# Legalising General Prohibitions on Cultivation of Genetically Modified Organisms

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## A. Introduction

In a pluralistic society, agreement over complex issues is frequently difficult to achieve. This is amply demonstrated by the question of cultivation of Genetically Modified Organisms (GMOs), where scientific uncertainty relating to potential threats to the environment[1] or human health[2] runs parallel with concerns over ethics,[3] freedom of choice,[4] and competing agricultural and economic interests.[5] Conflict centres over the objective of free trade of GMOs and the circumstances in which restrictions may legitimately be imposed to deal with the abovementioned concerns, in particular regarding cultivation.

In contrast with the USA, which follows a product approach by regulating according to the nature and characteristics of the individual product, the European Union (EU) upholds a process approach,[6] which regulates according to the process by which a product is created rather than its individual attributes. Consequently, the EU has regulated GMOs due to

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[1] *E.g.*, outcrossing and "superweeds" due to pesticide resistance.

[2] *E.g.*, antibiotic resistance, allergens, and general potential long-term effects.

[3] *E.g.*, through interfering with nature or taking/imposing unnecessary risks versus the possibility of developing crops suitable for climates where conventional crops are incapable of being grown in famine ridden countries.

[4] Of both producers and consumers, e.g., whether there is a veritable possibility to have a choice between GM and truly non-GM crops/products, considering issues of admixture.

[5] Of producers and States, where for instance there is a valuable market for organic products.

[6] Coordinated Framework for the Regulation of Biotechnology, 51 Fed Reg 23,302 (June 26, 1986); Adam Sheingate, *Promotion versus Precaution: The Evolution of Biotechnology Policy in the United States*, 36 Brit. J. Pol. Sci. 243 (2006); Rebecca Bratspies, *Some thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 Kan. J.L. & Pub. Pol'y 393 (2007).

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their genetic modification, with specific purpose-built legislation developed since Directive 90/220 on GMOs[7] with a requirement for prior authorisation for deliberate release into the environment. However, the Directive omitted aspects relating to the nature of the risks, potential threats, monitoring, traceability, etc. As well as risks to the environment, concern grew over the risk to human health and the lack of specific legislation for GM food or feed.[8] Linked to this, there was little protection as regards freedom of choice for consumers or indeed farmers if admixture occurred (i.e., if there were mingling or cross-contamination between GM and non-GM crops, in particular if non-GM crops were found to contain a percentage of GMOs). Member States' governments were also not happy with the extent of the Commission's control over the release of GMOs,[9] and used the "safeguard clause" in Article 16 of the 1990 GMO Directive to impose nine national bans[10] and the *de facto* moratorium.[11]

This led to the World Trade Organisation (WTO) Biotech dispute,[12] where the USA, Canada, and Argentina challenged the legality of the EU permitting the delays, bans, and moratorium, due to restricting trade and not being based on thorough scientific risk assessments. This challenge, which was later upheld by the Dispute Panel,[13] spurred on

[7] Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, 1990 OJ (L 117) 15.

[8] This issue fell within the scope of Regulation 258/97/EC concerning novel foods and novel food ingredients, 1997 OJ (L 43) 1 where the concept of "substantial equivalence" applied.

[9] Highlighted by the Novartis Affair; Yves Tiberghien, *Competitive Governance and Legitimacy: Regulation of GMOs since the mid 1990's*, 31 J. EUR. INTEGRATION 389, 400 (2009); European Parliament's Resolution on Genetically Modified Maize, 1997 OJ (C 432) 2.

[10] European Commission, *GMOs in a Nutshell*, *available at* http://ec.europa.eu/food/food/biotechnology/qanda/d1_en.htm#d (accessed Dec. 8, 2010).

[11] Denmark, France, Greece, Italy and Luxembourg declared at the Council meeting of 24/25 June 1999 that they would 'take steps to have any new authorisations for growing and placing on the market suspended', until their concerns over risk assessments, traceability and labelling were resolved through new legislation. Europa Press Release: 2194th Council Meeting-Environment-Luxembourg, 24/25 June 1999, 9409/99, No. 203, *available at* http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/ACF5B.htm (accessed Dec. 8, 2010). At the same meeting, Austria, Belgium, Finland, Germany, the Netherlands, Spain and Sweden all declared their concerns, and a quasi temporary moratorium pending assurances of safety. Both groups noted public concerns, transparency and the precautionary principle as motivations for their Declarations. Ian Sheldon, *Europe's Regulation of Agricultural Biotechnology: Precaution or Trade Distortion?* 2 J. AGRIC. & FOOD INDUS. ORG. 1 (2004); and Elsa Tsioumani, *Genetically Modified Organisms in the EU: Public attitudes and Regulatory Developments*, 13 RECIEL 279 (2004).

[12] Thomas Bernauer and Erica Meins, *Technological revolution meets policy and the market: Explaining cross-national differences in agricultural biotechnology regulation*, 42 EUR. J. POL. RES. 643 (2003); and Dispute Settlement, European Communities — Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R and WT/DS293/R, DSR 2006:III, 847.

[13] The Panel found that the *de facto* moratorium, the substantial delays in authorization and the national bans were all in breach of certain provisions: Section VIII Conclusions and Recommendations of the Panel's Report *ibid*.

the EU to deal with the criticisms encapsulated therein, while compromising with the Member States in order to allay concerns and hopefully deal with national prohibitions and hesitancy.[14]

The current regime centres on the Deliberate Release Directive 2001/18,[15] Regulation 1829/2003 on GM food and feed,[16] and Regulation 1830/2003 on the labelling and traceability of GMOs.[17] The risk assessments and information to be considered therein were substantially enhanced; this is demonstrated by the inclusion of indirect and long-term effects, and even potential threats, as for instance the environmental risk assessments were to take into account scientific uncertainty, in light of the precautionary principle.[18] Monitoring, tracing and labelling were provided for, coexistence measures authorised and improvements occurred in relation to decision-making to increase democracy as well as the use of independent, scientific expertise.

