Centrifugal and Centripetal Forces in the marketing and Cultivation of GMOs in the EU

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L'introduction d'OGM en Europe a suscité d'importants débats. À l'occasion de l'adoption de la récente directive 2015/412, il est intéressant d'examiner comment celle-ci octroie la possibilité aux États membres d'interdire ou de limiter la culture d'OGM en lien avec une procédure d'autorisation harmonisée. Surtout, cette réforme semble à première vue déconcertante au regard du fonctionnement du marché intérieur.

The introduction of GMOs in Europe has given rise to considerable debate. From the time of the adoption of the recent Directive 2015/412, it is interesting to examine how it allows Member States to prohibit or limit the cultivation of GMOs in connection with an authorization procedure harmonized. Above all, this reform seems at first sight disconcerting in view of the functioning of the internal market.

I. – Introduction

GMOs[1] have repeatedly been a matter of much controversy, especially in Europe. This scepticism of many NGOs and several regulatory agencies has focused both on their impact on human health (allergenicity, genes expressing resistance to antibiotics in use for medical or veterinary treatment),[2] as well as the impoverishment of biodiversity which their cultivation could cause (wild species resisting GM plants, resis-

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1 Regarding the scope of the definition, see Case C-442/09 *Bablok* [2011] ECR I-7419, para. 62.

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

tance to herbicides, hybrid plants, gene flow through pollen transfer, impacts upon soils, etc.).[3]

Probably no other piece of legislation has produced as much controversy as does Directive 2001/18/EC on the deliberate release of GMOs. As other EU acts regulating GMOs, this directive attempts to strike a balance between the functioning of the internal market and the Treaty requirements of a high level of consumer and environmental protection. Its transposition turned into a minefield for the majority of the Member States.[4]

Directive 2015/412 has amended Directive 2001/18/EC with a view of granting the Member States the right to prohibit or to limit the cultivation of GMOs in accordance with a harmonised authorisation procedure. This chapter 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.

II. – The marketing authorisation procedures of GMOs for cultivation

Since Directive 2001/18/EC amounts to 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,[5] it is deemed to be the centrepiece of GMOs EU legislation. Accordingly, it has to interact with other sectoral regulations.[6] Given that it works as a safety net, several other directives refer to its risk assessment procedures.

If its core features are considered, Directive 2001/18/EC is based on the key principle that no GMO may be released into the environment for experimental purposes (Part A) or subsequently marketed unless it has been previously authorised by the competent authorities upon conclusion of a scientific assessment (Part B). In other words, the assessment has to come first, after which the decision is made. The assessment procedure for something as important as the authorisation of experimental

[3] 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.

[4] 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-684Case C-478/13 *Commission v Poland* [2013].

[5] Article 12.

[6] 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.

release and the subsequent marketing of a GMO is conditional upon the requirement that it is "safe for human health and the environment".[7] 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.[8] It follows that in accordance with a 'one door one key' approach, undertakings are authorised to use a GMO for cultivation purposes.

Established by Regulation (EC) No 178/2002, EFSA is playing a primary role in the assessment of the risks entailed by the GMOS subject to the authorisation and the renewal procedures. Indeed, this authority takes on the role of an independent scientific point of reference in risk assessment'.[9] Its scientific opinions buttress the authorisations granted by the EU institutions. Though the EFSA has not been established a superior scientific authority to the national health institutes,[10] its scientific opinions have nonetheless considerable weight. Nonetheless, "the cooperation with national authorities on GMOSs assessments has been hampered by a lack of trust and conflicting views over GMO safety".[11] In effect, EFSA and several national institutes have been at loggerheads over the level of uncertainty raised by the cultivation of several GMOs. These controversies have been compounding the deadlock at both comitology and Council levels regarding the issuance of GM food and feed authorisations.

To date, this authorisation regime has not had the desired effects. Due to persistent differences of opinion between the EU institutions and the Member States, a limited number of authorisations for deliberate dissemination have been granted, the most renowned being for maize MON810.[12] The deadlock in both comitology and the Council has been illustrated by the *Amflora* case.[13] The lack of a qualified majority within the Council of Ministers enabled the Commission to grant an MA in 2010 for the marketing of a genetically modified potato called *Amflora*. However, the General Court quashed this MA on the grounds that the Commission had affected the institutional balance of the EU. In effect, the members of the regulatory committee could have been reviewing their initial position if they had obtained new scientific opinions expressing greater uncertainty than the previous opinions.[14]

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7 Recital 47.

