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National Control of GMO Cultivation in the EU
The path to reconciliation of opposed interests

*Nicolas de Sadeleer**

Abstract

EU law on GMOs is undoubtedly the product of a trade-off between, on one side, the functioning of the internal market and, on the other side, health and environmental issues, alongside ethical and even religious concerns. On the one hand, the risk assessment is carried out and the placing GM products on the market is authorized in accordance with EU centralized procedures. On the other, the cultivation of authorized GM seeds and plants may be either banned or restricted by the national authorities in accordance with harmonized safeguard clauses. It follows that neither the free movement of authorised GMOs nor their cultivation is absolute. However, Member States felt deeply dissatisfied with a narrow interpretation of their regulatory powers and the impossibility to ban GMOs in the light of socio-economic and genuine agricultural considerations. Needless to say, the low number of marketing authorisations granted by the European Commission and the invocation of safeguard clauses by the Member States have had a dissuasive effect on the cultivation of GMOs. In 2015, the EU lawmaker decided to increase the Member States' control of the cultivation of GMOs. In particular, economic considerations, and not exclusively environmental and health factors, may be taken into account by the national authorities. Regarding the functioning of the internal market, this seems to be a revolution in its own right. This article is attempting to set the scene to explain how the new compelling grounds regarding agricultural, economic and consumer considerations are consistent with the principle of free movement of GMOs within the internal market.

Key words: Internal market – Placing on the market of GMOs – EU authorisation schemes – EFSA risk assessment – Restrictions placed on the cultivation of GMOs – Safeguard clauses – Consistency with the principle of free movement of goods – Complete harmonisation – Ecological considerations – Economic considerations – Agricultural policy – Proportionality

Introduction

Faith in biotechnology was initially so unswerving that its deployment in agriculture was supposed to herald a bright future in which modern intensive agriculture will be able to satisfy the growing needs for food, exacerbated by galloping population increases. However, genetically modified organisms (GMOs)[1] have repeatedly

* Professor at Saint-Louis University, Guest Professor, UCLouvain. Distinguished International Law Professor at the University of Canberra.

[1] An organism is deemed to be genetically modified where its genetic endowment is modified in a way that cannot be achieved naturally either by multiplication or recombination. See in particular Article 2(2) of the Convention on Biological Diversity, Article 5(5)(2) of the German Federal Law of 21 March 2003 on Non Human Gene Technology, and Article L 531-1(2) of the French Environmental Code. Directive 2001/18 defines it as "any biological entity capable of replication or of transferring genetic material." When the pollen stemming from a variety of genetically modified corn loses its capacity of reproduction and is devoid of any capacity to transfer genetic material, it does not constitute a GMO within the meaning of secondary law anymore. See Case C-442/09 *Bablok* [2011] ECR I-7419, para. 62.

been a matter of much controversy, especially in Europe. This scepticism of many NGOs and several regulatory agencies has focused both on their impact on human health (allergenicity, genes expressing resistance to antibiotics in use for medical or veterinary treatment[2]), as well as the impoverishment of biodiversity which their cultivation could cause (wild species resisting GM plants, resistance to herbicides, hybrid plants, gene flow through pollen transfer, impacts on soils, etc.).[3] What is more, contrary to the claims of agro-chemical firms, the cultivation of GMOs has not led to a reduction in the use of plant protection products and artificial fertilizers.[4]

EU regulatory approach to GMOs has been fraught with controversies since its inception. The authorisation granted to Syngenta Crop Protection AG to place on the market BT 176 maize in accordance with Directive 90/220/EEC was followed by strong national opposition. Several Member States opposed the commercialisation of that maize in invoking safeguard clauses that the Commission didn't succeed to lift. That led the Council to declare a *de facto* moratorium on GMOs in June 1999. As a result no authorisation were granted until Directive 90/220/EEC was replaced by another legislation. In November 2006, a WTO panel condemned the ban as well as national bans on EU-approved GM products, on the grounds that there were not being based on a genuine risk assessment.[5]

These tensions led the EU lawmaker to replace Directive 90/220/EEC by Directive 2001/18/EC on the deliberate release of GMOs. Probably no other piece of legislation has produced as much controversy as does this. As other EU acts regulating GMOs, this directive attempts to strike a balance between the functioning of the internal market and the Treaty requirements of a high level of consumer and environmental protection. Its transposition turned into a minefield for the majority of the Member States.[6] However, the importance of that directive has been belittled ever since the European Commission has endorsed a 'one door one key' approach, according to which undertakings can be authorised either by Directive 2001/18/EC or by Regulation (EC) No 1829/2003 on genetically modified food and feed to place on the market a GMO for cultivation purposes. As a result, the majority of GM plants have recently been authorised by the EU institutions in accordance with Regulation (EC) No 1829/2003. Along the same lines, this Regulation is attempting to ensure a high level of protection of human health and consumers' interest, whilst ensuring the effective functioning of the internal market, of which the free movement of GMOs is an essential aspect.

However, the balance struck by the law-

[2] Article 4(2) of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms, OJ 2001 L 106/1. The maize 5010 case epitomizes the risks stemming from genes expressing resistance to antibiotics. See T-240/10, *Hungary v Commission,* EU:T:2013:645, para. 38.

[3] EFSA Panel on Genetically Modified Organisms (GMO), « Scientific Opinion on the assessment of potential impacts of genetically modified plants on non-target organisms » (2010) 8(11) *EFSA Journal* 1877, 72 pp.

[4] The spread of GMO crops has dramatically increased the amount of pesticide and herbicide usage per hectare in recent years, and contributed to the spread of glyphosate- resistant weed. See C.M. Benbrook, "Impacts of Genetically Engineered Crops on Pesticide Use in the U.S.-The First Sixteen Years" (2012) 24 : 1 *Environmental Sciences Europe*.

[5] WT/DS291/R; WT/DS292/R; WT/DS293/R, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products.*

[6] Case C-170/94 *Commission v Greece* [1995] ECR I-1819; Case C-312/95 *Commission v Luxemburg* [1996] ECR I-5143; Case C-343/97 *Commission v Belgium* [1998] ECR I-4291. Regarding the transposition of Directive 2001/18: Case C-429/01 *Commission v France* [2003] ECR I-14355; Case C-165/08; *Commission v Poland* [2009] ECR I-684; Case C-478/13 *Commission v Poland* [2013] C:2015:379.

maker between the safeguard of health and the environment and the functioning of the internal market was deemed to be unsatisfactory. Adopted by the European Parliament and the Council on 11th of March 2015 Directive (EU) 2015/412 as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory has amended Directive 2001/18 with a view to granting the Member States the right to prohibit or to limit the cultivation of GMOs in accordance with a harmonised authorisation procedure.[7]

It is the aim of this article to explore the novelty of the changes brought to the existing regulatory schemes by Directive (EU) 2015/412. The article is structured as follows. In a first section, we shall explain the two-pronged approach endorsed by the EU regarding the approval of GM agricultural products. A second section describes the various safeguard clauses the Member States can activate in order to limit the cultivation of authorized GMOs. Against this background, a third section explains the rationale for this reform, which might at first sight appear to be somewhat disconcerting from the viewpoint of the proper functioning of the internal market. In so doing, we shall assess the extent to which the upstream approach (centralized procedures for granting marketing authorisations) is entangled with a downstream approach (national measures restricting or controlling the cultivation of GM plants). Last, in a fourth section we shall assess the consistency of the new grounds provided under Directive 2015/412 with the principle of free movement of goods. Our analysis does not encompass field trials.

Part I. Procedural requirements for GMO marketing authorisation

The EU marketing regime is centred around two axes, the first concerning the deliberate release of GMO into the environment in general (Directive 2001/18/CE) and the second concerning specifically genetically modified food and animal feed (Regulation 1829/2003/CE).[8] The scope of these two legislations differ: whereas Directive 2001/18/EC applies to the deliberate release of all GMOs 'as or in products', including non-foods like the Amflora potato, Regulation (EC) No 1829/2003 applies exclusively to genetically modified food and feed.

However, this dividing line has been somewhat blurred. In effect, due to the development of the European Commission's administrative practice, which favours a greater centralisation of the decision making process, this distinction has gradually been superseded, with the latter procedure prevailing over the former. It follows that in accordance with a 'one door one key' approach, an undertaking is authorised to use a GMO both in food and feed as well as for cultivation purposes. Against this background, we shall stress the advantages and the drawbacks of each procedure.

A. Directive 2001/18/EC

Directive 2001/18/EC on the deliberate release into the environment of GMOs amounts to horizontal legislation under which the requirements applicable to marketing (part C) are intended to apply to all GMOs[9] other than those covered by a

[7] 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* L 68, 1.

[8] The GMOs authorised for cultivation are listed in the common catalogue pursuant to Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, OJ 2002 L 193, p. 1.

[9] The question whether or not plants obtained by genome editing are covered by the directive has been recently the subject of proceedings before the CJEU. AG Bobek took the view that such plants are exempted from the directive. See L. Krämer, 'The genome editing is

sectoral framework,[10] it is deemed to be the centrepiece of GMOs EU legislation. Accordingly, it has to interact with other sectoral regulations.[11] Given that it works as a safety net, several other directives refer to its risk assessment procedures.[12]

If its core features are considered, Directive 2001/18/EC is based on the key principle that no GMO may be released into the environment for experimental purposes (Part A) or subsequently marketed unless it has been previously authorised by the competent authorities following the conclusion of a scientific assessment (Part B). In other words, the assessment has to come first, after which the decision is made. The assessment procedure for something as important as the authorisation of experimental release and the subsequent marketing of a GMO is subjected to the requirement that it is "safe for human health and the environment".[13] Under the directive, the risk assessment is prepared by the national authority and is forwarded to EFSA if there are disagreements among the different Member states.[14] This regime involving prior assessment[15] and administrative authorisation on a case-by-case basis is justified by the uncertainty resulting from the novel nature of this technology.[16]

The principle underlying the harmonised procedure in Directive 2001/18 is that the competent authority of a Member State, having received a notification from a company together with an environmental risk assessment, takes the initiative of issuing consent, in relation to which the competent authorities of the other Member States, or the European Commission, may make their observations or objections known.[17] In cases where an objection is raised and maintained by another national authority or the European Commission, a decision shall be adopted by a regulatory committee, the Standing Committee on the Food Chain and Animal Health (SCFAH).[18]

'If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered', pursuant to Decision 1999/468 Article 5(4) the Commission must 'without delay, submit to the Council a proposal relating to the measures to be taken' and inform the European Parliament. The Council of Min-

covered by Directive 2008/18. Comment on AG Bobek's Opinion in Case C-528/16', 1/18 (2018) *ELNI Rev.* 2–18. However, the CJEU dismissed that interpretation. It held that Article 2(2) of Directive 2001/18/EC 'must be interpreted as meaning that organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms within the meaning of that provision'. See Case C-528/16 *Confédération paysanne* [2018] EU:C:2018:583.