These changes were introduced in order to improve the effective protection of the environment and human health, democracy and transparency, and freedom of choice of producers and consumers.[19] However, this was according to the EU's chosen levels of protection rather than those of the Member States; the States have continued to display, via in particular national prohibitions,[20] a desire to retain a greater degree of control over

[14] Gregory C. Shaffer & Mark .A. Pollack, *The EU regulatory system for GMOs*, *in* UNCERTAIN RISKS REGULATED: FACING THE UNKNOWN IN NATIONAL, EU AND INTERNATIONAL LAW 269 (M. Everson & E. Vos eds., 2008).

[15] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2001 OJ (L 106) 1.

16 Regulation 1829/2003/EC of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, 2003 OJ (L 268) 1.

[17] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, 2003 OJ (L 268) 24.

[18] Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2002 OJ (L 200) 22.

[19] The last two were to be protected through the combined means of labelling and coexistence: Justo Corti-Varela, *Coexistence of Genetically Modified, Conventional and Organic Products in the European Market: State of the Art Report,* 1 Eur. J. Risk Reg. 63, 65 (2010).

[20] EU's Press Release, Questions and Answers on the EU's new approach to the cultivation of GMOs, Brussels, 13th July 2010, MEMO/10/325, *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/325&format=HTML&aged=0&language=EN&guiLanguage=en (accessed Dec. 8, 2010. *See also* GMO Free Europe 2010, *GE Cultivation Bans in Europe*, *available at* http://www.gmo-free-regions.org/gmo-free-regions/bans.html (accessed Dec. 8, 2010). The usual list of safeguard measures is currently unavailable on the Commission's website due to restructuring.

the release of GMOs to protect these values, and probably also for political and economic reasons. Despite the Commission's objections regarding lack of appropriate scientific evidence, some States profess their intention to maintain these prohibitions.[21]

In an attempt to reconcile the Member States, while complying with external obligations, the Commission proposed a seemingly revolutionary package in July 2010, which would provide for de-harmonisation of a central element of the GMO regime.[22] The Commission recommended providing the States not merely with greater flexibility in creating coexistence measures,[23] but also with the potential to legally prohibit cultivation of GMOs nationally, via the proposed Article 26b[24] to be inserted into the Deliberate Release Directive 2001/18.[25] This would provide a post-authorisation national veto for Member States, and potentially lessen their controversial use of safeguard clauses.

This article assesses the potential scope of the proposed Article 26b to permit Member States to exclude cultivation legally within the EU and WTO in order to protect legitimate concerns at the level chosen nationally; it does so without making a judgment on the safety or otherwise of authorised GMOs but on the basis that Member States may have reason to believe that GM crops interfere with various national objectives, which they desire to protect.

In order to examine the Proposal in context, it is necessary to briefly introduce in Section B the current use of the safeguard clauses by Member States, as the main means of excluding cultivation. It will become apparent that the potential of the safeguard clauses is undermined, both through the overly restrictive interpretations by the European Food Safety Authority, the Commission and the EU Courts where relevant and also through the legally questionable refusals by the individual Member States or Council to force the lifting of the prohibitions. The continuing conflict further highlights the desire by some Member States for a greater discretion or competence to control, or even exclude, the cultivation of

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[21] A number of Member States have already banned the cultivation of Amflora Potato since its EU authorization in March 2010. *Commission Communication on the freedom for Member States to decide on the cultivation of genetically modified crops*, COM (2010) 380 final (Jul. 13, 2010).

[22] EU move to break GM deadlock could sow discord, EURACTIV WITH REUTERS (June 30, 2010), http://www.euractiv.com/en/eu-move-break-gm-deadlock-could-sow-discord-news-495753.

[23] Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, 2010] OJ (C 200) 1.

[24] *Proposal for a Regulation 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 (July 13, 2010).

[25] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2001 OJ (L 106) 1.

GMOs within their territories to protect a broader range of objectives, which the safeguard procedures do not formally provide.

Section C examines the Commission's response, in particular in the form of the proposed Article 26b, which could potentially in effect substantially de-harmonise this aspect of the GMO regime, providing the MS with a renewed competence to exclude GMO cultivation within their territories. It centres on the interaction of the proposed Article 26b with the provisions of the Treaty on the Functioning of the EU (TFEU) on the quantitative restrictions and context of the EU GMO regime, focusing on how the choice of a legitimate objective and establishing proportionality limit the apparent *carte blanche* to veto cultivation nationally.

Finally, if to be of long-term value, it is essential to understand the possibilities within the WTO for the application of Article 26b. In Section D, it is argued that, in contrast with the safeguard clauses, the SPS Agreement is of no relevance to Article 26b. It is argued that the public morality exemption within Article XX of GATT is applicable, thereby providing a broad basis to exempt the quantitative restrictions on the condition that necessity is established.

If adopted into Directive 2001/18, Article 26b may provide the necessary bypass of the safeguard clauses and the SPS Agreement for EU Member States, which may have further implications for the general GMO cultivation regime within the EU. However, this new derogation would not be unfettered and will involve a heavy evidentiary burden if States are challenged legally.

