Marketing and Cultivation of GMOs in the EU

An Uncertain Balance between Centrifugal and Centripetal Forces

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I. Introduction

Due to the astounding revolution sparked off by genetic engineering, the artificial modification of the genome through targeted alterations of DNA and RNA is now competing with the traditional phenotype use of living organisms (selective plant and animal breeding, consumption, manufacturing of products, energy production, etc.). Although until recently these were insurmountable obstacles, interspecies barriers to reproduction are fading away, and it is now possible to transfer genes from one species to the genome of another. In short, the artificial genetic engineering is replacing selective breeding. Furthermore, a new age is dawning – that of synthetic biology – in which man will no longer content himself with modifying existing organisms but, thanks to the radical modification of the genome, will be able to create new cells and new organisms.[1]

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, GMOs[2] have repeatedly been a matter of much controversy, especially in Europe. This scepticism has focused both on their impact on human health (allergenicity, genes expressing resistance to antibiotics in use for medical or veterinary treatment[3]), 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 upon soils, etc.).[4] In addition, both the enhancement of a model of intensive agricultural exploitation and the patentability of living organisms have been regularly objected to on ethical grounds. And yet one might ask whether it is worth the risk where the cultivation of GMOs has not by contrast led to a reduction in the use of plant protection products and artificial fertilisers, contrary to the claims of agrichemical firms? Whilst supporters and opponents of this new technology continue to occupy diametrically opposed positions, secondary EU law is attempting to reconcile these conflicting interests.

The fact that competence over agriculture, environment and the internal market is shared[5] has not prevented the powers of national bodies from being whittled down by an almost exclusive harmonisa-

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1 SANU, *L'utilisation des ressources génétiques en biotechnologie et son cadre réglementaire* (Durabilitas, 2014); Gerd Winter, "The Regulation of Synthetic Biology by EU Law", in B. Giese et al. (eds), *Synthetic Biology* (Heildelberg: Springer, 2014) p. 213.

2 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.

3 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 epitomises the risks stemming from genes expressing resistance to antibiotics. See T-240/10, *Hungary v Commission,* EU:T:2013:645, para. 38.

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

5 Article 4(2)(a), (d) and (e) TFEU. In virtue of Article 2(2) TFUE, the EU has the power to legislate and to adopt legally binding acts in these areas. However, Member States exercise their competence inasmuch as the EU has not exercised its own competence.

tion[6] of the regulations on contained use, deliberate release, marketing, labelling and traceability, as well as international transfers of GMOs.[7] Distinguished by its approach based on the principle of prevention due to a variety of administrative measures as well as the precautionary principle[8] due to epistemological and methodological uncertainties[9] inherent within this technology, the law on GMOs[10] has consistently expanded its scope both in order to ensure the proper functioning of the internal market and to meet the Treaty requirements of a high level of consumer and environmental protection. At the same time, these different levels of harmonisation have overlapped with the scattered national rules. The Member States were called on to add these EU secondary law regimes to dispersed legal regimes dealing with agriculture (registration of plant varieties, coexistence of cultivations, etc.), intellectual property rights (plant variety rights), nature protection (wild flora conservation), environmental law (listed installations), criminal law as well as civil liability.

The EU harmonisation process has always been fraught with controversies. Probably no other piece of legislation has produced as much controversy as does Directive 2001/18 on the deliberate release of GMOs. Its transposition turned into a minefield for the majority of the Member States.[11] What is more, the French Council of State reviewed the merits of several ministerial decisions refusing the marketing of the Monsanto GM corn.[12]

The discussion within this article will be structured in the following manner. The first part will explain why the GMO marketing authorisation (MA) has become a very contentious matter. It will emphasise the centralisation of the procedural arrange-

6 Although competence over such matters is shared, the area could also be subject to exclusive harmonisation if harmonised completely or exhaustively. The extent to which any harmonisation will be exhaustive will not be affected by the distinction between directives and regulations or by the fact that the harmonising measure was adopted under Article 114 TFEU or on another legal basis. E.g. P. Syrpis, 'The Relationship between Primary and Secondary Law in the EU' 52:2 (2015) *CMLRev* p. 465. See Case C-218/85 *CERAFEL v Albert le Campion* [1986] ECR I-1513, para. 16; Case C-255/86 *Commission v Kingdom of Belgium* [1986] ECR I-693, para. 10 ; T-31/07, *Du Pont de Nemours (France) e.a. v Commission,* EU:T:2013:267, paras. 203-205. See T. Christoforou, "GMO in EU Law", in N. de Sadeleer (eds), *Implementing Precaution. Approaches from Nordic Countries, the EU and USA* (London: Earthscan, 2007) pp. 214-215.

7 The EU lawmaker has been harmonising the traceability and labelling of GMOS (Regulation 1830/2003), their transboundary movements (Regulation 1946/2003), the contained use of genetically modified micro-organisms (Directive 2009/41). By the same token, genetic therapy applied to man, as well as access to genetic resources and the sharing of benefits arising from their use, are also addressed (Regulation (EC) No 511/2014). Finally, several provisions regulate the road and rail transport of GMOs (Directives 94/55/EC, OJ 1994 L 319 and Directive 96/49/EC, OJ 1996 L 235).

8 According to the ECJ, this principle "is reflected in the different measures contained in prior authorisation, supervisory and safeguard procedures" put in place by the directive on the deliberate release into the environment of genetically modified organisms. See Case C-6/99 *Greenpeace France* [2000] ECR I-1676, para. 44; T-240/10, *Hungary v Commission,* EU:T:2013:645, para. 1; French Council of State, *Assoc. Greenpeace France*, 25 September 1998, n° 194348.

9 A. I. Myhr, "Uncertainty and Precaution: Challenges and Implications for Science and the Policy of GMOs", in N. de Sadeleer (ed.), I*mplementing Precaution, supra* note 5, pp. 186-196.

10 For an overview of secondary law, see in particular N. de Sadeleer and C. Noiville, "La directive communautaire 2001/18/CE sur la dissémination volontaire d'organismes génétiquement modifiés dans l'environnement: un examen critique" (2002) 88 *JTDE* pp. 81-85; S. Francesconi, "The New Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms: Changes and Perspectives" (2001) 10:3 *RECIEL* pp. 309-321; J. Scott, "European Regulation of GMOs and the WTO" (2003) 9 *ColJEurL* pp. 213-239; B. Sheridan, *EU Biotechnology Law & Practice. Regulating Genetically Modified & Novel Food Products* (Bembridge, UK: Palladian Law Publishing Ltd, 2001) p. 368; T. Christoforou, "The Regulation of GMOs in the EU: The Interplay of Science, Law and Politics" (2004) 41 *CMLR* pp. 637-709; M. Lee, *EU Regulation of GMOS* (Cheltenham: Elgar Publishing, 2008); C. Noiville, M. A. Hermitte, and E. Brosset, "Organismes génétiquement modifiés" (2009) 4100 *JurisClasseur Environnement et Développement durable.* ; P. Thieffry, *Droit de l'environnement de l'union européenne,* 2nd edn (Bruxelles: Bruylant, 2010) pp. 547-583; E. Brosset, "Le droit de l'UE relatif aux OGM : observations sur la réforme et la résistance du (au) droit", in S. Mahieu et K. Merten-Lentz (coord.), *Sécurité alimentaire. Nouveaux enjeux et perspectives* (Bruxelles: Bruylant, 2013) p. 61; I. Urrutia Libarona, "Comercialización de transgénicos y medio ambiente", in F. Javier Sanz Larruga, M. García Pérez and J. José Pernas García (dir.), *Libre mercado y protección ambiental. Intervención y orientación ambiental de las actividades económicas* (Madrid: INAP, 2013) p. 281.

11 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]. For instance, the CJEU has been condemning thrice France for failing to implement correctly the Directive (see Case C-429/01 *Commission v France* [2003] ECR I-13909; Case C-269/127 *Commission v France* [2003] ECR I-14355; Case C-121/07 *Commission v France* [2008] ECR I-9159).

12 For several years now, the Council of State has been annulling ministerial decisions banning the placing on the market of transgenic maize. See French Council of State, *Sté. Monsanto,* 28 November 2011, n°312921; *EARL de Commenian*, 18 May 2012, n°358614, followed in substance by *Assoc. Générale des producteurs de maïs, SRL Le Trouilh et EARL de Candelon*, 1 August 2013, n°358103; *Assoc. Générale des producteurs de maïs, SRL Le Trouilh et EARL de Candelon*, 5 May 2014, n°377133.

ments that have been reducing the regulatory powers of the Member States.

Against this backdrop, the second part will assess the scope and the effects of the changes recently introduced through Directive 2015/412 amending Directive 2001/18/EC on the deliberate release into the environment of GMOs. The Member States are henceforth granted the right to prohibit or to limit the cultivation of GMOs in accordance with a harmonised authorisation procedure. This part will explain 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. We will understand as we move through these two parts the extent to which the upstream approach (centralised procedures for granting marketing authorisations) is entangled with a downstream approach (national measures restricting or controlling the cultivation of GM plants).

II. Marketing Authorisation Procedures of GMOs or/and Products Containing them and their Problematic Application

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). 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.

1. The Marketing Authorisation Regime under Directive 2001/18

The centrepiece of European Community (EC) legislation at the start of the 1990s, Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms was replaced in 2001 by Directive 2001/18/CE. This directive regulates the development and marketing of these products within the EC.[13]

Directive 2001/18/EC amounts to an horizontal legislation under which the requirements applicable to marketing (part C) are intended to apply to all GMOs other than those covered by a sectoral framework.[14] Since it is applicable horizontally, it has to interact with other sectoral regulations.[15] Given that it works as a safety net[16], several other directives refer to its risk assessment procedures. This is the case of the directive on the common catalogue of varieties of agricultural plant species[17], the directive on the marketing of vegetable propagating and planting material[18], and the one on the marketing of material for the vegetative propagation of the vine [19].

If its core features are considered, Directive 2001/18/EC is based – as was the old Directive 90/220/EEC – on the key principle that no GMO may be released into the environment for experimental purposes (Part A) or subsequently marketed unless

13 OJ 1990 L 117/15. Under Directive 90/220/EEC, numerous marketing applications for GMOs had aroused objections from the Member States, which ultimately led to an almost generalised blockage of the procedure applicable to the granting of authorisations. A mere eighteen MAs were issued during this period, only three of which did not attract any objection from the Member States. This free-for-all resulted in the imposition of a *de facto* moratorium on 24 June 1999 on the marketing of new GMOs. However, a WTO panel reached the conclusion that the moratorium infringed the SPS Agreement. See Report of the Appellate Body of 29 September 2006 *European Communities - Measures Affecting the Approval and Marketing of Biotech products* WT/DS291/R, WT/DS292/R and WT/DS293/R. Regarding the vicissitudes of Directive 90/220/EEC, see M. Lee, *supra* note 10, pp. 2-4, 63.

14 Article 12.

15 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.

16 E. Brosset, *supra* note 10, p. 35.

17 Council Directive 2002/53/EC, *supra* note 15.

18 Council Directive 92/33/EEC on the marketing of vegetable propagating and planting material, other than seed, OJ 1992 L 157/1.