[10] Article 12.

[11] See in this respect Regulation (EC) No 2309/93 establishing a European Agency for the Evaluation of Medicinal Products, OJ 1993 L 214; Regulation (EC) No 1829/2003 on genetically modified food and feed, OJ 2003 L 268, and Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, OJ 2002 L 193.

[12] Regulation (EC) No 1829/2003 on genetically modified food and feed, Recital 33 and Article 5(5)(a).

[13] Recital 47.

[14] Article 28.

[15] Given the need to strengthen the environmental risk assessment of GMOs provided for under Part C of Annex II, Directive 2001/18/EC has been modified the 8th March 2018 by Commission Directive (EU) 2018/350. The scope of the impacts has been broadened. Though the evaluation must be expressed in quantitative terms, a qualitative analysis ("high", "moderate", "low" or "negligible") may be used (Annex II, C 3.2). A noteworthy amendment is that where the environmental risk assessment concerns a genetically modified plant made tolerant to a herbicide, its scope should be consistent with Directive 2001/18/EC. Accordingly, the environmental risk assessment of the use of a plant protection product, including its use on a GM plant, falls under the scope of Regulation (EC) No 1107/2009 and will be carried out at Member State level to take into account the specific agricultural conditions (Recital 9 Commission Directive (EU) 2018/350).

[16] A. I. Myhr, « Uncertainty and Precaution: Challenges and Implications for Science and the Policy of GMOs », in N. de Sadeleer (ed.), *Implementing Precaution. Approaches from Nordic Countries, the EU and USA* (London, Earthscan, 2007) 185–196.

[17] Articles 13 to 19.

[18] Article 18(1).

isters is required to reach a qualified majority either against or in favour of the Commission's proposal. As a matter of fact, it is difficult for the Council to achieve this majority as the Member States have always been extremely divided on such issues. Where the Council is unable to state its position within three months, the ball is put back in the Commission's court.[19] The Commission then decides whether to grant the marketing authorization (MA) initially proposed by it to the regulatory committee, and subsequently to the Council. This means that the recurring divisions between the Member States end up giving the Commission decision-making powers in a very controversial area.

It must also be borne in mind that the precautionary principle applies to the decision-making process. First of all, the principle is proclaimed in Recital 8, in Articles 1 and 4, and in Annex II on the risk assessment.[20] Secondly, the prior authorisation procedure put in place by the legal acts on GMOs emanate from the precautionary principle.[21] Thirdly, in *Greenpeace*, a case concerning marketing approval for genetically modified maize, the CJEU held that the principle of precaution implies that the former EC Directive 90/220/EEC relating to the placing on the market of GMOs should be interpreted in such a way that gives full weight to environmental protection requirements.[22] Although the precautionary principle was not supposed to affect the interpretation of the directive' requirements as regard the obligation on the national authorities to give their consent to GM products already authorized by the Commission, the Court held that 'the Member State concerned cannot be obliged to give its consent if in the meantime it has new information which leads it to consider that the product for which notification has been received may constitute a risk to human health and the environment.'[23]

Authorisations are granted for a maximum period of ten years.[24]Any request for renewal must be submitted to the competent authority by the holder of the authorisation.[25] Renewals of authorisations initially granted under the 2001/18 Directive are now governed by Regulation 1829/2003.

Established by Regulation (EC) No 178/2002, the European Food Safety Authority (EFSA) is playing a primary role in the assessment of the risks entailed by the GMOS subject to the authorisation and the renewal procedures. Indeed, this authority takes on the role of an independent scientific point of reference in risk assessment'.[26]

It must be noted that the Commission is not bound by the EFSA's opinion in adopting its decision to authorise the placing on the market of a GMO.[27] Bound by their obligation, under Article 191(1) and Article 168(1) TFEU, to ensure a high level of human health and environmental protection, the Commission is under the obligation

[19] Article 5(6)(2) of the Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ 1999 L 184/23. See M. Lee, *EU Regulation of GMOS* (Cheltenham: Elgar Publishing, 2008) 71.

[20] J. Kauppila, « GMOs and Precaution in Finnish and Swedish Law », in N. de Sadeleer (ed.), *Implementing Precaution. Approaches from Nordic Countries, the EU and USA* (London, Earthscan, 2007) 250.

[21] With respect to pesticides, the General Court has already been taking the view that 'the prior authorisation and approval procedures put in place by Regulation No 1107/2009 (and, previously, by Directive 91/414) for plant protection products and their active substances emanate from the precautionary principle (see, to that effect, Case T-31/07 *Du Pont de Nemours (France) and Others* v *Commission* [2013] EU:T:2013:167, para. 133 ; Case T-584/13 *BASF Agro* v. *Commission* [2018] T:2018:279, para. 57.

[22] Case C-6/99 *Greenpeace France* [2000] ECR I-1676.

[23] Ibid., para. 45.

[24] Articles 15(4) of Directive 2001/18/EC.

[25] Article 11(1) of Directive 2001/18/EC.

[26] Recital 34 of Regulation (EC) No 178/2002.

[27] Case T-177/13 *TestBioTech eV* [2016] T:2016:736, para. 103.

to determine the level of risk, which is deemed unacceptable.[28] That level of protection does not have to be the highest that is technically possible.[29]

Though the EFSA has not been established a superior scientific authority to the national health institutes,[30] its scientific opinions have nonetheless considerable weight. These opinions buttress the authorisations granted by the Commission. For instance, their content form an integral part of the reasons given for decisions on placing on the market the GM product.[31] What is more, when deciding to set aside a scientific opinion in order to upgrade the level of protection, the Commission 'must provide specific reasons for their findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter'[32], a requirement which can be difficult to fulfil. So far, the Commission has always been endorsing the EFSA's opinion, by submitting a draft authorization to the SCFAH.

That being said, EFSA and several national institutes have been at loggerheads over the level of uncertainty raised by the cultivation of several GMOs.[33] In particular, the EU authority has held that it was not empowered to include ethical and social considerations into its assessments.[34] As discussed below, the authorisations granted by the Commission to BASF (Amflorea) and Pioneer (Maize 1507) were dogged by controversies on the account that EFSA and several national institutes were crossing swords over the level of uncertainty. According to Weimer, "the cooperation with national authorities on GMOs assessments has been hampered by a lack of trust and conflicting views over GMO safety".[35] These controversies have also been compounding the deadlock at both comitology and Council levels regarding the issuance of GM food and feed authorisations.

To date, this authorisation regime has not had the desired effects. Due to persistent differences of opinion between the EU institutions and the Member States, a limited number of authorisations for deliberate dissemination have been granted, the most renowned being for maize MON810.[36] The deadlock in both comitology and the Council has been illustrated by the *Amflora* case.[37] The lack of a qualified majority within the Council of Ministers enabled the Commission to grant an MA in 2010 for the marketing of a genetically modified potato called *Amflora*. However, the General Court quashed this MA on the grounds that the Commission had affected the institutional balance of the EU. In effect,

[28] Case T-475/07 *Dow AgroSciences* v *Commission* [2011] T:2011:445, para. 148.

[29] Case C-284/95 *Safety Hi-Tech* [1998] C:1998:352, para. 49, and Case T-475/07 *Dow AgroSciences*, para. 149.

[30] Articles 6(4) and 18(4).

[31] T-240/10, *Hungary v Commission* [2012] EU:T:2013:645, para. 91. See also by analogy Case T-326/99 *Fern Olivieri/ Commission and EMEA* [2003] ECR II-6053, para. 55.

[32] Case T-13/99 *Pfizer* [2002] ECR II-3305, para. 199.

[33] By way of illustration, in support of the ban of the cultivation of GM maize MON 810, the Italian Government submitted to the European Commission scientific studies carried out by the national agricultural and environmental research councils. See Opinion A G Bobek delivered on 30 March 2017, Case C-111/16, *Giorgio Fidenato and others* [2017] C:2017:248, para. 19. To the contrary, the EFSA had not identified, in the documents provided by the Italian Government in support of the emergency measures relating to maize MON 810, any new science-based evidence which justified the emergency measures requested.

[34] M. Geelhoed, 'Divided in Diversity: Reforming the EU's GMO Regime' (2016) 18 *Cambridge Yb. Eur. Legal Studies* 25.

[35] M. Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance. GMO Regulation and Its Reform' (2015) *ELJ* 7.

[36] The authorisations granted for maize Bt 176 and maize T 25 were withdrawn.

[37] Commission Decision 2010/135/EU concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (*Solanum tuberosum* L. line EH92-527-1) genetically modified for enhanced content of the amylopectin coment of starch, OJ 2010 L 53/11.

the members of the regulatory committee could have been reviewing their initial position if they had obtained new scientific opinions expressing greater uncertainty than the previous opinions forwarded by the Commission.[38]

The maize TC1507 saga – transgenic insect-resistant maize produced by Pioneer Hi-Bred International – also illustrates the difficulties encountered in the marketing procedure.[39] On three occasions (2004, 2006 and 2008), EFSA issued opinions concluding that there was no risk for human health or the environment, and accordingly supported the applications made by Pioneer. Due to the absence of a qualified majority either in favour of or against the draft authorisation, the Commission was required – pursuant to Article 5 of Directive 2001/18 – to submit to the Council '*without delay*' a proposal concerning the action to be taken. On account of the Commission's procrastination in dealing with its application, Pioneer lodged an action for failure to act[40] before the General Court, alleging a violation of the duty of diligence applicable to the Commission.[41] The General Court ruled that the Commission failed to act in accordance with the procedure.[42]

B. Regulation 1829/2003

In contrast to Directive 2001/18, Regulation 1829/2003 is not limited exclusively to the environment; it provides for a specific administrative procedure to authorize the placing on the market of GMOs for food or feed use, food or feed containing or consisting of GMOs, and food or feed produced from or containing ingredients produced from GMOs. Accordingly, it pursues goals relating to quality of life, human health, animal welfare and consumer protection.[43]

In accordance with a 'one door one key' approach, an administrative practice allows applications for an authorisation for deliberate release of GMOs into the environment (falling within the scope of Directive 2001/18) as part of the application for authorisation for GM food and feed. As a result, the scope of the authorisation granted in accordance with Regulation 1829/2003 can include the cultivation of GM crops for feed or food uses. Nonetheless, the scope of the Regulation is restricted to GMOs for food and feed use. It follows that the authorisation of GM crops for non-food or non-feed uses (for example, growing GM potatoes for processing into industrial starch such as the Amflora, flowers that have no food or feed purposes, etc.) is still governed solely by Directive 2001/18.[44] Needless to say, the 'one door one key' approach has reinforced the centralisation of decision-making at EU level regarding both the risk assessment and the granting of the authorisation.[45]

Moreover, decisions on authorization adopted in accordance with Regulation 1829/2003 must be taken in consultation with the relevant competent authorities under Directive 2001/18/EC and are subject to an environmental risk assessment under that directive.

