commission shall not adopt the draft implementing act."

The reform of comitology and the new procedural rules are aimed at facilitating deliberation and consensus-based decision-making, which would constitute a crucial step toward improving the functioning of the GMO governance. It also introduces the means for better decision-making on GMO approvals, in terms of less politicisation, and more flexibility and simplification compared to the old comitology decision.[66] On the other hand, the implementation of the reform will greatly depend on the Commission's behaviour and its understanding of its role.

In terms of the latter, it must be said that the prospects so far appear somewhat pessimistic. For example, since the new rules entered into force on 1 March 2011, the Commission has always transferred the decision on approval to the appeal committee level, not making use of the flexibility clauses. This means that in each case the Commission was of the opinion that the GMO authorisation decisions were 'deemed to be necessary'. Consequently, the voting practice in the appeal committee has brought no change in comparison to the old rules, and there has also been no evidence of any consensus-building efforts on the part of the Commission. No opinion was delivered in each of the transferred cases, and the distribution of voices has featured a high level of abstentions in voting.

2.2. The Proposal for the Re-nationalisation of GMO Cultivation

The next essential reformative element in the EU governance on GMOs regards the proposal of the Commission to re-nationalise and decentralise competence on GMO cultivation.[67]

The proposed change to the Deliberate Release Directive foresees an insertion of a new article 26b entitled 'Cultivation', which reads as follows:

'Article 26b Cultivation

Member States may adopt, after a case-by-case examination, measures restricting or prohibiting the cultivation of all or particular GMOs or of groups of GMOs defined by crop or trait or of all GMOs authorised in ac-

[66] M. Weimer, pp. 160–162.

[67] See: S. Poli, *The Member States'…*, op.cit. Cf. also art. 2 par. 2 of the TFEU. 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. See also Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ 2010 C 200/1.

cordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties placed on the market in accordance with relevant Union legislation on the marketing of seed and plant propagating material, in all or part of their territory, provided that: [Am 40]

(a) those measures are based on

(i) duly justified grounds other than those related to the assessment of the adverse effect on health and environment-relating to local or regional 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 scientific assessment of the impacts on the environment conducted under Part C of this Directive, or grounds relating to risk management. Those grounds may include:

- the prevention of the development of pesticide resistance amongst weeds and pests;
- the invasiveness or persistence of a GM variety, or the possibility of interbreeding with domestic cultivated or wild plants;
- the prevention of negative impacts on the local environment caused by changes in agricultural practices linked to the cultivation of GMOs;
- the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability;
- the maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features;
- the absence or lack of adequate data concerning the potential negative impacts of the release of GMOs on the local or regional environment of a Member State, including on biodiversity;

(ii) grounds relating to socio-economic impacts. Those grounds may include:

- the impracticability or the high costs of coexistence measures or the impossibility of implementing coexistence measures due to specific geographical conditions such as small islands or mountain zones;
- the need to protect the diversity of agricultural production;
- the need to ensure seed purity; or

(iii) other grounds that may include land use, town and country planning, or other legitimate factors; [Am 41](aa) in cases where those measures concern GM crops which are already authorised at Union level, Member States ensure that farmers who cultivated such crops legally have sufficient time to finish the current cultivation season; [Am 17]

(ab) those measures have been the subject of a prior independent cost-benefit analysis, taking into account alternatives; [Am 42]

(ac) those measures have been the subject of a prior public consultation lasting at least 30 days; [Am 19] and (b) those measures are in conformity with the Treaties, in particular the principle of proportionality. [Am 20] Under the same conditions, regions within Member States may also adopt measures restricting or prohibiting the cultivation of GMOs on their territory. [Am 51]

Member States shall make publicly available any such measures to all operators concerned, including growers, at least six months before the start of the growing season. In the event that the GMO concerned is authorised less than six months before the start of the growing season, Member States shall make those measures publicly available upon their adoption. [Am 43]Member States shall adopt those measures for a maximum of five years and shall review them when the GMO authorisation is renewed. [Am 22]

