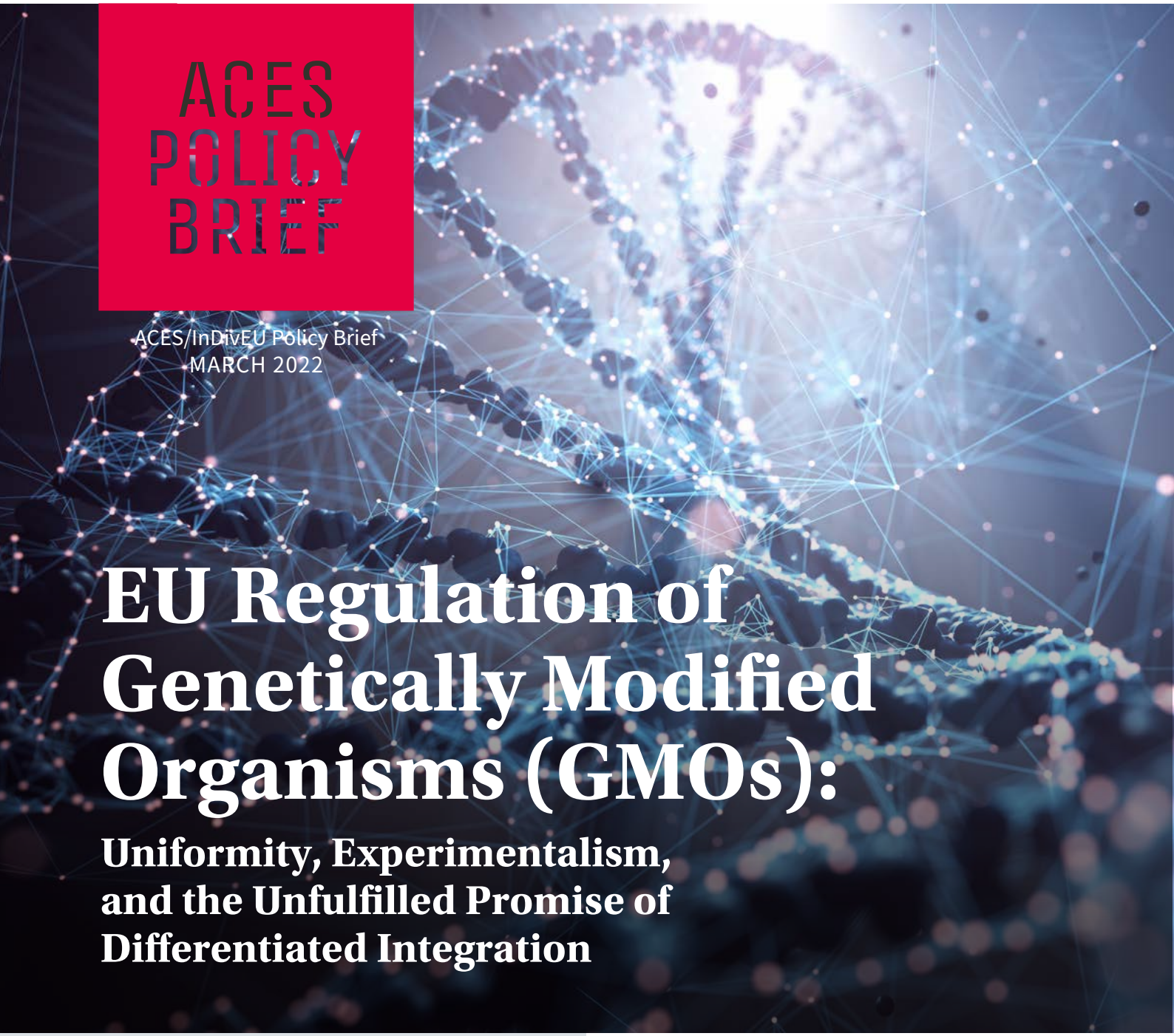

ACES POLICY BRIEF

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EU Regulation of Genetically Modified Organisms (GMOs):

Uniformity, Experimentalism, and the Unfulfilled Promise of Differentiated Integration

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Author: Patrycja Dąbrowska-Kłosińska
Researcher, professor, EU projects coordinator and editor.