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[38] T-240/10, *Hungary v Commission,* EU:T:2013:645.

[39] Maize TC 1507 had already been authorised for import into European territory for human and animal consumption. Here we are talking about the culturing of the variety.

[40] Article 256 of the TFEU.

[41] Article 18 of Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms, OJ 2001 L 106.

[42] T-164/10 *Pioneer Hi-Bred International*, EU:T:2013:503, para. 42.

[43] Regulation (EC) No 1829/2003 relies on three distinct legal bases, namely Articles 37, 95 and 152(4)(b) of the EC (Articles 43, 114 and 168(4) of the TFEU).

[44] Guidance Notes from Food and Standards Agency and Department for Environment, Food and Rural Affairs on Regulation (EC) No 1829/2003 and on Regulation (EC) No 1830/2003, p. 6.

[45] L. Salvi, 'The EU Regulatory Framework on GMOs and the Shift of Powers towards Member States' (2016) 3 *EFFL* 202.

The *Bablok* case regarding honey that was accidentally contaminated by the pollen of maize MON 810 illustrates the broad scope of the regulation. The cultivation of this maize was at the centre of a case brought by beekeepers operating apiaries near to land owned by the State of Bavaria on which GM maize produced by Monsanto had been grown for research purposes. In this case, the Court was required to rule on the legal status of food such as honey as well as pollen-based food supplements in which an unintended pollen content originating from GM plants had been detected. Once the contested pollen is incorporated into honey or into pollen-based food supplements, it loses its ability to reproduce. The question thus arose as to whether the simple presence in apiculture products of pollen from GM maize that had lost its ability to reproduce resulted in the requirement that the marketing of these products be subject to the issue of an authorisation, along with rules on labelling and monitoring provided for by the regulation.

First, the Court recalled that pollen cannot be classified as a GMO for the purposes of Regulation 1829/2003 unless it amounts to an "organism". This concept is defined, by reference to Directive 2001/18, as "any biological entity capable of replication or of transferring genetic material". Where the pollen resulting from a variety of GM maize loses its ability to reproduce and is totally incapable of transferring the genetic material, it no longer comes within the scope of the concept of GMO.[46] It falls to the national court to make this assessment. Nevertheless, honey and food supplements containing this kind of infertile pollen are foods containing ingredients produced using GMOs. Since the scope of Regulation 1829/2003 also covers "food produced from or containing ingredients produced from GMOs",[47] these ingredients fall within the scope of the Regulation.[48] They must therefore be subject to an authorisation regime, irrespective of whether the contamination of the honey by the pollen was intentional or adventitious. Accordingly, the authorisation regime provided for under Regulation 1829/2003 extends to products accidentally contaminated by pollen originating from GM plants. Depending on the circumstances, such an extension could entitle the victims to bring a civil liability claim against the farmers suffering economic losses due to the accidental contamination.

The uniform regime of marketing authorisation specific to the GMOs falling within the scope of Regulation 1829/2003 bypasses the decentralised regime provided for under Directive 2001/18/EC, as the role of the Member State is essentially reduced to that of a postman. Under this unitary regime, requests for authorisation are dealt with on Union level, in consultation with the Member States, and definitive decisions concerning authorisation fall to the Commission or, depending of the circumstances, the Council. Authorisation may only be granted after an environmental risk assessment[49] has been carried out by the EFSA. The EU authority is called on to assess the potential environmental risks in accordance with the 2001/18 risk assessment procedure. All in all, the role of national authorities is belittled. However, the EU institutions are endowed with some leeway in deciding to adopt the decision, given that it must take into account not only the opinion of the Authority, but also

[46] Case C-442/09 *Bablok* [2011] ECR I-7419, para. 62. See M. Lamping, « Shackles for Bees? The ECJ's Judgment on GMO-Contaminated Honey »(2012) 1 *EJRR* 123–129.

[47] Article 3(1)(c). As a constituent particular to honey, pollen shall, in the future, not be considered as an "ingredient" anymore within the meaning of Regulation (EC) No 1169/2011 on the provision of food information to consumers, OJ 2011 L 304/18.

[48] *Bablok, supra* note 2, para. 79.

[49] Articles 5(5) and 17(5).

'other legitimate factors relevant to the matter under consideration'.[50] These factors (societal concerns, socioeconomic considerations, etc.) are broader than the scientific issues dealt with in the risk assessment. Once authorised, the GMO or the product containing GMOs must be included in a Community register.[51]

Along the same line that Directive 2001/18 procedure, authorisations to the placing on the market of GMOs falling within the scope of Regulation 1829/2003 are granted for a maximum period of ten years.[52]Any request for renewal must be submitted to the competent authority by the holder of the authorisation.[53] Renewals of authorisations initially granted under the 2001/18 Directive are now governed by Regulation 1829/2003.[54]

This centralized procedure has been more successful than the decentralised one provided for under the 2001/18 Directive. In spite of a significant opposition from a number of Member States, the Commission has been following the EFSA' scientific opinions and has been authorizing so far the GM applications submitted to it.[55] In April 2015, 63 authorisations have been granted mostly for cotton, oilseed rape, maize, soybean, sugar beet, and beetroot, plants that were genetically modified with a view to protecting them from pests or to enhance their resistance to plant protection products.[56] Broadly speaking, these authorisations were granted for a restricted use: cultivation, feeding, importation, etc. The authorisation allowing the placing on the market of MON 810 allowed the registration of 221 varieties of this corn in the catalogue of plant varieties. Nonetheless, despite its centralised operation, this procedure is not renowned for its speed on the account of the deadlock in committees and the Council.[57]

C. The pitfalls of the authorization regimes

So far, a number of State authorities have been in open conflict with the European Commission. Until now, disagreement has persisted as the regulatory committees and the Council of Ministers have still been unable to arrive at a qualified majority either to confirm or reject the proposals made by the Commission regarding the marketing of different GM products. Several national authorities called into question the inability of the European Commission to take into consideration those concerns not relating to GM safety, such as the ones related to socio-economic and agricultural considerations. The new comitology procedure under Regulation 182/2011 (the examination procedure)[58] did not bring to an end the opposition between the European Commission and the Member States.[59] On the one hand, an appeal committee that is composed of Member

[50] Articles 19(1) of Regulation (EC) No 1829/2003.
[51] Article 28.
[52] Articles 7(5) and 19(5) of Regulation (EC) No 1829/2003.
[53] Article 23 of Regulation (EC) No 1829/23.
[54] Joined cases C-58/10 to C-68/10 *Monsanto SAS e.a.* [2011] C:2011:553.
[55] M. Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance. GMO Regulation and Its Reform' (2015) *ELJ* 5.
[56] For a list of the authorisations granted or the applications for permission processed by the EU, see http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
[57] So far, the EU institutions have still to deal with fifty-eight authorisation requests, which is more than the number of GMOs that have been approved in the EU thus far. However, the EFSA has already completed the risk assessment and given a favourable opinion of eighteen of them. Six varieties of cotton (five authorisation requests and one renewal application), four varieties of maize (of whom NK603, MON 87460 and the renewal application of T25), five varieties of Monsanto soybean and one variety of colza (renewal application of GT73).
[58] 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 L 55, p. 13.*
[59] F. Randour, C. Janssens, and T. Delreux, The Cultivation of GMOs in the EU: A Necessary Trade-Off' (2014) 52:6 *JCMS* 1311.

State representatives replaces the Council. However, this Council in everything but name does not succeed in reaching a qualified majority. Accordingly, the absence of a qualified majority of the appeal committee in favour of or against the authorisation proposal has led the European Commission to authorize the product.[60] On the other, the Commission enjoys more flexibility under the new comitology procedure given that it may – and not shall[61] – adopt the implementing act authorising the GM product.[62]

As a result, in 2015 and 2016 the European Commission adopted 17 acts, which concerned 'the authorisation of sensitive products and substances such as glyphosate or GMOs, despite Member States being unable to take position either in favour or against the decisions.'[63]

There is no doubt that the low number of MA granted and the invocation of safeguard clauses as discussed above have had a dissuasive effect on the cultivation of GMOs. As a result, very little GM crops are cultivated in the EU. Whilst in 2015 almost 200 million hectares of GMO were cultivated worldwide, only 114,624 hectares of these were located in the EU (of which 97,346 were located in Spain). The MON 810 GMO authorised for cultivation is so far cultivated in only five Member States: Spain, Portugal, Czech Republic, Rumania, and Slovakia.

Part II. The prohibitions and restrictions placed on the free movement of GMOs

We will start by considering the free circulation of GMOs within the internal market. We will continue by considering the safeguard clause provided for under Directive 2001/18, moving on to address the issue of the safeguard clause provided for under Regulation 1829/2003. We shall also address the coexistence clauses provided for under Directive 2001/18. We shall finally address the restrictions placed by the CJEU on the possibility for Member States to enact more protective measures under Article 114 TFEU.

A. Free movement of authorized GMOs

Given that both Directive 2001/18/EC and Regulation 1829/2003 have been adopted on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU), they are enhancing the free circulation of GMOs. This choice is not innocent given that the harmonization on the basis of Article 114 TFEU of rules on the marketing of GMOs creates a precise legal framework limiting Member States' ability to lay down their own product standards.[64] Once a GMO has been authorised for cultivation purposes in accordance with the legal framework on GMOs and complies, as regards the variety that is to be placed on the market, with the requirements on the marketing of seed and plant propagating material, Member States are not authorised to

[60] S. Poli, 'The reform of the EU legislation on GMOs: A journey to unknown destination' " (2015) 4 *EJRR* 561.

[61] Under the former comitology procedure, if the Council has neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures, the proposed implementing act shall be adopted by the Commission. See Article 5(6) of the Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ L 184, p. 23.

[62] In the State of the Union Speech of September 2016, the President of the European Commission announced that 'It is not right that when EU countries cannot decide among themselves whether or not to ban the use of glyphosate in herbicides, the Commission is forced by Parliament and Council to take a decision. So we will change those rules – because that is not democracy.' In its work programme 2017, the Commission announced the modernisation of comitology procedures among new initiatives for 2017. On 14 February 2017, European Commission adopted a proposal to amend Regulation (EU) 182/2011, aimed at increasing transparency and accountability of the decision-making process leading to the adoption of implementing acts.

[63] Communication COM (2015) 176 final.

[64] N. de Sadeleer, *EU Environmental Law and the Internal Market* 114.

prohibit, restrict, or impede its free circulation within their territory,[65] except under the conditions defined by the legislative acts (safeguard clauses). It follows that the Member States' room for manoeuvre with respect to the control of the placing on the market of GMOs authorised under Directive 2001/18 and their cultivation has been somewhat limited.