By way of derogation from Directive 98/34/EC, Member States that intend to adopt reasoned measures under this Article shall communicate them to the other Member States and to the Commission not later than one month prior to their adoption for information purpose'.[68]

In brief analytical terms, the envisaged reform again provides for the extension of flexibility in GMO policy through the decentralisation of powers and less harmonisation with respect to GMOs. It maintains an EU-wide GMO approval, which becomes more extensively combined with national freedom to decide on GMO cultivation (an opt-out clause). Finally, it appropriately introduces the socio-economic and other non-scientific concerns as 'new mandatory requirements',[69] which in theory can justify restrictions on the internal market. So the proposal may be said to respond to national demands, as it increases the flexibility of GMO provisions, further decentralises EU powers, allows for differentiated integration, and it can be equally advantageous for international trade as it offers the potential of resolving the regulatory deadlock.[70] In principle, the proposed reform provides for modifications which should be very welcomed from the perspective of experimentalist governance,

[68] The text based on: European Parliament legislative resolution of 5 July 2011 on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, P7_TA(2011)0314, OJ 2011 CE C 33 E/38.

[69] S. Poli, *The Commission's New Approach…*, op.cit.

[70] Ibidem, p. 344.

but until its final adoption it is difficult to unambiguously predict its effects.[71]

At the present time, since July 2011 the original proposal as amended by the European Parliament has been awaiting adoption by the Council.[72] In order to facilitate the adoption of the act, the Danish Presidency put forward a compromise proposal in 2012. It included a few slightly modified possibilities: (i) to exclude part or all of the MS territory in the authorisation decision; and (ii) to restrict or prohibit the cultivation provided that the national measure does not conflict with EU level ERA. The Danish proposal had the support of more than 20 EU Member States in the March and June 2012 Environment Councils, but it was not enough to break the blocking minority. The specific problems which Member States have not been able to reach consensus on concern the compatibility of the proposal with WTO obligations, as not following a strict scientific discipline and EU internal market rules, and the problem of consistency between EU level environmental risk assessment (ERA) and national environmental measures.[73] A small number of the larger EU Member States were not able to support the Danish compromise text, although it was lauded for being creative and being balanced.[74]

Finally, after the two-year 'reflection period', on 3 March 2014 the Council held a public exchange of views on the draft regulation amending the Deliberate Release Directive. The exchange of views confirmed the Member States' willingness to re-open discussions on this legislative proposal on the basis of the Danish presidency's compromise text. The Hellenic presidency aims to reach a political agreement and prepare the adoption of this important legislation by the end of 2014.[75]

2.3. Remaining Problems

The analysis of the proposed and implemented reforms, significant for GMO governance in the EU, prompts the observation that they resonate

[71] Cf. 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 Reform Post-Lisbon*, "European Journal of Risk Regulation" 2010, Vol. 1(4), pp. 345–352.

[72] See: http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2010/0208%28COD%29.

[73] S. Poli, *The Commission's New Approach…*, op.cit., p. 342.

[74] See: Press Release, 3152nd Council meeting (Environment) Brussels, 9.03.2012, doc.ref. 7478/12; and also: http://eu2012.dk/en/NewsList/Marts/Uge-10/Auken.

[75] Press Release, 3297th Council meeting (Environment) Brussels, 3.03.2014, doc. ref. 7094/14.

with the premises of experimentalism. They introduce greater flexibility for decision-making and implementation, decentralisation, and they favour the implementation by lower-level units and their incorporation in decisions concerning a broad range of factors, which can assist in representing the variety of stakeholders' interests. It is still too early to assess their significance, and much will depend on their implementation by the EU institutions. Several obstacles to their successful application are already signalled on the basis of the past experience with the GMO approvals (see sections 2.1.–2.2. above).