**B. Existing possibilities for Member States to exclude GM cultivation?**

Due to the nature of the EU and internal market whereby barriers to the free movement of goods within the EU are to be removed, where a regime has been harmonised or even partially harmonised the competence and discretion of the State are reduced and any apparent disparities must be provided for within EU law, via derogations or exceptions. Article 288 TFEU provides for those secondary legislative instruments which are of binding force and may be used to harmonise regimes, including Regulations and Directives. States must comply with the EU legislation even where in conflict with their own laws.[26] Where a Member State is suspected to have acted beyond its competence or in breach of EU law, then its actions may be challenged before its national courts or the EU Courts, by a private party, another Member State, or the Commission. The Courts may order the State to

[26] Due to the principle of supremacy (e.g. Costa v ENEL, 1964 E.C.R. 585) and duty of loyal or sincere cooperation (to be found in ex Article 10 EC Treaty and in Article 4 Treaty on the EU).

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comply with the relevant EU law and impose a fine[27] or damages to be paid to the injured party (under Francovich liability[28]).

In the context of GMOs, the 2001 Directive and 2003 Regulations complemented by further documents such as the guidance notes on Environmental Risk Assessments,[29] provide for a high level of harmonisation, thereby limiting the discretion of MS severely. Their main powers lie in relation to the original national assessments and coexistence measures under Article 26a of Directive 2001/18 to prevent admixture, although even this discretion is somewhat limited by the Commission's development of Recommendations,[30] a Co-existence Network,[31] a Co-existence Bureau, etc.[32] Once a GMO receives EU authorisation it is automatically authorised within each and every Member State,[33] provided that seeds to be cultivated are published on a register[34] and licensing conditions are complied with. Member States who wish to exclude cultivation may only do so within the framework provided for by EU law, whether under the GMO legislation, other relevant secondary legislation such as conservation Directives or under the TFEU itself, or else risk being held in breach of EU law.

The EU regime provides for the possibility of States excluding GM cultivation where specific conditions are fulfilled. Although exclusion may be achieved via coexistence measures depending on the agri-type preferred,[35] as well as through other EU legislation such as the

[27] Under Article 260 TFEU. In Case C-121/07, Commission of the European Communities v. France 2008 E.C.R. I-9159, the Court imposed a fine upon France for failure to implement Directive 2001/18 (n15).

[28] Joined Cases C-6/90 and C-9/90 Francovich v Italy, 1991 E.C.R. I-5357.

[29] Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC 2002 OJ (L 200) 22.

[30] Commission Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, 2003 OJ (L 189) 36, and the 2010 Recommendation (n23).

[31] Decision 2005/463/EC, 2005 OJ (L 164) 50.

[32] Maria Lee, *Multi-Level Governance of GMOs in the EU: ambiguity and hierarchy*, *in* THE REGULATION OF GMOS: COMPARATIVE APPROACHES (L. Bodiguel & M. Cardwell, eds. 2010).

[33] Directive 2001/18, *supra* note 15, art. 22.

[34] Corti-Varela, *supra* note 19, at 64.

[35] "Appropriate measures" may be taken by Member States via Article 26a of Directive 2001/18 as inserted by Regulation 1829/2003. On preferences to competing agri-types, see Les Levidow & Karin Boschert, *Coexistence or contradiction? GM crops versus alternative agricultures in Europe?*, 39 GEOFORUM 174, 174, 181, 187 (2008).

Habitats Directive,[36] these mechanisms are intended to target local and individual situations rather than providing for a national prohibition. The central mechanisms for Member States to prohibit GM cultivation throughout their territories are via the safeguard clauses, although these are limited in legal scope.

The use of these clauses is supervised in particular by the Commission, with the assistance of the European Food Safety Authority. Established by Regulation 178/2002 on the General Principles of food Law,[37] the European Food Safety Authority assesses the scientific evidence provided in notifications for authorisation and also by States attempting to derogate via the safeguard clauses on health or environmental reasons. It is to provide independent scientific assessments/opinions at an EU level, which are heavily relied upon by the Commission in coming to its risk management decision and by the EU Courts in assessing the Commission's decisions.[38] Both of these bodies play crucial roles in the application of the safeguard clauses.

*I. Safeguard Clauses*

Safeguard clauses provide a failsafe, to facilitate swift and effective protection where evidence indicates that, despite authorisation or harmonisation, the product or process in question poses a real risk. Along with specific safeguard clauses or emergency provisions within the GM legislation,[39] there is also the possibility of availing of the provisions within Article 114 (4) and (5) TFEU (ex 95(4) and (5) EC) to maintain or introduce national measures respectively, as well as Article 18 of Directive 2002/53/EC.[40] Of greatest relevance for cultivation are Article 23 of Directive 2001/18 and Article 114 (5) TFEU. Although availed of by Member States, they are of limited scope compared to the wide breadth of concerns in question and further the Commission, the European Food Safety Authority and the Courts have attempted to control their use stringently.

[36] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora 1992 OJ (L 206) 7. On the relevance of conservation Directives to managing authorized GM crops see: Commission Staff Working Document, PARL. EUR. DOC. (SEC 313) (2006), annexed to the Commission Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming, (COM 104) (2006).

[37] Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1.

[38] Paul Craig, EU ADMINISTRATIVE LAW 156 (2010).

[39] For example, Article 16 in the 1990 GMO Directive, *supra* note 7, Article 23 in the Deliberate Release Directive 2001/18, *supra* note 25, and Article 34 in Regulation 1829/2003, *supra* note 16.

[40] Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, 2002 OJ (L 193) 1. *E.g.* Commission Decision 2006/10/EC of 10 January 2006 concerning the provisional prohibition in Greece of the marketing of seeds of maize hybrids with the genetic modification MON 810 inscribed in the common catalogue of varieties of agricultural plant species, pursuant to Directive 2002/53/EC, 2006 OJ (L 7) 27.