Nevertheless, the assertion of free movement in both legal acts does not affect the right of the Member States to limit the free movement of GMOs in as much as they comply with the requirements laid down under the EU legislation. In order to restrict or to ban the cultivation of authorised GM crops, national authorities may have recourse to the safeguard clauses provided for under Article 23(1) of Directive 2001/18, or Article 34 of Regulation 1829/2003.[66] By way of illustration, even if the free movement of safe and wholesome food and feed is an essential aspect of the internal market,[67] a prohibition or restriction of the cultivation of GMOs authorised under Regulation 1829/2003 may be adopted by a Member State 'in situations expressly provided for under EU law'.[68]

Given the opposition of many sectors to the cultivation of GMOs, Member States and the European Commission have been constantly fighting a turf war. In effect, the disagreements between the European Commission and a number of Member States regarding the marketing of GM products have been perpetuated downstream at the cultivation stage. Testament to the precautionary principle[69], these two clauses were relied on by several Member States in order to oppose the cultivation of various GMOs that had been authorized by the European Commission. However, since they depart from the general principle of free movement, these clauses have been interpreted narrowly by the Commission as well as by the CJEU, in particular in cases concerning the cultivation of maize MON 810. Besides, Austria has made use of Article 114 (5) TFEU that provides for national reinforced protection.[70]

B. Restrictions placed on the marketing and the use of GMOs under EU secondary law

1. The safeguard clause provided for under Article 23(1) of Directive 2001/18

Article 23(1) of Directive 2001/18 reads as follows: 'Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk

[65] Recital 5 of the preamble of Directive 2015/412.

[66] Recital 7 of Directive 2015/412. If following the granting of a MA a Member State wishes to counter a new risk for the environment or human health by imposing a ban or a restriction, it can also invoke Article 16(2) of Directive 2002/53 on the common catalogue of varieties of agricultural plant.

[67] Recital 1 of Regulation No 1829/2003.

[68] See, to that effect, Case C-36/11, *Pioneer Hi Bred Italia*, C-36/11, [2012] EU:C:2012:534, paras. 63 and 70.

[69] Case C-6/99 *Greenpeace France* [2000] ECR I-1676, para. 44 ; Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, para. 111. With respect to the safeguard clause contained in Article 12 of Regulation No 258/97 (concerning novel foods and novel food ingredients (repealed by Regulation 1829/2003) that 'the safeguard clause must be understood as giving specific expression to the precautionary principle … [Thus] the conditions for the application of that clause must be interpreted having due regard to this principle'. (Case C-236/01, *Monsanto Agricoltura Italia and Others*, C:2003:431, para.110). See N. de Sadeleer, N. de Sadeleer, *Environmental Principles* (Oxford: OUP, 2005) 112–114.; and "The Precautionary Principle in EC Health and Environmental Law" (2006) 12 *ELJ* 139–172.

[70] Regarding the recourse to Article 114(5) TFEU, see Joined Cases C-439/05 P and C-454/05 P *Land Oberösterreich and Republic of Austria v Commission* [2007] ECR I-7441, para. 64.

to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

The Member State shall ensure that in the event of a risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.'

Accordingly, national suspensions or bans must comply with the following requirements.

Firstly, the Member States can invoke the safeguard clause under special circumstances for a limited period of time. The national measures are deemed to be provisional. It follows that a 'general prohibition on the marketing of GMO seed' would evidently violate the conditions laid down in the safeguard clause in Directive 2001/18.[71]

Secondly, in accordance with Article 114 (10) TFEU, the national measures must be justified in the light of the non-economic reasons mentioned in the safeguard clauses. Accordingly, the Member States bear the brunt of the proof that the contested GMO constitutes 'a risk to human health or the environment'[72] In contrast to Article 34 of Regulation (EC) No 1829/2003, the risk to be dealt with must neither be 'serious' nor 'significant'.

Thirdly, it is settled case law that health-related and environmental reasons must be supported by "new" or "additional" scientific evidence refuting the expert reports provided by the EFSA. In this connection, Article 23(1) subjects the invocation of the clauses to the requirement to present 'new or additional information' made available since the date of the consent.[73]

Fourthly, in accordance with principles traditionally applicable to safeguard clauses, the application of a derogation clause under paragraph 10 of Article 114 TFEU should also be subject to a "control procedure" undertaken by the European Commission. Pursuant to Article 23(1), the safeguard clause entails an obligation for the Member State to notify the Commission of the derogating measures taken, in order to enable the latter to ascertain whether they are consistent with the relevant legislation. [74] Indeed according to both legislations, the recourse to these clauses implies a duty to provide immediate information. Generally speaking, the Commission shall either authorise the provisional measure for a time period defined or require the Member State to revoke the provisional measure. As a result, the interim national measure is temporary.

Disagreement has persisted, as the regulatory committees have still been unable to arrive at a qualified majority either to confirm or reject the proposals made by the Commission regarding the legality of the safeguard clauses.[75]

[71] Case C-165/08 *Commission v Poland* [2009] ECR I-6843, para. 61.

[72] Article 23(1) of Directive 2001/18/EC.

[73] Case C-6/99 *Greenpeace France, supra.*

[74] Regarding the obligation to inform 'immediately' the other member States and the Commission of the interim protective measures adopted, see Cases C-58/10 to C-68/10 *Monsanto and Others* [2011] ECR 1-7763, para. 70.

[75] In 2005, by contrast, the Council obtained the required majority to reject the European Commission proposal to lift the bans on diverse varieties of genetically modified maize and colza subject to national safeguard clauses prohibiting their cultivation and marketing in various European Union countries, such as France, Austria or Germany (maize T25 and MON810 are prohibited in Austria, maize Bt-176 is prohibited in Austria, Germany

2. The articulation of the safeguard clauses provided for under Directive 2001/18/EC and Regulation 1829/2003

The articulation of the safeguard clauses provided for under Directive 2001/18/EC and Regulation 1829/2003 has led to interpretative difficulties. Maize MON 810, which attracted a great deal of media attention, shook up the legal fraternity. To summarise, the marketing of this maize was authorised in 1998 according to Directive 90/220, which was repealed and replaced by Directive 2001/18. In 2004, Monsanto did not seek to renew the MA for maize MON 810 in accordance with the procedure laid down by Article 17 of Directive 2001/18 and gave notice to the Commission of its agricultural product as an "*existing product*" under Article 20(1)(a) of Regulation 1829/2003. In 2004, the Commission also approved the inclusion of 17 derived varieties of maize MON 810 in the common catalogue of varieties of agricultural plant governed by Directive 2002/53**.** This means that maize MON 810 was covered both by the regime established under Regulation 1829/2003 as well as that provided for under Directive 2002/53.[76] In addition, in *Pioneer Hi Bred*, AG Bot held that Italian cultivation prohibitions are subject to 'the provision of strict proof' that technical measures would not suffice.[77]

Due to this change in regime, there was a question as to whether the Member States were still entitled to apply the safeguard clause provided for under Directive 2001/18. The referring French court, on application by Monsanto, asked about the conditions on which the French authorities could adopt an emergency measure on the basis of Article 23 of Directive 2001/18/EC.

In the French 2011 *Monsanto* case, the CJEU held that even though it was authorised on the basis of Directive 90/220/EC (replaced by Directive 2001/18/EC), a GMO like MON 810 maize which was notified as an 'existing product' within the meaning of Regulation 1829/2003, and was subsequently the subject of an application for renewal of authorisation under the same Regulation, can no longer be the subject of safeguard measures pursuant to Article 23 of Directive 2001/18. Accordingly, since maize MON 810 did not fall within the scope of Directive 2001/18, only Article 20(1) of Regulation 1829/2003 was applicable. By authorising the continuing use of the products to which it applies, this provision covers the use as seeds of the modified maize.[78]

According to the *Monsanto SAS* judgment, the Member State concerned must comply with both the substantive conditions laid down in Article 34 of the Food and Feed Regulation and the procedural conditions provided for in Article 54 of the Food Safety Regulation (EC) No 178/2002, to which Article 34 of Regulation (EC) No 1829/2003 refers.

Given that the majority of GM plants that have been authorized for cultivation in accordance with Regulation 1829/2003, the Member States are called on to have recourse exclusively to Article 34 of that regulation. We shall see that the requirements stemming from this provision are much more stringent for the national authorities than the former safeguard clause.

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and Luxemburg, colza Topas 19/2 is prohibited in France and Greece, and colza MSI-RF1 is prohibited in France).

[76] Opinion AG Bot in Joined Cases C-58/10 to C-68/10 *Pioneer Hi Bred Italia* [2011] ECR I-7763, para. 21.

[77] Ibid., para. 61.

[78] Joined cases C-58/10 to C-68/10 *Monsanto SAS e.a.* [2011] C:2011:553, paras. 70-71; Opinion AG Bot in *Monsanto and Others, supra* note 106, para. 55. See M. Weimer, "The Right to Adopt Post-Market Restrictions of GM Crops in the EU" (2012) *EJRR* 447 and following; M. Clément "Arrêt *Monsanto* : Du principe de précaution au risque manifeste" (2012) *REDC* 163 and following.

3. The safeguard clause provided for under Article 34 of Regulation No 1829/2003

Where it is evident that products authorised by or in accordance with Regulation 1829/2003 are likely to constitute a serious risk to 'human health, animal health or the environment', Article 34 of that Regulation refers to the conditions laid down in Articles 53 and 54 of the Food Safety Regulation No 178/2002.

Pursuant to Article 53(1):

> Where it is evident that food or feed originating in the (EU) …. is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission … shall immediately adopt' different safety measures, depending on the gravity of the situation (suspension of the placing on the market, special conditions, etc.).

From a procedural point of view, Article 54(1) of Regulation 178/2002 requires Member States, first, to inform the Commission 'officially' of the need to take emergency measures and, second, where the Commission has not acted in accordance with Article 53 of that regulation, to inform it and the other Member States 'immediately' of their interim protective measures. These national interim protective measures may be maintained until the European Commission has adopted its own measures.

The national courts have jurisdiction to assess the existence of such a "serious" risk, except when the European Commission has been enacting the safety measures. Where a decision has been adopted at Union level pursuant to Article 53 of the above-mentioned Regulation 178/2002, the factual and legal assessments contained in such a decision are binding on all bodies of the Member State concerned, including its courts. In this way, 'the assessment and management of a serious and evident risk ultimately come under the sole responsibility of the Commission and the Council, subject to review by the European Union Courts.'[79]

With respect to the substantive condition, it must be noted that in contrast to Directive 2001/18, Regulation 1829/2003 restricts the national measures to ward off a 'serious risk to human health, animal health or the environment'.