8 N. DE SADELEER, *Environmental Principles* (Oxford: OUP, 2005) pp. 112-114.

9 Recital 34 of Regulation (EC) No. 178/2002.

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

11 M. WEIMER, "Risk Regulation and Deliberation in EU Administrative Governance. GMO Regulation and Its Reform" (2015) *ELJ* 7.

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

13 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.

14 T-240/10, *Hungary v Commission,* EU:T:2013:645.

The maize TC1507 saga – transgenic insect-resistant maize produced by Pioneer Hi-Bred International – also illustrates the difficulties encountered in the marketing procedure.[15] On three occasions (2004, 2006 et 2008), EFSA issued opinions concluding that there was no risk for human health or the environment, and accordingly supported the applications made by Pioneer. Due to the absence of a qualified majority either in favour of or against the draft authorisation, the Commission was required – pursuant to Article 5 – to submit to the Council '*without delay*' a proposal concerning the action to be taken. On account of the Commission's procrastination in dealing with its application, Pioneer lodged an action for failure to act[16] before the General Court, alleging a violation of the duty of diligence applicable to the Commission.[17] The General Court ruled that the Commission failed to act in accordance with the procedure.[18]

What is more, given that Directive 2001/18/EC has been adopted on the basis of Article 114 TFEU, it is enhancing the free circulation of GMOs. This choice is not innocent given that the harmonization on the basis of Article 114 TFEU of rules on the marketing of GMOs creates a precise legal framework limiting Member States' ability to lay down their own product standards. Accordingly, Member States' room for manoeuvre with respect to the control of the placing on the market of GMOs authorised under Directive 2001/18/EC and their cultivation has been somewhat limited.

Nevertheless, the assertion of free movement in this directive does not affect the right of the Member States to limit the free movement of GMOs In order to restrict or to ban the cultivation of authorised GM crops, some national authorities had recourse to the safeguard clauses provided for under the directive.[19] Other Member States have made use of Article 114(5) TFEU that provides for national reinforced protection.[20]

There is no doubt that the low number of MA granted and the invocation of safeguard clauses as discussed above have had a dissuasive effect on the cultivation of GMOs. As a result, very little GM crops are cultivated in the EU. Whilst in 2015 almost 200 million hectares of GMO were cultivated worldwide, only 114,624 hec-

15 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.

16 Article 256 of the TFEU.

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

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

19 Case C-6/99 *Greenpeace France* [2000] ECR I-1676, para. 44; Case C-236/01 *Monsanto Agricoltura Italia* [2003] ECR I-810; Case C-36/11 *Pioneer Hi Bred Italia* [2012] *OJ* C355; Case T-69/08 *Poland v Commission* [2010] ECR II-5629, para. 69.

20 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.

tares of these were located in the EU (of which 97,346 were located in Spain). The MON 810 GMO authorised for cultivation is so far cultivated in only five Member States: Spain, Portugal, Tcheckia, Rumania, and Slovakia.

III. – The "repatriation" of cultivation

Since 2009, various Member States have called for a change to the marketing regime which has proved to be favourable to the European Commission. After several years of tedious negotiations, the Parliament and the Council adopted on March 11th 2015, Directive 2015/412 which inserts Articles 26a-c into the 2001/18 Directive.[21]

A. – PROCEDURE

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

Phase 1. First of all, 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.[22] 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.[23] Regarding the temporal scope, that request has to be communicated to the Commission at the latest 45 days from the date of circulation of the assessment report under Article 14(2) of the Directive 2001/18. The Commission is called on to make the demand publicly available by electronic means. The Commission must forward the request to the applicant. The latter can adjust his application, though he 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.[24]

Phase 2. Thereafter, where the applicant refuses to alter its application, or where no request is notified by a national authority,[25] the Member States still may exercise an opt-out, invoking one or several "compelling grounds" that are not at odds with the assessment of health and environmental risks carried out by the EFSA.

The Article 26b(3) 'compelling grounds' can be invoked individually or in combination depending on "the particular circumstances of the Member State, region or area

[21] *OJ* L 68/1. The legal basis chosen is Article 114 TFEU.
[22] Article 26b(1) of Directive 2015/415.
[23] Article 26b(2).
[24] Recital 21, and Article 26b(5).
[25] Article 26b(3). The European Parliament obtained that phase 2 is not subjected to phase 1.

in which those measures will apply".[26]These grounds can be invoked in a generalized form or they can be more concrete.

