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(InDivEU)

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Uniformity, Experimentalism, and the Unfulfilled Promise of Differentiated Integration in EU Regulation of GMOs: Which Way Forward?

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The objective of InDivEU is to maximize the knowledge of Differentiated Integration (DI) on the basis of a theoretically robust conceptual foundations accompanied by an innovative and integrated analytical framework, and to provide Europe's policy makers with a knowledge hub on DI. InDivEU combines rigorous academic research with the capacity to translate research findings into policy design and advice.

InDivEU comprises a consortium of 14 partner institutions coordinated by the Robert Schuman Centre at the European University Institute, where the project is hosted by the European Governance and Politics Programme (EGPP). The scientific coordinators of InDivEU are Brigid Laffan (Robert Schuman Centre) and Frank Schimmelfennig (ETH Zürich).

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Integrating Diversity in the European Union

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Abstract

EU governance in the field of agricultural biotechnology, especially authorizations for commercial use and cultivation of genetically modified organisms (GMOs), has always been an exemplary field of intense policy controversies leading to regulatory impasses. Notwithstanding repeated attempts to improve the functioning of the regime, the longstanding problems with insufficient democratic legitimacy of EU-level GM product approvals in comitology decision making have persisted, affecting the overall profile of the policy. This paper appraises the most recent reform of the GMO regime through a case study of the implementation of the Opt-out Directive 2015/412, which returned powers over GMO cultivation to the national level, from the perspective of differentiated integration (DI) in relation to other regulatory approaches, namely experimentalist governance (XG) and uniform regulation (UI). In order to do so, the paper addresses the conceptualization of the GMO regime, its successes and pitfalls, the origins of the DI reform, and national implementation in six Member States. The regulatory appraisal of the impact of the reform on the accommodation of diversity within the EU is carried out through the lens of the functioning of the Internal Market and GMO approvals through the comitology voting system. The paper establishes that the DI approach introduced by the 2015 Opt-out Directive failed to effectively foster accommodation of diversity in the GMO regime. It argues that 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. The paper 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). Finally, the paper outlines three possible scenarios in the present situation. It argues that the most promising scenario would involve a combination of more radical DI and more extensive use of XG, including a complete return of decision-making powers over cultivation to the Member States and opening up debates about GMO authorizations to socio-economic and ethical-cultural factors beyond scientific risk assessment.

Keywords

GMO governance, experimentalist governance, risk regulation, differentiated integration, GMO cultivation, EU division of powers, comitology, biotechnology, gene editing.

Bio note

Dr Patrycja Dąbrowska-Kłosińska is an EU legal scholar who works at the intersection of risk regulation, public health governance and human rights law focusing on European/comparative jurisprudence and interdisciplinary approaches. At the School of Law, Queen's University Belfast she has contributed to the EU Horizon consortium InDivEU (2021) and as Marie Skłodowska-Curie Fellow led the EU Horizon project THEMIS *„Protecting Human Rights and Public Health in Global Pandemics A Map of the Standards Applied by EU and US Courts"* (2018-2021). For the latter work, she was awarded "Researcher of the Year 2019" Prize of the Queen's Faculty of Arts, Humanities and Social Sciences. In the past, she held positions of Assistant Professor at the Centre for Europe, University of Warsaw; managing editor of the Polish Yearbook of European Studies; and served as an EU law counsel at the Polish Office for Registration of Medicinal Products, within the Ministry of Health. She holds degrees from the Jagiellonian University in Cracow and the European University Institute in Florence. She publishes widely on human rights protection under global health threats, EU biotechnology, the role of courts, and novel modes of governance. She is also a member of the German Law Journal Editorial Board.

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1. Introduction

EU regulatory governance in the field of agricultural biotechnology, like EU electricity and financial regulation (Rangoni 2020, 2019; Zeitlin 2021; Zeitlin and Rangoni 2021), challenges the view that the Internal Market domain is characterized by high interdependence and low politicization (e.g. Schimmelfenning et al. 2015; Schimmelfennig and Winzen 2019). On the contrary, risk regulation for genetically modified organisms (GMOs), especially their cultivation, features frequent conflicts over regulatory authority (Dobbs 2016: 246) (high politicization) as well as varying degrees of interdependence (low for GMO cultivation and higher for cross-border marketing of GM products). Accordingly, commercial use and cultivation of GMOs in the EU has always been an exemplary field of intense policy controversy (Vogel 2012; Holder and Lee 2007: 61-84; Bernauer 2003). Divergent views among competent authorities and stakeholders are usually accompanied by societal concerns about GM products (Eurobarometer 2019: 42, 53; 2010). These differences and fears concern, *inter alia*, the costs and benefits of agricultural biotechnology, the level of acceptable risk, interpretation of scientific evidence on GMOs' safety while applying the precautionary principle, as well as the accommodation of public health, environmental, and socio-economic preferences (Weimer 2019: 4-10; Leonelli 2021: ch. 4).

The major contested issue has always remained approvals of GMOs enabling EU-wide authorization on the Internal Market. The multi-level authorization procedures – which are at the core of the regulatory regime – have thus been the most problematic aspect of policy making (European Commission 2015a). Due to conflicting and politicized views of national authorities during both the risk assessment and risk management phases, proposals for GMO approval decisions never gain support of a qualified majority (QM) of Member States in the comitology voting system (European Commission 2017: 1; more generally, see Craig 2019: ch. 4). This situation, which is often termed either "regulatory deadlock" or "impasse", causes considerable concerns over the democratic legitimation of those decisions and the adequacy of the applied regulatory policy more broadly (Salvi 2016: 201; Geelhoed 2014: 6; Weimer: 2010: 345).

In the Commission's own words: "there has never been a qualified majority amongst Member States in favor or against a draft Commission decision authorizing genetically modified organisms (GMOs) and genetically modified (GM) food and feed. Instead, all votes resulted in so-called 'no opinion' outcomes, i.e. that the committee could not reach a position either in favor or against a draft act. This result was then always repeated in the appeal committee, a body that is meant to help decision-making in sensitive and problematic cases. As a consequence, decisions in this field had to be taken systematically without the support of a qualified majority of Member States in the Committee." (European Commission 2017: 1; European Commission 2016; see also section 3 below).

To respond to these divergent views and effectively accommodate diversity between Member States within the Internal Market in this area, over the last two decades the European GMO regime can be said to have been a "test site" of varying regulatory approaches, for example, unity and diversity, centralization and decentralization (see sections 4 and 5). In fact, over the past twenty years, the EU multi-level system for GMO regulation has developed into a system combining features of those approaches as the applicable legislation was revised several times (Kritikos 2018; Morris and Spillane 2010). The latest reform took place through the adoption of the Directive 2015/412 ("Opt-out Directive") amending the Directive 2001/18 on the deliberate release of GMOs into the environment ("Deliberate Release Directive") in 2015 after a five-year long legislative process (Salvi 2016: 204-208; Poli 2010). The Opt-out Directive brought about partial renationalization of decision making specifically in the area of GMO cultivation, provoking numerous scholarly analyses of its nature and grounds for opting out (e.g. Weimer 2019; Kritikos 2018; De Sadeleer 2017; Dobbs 2016; 2017; Lee 2016; Geelhoed 2014; Poli 2013; 2010; see also section 6 below).

However, notwithstanding repeated attempts to improve the functioning of the regime (Salvi 2016; Dąbrowska-Kłosińska 2014; Weimer 2010), the longstanding problems with insufficient democratic legitimacy of EU-level GM product approvals in comitology decision making have persisted, affecting the overall profile of the policy (Weimer 2019: 115-140). Scholarly analyses continue to explore biotechnology regulation in the EU and beyond (recently: Kuzma 2021; Leonelli 2021).

At the same time, these studies are usually conducted from the perspective of the EU and/or transnational/comparative regulation/multi-level governance where a broader in-depth examination of national-level implementation is lacking (cf. however Weimer 2019: 187-189). Further, given the high expectations of the latest reform and general appreciation expressed in academic works (e.g. Weimer 2019; De Sadeleer 2017; Dobbs 2017; Lee 2016), there is an urgent need to study its effects more comprehensively.

Accordingly, the key objective of this paper is to offer an assessment of the reform from the perspective of the employed regulatory mode of differentiated integration (DI) in the context of other regulatory approaches, namely experimentalist governance (XG) and uniform integration (UI), through a case study of the implementation of the recent 2015 reform. The paper does so because XG, more generally, is said to be an alternative approach in EU governance effectively accommodating diversity (Zeitlin 2016) (see further sections 4-5 and 7-8 respectively). Specifically, the focus of the paper is on the functioning of the GMO regime as a result of the implementation and application of the Opt-out Directive as a way to accommodate diversity in EU GMO policy. The paper asks the following questions: how far did DI through partial return of competences on GMO cultivation to the Member States help to accommodate diversity of national positions on GMOs while respecting the principles of the Internal Market? Did the introduction of DI contribute to an improvement of the democratic legitimacy of EU decision making through instigating deliberation in comitology?

To answer these questions, the paper examines national regulatory conditions of GMO cultivation in selected Member States and investigates the impact of the 2015 reform in the context of national policies and on comitology decision-making, including Member States' voting positions at the EU level. It assesses the relative effectiveness of the DI reform (diversity accommodation) through: (i) the lens of the functioning of the Internal Market (free movement) and national-level practice; and (ii) the lens of functioning of comitology decision making and EU-level practice.

The paper proceeds as follows. First, after an explanation of the case-study design and the conceptualization and interpretation of the EU regime of GMOs in the context of various regulatory approaches (sections 2 to 4), past experience with their application is summarized (section 5) to offer a background for understanding of the origins of the differentiated integration reform. Second, the Opt-out Directive of 2015 is characterized as an atypical example of DI within the EU Internal Market, and its premises and immediate normative effects are described (section 6). Third, the specific research findings from the case study designed for the paper are analyzed. Accordingly, section 7 presents the transposition and implementation of the Opt-out Directive 2015/412 and contains an overview of national regulatory conditions in the states chosen to study the DI approach. Section 8 proceeds to trace the relative effectiveness of the DI reform (diversity accommodation within the Internal Market and at comitology level). It is established that DI in this field has so far not fulfilled its promises and expectations. Next, the findings from sections 7 and 8 are linked to identify which issues were not addressed by the DI reform (section 8.3). Next, the other regulatory approaches relevant for the GMO regime in EU are discussed to argue how they could help accommodate diversity while taking into account important features of the policy field (section 9). Finally, in the concluding section three possible scenarios are outlined to suggest a possible way forward in the present situation.

2. Research Design: Case Selection and Methods

The research for this paper was designed as a comparative case study of the 2015 reform – so far, according to present knowledge – the first such study of this kind. The case study was carried out in six EU Member States and at the EU level. It covered the period from the adoption of the reform until now (2015-2021). The research included analysis of primary and secondary sources, concerning both hard and soft law: legislation adopted by the European Parliament and the Council, national legislation and publicly available policy documents at the national and EU level (legislative proposals from the European Commission, minutes of the Regulatory Committee for Directive 2001/18, the Appeal Committee, reports, etc.), as well as research on debates in the national leading newspapers post-2015.[1]

The findings were cross-checked through interviews and emails/written replies with seven national/EU authorities (eleven officials in total). The interviews were semi-structured and included pre-prepared, open questions sent previously to interviewees. The scope of the research and choice of interviewees was aligned with the DI reform under investigation (Opt-out Directive), i.e. GMO cultivation and sometimes complemented with the analysis of the relevant issues regarding GM feed/food use. Interviewees were selected for their knowledge/competence in the policy issues under analysis. All but one interviewee chose the full anonymity option, and thus, we decided to anonymize all the respondents' positions and affiliations. A full list of anonymized interviews is included in Appendix 1.

The comparison was based on three pairs of Member States. The choice of comparators included: two large states (one federal, one unitary), Spain and Poland; two medium-small federal states: Belgium and Austria; and two small unitary states Slovakia and Ireland. Within these pairings, countries are fairly similar concerning population, state system and voting weight in the Council of the EU (for the purposes of QM voting), but diverse in terms of agricultural, environmental, and geographical conditions, location within EU, length of EU membership (different enlargement rounds), and most importantly, attitude towards GMOs, voting position in the Council on GM authorizations, and the use/non-use of the opt-out under Directive 2015/412. With regard to voting patterns and positions of Member States in the comitology committees and in the Council and the Appeal Committee, the paper draws on the extensive analysis of Mühlböck and Tosun (2018) as well as on the Commission's analysis reviewing the decision-making process for GMOs (European Commission 2015a; see also Navah et al. 2013).

3. Key Features of the European GMO Regime

The current EU GMO regime of was shaped between 2001 and 2004 (L. Drott et al. 2013: 1127; cf. Morris and Spillane 2010: 363) with later amendments (Weimer 2019; Kritikos 2018). It is based on the following features. All GM products (e.g. seeds, cut flowers, feeding stuffs and foods) are subject to pre-market approval, incorporating the precautionary principle (i.e. an authorization procedure with a case-by-case risk assessment for the marketing and release of GMOs) and post-market control, which includes extensive environmental monitoring, labelling, and traceability obligations. The core of this normative system comprises the Deliberate Release Directive 2001/18 applicable to research (field trials, part B) and commercial releases, including industrial, decorative, non-food agricultural uses, and cultivation (part C); and the GM Food/ Feed Regulation 1829/03 applicable to any use as food and feed, accompanied by the Traceability Regulation 1830/03, which are complemented by implementing acts and soft law measures.[2]

1 Main newspapers consulted: Der Standard; Irish Times; Independent; Hospodárske Noviny; Pravda; Sme; Gazeta Wyborcza; Wprost; El País; El Mundo. Unless indicated otherwise, the links provided were accessed on 30 September 2021.

2 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms OJ [2001] L 106/1; Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified

Specifically, EU-level legislation on biotechnology constituting means of positive integration includes: (i) harmonizing directives that need to be implemented in national laws concerning contained use of GMOs, their research and field trials, their commercial deliberate release into the environment, labelling and cultivation as well as principles and standards of environmental risk assessment (ERA); and, (ii) directly applicable regulations concerning marketing of GM food and feed and food/feed stuffs containing and/or produced from GMOs, their traceability and labelling (Weimer 2019; Dąbrowska-Kłosińska 2006). All acts contain substantive rules establishing health and safety product requirements and extensive procedural rules regulating pre-market authorization procedures and post-market environmental monitoring (Scott 2004; Dąbrowska-Kłosińska 2010 in Sabel/Zeitlin). The role of ERA regulation is to harmonize the practices of knowledge production which decide about GMO risks (Valve and Kaupilla 2008: 341).