Regarding the burden of proof, the Court ruled in *Monsanto Agricultura Italia* with respect to the procedure laid down under Regulation 258/97/EC (replaced by Regulation 1829/2003/EC) that 'protective measures, notwithstanding their temporary character and even if they are preventive in nature, can be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case'.[80] Whilst the Member State need not furnish proof of the risk when invoking this clause – the precautionary principle effectively relieves it of the burden of proof – it cannot however base its decision on 'mere suppositions which are not yet verified'.[81] As a matter of practice, the European Commission has been discarding most of the scientific evidence provided by the Member States on the grounds that these risk assessments did not call into question the findings of EFSA' risk assessments or that they addressed other concerns than the genuine environmental and health issues.[82]

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[79] Cases C-58/10 to C-68/10 *Monsanto and Others* [2011] ECR 1-7763, para. 78.

[80] *Monsanto Agricoltura Italia, supra*, para. 107.

[81] See, by analogy, the interpretation of the safeguard clause laid down in former Regulation (EC) No 258/97, OJ 1997 L 43; Case C-236/01 *Monsanto Agricoltura Italia* [2003] ECR I-8105, paras. 106 and f.

[82] By the same token, in *Biothec products* the DSB panel ruled that there was sufficient scientific evidence for the Member States to perform a full risk assessment in accordance with the SPS Agreement. As a result, national authorities invoking the safeguard clauses could not

Furthermore, in the French 2011 *Monsanto* case, the CJEU interpreted the conditions laid down in Article 34 of Regulation 1829/2003 combined with Articles 53 and 54 of the Food Safety Regulation quite strictly.

Firstly, the Court held that in addition to urgency, Article 34 of Regulation No 1829/2003 requires the Member States to establish 'the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment'.[83]

The precautionary principle was not invoked by the CJEU whereas previously, in the *Monsanto Agricoltura* case, the Court had not hesitated to interpret the safeguard clause provided for under Regulation 258/97/EC, which has now been replaced by Regulation 1829/2003, with reference to this principle.[84]

In the context of criminal proceedings against farmers prosecuted for having grown genetically modified maize MON 810 in breach of a decree prohibiting its cultivation on the Italian territory, the Tribunale di Udine referred a number of questions to the CJEU. One of the questions posed by the referring court concerned the relationship between Article 34 of Regulation No 1829/2003 and the precautionary principle.[85] The CJEU had therefore to assess whether the conditions for the adoption of emergency measures listed in Article 34 were exhaustive.

In *Fidenato*, the CJEU discarded an autonomous application of the precautionary principle in spite of the fact that the principle is enshrined in Article 7 of the General Food Regulation 178/2002.[86] In other words, the precautionary principle, which presupposes scientific uncertainty as regards the existence of a particular risk, is not sufficient for justifying the adoption of restrictive national measures.

As a result, though the precautionary principle applies to the area of food in general, it does not allow for the requirements laid down in Article 34 in relation to genetically modified foods to be disregarded or modified, in particular by relaxing them, since those foods have already gone through a full scientific assessment before being placed on the market.[87]

Advocate General Bobek took the view that 'it follows from Article 34 of Regulation No 1829/2003, read in conjunction with Articles 53 and 54 of the Regulation No 178/2002, that interim protective measures may be taken by the Member States where it is evident from new scientific information that a product that has already been authorised presents a significant risk which clearly endangers human health, animal health, or the environment.'[88] Conversely, where it is not evident that genetically modified products are likely to constitute a serious risk to human health, animal health or the environment, neither the Commission nor the Member States have the option of adopting emergency measures such as the prohibition on the cultivation of maize MON 810. As a matter of fact, given Member States face lingering uncertainties regarding the health or environmental impact of the GM crops cultivated for the purposes of the production of food or feed, it would be difficult, let alone impossible, for them to demonstrate that it is evident from

have recourse to provisional measures under Article 5.7 of the SPS Agreement.

[83] Cases C-58/10 to C-68/10 *Monsanto and Others* [2011] ECR 1-7763, para. 79. See G. Kalfleche, "Application du droit de l'Union par les juridictions administratives" (novembre 2011–mai 2012)" (2012) 7 *Europe* pp. 10-11.

[84] Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, para. 112.

[85] Case C-111/16, *Giorgio Fidenato and others* [2017] C:2017:676.

[86] Regarding the scope of that principle, see Case C-282/15 *Queisser Pharma* [2018] C:2017:26, paras. 54 to 60.

[87] Case C-111/16, *Giorgio Fidenato and others*, para. 52.

[88] Ibid., para. 48.

new scientific information that the product at issue presents a significant risk.

Needless to say, the *Fidenato* judgment renders the precautionary principle nugatory in the area of GM food and feed. This seems to be paradoxical on the account that GM food and feed risks are subject to a higher level of scientific uncertainty, given their novelty, than traditional food and feed. It must also be noted that according to the preamble of Directive 2015/412, 'the precautionary principle should always be taken into account in the framework of Directive 2001/18/EC and its subsequent implementation.'[89]

4. Coexistence clauses

Under Article 26a of Directive 2001/18, the Member States have kept their sovereignty on the establishment of coexistence rules for traditional crops and GMO crops.[90] These coexistence clauses enable Member States to protect farmers who would be detrimentally affected by the contamination of their non-GM crops by GM crops. Given the silence of the Directive as to the scope of these rules, the Commission has been adopting non-binding recommendations.[91]

To date, there has been little room for manoeuvre of the Member States in authorising the cultivation of GMOs authorised under secondary law thanks to an extensive interpretation of the coexistence arrangements. *Pioneer Hi Bred Italia* where maize MON 810 returned to centre state of the legal scene is a case in point. In that case, the CJEU was asked by an Italian court whether Italy could impose a supplementary risk control procedure in addition to the EU MA procedure. In other words, could a national authorisation regime for the cultivation of GMOs operate in addition to the MA provided for under Regulation 1829/2003? Endorsing the arguments of Advocate General Bot, the CJEU found that Italy was not entitled to subject the cultivation of GMOs already authorised under Regulation 1829/2003, which had been included in the common catalogue pursuant to Directive 2002/53, to a requirement of a national authorisation based on health or environmental protection concerns. Essentially, the right of Member States to regulate the coexistence between different types of crops (GMOs, organic and traditional crops) does not however entitle them to impose an authorisation procedure of this type. The Court took the view that 'an interpretation of Article 26a of Directive 2001/18 which would enable the Member States to establish such a prohibition would therefore run counter to the system implemented by Regulation No 1829/2003 and Directive 2002/53, which consists in ensuring the immediate free movement of products authorised at a Community level and accepted for inclusion in the common catalogue, once the requirements of protection of health and the environment have been taken into consideration during the authorisation and acceptance procedures'.[92]

Another issue are "the high cost, impracticability or impossibility of implementing coexistence measures due to specific geographical

[89] Recital 2 of the preamble.

[90] Article 26a of Directive 2001/18 provides only that the Member States may institute coexistence measures.

[91] Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming [2003] OJ L 189/36, and Communication from the Commission to the Council and the European Parliament on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming, (COM(2006) 104 final). See also the 2009 report of the European Commission (COM(2009) 153 final). See M. Lee, "The Governance of Coexistence Between GMOs and Other Forms of Agriculture: A Purely Economic Issue ?" (2008) 2 *JEL* 193–212; J. Corti Varela, "The new Strategy on Coexistence in the 2010 European Commission Recommendation" (2010) 4 *EJRR* 353–358.

[92] *Pioneer Hi Bred Italia*, *supra*, para. 74.

conditions, such as small islands or mountain zones, or the need to avoid GMO presence in other products such as specific or particular products."[93]

C. Restrictions placed on the marketing and the use of GMOs under EU primary law

Paragraph 5 of Article 114 TFEU authorizes the Member States, insofar as certain conditions are fulfilled, to 'introduce' more stringent measures than those provided for by an EU measure related to the functioning of the internal market.[94] These measures must be based on 'new scientific evidence'. The question arose as to whether an Austrian province could ban GMOs on its territory with the aim of protecting nature as well as organic farming pursuant to that paragraph. The European Commission contended that the scientific evidence gathered by the Austrian authorities in the light of the precautionary principle was not 'new scientific evidence' in the sense of paragraph 5 of Article 114 TFEU. AG Sharpston took the following view in her opinion: 'Having regard to … the precautionary principle, …, no amount of precaution can actually render that evidence or that situation new. The novelty of both situation and evidence is a dual criterion which must be satisfied before the precautionary principle comes into play.'[95] The Court of Justice dismissed the appeal lodged by the Austrian authorities, claiming that the General Court did not erred in law by stating that EFSA's findings concerning the absence of scientific evidence demonstrating the existence of a specific problem had been taken into consideration by the Commission.[96] In other words, the principle does not prevail over the obligation for the Member State to bear the burden of the proof as regard the novelty of the scientific evidence.

Part III. The "repatriation" of cultivation under Directive 2015/412

Since 2009, various Member States have called for a change to the marketing regime, which has proved to be favourable to the European Commission. Indeed, according to comitology rules, the European Commission is likely to have the last words in face of continuous disagreement between the Member States.

After several years of tedious negotiations, the Parliament and the Council adopted on March 11th 2015, Directive 2015/412, which inserts Articles 26a-c into the 2001/18 Directive.[97] Though the amending directive does not call into question the authorisation schemes regarding the placing on the market of GMOs, the lawmaker took the view that "cultivation may … require more flexibility in certain instances as it is an issue with strong national, regional and local dimensions, given its link to land use, to local agricultural structures and to the protec-

[93] Recital 15 of Directive 2015/412.

[94] See N. de Sadeleer, *EU Environmental Law and the Internal Market* above 358–377.

[95] Opinion AG Sharpston in Joined Cases C-439/05 P and C-454/05 P *Land Oberösterreich and Republic of Austria v Commission of the European Communities* [2007] ECR I-7441, para. 134.

[96] Joined Cases C-439/05 P and C-454/05 P *Land Oberösterreich and Republic of Austria v Commission of the European Communities* [2007] ECR I-7441, para. 64.

[97] OJ L 68/1. The legal basis chosen is Article 114 TFEU. See E. Brosset, 'Flexible droit de l'UE en matière d'OGM' (2016) 51: 2–3 CDE 651–681; N. de Sadeleer, 'Marketing and Cultivation of GMOs in the EU. An Uncertain Balance between Centrifugal and Centripetal Forces' (2015) (4) *E.J.R.R.* 532–558 ; Ibid., 'Terroir et génie génétique: la réglementation des OGM à l'épreuve des forces centrifuges et centripètes' (2015) *Rev.Tr.Dr. Eur.* 497–528; I. Urrutia Libarona, 'El reconocimiento del derecho a decidir sobre la prohibición (o no) de cultivos transgénicos en la reciente normativa de la UE', in A. Garcia Ureta (dir.) *New Perspectives on Environmental Law in the 21st c* (Barcelona, M. Pons, 2018) 195–220. The General Court ruled that an action for annulment lodged by a claimant against Directive 2015/412 was manifestly inadmissible. Order 6 June 2017, *Società agricola Taboga Leandro e Fidenato Giorgio*, T:2017:419.

tion or maintenance of habitats, ecosystems and landscapes'. [98] Accordingly, in accordance with the principle of subsidiarity enshrined in Article 2(2) TFEU, Member States are henceforth entitled to have the possibility to adopt legally binding acts restricting or prohibiting the cultivation of GMOs in their territory after such GMOs have been authorised to be placed on the Union market. The amending directive aims thus at granting the Member States more flexibility to decide whether or not they wish to cultivate GMOs on their territory without affecting the risk assessment provided in the system of Union authorisations of GMOs.