The national measures are wide in scope: they range from full bans to more narrow restrictions. They can lay down specific conditions for cultivation. They are likely to apply to a "GMO, or […] a group of GMOs defined by crop or trait".[27] According to Winter, this implies that the Member States may not generally prohibit the cultivation of GM seeds per se. Rather, this can be done with regard to a particular seed or a certain group of seeds.[28] 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 a marketing authorisation,[29] other considerations, including in particular the socio-economic balance between the advantages and disadvantages of genetic engineering may now be invoked downstream in order to oppose the cultivation of authorised GM seeds. This new regime appears to be based on the following reasoning: in contrast to questions relating to the marketing of GMOs, their cultivation is more of a local or regional matter than an international one.[30] Therefore, Member States are allowed to restrict cultivation to a greater extent than they are allowed with the previous regime.

B. – 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.

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[26] Recital 13 of Directive 2015/415.

[27] Article 26b(3)(1) Directive 2015/412.

[28] 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.

[29] Recital 7 of Directive 2015/415.

[30] Recital 5 of Directive 2015/415.

Regarding the formal conditions, the national measures are subject pursuant to Article 26b(4) to a procedure of information at EU level, a procedure that is not as stringent as the review procedure provided for under the traditional safeguard clauses. During a period of 75 days starting from the date of such communication, the Member State shall refrain from adopting and implementing the proposed restrictive measures. On expiry of that period, the Member State concerned may "adopt the measures either in the form originally proposed, or as amended to take account of any non-binding comments received from the Commission". On the one hand, this procedure is rather similar to the one provided for under Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards.[31] On the other hand, it departs significantly from the Article 114(6) TFEU procedure according to which the Commission is called on to approve the national requests for derogating harmonized internal market standards.[32]

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

(a) Environmental policy objectives;

(b) town and country planning;

(c) land use;

(d) socio-economic impacts;

(e) avoidance of GMO presence in other products without prejudice to Article 26a;

(f) agricultural policy objectives;

(g) public policy.

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

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

Some may question whether the new opt-out regime is compatible with Article 34 TFEU that prohibits measures of equivalent effect to a quantitative restriction (MEEQRs) contrary to Articles 34 TFEU. Let be noted that the issue of compatibility can be resolved exclusively by the CJEU.

[31] Directive 98/34/EC does not apply to the national measures at issue. See Recital 17 of Directive 2015/415.

[32] N. DE SADELEER, *EU Environmental Law and the Internal Market* (Oxford: OUP, 2014) 369-370.

Given the lack of standing of the GMO producers or retailers to challenge directly the directive before the CJEU,[33] it is more likely that they will challenge the national implementing measures before the competent national courts. These courts will have the possibility to refer one or several of the three separate, albeit related, questions for preliminary rulings in accordance with Article 267 TFEU:

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

– as to the compatibility of the national measure at issue with the principle of free movement of goods;

– as to the compatibility of Directive 2015/412 with the principle of free movement of goods.

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

A. – Applicability of Article 34 TFEU

The CJEU is likely to be called on to verify whether the restrictive national measures are consistent with Article 34 TFEU, which is applicable only to the extent that the matter cannot be determined exhaustively on the basis of the Directive.[34]

Our view is that the Court will have to recognize that Directive 2015/412 does not fully harmonize national rules. In contrast to the marketing procedures where the Member States are endowed with any room for manoeuvre, the amending Directive gives Member States considerable leeway in allowing them to decide the personal, temporal, geographical, and material scope of their restrictive measures. It follows that the CJEU can verify whether the national restriction arrangements allowed under Article 26*bis* are compatible with Article 34 TFEU.

The CJEU will have thus to determine whether the national restriction falls under that Article 34 TFEU.

Our view is that national measures regulating the use of GMOs for cultivation purposes have to be qualified as a measure of equivalent effect to a quantitative restric-

[33] 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* 177-208.

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

tion given that this notion covers 'any other measure which hinders access of products originating in other Member States to the market of a Member State'.[35]

B. – THE JUSTIFICATION FOR THE RESTRICTION ON THE FREE MOVEMENT OF GOODS

Given that that primary law prevails over secondary law, the CJEU will have to take into consideration whether the compelling grounds listed under Article 26b(3) are compatible with the principles of EU law. In case they are not, they cannot objectively justify the national measure regulating the cultivation of GM crops. Some of the 'compelling grounds' do not present any difficulties at all on the account that they are listed under Article 36 TFEU ('public policy') 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.

1. – *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 environment.