19 Council Directive 2002/11/EC amending Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine and repealing Directive 74/649/EEC, OJ 2002 L 53/20. This directive provides the opportunity (subject to an assessment equivalent to that of Directive 2001/18/EC) to market genetically modified propagating material for trials, selection work and ultimately even for the production (Article 5ter bis). If products, stemming from GMO vines, are intended for use as food or food ingredient, they also fall within the scope of Regulation (EC) No 1829/2003, commented *supra* note .

it has been previously authorised by the competent authorities upon conclusion of a scientific assessment (Part B). In other words, the assessment has to come first, after which the decision is made.[20] The assessment procedure for something as important as the authorisation of experimental release and the subsequent marketing of a GMO is conditional upon the requirement that it is "safe for human health and the environment".[21] This regime involving prior assessment and administrative authorisation on a case-by-case basis is justified by the uncertainty resulting from the novel nature of this technology.[22] Indeed, the obligation to assess GMOS and the requirement that they may only be introduced into the natural environment in stages – voluntary release for experimental purposes, followed by marketing – is intended to enable the authorities to assess the risks associated with the release of these organisms before they become manifest. The significance of the assessment mechanisms is thus anything but negligible.

In contrast to the procedure applicable to experimentation in virtue of which national competent authorities grant consent (Part A), decision making in relation to the dissemination of GMOs falling within the scope of Directive 2001/18/EC is decidedly more centralised. The recourse to an integrated MA regime is justified on the grounds that it ensures the proper functioning of the internal market which, due to the scientific controversies resulting from debates on the safety of GMOs, could be compromised by different national regimes. This explains why Directive 2001/18/EC was adopted on the basis of the old Article 95 (replaced by Article 114 TFEU). This legal basis restricts significantly the Member States ability to enact more stringent standards than the ones laid down in the Directive.[23] In order to enable the Member States to file objections, and ultimately to arrive at a consensus, the procedure is based on close cooperation between the national authorities and the EU institutions.

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.[24] In cases where an objection is raised and maintained by a competent authority or the Commission, a decision shall be adopted by a regulatory committee.[25]

'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 Ministers 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.[26] The Commission then decides whether to grant the 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.

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.[27] The deadlock in both comitology and the Council can be illustrat-

20 C. Noiville and N. de Sadeleer, "La gestion des risques écologiques et sanitaires à l'épreuve des chiffres. Le droit entre enjeux scientifiques et politiques" (2001) 2 *RDUE* pp. 389-449; C. Joerges and K.-H. Ladeur, *Integrating Scientifc Expertise into Regulatory Decision-Making* (Baden-Baden: Nomos, 1997); A. Alemano, *Trade in Food* (London: Cameron & May, 2007) pp. 77-104; S. Mahieu, *Le droit de la société de l'alimentation* (Bruxelles: Larcier, 2007) p. 674.

21 Recital 47.

22 N. de Sadeleer, *Environmental Principles* (Oxford: OUP, 2005) pp. 112-114.

23 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.

24 Articles 13 to 19.

25 Article 18(1).

26 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, *supra* note 10, pp. 71.

27 The authorisations granted for maize Bt 176 and maize T 25 were withdrawn.

ed by the *Amflora* case.[28] 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*. In Case T-240/10, the General Court quashed this MA. In that case, having established that a qualified majority could not be achieved, the Commission had requested a new opinion from the EFSA, which had not been transmitted to the regulatory committee responsible for draft authorisations presented by the EU executive. The General Court held that, whilst the enacting terms of the final decision on authorisation were identical to those of the draft decision initially drawn up according to the comitology procedure, that was not the case for "*the scientific basis relied on by the Commission to adopt those decisions*".[29] The provision of new scientific opinions expressing greater uncertainty than the previous opinions could have led the members of the regulatory committee to review their initial position, and accordingly to arrive at a qualified majority either against or in favour of the Commission's draft,[30] which would have ultimately have prevented the latter from adopting the contested decision. As it affected the institutional balance of the EU, the failure to comply with the comitology procedure thus invalidated the authorisation.[31]

The maize TC1507 saga – transgenic insect-resistant maize produced by Pioneer Hi-Bred International – also illustrates the difficulties encountered in the MA procedure.[32] On three occasions (2004, 2006 et 2008), the EFSA issued opinions concluding that there was no risk for human health or the environment, and accordingly supported the applications made by Pioneer. Subsequently, acting in accordance with Article 5(2) of Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, on 25 February 2009 the Commission convened an *ad hoc* regulatory committee. Due to the absence of a qualified majority either in favour of or against the draft authorisation,[33] the Commission was required – pursuant to Article 5 – to submit to the Council '*without delay*' a proposal concerning the action to be taken and to give notice to the European Parliament. On account of the Commission's procrastination in dealing with its application, Pioneer lodged an action for failure to act[34] before the General Court, alleging a violation of the duty of diligence applicable to the Commission.[35]

Finding first and foremost that the expression '*without delay*' contained in Article 5(4) of Decision 1999/468 left a certain degree of room for manoeuvre to the Commission, whilst nonetheless requiring it to act quickly,[36] the General Court stressed that the procedure could not under any circumstances last for longer than 120 days from the end of the conciliation period, considering also that this period may be suspended for up to a maximum of 90 days when the Commission seeks the opinion of a scientific committee.[37] However, this time limit had been amply passed at the time formal notice was given (i.e. 29 December 2009), as the start date for the 120 days period was at the latest 17 November 2006, the date on which the second opinion was provided by the EFSA.[38] The Commission was thus under an obligation to take action before this date. Finally, the failure to state its reasons in accordance with Article 296 TFEU could not be justified by any delaying tactics on the part of the applicant or by the complex nature of the case.[39]

The Commission, and indirectly the Council, are thus subject to an obligation to rule in accordance with a framework put in place thirteen years ago. However, the maize 1507 case initiated by Pioneer Hi-Bred appears to have speeded up the instruction of other applications for authorisation that are still pending (around a dozen, three of which are at an

28 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 component of starch, OJ 2010 L 53/11.

29 *Hungary v Commission, supra* note 3, para. 82.

30 *Ibid*, para. 85.

31 *Ibid*, para. 86.

32 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.

33 Nineteen out of twenty-eight Member States declared their opposition against the marketing of this maize variety. However, in the absence of a qualified majority (73,9% of the votes), the Council was unable to obstruct the marketing authorisation process. See M. Lee, *supra* note 10, pp. 63-64, 70-71.

34 Article 256 of the TFEU.

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

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

37 Article 18(1) of the Directive 2001/18/EC, *supra* note 3.

38 *Pioneer Hi-Bred International, supra* note 36, para. 47.

39 *Ibid*, para. 72.

advanced stage).[40] Due to deep-seated disagreements between the Member States, the comitology procedure continues to be that favoured by the European Commission. Nevertheless, misgivings are so widespread that, in its work programme for 2015,[41] the European Commission called for a change to the decision making procedure, with a view to accommodating the States that oppose the marketing of GMOs.

2. The Marketing Authorisation regime of GM Food and Feed and Products Containing GMOs under Regulation 1829/2003

Regulation 1829/2003 is not limited exclusively to the environment and also pursues goals relating to quality of life, human health, animal welfare and consumer protection.[42] Key safety obligations are laid down with respect to both GM food and feed:

- GM food must not have adverse effects on human health, animal health or the environment, mislead the consumer, and 'differ from the food which it is intended to replace to such an extent that its normal consumption would be nutrition-ally disadvantageous for the consumer [43] (chapter II);
- GM feed can be marketed provided that they don't have adverse effects on human health, animal health or the environment, mislead the user or 'differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans' [44] (chapter III).

This section is dedicated to the scope of ambit of the Regulation and its marketing procedure.

The scope of Regulation 1829/2003[45] is extremely broad. Authorisations apply to 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. Food processed from GMOs that no longer contains modified organisms can only be authorised under Regulation 1829/2003 whereas GMOs for food or feed use can in principle be authorised under both legislations. Furthermore, in contrast to the previous regime, new foods that are "substantially equivalent" to existing foods are also covered.[46] In the final analysis, the decisive element is how the GMO products or derived products are used along the food production chain.

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 ambit of Directive 2001/18) as part of the application for authorisation for GM food and feed. As a result, the scope

40 Due to the absence of a qualified majority in favour or against these authorisations within the Standing Committee on the Food Chain and Animal on 23 May 2014, the Commission should soon approve the marketing for food and feed of three new varieties of transgenic soya and of one transgenic maize. These varieties are soy 305423 (Pioneer), MON 87705 (Monsanto), BPS-CV127-9 (BASF), and maize T25 (Bayer). On 24th April 2015, the Commission adopted 10 new authorisations for GMOs for food/feed use (MON 87460 maize, MON 87705 soybean, MON 87708 soybean, MON 87769 soybean, 305423 soybean, BPS-CV127-9 soybean, MON 88302, oilseed rape, T304-40 cotton, MON 88913 cotton, LLCotton25xGHB614 cotton), 7 renewals of existing authorisations (T25 maize, NK603 maize, GT73 oilseed rape, MON 531 x MON 1445 cotton, MON 15985 cotton; MON 531 cotton and MON 1445 cotton), and also the authorisation for the importation of 2 GMO cut flowers (carnations line IFD-25958-3 and line IFD-26407-2). It must be noted that these authorisations had received "no opinion" votes from Member States in both the Standing and Appeal Committees, since no qualified majority either in favour or against was expressed.

41 Commission Work Programme 2015, COM(2014) 910 final, p. 10.

42 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).

43 Article 4.

44 Article 16.

45 Regulation (EC) No 1829/2003, *supra* note 15. Regarding the modalities of its application, see Commission Regulation (EC) No 641/2004 OJ 2004 L 102/14. The regulation has replaced the existing approval procedures for GM foods under the Novel Foods Regulation (EC) No 258/97, that was not entirely satisfactory. See Case C-236/01 *Monsanto Agricoltura Italia* [2003] ECR I-8105.

46 Recital 6. Regulation (EC) No 258/97/CE concerning novel foods and novel food ingredients provided for a simplified procedure for the placing on the market of "substantially equivalent" genetically modified food, pursuant to which several marketing authorisation had been granted. This procedure gave rise to litigation. The ECJ held that the mere presence of traces of transgenic proteins in novel foods did not prevent these foods to be considered as substantially equivalent to existing foods and, consequently, to be subject to a simplified procedure. Account must be made of the fact that foodstuffs covered by an authorisation granted pursuant to the new Regulation (EC) No 1829/2003 are now exempted from the requirements of Regulation (EC) No 258/97, unless they fall within the scope of ambit of Article 1(2)(a) of that Regulation in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.

of the authorisation granted in accordance with Regulation 1829/2003 can include the cultivation of GM crops for feed or food uses. That being said, decisions on authorisation 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.

However, the authorisation of GM crops for non-food or non-feed uses (for example, growing GM potatoes for processing into industrial starch, flowers that have no food or feed purposes, etc.) is still governed solely by Directive 2001/18/EC.[47]

The *Bablok* case, which concerned honey that had been accidentally contaminated by pollen from 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 genetically modified (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.[48] 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", [49] these ingredients fall within the scope of the Regulation.[50] 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 upon the circumstances, such an extension could entitle the victims to bring a civil claim against the farmers responsible for the accidental contamination.

As a sectoral legislation departing from the general regime laid down by Directive 2001/18/EC set out above, Regulation 1829/2003 provides for a uniform regime of MA specific to the GMOs falling within its scope. This regime 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 assess direct on Union level, in consultation with the Member States, and definitive decisions concerning authorisation fall to the Commission or, depending upon the circumstances, the Council. Authorisation may only be granted after an environmental risk assessment[51] has been carried out by the EFSA, which in case of overlap with Directive 2001/18 must also assess risks in accordance with the 2001/18 risk assessment procedure. All in all, the role of national authorities is belittled. Once authorised, the GMO or the product containing GMOs must be included in a Community register.[52]

Due to the uncertainty in such cases, authorisations are granted for a maximum period of ten years.[53] Any request for renewal must be submitted to the authorising body by the holder of the authori-

47 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.