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Integrating Diversity in the European Union

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Introduction: key problems of EU governance of GMOS

The current EU GMO regime is based on the precautionary principle and the process-based approach, meaning that any market access of a product resulting from a production process based on genetic modification is conditioned on its general compliance with the level of risk, standards, and procedures prescribed by EU rules. The system consists of an authorization procedure with a case-by-case risk assessment for the marketing and release of GMOs and post-market control, including environmental monitoring, labelling, and traceability obligations. It comprises three main acts of secondary law, the Deliberate Release Directive 2001/18, the GM Food/Feed Regulation 1829/03, and the Traceability Regulation 1830/03.

The EU GMO regulatory regime is characterized by the following features:

- Varying degrees of market interdependence (low for cultivation and higher for cross-border product trade, especially GM feed).
- Reliance on a combination of regulatory approaches: uniform regulation (UI), differentiated integration (DI), and experimentalist governance (XG) to respond to various policy needs and accommodate conflicting interests, but often unsuccessfully.
- Shared authority for GMO authorizations on the EU market involving the Commission, the European Food Safety Authority (EFSA), decentralized transnational networks of national competent authorities (CAs) and technical experts, such as the Regulatory Committee under Directive 2001/18; the Standing Committee on Plants, Animals, Food and Feed under the GM Food and Feed Regulation; and the European Network of GMO Laboratories.
- Complexity of the administrative and procedural framework which orchestrates the input of various EU and national actors into the authorization process, with three types of purpose-differentiated, marketing approval procedures: (i) national for research releases; (ii) national/EU for non-food/feed marketing; and (iii) the EU procedure for GM food/feed.
- Comitology decision-making at the EU level: the so-called examination procedure (Comitology Regulation 182/2011) where Member States express their opinion through qualified majority (QM) voting, and, if no opinion is delivered, the Commission makes the decision.
- Free market circulation of approved products unless limited by national competence: safeguard clauses, coexistence measures, or opt-outs from cultivation of an individual GMO (2015 reform).
- The number of EU countries cultivating GM crops has recently been shrinking: farmers from Romania Czech Republic and Slovakia have voluntarily stopped cultivation of GM crops, while Spain remains the only Member State cultivating GMOs (MON810 – the sole GM crop approved for cultivation in EU).

Regulation of GMO trade and use cuts across the EU's food, environmental and agricultural policy within the Internal Market. EU governance in the field of biotechnology has always featured intense policy controversies regarding authorizations for cultivation of GMOs and commercial GM food and feed use. The problems of the GMO regime are well-known. First, continuous no-opinion voting on GM product approvals in relevant

comitology committees, the appeal committee, and in the Council, which often undermines legal and procedural rules of multi-level authorization processes. Second, divergent views among stakeholders, and European societies regarding the costs and benefits of agricultural biotechnology, the level of acceptable risk, and public health, environmental, and socio-economic preferences. Third, politicization and conflicting views of national authorities on scientific evidence concerning GMO safety and effective risk management. Fourth, Member States remain divided on the issue of adequate regulation of New Plant Breeding Techniques (NPBTs), while the regulatory system has become outdated. As a result, the overall profile of the policy is affected by insufficient democratic legitimacy of EU-level decision making and by the disparity between the law on the books and the politicised world of regulatory governance in the EU Internal Market. It follows that the major problem of the GMO governance has been an effective accommodation of diversity in this area. How can this be achieved and implemented without impediment of the EU rules? To what extent has the most recent reform of differentiated integration (the Opt-Out Directive 2015/412) resolved these tensions?

This Policy Brief reports the findings of a detailed case study completed within the InDivEU project[1] on the national implementation of the Opt-out Directive 2015/412 in six Member States (Austria, Belgium, Ireland, Poland, Slovakia, Spain) and the functioning of GMO approvals in the Regulatory Committee under Directive 2001/18 after the adoption of the 2015 reform. The study appraised the reform in the context of various regulatory approaches, namely, differentiated integration (DI), experimentalist governance (XG), and uniform regulation (UI). The Policy Brief concludes by outlining three scenarios for further policy reforms and drawing out some key policy insights.

Key empirical findings of the study

Market differentiation vs diversity accommodation.