In this regime, any market access of a product resulting from a production process based on genetic modification (process-based approach) is conditioned on its general compliance with the level of risk, standards, and procedures prescribed by the EU rules. There are three types of approval procedures: (i) national for research releases; (ii) national/EU for non-food/feed marketing releases, where the EU stage is triggered by national objections (under Article 18 of Deliberate Release Directive 2001/18), which is in fact almost always the case; and (iii) the EU procedure for GM food and feed products (under Regulation 1829/03) (Weimer 2019: 93-94).

Once a GM product is approved through the complex EU procedure (under either ii or iii), which belongs to the category of multi-level, composite procedures in EU governance (Hofmann 2009), it can circulate freely on the Internal Market, unless national authorities either invoke a safeguard clause, specified as emergency measures which must be based on new scientific evidence, or in case of GMO cultivation (since the 2015 reform) opt out from the EU-wide approval, during or after an authorization process (Weimer 2019: 159-172; 206ff). The latter (either ii or iii) comprises typically a national stage (formal only in case of iii; and fully developed in case of ii), European Food Safety Authority (EFSA) risk assessment, comitology stage, and final decision making by the Commission, when a qualified majority (QM) of Member States for or against the proposal cannot be reached.

The applicable comitology procedure in the GMO regime has been the so-called examination one since 2011 (Art. 2 and 5, Comitology Regulation 182/2011; see Weimer 2019: 109-112).[3] In such procedure, Member States have two possibilities to express their opinion through QM voting. First, in a committee composed of Member State competent authorities (CAs) representing a given sector (here: Regulatory Committee under Directive 2001/18 for deliberate releases into the environment or Standing Committee on Plants, Animals, Food and Feed for GM food/feed). Second, if no opinion is delivered by the committee (which is typically the case), the matter can be referred to the Appeal Committee (Article 6, EU Regulation 182/2011). When again no opinion is delivered, the Commission may adopt its proposal, and in the GMO regime, it interprets this as a *de facto* obligation to do so,

organisms OJ [2018] L 67/30; Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory OJ [2015] L 68/1; Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms OJ [2009] L 125/75; Regulation (EC) 1829/2003 of the European Parliament and of the Council on genetically modified food and feed OJ [2003] L 268/1 and Regulation (EC) 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms OJ [2003] L 268/24; Commission Recommendation of 13 July 2010 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; 2004/787/EC: Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003, OJ [2004] L 348/18. See also Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19) OJ [2020] L 231/12 which is beyond the scope of this paper concerning agri-food biotechnology.

3 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 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.

following the interpretation of the Court of Justice of the claim for failure to act against the Commission, and the wording of the Comitology Regulation (cf. Art. 5 and 6, EU Regulation 182/2011).[4]

A dense procedural framework orchestrates the input of various EU and national actors in the authorization process. It follows that shared authority for GMO authorizations is a key feature of this regulatory regime (Weimer 2019: 114) (although not necessarily shared accountability: see Drott et al. 2013). Both the Commission as the risk manager and the European Food Safety Authority (EFSA) as the risk assessor are embedded in decentralized transnational networks of national authorities and technical experts, including the Regulatory Committee under Directive 2001/18 and the European Network of GMO Laboratories (Spina 2010; Dabrowska-Kłosińska 2010).

Finally and importantly, Member States retain autonomy in the area of coexistence of GM and non-GM crops. They are entitled to introduce, based on socio-economic concerns, national and/ or regional measures to avoid the unintended presence of GMOs in other products (e.g. through the declaration of GM-free zones), but this must be done in line with the Treaty provisions on the Internal Market (Dobbs 2011; Balias 2005). After the 2015 reform, Member States have also authority to decide whether they will allow (or not) cultivation of any individual GMO on their territory (see further section 6 below).

4. Conceptualization of the GMO Regime in Relation to Varying EU Regulatory Approaches

The literature dealing with GMO regulation in the EU offers alternative interpretations of the legislative framework, institutional structure, and practical operation of the regime. Policy makers likewise differ on GMO risk perceptions and solutions. Some authors argue that the GMO sector is an example of “ambiguity and hierarchy” (Lee 2010) and failure of cooperation (Pollack and Shaffer 2009), while others consider that greater decentralization and differentiation would bring positive results for the accommodation of diversity in this area (e.g. Weimer 2019; Geelhoed 2014; Poli 2013). Those views find support in the literature arguing that a combination of politicization and interdependence should lead us to expect differentiated integration (Leuffen et al. 2013).

However, it needs also to be recalled that the degree of interdependence in case of GM products in the EU is variable. Interdependence is low for cultivation because GM plants are effectively cultivated in Spain only (as of 2021), a decrease since 2013-2015 when five EU states cultivated GMOs (also: Portugal, Slovakia, Czech Republic and Romania, COM 2015a). MON 810 maize – which is the only product approved for cultivation in EU – covered 150,000 hectares (including 137,000 hectares in Spain) amounting to less than 1.5% of the EU total. Interdependence is also lower for cultivation than for commercially traded products, because cultivation only potentially affects immediately neighboring Member States, while contamination risks can be minimized through coexistence measures (cf. however Dobbs 2011). However, interdependence is higher for commercially traded products, especially for GM crops widely used for animal feeding purposes. According to 2013 data, the EU imported 18.5 million tonnes of soymeal and 13.5 million tonnes of soybean, representing more than 60% of its plant protein needs. Most of these imports come from countries where GM crops are widely cultivated: 90% originate from four countries in which around 90% of cultivated soybeans are genetically modified (European Parliament 2015a: 3; European Commission 2015c).

Further, the studies which were conducted earlier on this field evidenced both successes and failures of different regulatory approaches in the GMO sector, extending from hierarchical, uniform regulation through transnational networks and proceduralization (e.g. Kritikos 2018; Vos and Weimer

4 Cf. T-164/10: Judgment of the General Court of 26 September 2013, Pioneer Hi-Bred International v Commission (failure to act), which concerned the old comitology rules of the regulatory committee procedure, art. 5 of the Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission OJ [1999] L 184/23.

2017, Dobbs 2016; Spina 2010, Lee 2010) to "a sophisticated composite regime of administrative risk governance" (Weimer, 2019: 112) and new modes of experimentalist governance with networked coordination and decentralized cooperation (Dąbrowska-Kłosińska 2010, 2015; for an early account, Dąbrowska-Kłosińska 2006). According to the latter view, the GMO regime also embodies means for reporting, monitoring, and peer review of policy results, allowing for revisability of both rule making and application in non-hierarchical settings involving lower-level actors (Dąbrowska-Kłosińska 2015: 83; 2014:117; 2010: 198-203). These include specific monitoring mechanisms focusing either on general risk governance of the GMO domain to ensure scientific and technical progress (e.g. through statutory reporting obligations, the role of the EU Food and Veterinary Office, comitology decision making) or risks arising from individual products to provide for safety re-evaluation, e.g. through the Rapid Alert System for Food and Feed and post-market environmental monitoring (Weimer and Vos 2015: 63-73; Weimer 2019: 86-112).

Clearly, there are competing views on regulatory responses to GMO dilemmas (Leonelli 2021: 145; Dąbrowska-Kłosińśka 2015: 82). Accordingly, this paper draws on the existing literature, but also goes beyond it by juxtaposing the analytical frameworks of different regulatory approaches in the EU which are known ways for accommodation of diversity (DI and XG) and alternatives to uniform regulation. The latter, the uniform integration approach (UI), typically relies on so-called "one-size-fits-all" conventional regulation, usually uniformly binding and imposed by centralized actors/ structures as rigid solutions (Rangoni 2020: 5; Zeitlin 2021: 7; Monti and Rangoni 2021:10). The contestation of UI as an adequate means to respond to problems of the Union is also longstanding.

Differentiated integration (DI) is often seen as one possible response to the lack of homogeneity within the EU (Zeitlin 2021: 4). In a typical DI scenario, some Member States who favor deeper integration in a given domain accept policies and rules that apply to them only, while others remain outside the application of those rules through opt-outs (Schimmelfennig and Winzen 2020). Secondly, in an EU facing global challenges and required to manage increasing diversity of 27 Member States, yet another conceptualization, that of experimentalist governance, offers a prominent alternative as a means for accommodation of diversity among the Member States (Zeitlin and Rangoni 2021; Rangoni 2020; Zeitlin 2015, 2016; Sabel and Zeitlin 2010, 2008).

XG involves provisional goal setting and revision, based on learning from comparative review of implementation in different local contexts (Zeitlin 2021: 5). As explained by Zeitlin: "In this iterative, multi-level architecture, framework goals, rules, and metrics for assessing their achievement are established jointly by the EU institutions and the Member States, typically following consultation with relevant stakeholders. 'Lower-level' units (such as national administrations and regulatory authorities) are then given substantial discretion to pursue these goals in ways adapted to their local contexts. But in return for this autonomy, they must report regularly on their performance and participate in a peer review in which their results are compared to those of others following different means towards the same ends. Where Member States are not making good progress, they are expected to take corrective measures, based on a plausible plan for improvement informed by the experience of their peers. The goals, rules, metrics, and decision-making procedures are then periodically revised in response to the problems and possibilities revealed by the review process, and the cycle repeats" (Zeitlin 2021: 5-6). In addition, XG is dynamic toward revisability of policy goals, treats diversity as an asset, but can also lead to its temporary reduction and develop into a simplified two-step experimentalist cycle combining synchronic uniformity with diachronic revisability (Rangoni 2020: 9; Zeitlin and Rangoni 2021).

As a result of these reflexive features and iterative, dynamic policy cycles, XG offers a potentially viable alternative to DI, especially in domains underpinned by strategic uncertainty such as modern agricultural biotechnology which belongs to the category of emerging disruptive technologies. It is maintained that challenges of regulating those technologies "highlight the need for regulatory regimes which feature not just effective corrections to apparent problems, but also anticipatory capacities which allow governments to identify and react appropriately to new challenges" (Taeihagh et al.

2021: 1014). Thus, adaptable and responsive regulatory approaches (like XG) offer a promising strategy for responding to emerging technological disruptions under conditions of uncertainty.

Hence it can be argued that some intrinsic features of the GMO domain make it a strong case for XG (e.g. Dąbrowska 2010; cf. Weimer 2019: 112-114), that is, deeply-embedded strategic uncertainty (see Zeitlin and Rangoni 2021) regarding adequate ways of dealing with rapid innovations posing risk; polyarchic distribution of powers and risk assessment/risk management capacities; and an unavoidable need to work out common solutions in face of technological progress and health and safety concerns (Dąbrowska-Kłosińska 2015: 82-83).

Consequently, in order to assess comprehensively the implementation and effects of the most recent reform which sanctioned a DI approach within the GMO legal system (the Opt-out Directive), the paper engages with both regulatory modes (DI and XG). Further, the paper also considers the regulatory features which had not been addressed by the reform to reflect on whether an XG approach could offer better-suited solutions as a way forward in the GMO regime.

This assessment of the relative effectiveness of diversity accommodation through the lens of the functioning of the Internal Market for GMO cultivation and comitology decision making in GMO authorizations also links to established conceptualizations of the methods of diversity accommodation in EU regulatory domains. In such conceptualizations, accommodation can occur either through differentiation of (Internal Market) rules and their implementation or increased deliberation (Hristova 2013). Deliberative and argument-based problem solving also belongs to the core of an ideal-type of experimentalism (De Burca, Keohane and Sabel 2014; Sabel and Zeitlin 2008) and refers to the long-accepted view that consensual problem solving in comitology committees ("deliberative supranationalism") contributes to the enhancement of democratic legitimacy of EU decision making (Joerges and Neyer 1997; see also Hristova 2013).

5. The Successes and Pitfalls of Different Regulatory Approaches in the EU GMO Regime for Cultivation: Examples and Origins of the Differentiated Integration Reform

Before turning to the analysis of the specific and empirical findings of this paper, the present section offers a short recapitulation of the reliance of the GMO regime for cultivation on the various regulatory approaches which are the of interest in this paper (UI, DI, and XG) and their respective (non-) functioning. The focus is specifically on the question to what extent the regulatory framework up until the 2015 reform was responsive to the need to accommodate national differences and disagreements vis-à-vis GMOs.

The EU regime applicable to GMO cultivation was originally designed to rely on a combination of regulatory approaches which could respond to the need to accommodate the diversity of national preferences, interests, and conflicting values (Weimer 2019; Dabrowska-Kłosińska 2010). It was a response to the policy challenges posed by novel biotechnologies requiring a range of regulatory policy tools – both procedural and substantive – to address them (cf. Taeihagh et al 2021: 1014). The main aim of the regime has been to ensure public health and environmental safety alongside the smooth functioning of the Internal Market.

First, in order to achieve its objectives, the EU legal system for GMO cultivation relied on harmonization in the form of directives (see section 3 above). Those laws amounted to a system regulating all aspects of agri-food biotechnology with a high degree of uniformity, including the risk assessment and risk management phases of product authorization procedures (Weimer 2019). In other words, it meant uniform application of substantive and procedural normative requirements (UI) and implementation within national legal systems to regulate the detail suitably to national conditions (see section 7 below). Until the 2015 reform, possibilities for differentiation (DI) within the regime were typical of EU food and product regulation on the Internal Market (Vos 2000), that is, either

through derogations pursuant to Art. 114(4-5) TFEU or a safeguard clause included in the Deliberate Release Directive Art. 23 for health emergency situations.

Pursuant to the latter, recourse to the safeguard clause is conditional upon material and procedural requirements, especially acceptance through comitology. Further, it can only be used when "new" or "additional" information becomes available on the basis of "new" or "additional" scientific knowledge which affects the environmental risk assessment or requires reassessment of existing information, and, as a result of this new information a Member State has detailed grounds for considering that a GMO constitutes a risk to human health or the environment.