48 *Bablok, supra* note 2, para. 62. See M. Lamping, « Shackles for Bees ? The ECJ's Judgment on GMO-Contaminated Honey », 1(2012) *EJRR* pp. 123-129.

49 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.

50 *Bablok, supra* note 2, para. 79.

51 Articles 5(5) and 17(5).

52 Article 28.

53 Articles 15(4) of the Directive 2001/18/EC, *supra* note 3, and Articles 7(5) and 19(5) of Regulation (EC) No 1829/2003, *supra* note 16.

sation.[54] Renewals of authorisations initially granted under the 2001/18 Directive are now governed by Regulation 1829/2003.

Despite stiff opposition from a number of Member States, the Commission has followed the positive scientific opinions of the EFSA and has so far authorised the GM applications submitted to it.[55] 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. Despite its centralised operation, this procedure is not renowned for its speed due to the account of the deadlock in committees and the Council.[57]

3. The Prominent Role of EFSA in the Release of the MAs

Although ethical and religious concerns play a secondary role in the procedures governing the granting of MA,[58] risk assessment has been placed on a pedestal:[59] the two MA procedures described above allowed the EFSA[60] to play a primary role in the assessment of the risks entailed by the GMOS subject to the authorisation or the renewal procedures,[61] which was reinforced following the adoption of Regulation 1829/2003. In effect, for MA procedures applicable to new foods, the national scientific authorities no longer consider the file before it is referred to the EFSA, and only become involved at a later stage, during which they may issue *ex post* criticisms of the Authority's assessment.[62]

Established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law[63] , the EFSA 'takes on the role of an independent scientific point of reference in risk assessment'.[64] The Authority scientific opinions buttress the authorisations granted by the EU institutions. Furthermore, if the opinion requested does raise any significant scientific uncertainty, according to the precautionary principle, the Commission will then have to consult the EFSA once again "in order to obtain clarification on the scientific assessment of the risks".[65] The environmental principle thus prevents a decision from being taken until after this doubt has been resolved.

Though the EFSA has not been established a superior scientific authority to the national health in-

54 Article 11(1) of the Directive 2001/18/EC, *supra* note 3, and Article 23 of Regulation (EC) No 1829/23, *supra* note 15.

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://www.gmo-compass.org/eng/gmo/db/.

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 Articles 5(3) and 33 of Regulation (EC) No 1829/23, *supra* note 15.

59 *Monsanto Agricoltura Italia, supra* note 45, paras. 78, 79 and 84.

60 A permanent scientific panel on GMOs was created within the EFSA, that is deemed to be a "European regulatory agency". This concept is defined by the Commission as "an autonomous legal entity set up by the legislative authority in order to help regulate a particular sector at European level and help implement a Community policy." See Draft Interinstitutional Agreement of 25 February 2005 on the Operating Framework for the European Regulatory Agencies (COM(2005) 59 final), p. 5. In 2012, the European Parliament, the Council and the Commission adopted a "common approach" to the EU decentralised agencies, which gives some guidance regarding the principles of good governance that apply to these agencies. See. E. Bernard, "Accord sur les agences européennes: la montagne accouche d'une souris" (2012) 3 *RDUE* pp. 399-446.

61 GMOs for cultivation are to undergo an individual risk assessment before being authorised to be placed on the Union market taking into account the direct, indirect, immediate and delayed effects, as well as the cumulative long-term effects, on human health and the environment. That risk assessment provides scientific advice to inform the decision-making process and is followed by a risk management decision. The assessment is carried out in accordance with Annex II of the Directive.

62 Articles 22(7), 23, and 36 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law. See M. Weimer, supra note 55, p. 6.

63 OJ 2002 L 31/1.

64 Recital 34 of Regulation (EC) No 178/2002, supra note 63. See A. Alemano, *Trade in Food, supra* note 20, pp. 161-223; *Ibid*, "L'AESA souffle ces cinq premières bougies : un premier bilan d'activité" (2007) 3 *RDUE* pp. 585-632.

65 *Hungary v Commission, supra* note 3, para. 103. Regarding the scope of this principle in the field of food safety, see N. de Sadeleer, "Précaution et sécurité alimentaire", in *Sécurité alimentaire. Nouveaux enjeux et perspectives* (Brussels: Bruylant, 2013) pp. 307-346.

stitutes,[66] its scientific opinions have considerable weight for four reasons. Firstly, their content forms an integral part of the reasons given for decisions on MA.[67]

Secondly, where the European Commission does not dispose of scientific expertise comparable to that of the Agency, it tends to follow the opinions given by the EFSA almost systematically. In effect, when deciding to set aside a scientific opinion in order to upgrade the level of protection, the Commission 'must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter.' In addition, as a matter of procedure, 'the statement of reasons must be of a scientific level at least commensurate with that of the opinion in question'.[68] Nevertheless, since there is nothing monolithic about science and the Agency's opinions are not necessarily adopted unanimously, the Commission and the Council have the last word.[69] Thus, nothing prevents them from basing their decisions on scientific research carried out by national institutes that highlight risks not considered by the Agency.[70] In effect, the institutions 'may disregard the conclusions' drawn in the official scientific body of opinion, 'even though, in some places, it relies on certain aspects of the scientific analysis in the opinion.'[71] In other words, the institutions may also avail themselves of those parts of the scientific reasoning which they do not dispute.

Thirdly, with respect to requests for derogations provided for in Article 114(4) and (5) TFEU, the right for the Member State lodging the request to be heard does not apply neither to paragraph 4 nor to paragraph 5 procedure.[72] It follows that the national authorities cannot contradict the scientific arguments buttressing the Commission's refusal.

Finally, the opinions given by the EFSA are preparatory acts which cannot have legally binding effects on third parties.[73] Accordingly, they cannot be regarded as equivalent to acts falling under Article 263 TFEU. Since these opinions only account for one stage in a multi-stage procedure, only decisions granting or refusing MA are capable of being annulled on the grounds that they are *ultra vires*. Nonetheless, where the scientific opinions of the EFSA are flawed, the imperfect risk assessment will have ramifications on the subsequent decisions taken by the Commission or the Council, which are subject to judicial review. In other words, any unlawfulness of a requested opinion could be regarded as a breach of an essential procedural requirement, thereby rendering the institutions' decision unlawful. Indeed, the EU judicature may be called upon to review, first, the formal legality of the scientific opinion and, second, the Commission's exercise of its discretion.[74]

To conclude with, though the EFSA's opinions are endowed with a certain authority, "the cooperation with national authorities on GMOSs assessments has been hampered by a lack of trust and conflicting views over GMO safety".[75] It will come as no surprise that these disputes have compounded the deadlock at both comitology and Council levels relating to the issue of GM food and feed authorisations. As discussed above, the authorisations granted by the Commission to BASF (Amflorea) and Pioneer (Maize 1507) were dogged by controversy as the EFSA and several national institutes were at loggerheads over the level of uncertainty.

66 Articles 6(4) and 18(4).

67 *Hungary v Commission, supra* note 3, para. 91. See also by analogy Case T-326/99 *Fern Olivieri/Commission and EMEA* [2003] ECR II-6053, para. 55.

68 Case T-13/99 *Pfizer* [2002] ECR II-03305, para. 199.

69 Case C-120/97 *Upjohn* [1999] ECR I- 223, para. 47 ; Case C-405/92 *Mondiet* [1993] ECR I-6133, paras. 31-32 and 36 ; Case T-76/96 R *Pfizer* [1996] ECR II-815, paras. 196-201. See also A. Alemano and S. Mahieu, "The EFSA before the European Courts" (2008) 5 *EF&FLR* p. 325 ; M. Lee, *EU Regulation of GMOS, supra* note 8, p. 86 ; C. Pintado, "La valeur des avis scientifiques de l'EFSA", in *Actualité en droit alimentaire* (Limal: Anthémis, 2014) pp. 173 and 209-237.

70 The jurisdictions allow that the institutions could rely on national studies in so far the risks are regulated. In that connection, the CFI has allowed the Commission to prohibit an antibiotic, virginiamycin, on the basis of studies carried out by the Danish authorities; even if this study was in contradiction with the opinion delivered by the Standing Committee on Plants, Animals, Food and Feed. See *Pfizer, supra* note 69, para. 298. On the possibility of carrying out a risk assessment of a product in the light of its applications in Sweden, Norway and the United States, see *Polyelectrolytes Producers Group,* C-199/13, EU:C:2014:205, para. 41.

71 *Pfizer, supra* note 69, para. 200.

72 Case C-3/00 *Kingdom of Denmark v Commission* [2003] ECR I-2643, paras. 49 and 50; and Joined Cases T-366/03 and T-235/04 *Land Oberösterreich* [2005] ECR II-4005, paras. 41 and 43.

73 Case T-311/06 *FMC Chemical and Arysta Lifesciences v EFSA* [2008] ECR II-88, paras. 67-68; Case T-397/06 *Dow AgroSciences v EFSA*[2008] ECR II-90, paras. 59-60. See M. Chamon, "EU Risk Regulators and EU Procedural Law" (2014) 3 *EJRR* pp. 324-337.

74 See Joined Cases T-74/00, T-76/00, T-78/00, T-132/00 and T-141/00 *Artegodan* [2002] ECR II-4945, para 199.

75 M. Weimer, supra note 55, p. 7.

4. Free Movement of GMOs and of Products Containing GMOs in Accordance with Directive 2001/18/EC and Regulation 1829/2003

Given that both Directive 2001/18/EC and Regulation 1829/2003 were adopted on the basis of Article 114 TFEU, they have been enhancing the free circulation of GMOs and of products containing GMOs within the internal market. Accordingly, Member States' room for manoeuvre with respect to the control of the placing on the market of GMOs has been restricted. However, things are made none the simpler. The disagreements between the Commission and a number of Member States regarding the marketing of GM products have been perpetuated downstream at the cultivation stage. Indeed, in order to restrict or to ban the cultivation of authorised GM crops, some national authorities have invoked the safeguard clauses provided for under both the directive and the regulation.[76] Other Member States have relied on Article 114 (5) TFEU, which provides for national reinforced protection. Nevertheless, both safeguard clauses and Article 114(5) TFEU derogation clauses have been interpreted narrowly by both the Commission and the CJEU.

a. Proclamation by Secondary Law of the Principle of Free Movement of Goods

The EU lawmaker has adopted both Directive 2001/18/EC and Regulation 1829/2003[77] on the basis of Article 114 TFEU. This choice is not innocent given that the harmonisation 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. The advantage of such harmonisation is undeniable for producers, importers, and retailers since in fleshing out the principle of mutual recognition it facilitates the free circulation within the internal market of the authorised GMOs.