In reallocating competences at a national level, this legislative reform is breaking new grounds. This reform is even more striking given the failed attempt of the European Commission to allow Member States to restrict the use of GM food and feed products on non-safety grounds in adding an Article 34a to Regulation 1829/2003.[99]

A. Procedure

Under the terms of a somewhat convoluted compromise, the new powers of the Member States under the new Article 26c are spread over two stages that can be briefly described.

Phase 1. First of all, the Member States may request the undertaking applying for MA for GM seeds to exclude all or part of their territory from the geographical scope of the authorisation.[100] In contrast with phase 2, no justifications are needed. Regarding the temporal scope, that request has to be communicated to the Commission at the latest 45 days from the date of circulation of the assessment report under Article 14(2) of the Directive 2001/18. The Commission is called on to make the demand publicly available by electronic means. The Commission must forward the request to the applicant. If such a request is made, the MA applicant may limit the geographical scope of its initial application.[101] The latter can adjust his application, though he is not obliged to do so. The written consent issued under both marketing authorisation procedures shall then be issued on the basis of the adjusted geographical scope of the application. Nothing precludes the Member States to renounce their geographical claims.[102]

Phase 2. Thereafter, where the applicant refuses to alter the geographical scope of its application, or where no request is notified by a national authority,[103] the Member States still may exercise an opt-out, invoking one or several "compelling grounds" that are not at odds with the assessment of health and environmental risks carried out by the EFSA.

The Article 26b(3) 'compelling grounds' can be invoked individually or in combination depending on "the particular circumstances of the Member State, region or area in which those measures will apply".[104]These grounds can be invoked in a generalized form or they can be more concrete.

The national measures are wide in scope: they range from full bans to more narrow restrictions. They can lay down specific conditions for cultivation. They are likely to apply to a "GMO, or […] a group of GMOs defined by crop or trait".[105] According to Winter, this implies that the Member States may not generally prohibit the cultivation of GM seeds per se. Rather, this

[98] Recital 5 of the preamble of Directive 2015/412.
[99] See Proposal for Regulation amending Regulation 1829/2003, COM (2015)177 final. On 28 October 2015, the European Parliament rejected the Commission's proposal.
[100] Article 26b(1) of Directive 2015/412.
[101] Article 26b(2).
[102] Recital 21, and Article 26b(5).
[103] Article 26b(3). The European Parliament obtained that phase 2 is not subjected to phase 1.
[104] Recital 13 of Directive 2015/412.
[105] Art. 26b(3)(1) Directive 2015/412.

can be done with regard to a particular seed or a certain group of seeds.[106] However, as long as they are not cultivated, the marketing of new GM food authorised under Regulation 1829/2003 is not affected by this new regime.

As regards their geographical scope, the restrictions or prohibitions may cover all or part of the national territory (a region, a county, a municipality, a designated natural area, a nature sanctuary, etc.).

It thus follows that the Member States are entitled to prohibit or limit the cultivation of GMOs authorised on EU level within all their territory without having to invoke the safeguard clause provided for under Directive 2001/18/EC and Regulation 1829/2003, the scope of which – as noted above – have been interpreted narrowly.

The change has thus been appreciable: whilst only health-related and environmental risks, as duly confirmed in a risk assessment, could be invoked against the granting of a marketing authorisation,[107] other considerations, including in particular the socio-economic balance between the advantages and disadvantages of genetic engineering may now be invoked downstream in order to oppose the cultivation of authorised GM seeds. This new regime appears to be based on the following reasoning: in contrast to questions relating to the marketing of GMOs, their cultivation is more of a local or regional matter than an international one.[108] Therefore, Member States are allowed to restrict cultivation to a greater extent than they are allowed in accordance with the previous regime.

So far, the opt-out mechanisms have been successful. Member States were allowed to adopt between April and October 2015 transitional measures to products (Maize MON 810, 1511, BT 11, 59122, etc.) which have been authorised or which were in the process of being authorised before the entry into force of the directive.[109] In the course of this transitional period, the notifiers acceded to all relevant requests made by 17 Member States and four regions (Wallonia, Wales, Scotland, Northern Ireland) regarding the geographical adjustment of their authorisations.[110] Several Member States are divided. For instance, in Belgium the Walloon authorities banned 8 GM crops whereas their cultivation is allowed in Flanders. In the UK there is a wide divide between GMO-sympathetic England and GMO-reluctant Scottish and Welsh nations.

B. Conditions

In relying on the new compelling grounds, the Member States are not endowed with unfettered discretion. They must fulfil a number of procedural and substantive conditions.

Regarding the formal conditions, the national measures are subject pursuant to Article 26b(4) to a procedure of information at EU level, a procedure that is not as stringent as the review procedure provided for under the traditional safeguard clauses. During a period of 75 days starting from the date of such communication, the Member State shall refrain from adopting and implementing the proposed restrictive measures. On expiry of that period, the Member State concerned may "adopt the measures either in

[106] G. Winter, *National Cultivation Restrictions and Bans of Genetically Modified Crops and Their Compatibility with Constitutional, EU and International Law,* Legal Report Commissioned by the Federal Nature Conservation Agency (May 2015) 9.

[107] Recital 7 of Directive 2015/412.

[108] Recital 5 of Directive 2015/412.

[109] Recital 26 and Article 26c(1) of Directive 2015/412.

[110] European Commission, Restrictions of geographical scope of GMO applications/authorisations: Member States demands and outcomes.
https://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en

the form originally proposed, or as amended to take account of any non-binding comments received from the Commission". On the one hand, this procedure is rather similar to the one provided for under Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards.[111] On the other hand, it departs significantly from the Article 114(6) TFEU procedure according to which the Commission is called on to approve the national requests for derogating harmonized internal market standards.[112]

Regarding the substantive conditions, the directive requires that such national measures justified in the light of one or several compelling grounds are "in conformity with Union law, reasoned, proportional and non-discriminatory'. These "compelling grounds" cover a very large number of reasons ranging from socio-economic to public order; they encompass:

(a) Environmental policy objectives;
(b) town and country planning;
(c) land use;
(d) socio-economic impacts;
(e) avoidance of GMO presence in other products without prejudice to Article 26a;
(f) agricultural policy objectives;
(g) public policy.

Moreover, the compelling grounds must not be at odds with the assessment of health and environmental risks carried out by the EFSA.

Part IV. Compatibility with the principle of free movement of goods

A. Introduction

A better protection of the environment or the enhancement of small-scaled agriculture through limiting the placing on the market or the use of hazardous products and substances might be looked at as a plausible alibi for reinforcing competitiveness of national farms. Should such restrictions be swept aside by the free movement of goods, considered by the Court of Justice as 'one of the fundamental principles of the Treaty' [113] and by most academic authors as a major achievement of the European integration process? In this connection, some may question whether the new opt-out regime is compatible with Article 34 TFEU that prohibits measures of equivalent effect to a quantitative restriction (MEEQRs) contrary to Articles 34 TFEU. Let be noted that the issue of compatibility can be resolved exclusively by the CJEU.

Given the lack of standing of the GMO producers or retailers to challenge directly the directive before the CJEU,[114] it is more likely that they will challenge the national implementing measures before the competent national courts in order to challenge the directive itself. These courts will have the possibility to refer one or several of the three separate, albeit related, questions for preliminary rulings in accordance with Article 267 TFEU:

- as to the compatibility of the national measure restricting or banning cultivation of authorised GMOs with the procedural and substantive requirements of Article 26b;

[111] Directive 98/34/EC does not apply to the national measures at issue. See Recital 17 of Directive 2015/412.
[112] N. de Sadeleer, *EU Environmental Law and the Internal Market* above 369–370.
[113] See, e.g. Case 265/65 *Commission v. France* [1997] ECR I-6959.
[114] N. de Sadeleer and C. Poncelet, « Protection Against Acts Harmful to Human Health and the Environment Adopted by the EU Institutions »(2011-2012) 14 *Cambridge Yearbook of EU Law* 177–208.

- as to the compatibility of the national measure at issue with the principle of free movement of goods;
- as to the compatibility of Directive 2015/412 with the principle of free movement of goods.

In answering these questions, the CJUE will have to decide the extent to which Directive 2015/412 may authorize Member States to prohibit or restrict trade between Member States.

It must be noted that the French Constitutional Court dismissed a lawsuit requesting to review the consistency of the national ban of cultivation of varieties of GM maize with both Articles 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003. The Constitutional Court held that such a review falls under the jurisdiction of ordinary and administrative courts. Moreover, the Council took the view that the French Constitution precludes it to make a reference for preliminary ruling to the CJEU in accordance with Article 267 TFEU[115].

B. Applicability of Article 34 TFEU

There are two ways in which to ascertain the compatibility of the compelling grounds with the free movement of goods. Either the domestic measure justified by the compelling ground will be assessed only in light of Directive 2015/412 as in the case of complete harmonization, or it will be observed that the directive gives rise to incomplete harmonization, and its lawfulness will be assessed directly in the light of Article 34–36 TFEU. In other words, the question arises as to whether Directive 2015/412 gives rise to a complete or an incomplete harmonization of the subject matter. The CJEU will have thus to determine whether the national restriction falls under that Article 34 TFEU.

Our view is that the CJEU will have to recognize that Directive 2015/412 does not fully harmonize national rules.[116] Indeed, in contrast to the marketing procedures where the Member States are endowed with any room for manoeuvre, the amending Directive of 2015 gives Member States considerable leeway in allowing them to decide the personal, temporal, geographical, and material scope of their restrictive measures. In addition, the national measures regulating the use of GMOs for cultivation purposes have to be qualified as a MEEQR given that this notion covers 'any other measure which hinders access of products originating in other Member States to the market of a Member State'.[117] Given that the harmonization is not deemed to be complete, the CJEU will have to verify whether the national restriction arrangements allowed under Article 26bis are compatible with Article 34, which is applicable only to the extent that the matter cannot be determined exhaustively on the basis of the Directive.[118]

However, account must be taken of the fact that Article 34 TFEU will not apply to cases where all the elements are confined within a sin-

[115] Decision n° 2014-694 DC of 28 May 2014.

[116] However, G. Winter took the view that Article 26b should be treated as a self-standing provision of secondary law. See *Nationale Anbaubeschränkungen und -verbote für gentechnisch veränderte Pflanzen und ihre Vereinbarkeit mit Verfassungs-, Unions – und Völkerrecht*, Rechtsgutachten im Auftrag des Bundesamtes für Naturschutz (May 2015).