Pursuant to Art. 114(4), if – after the adoption of an EU harmonization measure – a Member State deems it necessary, it can *maintain* national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment; and it must notify the Commission of these provisions as well as the grounds for maintaining them. Pursuant to Art. 114(5), if – after the adoption of an EU harmonization measure – a Member State deems it necessary, it can *introduce* national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonization measure; and it must notify the Commission of the envisaged provisions as well as the grounds for introducing them. Under the Art. 114 procedure, the Commission decides whether the condition for a derogation are fulfilled.

The practice of the application of the safeguards and derogation mechanisms showed that they left too little margin for maneuver to deviate from the EU standard (Poli 2013:145-148). This was mainly due to the literal interpretation of conditions for derogations by both the Commission and the Court of Justice pursuing Internal Market discipline as a key objective, and the resulting impossibility to rely either on scientific uncertainty underpinned by the precautionary principle or non-science based arguments and socio-economic grounds, as well as a narrow understanding of geographical, agricultural, sustainability-related and ethical circumstances of Member States (Weimer 2019: 153-166). As a result, national authorities typically invoked safeguard clauses as *de facto* derogations contesting UI and Internal Market discipline, and leading to *de facto* DI through health emergency instruments (Weimer 2019: 167; Hrostova 2015: 117; see further section 8 below).

At the same time, the EU legal framework governing GMO authorization demonstrated the creation of a sophisticated regime combining uniform regulation with experimentalist risk governance (Weimer 2019: 112; Dabrowska-Kłosińska 2010). This was due to a high degree of EU procedural harmonisation implemented through shared administration (especially comitology committees, the Commission and EFSA, and numerous networks of national competent authorities) combined with experimentalist interactions within decentralized administrative networks through so-called composite procedures (Weimer 2019: ch. 4; see also Spina 2010). Such proceduralization aims at flexibility and reflexivity as well as fostering ideals of deliberative democracy; it also shifts the regulatory focus from substantive ends to knowledge generation and decision-making procedures (Valve and Kaupilla 2008: 342). Both the institutional and regulatory framework, and intrinsic features of the GMO domain (section 4 above), should in principle facilitate the functioning of XG within the system (see also Weimer 2019: 86-112).

Indeed, as previous research documents, experimentalist features could be identified in coexistence management, post-market environmental monitoring, and traceability/segregation of GM and non-GM products (Weimer 2019; Dabrowska-Kłosińska 2015). Especially experimentalist risk management and traceability/segregation measures have worked better (also because the more controversial issues have been bracketed), including in relation to international trade, where they concerned withdrawal of unauthorized products from the EU market (Dabrowska-Kłosińska 2015: 93-99). This also shows that XG worked better in implementation of measures limiting/managing GMO cultivation and/or in areas of non-harmonization and decentralized cooperation (Weimer 2019:

172-177), but also with lower interdependence, because so few GMOs have been authorized for cultivation in the Member States.

But studies of GMO decision-making practices have also demonstrated shortcomings of the EU procedure, particularly of its cooperative and experimentalist structures (Weimer 2019: ch. 5, 2015; cf. Lee 2010; Pollack and Shaffer 2009). The operation of the GMO authorization procedures is the main example.

Under current comitology rules (2011, see section 3 above), when authorizing GMOs the Commission is obliged to follow the examination procedure, which should compensate for the loss of national regulatory competences by serving as a forum for the Member States to express their concerns, if any country raises and maintains objections against the initial national-level risk assessment. If there are no objections, a national authority may approve a product without going through the EU voting procedure in case of the Deliberate Release Directive; otherwise, the process moves to the EU level with an EFSA opinion on objections and its own risk assessment. Next, EFSA has been designed not as an authority superior to national scientific authorities, but as a networked agency promoting networking and scientific cooperation between national authorities while mediating divergent scientific risk assessments.

Both aspects of the procedure, however, do not lead to consensus-based decision making, as pursuant to comitology rules, the Commission always takes the final decision in the absence of a qualified majority opinion, which is *de facto* always the case. In the Commission's own words, it has become "a norm" to refer matters back to it for a final decision when Member States cannot reach qualified majority opinion (European Commission 2015a: 6).

This means that deliberation within comitology did not prove effective at addressing Member State concerns and building consensus – as XG and related approaches might expect. Although Member States' objections should be mediated during the procedure, any deliberative practice of the committee members/national authorities possibly occurring during the process is never reflected in the qualified majority voting where positions are deeply politicized and entrenched.

Several causes of such failures can be identified. Arguably, deliberation was stymied by a combination of issues. First of these is the Commission's unwillingness to address "other legitimate factors" (such as socio-economic, ethical, and cultural concerns) in addition to scientific risk assessments in its risk management decisions. Both the Commission and EFSA are said to be unwilling to admit and explore scientific uncertainties surrounding risk assessment of products, employing a reductionist approach to risk assessment (Hilbeck et al. 2020; Weimer 2019; van Asselt and Vos 2006; see also Valve and Kauppila 2008: 362), which has intensified national public contestation against EU-level technocratic and expert decision making. Especially under the Regulation for GM Food and Feed, the Commission can take into account "other legitimate factors" (apart from the EFSA scientific opinion), but in practice it has never done so (Weimer 2019; Dąbrowska-Kłosińska 2010: 195-96). Second, the comitology voting rules are problematic, which prompt the Commission to take the decision in the absence of the Member States opinion in the Regulatory/Appeal committee(s). In that sense, the promises of the new Comitology Regulation 182/2011 to facilitate more deliberative and consensus-building practice have also not been fulfilled in the GMO regime (cf. Weimer 2019: 112; Dabrowska-Kłosińska 2014).

As a result, the potential of XG to develop provisional solutions to contested issues within the comitology procedure which could then be refined and revised through comparative review of local implementation experience has been largely short-circuited through the top-down decision making of the Commission and – in effect – hierarchical restriction of deliberation around assessment of GMO risks. This has reinforced politicization, which in turn makes further deliberation more difficult, thereby intensifying deadlock.

It follows from this analysis that before the 2015 reform accommodation of diverse national preferences could neither occur effectively through differentiation of rules via derogation from EU harmonization nor through increased deliberation in comitology (cf. Hristova 2013). In both cases, one of the key problems seemed to be the *de facto* exclusion from both risk assessment and risk management of broader issues, such as agricultural sustainability and socio-economic concerns. This triggered the introduction of *de jure* DI as an alternative regulatory approach.

6. GMO Cultivation Reform as an Unique Example of Differentiated Integration in EU Internal Market Governance

EU Directive 2015/412, the so-called Opt-out Directive, was adopted in March 2015 after a burdensome five-year legislative process (Weimer 2019; Geelhoed 2014). The Opt-out Directive allows the Member States to restrict or prohibit the cultivation of GMOs in their territories pursuant to the application of the principle of subsidiarity (Dobbs 2016). To recap, this DI reform occurred in the GMO sector in response to the problems experienced with the functioning of approval procedures within the regulatory framework and in response to deep dissatisfaction among national authorities (voting impasses in comitology; diverse interests of Member States opposing GMOs and refusing to accept them on the EU market).

6.1. Background of the Proposal for the Opt-out Directive

The process toward the final adoption of the reform took years. It started in 2008 when the French Presidency and Jose Manuel Barroso, the President of the Commission, independently proposed initiatives to find adequate solutions to the deadlock of GMO authorizations (Dąbrowska-Kłosińska 2014: 127; Carrau 2009). In the same year, the Commission held an orientation debate on GMOs and the Council adopted Conclusions on the need for the reform (Council 2008). In 2009 thirteen Member States explicitly called for the revision of the existing regime, and following this the Commission put forward a proposal for renationalization of EU competences for GMO cultivation, allowing Member States to restrict or prohibit it in their territories (European Commission 2010). In the meantime, the Commission commissioned two independent studies to involve competent authorities, EFSA, institutionalized civil society and stakeholders (private companies, research institutes) in exploration of possible solutions (European Commission 2011a).

However, it was not until 2014-15 when the reform was finalized. Between 2012-2014, the proposal was put on hold by the Council (notwithstanding the Danish Presidency compromise text supported in June 2012 by twenty Member States), which could not agree on the compatibility of the solutions with the EU Internal Market and WTO rules (Dąbrowska-Kłosińska 2014: 138; Poli 2013: 152). The adoption of the GMO reform finally accelerated when the new President of the Commission, Jean-Claude Juncker put it on the agenda.[5]

The adoption of the GMO reform in March 2015 was followed promptly by two other legislative proposals which aimed to mediate disagreements between the Commission and Member States in the health and safety field. Both proposals followed the so-called pesticide crisis. In the latter case, Member States could not agree on the renewal of the authorization of glyphosate on the EU market due to its possible carcinogenic effects. Again, President Juncker decided to tackle the issue. In the

5 As Juncker promised in a speech to the European Parliament outlining his "Political Guidelines for the New Commission": "I also intend to review the legislation applicable to the authorisation of Genetically Modified Organisms. To me, it is simply not right that under the current rules, the Commission is legally forced to authorise new organisms for import and processing even though a clear majority of Member States is against. The Commission should be in a position to give the majority view of democratically elected governments at least the same weight as scientific advice, notably when it comes to the safety of the food we eat and the environment in which we live." (J.-C. Juncker, *A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change, Strasbourg, 15 July 2014: 11*).

State of the Union address in September 2016, he stated: "It is not right that when EU countries cannot decide among themselves (…), the Commission is forced by Parliament and Council to take a decision. So we will change those rules – because that is not democracy."

First, another, broader reform of the Comitology Regulation, which at the end of 2021 is still in the pipeline,[6] was proposed. Second, a further proposal for renationalizing EU competences in the GMO regime was tabled, that is, for GM food/feed products to amend Regulation 1829/2003. This proposal was an act analogous to the Opt-out Directive (European Commission 2015b). The latter, however was rejected straightaway by the European Parliament (EP) in the first reading (European Parliament 2015). The EP – along with the Economic and Social Committee and the Committee of the Regions – was concerned about the functioning of the Internal Market for GM feed and the interests of the EU agro-food industry, which strongly relies on GM feed imports. In comparison to GMO cultivation, the GM food and feed market in EU is more interdependent. There is a substantial market in the EU for GM feed, especially compound feed, a mixture of feed materials for farm animals. As discussed in section 4 above, most of the feed used in the EU is imported (essentially soybean and soya meal), and imports come mainly from countries where cultivation is dominated by GMOs. The main reasons for the widespread use of GM soymeal appear to be availability, price, and competitiveness (European Commission 2015a: 5). Thus, the Commission's attempt to follow the path of differentiation also in the area of GM food/feed proved unsuccessful.

It seemed that matters would be different with the Opt-out Directive. Unlike marketing of GM feed, cultivation of GMOs in the EU is limited, as discussed in section 4. Since 1990, only three GMOs have been authorized for cultivation, and only one product (MON810 maize) is currently authorized, which accounts for a tiny fraction of the area devoted to maize production in the EU (European Commission 2015a: 4). This is why, as explained in the Preamble to the Opt-out Directive: "Cultivation of GMOs is an issue, which is more thoroughly addressed at Member State level." Further, it is seen as having "strong national, regional, and local dimensions, given its link to land use, to local agricultural structures and to the protection or maintenance of habitats, ecosystems and landscapes", thus requiring more flexibility (Recital 6).

In sum, the GMO Opt-out Directive, and the DI approach more broadly, seemed to have been part of a conscious strategy for defusing conflicts between the Commission and Member States. This was clearly a response to the non-functioning of existing policy solutions by way of (differentiated) dis-integration. In that sense, the 2015 reform could be seen as a correction of the earlier integration process in the field of GMOs, which might have gone too far (Weimer 2019). In any case, however, the nature of the Directive has not been easy to grasp conceptually since its adoption.

6.2. Conceptualisation of the Opt-out Directive as "Atypical DI"[7]

There have been numerous attempts in the scholarship to theorize the nature of the Opt-out Directive and its potential effects more broadly since the adoption of the proposal (e.g. Weimer 2019; Kritikos 2018; De Sadeleer 2017; Dobbs 2016; 2017; Lee 2016; Geelhoed 2014; Poli 2013; 2010) due to its "unprecedented" and "unusual" character (see Weimer 2019: 181). Put simply, these interpretations can be broadly categorized in two groups: authors who consider the Opt-out Directive either as an example of (partial) de-harmonization (e.g. Weimer 2019: 194-198, 222, also using the term "constructive disintegration"; Dobbs 2017: 1095); or as a modified version of an existing safeguard clause under Art. 23 of the Deliberate Release Directive (e.g. Kritikos 2018: 209). This section recaps the key issues characterizing the act and shows that conceptually it can best be classified as an example of "*atypical DI".*

6 https://eur-lex.europa.eu/legal-content/EN/HIS/?uri=CELEX:52017PC0085&qid=1640297693817 – Procedure 2017/0 035/COD.

7 Term coined by Maria Weimer.

Formally, the Opt-out Directive was an amendment to the basic regulatory instrument, the Deliberate Release Directive 2001/18. Both acts are consequently based on Article 114 (1) (earlier Art. 95 TEC) TFEU, the typical legal basis for EU harmonization measures which aim at achieving internal market objectives in the sense of Article 26 TFEU (positive integration, see also section 3 above). Based on the principles of subsidiarity and flexibility,[8] the Opt-out Directive granted Member States broad policy discretion with regard to GMO cultivation in their territories (importantly, also in case of GMO authorization for cultivation under Regulation 1829/2003 for GM food/feed, which is possible). Before 2015, the total harmonization of GMO commercial releases, marketing, and cultivation had worked through EU-level decisions authorizing a GM product (approvals for a given purpose) combined with the free market clause enshrined in Art. 22 of the Directive 2001/18, with the exclusion of some matters, e.g. coexistence of GM and non-GM crops (see Weimer 2019; Dąbrowska-Kłosińska 2006).

The new Articles 26b and 26c explicitly allow Member States to "opt-out" (derogate) from any new and/or existing EU GMO individual authorization decisions on their national territories, which resembles the legal construction of a safeguard clause. This means that Member States became entitled to adopt legally binding acts restricting or prohibiting the cultivation of GMOs, as provided for in the EU administrative decision (individual act) (Art. 26b.3). They enjoy considerable leeway in determining the temporal, geographical, and material scope of the cultivation restrictions if they invoke an opt-out for a given product. This can be done on grounds other than public health and environmental safety through the explicitly non-exhaustive list of compelling grounds (Art. 26b), provided there is no conflict with the EU environmental risk assessment, and subject only to the EU Treaty (TFEU) free movement of goods provisions (cf. de Sadeleer 2017: 8-11). The latter would in any case apply to national opt-outs, as to any other measure having a potentially equivalent effect to quantitative restrictions. Invoking an opt out by a Member State means excluding biotechnology cultivation on the national territory according to the conditions set in national law and notified to the Commission.