Both Directive 2001/18/EC and Regulation 1829/2003 as well as Directive 2002/53 on the common catalogue of varieties of agricultural plant species flesh out the principle of free movement of authorised GMOs[78]. As a result, GMOs authorised following completion of the EU procedures may be marketed throughout the Union, and may only be prohibited if the strict conditions laid down under secondary law are met.[79]

Nevertheless, the assertion of free movement in this legislation does not affect the right of the Member States to limit the free movement of GMOs or of products containing GMOs either under the derogation mechanisms provided for under Article 114(4)-(6) TFEU[80] or with reference to the safeguard clauses provided for under the harmonised measures. It is now necessary to consider the drawbacks of these two derogation mechanisms, with a view to stressing the added value for the Member States of the new regime on the control of the cultivation GMO crops, which will undoubtedly cause rivers of ink to be spilled (Part IV).

b. National Provisions Derogating from Harmonised Measures Allowing the Free Circulation of GMOs

Pursuant to Article 114(4) to (6) TFEU Member States have the possibility of adopting national provisions derogating from harmonised measures provided that the Commission approves the national measures. Given that new unilateral measures are likely to jeopardise the functioning of the internal market,[81] this derogation mechanism is subject to strict conditions.[82] Accordingly, national measures should satisfy three requirements: the risk that the measure is

76 Recital 7 of Directive 2015/412.

77 Whereas Directive 2001/18/EC was adopted on the basis of former Article 95 EC (Article 114 TFEU), Regulation (EC) No 1829/2003 was adopted on the basis of Articles 43, 114 and 168(4) TFUE. In contrast, Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species was adopted on the basis of the CAP legal base (Article 43 TFEU). It is settled case law that the genuine environmental legal basis encapsulated in Article 192 TFEU does not alter the competences which the EU lawmaker holds under the terms of Article 114 TFEU. See N. de Sadeleer, *EU Environmental Law and the Internal Market* (Oxford: OUP, 2014) p. 148; Ibid., « Environmental Governance and the Legal Bases Conundrum », *Oxford Yearbook of European Law* (2012) pp. 1–29.

78 Article 22 of the Directive 2001/18/EC, *supra* note 3; Article 19(5) of Regulation (EC) No 1829/2003, *supra* note 15; Article 16(1) of the Directive 2002/53/EC, OJ 2002 L 193. See I. Urrutia Libarona, *supra* note 8, p. 301.

79 Case C-165/08 *Commission v Poland* [2009] ECR I-6843.

80 N. de Sadeleer, *EU Environmental Law and the Internal Market, supra* note 77, pp. 358-380.

81 *Denmark v Commission*, *supra* note 72, para. 58.

82 The CJEU held that 'the adoption of new national legislation is more likely to jeopardise harmonization. The EU institutions could not, by definition, have taken account of the national text when drawing up the harmonization measure.' See Case C-512/99 *Germany v Commission* [2003] ECR I-84, para. 41; and *Denmark v Commission, supra* note 72, para. 58.

supposed to counter should be specific to the Member State requesting the derogation, it should manifest itself after the adoption of the harmonisation measure, and should be supported by scientific proof. These conditions are clearly cumulative.[83]

The "problem" or risk justifying the intervention of the Member State should be "specific" to the applicant Member State. *A contrario*, the condition of risk specificity prohibits the adoption of national measures designed to solve a problem common to the whole of the EU. The intention of the framers of the Treaty of Amsterdam was clearly to avoid the adoption of all regulations of general character. With respect to the prohibition of the cultivation of seed and planting material composed of or containing GMOs in the *Land Oberösterreich*, the Republic of Austria claimed that the territory of the Land Oberösterreich contained unusual or unique ecosystems that required separate risk assessments from those conducted for Austria as a whole or in other similar areas of Europe. The Commission dismissed the Austrian request taking into consideration EFSA's findings concerning the absence of scientific evidence demonstrating the existence of a specific problem. Both the General Court and the Court of Justice held that Austria failed to establish sufficient evidence capable of invalidating the concrete findings set out by the Commission in its contested decision.[84] In particular, Austria had not adduced any scientific evidence proving the existence of 'unusual' ecosystems.[85]

In addition, the right to introduce a national measure more stringent than the EU standard must be justified in the light of 'new scientific evidence'. To the extent that the draft of the EU harmonisation measure proposed by the Commission must already take into consideration in accordance with Article 114(3) TFEU 'any new development based on scientific facts', the novel character of the scientific evidence has to be assessed in the light of those scientific discoveries which occurred after the adoption of the harmonised measure. In *Land Oberösterreich*, the European Commission argued that the evidence provided by the Austrian authorities was not amounting to 'new scientific proof' within the meaning of paragraph 5. AG Sharpston noted that:

> 'Having regard to the stress laid by the appellants on the precautionary principle, I would add that, relevant though the principle may undoubtedly be when assessing new evidence concerning a new situation, 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'.[86]

As a result, the precautionary principle enshrined in Article 191(2) TFEU does not prevail over the Member State duty to bring 'scientific facts' within the meaning of paragraph 5 of Article 114 TFEU.

Last, pursuant to Article 114(6) TFEU the Commission is allowed a period of six months in order to approve or reject the national project. Paragraph 6 sanctions breaches of this time limit: in the absence of a decision by the Commission within six months of the notification of the national measure, the latter is deemed to have been approved. In other words, the Commission's silence has to be regarded as indicating tacit consent to the adoption of the national measures derogating from harmonised measures.

The time limit starts to run from the day after receipt of notice of its decision.[87] The sole decisive criterion for establishing when the period of 6 months takes effect is the date on which the decision is notified to the recipient. It follows that the simple fact that a decision is taken by the Commission – for example according to the accelerated written procedure – will not result in any legal effects for the recipient Member State unless it is informed prior to expiry of the six-month period provided for under Article 114(6) TFEU.

On 13 April 2007, Poland notified the Commission pursuant to former Article 95(5) EC several provisions of a draft Polish Act concerning GMOs, as derogations from the provisions of Directive 2001/18. On 12 October 2007, the Commission adopted a decision rejecting, on the basis of Article 95(6) EC, the derogations from the provisions of Directive 2001/18. Owing to a technical error, the information did not reach

83 *Germany v Commission, supra* note 82, para. 81; *Land Oberösterreich and Austria v Commission, supra* note 23, para. 57.

84 *Land Oberösterreich* [2005] ECR II-4005, *para*. 67; and *Land Oberösterreich and Republic of Austria v Commission, supra* note 23, paras. 65-66.

85 *Ibid,* para. 66.

86 Opinion AG Sharpston in *Land Oberösterreich and Republic of Austria v Commission, supra* note 23, para. 134.

87 Communication from the Commission concerning Article 95 (paragraphs 4, 5 and 6) of the Treaty establishing the European Community (COM(2002)760 final), para. 19.

Poland on the day on which that decision was adopted. On finding that the information had not reached the addressee, the Commission communicated its decision to Poland on 4 December 2007. Despite that delay in the communication of the information, the Commission asked Poland to comply with the terms of the decision adopted and to refrain from adopting any legal act entailing provisions in derogation from Directive 2001/18. The contested decision was challenged by Poland on the grounds that Article 95(6) EC, read in conjunction with Article 254(3) EC, has been infringed.

Contrary to the assertions made by the Commission, the General Court took the view that the mere adoption of a decision by the Commission within that six months period does not interrupt that period, irrespective of when that decision is notified. [88] Accordingly, such a decision cannot be construed as interrupting the six-month period and could not call into question Polish legislation which imposed more stringent procedures when transposing Directive 2001/18/EC. [89]

c. Safeguard Clauses

The principle of free movement of goods enshrined in harmonised measures can also be subject to some limitations in accordance with a safeguard clauses provided for under secondary law.[90] 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 must invoke either Article 16(2) of Directive 2002/53 on the common catalogue of varieties of agricultural plant, Article 23(1) of Directive 2001/18, or Article 34 of Regulation 1829/2003. The last two clauses were introduced into this legislation in accordance with Article 114(10) TFEU. The latter provides for that the harmonisation measures adopted on the basis of Article 114 TFEU shall, in appropriate cases, ' include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure'. The purpose of this paragraph 10 – replicating paragraph 5 of former Article 100a EEC – is to allow a Member State, subject to a EU control procedure, to adopt temporary measures in the event of a sudden and unforeseen danger to health, life, etc.[91]

Testament to the precautionary principle[92], the safeguard clauses mentioned above were relied on by several Member States in order to oppose the marketing of various GMOs. However, since they depart from the general principle of free movement, these clauses have been interpreted narrowly, in particular in the cases concerning the cultivation of maize MON 810. Accordingly, national suspensions or bans must also comply with the following requirements.

Firstly, they must enable the Member States to deal with special circumstances for a limited period of time. 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.[93]

Secondly, in accordance with Article 114 (10), 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 burden of proof that the contested GMO constitutes 'a risk to human health or the environment'[94] or a 'serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily'[95].

In addition, it is settled case law that health-related and environmental reasons must be supported by new scientific evidence refuting the expert reports provided by the EFSA. In this connection, Article 23(1) of Directive 2001/18 subjects the invocation of these clauses to the requirement to present 'new or additional information' made available since the date of the consent.[96] Regarding the burden of proof, the Court ruled in *Monsanto Agricoltura Italia* that 'protective measures, notwithstanding their temporary

88 Case T-69/08 *Poland v Commission* [2010] ECR II-5629, para. 69.

89 *Ibid*.

90 Case C-36/11 *Pioneer Hi Bred Italia* [2012] OJ C355; Opinion AG Bot in Case C-36/11 *Pioneer Hi Bred Italia* [2012] OJ C355, para. 51.

91 P. Craig and G. De Burca, *EU Law: Text, Cases, and Material, 3rd ed.* (Oxford: OUP, 2003) p. 1186.

92 *Greenpeace France, supra* note 8, para. 44 ; *Monsanto Agricoltura Italia, supra* note 45, para. 111. See N. de Sadeleer, "The Precautionary Principle in EC Health and Environmental Law" (2006) 12 *European Law Journal* pp. 139-172.

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

94 Article 23(1) of Directive 2001/18/EC, *supra* note 3.

95 Article 34 of Regulation (EC) No 1829/2003, *supra* note 16 referring to Article 53 of Regulation (EC) No 178/2002, *supra* note 72.

96 *Greenpeace France, supra* note 8.

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'.[97] 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'.[98] 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.[99]

Thirdly, in accordance with principles traditionally applicable to safeguard clauses, the application of a derogation clause under paragraph 10 should also be subject to a "control procedure" normally undertaken by the Commission. In practice, 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. Indeed according to both legislations, the recourse to these clauses implies a duty to provide immediate information.[100] 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.

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 legality of the safeguard clauses.[101]

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 a second time. 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 this Directive and gave notice to the Commission of its agricultural product as an "*existing product*" under Article 20(1)(a) of Regulation 1829/2003. However, 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.[102] 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.

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.[103]

Article 34 of Regulation No 1829/2003 refers to the procedural conditions laid down in Article 54 of Regulation No 178/2002. In *Monsanto*, the CJEU interpreted the conditions quite strictly. In addition to urgency, Article 34 of Regulation No 1829/2003 requires

97 *Monsanto Agricoltura Italia, supra* note 45, para. 107.

98 See, by analogy, the interpretation of the safeguard clause laid down in former Regulation (EC) No 258/97, OJ 1997 L 43; *Monsanto Agricoltura Italia, supra* note 45, paras. 106 and f.

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

100 Article 23(1)(3) of the Directive 2001/18/EC, *supra* note 3; Article 54(1) of Regulation (EC) No 178/2002, *supra* note 62. 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.

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

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

103 Joined cases C-58/10 to C-68/10 *Monsanto SAS e.a.* [2011], 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* pp. 447 and following; M. Clément "Arrêt *Monsanto* : Du principe de précaution au risque manifeste" (2012) *REDC* pp. 163 and following.