[117] Case C-110/05 *Trailers* [2009] ECR I-519, para. 37; Case C-142/05 *Mickelsson and Roos 'Swedish Watercrafts'* [2009] ECR I-4273, para. 24. See P. Oliver, 'Of Trailers and Jet-Skis: is the Case Law on Article 34 TFEU Carrering in a New Direction' (2010) *Fordham Intl L J* 4.

[118] It is settled case law that where full harmonization is achieved, Member States may not invoke grounds contained in Article 36 TFEU or a mandatory requirement of general interest with a view to impeding free movement of authorized GMOs. See, among others, Case C-573/12, *Ålands vindkraft AB v Energimyndigheten* [2014] C:2014:2037, para. 58.

gle Member State.[119] Given the local dimension of several restrictions, this case law should preclude the invocation of Article 34 TFEU.

Last, the Member States prohibiting or restricting the cultivation of GM crops have to demonstrate that their measures are justified and proportionate to the aim of that justification.

Conversely, Article 36 TFEU remains applicable 'as long as full harmonization of national rules has not been achieved'.[120] If the CJEU holds that in adopting Directive 2015/41 the EU lawmaker has pre-empted the field (exhaustive, full, or complete harmonisation), the national restrictive measures must be reviewed in light of the directive itself. It follows that the CJEU will have to take fully into consideration the opt-out clauses in their own rights.

C. The justification for the restrictions on the free movement of GM crops

Given that that primary law prevails over secondary law, the CJEU will have to take into consideration whether the compelling grounds listed under Article 26b(3) are compatible with the derogations to the principle of free movement of goods. In case they are not, they cannot objectively justify the national measure regulating the cultivation of GM crops.

Some of the 'compelling grounds' do not present any difficulties at all on the account that they are listed under Article 36 TFEU ('public policy')[121] or that they have been proclaimed as mandatory requirements of general interest ('environmental protection', 'town and country planning', 'land use', and 'consumers protection').[122] Given their novelty, other compelling grounds are likely to spark off a debate of unprecedented nature. Our analysis focuses on the most controversial compelling grounds.

1. Absence of conflict with the EFSA's risk assessment

Whilst the Member State may invoke one or more of the grounds listed under Article 26b(3),[123] it is specified that they "shall, in no case, conflict with the environmental risk assessment" carried out by EFSA.[124] According to recital 14 of the preamble of Directive 2015/412 "to avoid any interference with the competences which are granted to the risk assessors and risk managers under Directive 2001/18/EC and Regulation (EC) No 1829/2003, a Member State should only use grounds with respect to environmental policy objectives relating to impacts which are distinct from and complementary to the assessment of risks to health and the environment which are assessed in the context of the authorisation procedures provided in Directive 2001/18/EC and in Regulation (EC) No 1829/2003, such as the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability, or maintenance of local biodiversity, including cer-

[119] Case C-134/94, *Esso Española* [1995], EU:C:1995:414, para. 13, and Case C-268/15, *Ullens de Schooten*, [2016], EU:C:2016:874, para. 47. Article 26b(3) of the Directive stresses that the opt-out clauses must be 'in conformity with Union law'. However, such an express reference cannot extend the scope of application of Articles 34 to 36 TFEU to situations that have no cross-border aspect. See Case C-282/15 *Queisser Pharma* [2018], para. 41.

[120] See Case 215/87 *Schumacher* [1989] ECR 617, para. 15; Case C-369/88 *Delattre* [1991] ECR I-1487, para. 48; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, para. 26; Case C-62/90 *Commission v Germany* [1992] ECR I-2575, para. 10; and Case C-320/93 *Ortscheit* [1994] ECR I-5243, para. 14

[121] This compelling ground has always been subject to a narrow interpretation. See *Oliver on Free Movement of Goods in the European Union*, 5th ed. (Oxford, Hart, 2010) 253.

[122] See our analysis of the scope of these different justifications, in 'Marketing and Cultivation of GMOs in the EU. An Uncertain Balance between Centrifugal and Centripetal Forces' (2015) (4) *E.J.R.R.* 532–558.

[123] Public order may not however be invoked alone.

[124] Recital 4 of Directive 2015/412.

tain habitats and ecosystems, or certain types of natural and landscape features, as well as specific ecosystem functions and services.' In contrast to safeguard clauses discussed above, the opt-out granted to the Member States does not therefore call into question the risk assessment carried out at EU level.

What is the room of manoeuvre left to the Member States? Does the existence of a risk assessment preclude any other justifications?

In our view, in a field marked by uncertainty such as the one at issue, the EFSA scientists do not necessarily have an answer to everything. Their investigations do not always allow for an identification of the risks in a convincing manner. Indeed, in many cases, their assessments are likely to demonstrate that there is a high degree of scientific and practical uncertainty in that regard. Moreover, some risk assessments carried out prior to the granting of MA do not cover all risks for wildlife or for the soil. Furthermore, the preamble of Directive 2015/412 stresses that the risk assessments carried out under Directive 2001/18 are far from being perfect; accordingly, they need to be "regularly updated to take account of continuous developments in scientific knowledge".[125] In short, Article 26bis does not exclude different views about the overall risk assessment.[126]

Among the impacts that could be assessed by the national scientific authority, one could mention:

- the effects on certain non-target organisms,
- the likelihood of horizontal gene transfers,
- the failure to account for particularly vulnerable areas under cultivation or nature reserves,
- the emergence of resistances against BT-seeds,
- a change in agricultural cultivation practices (such as a heightened use of herbicides in case of herbicide-resistant plants).

It follows that the Member State bears the burden to demonstrate that the EFSA's risk assessment is incomplete.

2. Environmental grounds

The danger of insertion of transgenic elements into the environment is high.[127] Despite the fact that the genes being transferred occur naturally in other species, there are unknown consequences to altering the natural state of an organism through foreign gene expression.[128] These consequences may influence not only the GMO itself, but also the natural environment where it is released.[129] It comes thus as no surprise that one of the compelling grounds relates to the environment. What is more, the two next compelling grounds, town and country planning (ground b)) as well as land use (ground c)) are genuine components of the environment *lato sensu* (ground a)).[130] It is settled case law that the Member States can impede the free circulation of goods on these three grounds.[131] For instance, the integration of landscape planning into general land planning could be used to limit the cultivation of GMOs in specific areas.[132]

[125] Recital 3 of Directive 2015/412. However, Directive 2015/412 does not really address the role of uncertainty in the risk assessment and the cooperation between the EFSA and the national scientific authorities.

[126] G. Winter, 'Cultivation Restrictions for Genetically Modified Plants' above 127.

[127] German Advisory Council of Global Change, *Conservation and Sustainable Use of the Biosphere* (London, Earthscan, 2001) 55.

[128] Advisory Opinion of the International Monsanto Tribunal, The Hague, 18 April 2017, 33.

[129] T. Phillips, 'Genetically Modified Organisms (GMOs): Transgenic Crops and Recombinant DNA Technology'(2008) 1:1 *Nature Education* 213

[130] Opinion AG Leger in Case C-36/98 *Spain v Council* [2001] ECR I-779, para. 106.

[131] N. de Sadeleer, *EU Environmental Law and the Internal Market*, above, 284–301.

[132] G. Winter, supra, 17.

Given that a number of disagreements between the national scientific authorities and the EFSA concerned the environmental component of the risk assessment carried out by the EU Authority, it comes as no surprise that the first compelling ground relates to the environment. Of importance is to stress the wide scope of that ground on the account that it relates to the environmental policy objectives.[133] Under EU primary law, these objectives are extremely broad given that they range from the protection of human health to the 'prudent and rational utilisation of natural resources'.

3. Agricultural grounds

'Agricultural policy objectives' (ground f)) can also be invoked as a compelling ground [134], though these objectives have seldom been invoked in disputes concerning the free movement of goods. The preamble of the directive stresses that "cultivation may … require more flexibility in certain instances as it is an issue with 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."[135] In addition, these grounds may include "the need to protect the diversity of agricultural production and the need to ensure seed and plant propagating material purity".[136]

By the same token, restrictions could aim at promoting the diversity of seeds, local markets, maintenance of jobs in extensive agriculture, etc.[137] It is unlikely that these objectives will overlap with environmental policy objectives (conservation of biodiversity).

What is more, the national decision of banning the cultivation of GMOs has an impact on the agricultural practices of the neighbouring Member States in which GMOs are cultivated. These Member States are called on 'to take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited'.[138]

Account must also be made of the fact that an array of national agricultural measures have been validated on the ground that they were aiming at protecting the health and life of animals and plans within the meaning of Article 36 TFEU.[139] What is more, it must be noted that cultivation of a plant variety included in the common catalogue of varieties could be prohibited in any Member State where it is harmful from the point of view of plant health to the cultivation of other varieties or species.[140] In *Ospelt*, the CJEU held that several public-interest objectives, such as the preservation of agricultural communities, the maintenance of distribution of land ownership allowing the development of viable farms and sympathetic management of green spaces and the countryside are likely to justify restrictions on the free movement of capital.[141] In particular, the Court stressed that 'the objective of sustaining and developing viable agriculture on the basis of social and land planning considerations entails keeping land intended for agricul-

[133] Pursuant to Article 191(1) TFEU, the environmental policy pursues four objectives. Nothing precludes Member States to pursue additional objectives. See N. de Sadeleer, *EU Environmental Law and the Internal Market*, above 33–40.

[134] C. Blumann et al., *Commentaire Mégret. PAC et PCC* (Brussels: ULB, 2011) 25 to36

[135] Recital 6.

[136] Recital 15.

[137] Ibid.

[138] Article 26a, 1 a.

[139] See P. Oliver, supra, p. 401–411.

[140] Article 18 of Directive 2002/53 *supra* note 3; recital 4 of Directive 2015/412.

[141] Case C-452/01 *Osplet* [2003] ECR I-9743, para. 39.

ture in such use and continuing to make use of it under appropriate conditions'.

The reference to agricultural policy should now make it possible to put to rest the rather narrow interpretation of Article 114(5) TFEU regarding the consideration of the scale of operations and the maintenance of organic agriculture when establishing provincial regimes banning GMO cultivation.[142]

Last but not least, it must be borne in mind that this compelling ground must not conflict with the results of the EFSA's risk assessment that must encompass 'changes in management, including, where applicable, in agricultural practices'.[143] It must be noted that the use of pesticides on tolerant GM plants (such as glyphosate) are taken on board in the environmental risk assessments. According to EFSA, the applicant is requested to assess the potential environmental effects due to the cultivation of the GM crop in the receiving environment where the GM plant is likely to be cultivated, specify under what circumstances the potential herbicide regimes likely to be adopted for the GM plant may lead to environmental effects than the current management systems they are likely to replace, and consider the impact of the herbicide treatments on biodiversity within farming regions.[144]

However, national measures aiming at fostering agro-sustainability and agrobiodiversity focus on agricultural issues rather than on the environmental risks that are assessed in the risk assessment.[145]

4. Socio-economic grounds

The compelling grounds d) ('socio-economic') and e) ('avoidance of GMO presence in other products') are directed to avoiding the costs of coexistence measures and to accommodating consumer preferences. Needless to say, these grounds go beyond the genuine scientific assessment carried out by EFSA in accordance with the authorisation procedure.