Practically, however, the opt-out clauses (Art. 26b-c) introduced by the 2015 reform now provide an opportunity for legal exemptions from Part C of the basic act: commercial releases/marketing and cultivation of GMOs. From a legal system perspective, a combination of individual derogations of various states (national notifications) from EU-level administrative authorization decisions approving a given product leads to a derogatory effect similar to Art. 114 TFEU (cf. Vos and Weimer 2017; see also section 5 above).

In other words, the 2015 reform means both derogation from an EU individual act(s) (authorization) and abstract/general legislative norms (harmonization) of the Deliberate Release Directive, including disapplication of the free market clause (Art. 23). It also means renationalization of powers over cultivation, as the Opt-out Directive explicitly refers to Art. 2 (2) TFEU in its preamble.[9] The latter Article concerns return of EU (Treaty) powers to Member States when the Union ceases to exercise its competence, i.e., in the area of GMO cultivation. Weimer notes (2019) that this was also the first time – known to date – that the EU has agreed to give back to the Member States the exercise of a shared competence previously exercised at Union level.

Arguably, the Opt-out Directive changed the level of harmonization established by the basic acts in the field of GMO commercial releases: marketing and cultivation (Part C of the Directive 2001/18). A change was made from total/exhaustive harmonization to optional/alternative harmonization (cf. Salvini 2016: 210, "reverse harmonization"). That is, those Member States who wish to do so now have an option to invoke an opt out from all GMO approvals for cultivation decision(s) as well as individual products. In that case, they do not follow the free market rules established by the Deliberate

8 See Directive (EU) 2015/412, recital 8: "it appears appropriate to grant Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivate GMOs on their territory".

9 See Directive (EU) 2015/412, recital 6.

Release Directive in the field of cultivation of GMOs. Other states can choose not to opt out, revoke an opt out, or freely to choose to cultivate GMOs. But in the latter case, they are still bound by all the cultivation-related provisions of the Directive.

So one can say that normatively and functionally, the 2015 reform aims at reconciling the tension between the centralizing forces of internal market harmonization and national and regional diversity. It represents a substantial policy turn when compared to EU policy towards national restrictions of GMO cultivation (and of free movement of goods more generally) to date. This interrpretation is supported by the fact that the reform was an attempt to end the years-long deadlock and national non-compliance with EU rules on GMOs especially regarding cultivation.

At the same time, whichever GMO cultivation standard (EU or national) is chosen by a given country, all Member States are bound by harmonized procedural rules of approvals applicable to authorizations, including for cultivation; EU-level harmonized risk assessment of a product, if done by EFSA; and comitology voting rules, as well as other national authorities voting yes/no on a given approval. In practice, this happens every time when Member State authorities raise objections to national risk assessments, because the authorization process then moves to the EU level (which is almost always the case). The renationalization of powers introduced by the Opt-out Directive was thus partial and inconsistent. Arguably, a true de-harmonization would need to remove the EU-level approval procedure for GMO cultivation. That would mean a real return of powers to the national level akin to part B provisions of the Deliberate Release Directive (research releases and field trials).

From a DI perspective, the following can be said. The Opt-out Directive introduces DI in the GMO domain because legal rules are/can effectively be differentiated *de jure* and they are not equally valid across all EU states (Rangoni 2020: 7). It is thus legislative DI because the Deliberate Release Directive rules are not uniform across the EU, as Member States can choose to opt in or out of cultivation of a given product (cf. Schimmelfennig and Winzen 2019). At the same time, it is also heterogeneous DI in its implementation because national rules restricting and/or banning GMO cultivation can vary regarding geographical scope within states, between products and type of legal rules (regional/state, legislative/executive, etc.)

Further, differentiation in GMO cultivation is temporally variable or multi-speed: Member States can temporarily as well as permanently restrict cultivation of a given GM product (opt outs can also be revoked). It is also arguably multi-menu: Member States are free to choose a cultivation opt out differently for different products (this is only a potential possibility at the moment because there is just one product currently approved for cultivation in the EU). Finally, with regard to MON810 maize, DI is multi-tier, that is, Member States could opt-out from cultivation of that existing approval until 2 October 2015, and so in that regard, it created permanent divisions between in and out groups of Member States.

Accordingly, from a DI perspective, the Opt-out Directive does not fit standard dichotomies, because it falls under categories which should be mutually exclusive. Conceptually, the 2015 Directive can thus be seen as an atypical example of differentiated integration. To conclude this reflection, a kind of a “legal oxymoron” was established through the provisions of the 2015 Opt-out Directive which affects both its conceptualization and its functioning (see also sections 7 and 8 below).

6.3. The Promises of the 2015 Reform: Renationalizing the EU Competence in the GMO Field and its Immediate Effects

Pursuant to the reformed provisions of the Deliberate Release Directive (2001/18), as amended by the Opt-out Directive, Member States can opt out from cultivating GMOs on their territories. There are two options for this (Art. 26.b-c). (1) Member State can request *ex ante* geographical restriction of a product cultivation in the course of the approval process from the applicant company which must consent accordingly; no reasons are required in that case, but the Commission and other states

need to be informed. (2) Member States can invoke *ex post* unilateral restriction on cultivation of a given product at the national or regional level, which must be justified by a legitimate objective. The justification needs to be based on the following non-exhaustive list of objectives: *environmental policy objectives; town and country planning; and use; socioeconomic impacts; avoidance of GMO presence in other products without prejudice to Article 26a; agricultural policy objectives; public policy.*

The first option was applied by seventeen and a half of the current 27 EU Member States, including one of the Belgian federal states: Wallonia through the invocation of an opt out (notification to the Commission). Brussels Capital Region has also opted out. This was possible thanks to the transitional provisions of the Deliberate Release Directive (Art. 26c), which set the date for adjustment of pre-existing authorizations on 3 October 2015.[10] The next potential opt-out applications can be filed on a rolling basis in case of any new approva.l using either the first (during the course of the procedure) or second option (without deadline) (Art. 26b).

Those states which have decided not to use the opt-out clause for the GM product currently approved for cultivation in the EU were obliged to communicate to the Commission their national measures ensuring coexistence between GM and non-GM crops. As of the required date (3rd April 2017), four states, which also had cultivated GMOs before the reform entered into force, have notified the relevant legislation: Czech Republic, Spain, Slovakia, and Romania.[11]

Currently, however, GMOs are cultivated only in Spain. There is also one type of GM maize (MON810) currently approved for cultivation in the EU. In fact, the renewal of approval for this product has been pending since 2009 because there has never been an opinion of the Member States in favor or against the decision proposal, while the Commission itself has not taken the final decision (see section 8.2. below).

There are five Member States which neither notified the opt-out for the GM product approved for cultivation in the EU nor communicated any coexistence measures (Ireland, Portugal, Sweden, Finland, Estonia). This position which can be characterized as “no current cultivation and no opt-out” indicates that those states might not exclude cultivation of GMOs in the future. It also sends a signal of being open to modern biotechnologies, while knowing that not invoking an opt-out for MON810 GM maize is not significant because in most of those states (apart from Portugal), it would anyway not be possible to cultivate it, due to objective agricultural and environmental conditions.

The main expectation of the reform was that, first, it would allow for better accommodation of diversity of national preferences on the EU internal market by allowing anti-GMO Member States to invoke cultivation opt outs for their territories and pro-GMO Member States to cultivate GM products following EU-level authorizations. The second expectation was that the Opt-out Directive would help to unblock the longstanding procedural impasse in the comitology committee issuing opinions concerning GMO authorizations. Accordingly, the reform was also meant to improve the democratic legitimacy of EU decision-making processes on GMO approvals. As already mentioned, there has been repeated no-opinion voting in the committees (including the Appeal Committee) and the Council on the Commission proposals for GM product authorizations ever since the creation of the EU legal framework (2001-2003). As a result, the Commission has always felt procedurally forced to take the final decision on EU-wide GMO approval. This impasse concerns both deliberate release into the environment and GM food/feed products marketing.

10 Austria; Region of Wallonia, (Belgium); Bulgaria; Croatia; Cyprus; Denmark; France; Germany; Greece; Hungary; Italy; Latvia; Lithuania; Luxembourg; Malta; Netherlands; Poland; Slovenia
https://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en#nl

11 Art. 26a of the Deliberate Release Directive, https://ec.europa.eu/food/sites/food/files/plant/docs/plant_gmo_auth_nat-measures_summary-cross-border-national-measures.pdf.

Thus, it had been hoped that knowing that GM products will not enter their national territories, anti-GMO Member States would no longer vote against authorizations and that the reform – at least to some extent – would trigger a more deliberative/consensual decision-making process on GMO approvals in comitology, at least with reference to cultivation. These hopes for improvements were expressed both in the scholarship (e.g. Weimer 2019; Dąbrowska-Kłosińska 2014) and by the EU institutions (European Commission 2010).

7. The Transposition and Implementation of DI in the Opt-out Directive 2015/412: A Comparative Overview of National Regulatory Frameworks and Conditions

Regrettably, six years after the introduction of the DI reform, it can be concluded that the above expectations have not materialized. The practice of comitology voting on GMO cultivation between 2015 (the adoption of the Opt-out Directive) and now (end 2021) demonstrates that changes have not occurred in terms of unblocking the no-opinion impasse in the voting proceedings (comitology, the Appeal Committee) and in potential modification of attitudes toward GMO approvals among Member States (see also further section 8.2).

In order to better understand the relevant processes and occurrences as well as the significance of the DI in the GMO regime, in our comparative case studies we explored the national implementation of the Opt-out Directive in the context of basic regulatory conditions in the chosen states. The following subsections briefly present the national legal and institutional frameworks, division of powers and regulatory features, including the public attitude towards agricultural biotechnology. It is important to be aware of those conditions, as they influence Member States' positions regarding GMO cultivation at both the EU level and in their internal politics, and in turn, affect the feasibility of diversity accommodation. Those issues return in the analysis of section 8, where the impact of the 2015 reform on the functioning of the internal market and the decision-making through the comitology procedure is examined.

7.1. Austria

Austria has traditionally been an anti-GMO Member State. The relevant powers in the GMO field are shared between the Ministry of Health and Women (responsible for matters of GM food, feed, cultivation and contained use research in the private sector) and the Ministry of Education, Science and Culture (contained use research at academic institutions). The Ministry of Health further cooperates and shares the competence in the GMO matters with the Ministries of Agriculture, Forestry, and Water Management and Ministry of Climate Action.[12]

Austria has always voted against GM product approvals (along with CR, CY, GR, LU) both in the comitology committees, the EU Council and the Appeal Committee. Since the adoption of the EU regulatory framework (2001-03), Austria has used every opportunity for differentiation. It submitted an old Art. 95 (now 114 TFEU) of the EU Treaty notification to depart from the EU harmonization in 2003, which was unsuccessful following the EU Court of Justice judgment (Poli 2013), and has for years invoked and maintained laws based on the EU Deliberate Release Directive safeguard clauses prohibiting, inter alia, the cultivation of the MON810 maize on its territory, starting from 2005 (Weimer 2019).

Austria is also a state which in 2009 prepared the proposal for the devolution of national powers in this area (Hristova 2013), and so the Austrian government strongly supported the solutions negotiated

12 See the main legislative act, the Gene Technology Act, Bundesgesetz, mit dem Arbeiten mit gentechnisch veränderten Organismen, das Freisetzen und Inverkehrbringen von gentechnisch veränderten Organismen und die Anwendung von Genanalyse und Gentherapie am Menschen geregelt werden (Gentechnikgesetz – GTG) https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826 § 62b.

in the Opt-out Directive.[13] This helped to ensure that Austria would remain free from GMO cultivation while complying with EU rules.

Following the reform, the Opt-out Directive was implemented in two phases.[14] The first phase involved the amendment of the Austrian Gene Technology Act which enabled he submission of the notification to the EU Commission. Next, a new federal law was enacted, the so-called framework act, to allow the Austrian states (Länder) to adopt laws concerning either prohibition or restriction of cultivation along with the relevant ground provided in the EU provisions.[15] Under the 2015 reform, Austria also took the opportunity to opt out from cultivation of MON810. One of the important reasons considered in Austria as a possible justification for opting-out has been socio-economic conditions and the role of organic agriculture.[16] The country is an EU leader in the latter field with approximately 30% of its agriculture being organic. Austria has never allowed any GMO cultivation. In case of the proposal for cultivation approval, an obligatory public hearing must be held with any interested party.[17]

After the reform entered into force, the Austrian government did not change its voting position on any GMO file within the comitology committee, apparently because of internal politics. Austrian public opinion has been against gene technology agriculture since the nation-wide referendum held in 1997 when a vast national majority expressed its negative attitude. The approach to keep the state strictly GMO-cultivation free is shared among all Austrian regions and is supported by all parties across the whole political spectrum.

7.2. Belgium

The current legislative framework applicable to GMOs in Belgium is based on the Royal Decree of 21 February 2005, which transposes Directive 2001/18/EC. It was modified by the Royal Decree of 19 February 2020, which transposes the Commission Directive (EU) 2018/350 as regards the environmental risk assessment of GMOs.[18]

The competence in the field of GM products is shared between the federal and regional level. At the national level, the Belgian federal government (particularly the Ministries for the Environment and for Public Health) is the principal authority with regard to regulating GMOs. The main authorities in charge of supervising GM-related activities are the: Federal Public Service Health, Food Chain Safety and Environment (FPS Health), Federal Food Agency, Belgian Biosafety and Biotechnology Service and Regional Departments of Agriculture. The Belgian Biosafety Council is a body responsible for GMO risk assessment for all levels.