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'.[104] The precautionary principle was not invoked in this case 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.[105]

III. The "Repatriation" of Cultivation

1. Background

It soon became apparent that Directive 2001/18 had much unfinished business: based exclusively on a case-by-case assessment and authorisation system, socio-economic issues could not be considered under this procedural framework. In particular, no global management of risks was provided for.[106]

As the issue was particularly controversial in certain Member States, the implementation of Directive 2001/18 has not come without its challenges. As for the 1990 Directive, it was transposed with a considerable delay in various Member States, which resulted in particular in several rulings against a number of Member States.[107] Surprisingly France even failed to comply with previous ECJ judgments.[108] Similarly, "the views of a section of public opinion" in Poland relating in particular to "a Christian conception of life" could not prevent its transposition in this country.[109]

As discussed above, both the marketing schemes and the implementation of safeguard clauses were deadlocked. 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. It comes thus as no surprise that, in contrast to other countries, very few 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).[110] The MON 810 GMO authorised for cultivation is so far cultivated in only five Member States: Spain, Portugal, the Czech Republic, Rumania, and Slovakia.

Since 2009, various Member States have called for a change to the MA regime which, due to the vagaries of the comitology procedure, has proved to be excessively favourable to the European Commission. In 2010, the Commission proposed that Directive 2001/18 be amended by repatriating decisions on the cultivation of GMOs, though not on their marketing.[111] Its proposal sought to enable the Member States to restrict or prohibit the cultivation of GMOs in all or part of their territory on grounds other than environmental or health concerns. However, this proposal was not regarded as satisfactory by a majority of Member States on the grounds that it was not certain that it would enable risks to be reduced satisfactorily. After several years in the long grass, the Parliament and the Council finally held a trilogue on 3 December 2014 at which an informal agreement was concluded. Adopted on March 11th 2015, Directive 2015/412 inserts Articles 26a-c into the 2001/18 Directive.[112]

Obviously, several Member States had high expectations for this new regime. By way of illustration, though the French lawmaker belatedly transposed Directive 2001/18, he fleshed out in advance the forthcoming directive in adopting on the 2nd of June 2014 Act n° 2014-567 on the cultivation of GM maize.

2. Procedure

Under the terms of a somewhat convoluted compromise, the new powers of the Member States under

104 *Monsanto and Others*, *supra* note 103, para. 81; See G. Kalfleche, "Application du droit de l'Union par les juridictions administratives (novembre 2011- mai 2012)" (2012) 7 *Europe* pp. 10-11.

105 *Monsanto Agricoltura Italia, supra* note 45, para. 112.

106 This approach seems less ambitious then the one regarding pesticides, where the EU legislator adopted Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides, OJ 2009 L 309.

107 See the case law listed in note 11.

108 Case C-121/07 *Commission v France* [2008] ECR I-9159.

109 Case C-165/08 *Commission v Poland* [2009] ECR I-6843, para. 56.

110 I. Urrutia Libarona*, supra* note 10.

111 Proposal for a Regulation of the European Parliament and the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory (COM(2010) 375 final). See. S. Poli, "The Commission's New Approach to the Cultivation of GMOs" (2012) 4 *EJRR* pp. 339-344; K. Zurek, "Indicating Reasons for National GM Opt-Outs" 2(2011) *EJRR* pp. 241-3 ; J. Corti Varela, "Opt-Out Clause in Cultivation of GMOs is closer (or not)" 3(2014) *EJRR* pp. 359-361.

112 OJ L 68/1. The legal basis chosen is Article 114 TFEU.

the new Article 26c are spread over two stages that can be briefly described.

Phase 1. First of all, they 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.[113] In contrast with phase 2, no justifications are needed. If such a request is made, the MA applicant may limit the geographical scope of its initial application.[114] 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, or from receiving the opinion of the EFSA under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission is called on to make the demand publicly available by electronic means. The Commission must forward the request to the applicant. The latter can adjust its application, although is not obliged to do so. The written consent issued under both MA 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.[115]

Phase 2. Thereafter, where the applicant refuses to alter its application, or where no request is notified by a national authority,[116] 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. 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.

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".[117] These grounds can be invoked either in a general manner or in more specific form.

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".[118] According to Winter, this implies that the Member States may not generally prohibit the cultivation of GM seeds per se. This can rather be done with regard to a particular seed or a certain group of seeds.[119] However, as long as they are not cultivated, the marketing of new genetically modified food authorised under Regulation 1829/2003 is not affected by this regime.

As regards its 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 MA or the implementation of a safeguard clause,[120] 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 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.[121]

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113 Article 26b(1) of Directive 2015/415.

114 Article 26b(2).

115 Recital 21, and Article 26b(5).

116 Article 26b(3). The European Parliament obtained that phase 2 is not subjected to phase 1.

117 Recital 13 of Directive 2015/415.

118 Art. 26b(3)(1) Directive 2015/412.

119 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.

120 Recital 7 of Directive 2015/415.

121 Recital 5 of Directive 2015/415. In the same vein, experimental release control of GMOs - also commonly known as field or clinical trials -, the potential impact of which is more limited in geographical terms, falls under the competence of the national authorities (Part B of Directive 2001/18). These types of releases are mainly carried out for the purposes of study, research, demonstration and development of novel varieties.

Last but not least, it should be noted that these compelling grounds are not set out in a closed list, given that Article 26b(3) mentions that "such as those related to".

3. Conditions

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

As regards the formal conditions, pursuant to Article 26b(4) the national measures are subject to an information procedure at EU level, which is not however as stringent as the review procedure provided for under the different 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 measures. On expiry of that period, the Member State concerned may "adopt the measures either in the form originally proposed, or as amended to take account of any non-binding comments received from the Commission". This procedure can be placed upon equal footing with the one provided for under Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations that does not apply to the national measures at issue.[122] 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 harmonised internal market standards.[123]

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

4. Compatibility with the Principle of Free Movement of Goods

a. Introductory Remarks

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 (MEQRs) contrary to Articles 34 TFEU.[124] The drafters of the amending directive were aware of this potential conflict. In effect, recital 16 of the preamble stresses that the restrictions or prohibitions 'should refer to the cultivation, and not to the free circulation and import, of genetically modified seeds and plant propagating material as, or in, products and of the products of their harvest, and should, furthermore, be in conformity with the Treaties, in particular as regards the principle of non-discrimination between national and non-national products, the principle of proportionality and Article 34, Article 36 and Article 216(2) TFEU'.

The following observations must be made in relation to the compatibility of the new opt-out regime with the principle of free movement of goods that the CJEU has been considering as 'one of the fundamental principles of the Treaty'[125] and that has been hailed by most academic authors as the key component of the European integration process.

The issue of compatibility can only be resolved by the CJEU. Cases regarding the validity of Directive 2015/412 could come before the CJEU in one of two ways: either directly via an action for annulment brought by an undertaking pursuant to Article 263 TFEU, or indirectly, under Article 267 TFEU, via preliminary references from a national court. Given the lack of standing of the GMO producers or retailers to challenge directly the directive before the CJEU,[126] it is more likely that they will challenge the national implementing measures before the competent national courts. These courts will be able to refer one or more of the three separate, albeit related, questions for preliminary rulings:

– regarding the compatibility of the national measure restricting or banning cultivation of autho-

122 Recital 17 of Directive 2015/415.

123 N. de Sadeleer, *EU Environmental Law and the Internal Market, supra* note 77, pp. 369-370.

124 M. Weimer, "What Price Flexibility?-The Recent Commission Proposal to Allow for National Opt-Outs on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon" 4(2010) *EJRR* pp. 345-352.

125 Case 37/83 *Rewe-Zentrale* [1984] ECR 1229, para. 18 ; Case 265/65 *Commission v. France* [1997] ECR I-6959.

126 N. de Sadeleer and C. Poncelet, « Protection Against Acts Harmful to Human Health and the Environment Adopted by the EU Institutions », 14 (2011-2012) *Cambridge Yearbook of EU Law*, pp. 177-208.

rised GMOs with the procedural and substantive requirements of Article 26b;
- regarding the compatibility of the national measure at issue with the principle of free movement of goods;
- regarding the compatibility of Directive 2015/412 with the principle of free movement of goods.

In answering these questions, the CJEU will have to decide whether Directive 2015/412 can authorise Member States to prohibit or restrict trade between Member States. This begs the question as to whether any restrictions admitted under EU legislation must comply with the derogations laid down by Article 36 TFEU or admitted under mandatory requirements of general interest.

b. The Compatibility of the National Measure with the Directive 2015/412 Requirements

The first question that needs to be asked is whether the national measure complies with the Directive 2015/412 material and procedural requirements.

c. The Applicability of Article 34 TFEU

The Court will then have to turn to Article 34 TFEU, which is applicable only to the extent that the matter cannot be determined exhaustively on the basis of the Directive. Indeed, it is settled case law that where full harmonisation is achieved by the EU, 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 authorised GMOs.[127] As stressed by Oliver, it is not open to a Member State to argue that a national rule which hinders the free movement of goods falls outside Article 34 TFEU simply because it can be set aside by the adoption of an harmonising measure.[128] The CJEU will have thus to verify the extent to which the harmonisation is deemed to be complete or not.

So far, the original directive as well as Regulation 1829/2003 provided exhaustively for the harmonisation of national rules regarding the placing on the market of GMOs. Accordingly, the contested national measures had to be reviewed in the light of the requirements laid down by these harmonised measures. Moreover, as discussed above,[129] the Member States were called on to make use of the safeguard clauses procedures foreseen either by Article 114 TFEU or by the harmonised measures. In banning or restricting the cultivation of GM crops, they could invoke neither Article 36 TFEU nor a mandatory requirement of general interest.

Nevertheless, the Court will have to determine whether Directive 2015/412 precludes any examination of the national measures in the light of primary law. This is not an easy question to which there is a clear-cut yes-no answer.

Our view is that the Court will have to recognise that Directive 2015/412 does not fully harmonise national rules. In contrast to the marketing procedures where the Member States are not endowed with any room for manoeuvre, the amending Directive gives Member States considerable leeway in allowing them to decide on the personal, temporal, geographical, and material scope of their restrictive measures. Moreover, the list of compelling grounds is not exhaustive. To conclude with, the harmonisation brought about by Directive 2015/412 ought to be regarded as being of such a kind as not to preclude an examination of whether the national restriction arrangements allowed under Article 26bis are compatible with Article 34 TFEU.

Accordingly, the Member States may invoke 'the protection of the health and the life of animals and plants' listed under Article 36 TFEU. Nonetheless, given that the Member States are not authorised to counter the scientific conclusions of the risk assessments carried out by the EFSA, [130] that would be a Catch-22 situation.

d. The Existence of a Restriction on the Free Movement of Goods

Given that the control of GM crops cultivation is not subject to an exhaustive harmonisation regime, the

127 Case C-323/93 *Centre d'insémination de La Crespelle* [1994] ECR I-5077; Case C-249/92 *Commission v Italy* [1994] ECR I-4311; Case C-3/99 *Cidrerie Ruwet* [2000] ECR I-8749 ; and Case C-350/97 *Monsees* [1999] ECR I-2921, para. 27; ; Case C-309/02 *Radlberger* [2004] ECR I-11763, para. 53; Case C-350/97 *Monsees* [1999] ECR I-2921 and Case C-216/11 *Commission v France* [2013] ECR I-000, para. 27; Case C-216/11 *Commission v France* [2013] EU:C:2013:162, para. 27; Case C-573/12, *Ålands vindkraft AB v Energimyndigheten,* EU:C:2014:2037, para. 58.