The 2015 reform of the GMO regime through the implementation of the Opt-Out Directive resulted in differentiation of the EU Internal Market for cultivation of GMOs between the Member States. The reform led to a *de facto* "reversal" of the original Internal Market paradigm for GMO cultivation (free movement) to market differentiation where no cultivation of GMOs becomes the rule, rather than the exception. Yet, no particular problems regarding the actual functioning of the Internal Market for GMOs and GM seeds have been reported because of low cross-border interdependence of agricultural biotechnology in EU. The reform created additional asymmetries by coupling the ability of Member States to opt-out with their continued power to vote on authorization on the cultivation of GMOs by other Member States who wish to do so. In that sense, it cannot be claimed that the reform effectively accommodated diversity between member States.

Asymmetries:

The functioning of the 2015 reform in practice has been a success for GMO adversaries, favor-

1 See P. Dąbrowska-Kłosińska, *Uniformity, Experimentalism, and the Unfulfilled Promise of Differentiated Integration in EU Regulation of GMOs: Which Way Forward?*, EUI RSC Working Paper 2022/11 and ACES SSRN Research Paper 2022/01.

ing those Member States who oppose those products. This is because anti-GMO Member States can not only invoke opt-out clauses, so as to effectively exclude products from their territories, *but also* can still vote on the approval of a GM product in the EU-level authorization process. Member States opposing GMO cultivation have both the demanded right to ban GM products in their own territories and in the same capacity they have the power to influence approvals at the EU level. This usually means either blocking or slowing down the authorization process substantially through no-opinion voting (no QM either in favor or against). In those cases, the Commission takes final decisions following comitology rules. Consequently, the reform created an asymmetry between Member States opposing and supporting GMO cultivation, effectively beneficial only to the former. This asymmetry has been created also through specific regulatory requirements placed on those Member States who wish to cultivate: they are obliged to adopt coexistence legislation and notify it to the Commission. The result of this process is nevertheless that actual GMO commercial cultivation areas is also asymmetrically distributed between Member States because GM crops are only grown in Spain. In short, the EU market for GMOs features two asymmetries of integration at the moment (2022): both factual/territorial in terms of GMO agricultural areas *and* normative, as the situation of the Member States who either support cultivation or would like to exploit it in the future is less favorable.

Politicization vs accommodation of diversity:

High politicization continues to dominate comitology voting procedures on GMOs notwithstanding the 2015 reform (differentiation). The latter did not diminish politicization and Member States continue to receive political instructions regarding their voting position from their top officials/ministries. This clearly affects the quality of deliberation and the ability to develop common positions out of discussions and reach a constructive consensus. The study showed that differentiation at the national level is not automatically linked to potential accommodation of diversity through enhanced deliberation in comitology (voting procedures), as there are numerous variables resulting from national-level implementation and regulatory systems which affect Member States' positions. Differentiation effects are thus not symmetrical: voting position on GMO approvals is not fully indicative of accommodation of national diversity vis-à-vis the EU level (*de facto* territorial differentiation of GMO cultivation), but no cultivation in a given state is also not always indicative of national position in comitology (which can be against, in favor, or abstaining).

Differentiated integration reform in the GMO regime

The study demonstrated that the 2015 reform addressed the problem of illegality of pre-existing national bans, as it formally realized the aim of legalizing space for differentiation of national positions toward biotechnological agriculture. The DI approach through the Opt-out Directive created the legal framework for the previously existing *de facto regulatory situation* in the GMO regime pre-2015 where safeguard clauses were used as a *de facto* differentiation mechanism, often outside the legal framework. This concerns principally GM maize MON810 currently approved

for cultivation in the EU. Functionally, DI introduced optional/alternative harmonization in the area of commercial releases of GM products into the environment for cultivation, because it effectively allows for the choice of disapplication of the EU positive integration regime established by the GMO laws in case of those Member States who choose to opt out from cultivation of a given product(s). DI de-harmonization was yet not consistent because all Member States still vote on product authorizations. During the researched period between the enactment of the 2015 Directive and mid-2021, the comitology voting records do not show any change in political gridlock on GMO approvals.