What is more, the two next compelling grounds, town and country planning (ground b)) as well as land use (ground c)) are genuine components of the environment *lato sensu* (ground a))[36]. It is settled case law that the Member States can impede the free circulation of goods on these three grounds.[37]

Secondly, 'agricultural policy objectives' (ground f)) can also be invoked as a compelling ground[38], though these objectives have seldom been invoked in disputes concerning the free movement of goods.

Whilst the Member State may invoke one or more of the grounds listed under Article 26b(3),[39] it is specified that they "shall, in no case, conflict with the environmental risk assessment carried out by EFSA.[40] 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.

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35 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.

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

37 N. DE SADELEER, *EU Environmental Law and the Internal Market,* above, 284-301.

38 C. BLUMANN *et al.*, *Commentaire Mégret. PAC et PCC* (Brussels: ULB, 2011) 25 à 36.

39 Public order may not however be invoked alone.

40 Recital 4 of Directive 2015/412.

What is the room of manoeuvre 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. Furthermore, the preamble of Directive 2015/412 stresses that the risk assessment carried 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".[41]

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

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

2. – *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 the genuine scientific assessment carried out by EFSA in accordance with the authorisation procedure.

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

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."[42]

[41] 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.
[42] Recital 15 of Directive 2015/412.

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

- the costs of accidental contamination and of the destruction of contaminated products as epitomized in the *Balbok* case;[43]
- the costs of separating GM and GM-free fields;
- the administrative costs of enforcing the various preventive regulations;
- the costs incurred by producers of non-GM seeds insofar as they must pay heed to the purity of their varieties in the production process;
- the costs incurred by producers of non-GM food and feed insofar as they separate their products from GMO products.[44]

Another issue are "the high cost, impracticability or impossibility of implementing coexistence measures". Under Directive 2001/18, the Member States have kept their sovereignty on the establishment of coexistence rules for traditional crops and GMO crops.[45] Given the silence of the Directive as to the scope of these rules, the Commission has been adopting non-binding recommendations.[46] However, the room for manoeuvre left to the Member States is not unfettered.

Pioneer Hi Bred Italia regarding the cultivation in Italy of maize MON 810 is a case in point. In that case, an Italian court asked the CJEU whether Italy could impose a supplementary risk control procedure in addition to the EU marketing procedure. 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 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 …'.[47]

To conclude with, 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. 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.

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43 *Bablok*, *above*.

44 G. WINTER, above, 18.

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

46 M. LEE, "The Governance of Coexistence Between GMOs and Other Forms of Agriculture: A Purely Economic Issue ?" 2(2008) *JEL* 193-212; J. CORTI VARELA, "The new Strategy on Coexistence in the 2010 European Commission Recommendation" 4(2010) *EJRR* 353-358.

47 *Pioneer Hi Bred Italia*, *above*, para. 74.

3. – *Ethical and religious concerns*

Given that Article 26b(3) only lists compelling grounds as examples, nothing precludes the Member States to invoke other justifications, such as ethical and religious concerns. As a matter of course, GM technology remains a matter of debate. By way of illustration, because the insertion of certain genes such as pork genes in the DNA of another species is problematic for the Islamic religion, this subject matter cannot be addressed by the EFSA. So far, ethical and religious concerns play a secondary role in the procedures governing the granting of MA.[48] In addition, the CJEU has been somewhat reluctant to uphold national measures pursuing religious and ethical goals.[49] The fact that ethical grounds could be invoked under Directive 2015/412 would oblige the CJEU to weigh the free movement of GMOs with this value.

4. – *Proportionality*

National measures restricting GM seeds cultivation need to be proportional.[50] There is nothing new under the sun.

The first issue is whether the facts analysed by the national authorities justify a need for a measure to achieve one or several of the compelling grounds. In other words, does the socio-economic impacts of GM cultivation or the new environmental risk require Member State intervention? Our view is that 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".[51] In light of the variety of interests and

[48] Recital 9 of Directive 2001/18.

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

[50] Art. 26b(3)(1) Directive 2015/412.

[51] 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,

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. [52]

V. – Conclusions

Directive 2008/18/EC 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 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, [53] to "repatriate" controls over cultivation.

The new opt-out clause regime facilitates the task of Member States seeking to prohibit the cultivation of GMOs for which an authorisation has been granted as they are no longer required to demonstrate the "seriousness" of the risks incurred and as their measures is not subject to an *ex post* review by the Commission. In effect, the Member States are objectively required to make less of an effort in implementing the opt-clauses than in invoking the traditional safeguard clauses.

para. 14; and Opinion AG Poiares Maduro in Cases C-434/04 *Jan-Erik Anders Ahokainen* [2006] ECR I-9171, paras. 23-26.

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

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