The successful employment of experimentalism in the decision-making processes with respect to GMOs depends on the ability of the institutional practice to be open to arguments, transparent, and participatory. Unfortunately, this seems to be linked to the personalities of officials and politicians involved. For example, the former Commissioner John Dalli proceeded with approval for the cultivation of GM potatoes, causing surprise and disappointment in many Members States, who believed that the process of scientific and administrative co-operation on this file was not yet complete. In 2012 the European Parliament refused to grant a discharge to the agency's budget for 2010 due to claims concerning its lack of independence, among other problems, after it came out that the chief of the EFSA Management Board worked simultaneously for a biotech-sponsored Institute and went to work there directly after resignation. This reinforced national distrust in the EFSA's opinions and augurs more difficulty in the settlement of deliberative practices in the future.[76]

Furthermore, the co-operation between EFSA, the Commission and the national authorities will also depend on the flexible application of procedural rules in order to allow enough time-space for consultation processes to take place. Authorities complain that, in view of the tight statutory time-limits and over-formalism of procedures, there is very little time for the re-consideration of arguments, national feedback on the EFSA opinions, informal meetings among experts, submission of comments, etc.[77]

There is also a recent indication that the Commission currently does not want to be involved in either more flexibility or more transparency in the GMO policy-making process. Officials admit that: 'The Commission doesn't like flexibility. When there's flexibility you have to justify your choices and you risk an action in Court. The Commission prefers a clear

[76] Interview with Polish official, May 2010; See also: Summary Report of the SCFCAH meeting, GMO Section, 09.03.2010, p. 4.

[77] Interview with a Polish official, May 2010.

statutory rule to be followed, without the need to consider what to do'[78] adding that: 'there is no debate on GMOs in the Commission nowadays'.[79] This in a way confirms some earlier claims of national authorities that the Commission does not eagerly participate in mediation efforts.[80]

Finally, the chances for more successful co-operation on GMO approvals will also depend on the external conditions for decision-making.[81] Until now, the enlargements, including the big one of 2004, treaty reforms, and the consequent changes in voting patterns (now 260 of the 352 votes are required; the previous requirements were 255 out of 345 votes until 2013, and 232 out of 321 votes until 2007) have arguably affected the stability of those conditions and the capacity of experts to engage in deliberation.

Conclusions

The conclusions of my earlier work on the GMO regime in the context of experimentalism identified the need for the revision of policy objectives in this field and for an institutional choice between political bargaining and experimentalist measures. The first of the claims became visible in the recent reform of the policy-sector, where the EU went through a revision process marked by market experience, the input of lower-level units and peer-review exercises. The effect of this process is the redefinition of regulatory objectives in the proposed reform. The need for regulatory modifications also reinforced two central, experimentalist features of the EU internal regime, which are: (a) constant attempts made by policy-actors to respond to GMO risks under conditions of uncertainty and in the light of experience; and (b) on-going recursive revision of goals and a reflective approach to GMO policy.

In view of the present research, I would modify my second claim into a more definite statement. I believe that a desirable pathway toward further improvement of the GMO regulatory framework in the EU leads through the further conscious and consequential employment of experimentalist solutions in decision-making on GMO approvals. The evidence from the operation of the authorisation procedures over the last decade demon-

[78] Informal talk with a Commission official, April 2013.

[79] Interview with a Commission official, July 2013.

[80] Interview with a Polish official, May 2010.

[81] See also: P. Dąbrowska-Kłosińska, *EU Governance of GMOs…*, op.cit., pp. 209–212.

strates that hierarchical decision-making, if accompanied by non-transparent, inflexible and non-participatory institutional practice, leads to further frustration of all actors and narrows the space for the emergence of deliberative practices. The democratic legitimacy of the decisions reached can also be questioned in view of deliberative ideals. There is a potential for the new regulatory framework, strengthened by the proposed reforms, to function in a more experimentalist way, on the condition that the involved EU institutions will be open to modifying their practices in a more stable manner and that the Member States agree on the entry into force of the reforms. The lack of successful co-operation in the approval procedures seems to be linked to inadequate institutional practices, apart from political disagreements. The latter cannot be removed in their entirety, but in order to ensure better policy outcomes there is a need to improve the institutional practices of the EFSA and the Commission in the first place.