Given that Belgium is a federal state, however, regional authorities play a relatively strong role in the regulation of GMOs, mainly within the framework of a 1997 cooperation agreement between the federal government and the regions with regard to administrative and scientific coordination for biosecurity issues. The federal government is responsible for most of the regulatory aspects

13 https://www.derstandard.at/story/2000001892982/oesterreich-setzt-sich-bei-gvo-anbauverbot-durch ; https://www.derstandard.at/story/2000009017990/gentechnik-anbauverbote-kuenftig-erlaubt

14 https://gmo.kormany.hu/download/2/4d/e0000/Dietmar%20Vybiral%20AT%20presentation%202nd%20day.pdf

15 https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:32015L0412 (accessed 20 July 2021). See Art. 26b of the Deliberate Release Directive as amended by the Opt-out Directive.

16 Cf. Greiter Anita, Miklau Marianne, Heissenberger Andreas, Gaugitsch Helmut (2011): Socio-Economic Aspects in the Assessment of GMOS-Options for Action. Vienna, Environment Agency Austria Report 0354, ISBN: 978-3-99004-157-4.

17 https://www.verbrauchergesundheit.gv.at/gentechnik/gentDescription.html (accessed 30 April 2021).

18 All documents, Royal Decrees, regulations, information on field trials etc. can be found on the official website https://www.biosafety.be/ (accessed 20 July 2021).

regarding GM products (e.g. GM food and feed), apart from GMO contained use and cultivation because traditional agriculture, including matters of seeds and plant propagation material, belongs to regional competences (CA4). Competence sharing offers the regions the power to decide on matters within the field of their competence.

Practically, this means that in case of comitology voting on EU-wide approval of a GMO for cultivation, the regions must be consulted and they can either express their position or propose solutions which needs to be considered by the federal government. If there are different opinions of the regions on a given dossier, the government must abstain in the voting.[19] This is relevant in the present case because the attitude toward GMOs, especially GMO cultivation, between the Belgian regions is contradictory resulting from very polarized public opinion in the North and the South (CA4). This polarization had been exemplified by the differentiated regional rules on coexistence already before the adoption of the EU 2015 reform, and later, by the fact that two Belgian regions, Brussels Capital region and Wallonia, have opted out from GMO cultivation using the opportunity of the 2015 reform, while the other, Flanders, has not. Following this disparity, the position of Belgium in the voting procedures on GMOs has been often mixed, both anti- and pro-GMOs. It usually voted either in favour or abstained, and only in 10% cases directly against (Mühlböck and Tosun 2018).

The *Flemish Region* takes a neutrally supportive stance: it is in favor of GMOs, providing they have been approved by EFSA, and where they have been shown to contribute to more profitable agricultural production. Rules on coexistence are laid out in the Decree of 3 April 2009, and also include a compensation mechanism. At the same time, the Brussels and Walloon regions have expressed unfavorable views of GMOs. This has led the *Walloon Region* to prohibit the cultivation of certain GM crops on its territory and adopt very strict coexistence rules that discourage the cultivation of GMOs. Wallonia also availed itself of the EU opt-out opportunity. The *Brussels Region* prohibits the open-air cultivation of GM crops on its territory altogether.[20]

Accordingly, Belgium supported the EU 2015 reform, because it allowed individual regions within Member States to invoke the opt outs from GMO cultivation. In that sense, the solution seemed suitable for a federal state as Belgium where diverging political viewpoints between the regions have created a complex landscape. In practice, however, the Walloon region has not changed its position on GMO authorizations after the 2015 Directive entered into force and they opted out. The reason for this was public opinion, opposed to GMOs, and the very strong support for the organic farming and food production there (CA4). When it comes to organic farming, 7 % of the Belgian agricultural surface area is organic, and 90.7 % of this dedicated organic area is in Wallonia, which also explains why the region has always banned GMO cultivation.[21]

There is no commercial GMO cultivation in Flanders either, but the region has not opted out because it strongly supports biotechnology research and field trials of GM potatoes have been carried out (now ended, CA4). The latter caused a widely-publicized case of damage caused by a group of activists organized by the *Field Liberation Movement* (civil action against GMOs in Belgium), which, alongside Greenpeace and Friends of the Earth, is very active in Belgium.[22] This marked the first very public case against GMOs, followed by the lawsuit (2011), and was covered by the media between

19 A similar situation can be observed in Germany, where, for example, Bavaria is an anti-GMO state and the federal government often abstains in the voting.

20 It was legally accepted already before the 2015 reform because the Brussels region does not include any agricultural areas so the cultivation rules do not anyway apply there (CA4).

21 https://statbel.fgov.be/en/themes/agriculture-fishery/organic-farming#:~:text=7%20%25%20of%20the%20Belgian%20agricultural%20surface%20area%20is%20organic&text=Between%202018%20and%202019%2C%20the,of%20the%20utilised%20agricultural%20area (accessed 20 July 2021)

22 https://aseed.net/patattenproces-voorwaardelijke-celstraffen-voor-het-rooien-van-illegale-ggo-aardappelen/; http://www.fieldliberation.org/en/courtcase/timeline/ (accessed 20 July 2021)

the years 2011-2014, where public concern over GMOs increased. It also confirmed the division of Belgian public opinion toward the use of modern biotechnology, including cultivation (Kuntz 2012).

7.3. Ireland

The Republic of Ireland has traditionally been perceived as a "green state", pursuing an anti-GMO policy (Weimer 2019). This is also declared by the Irish competent authorities who state that "Ireland has a policy to opt out of cultivation on its territories and to vote against cultivation more generally." (CA7). At the same time, Ireland has often changed its voting position in the EU-level procedures (Mühlböck and Tosun 2018). It voted in favor in 30% of cases and in 5% against, and in the remaining cases abstained (approx. 65%).

Powers in the area of agricultural biotechnology are exercised by the Ministry of Department of Communications, Climate Action and Environment, responsible for GMO decision making, approvals for cultivation, and EU regulatory affairs (risk management), while the Department of Agriculture, Food and the Marine is responsible for matters of food and security. They are supported by the Environmental Protection Agency (EPA).

Formally, the 2015 reform (The Opt-out Directive) was implemented in Ireland only in 2020 when the EU (Genetically Modified Organisms) (Restriction or Prohibition of Cultivation) Regulations 2020 were published.[23] The formal transposition of the EU 2015 GMO reform in Ireland was preceded by a legislative process and intense parliamentary debate, which suggests that the perception of Ireland as an anti-GMO state may not be completely unequivocal.[24] The adoption of the law, even though five years later than the Directive, was communicated by the Government as it was a specific success in approving wider restrictions on GMO cultivation. In line with the Directive, the act enabled, though did not compel, Ireland to opt out of cultivation of GMO crops if approved for cultivation in the EU. However, Ireland did not make use of the opt-out possibility in case of the already authorized MON810 varieties as did other EU Member States, although it does not cultivate GMOs.

The explanation for this may be two-fold. First, maize crops are generally not cultivated in Ireland.[25] Second, although the Irish Government finds it critically important to maintain GMO cultivation-free status in order to uphold its international reputation as a green, sustainable food producer,[26] it also intends to keep the policy on GMO cultivation under ongoing review under pressure from scientific experts who argue that the next generation of gene-edited crops offer the potential to cut climate emissions in agriculture and boost global food production.[27]

23 Statutory Instruments No. 216 of 2020; http://www.irishstatutebook.ie/eli/2020/si/216/made/en/print (accessed 20 July 2021)

24 https://www.oireachtas.ie/en/debates/question/2018-10-11/182/#pq_182 (accessed 20 July 2021)

25 Maize is not grown in Estonia, Ireland, Latvia, Cyprus and Malta. Source: M. Czułowska, Wybrane informacje statystyczne o zbożach przeznaczanych na pasze – w Polsce i w innych krajach Unii Europejskiej, IERiGŻ-PIB Warszawa, 05 marca 2021 roku, https://www.ierigz.waw.pl/download/24326-Wyniki_ze_zboz_2018-2020_Augustynska_Czulowska.pdf (accessed 27 July 2021).

26 https://www.irishtimes.com/news/environment/genetically-modified-organisms-restriction-proposal-for-cabinet-1.3559403; see also: https://www.independent.ie/business/farming/tillage/government-approves-wider-restrictions-on-the-cultivation-of-genetically-modified-organisms-gmos-in-ireland-37101720.html (accessed 20 July 2021)

27 https://www.agriland.ie/farming-news/governments-gmo-decision-a-grave-mistake-plant-scientists-warn/; https://www.irishtimes.com/news/science/ban-on-gm-crops-is-a-blight-on-irish-agriculture-1.3767996#:~:text=In%20July%202018%2C%20the%20Government,crops%20(GMO)%20in%20Ireland (accessed 20 July 2021)

7.4. Poland

Poland has been known for pursuing a strategy of GMO skepticism since it became an EU Member State (Dąbrowska-Kłosińska 2009). It voted against GMO approval proposals in over 90% cases, and in the remaining ones usually abstained (Mühlböck and Tosun 2018).

Similarly to Austria, Poland has made use both of the differentiation option available under the EU Treaty Art. 114 (earlier 95) in July 2006[28] and of safeguard clauses included in the secondary legislation. In March 2005, the Polish authorities first requested the introduction of a temporary two-year ban on the use and placing on the market of seed material from GM-corn MON 810 varieties based on a safeguard clause in the seed Directive.[29] After the unanimous favorable vote of the Member States in the regulatory committee, the Polish employment of safeguard clauses was accepted by the Commission.[30] It was still in force when Poland also requested the opt-out under the 2015 EU reform.

With regard to the institutional framework, pursuant to the Polish GMO Act, the Ministry of Environment is the governmental administrative authority competent for GMO contained use and deliberate release into the environment, including cultivation. In the latter case it shares the competence with the Ministry of Agriculture. The sectoral competences for GM food, feed and seeds are devolved to the Chief Sanitary Inspectorate and National Chief Veterinarian established within the Ministry of Health, and the Minister of Agriculture respectively.[31]

The reform was implemented in Poland through revision of the 2001 GMO Act. The Act now declares that Poland is free from GMO cultivation and regulates that this principle is carried out, inter alia, via national powers acknowledged in the Opt-out Directive.[32] Effectively, the premise of the legal regulation is that the Polish authorities will always apply for the cultivation opt out unless otherwise decided at the national level.[33] This regulatory solution reflects the attitudes of consumers and environmental NGOs who support organic farming and oppose the use of novel biotechnology.[34] Even if parts of the research and agricultural sector have a different view, these voices are overwhelmed by the majority and political position against GMOs. There is a lot of contained use research in Poland, but no released field trials at the moment.

Poland also declares that the use of GM feed is prohibited, but the effect of this rule is suspended. This is because the Polish agricultural sector, as in many other EU Member States, relies on GM

28 See the judgment in case T-69/08 Poland v. Commission lost by the Commission on procedural grounds.

29 Article 16(2), Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, OJ 2002 L 193/1. These varieties were inscribed in the Common Community Catalogue of agricultural plant species on 17 September 2004.

30 See Summary Record of the Meeting of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry, 09.03.04. and Commission Decision 2006/335/EC authorising the Republic of Poland to prohibit on its territory the use of 16 genetically modified varieties of maize with the genetic modification MON 810 listed in the Common catalogue of varieties of agricultural plant species, pursuant to Council Directive 2002/53/EC, OJ 2006 L 124/26; Commission Decision 2006/338/EC authorising the Republic of Poland to prohibit on its territory the use of certain varieties of maize listed in the Common catalogue of varieties of agricultural plant species, pursuant to Council Directive 2002/53/EC, OJ 2006 L 125/31

31 Art. 9 and ff, the Polish GMO Act.

32 http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20190000706/U/D20190706Lj.pdf.

33 See Ibidem, Art. 49a. (Non-authorized translation: 1. The Republic of Poland is GMO-free. 2. The provision of para. 1 is implemented by: 1) application of the minister responsible for the environment submitted for the purpose of exclusion of a given GMO from cultivation throughout the territory of the Republic of Poland, about which referred to in Art. 49b; 2) a regulation of the Council of Ministers prohibiting the cultivation of a given GMO on the territory of the Republic of Poland, referred to in art. 49c; 3) entry in the Register of GMO Crops, referred to in Art. 49e.).

34 https://biznes.wprost.pl/gospodarka/rolnictwo/10286155/polscy-konsumenci-nie-chca-produktow-z-gmo.html (accessed 24 July 2021).

feed imports, notwithstanding some recent initiatives to change the situation.[35] The strong influence of the agricultural lobby can also be seen in the final wording of the new law on product labelling. While advancing statutory requirements and clarifying rules on consumers information on GM food and feed, including GM-derived animal products (produced with or without use of GMOs) and non-GM plant products, this law also effectively liberalizes the ability of farmers to label products as non-GM. This is implemented through a complicated system of exemptions. The most significant are grace periods for the use of GM feed. Milk, meat or eggs can be labelled "non-GMO" even if the animal is fed with GMO feed during some periods, not directly preceding production. So, it is enough that the producer does not use such feed within a certain period of time prior to obtaining the product. It is also be possible to include this entry in the case of the use of genetically modified feed materials, so long as GMO-free feed materials were not available. The latter condition is unclear and subject to interpretation by the control authorities.[36]

7.5. Slovakia

There are no GM plants cultivated in the Slovak Republic at the moment although GM crops were cultivated in the country until 2017 (Ichim 2021). At the same time, Slovakia did not make use of the first opt-out opportunity available under the new EU 2015 regime to permanently exclude the cultivation of GM maize MON810 on its territory.

The Ministry of Environment of the Slovak Republic is the Competent Authority under Directive 2001/18. In the case of cultivation of GM plants in agricultural production, the Competent Authority is the Ministry of Agriculture and Rural Development which would be also entitled to propose restrictions or bans on cultivation under the new EU rules in the future, if there is a decision to do so (CA5). While the cultivation of GM crops had been supported in the past, the anti-GMO movement has recently grown stronger, both within political parties and NGOs, and started pressurizing the government to remove those plants from Slovakian territory.

For example, in December 2015, the political party OĽaNO accused the government that not using the first opt-out possibility under the EU reform of 2015 meant wasting a unique chance to limit or ban the cultivation of permitted GMO crops on its territory. Later, this party submitted a proposal for a bill to ban GM crops in Slovakia, which however failed to gain sufficient support. Starting in 2016, the civil society organization *Slovakia without GMOs* repeatedly called on the chairs of the responsible parties and the competent ministries for immediate implementation of the reformed EU rules, as well as the introduction of a ban on the cultivation of GM crops and the sale of GM seeds in Slovakia.