128 P. Oliver (ed.), *Oliver on Free Movement of Goods in the EU* (Oxford: Hart, 2010) p. 484.

129 See the discussion above, Part II, Section 4.

130 Article 26b(3), second paragraph.

CJEU will have to determine at a second stage whether the national restriction falls under Article 34 TFEU. In other words, does the measure at issue qualify as a MEQR?

A possible objection to that qualification might be that the national contested measures regulate not the placing on the market of the authorised GMOs but their use for cultivation purposes.

However, this objection must be dismissed. In addition to 'measures discriminating directly or indirectly against foreign producers' and to 'product requirements', MEQRs cover also 'any other measure which hinders access of products originating in other Member States to the market of a Member State'.[131] In that connection, in both *Trailers* and *Swedish Watercrafts* cases, the CJEU held that a national measure regulating the use of a product was falling within the scope of Article 34 TFEU.[132] Three categories can be drawn from these two cases: a) measures completely prohibiting the use of a product; [133] b) measures preventing users from using products for the specific and inherent purposes for which they were intended; [134] and c) measures greatly restricting their use [135]. As a result, non-discriminatory measures impeding to some extent the use of products[136], or totally banning the use of a product or having 'a considerable effect on the behaviour or the consumers' have to be qualified as MEQRs.[137]

Therefore, the CJEU is likely to reach the conclusion that the regulation of the cultivation of GMOs measures is capable of impeding imports from other Member States in as much as it has 'a considerable effect on the behaviour or the consumers'. It follows that Article 34 TFEU is more likely to catch a blanket ban rather than a mere restriction.

e. The Justification for the Restriction on the Free Movement of Goods

Though it constitutes 'one of the fundamental principles of the Treaty', the principle of free movement of goods is not absolute.[138] Accordingly, Articles 34 TFEU does not enshrine a general freedom to trade or the right to the unhindered pursuit of one's commercial activities. [139] It follows that the CJEU will have to assess whether the compelling grounds listed under Article 26b(3) or other mandatory requirements of general interest can objectively justify the national measure at issue.

In this connection, the recent *Alands Vindkraft* and *Essent* are cases in point. In his opinion in *Alands Vindkraft*, AG Bot recommended that the CJEU should declare a provision of Directive 2008/29, which confers on Member States the power to prohibit, or to restrict, access to their national green electricity support schemes for producers whose renewable electricity sites are located in another Member States, was contrary to Article 34 TFEU, and, as a result, invalid.[140] In *Essent*, a similar case decided shortly afterwards, AG Bot endorsed similar reasoning.[141]

However, the CJEU sitting in Grand Chamber in *Alands Vindkraft* did not endorse the AG's reasoning. The Court held that the objective of promoting renewable energy as part of the fight against global warming could justify the Swedish green electricity support arrangements that were objectively contrary to Article 34 TFEU, provided that they were proportionate with regard to that objective.[142] Later on, in *Essent*, the 4th chamber of the Court endorsed the same reasoning.

It must be remembered that in these two judgments the CJEU did not rely on the express permission granted to Member States by the two directives in question. Both Article 36 TFEU and the mandatory environmental requirement could justify the contested national schemes in their own right.[143] However, it may be difficult to avoid this issue in relation to the cultivation of GM crops.

131 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.

132 *Trailers*, *supra* note 131, para. 58.

133 Case C-265/06 *Commission v Portugal* [2008] ECR I-2245, para. 33; *Trailers*, *supra* note 131, para. 56.

134 *Mickelsson and Roos 'Swedish Watercrafts'*, *supra* note 131, para. 28.

135 *Ibid.*

136 N. de Sadeleer, *EU Environmental Law and the Internal Market, supra* note 77, pp. 275-278.

137 *Trailers*, *supra* note 131, para. 56; *Mickelsson and Roos 'Swedish Watercrafts'*, *supra* note 132, paras. 26-27.

138 Case C-51/93 *Schmidberger* [2003] ECR I-5659, para. 78.

139 Case C-292/92 *Hünermund* [1993] ECR I-6787, 6813.

140 Opinion AG Bot in *Ålands vindkraft AB v Energimyndigheten,* C-573/12, EU:C:2014:2037, paras. 74-110.

141 Opinion AG Bot in *Essent Belgium NV,* C-204/12 to C-208/12, EU:C:2014:2192.

142 Joined cases C-204/12 to C-208/12, *Essent Belgium NV,* EU:C:2014:2192, paras. 89-116; case C-573/12, *Ålands vindkraft AB v Energimyndigheten,* supra note 127, paras. 76-119, annotated by M. Sydlo in 52:2 (2015) *CMLRev* pp. 489-510.

143 M. Sydlo, *supra* note 142, p. 497.

f. Compatibility of Directive 2015/412 with the Principle of Free Movement of Goods

Another consequence of the principle that primary law prevails over secondary law relates to the compatibility of Directive 2015/412 with the principle of free movement of goods. In effect, Article 34 TFEU applies not only to national measures aiming at controlling the cultivation of GM crops but also at the harmonised measure empowering the Member States to adopt such measures.[144] This gives rise to four comments.

Firstly, EU institutions must have regard to the principle of free movement of goods in framing their legislation. Even if the principle of free movement of goods applies less strictly to EU institutions than it does to Member States,[145] the former are required to comply with Article 34.[146]

Secondly, whilst the EU institutions are required to take into account Article 34 TFEU when adopting harmonisation measures, it is applied less strictly by the CJEU than it is by the national authorities.[147] Indeed, the Court is somewhat reluctant to review the validity of secondary law. Given that the CJEU leaves a large degree of discretion as to the means of achieving the internal market, its judicial review is highly deferential, to say the least.[148] On very few occasions, it has of its own motion declared invalid EU legislation on the grounds that it infringes primary law.[149]

Thirdly, instead of nullifying harmonisation measures, the Court is keen on interpreting secondary law obligations hindering free trade in goods consistently with primary law. It is indeed settled case law that where a provision of secondary law is open to more than one interpretation, preference should be given to the interpretation which renders the provision consistent with the Treaties rather than the interpretation which leads to its being found incompatible with them.[150] Such consistent interpretation has prevented the CJEU from engaging in a tedious debate as to whether secondary law trumps primary law.[151]

Fourthly, it is not always an easy task to interpret an harmonisation measure consistently with primary law. With respect to Directive 2015/412, the Court will have to decide whether preference must be given either to the interpretation rendering the opt-out clause compatible with treaty law or whether that Directive can take priority over primary law.[152]

This issue can be exemplified by the *Essent* and *Alands Vindkraft* judgments commented upon above. As stressed above, in these two cases, the CJEU did not consider the issue of compatibility of secondary law on renewable energy with Article 34 TFEU. It merely relied upon Article 36 TFEU as well as the environmental mandatory requirement. In so doing, the CJEU avoided having to engage with the political choices made by the EU lawmaker. That said however, it remains to be seen whether the CJEU

144 See, by analogy, case C-59/11 *Association Kokopelli* [2012] ECR, paragraph 80 and the case-law cited. See also Para 65 Bott.

145 Opinion of AG Poiares Maduro of 14 September 2004 in Case C-42/02 *Commission v. Netherlands* [2004] ECR I-11375, paras. 30 to 33. See also F.G. Jacobs, 'Recent developments in the principle of proportionality in EC law' in E. Ellis (ed.), *The Principle of Proportionality in the Laws of Europe* (Oxford, Hart, 1999) 21; T. Tridimas, 'Proportionality in European Community Law: Searching for the Appropriate Standards of Scrutiny', in *The Principle of Proportionality in the Laws of Europe,* above, 66; P. Kapteyn and P. VerLoren Van Themmat, above, 640; H. Unperath and A. Johnston, 'The Double-headed Approach to the ECJ concerning Consumer Protection' (2007) 44 *CMLR* 1237-1284.

146 Joined cases 80 & 81/77 *Commissaires réunis* [1978] ECR I-1978, para. 297; Case 15/83 *Denkavit Nederland* [1984] ECR I-2171, para. 15; Case C-51/93 *Meyhui* [1994] ECR I-3879, para. 11; and Case C-114/96 *Kieffer and Thill* [1997] ECR I-3629, para. 27; Case C-469/00 *Ravil v. Bellon* [2003] ECR I-5053, para. 86 ; C-108/01 *Consorzio del Prosciutto di Pama v. Asda Stores* [2003] ECR I-5121, para. 53 C434/02 *Arnold André v. Herford* [2004] ECR I-11825, para. 57 ; Case C-210/03 R *Swedish Match* [2004] ECR I-11893, para. 59 and Joined Cases C-154 and 155/04 R *Alliance for Natural Health* [2005] ECR I-6451, para. 47. See P. Oliver, *supra* note 128, pp. 60-67.

147 Opinion AG Moiares Maduro in Case C-41/02 *Commission v Kingdom of the Netherlands* [2004] ECR I-11378, paras. 30-33. See also F.G. Jacobs, "Recent developments in the principle of proportionality in EC law" in E. Ellis (eds), *The Principle of Proportionality in the Laws of Europe* (Oxford: Hart, 1999) p. 21; T. Tridimas, "Proportionality in European Community Law: Searching for the Appropriate Standards of Scrutiny", in E. Ellis (eds), *The Principle of Proportionality in the Laws of Europe* (Oxford: Hart, 1999) p. 66; H. Unperath and A. Johnston, "The Double-headed Approach to the ECJ concerning Consumer Protection" (2007) 44 *CMLR* pp. 1237-1284; N. de Sadeleer, *Commentaire Mégret. Environnement et Marché Intérieur* (Brussels: ULB, 2010) p. 374; P. Oliver, *Oliver on Free Movement of Goods in the EU* (Oxford: Hart, 2010) p. 60; C. Barnard, *The Substantive Law of the EU*, 3rd ed. (Oxford : OUP, 2011) p. 151.

148 M. Weimer, *supra* note 55, p. 349; R. Streinz, *Europarecht* 9th ed. (Heidelberg, C. F. Müller, 2012) paras. 759 and 847; P Craig, *EU Administrative Law* (Oxford : OUP, 2006) p. 520; P. Syrpis, 'The Relationship between Primary and Secondary Law in the EU' 52:2 (2015) *CMLRev p.*484. See also C. Verdure, "La libre circulation des denrées alimentaires", in *Sécurité alimentaire. Nouveaux enjeux et perspectives* (Louvain: Anthemis, 2014) pp. 218-232.

149 Case C-305/05 *Ordre des barreaux francophones et germanophone and Others* [2007] ECR I-5305, para. 28. AG Bot Opinion Bot in *Ålands vindkraft AB v Energimyndigheten supra* note 127, para. 64.

150 P. Syrpis, supra note 6, pp. 473-477.

151 Ibid., p. 468.

152 Ibid.

could endorse the same reasoning in a further case on the cultivation of GM crops.

In conclusion, the objective pursued by the lawmaker is to accommodate the diversity of national preferences regarding the cultivation of GM seeds in outlining an approach that is more flexible than that endorsed in relation to marketing arrangements. Accordingly, the CJEU should have respect for the manner in which the EU lawmaker has weighed up countervailing antagonistic interests in an area dogged by controversy.

5. Validity of the Compelling Grounds

a. Introductory Comments

As discussed above, the CJEU will have to assess whether the compelling grounds listed under Article 26b(3) can objectively justify the national measure regulating the cultivation of GM crops. Given that that primary law prevails over secondary law, the CJEU will have to take into consideration whether these grounds are compatible with the principles of EU law. As a result, the Court might have to strain the scope of some compelling grounds so that they most closely correspond with primary law. That being said, it ought to be remembered that the legal base of Directive 2001/18, Article 114 TFEU, refers to Article 36 TFEU only in its 4th paragraph. Accordingly, we are taking the view that nothing precludes the EU lawmaker to add new grounds than the ones listed under Article 36 TFEU.