Use of the Article 23 safeguard clause is only permitted where a State, "*as a result of new or additional information . . . affecting the environmental risk assessment . . . on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO . . . constitutes a risk to human health or the environment".*[41] Article 23 has been used on multiple occasions by various Member States.[42] However, the Commission[43] and the European Food Safety Authority[44] have yet to hold any of these restrictions or prohibitions as justified, due to a lack of new or additional scientific information indicating risks.

This requirement of "newness" is understandable in so much as the risk assessment was to be based on all available evidence and ensure that any actual or potential threats be dealt with within the risk management measures, such as licensing conditions. However, this is in an area of scientific uncertainty and it is possible to have varying interpretations of the existing data. The Courts have also specifically declared that safeguard clauses embody the precautionary principle,[45] which has not merely been incorporated into Article 191 TFEU46 (ex Article 174 EC), but also declared as a general principle of EU law.[47] Reading the clause in the light of the precautionary principle in conjunction with the principle of

[41] Directive 2001/18, *supra* note 15, art. 23.

[42] *See* note 20, *supra*.

[43] Commission Proposals to compel Member States to remove safeguard measures as unjustified: (COM 161) (2005), (COM 162) (2005), (COM 164) (2005), (COM 165) (2005), (COM 166) 2005, (COM 167) (2005), (COM 168) (2005), (COM 169) (2005), (COM 509) (2006), (COM 510) (2006), (COM 713)(2006), (COM 586) (2007), (COM 589) (2007), (COM 12) (2009), (COM 51) (2009), and (COM 56) (2009).

[44] *E.g.*, *Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission related to the safeguard clause invoked by Austria on oilseed rape MS8, RF3 and MS8xRF3 according to Article 23 of Directive 2001/18/EC*, 2009 EFSA J. 1153. In addition, see the list of questions referenced by Corti-Varela, *supra* note 19, at n. 8.

[45] Case C-6/99, Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others, 2000 E.C.R. I-1651, para. 44, where the Court ruled that Directive 90/220 dealt with environmental and human health risks in compliance with the precautionary principle via *inter alia* the safeguard clause in its Article 16 and the risk assessment procedure.

[46] It has been present within the Environmental Title since the Maastricht Treaty, 1992. A high level of environmental protection is to be achieved in accordance with a number of principles including the precautionary principle.

[47] *E.g.*, Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00, & T-141/00, Artegodan GmbH v. Commission, 2002 E.C.R. 11-4945, para. 184; Case C-132/03, Ministero della Salute v Coordinamento delle Associazioni per la Difesa dell'Ambiente e dei Diritti degli Utenti e dei Consumatori (Codacons), 2005 E.C.R. I-4167, para. 35 ("That interpretation of Community law is compelling not only because it reflects the logic of the system but also on account of the precautionary principle, a general principle of Community law, which demands the best possible information."). On general principles of law, in the context of the EU, see TAKIS TRIDIMAS, THE GENERAL PRINCIPLES OF EU LAW (2d ed. 2007).

precedence,[48] it would seem appropriate to interpret the provision broadly and consequently for "new or additional knowledge" to include new understandings of the original data.

Although the Court of Justice of the EU (CJEU) has not dealt with a Member State relying on Article 23 directly,[49] it has had opportunity to examine it in Case C-121/07 *Commission v France*.[50] In his Opinion of 5 June 2008, Advocate General Mazák argued that the relevant French decree[51] failed to implement Article 23 satisfactorily as it allowed for new interpretations to justify measures, rather than requiring new evidence.[52] The Court's Judgment does not analyse the issue, as it decided to award a lump sum against France for failure to meet the deadline, rather than a continuing fine for failure to implement.[53] The CJEU were willing to take into consideration the efforts by France reflected in the March 2007 Decrees, which made substantial inroads into correct implementation, noting that according to the Commission, only three provisions remained unimplemented (including Article 23).[54] Although inconclusive, it is probable that the Courts would follow the Advocate General's Opinion, and uphold the requirement similarly to their approach to that of Article 114 (5) TFEU, which currently excludes new interpretations of old evidence.

Despite the Commission and European Food Safety Authority's opinions that they do not meet the requirements of Article 23,[55] the decision-making structure in relation to Article 23 has permitted States to maintain their prohibitions; if the Council vote by qualified majority against the Commission's proposal to take action against the States in question, the Commission must either drop the issue or suggest a different proposal that the Council will agree to.[56] The Council have rejected every proposal by the Commission in relation to

[48] *E.g.*, Artegodan, *supra* note 47, at para. 184, 186.

[49] As the Council block actions by the Commission to lift these prohibitions-outlined in following paragraph.

[50] Comm'n v. France, *supra* note 27.

[51] In particular Article 16 of Decree 2007-359 and its relationship with L535-2 and L533-6 of the Code de l'Environnement (since repealed by Article 14 of *Loi nº 2008-595 du juin 2008 relative aux organismes génétiquement modifies* JORF 26/6/08, p.10218, http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000019066077&dateTexte= (accessed 8 December 2010*).*

[52] Comm'n v. France, *supra* note 27, Advocate General's Opinion, at para. 44.

[53] By the time of the CJEU's Judgment, France had made major steps in implementation and were also near to promulgating *Loi nº 2008-595 du juin 2008* (n49) which would implement Directive 2001/18 fully.

[54] Comm'n v. France, *supra* note 27, at para. 85.