Firstly, the justification regarding 'avoidance of GMO presence in other products' (ground e)) relates to consumers protection, a mandatory requirement according to the *Cassis de Dijon* case law.[146]

Secondly, "socio-economic impacts" are deemed to be compelling grounds. The preamble of the directive sets forth that this ground may be related to "the need to avoid GMO presence in other products such as specific or particular products."[147]

Under the socio-economic compelling ground, national authorities will be allowed to take into consideration the following costs:

- The costs of accidental contamination and of the destruction of contaminated products as epitomized in the *Balbok* case;[148]
- The costs of separating GM and GM-free fields;
- The administrative costs of enforcing the various preventive regulations;
- The costs incurred by producers of non-GM seeds insofar as they must pay heed to the purity of their varieties in the production process;
- The costs incurred by producers of non-GM food and feed insofar as they separate their products from GMO products.[149]

[142] See the case law commented on above, *supra* III, 3. *Land Oberösterreich supra*.

[143] Directive 2001/18/EC, Annex II, C.3.

[144] EFSA Panel on GMOs, *Guidance on the environmental risk assessment of GM plants* (2010) *EFSA Journal* 78.

[145] M. Dobbs, 'Genetically Modified Crops, Agricultural sustainability and National Opt-outs': Enclosure as the Loophole' (2017) 54 *CMLR* 1114.

[146] Case 120/78 *Cassis de Dijon* [1979].

[147] Recital 15 of Directive 2015/412.

[148] *Bablok*, *above*.

[149] G. Winter, 'Cultivation Restrictions for Genetically Modified Plants' above, 126.

By way of illustration, a Member State could take the view that the cultivation of potatoes with higher starch content will be done to the detriment of the production of foodstuffs.[150]

To conclude with, the national measures justified in the light of this socio-economic compelling ground will have to reckon on non-scientific considerations, or in other words of socio-economic reasons. Needless to say, these distinct grounds are not likely to conflict with the results of the risk assessment[151] on the account that they require a qualitative analysis rather than a quantitative assessment.[152]

However, it must be noted that there is no reference to other considerations of socioeconomic nature (ground d)) either in Article 36 TFEU or in the case law on mandatory requirements of general interest.[153] In that respect, it ought to be remembered that the weighing up of the benefits and drawbacks of authorising GMOs is permitted both under international law by the Cartagena Protocol[154] and under EU law by the Regulation 178/2002 laying down the general principles of food safety[155] along with Regulation 1829/2003.[156] Furthermore, the Commission has, as requested in the 2008 Council conclusions, reported to the European Parliament and the Council on socioeconomic implications of GMO cultivation. Along the same lines, national legislations require the weighing up of the benefits and drawbacks of the GM products.[157] Our view is that the CJEU should pay heed to these legal developments in taking seriously this compelling ground.

5. Ethical and religious concerns

Given that Article 26b(3) only lists compelling grounds as examples, nothing precludes the Member States to invoke other justifications, such as ethical and religious concerns. As a matter of course, GM technology remains a matter of debate. By way of illustration, because the insertion of certain genes such as pork genes in the DNA of another species is problematic for the Islamic religion, this subject matter cannot be addressed by the EFSA. So far, ethical and religious concerns play a secondary role in the procedures governing the granting of MA.[158] In addition, the CJEU has been somewhat reluctant to uphold national measures pursuing religious and ethical goals.[159] The fact that ethical grounds could be invoked under Directive 2015/412 would oblige the CJEU to weigh the free movement of GMOs with these concerns.

6. Proportionality

National measures restricting GM seeds cultivation need to be proportional.[160] At the outset, the restraints stemming from the principle of proportionality seem to be at odds with the autonomy sought by the Member States. However, given that proportionality is deemed to be a general principle of EU law, there is nothing new in this respect.

The first issue is whether the facts analysed by the national authorities justify a need for a

[150] Ibid.
[151] M. Lee, "GMOs in the Internal Market: New Legislation on National Flexibility" (2016) 79 (2) *MLR* 339.
[152] G. Winter, 'Cultivation Restrictions for Genetically Modified Plants' above 127.
[153] Case 7/61 *Commission v Italy* [1961] ECR 317; Case 288/83 *Commission v Ireland* [1985] ECR 1761; and Case C-324/93 *Evans Medicals* [1995] ECR I-563. See P. Oliver, supra note 129, p. 239–241.
[154] Article 26.
[155] Recital 19, and Article 7.
[156] Recital 32, Article 7, and Article 19(1).
[157] See also Article 531–4 of the French Environmental Code.
[158] Recital 9 of Directive 2001/18.
[159] Case C-165/08 *Commission v Poland* [2009] ECR I-6843, paras. 51–55.
[160] Art. 26b(3)(1) Directive 2015/412.

measure to achieve one or several of the compelling grounds. In other words, does the socio-economic impacts of GM cultivation or the new environmental risk require Member State intervention? Our view is that a national ban or a restriction placed on the cultivation of authorized GM seeds must constitute a reasonably intelligible means of ensuring the various objectives listed under Article 26(b)(3). By way of illustration, where the ban is justified by the policy objective of restricting intensive agriculture in a peculiar area with a view to safeguarding traditional agricultural practices, the State authority should demonstrate that prohibiting the cultivation of the GM seeds at issue is enhancing traditional extensive agriculture. It may therefore be useful for a national authority to underline the reasons behind the contested measure with a view to demonstrating that it reflects the best methodological approach to deal with the compelling ground. One has to bear in mind that the Member State bears the brunt of the burden of proof.

Second, the principle of proportionality implies a comparison of measures likely to attain the desired result and the selection of the one with the least disadvantages. Indeed, it is settled case law that "when there is a choice between several appropriate measures recourse must be had to the least onerous and the disadvantages caused must not be disproportionate to the aims pursued".[161] In light of the variety of interests and factors to take under consideration regarding GM crops cultivation, a Member State often has a choice between numerous measures. Some measures are likely to be 'more effective', 'more proportionate' or 'less restrictive' than others. [162] For instance, it could be argued that from a consumer point of view, that consumers' interests could be as well protected by labelling requirements. Indeed, the sale of a product should never be prohibited when the consumer will be sufficiently protected by labelling requirements.[163]

When applying this test, the EU courts should display greater regard for the efficacy of the measures concerned by taking account in particular of the specific circumstances of the cultivation of the GM crop. For instance, it was stressed that very broad restrictions may be necessary to achieve social objectives in Central European countries that are dominated by small-scale or organic farming practices.[164] In addition, a ban can be more effective than mitigation measure aiming at the use of an herbicide incorporated into a GM crop. Moreover, the costs and the technical difficulties of implementing the various facets of the alternative should be carefully weighed up.[165] Last but not least, the necessity test cannot conceal an axiological review of proportionality *stricto sensu*.[166]

V. Conclusions

Whilst supporters and opponents of biotechnology continue to occupy diametrically opposed positions, secondary EU law is attempting to ensure a high level of protection of human health and consumers' interest, whilst ensuring the effective functioning of the internal market, of which the free movement of GMOs is an essential aspect. However, the conciliation of these two opposed interests has constantly be dogged

[161] Case C-331/88 *Fedesa* [1990] ECR I-4023, para. 13. See, to the same effect, Opinion AG Van Gerven in Cases C-312/89 *Sidef Conforama* and C-332/89 *Marchandise* [1991] ECR I-997, para. 14; and Opinion AG Poiares Maduro in Cases C-434/04 *Jan-Erik Anders Ahokainen* [2006] ECR I-9171, paras. 23–26.

[162] See, inter alia, Case C-108/96 *Mac Queen and Others* [2001] ECR I-837, paras. 33 and 34.

[163] P. Oliver (gen. Ed.), *Oliver on Free Movement of Goods in the EU,* 5th ed. (Oxford, Hart, 2010)286.

[164] M. Geelhoed, supra, 32.

[165] N. de Sadeleer, *Environmental Principles*, above, 384.

[166] Ibid. 320-22.

by controversies. The centripetal forces inherent within the functioning of the internal market, which are reflected by the principle of mutual recognition along with a strict interpretation of safeguard clauses and the derogation mechanisms provided for under Article 114 TFEU, clash head-on with the centrifugal forces, which are exacerbated by the growing hostility of certain Member States or their populations to this type of technology.

As a result, given the extent of conflicting interests, the EU institutions are constantly touting middle ground. Against this background, Directive 2008/18 has undoubtedly be the product of a trade-off between the functioning of the internal market and health and environmental issues, alongside ethical or even religious concerns.

Given a narrow interpretation of the safeguard clauses provided for under EU secondary law, a number of Member States felt deeply unsatisfied with the regulatory framework that was deemed to be too favourable to the trading interests. There is no doubt that the devil lies in the regulatory detail. The structure put in place by the institutions is so baroque that one ends up getting lost inside it. Furthermore, the Member States' room for manoeuvre in order to restrict the cultivation of GM seeds authorized by the European Commission has been belittled by the CJEU.

A better equilibrium had to be found. The EU lawmaker, in accordance with the principle of subsidiarity and Article 2(2) TFEU,[167] decided in 2015 to "repatriate" controls over cultivation. In effect, the EU lawmaker took the view that 'cultivation may … require more flexibility in certain instances as it is an issue with 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'.[168] Accordingly, Directive 2008/18/EC was amended by Directive 2015/412 in order to allow the Member States to ban or to restrict the cultivation of GMOs. The new opt-out clause regime facilitates the task of Member States seeking to prohibit the cultivation of GMOs for which an authorisation has been granted as they are no longer required to demonstrate the "seriousness" or the "significance" of the risks incurred and as their measures is not subject to an *ex post* review by the Commission. In effect, the Member States are objectively required to make less of an effort in implementing the opt-clauses than in invoking the traditional safeguard clauses. Last, the placing on the market and the import of GMOs shall remain regulated at EU level to preserve the functioning of the internal market. At the outset, the renationalisation of the control of the cultivation of GM crops and the free movement of goods, enshrined in the TFEU, are at odds with one another. However, in adopting Directive 2015/412, the EU lawmaker attempts to reconcile the conflicts between this fundamental freedom and the various national interests underpinning the restrictions placed on the cultivation of GM crops. The amending 2015 directive is thus testament to the willingness of the EU institutions to accommodate these antagonistic interests. It also allows the Member States for the very first time to pay heed to the socio-economic interests underpinning the cultivation of GMOs.

[167] Recitals 6 and 8 of Directive 2015/412.

[168] Recital 6.