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') or that they have been proclaimed as mandatory requirements of general interest ('environmental protection', 'town and country planning', 'land use', and 'consumers protection'). Given their novelty, other compelling grounds are likely to spark off a debate of unprecedented nature. The aim of this section is to explore some of the key issues that are likely to arise in the assessment of the conformity of these compelling grounds with primary law. Instead of examining each ground separately, they will be schematised into four categories.

b. The Public Policy Ground

It should be noted first of all that only the reason of 'public policy' (ground g)) which is listed under Article 26b(3) is also specified under Article 36 TFEU. However, the Court has on all occasions adopted a relatively strict stance when confronted with attempts to invoke this justification.[153] In *Commission v France*, the CJEU held that the social unrest that could have resulted from the implementation of Directive 2001/18 could not justify non-compliance.[154] That being said, this derogation has increasingly been invoked by Member States in the context of public protests.[155] In this connection, *Schmidberger* is a case in point. Austrian authorities allowed victims of noise pollution to lock a stretch of a highway. The resulting MEQR was deemed to be proportionate to the freedom of expression and freedom of assembly guaranteed by the ECHR and the Austrian constitution.[156] The Court held that "the national authorities were reasonably entitled, having regard to the wide discretion which must be accorded to them in the matter, to consider that the legitimate aim of that demonstration could not be achieved in the present case by measures less restrictive of intra-Community trade".[157] This judgment takes on particular significance in the context of GM plants cultivation, a matter that leaves citizens and undertakings marketing GMOs at loggerheads. Moreover, in granting greater political control as to the cultivation of authorised GM seeds, the EU lawmaker has been attempting to enhance public participation as well as democratic accountability.[158]

c. Environmental-agricultural Grounds

Given that a number of disagreements between the national scientific authorities and 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

153 P. Oliver, *supra* note 128, pp. 251-253; L. W. Gromley, *EU Law of Free Movement of Goods and Customs Union* (Oxford: OUP, 2009) pp. 460-462.

154 *Supra* note 11, para. 72.

155 C. Barnard, *supra* note 147, p. 152.

156 Case C-112/02 *Schmidberger* [2003] ECR I-5659, noted by M. Humphreys (2004) *EnvLR* 190-203. The Court took care to underline the Case's differences with regard to the *Commission v. France* Case the judgment of which was delivered on 9 December 1997.

157 *Ibid*, para. 93.

158 M. Weimer, *supra* note 55, p. 16.

environment. Of importance is to stress the wide scope of that ground on the account that it relates to the environmental policy objectives. 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'.[159] The fact that neither Article 114 (10) nor Article 36 TFEU provide for the possibility to justify a national measure in the light of an environmental risk is not preventing the EU lawmaker to lay down such a clause in an harmonisation measure.[160]

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))[161]. It is settled case law that the Member States can impede the free circulation of goods on these three grounds.[162]

Secondly, 'agricultural policy objectives' (ground f)) can also be invoked as a compelling ground [163], 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."[164] For instance, the integration of landscape planning into general land planning could be used to limit the cultivation of GMOs in specific areas.[165] By the same token, restrictions could aim to promote the diversity of seeds, local markets, jobs in extensive agriculture, etc.[166] These objectives are likely to overlap with environmental policy objectives (conservation of biodiversity).

That being said, 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.[167] 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.[168]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.[169]

Whilst the Member State may invoke one or more of the grounds listed under Article 26b(3),[170] it is specified that they "shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003".[171] In contrast to safeguard clauses, the opt-out granted to the Member States does not therefore call into question the risk assessment carried out by the EFSA. At the outset, this exclusion must be approved. The empowerment to introduce restrictions and bans does not alter the authorisation procedures and consequently the risk assessments underpinning the MA. Member States opposing the cultivation of GM crops must do it for other reasons that the ones addressed in the EFSA risk assessments.[172]

What room of manoeuvre is left to the Member States? 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. The preamble of Directive 2015/412 stresses that the risk assessments carried

159 Pursuant to Article 191(1) TFEU, the environmental policy pursues four objectives. Nothing precludes Member States to pursue additional objectives.

160 Indeed, national environmental safeguard measures environmental can be justified given that Article 192(2) TFEU permits that 'harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union'.

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

162 N. de Sadeleer, *supra* note 77, pp. 284-301.

163 C. Blumann et al., *Commentaire Mégret. PAC et PCC* (Brussels : ULB, 2011) pp. 25 à 36

164 Recital 6.

165 G. Winter, *supra* note 119, 17.

166 Ibid.

167 See P. Oliver, *supra* note 128, p. 401-411.

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

169 See the case law commented on above, *supra* III, 3. *Land Oberösterreich supra* note 23.

170 Public order may not however be invoked alone.

171 Recital 4 of Directive 2015/412.

172 S. Poli, *supra* note 111, p. 341.

out under Directive 2001/18 are far from being perfect; they need to be "regularly updated to take account of continuous developments in scientific knowledge".[173] When confronted with such gaps, nothing prevents the Member State from carrying out additional scientific studies with the aim of invoking one or several of the compelling grounds in as much as these risk assessments are "distinct from and complementary to"[174] the environmental and health impacts assessed by EFSA. Accordingly, it would appear that national measures aiming at improving soil protection or at achieving land planning and environmental policy objectives should be admitted more easily if they are backed up by national scientific analyses other than the assessment carried out by the EFSA owing to discordant scientific results. Since ecological impacts are particularly widespread, the possibility of successfully carrying out such risk assessments does not appear to be particularly challenging, though it will not be easy to identify the dividing line between scientific evidence justifying restrictions on the grounds of land usage, nature protection, etc. and the EFSA risk assessment.

The impacts that could be assessed by the national scientific authority include:
- 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 sanctuaries;
- 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).

In accordance with WTO law, in as much as the restrictions on cultivation are qualified as SPS measures,[175] the Member States are required to provide evidence of the risks.[176] Therefore, the Member States will have to support their measures in identifying environmental or ecological impacts that were not yet assessed by the EFSA.

d. Socio-economic Grounds

The compelling grounds d) and e) are intent upon avoiding the costs of coexistence measures and at accommodating consumer preferences. Needless to say, these grounds go beyond a genuine scientific assessment.

Firstly, the justification regarding 'avoidance of GMO presence in other products' (ground e)) relates to consumers, a mandatory requirement according to the *Cassis de Dijon*. The preamble stresses that the new regime "is also likely to ensure freedom of choice of consumers, farmers and operators whilst providing greater clarity to affected stakeholders concerning the cultivation of GMOs in the Union."[177] It cannot be denied that consumer expectations in relation to food have developed considerably in the early 21st Century. In particular, Regulation 1829/2003 takes into account the protection of the 'users' of GM food and feed.[178] Nevertheless, it is necessary to demonstrate here how restrictions on cultivation are necessary in order to protect them.

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 high cost, impracticability or impossibility of implementing coexistence measures due to specific geographical conditions, such as small islands or mountain zones, or the need to avoid GMO presence in other products such as specific or particular products."[179] As discussed as above, the justifications regarding specific geographical conditions such as mountain areas were dismissed by the CJEU in *Land Oberösterreich*.[180]

Another issue are "the high cost, impracticability or impossibility of implementing coexistence measures". Under Directive 2001/18, the Member States

173 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. According to M. Weimer, the reform puts "too much emphasis on the uniformity of the risk assessment". M. Weimer, *supra* note 55, p. 16.

174 Recital 13 of Directive 2015/412.

175 Recital 2 of Directive 2015/412.

176 Pursuant to Article 5(1) of the SPS Agreement, 'Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.' According to Annex A4 of that agreement a risk assessment consists of 'The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.'

177 Recital 8 of Directive 2015/412.

178 Articles 4(1)b) and 16(1)c).

179 Recital 15 of Directive 2015/412.

180 See the discussion above in Part II, section 4.

have retained their sovereignty over the establishment of coexistence rules for traditional crops and GMO crops.[181] Given the silence of the Directive as to the scope of these rules, the Commission has been adopting non-binding recommendations.[182] 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 Court of Justice 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 CJEU 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'.[183]

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

- The costs of accidental contamination and the destruction of contaminated products, such as in the *Balbok* case;[184]
- 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 are required to consider the purity of their varieties in the production process;
- The costs incurred by producers of non-GM food and feed for separating their products from GMO products.[185]

In addition, another dimension of GM seed cultivation relates to the need to balance the costs and benefits of such technologies. In effect, some Member States are likely to weigh the socio-economic costs of this type of cultivation with the benefits. By way of illustration, a Member State could take the view that the cultivation of potatoes with higher starch content would be detrimental for the production of foodstuffs.[186] 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[187] and under EU law by the Regulation 178/2002 laying down the general principles of food safety[188] along with Regulation 1829/2003.[189] 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.[190] Our view is that the CJEU should take account of these legal developments.

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

182 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 ?" 2 (2008) *JEL* pp. 193-212; J. Corti Varela, "The new Strategy on Coexistence in the 2010 European Commission Recommendation" 4(2010) *EJRR* pp. 353-358.

183 *Pioneer Hi Bred Italia*, *supra* note 90, para. 74.

184 *Bablok*, *supra* note 2.

185 G. Winter, *supra* note 119, p. 18.

186 Ibid, p. 19.

187 Article 26.

188 Recital 19, and Article 7.

189 Recital 32, Article 7, and Article 19(1).

190 See also the French Environmental Code.

The national measures justified in the light of this compelling ground will have to reckon upon non-scientific considerations, or in other words upon socio-economic reasons. One can wonder how national restrictions and bans justified by socio-economic considerations are likely to be in conformity with the principle of free movement of goods. 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. Regarding the justification of MEQR, it is settled case law that a purely economic consideration cannot constitute an overriding reason in the public interest.[191] Be they admitted on the basis of a mandatory requirement or on the basis of Article 36 TFEU, reasons of general interest are of a non-economic nature. Expressing general interest, they indicate a supremacy of non-commercial values over free movement of goods. It follows that one may invoke neither Article 36 TFEU nor a mandatory requirement for economic reasons. That said, nothing prevents the Member State from justifying its measure with reference to a genuine non-economic interest (environmental, soil protection, etc.) or socio-economic considerations (economic impacts brought about by the rise of intensive agriculture on small-scale farming communities). Moreover, the Court has already had the opportunity to consider the preservation of the financial balance of social security systems in assessing the justification of MEQR.[192]

e. Ethical and Religious Concerns

Since Article 26b(3) only lists compelling grounds as examples, nothing prevents the Member States from invoking 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. Ethical and religious concerns play a secondary role in the procedures governing the granting of MA.[193] It should be noted in this regard that the CJEU has held that measures to ban genetically modified seeds in Poland which were justified on the grounds of public opposition to GMOs and the importance attached by Polish society to Christian values pursued goals at odds with the environmental and health goals and the objectives of free movement on which Directive 2001/18 is based. The CJEU also held that Poland had been unable to establish that its legislation would have effectively pursued the religious and ethical goals averred. In its eyes, public morality had not been invoked as a self-standing ground, but was confused with the environmental and health-related justification.[194] Therefore, it concluded that Articles 22 and 23 of Directive 2001/18, which obliged the Member States to refrain from prohibiting, restricting or impeding the placing on the market of GMOs, unless there is an overriding requirement for safeguard measures, had been violated.[195] It follows that a Member State cannot base its position on the viewpoint of one part of public opinion in order to call into question unilaterally an EU harmonisation measure.[196] Since the safeguard clauses do not include general ethical grounds, this was a mission impossible for the Polish authorities.