[55] GMOs in a Nutshell, *supra* note 10.

[56] Article 5 of Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, 1999 OJ (L 184) 23, as amended by Council Decision 2006/512/EC amending

the use of safeguard measures relating to cultivation, leading the Commission to split a proposal regarding lifting bans within Austria on cultivation and marketing in order to hopefully lift the ban on marketing. The Council were unable to achieve a qualified majority in the latter decision[57] and, consequently, the Commission were able to make the final decision in that regard.[58] However, this measure may still only be used in relation to individual GMOs, and it is unsatisfactory that the measures may be of some practical success only through the political stubbornness of the Council or the recognition of the futility of action by the Commission, despite the belief by the Commission and the European Food Safety Authority amongst others that they are illegitimate. Legal certainty is undermined as the possibility and consequences of a safeguard measure are unknown.

The main alternative for Member States is that of Article 114 (5) TFEU whereby a State may attempt to justify the introduction[59] of measures that conflict with harmonising measures. In order to achieve this, the State must show that there is "*new scientific evidence relating to the protection of the environment or working environment*[60] *on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure,*" which are cumulative conditions,[61] and may be very difficult to fulfil.[62] As with Article 23, the State must again demonstrate "newness," which has been

Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, 2006 OJ (L 200) 11.

[57] Commission Decision 2008/495/EC concerning the provisional prohibition of the use and sale in Austria of genetically modified maize (*Zea mays* L. line MON810) pursuant to Directive 2001/18/EC of the European Parliament and of the Council, 2008 OJ (L 172) 25. It details the Council's previous refusal to take action, as well as the Commission's decision to propose action only on food and feed.

[58] *Id.*

[59] Member States may also maintain measures via Article 114 (4) TFEU, where necessary to protect the environment, working environment or those objectives within Article 36 TFEU. The restrictions of 'specificity' and new scientific evidence' on Article 114 (5) TFEU are not imposed here, however limitations still apply and the provision is less relevant to the issue of GMOs.

[60] Consequently health protection is excluded, as are the other concerns of Member States.

[61] Therefore, as highlighted by the Advocate General Sharpston in her opinion of 15 May 2007 in C-439/05, Land Oberösterreich and Austria v Commission, 2007 E.C.R. I-07141, para. 139, the Member State must fulfil 5 conditions cumulatively: 'i) new evidence must be presented, (ii) the evidence must be scientific, (iii) it must relate to protection of the environment or the working environment, (iv) there must be a problem specific to the Member State, and (v) the problem must have arisen after the adoption of the harmonising measure.'

[62] *See* Ludwig Krämer, EC ENVIRONMENTAL LAW (6th ed. 2007); N. de Sadeleer, *Procedures for Derogations from the Principle of Approximation of Laws under Article 95 EC*, 40 COMMON MKT. L. REV. 889 (2003); F.M. Fleurke, *What Use for Article 95 (5)? An Analysis of Land Oberösterreich and Republic of Austria v Commission,* 20 J. ENVNTL. L. 267 (2008).

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interpreted by the Commission,[63] European Food Safety Authority[64] and EU Courts[65] alike to indicate new scientific data and not merely a new interpretation of the old facts.[66] In particular, there must be a new element to the risk assessment, rather than merely the risk management element.

A further severe limitation is imposed through the requirement of "specificity." This does not entail that the problem be unique[67]; however, it must not be one generally present throughout the EU. In partial defence of this, where the Commission approves of the Member State's measures but believe that there are no specific circumstances within the nation, it may and must take appropriate EU wide measures instead. Nonetheless, if a measure meets the other criteria of the provision, including the usual requirement to comply with the principle of proportionality, it seems counterproductive to require fulfilment of specificity.

*II. Conclusion on the Use of Safeguard Clauses*

The clauses risk being used as a political tool to delay or prevent releases, and simultaneously being too difficult to legally be used successfully in cases where potential threats do exist but where the required "newness" or "specificity" is lacking. However, any change in the approach to the safeguard clauses would more than likely require a legislative proposal at this stage, as it would be a substantive alteration in EU jurisprudence

[63] *E.g.*, Commission Decision 2003/653/EC relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty, 2003 OJ (L 230) 34. Article 95(5) EC was renumbered as Article 114 (5) TFEU following the Lisbon Treaty.

[64] Reviews/reassessments were insufficient in *Opinion of the Scientific Panel on Genetically Modified Organisms on a question from the Commission related to the Austrian notification of national legislation governing GMOs under Article 95(5) of the Treaty*, 2003 EFSA J. 1.

[65] The General Court upheld the European Food Safety Authority's interpretation in Joined Cases T-366/03 and T-235/04, Land Oberösterreich and Republic of Austria v Commission, 2005 E.C.R. II-4005.

[66] Decision 2003/653/EC, *supra* note 63; Sheldon, *supra* note 11; Fleurke, *supra* note 62. However it should be highlighted that Advocate General Sharpston in Land Oberösterreich, *supra* note 61, at para. 142, indicated that a new analysis of original data could lead to new conclusions which could constitute new evidence. Further the Advocate General stated that if the problem was latent and the Member State only became aware of the problem since the harmonising measure, this could fulfil the requirement that the problem arise only since the harmonising measure. However Austria failed to establish that these two requirements were fulfilled on the facts. The CJEU did not comment on this issue as for the purposes of the appeal it was only necessary to establish if the Commission and GCEU had correctly assessed the requirement of a 'specific problem', as if this requirement was not fulfilled by a Member State, then they would not be able to justify the national measures under Article 114(5) TFEU.