In effect, DI sanctioned differentiation and politicization, but also created additional asymmetries. The study also showed that the 2015 reform did not take into account several factors crucial for an effective realisation of the accommodation of diversity which would be reflected in the comitology voting. These factors include complexities of the national regulatory conditions relevant for the voting positions of national governments in comitology; power-sharing resulting from division of competences in GMO matters between various ministries and regions in federal states; different cultures of risk assessment among national authorities; sustainability concepts and ethical/cultural concerns; national-level public opinion; and diverse structures of agriculture. Objectively, not all of these factors could have been addressed, but it could have been predicted, for example, which states would abstain due to their internal conditions (e.g. Belgium, Germany) and what is their voting power within QMV. Finally, the 2015 reform did not address clearly enough the fear of anti-GMO states that their support for any product approval would in the long term encourage more GM cultivation in the EU.

Uniformity and experimentalism in the GMO regime

The study showed that there has been a mismatch between the DI reform and needed revision of uniform regulation: the existing harmonization and the comitology procedural rules. The Opt-out Directive returned the competence for cultivation/non-cultivation of GMOs to the national level, but it maintained the GMO cultivation approval procedures and QM voting at the EU level. The effective reforms of comitology and revision of uniform rules of the GMO regime have not been undertaken in parallel. The study indicated that apparent failure of the DI reform coincides with an urgent need for profound revision of the current regulatory framework, especially, the Deliberate Release Directive (harmonized, binding rules; positive integration). The latter is outdated with regard to new plant breeding techniques like mutagenesis and other gene-editing methods (also named New Genomic Techniques, NGTs) where a new framework is urgently needed.

The study established that where XG institutional mechanisms exist in the GMO regime (e.g. expert and CA networks, comitology committees), these provide a useful forum for sharing/exchange of information and experience between national CAs and learning from comparison of different national approaches, including within working groups. In all policy areas, apart from product approvals, decisions are taken by consensus. It

also seems that exchange of information and learning processes between Member States and between national and EU institutions occurs principally either through comitology committees or through networks (e.g. under EFSA's auspices, or through the European Network of GMO Laboratories, JRC-ENGL). In that sense, at least to some extent, an XG mode exists in parallel to politicization and DI reform.

Simultaneously, it seems that XG opportunities are not fully exploited and do not lead to argument-based problem solving. Existing EU networks foster more horizontal exchange of information rather than vertical (multi-level, bottom-up) feeding back of detailed knowledge which can be discussed openly with regard to what goes on at the national level. Moreover, cooperation between national representatives and experts within various EU networks is fragmented and depends very much on the ability of different national authorities to communicate/ share information at the national level.

The failure of the 2015 DI reform in the GMO field does not appear to have led directly to the re-emergence of other governance modes, or at least, it is difficult to observe this explicitly. However, the failure of DI may lead to further reform of harmonized regulation in view of the need to create a better new framework (UI approach reform), while it may also trigger an intensified form of XG approach, but those processes are happening simultaneously and cannot be viewed as a cause-effect relation.

Conclusion and possible scenarios

The study confirms that the GMO regulatory regime has not improved following the 2015 reform. First, the DI approach has not led to an effective accommodation of diversity neither from the perspective of the Internal Market nor the comitology voting in the committee and has not translated into an improvement of the decision-making processes. Second, the problem of regulation of new gene-editing techniques (NPBTs) following the 2018 CJEU judgement that these fall under the existing GMO rules remains unresolved. NPBTs fall under the GMO regime while the legislation is outdated and ineffective because detection methods for these products are hardly available. Third, the system is "tired" by the dysfunctionality of various, already tested, regulatory approaches.

In these circumstances, the three possible scenarios can be identified.

Scenario 1

The first scenario might be the most preferable, but it is also the most unlikely one in the near future. It would require a wholesale reform of the entire GMO regulatory regime, including the GM Food and Feed Regulation, and the comitology voting rules. The coherence between the undertaken reforms and legislative processes would be key for a successful development of this scenario.

Scenario 2

The second scenario involves maintaining the *status quo*. In practice, this would mean continuing stagnation of the GMO regime, including the impasse in voting procedures without any legal modifications. In this scenario, NPBTs would continue to be excluded from the market unless

gene-edited products are approved through the existing authorization process. In that case, we can expect growing dissatisfaction among national CAs, market operators, and the broader public, together with further politicization and blame shifting. In parallel, either the Commission or a group of Member States might try to work out a new proposal for reform in the longer term.