The fact that ethical grounds could be invoked under Directive 2015/412 would oblige the CJEU to weigh up free movement of GMOs with this value.

6. Proportionality

National measures restricting GM seeds cultivation need to be proportional.[197] There is nothing new under the sun. To prevent the principle of free movement of goods from becoming nugatory by the enactment of EU measures allowing Member States to restrict the use of a product, the CJEU has been putting in place a series of criteria to assess the proportionality of these measures justified under the aforementioned exceptions. The principle of proportionality allows one to assess means used – ban, prohibition, restriction on use, etc. - with reference to

191 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 128, p. 239-241.

192 See P. Oliver, *supra* note 128, p. 193-194.

193 Recital 9 of Directive 2001/18; Articles 5(3)g and 33 of Regulation (EC) No 1829/23, *supra* note 15.

194 Case C-165/08 *Commission v Poland* [2009] ECR I-6843, *paras*. 51-55.

195 *Ibid*, paras. 51-64.

196 See by the same token Case C-1/96 *Compassion in World Farming* [1998] ECR I-1251, para. 67.

197 Art. 26b(3)(1) Directive 2015/412.

the objectives pursued –agricultural or environment policy objectives - to best take into account the legitimate interests of undertakings in freely trading their GM crops. As these criteria are applied in a flexible and evolutionary manner, it is difficult to establish a fixed definition of the principle.

As one need not kill a fly with a sledgehammer, the national measure should be adequate, suitable with a view to attaining its objective. The first question to answer is whether the facts noted by the national authorities justify a need for a measure to achieve one or several of the compelling grounds. Does the socio-economic impacts of GM cultivation or the new environmental risk require Member State intervention? The ban or the restriction must constitute a reasonably intelligible means of ensuring the various objectives listed under Article 26(b)(3). 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.

By way of illustration, where the ban is justified by the policy objective of restricting intensive agriculture in a peculiar area, the State authority will be called on to demonstrate that the cultivation of the GM seeds at issue are contributing to the development of that type of agriculture.

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".[198] 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. The intensity of the review of the proportionality is likely to vary significantly from one measure to another. Restrictions on the cultivation of GMOs constitute in principle less restrictive means than a ban.[199]

On the one hand, when the planned measure gravely hinders free movement of goods but offers little added value to the national policy objectives, the national authorities must carefully examine the possibility of adopting a less restrictive measure. The question arises as to whether the downstream national restriction on the cultivation of GM crops are likely to jeopardise the upstream EU decision-making process. On the other hand, where the need to regulate the cultivation of GM crops is so compelling, the Member State might have no choice other than to ban or to regulate the GMO. Nonetheless, the necessity test is not necessarily neutral, and may therefore hide subjective assessments of the interests in play.

The necessity of the suitable measures is greatly influenced by the level of protection set by the Member State regarding the different compelling grounds. It is settled case law that 'The fact that one Member State imposes less stringent rules than another Member State does not mean that the latter's rules are disproportionate and hence incompatible with [EU] law".[200] Therefore nothing precludes one Member State to choose a system of protection different from that adopted by another Member State.

A question also arises regarding the burden of proof of the proportionality of the prohibition. As far as health and environmental measures are concerned, they have to be backed up by indisputable scientific facts.[201] However, it would be difficult to require the Member State to furnish proof of a risk, as could be demanded both in relation to safeguard clauses and under Article 114(4) to (6) TFEU, in relation to socio-economic reasons and agricultural policy (grounds d) and f)). Furthermore, it is submitted here that it will be easier for the Member States to justify restrictions on agricultural policy, land protection and environmental policy grounds if the exclusion is intended to apply to conventional or organic crops where the use of insecticides or herbicides is limited.

Last but not least, given the complexity of the issues raised by GM seed cultivation, which are not easy for the Court to resolve, it may be wise for the CJEU to leave the issue of proportionality to the na-

198 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.

199 G. Winter, *supra* 119, 11.

200 See, inter alia, Case C-108/96 *Mac Quen and Others* [2001] ECR I-837, paras. 33 and 34; Case 219/07 *Andibel* [2008] ECR I-4475, para. 31; Case 100/08 *Commission v Belgium* [2009] ECR I-140, para. 95; Case 110/05 *Commission v Italy* [2009] ECR I-519, para. 65.

201 N. de Sadeleer, *EU Environmental Law*, supra note 77, p. 180.

tional courts. It is unlikely that the CJEU will be in possession of the factual issues or will be endowed with the relevant technical expertise.

7. Compatibility with the Principle of Freedom of Establishment

Alternatively, it could also be the case that a branch of an agri-business multinational might be unable to deploy its full know-how in Member States that invoke one or several opt-out clauses. Since case law accepts some limited controls of national measures with reference to two fundamental economic freedoms,[202] it is thus important to examine the compatibility of the new regime with Article 49 TFEU. That provision precludes any national measure which, even though it is applicable without discrimination on grounds of nationality, is liable to hamper or to render less attractive the exercise by EU nationals of the freedom of establishment guaranteed by the Treaty. [203]

That being said, the Court's case-law has identified a number of overriding reasons in the public interest capable of justifying restrictions on the fundamental freedoms guaranteed by the Treaty. Reasons already recognised by the Court include the objectives of environmental protection[204], land planning, [205]and consumer protection.[206] These reasons are set forth in Article 27ter of the modified directive. However, it is settled case law that a purely economic consideration cannot constitute an overriding reason in the public interest.[207]

202 The Court has already recognised that the compatibility of a national measure can be assessed in the light of the two fundamental freedoms. See Case C-390/99 *Canal Satélite Digital* [2002] ECR I-607.

203 See in particular Case C-299/02 *Commission v Netherlands* [2004] ECR I-9761, para. 15; Case C-140/03 *Commission v Greece* [2005] ECR I-3177, para. 27.

204 Case C-384/08 *Attanasio Group* [2010] ECR I-2025, para. 50 and the cited case-law.

205 See by analogy, Case C-567/07 *Woningstichting Sint Servatius* [2009] ECR I-9021, para. 29 and the cited case-law.

206 See, inter alia, Case C-220/83 *Commission v France* [1986] ECR 3663, para. 20; Case C-442/02 *CaixaBank France* [2004] ECR I-8961, para. 21; and Case C-393/05 *Commission v Austria* [2007] ECR I-10195, para. 52 and the cited case-law.

207 Case C-436/00 *X and Y* [2002] ECR I-10829, para. 50; Case C-96/08 *CIBA* [2010] ECR I-2911, para. 48; Case C-400/08 *Commission v Spain* [2011] ECR I-1915, para. 74.

208 S. Poli, , *supra* note 111, p. 343.

8. Added Value of the Reform

The new opt-out clause regime facilitates the task of Member States seeking to prohibit the cultivation of GMOs for which a MA has been granted as they are no longer required to demonstrate the "seriousness" of the risks incurred and their measures are not subject to an *ex post* review by the Commission. In effect, the Member States are objectively required to make less of an effort to implement the opt-clauses than to invoke the traditional safeguard clauses. Nonetheless, the safeguard clauses encapsulated in the different harmonised measures have not been cancelled. They may continue to be significant as a basis for justifying national prohibitions or restrictions where the Member State scientific agency is unable to depart from the conclusions of the assessment carried out by the EFSA.

Recital 6 of the preamble refers to Article 2(2) TFEU that reads as follows: 'Member States shall again exercise their competence to the extent that the Union has decided to cease exercising its competence'. Accordingly, for the first time in the history of the internal market, there has thus been a reverse harmonisation, as the freedom to use an authorised product, for which free movement is guaranteed, is now regulated by the national authorities. However, one might wonder whether the Member States have regained regulatory autonomy within a pre-empted field. One might argue that the Member States were empowered to regulate cultivation through a web of coexistence measures. However, one might also take the view that the EU did not really withdraw from an occupied field in granting greater freedom of action to the national authorities. In fact, the new opt-out clauses merely widen the scope of existing safeguard clauses. Given that the new directive does not alter the pre-existing legal framework[208], it was useless to invoke Article 2(2) TFEU.

V. Conclusions

Since the start of the 1990s, by playing a pioneering role in the regulation of the risks brought about by GMOs, the Union has imposed a procedural straightjacket which is decidedly stricter than that provided for in other countries, which explains why this issue has not yet been included so far in negotiations concerning a transatlantic trade treaty. Similarly, it is not

particularly easy to understand these rules. Within this array of convoluted regimes, and this criss-crossing of horizontal and vertical rules, it will hardly come as a surprise if the layman is led astray. This is because, in contrast to other areas of secondary law, the national rules on GMOs have been harmonised by several regulations, and are covered by various directives.

Insofar as scientific expertise is taken into account in applications seeking authorisation, the examination of these applications, the risk assessments carried out by the EFSA and the national institutions, as well as in litigation, the EU harmonised procedures are essentially caught between the devil and the deep blue sea, between scientific objectivity and legal requirements, which do not overlap precisely. On the one hand, there has been an increase in the power of the EFSA for assessing the health and environmental impacts of GMOs, although this has not been entirely immune from controversy, whilst on the other hand secondary law forces decision makers to weigh up antagonistic interests, both in relation to the granting of MA and the cultivation of GM crops. This delicate interface between science and the balancing of interests is also confused due to the obligation to separate risk assessment from risk management.[209] To complicate matters, so far scientific assessment requirements have not been able to resolve scientific disputes, and will undoubtedly be unable to do so.

Moreover, these procedural arrangements are still imperfect as the subject raises particularly thorny questions as regards the public's perception of new risks, the type of agriculture to be promoted, the costs of coexistence measures, the impacts of intensive agriculture on biodiversity, consumer choice, the role of science in decision-making processes and risk governance. Nonetheless, secondary law – which is procedural in nature – does not claim to give any answers to these questions.

Finally, the EU law is undoubtedly the product of a trade-off between the functioning of the internal market and health and environmental issues, alongside ethical or even religious concerns. 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[210] 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. The search for this elusive equilibrium has recently led EU lawmakers, in accordance with the principle of subsidiarity and Article 2(2) TFEU,[211] to "repatriate" controls over cultivation. As a result, Member States have been regaining their freedom to regulate GM crops cultivation, a freedom that was somewhat restricted on the account that safeguard clauses and other derogatory arrangements are interpreted narrowly. This is a significant departure from the traditional functioning of the internal market given that Member States are now empowered to address 'specific national or local aspects raised by the cultivation'[212] of authorised GM plants. Although it reduces the interest in safeguard clause and Article 114(4)-(6) TFEU arrangements,[213] which have not been regarded as satisfactory by the Member States, the opt-out clause has not abolished them entirely. Last, this reform raises questions as to the consistency of the forthcoming national opt-outs with the economic freedoms enshrined in the TFEU. There is a question regarding the extent to which the provisions of the new Article 26b will hold sway against these jurisprudential requirements.

There is no doubt that the restrictions placed on cultivation of GM seeds by certain authorities, along with objections by GMO producers, will give rise to new disputes which will end up before the Court of Justice.

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209 Article 6(2) and Article 6(3) of Regulation (EC) No 178/2002, *supra* note 62.

210 As a result and especially because the safeguard clauses are interpreted in a restrictive manner by the EJC, this full harmonisation leaves the Member States with little room for manoeuvre.

211 Recitals 6 and 8 of Directive 2015/412.

212 Recital 6.

213 Ibid.