[67] The General Court in Land Oberösterreich, *supra* note 65, at para. 65-67, referred to the necessity of the unique or unusual character of the State's problem. However the CJEU, *supra* note 61 at para. 65-67, clarified that specificity was broader than uniqueness, although what it entails exactly is still unclear.

for the Courts to commence a more lenient approach to the Member States' safeguards.[68] Even the Commission's decision not to take action against Portugal earlier in 2010 when it ignored the passing of the deadline in relation to the use of Article 114 (5) regarding Madeira, despite the European Food Safety Authority's opinion that no new scientific evidence had been presented,69 appears only to have been a temporary concession.70 It should not be presumed that this tolerance will necessarily continue following the new proposals discussed below.

A further inherent limitation of the safeguard clauses is their restriction to the areas of environmental or human health protection. Consequently, concerns over ethics, freedom of choice, democracy etc are not permitted as the main objectives in taking safeguard measures, although nonetheless affected. As the area is harmonised, and these issues are supposedly dealt with via the authorisation procedures, labelling, coexistence measures, etc., Member States lack the legal competence to prohibit cultivation for these reasons. Yet Member States have regularly indicated their desire and intention to prohibit cultivation nationally for scientific and non-scientific reasons, despite the Commission's protestations. Currently the States can achieve this via Article 23 with the support of the Council, yet the legality of such an approach is questionable. Further, it is unsatisfactory that protection of legitimate values should resort to such subterfuge.

Despite the efforts of the EU, many of the concerns of the Member States leading to the *de facto moratorium* and Biotech Dispute remain regarding cultivation. Likewise, national bans continue, while until March 2010 there had only been one authorisation of cultivation under Directive 2001/18. The Commission has attempted to resolve these issues in July 2010.

### C. Legalising Exclusion? The July 2010 Package

Over the past two years there have been indications of potential change. In June 2009 Austria, with the support of 10 other Member States, submitted a note to the Environmental Council suggesting the inclusion of an opt-out clause for States within the GM regime.[71] Commission President Barroso in 2009 also indicated the possibility of

[68] The CJEU recently side-stepped an opportunity to expand the concept; *see supra* note 66.

[69] *Scientific Opinion on a question from the European Commission related to the notification by Portugal, pursuant to Article 95 (5) of the EC Treaty, for the prohibition of cultivation of Genetically Modified Plants in the Autonomous Region of Madeira*, 2010 EFSA J. 1500.

[70] James Kanter, *E.U. Signals Big Shift on Genetically Modified Crops*, N.Y. TIMES, *May 9, 2010, available at* http://www.nytimes.com/2010/05/10/business/energy-environment/10green.html. The author refers to a memorandum by the Commission stating that the Commission did not want to add to the confusion at the time.

[71] Note Submitted by Austrian Delegation, Genetically Modified Organisms – A Way Forward (June 25, 2009), http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re01.en09.pdf (accessed Dec. 8, 2010).

Member States deciding upon national cultivation.[72] Following this, the Commission first extended the deadline regarding a safeguard measure by Portugal,[73] and then appeared to ignore the extended deadline in May 2010 thereby implicitly permitting its actions.

Nonetheless, the actions of the Commission in July 2010 are radical in the context of the development of the EU GMO regime. Following two decades of harmonising legislation, combined with a detailed soft law[74] coexistence Recommendation[75] despite legally being within the Member States' competence,[76] the Commission has decided to relieve the situation outlined above by making the post authorisation regime more flexible[77] through increasing the power or discretion of the States relating to coexistence and prohibitions on cultivation. It therefore theoretically should increase the formal legitimacy and legal certainty simultaneously as the States would have an appropriate legal basis for actions which had hereto been lacking.[78]

Within the 2010 Coexistence Recommendation,[79] the Commission expressly states that Member States may unilaterally declare certain areas as GM-free if less restrictive measures would not suffice in contrast with the 2003 Recommendation.[80] It also acknowledges explicitly that Member States may legitimately use measures that seek to prevent admixture below the labelling threshold, especially where organic crops are at stake[81]. Unlike in 2003, the Commission acknowledges that there are special attributes to

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[72] President Barroso, *Political Guidelines for the next Commission*, at 39 (Sept. 3, 2009), http://ec.europa.eu/commission_2010-2014/president/pdf/press_20090903_en.pdf (accessed Dec. 8, 2010).

[73] Commission Decision 2009/828/EC relating to the draft Regional Legislative Decree declaring the Autonomous Region of Madeira to be an Area Free of Genetically Modified Organisms, notified by the Republic of Portugal pursuant to Article 95(5) of the EC Treaty, 2009 OJ (L 294) 16.

[74] L. SENDEN, SOFT LAW IN EUROPEAN COMMUNITY LAW (2004). For a common definition see Francis Snyder, *The Effectiveness of European Community Law: Institutions, Processes, Tools and Technique*, 56 MODERN L. REV. 19, 32 (1993) ("rules of conduct which, in principle, have no legally binding force but which nevertheless have practical effects"). Oana Stefan, *European Competition Soft Law in European Courts: A Matter of Hard Principles?*, 14 Eur. L.J. 753 (2008), provides for an extension to Snyder's definition to include legal effects also.

[75] 2003 Coexistence Recommendation, *supra* note 30.

[76] See *supra* note 35.

[77] (COM 380 final) (2010), *supra* note 21; and Recital 7 of the 2010 Coexistence Recommendation, *supra* note 23.

[78] *E.g.*, Citizen's Summary- GMO cultivation – The Commission's flexible new approach, *available at* http://ec.europa.eu/food/food/biotechnology/docs/gmo_cultivation_citizen_sum_en.pdf (accessed Dec. 8, 2010).