The Ministry of Agriculture declared that it met the requirement to ban the cultivation of GM crops already in 2016, and then in 2020, but effectively it was only in 2021 that the legislative changes formally transposing the Opt-out Directive into national law entered into force.**37** The new provisions enable the Slovak government to use the possibility of opt out following the reformed EU rules, but it does not prohibit the cultivation of GM crops as such.[38] In order to implement the declarations, a memorandum of cooperation with the Chairman of the Board of the Association of Feed Producers was signed on protein self-sufficiency, including a voluntary labelling scheme for food, feed, and

35 Porozumienie Rolnicze o paszach i GMO, 27.03.2019, https://www.gov.pl/web/rolnictwo/porozumienie-rolnicze-o-paszach-i-gmo (accessed 31 April 2021).

36 https://biznes.wprost.pl/gospodarka/rolnictwo/10286155/polscy-konsumenci-nie-chca-produktow-z-gmo.html; https://www.prawo.pl/biznes/zywnosc-bez-gmo-od-poczatku-2020-r-nowe-zasady-znakowania,497017.html (accessed 31 April 2021).

37 Zákon č. 140/2021 Z. z., ktorým sa mení a dopĺňa zákon č. 151/2002 Z. z. o používaní genetických technológií a geneticky modifikovaných organizmov v znení neskorších predpisov a ktorým sa mení a dopĺňa zákon č. 184/2006 Z. z. o pestovaní geneticky modifikovaných rastlín v poľnohospodárskej výrobe v znení zákona č. 78/2008 Z. z, Zbierka zákonov SR; 21/04/2021, https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2021/140/ (accessed 28 August 2021).

38 § 8a, Ibidem.

primary agricultural products produced without the use of GMOs. Further, a joint working group is planned to be established to implement this cooperation, which will coordinate and prepare activities to achieve the memorandum's goal and limit the use of GMOs in Slovakia.

7.6. Spain

Spain is the only EU Member State at present which grows GM crops commercially and supports their use. It has always been pro-GMO and never voted against proposals for GM product approvals: in over 75% cases it voted in favor and in the remaining proceedings abstained.

The legal regime for the confined use, voluntary release and commercialization of GMOs in Spain is based on Law 9/2003 of April 25.[39] This act was amended by the Royal Decree 364/2017 (17 April 2017) implementing the provisions of Directive 2015/412 into Spanish national law, and outlining measures to avoid cross-border contamination from the cultivation of GMOs to neighboring Member States where cultivation of GMOs is prohibited.[40]

The Inter-Ministerial Council of Genetically Modified Organisms (CIOMG) is a collegiate body of the central administration competent to grant all authorizations for the commercialization of GMOs or products that contain them, tests of voluntary releases required within the authorization process for commercialization, and those related to the import and export of GMOs. It is also up to the CIOMG to authorize the contained use and voluntary release of GMOs when they are to be incorporated into drugs for human and veterinary use, in addition to the releases that are carried out within the framework of national research programs and those related to the examination technician for registration in the register of commercial varieties.

The CIOMG is supported by the National Biosafety Commission, an advisory body whose function is to report on the authorization requests (risk assessments) submitted to the general state administration and to the Autonomous Communities on genetically modified entities (contained use, voluntary release, and commercialization). This Commission is affiliated with the Ministry for the Ecological Transition and the Demographic Challenge, and is composed of representatives of the different ministries involved and representatives of the Autonomous Communities, as well as experts and institutions relevant in the field.

Although Spanish farmers and the government support GM crops, both Greenpeace (*Greenpeace España*) and Friends of the Earth (*Amigos de la Tierra*) are also very active in Spain, campaigning to ban the use and growth of GMOs. The public civil movement called *"No quiero los Transgénicos"* (I don't want GM food and crops) rallies every single year since 2010, campaigning for GMO-free food and agricultural sector. Further, four regions have declared themselves GMO-free – Asturias, the Basque Country, the Balearic Islands and the Canary Islands (though this does not affect the EU-level voting position of the central government). Growing consumer concerns over GM products force the government to keep the issue of reducing the GMO cultivation on the agenda, because those who want to buy organic food need to pay more for the imported product as there is very little organic farming in Spain.[41]

39 https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/comision-naciona-bioseguridad/ (accessed 28 August 2021).

40 Real Decreto 364/2017, de 17 de abril, por el que se modifica el Reglamento general para el desarrollo y ejecución de la Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente, aprobado mediante Real Decreto 178/2004, de 30 de enero, Boletín Oficial del Estado (B.O.E); Nr 92/2017; 18/04/2017; 30357-30359.

41 https://www.france24.com/en/europe/20200210-talking-europe-to-ban-or-not-to-ban-what-future-for-pesticides-and-gmos-in-the-eu-spain (accessed 28 August 2021).

At the same time, it is highly unlikely that GM products will disappear from Spanish agriculture in the near future, as it is reported that they bring benefits to the farmers, such as reduction of the use of insecticides, income growth due to increase of harvested amounts of crops, and extra production, which contributes to reducing pressure on farmers to use additional land for crop production, (Brookes 2019). It is also claimed that in some regions, such as Catalonia, GMOs are vital for saving farming because they have reduced insects up to 80%. Given those benefits, it seems likely that Spain will continue to support GM cultivation in the future.

8. DI in Action: The Impact of the 2015 Reform on the Accommodation of Diversity

8.1. Impact of the Reform on the Functioning of the Internal Market

As a result of the 2015 reform, the Internal Market in the EU for cultivation of GMOs is territorially differentiated between the Member States through the introduction of the "atypical DI" creating the "legal oxymoron" (see section 6.2. above).

Normatively, the reform resulted in the territorial adjustment of authorizations preexisting the reform (Art. 26c of the Deliberate Release Directive). This concerned principally GM maize MON810 currently approved for cultivation in the EU. Functionally, it results in the disapplication of the free market clause (Art. 23) and introduces the optional/alternative harmonization in the area of commercial releases of GM products into the environment for cultivation, because it effectively allows for 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). (Importantly, de-harmonization is not consistent because all Member States still vote on product authorizations, see sections 6.2. above and 8.2. below).

Looking specifically at the example of the six investigated Member States, the picture is as follows. Those Member States which oppose GM crops did legally ban their cultivation by invoking opt outs (e.g. Austria, Poland) and changing national regulatory frameworks, which sometimes even contain and explicit clauses prohibiting GMO cultivation (e.g. Poland). Second, Member States which cultivate GM plants continue to do so (Spain). Third, the solution provided by the Opt-out Directive also offered normative and political flexibility for Member States with conflicting goals in national politics. It was attractive for those who do not exclude cultivation in the future because the GM product currently approved in the EU could theoretically be grown in their territory, although currently the national public effectively opposes this type of product (e.g. Slovakia – no opt out, but communication of coexistence legislation to the Commission). It was also attractive for federal states where there are different regional attitudes toward the issue and regions could act in their own capacity (e.g. Belgium). In that sense, the reform formally realized the aim of legalizing space for differentiation of national positions toward biotechnological agriculture.

It can also be said that DI (in the form of the 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 (Weimer 2019:9 and 167; Dąbrowska-Kłosińska 2020). That situation had distorted the very *rationale* of law: safeguard clauses and emergency measures were employed by national authorities as preventive mechanisms for differentiation, and thus, outside their original purpose of rapid response to disaster situations (e.g., poisonous and/or unauthorized seed/food products entering the EU supply chains, Hristova 2013: 117; cf. Weimer and Vos 2015). Member States usually supported these practices although they were aware of their significance. ("No Member State which had adopted a so-called safeguard clauses had ever been in a position to put forward new evidence", CA7). The Directive thus responded to the reality on the ground because now it would be very difficult, if not impossible, to provide new evidence with regard to GM products containing the contested *cry1* modification because the research studies focusing on the aspect ended long ago and the publications are out-of-date (CA1). Accordingly, the addition of the

so-called "non-scientific grounds" to Art. 26.3b (Deliberate Release Directive, *"measures restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by crop or trait"*) may be said to have referred to national practice which had already occurred before the adoption of the reform (CA7).

At the same time, interviews with competent authorities indicate that the functioning of the opt-out reform in practice has been a success for GMO adversaries, favoring those Member States who oppose cultivation (CA2, CA6) and "satisfied only their wishes" (CA5). This is because Member States against GMO cultivation 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) which equals potential exclusion of GM crops from the entire EU territory. In those cases, the Commission takes final decisions following comitology rules, but is not happy to act against the will of (often) a majority of Member States (see also section 8.2. below). In effect, Member States who do want to cultivate GMOs remain unable to do so if negative (or no-opinion) voting occurs in the comitology committee and blocks approval at the EU level.

Consequently, the reform thus created an asymmetry between Member States opposing and supporting GMO cultivation, effectively beneficial only to the former. The 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, although cross-border contamination of GM and non-GM plants has not been an issue until now (according to committee minutes).[42] Further, the reform led to a *de facto* "reversal" of the original Internal Market paradigm for GMO cultivation (free market) through the opt-out system leading to the market differentiation where no cultivation of GMOs becomes the rule, rather than the exception. At the same time, it did not lead to any particular problems regarding the actual functioning of the Internal Market for GMOs and GM seeds because of low interdependence of agricultural biotechnology in EU.

In fact, the number of EU countries cultivating GM crops has recently been shrinking. Since 2015, farmers from Romania (in 2015), Czech Republic and Slovakia (in 2017), have voluntarily stopped commercial cultivation of GM crops (Ichim 2020), although the relation between this development and the Opt-out Directive as such is unclear. The result of this process is nevertheless that actual GMO commercial cultivation areas is also asymmetrically shared between Member States because GM crops are only grown in Spain.

In short, consideration of the impact of the DI reform on the functioning of the Internal Market for GMO cultivation prompts the following observation. The Opt-out Directive legalized national-level diversity within the GMO normative framework, but led to an apparent reversal of the basic paradigm (free market vs exceptions). Further, at present (2021), the market features two asymmetries of integration: 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. Thus, an effective impact of the DI reform on the accommodation of diversity within the Internal Market cannot be claimed. Let us now turn to the second aspect, that is the functioning of the comitology committee, because the renationalization of competences on GM cultivation is still linked to the EU-level decision-making process.

42 This was an issue within states because of research field trials, see e.g. judgment in C-442/09 Bablok and Others v. Freistaat Bayern.

8.2. Impact of the Reform on the Functioning of the GMO Approvals through Comitology Voting

Following the adoption of the 2015 reform, voting on GM products for cultivation occurred on 27th January 2017 in the Regulatory Committee and on 27th March 2017 in the Appeal Committee respectively. These votes concerned three GM maize seeds products: Bt11 maize and 1507 maize (EU authorizations for cultivation for the first time) and the MON810 maize (EU authorization renewal). In all six cases each voting procedure resulted in a no opinion vote, that is no qualified majority either for or against the products.

The proposals for these products' authorizations had been preceded by "thorough"/"considerable" discussions between the Commission, national CAs and the representatives of EFSA during the Regulatory Committee for the DRD and Standing Committee FCAH meetings in July, October and December 2016.[43] The draft proposals were updated in light of discussions which covered legal, practical, and technical aspects, scientific comments and questions from the Member States, clarifications from the EFSA, as well as economic aspects of coexistence and isolation distances for GM and non-GM crops. The summary records of the committees' meetings indicate that a process of mutual exchange of views and attempts at consensus-building debate took place between EU and national officials. All three proposals for approval decisions included the demands of nineteen Member States to exclude all or part of their territory from the cultivation of these three GMOs, pursuant to the provisions of the Opt-out Directive,[44] and regular revisions of their texts in light of discussions.

However, contrary to expectations of both some national and EU officials and the analyses of academic community (cf. e.g. Weimer 2019; Salvini 2016) that Member States opposing GMO cultivation would modify their positions following the discussion and revisions as well as the 2015 reform, this did not happen.[45] As usual, when the proposals were finally submitted for formal votes in January 2017, the qualified majority threshold was not met. Some Member States seemed to be frustrated by that fact. The Czech Republic annexed a written statement to the voting report explaining that its positions differed in the three voting cases due *"to lack of the consensus among the Member States at this stage"*.[46]

Some other Member States also followed different patterns. For example, Sweden, which had generally voted in favor of GM products, or abstained in the years 2004-14, especially, in case of non-cultivation GM food and feed products (Mühlböck and Tosun 2018), voted against all three GMOs for cultivation due to their product characteristics (both GM maize 1507 and Bt11 feature insect resistance and tolerance to the herbicides glyphosate and glufosinate ammonium). Although Sweden did not make use of the 2015 Directive opt-out clause as GM maize would not be grown in Sweden because of objective environmental/agricultural conditions, it declared "it must vote no".[47]

43 See Regulatory Committee under Directive 2001/18 and SCFCAH, Summary records of joint meetings, 8 July 2016, sante.ddg2.g.5(2016)4037470, point C.01; 14 October 2016, sante.ddg2.g.5(2016)6548835, point C.03; 9 December 2016, sante.ddg2.g.5(2016)7652201, point C.03.

44 Summary Report of the joint meeting of the Standing Committee on Plants, Animals, Food and Feed (Genetically Modified Food And Feed And Environmental Risk) and the Regulatory Committee Under Directive 2001/18/EC, 8 July 2016, point C.01.

45 Summary Report of the Joint Meeting, Standing Committee on Plants, Animals, Food and Feed section Genetically Modified Food and Feed and Environmental Risk, and Regulatory Committee Under Directive 2001/18/EC, 27 Jan 2017, sante.ddg2.g.5(2017)637128; Summary Report of the Appeal Committee Genetically Modified Food and Feed Regulatory Committee 2001/18/EC, 27 March 2017, sante.ddg2.g.5(2017)2073649.

46 Ibidem, point B.03 (" (…) let me to explain that the positions differed due to lack of consensus among the Competent Authorities at this stage. Therefore the Czech Republic voted in favor in the case of MON810 (under Regulation 1829/2003) and abstained as regards GM maize 1507 and Bt11 (under Directive 2001/18/EC).")