Scenario 3

The third and most promising scenario would involve a combination of more radical DI and more extensive use of XG. In such a scenario, competence over GMO cultivation, including the use of NPBTs, would be returned entirely to the national level, while authorizations of GM food and feed would remain at the European level. Cross-border interdependence resulting from national cultivation could be addressed through the existing procedures for management of coexistence between GM and non-GM crops, coupled with reinforced monitoring and review of their operation by the Commission and Member States within the comitology committees. More generally, experimentalist monitoring, follow-up, and peer review of national experience with cultivation of GMOs, including the use of NPTBs, within the comitology committees could create a new evidentiary basis for deliberation over authorization decisions, thereby helping to unblock the current voting impasse in EU-level approvals of GM food and feed products. Such experimentalist monitoring and peer review could likewise lead to the emergence of interest by farmers in other Member States in cultivating GM products and using NPBTs, which could then be authorized at the national level without needing to go through the EU approval procedure.

Key policy insights

Key Policy Insight #1

Consistent use of differentiated integration and experimentalism as complementary approaches

Appraisal of the impact of the regulatory reform on the accommodation of diversity within the EU establishes that the DI approach introduced by the 2015 Opt-out Directive failed to effectively foster accommodation of diversity in the GMO regime. The research shows that the reform reinforced asymmetries between Member States and did not fully address key problems of the GMO regime, including effective deliberation in comitology committees, pertinent national level issues, and the need to revise the regulation in view of development of New Plant Breeding Techniques (NPBTs). This was due to the atypical mode of DI which was introduced in the system, and lack of exploitation of the opportunities offered by XG within the GMO regime. Further reform needs to involve a combination of more radical differentiation, including a complete return of decision-making powers over cultivation to the Member States, with more extensive use of experimentalism. A reinvigoration of XG in this domain would need to be combined with a complete return of decision-making powers over cultivation – covering NPBTs as well as conventional GMOs – to the Member States (a more radical DI), while maintaining EU decision making over GMO food and feed. This combination would arguably reduce asymmetry because some Member States would be able to experiment with cultivation of GMOs, including NPBTs, subject to coexistence measures and intensive post-authorization monitoring, while those which oppose GMOs would be able to restrict cultivation through national-level risk assessment process/regulation subject to the Internal Market rules and Article 36 TFEU.

Key Policy Insight #2

Addressing obstacles to deliberative problem solving as a condition for experimentalism

To harness the potential of XG for reforming the EU GMO regime, longstanding obstacles to broader deliberation in this field would also have to be addressed. To make this possible, the Commission would need to open up debates about authorization decisions for GMO products to enable Member States and other stakeholders to raise their concerns about "other legitimate factors" beyond those considered in scientific risk assessments, from sustainability and socio-economic impacts to ethical and cultural issues, as the GM Food Regulation (but not the Deliberate Release Directive) already allows. Arguably, the failure of DI in its present form and the inadequacy of UI (currently applicable rules) in the GMO regime offers an opportunity of returning to XG, which is theoretically well-suited to reconcile common goals through accommodation of diversity and recursive revisability of rules based on deliberation, experience and comparison. This would surely require opening up the debates about GMO authorizations to non-scientific issues and seriously revisiting discussions on their socio-economic and ethical-cultural implications.

Key Policy Insight #3

Reforms in the GMO policy regulatory approaches (DI and XG) must be accompanied by the reform of comitology rules

The DI reform did not and could not address the question of specificity of voting rules and constitutional structure of comitology, including the aspect of national, horizontal power structures and internal politics of non-unitary states. From this perspective, the DI reform could have only been successful in the GMO domain if it had been accompanied by the systemic/constitutional reform of the EU voting system in comitology, especially, in the area of health and safety product regulation. DI did not respond to problems of other regulatory approaches apparently not working in the GMO regime. DI reform has not tackled national-level issues influencing individual states' voting positions and could have not have fully and adequately addressed institutional obstacles to deliberation in the GMO regime (linked to procedural rules and institutional behavior).