[79] 2010 Coexistence Recommendation, *supra* note 23, Guidelines, Section 2.4.

[80] *See supra* note 30.

[81] 2010 Coexistence Recommendation, *supra* note 23, Guidelines, Section 1.1.

organic farming and produce[82] for farmers and consumers; it further acknowledges that some farmers and operators may wish to "ensure that their crops have the lowest possible presence" of GMOs,[83] which may involve striving to avoid admixture entirely and the exclusion of GM crops.

However, the Commission continues to see coexistence as an economic issue,[84] and consequently any measures are intended to relate to the economic impact on farmers or others down the production/consumption line. Further, the measures must be established by the Member State as proportional, and are intended to facilitate the management of cultivation locally rather than providing for national prohibitions. Although the 2010 Recommendation is of significance within the regime as an example of soft law[85] and indicating a more flexible approach by the Commission, to a great extent it merely reflects the practices of some Member States already[86] and the obvious implications of the use of buffer zones, isolation distances, etc. The potentially revolutionary element of the package is that of the Proposal to insert Article 26b into Directive 2001/18.

*I. Article 26b: Legalising General National Prohibitions on GM Cultivation?*

In conjunction with the more flexible Coexistence Recommendation, the Commission proposed the insertion of Article 26b into Directive 2001/18[87]:

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[82] This was also seen in the Communication on the European Action Plan for Organic Food and Farming (COM 415) (2004) at Section 1.4 where organic farming was stated to be beneficial to public health, social and rural development, animal welfare and the environment.

[83] 2010 Coexistence Recommendation, *supra* note 23, Guidelines, Section 1.1. This more closely reflects Regulation 834/2007/EC on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, 2007OJ (L 189) 1, which states that should aim at the lowest possible level of presence in the Recitals, and Article 9 which states that no GMOs should be used in organic agriculture.

[84] It should be pointed out that there have been important statements in contradiction with this within the Commission. In his speech at the Conference, the Commissioner for the Environment, Stavros Dimas, stated that co-existence measures could protect the environment as well as economics. Stavros Dimas, Commissioner for the Environment, "Coexistence of genetically modified, conventional and organic crops: Freedom of choice," April 5, 2006, *available at* http://www.europa-eu-un.org/articles/en/article_5884_en.htm (accessed 8 December 2010).

[85] *See supra* note 74. As an example of soft law, it is capable of binding the Commission to their content due to the general principles of EU law including the principle of legitimate expectations, legal certainty and equal treatment. Generally it is also of interpretative value. *See* Case C-322/88, Grimaldi, 1989 E.C.R. 4407.

[86] Commission Staff Working Document, *supra* note 36; J. Corti-Varela, *The End of Zero-Risk Regulation of GM Crops in Europe: The Battle of Co-existence Rules*, presented at 'The End of Zero Risk Regulation: Risk Toleration in Regulatory Practice Conference', 2nd Annual Cambridge Conference on Regulation, Inspection and Improvement, Cambridge, UK, 11-12 September 2007, at 6-9, Annex II *available at* http://www.cbr.cam.ac.uk/pdf/Corti_Varela_Paper.pdf.

[87] (COM 375 final) (2010), *supra* note 24.

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> Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties placed on the market in accordance with relevant EU legislation on the marketing of seed and plant propagating material, in all or part of their territory, provided that: (a) those measures are based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs; and, (b) that they are in conformity with the Treaties.
>
> By way of derogation to Directive 98/34/EC, Member States that intend to adopt reasoned measures under this Article shall communicate them to the other Member States and to the Commission, one month prior to their adoption for information purposes.

This provision at first glance appears to be a spectacular turn about on EU GMO policy and to give States a general veto on national cultivation. The provision provides for Member States to create restrictions or prohibitions on cultivation, on a national level. However, two limitations apply: firstly, the measures may not be based on human health or environmental reasons, linked again to the presumption that the authorisation procedure and safeguard clause suffice; and secondly, the measures must comply with the EU Treaties. As the measures would amount to a quantitative restriction or measure of equivalent of effect in an area which would be in effect no longer harmonised, these would be prohibited generally under Articles 34 and 35 TFEU (ex Articles 28 and 29 EC). However, these prohibitions may then be justified under Article 36 TFEU (ex Articles 30 EC) objective justifications and mandatory requirements, although without the benefit of using the most obvious one of protection of the environment, human health, or animal or plant life. So, if the measures are challenged, on what bases may they be justified?

*II. Potential Objective Justifications?*

Article 36 TFEU contains an exhaustive list[88] of objective justifications for quantitative restrictions. Alongside these is the non-exhaustive list of mandatory requirements[89] for

[88] C-113/80, Commission v Ireland, 1981 E.C.R. 1625.

[89] P. CRAIG & G. DE BÚRCA, EU LAW: TEXT, CASES AND MATERIALS (4th ed. 2007).

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those measures of equivalent effect, developed following *Cassis de Dijon*,[90] which include *inter alia* consumer protection[91]. It is probable that the restrictions would be measures of equivalent effect, involving a general prohibition on cultivation of GMOs rather than a direct prohibition on import. Therefore there is more flexibility in identifying a legitimate objective.

Excluding the objectives of environmental and health protection, the most likely potential bases would be protecting public morality/ethics,[92] public policy including that of "quality" farming,[93] industrial and commercial property,[94] or consumer interests.[95] These objectives would cover most of the substantial concerns of Member States and appear to be permitted by Article 26b via mandatory restrictions. There should be little difficulty in establishing that the above objective justifications or mandatory requirements could apply to a restriction on GMO cultivation, especially considering the flexibility of the notions of public policy[96] and morality.[97] Whichever objective is presented as the basis for the national restrictions, it must be clear that it is a substantial reason behind the restriction, and not concealing other objectives such as environmental or health concerns,[98] political expediency or a disguised trade restriction.