47 Ibidem, points B.02-B.03.

Finally, the remaining Member States justified their positions by the following (known) arguments (*"No agreed national position, Negative public opinion, Political reasons, Risk of harm to the national agri-food industry, Uncertainties in risk assessment, Safety concerns for the environment, Potential risks for the environment and health due to tolerance of maize Bt11 and 1507 to glufosinate ammonium, Precautionary principle, and Lack of comprehensive data on long-term potential impact of GMOs)"*).[48]

Knowing that a large majority of Member States are opposed,[49] until the time of writing (January 2022) the Commission has not taken any final decision regarding the approval of those products. Consequently, the status of those products on the EU Internal Market is based on a *de facto* pending procedure. Following those voting procedures and until now, there have also been no further proposals for authorization of GMO cultivation of other products. This situation is exactly the same as the past practice of the Commission and comitology decision-making's lack of sufficient democratic legitimacy which had led to the reform (see broadly Weimer 2019; for earlier accounts, Geelhoed 2014; Dąbrowska-Kłosińska 2014, 2010).

During the researched period between the enactment of the 2015 Directive and mid-2021, the comitology voting records do not show any change in gridlock on GMO approvals. The voting proceedings continuously resulted in the impossibility of reaching a qualified majority either at Regulatory Committee or Appeal Committee level (no opinion outcome). The only case when a state tried to modify its voting position after the adoption of the 2015 reform was Italy who voted in favor of one of GM products for cultivation at the Regulatory Committee level, but in the Appeal Committee changed their voting position again (CA4). Although it did happen that some Member States change their voting positions in some cases (voting either in favor or against), the relationship between such changes and the 2015 DI reform is hard to establish.

This is further confirmed by the fact that some Member States vote against or abstain also in case of GMOs (like GM maize MON810) which would not be cultivated on their territories because of either climate or geographical conditions (e.g. Sweden). Member States admit that receiving political instructions regarding their voting position from their top officials/ministries (politicization) affects the quality of deliberation and the ability to build positions out of discussions and reach a definite consensus. As one of the national officials put it: "Sometimes a lot of Member States don't take part in the debate because they already know their position in advance. Why do a lot of work to improve a document if at the end, they will say no?" (CA4).

At the same time, if discussions take place, several substantive issues create additional difficulties in finding a consensus. Some Member States mention that the level of acceptable risk is an issue when scientific details of products' files are discussed (CA4). Some officials reflect that there are different cultures of risk governance between Member States, because some in their laws take only scientific risk assessments into account, while others include public opinion and socio-economic impacts. Further, positions against GMOs seem to be frozen because of political stances on GMO cultivation and national interests. For example, in one comitology debate, some Member States opposing GMO approval indicated that their position against cultivation would not change even if bigger isolation distances for coexistence were secured to avoid GM contamination. In the same procedure, pro-GMO Member States declared withdrawal of their support for approval if agreed distances were increased, because those additional meters would increase costs.[50]

48 Ibidem, points: B.01-B.03; and 1-3, respectively.

49 With 16 Member states opposing maize Bt11 and 1507, and only 6 member states voting in favour (with 14 against and 8 in favour of maize Mon 810), https://www.greens-efa.eu/en/article/news/gm-maize-for-cultivation

50 Regulatory Committee under Directive 2001/18 and SCFCAH, Summary record of the joint meeting, 9 December 2016, Sante. ddg2.g.5(2016)7652201.

In other voting procedures in the Regulatory Committee under the Deliberate Release Directive concerning no-cultivation use of GM products, voting patterns show similar effects. After 2015, there have been several proceedings under consideration of GM carnation flowers originating from applications filed with the Dutch competent authority (based on committee minutes).[51] In 2015, there were two applications where few Member States raised objections, but no QM opinion was reached in comitology. In 2017 and 2019, only one Member State raised objections triggering the EU-level procedure, but no QM opinion was reached in comitology, which means that some countries voted against or abstained although they had not raised objections earlier.

Comitology proceedings indicate that Member States did not support the authorization of those products (cut flowers) because the risk that someone would try to cultivate them could not be excluded.[52] Theoretically, it is possible that some Member States changed their opinion on those products in the course of committee deliberations, but the explanation that they did so because a (politically sensitive) cultivation issue was on the agenda is more probable. Effectively, Member States knowing that the Commission will take the final decision can vote according to their domestic political agendas. Given that there are several GM carnations already placed on the EU market, which can circulate freely, opposing marketing approval based on risk of cultivation has effect only an illusory symbolic effect.

In 2017 and 2019 there were also two product renewal procedures on GM carnations, cut flowers, already placed on the EU market, in which Member States did not raise objections (NL as consent-granting authority). When those products were originally placed on the market in 2009, few Member States raised objections, and there was a no opinion vote in the comitology procedure.

In sum, the practice of decision making is still problematic, notably for political reasons (CA6). The analyzed cases demonstrate clearly that the regulatory impasse in comitology voting proceedings has persisted, where procedural rules designate the Commission as the final EU-level decision-maker when committees do not express their opinion. Moreover, the voting positions do not (always) seem to relate to the subject matter at issue, and sometimes do not reflect committee deliberation between mid-level officials (CA representatives in the committees) on their merits.

Accordingly, consideration of the impact of the DI reform on the comitology voting pattern needs to begin by observing that its promise of accommodating diversity through enhanced deliberation between Member States has not been fulfilled. All interviewed competent authorities agree that the ability of Member States opposing GMOs to invoke opt outs from cultivation has not changed their voting positions in the committee and has not translated into an improvement of the decision-making process (CA1; CA2; CA4-CA7). The interviewed national CAs have confirmed that they receive instructions how to vote from national ministries and consequently the voting positions become politicized. The interviews with national CA representatives indicate that voting positions do not relate to the possibility of opting out on the Internal Market because they are rooted in internal political opinions, national politics, power-sharing and institutional structures (“The problem is political”; “fixed pre-voting positions”).

As a result, EFSA’s risk assessment becomes separated from the decision-making process to some extent because of political positions not referring to it (CA6). Further, it is clear though that the discussions at EU level in the committees about GM products and their cultivation refer not only

51 Formally, in case of the Deliberate Release Directive, it is a national competent authority who either issues or refuses a national-level consent for marketing authorization after the EU level procedure has been finalized by the decision (following comitology opinion or the Commission decision, see section 3 above). See e.g. Recital 5 of the Preamble to the Commission Implementing Decision (EU) 2019/1300 of 26 July 2019 as regards the placing on the market of a genetically modified carnation (Dianthus caryophyllus L., line FLO-40685-2) OJ L 204/46.

52 See Summary Report of the Regulatory Committee under Directive 2001/18/EC, 16 March 2015, sante.ddg2.g.dir(2015)1417034.

to science, but also to various considerations relating to national circumstances, including socio-economic impacts. This is however not reflected in the final decisions.

In light of the above, it is not possible to observe any positive impact of the DI reform on the changing of the voting positions of individual states in comitology and/or facilitation of deliberative problem-solving which could improve democratic legitimacy of decision-making on GMO cultivation. The functional accommodation of diversity of national preferences toward GMO cultivation (either for or against GMOs) which had been expected to allow national CAs to modify pre-determined voting positions of Member States toward a more deliberative/consensual process of decision-making has not materialized.

8.3. Summary of the Findings on DI Functioning

The GMO case study shows that DI, in the sense of returning decision-making powers to Member States, has not resulted in accommodation of diversity either through the lens of the functioning of the internal market at the national level or through that of problem-solving in comitology. The Opt-out Directive has not brought about any change because the problem is political (CA4). It does not really matter whether the functional interdependence between Member States is weak (as in the case of cultivation), or stronger (as in the case of non-cultivation use of GMOs for decorative purposes).

Further, while DI can be said to have addressed the problem of legality of national bans, it did not diminish politicization and the risk of sacrificing common objectives, such as the integrity of the internal market. It appears that the reform led to the *de facto* reversal of the free market paradigm and 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, the objectives of the 2015 reform have not been achieved.

It is also important to observe that this case study shows that accommodation of diversity through differentiation at the national level (Internal Market functioning) 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. DI effects are 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).

Further, DI did not address institutional and regulatory features of the GMO regime, namely comitology procedural rules and the fact that most voting procedures now take place under the Regulation for GM Food and Feed, either on combined files for products' feed/food use and processing or files combining use and processing of several GM events. As a result, DI could occur only for cultivation, leading to a limited effect of weak interdependence in this field, as opposed to high interdependence for GM feed.

Finally, the 2015 reform did not take into account the complexities of the national regulatory conditions relevant for the voting position of a national government: power-sharing resulting from division of competences in GMO matters between various ministries and regions (federal states), different cultures of risk assessment between national authorities, concepts of sustainability, ethical/cultural concerns, national-level public opinion, and the structure of agriculture. Objectively not all of these factors could easily be taken into account, but it could have been predicted, for example, which states would always abstain, e.g. Belgium, Germany, and what is their voting power within QMV.

It is also noteworthy that none of the interviewed authorities indicated that their national public is very concerned with the functioning of the EU internal market as such. Public views are mostly limited to matters directly relevant to their own territory and there is no concern for sincere cooperation and/or solidarity in GMO cultivation matters between Member States, which need to agree on a given

file and/or regional positions. While it is known from Eurobarometer surveys that a large majority of Europeans oppose GMOs, national public opinion within Member States is also often polarized (cf. Roger 2015: 272). Yet, although individual Member States "no" and/or "abstain" positions in comitology voting are often justified by their public views (opposing GMOs), there seems to be no explicit feeding back of the merits and diversity of public views into committee deliberations.

To conclude, in light of the preceding analysis, it is difficult to maintain that DI fostered accommodation of diversity in the GMO regime.

9. GMO Policy in the EU beyond DI: Implications for Other Regulatory Approaches

9.1. False assumptions?

The analysis of the GMO regime after the reform of 2015 and the impact of the Opt-out Directive (sections 6-8 above) prompts the conclusion that DI's potential success was based on some false premises and assumptions .

First, clearly, due to the atypical nature of DI in the GMO domain, this did not bring any of the expected impacts. There has been a mismatch betwen the DI reform, the de-harmonization and renationalization of EU powers *and* the process of decision making on GMO authorizations through comitology. That is, the Opt-out Directive returned the competence for cultivation/non-cultivation of GMOs to the national level, but it maintained the approval procedures and QM voting at the EU level which eventually favors those who are opposed to modern biotechnology. From a DI perspective, it also reinforces the asymmetry between the Member States.

Second, the DI reform process did not address clearly enough the fear of anti-GMO states that their support for any product approval (even if they opt out from its cultivation) would in the long term encourage more GM cultivation in the EU. For example, already during the legislative process of the Opt-out Directive, Luxembourg's Environment Minister Carole Dieschbourg expressed concern that the reform could lead to a new "wave of approvals of GM plants".[53] This statement additionally explains some states' continuous abstentions and/or negative vote – even after the DI 2015 reform acceptance – in the GMO authorization procedures at EU level.

Third, 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 (for example Belgium, but also Germany). These will always abstain in voting when an issue cannot be agreed uniformly at the national level. 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.

9.2. DI in relation to XG and UI

When we consider the relationship between the DI 2015 reform and experimentalist governance in the GMO regime, the following can be said.

DI did not respond to problems of other regulatory approaches apparently not working in the GMO regime (see section 5 above). A possible explanation for this might be that DI reform has not (or could have not) fully and adequately addressed institutional obstacles to deliberation in the GMO regime (linked to procedural rules and institutional behavior) as well as not tackling issues at national levels causing GM controversies and influencing individual states' voting positions.

53 Cited after: Global Agriculture, "EU vote could give biotech companies a say on GMO bans", 12.06.2014, https://www.globalagriculture.org/whats-new/news/en/29283.html (accessed 17 November 2021).

Although Member States usually vote yes/no/abstain due to national conditions, there seem to be no working mechanisms in this policy domain that would effectively feed back to the EU decision-making level, *specifically, on product market access via approvals*, and prompt comparative learning/problem solving through sharing of *knowledge* and *experience* about national politics, public opinion, and other conditions affecting voting positions. Where these mechanisms exist (e.g. networks in the GMO regime, comitology committees), it seems that they are not fully exploited. The only channel which reflects directly national situations is a given voting position of an individual state, but voting processes (on GM authorizations) as such do not (sufficiently) lead to argument-based problem solving.

At the same time, all interviews conducted for the purposes of the present paper confirmed that national CAs are generally satisfied with the functioning of the comitology committee for everyday policy making, especially when it comes to managing risks through *detecting of non-authorized products, withdrawal from the market of non-authorized products, and managing coexistence* (cf. Dąbrowska-Kłosińska 2015). For example, the most recent case where effective collaboration of national authorities through the comitology committee occurred concerned detection and withdrawal from the EU market of non-authorized GM flower plants: petunias (CA1).[54]

Further, there is a general perception among the interviewed authorities that the comitology committee provides 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 (CA1-CA2, CA4-CA6). In all policy areas, apart from product approvals, decisions are taken by consensus. In that sense, at least to some extent, an XG mode exists in parallel to politicization and DI reform. Some national officials even admit they would probably be able to find consensus also on product authorizations without political instructions coming from their governments and if issues were to be decided solely among experts. It is however impossible to hypothesize within the limits of this paper whether this type of technocracy would actually work better for GM product approvals.

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). But those 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.

For example, as compared to comitology itself, the evaluation of horizontal cooperation between the comitology committee composed of national CAs, on the one side, and EFSA and JRC-ENGL, on the other side, is more mixed. This is assessed either as a formal institutional relationship reduced to the mutual notification of issues or exchange of information (CA5); or, on the other side, as an adequate forum of meetings for exchange of opinions (CA6) and collaboration via technical working groups focusing on practical implementation issues, e.g. Recommendation 2004/787 on sampling, testing and detection of GM material presence in seeds, and status of new plant breeding techniques (CA7). This cooperation is perceived as "good" in the sense of EFSA's willingness to explain their views and openness to discuss the risk assessment, but not in terms of their willingness to modify their position as a result of exchanges with the Member State authorities (CA4). In that context, it noteworthy that some interviewed officials suggested that the focus on risk assessment in policy implementation is much needed through exchange of practices and working on these practices,

54 See also Summary report of the Regulatory Committee under Directive 2001/18/EC, Brussels, 26 April 2017, sante.ddg2.g.5(2017)2901410, point M.01; Summary report of the Regulatory Committee on Directive 2001/18/EC, Brussels, 13 October 2017, sante.ddg2.g.5(2017)6137269, point A.01; and https://www.verbrauchergesundheit.gv.at/gentechnik/gentechnisch_veraenderte_petunien_information_fuer_haendler..pdf?722kzg (accessed 18 November 2021).

but not in terms of further harmonization and extension of UI. When asked, national authorities also state that further uniformity and/or harmonization of, for example, coexistence measures would not be helpful (CA5; CA7).

The 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 twenty years old and contains outdated definitions with regard to new plant breeding techniques like mutagenesis and other gene-editing methods (also named New Genomic Techniques, NGTs). This has been confirmed by national authorities (CA4, CA6) and the recently published report of the European Commission (Commission 2021) that a new framework for NPBTs/NGTs is urgently needed (see also next section). Yet, it is unclear what pathway and regulatory approach such a reform should follow.

To sum up the reflections about the relation between differentiated integration and other regulatory approaches, 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. As a matter of fact, the failure of DI may lead to further reform of harmonized regulation in view of the need to create a better new framework, while it may also trigger an intensified form of XG (see section 9.4), but those processes are happening simultaneously and cannot be viewed as a cause-effect relation.

It further appears that the DI reform did not work in part because the reform of comitology regulation and its procedural rules (UI), which should have been adopted in parallel has also failed (the proposal is still in the pipeline); and arguably also due to the fact that the opportunity to use experimentalist comparison of national and local experiences was missed in case of NPBTs.

9.3. New Plant Breeding Techniques and a missed opportunity for XG

Back in 2001, when the Deliberate Release Directive 2001/18 was adopted, gene-editing techniques were not yet being applied to agricultural organisms. The new gene-editing technologies (so-called NGTs/NPBTs) were first discussed in the GMO comitology committee as early as 2006/2007 at the request of national authorities (CA1-CA2). Member States, based on their experience with national companies/research institutes, considered it crucial to debate regulatory issues in a manner prescient to potential market effects, although the CRISPR/Cas9 system was first described only in 2012 (GCSA 2018; Asquer and Krachkovskaya 2021).

Those novel developments were usually discussed in joint comitology committee where the committees for the GM Food and Feed and Deliberate Release Directives meet together. At the demand of the Member States and given the importance of the issue for the application of the EU GMO regime, a Working Group within this committee was then established in 2007 to come up with some proposals for the Commission. The representatives of the Member States, feeding in their national-level knowledge and experience, prepared a report in 2011. This report included a non-exhaustive list of new techniques which may fall within the scope of the Deliberate Release Directive. At that time, it was uncertain whether and which technologies were to be covered by the scope of the Directive (EU harmonized rules) and the Working Group made specific recommendations. The Commission has not taken any action following this report and repeated requests from some Member States within the committee. The report might have been followed by an intensification of discussions about possible solutions with competent authorities and comparative learning and revisability process resembling XG.

In fact, Member States have been trying for years to push the Commission to take action leading to changes in the EU Deliberate Release Directive regarding NPBTs. This pressure has recently intensified given growing application of techniques such as mutagenesis. At almost every committee meeting post-2015, there has been a question from some national competent authorities (not

specified) to the Commission what action is being undertaken, but the latter was not responsive and closed off any debate on the issue.

As observed above, no EU action had been taken following national requests, and until 2018 when the EU Court of Justice interpreted GMO provisions, the legislation and regulatory environment in Member States was diverse. Some Member States (e.g. Austria) have always believed that NPBTs should be covered by the EU regulatory framework and risk assessment/authorization procedures. Others (e.g. Belgium, France, the Scandinavian states) have followed the opinions of national risk assessment bodies, and had not considered products of a mutagenesis technique as falling within the scope of the Deliberate Release Directive and requiring authorization. A more liberal position of some states toward NPBTs may arguably be linked to national funding already invested in research, and the resulting acquired IP rights of national companies.

Following a preliminary ruling request from the French Conseil d'État, the CJEU was asked to determine whether organisms obtained by mutagenesis should be considered GMOs and are exempt according to the provisions of the GMO Directive. In particular, the Court was asked to determine whether organisms obtained by new directed mutagenesis techniques are exempt from the obligations imposed by the GMO Directive, like those obtained by conventional, random mutagenesis techniques that existed before the adoption of the Directive, or are regulated like those obtained by established techniques of genetic modification (ETGM). The Court declared that organisms produced by directed mutagenesis techniques/methods should be considered GMOs within the meaning of the Directive and subject to the relevant requirements.[55]

The background to the Court ruling was an action brought before the French Conseil d'État by the French agricultural union *Confédération Paysanne* together with eight other associations. This action contested the French legislation according to which organisms obtained by mutagenesis were not, in principle, considered as being the result of genetic modification, and asked for a ban on the cultivation and marketing of herbicide-tolerant oilseed rape varieties obtained by mutagenesis. The claimants argued that such herbicide-resistant seed varieties pose a risk to the environment and health.

As a result of the 2018 ruling – and unless the Deliberate Release Directive is revised – NPBTs including all forms of mutagenesis, are now covered by the regulatory requirements of the Directive, including the risk assessment and authorization procedure.

National CAs suggest that "scientists" (the research sector) were "not happy with the judgment" (CA4) fearing that it would reduce the competitiveness of the EU. Some Member States feel that it would be good to have a broader debate on scientific and other aspects of those techniques with the broader public (CA4). The judgment has also created a lot of practical policy issues that need to be dealt with: enforceability of regulation and its material scope as well as sampling and detection of gene-edited products. The latter especially – until now – has not been possible using a method that could be verified through ENGL network, and discussions have been taking place between the Commission, Member States, EFSA representatives and ENGL-JRC representatives in the comitology forum how to proceed.[56] The new CJEU case law on the referral from French Conseil d'État is also ongoing.[57] Given that it is practically impossible to distinguish between either plants produced by conventional mutagenesis and natural mutation or new mutagenesis techniques, the

55 C-528/16 *Confédération paysanne* et al. v. Premier minister et Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt, ECLI:EU:C:2018:583.

56 See e.g. Summary Report of the meeting of the Regulatory Committee 2001/18/EC, 12 November 2020, sante.ddg2.g.5(2020)8307144; and Summary Report of the meeting of the Regulatory Committee under Directive 2001/18/EC, 25 November 2021, sante.ddg2.g.5(2021)8935640.

57 C-688/21, Request for a preliminary ruling from the Conseil d'État (France) lodged on 17 November 2021 – *Confédération paysanne* and Others v Premier minister, Ministre de l'Agriculture et de l'Alimentation.

requirement to provide a detection method pursuant to the law as it stands and in light of the CJEU ruling has not been not enforceable since then (CA7).

Accordingly, an effective regulation of NPBTs would require an investment of huge sums of money in detection protocols, if it would be possible at all. Otherwise, it is impossible to fulfil the requirements of the present regulatory framework, especially in agriculture and cultivation. It can also be considered a market access barrier for crops resulting from the new techniques, as the requirement of indication of the method/technique by which a given variety has been bred was introduced (CA5). The 2018 CJEU judgment thus created a destabilization effect. The ruling forced the Commission to take action (although formally this was requested by the Council) and obliged all Member States to get involved in a detailed and comprehensive consultation process on national experience because the regulatory framework had become unenforceable. The consultation (detailed questionnaire sent to all national CAS) resulted in the publication of a report by the Commission in spring of 2021 (European Commission 2021). The wording of this report is surprisingly vague – although it states the need for revisions of the regulatory framework – and it remains to be seen what policy changes if any will follow. In the meantime, however, EU GMO regulation remains effectively unenforceable in relation to products derived from NPBTs, because although these products are covered by the regulation, they cannot be detected, as required by the Traceability Regulation.

9.4. In search of better solutions

Finally, it is clear that neither uniformity of rules and hierarchically imposed solutions nor DI have led to satisfactory results in the GMO domain. The voting impasse on GM product approvals continues, while in addition there is an urgent need for revision of the scope of application of rules with regard to NPBTs.

When asked for their opinion, national CAs suggested several possible ways out of this impasse, including: (i) mediation exercises where both sides need to outline their points, including “no goes” and points where they could offer some room for maneuver, and then work through them to see which points can in fact be discussed; (ii) opening the debate with the public both at the EU and national levels. It is also clear that “public participation” in GMO approval procedures needs to be re-designed in a more engaging way because at the moment it is just a formal consultation exercise, whose results are not recognized in the authorization process. Both national and EU-level experience show that granting a possibility to comment or offering “consultations” is often not sufficient, especially when those comments are not taken into account in the decision-making process itself (CA4, CA2; Dąbrowska-Kłosińska 2007). Interviewees also admitted that the system is “tired” and it is not clear what approach should be followed.

Arguably, the failure of DI in its present form and the inadequacy of UI (currently applicable rules) 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 (cf. Hristova 2013: 121-123; European Commission 2011b).

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 justifications (and consequently the interpretation of the CJEU, see section 9.3. above). It would also respond to the concerns of national public, including against NPBTs, in

some Member States where members of the public seem to prefer strict regulation of new gene-editing techniques. The Commission has just received over 70894 comments on its position paper on NPBTs (European Commission 2021) as feedback under the Impact Assessment process.[58]

Such effective de-harmonization and return to full negative integration in the area of GMO cultivation could paradoxically generate increased cooperation between Member States through comparative exchange of practices and knowledge of national risk assessment and cultivation, leading in turn to more trust, better-informed deliberation at EU level, and (possibly) learning and spillover effects of cultivation/non-cultivation. It could also mean a more extensive employment of XG, following disentrenchment of Member States' frozen practice in comitology voting.

In that context, it is noteworthy that the practice of mutual recognition of national risk assessment files is not entirely unknown in the GMO regime for commercial releases. In two cases of first authorizations through the EU-level procedure for GM carnation flowers (2016 and 2019), only one Member State maintained objections against the Dutch risk assessment following exchange of comments, mediation of objections of other countries, and EFSA's opinion. Yet, this did not change politicized national positions in the comitology voting. In neither of the two cases was a QM opinion of national competent authorities delivered: neither in the Regulatory Committee nor in the Appeal Committee.[59] This might be yet another argument against the retention of the EU-level stage of the procedure in case of non-food/feed marketing and cultivation: while one country only maintained its objections to the national risk assessments, no opinion was delivered in the QM voting. At the same time, there were two different cases for authorization renewals (also for GM flowers) where no objections were raised against the Dutch risk assessment and the marketing permits were renewed through the national-level procedure, but following EU-level exchange of information, mediation and comments between Member States which resolved the doubts expressed.[60]

Accordingly, the solution outlined in this section should be seriously considered as a way forward.

10. Scenarios and Recommendations: The way forward

This paper has demonstrated that the DI reform – as introduced by the 2015 Opt-out Directive – has not fulfilled its promises. The GMO sector is in further stagnation: voting deadlocks continue and it is unclear how to respond to the development of gene-editing techniques (NPBTs), the impact of the CJEU judgement, and the dysfunctionality of various (already tested) regulatory approaches.

Three possible scenarios can be identified in the present situation.

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 is key for a successful development of this scenario.

58 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/feedback_en?p_id=26519622&page=2 (accessed 20 January 2022).

59 Recital 5 and 13 Commission Implementing Decision (EU) 2016/2050 of 22 November 2016 as regards the placing on the market of a genetically modified carnation (Dianthus caryophyllus L., line SHD-27531-4), OJ [2016] L 318/13; Recital 5 and 12 of the Commission Implementing Decision (EU) 2019/1300 of 26 July 2019 as regards the placing on the market of a genetically modified carnation (Dianthus caryophyllus L., line FLO-40685-2), OJ [2019] L 204/46.

60 Consent renewal of 23 August 2019, Point 6, page 4 [in Dutch], https://webgate.ec.europa.eu/fip/GMO_Registers/files/docs/C-NL-06-01-001-Renewal-Consent.pdf?dt=20220128055208; and Consent renewal of 28 February 2017, Point 6-8, page 4 [in Dutch], https://webgate.ec.europa.eu/fip/GMO_Registers/files/docs/C-NL-04-02-001-Consent.pdf?dt=20220128055208 (accessed 2 September 2021).

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 picture, 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, in view of a further politicization and blame shifting (no QMV; no action of the Commission because of no QMV, etc.). 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, introduced in the previous section, would involve a combination of more radical DI and more extensive use of XG.[61] 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.

To make such a scenario work effectively and 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.

61 I am grateful to Jonathan Zeitlin for this suggestion.

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Appendix 1: List of Interviews

The GMO case study on implementation of the 2015 Opt-out Directive benefits from a round of interviews conducted between December 2020-March 2021 with EU and national competent authorities (CAs) representing six Member States (Austria, Belgium, Ireland, Poland, Spain, and Slovakia).[62] All authorities have responsibilities under the Directive 2001/18 for deliberate release of GMOs into the environment which was amended by the 2015 reform. All interviews were conducted via Queen's University Belfast MS Teams. All interviewees were offered the possibility of benefiting from anonymity or confidentiality and all but one chose that option. Finally, we decided to anonymize all the respondents' positions and affiliations. The text citations refer to a unique code explained in the table below, along with a complete list of interviews by date and place. Interviews were semi-structured, however, a pre-prepared list of questions had been sent in advance to all interviewees.

Number/ Code	Competent Authority: EU/MS	Date	Place	Name	Institutional Responsibility
CA 1	identification confidential	18 December 2020	MS Teams	1 person	GMO Policy
CA 2	identification confidential	28 January 2021	MS Teams	1 person	GMO Policy
CA 3	identification confidential	19 February 2021	MS Teams	2 persons	GMO Policy
CA 4	Identification confidential	26 February 2021	MS Teams	1 person	GMO Policy
CA 5	Identification confidential – email contact	February 2021 (several emails) 12 February 2021	written reply	2 persons	GMO Policy
CA 6	identification confidential	12 March 2021	MS Teams	2 persons	GMO Policy
CA 7	Identification confidential – email contact	Feb./March 2021 (several emails); 15 March 2021	written reply	2 persons	GMO Policy

62 The research interviews were conducted by Patrycja Dąbrowska-Kłosińska and transcribed by Zuzana Voskarova.

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