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[90] C-120/78, Rewe-Zentrale AG v. Bundesmonopolverwaltung für Branntwein (Cassis de Dijon), 1979 E.C.R. 649.

[91] *Id.*

[92] For example, Interfering with nature, "playing god," taking unnecessary risks, etc. Nuffield Council on Bioethics, *Genetically Modified Crops: the Ethical and Social Issues* (1999), *available at* http://www.nuffieldbioethics.org/gm-crops J.S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207 (2001).

[93] The EU provides protection for what are described as "quality products" and includes protected designation of origin, protected geographical indication and traditional specialties guarantees. See European Commission, Geographical Indications and Traditional Specialties, *available at* www.ec.europa.eu/agriculture/quality/schemes/index_en.htm. As well as the economic aspects acceptable to the Commission, there are further societal, cultural and potentially health benefits to these. In Case 196/85, Commission v France, 1987 E.C.R. 1597, protection of traditional and customary methods was upheld as a legitimate objective.

[94] Joined Cases C-465/02 and C-466/02, Germany and Denmark v Commission, 2005 E.C.R. I-9115, para. 69, state that this concept includes designations of origin and geographical indications. The specific marks mentioned *ibid* would also be covered.

[95] *E.g.* through facilitating genuinely GM-free produce.

[96] However the issue must involve a genuine and serious threat to fundamental interests of the Member State. Case 30/77, Bouchereau 1977 E.C.R. 1999 para. 34-35.

[97] Case C-244/06, Dynamic Medien Vertriebs GmbH v Avides Media AG, 2008 E.C.R. I-505, para. 44.

[98] In Case C-165/08, Commission v Poland, Jul. 16, 2009, paras. 54-59, Poland attempted to argue ethics; however these were held to be too closely linked to environmental and health concerns. Further, the views of certain sections of the public were held not to suffice as indicative of ethics or public moral.

This will prove even more difficult to establish where national approaches are inconsistent. France has proven a good example of this, varying between being a strong proponent of GMOs and a strong opponent. France has been one of the foremost Member States in cultivating GM crops and with a very wide range of field trials[99] over the past two decades,[100] although it has had difficulties at times with destructions of crops and protests. However, in 2008 with a new President at the helm, France declared that they would be imposing a suspension on the cultivation of MON810.[101] France also requested that the current process be amended and a wider range of environmental and safety factors be included, widening the basis of expertise.[102] Yet, concurrently, France were finalising legislation to implement Directive 2001/18.[103] It would be difficult to establish that the reasoning attaches to a public interest/mandatory requirement and demonstrate the necessity or proportionality of measures at one moment, which would not have been considered as such nationally the previous year. Although public morality in particular is not a static notion, the Court would be unlikely to accept that it changes with the executive.

However, choice of a suitable objective justification is only the first step in the process of justifying a national measure. Some potentially suitable objectives may in effect be undermined due to the cumulative requirements that the measures must be applied in a manner that is not arbitrarily discriminatory, a disguised restriction on trade, or disproportionate.[104]

*III. Proportionality of the Measures?*

Proportionality is a general principle of law within the EU[105], and applies equally to Article 36 TFEU justifications. It includes three cumulative elements[106]: the measures in question

[99] *Available at* www.ogm.gouv.fr (accessed Dec. 8, 2010).

[100] Co-Extra, *Genetically modified plants in France*, *available at* http://www.coextra.eu/country_reports/gmo_planting_FR_EN.html.

[101] This was upheld by the Conseil d'Etat in March 2008: Ordonnance du juge des référés du 19 mars 2008, http://www.conseil-etat.fr/cde/node.php?articleid=739 (accessed Dec. 8, 2010).

[102] *France proposes tough E.U. standards related to genetically modified crops,* MARKETWATCH, Mar. 4, 2008, http://www.marketwatch.com/news/story/france-proposes-tougher-eu-standards/story.aspx?guid={AA76A432-AE89-49C7-A44F-D986092F1718} (accessed Dec. 8, 2010).

[103] Loi nº 2008-595 du juin 2008*, supra* note 51.

[104] The first two requirements are found within the *chapeau* of Article 36 TFEU, while the third of proportionality has been imposed by the Courts from an early stage, e.g., Case 4/75, Rewe-Zentralfinanz eGmbH v Landwirtschaftskammer, 1975 E.C.R. 843.

[105] TRIDIMAS, *supra* note 47, at 137.

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must be suitable to achieving a legitimate aim or objective (effective); they must be the least restrictive alternative available to achieve this aim (necessary); and they must be proportional *stricto sensu*.[107] As these legitimate objectives apply where there is a lack of complete harmonisation, the Member States have a margin of appreciation in deciding upon the level of protection they wish to achieve, even where other Member States have less strict measures in place[108], and also regarding the content of public policy and morality.[109] Obviously, the higher the level, the more "costly" the measure may be while still being proportionate.

Nonetheless, if some evidence is adduced which suggests that either the objective is already protected, or that other less restrictive measures would fulfil the need as effectively, the Member States will have to bring weighty evidence to bear to contradict this. This will be the case in particular where the relevant EU legislation is intended to deal with these objectives already, as although not fully harmonised the EU legislation will be presumed to be proportionate, and any more severe measures will be difficult to justify.[110]

This is amply demonstrated by the Commission's arguments in *Commission v. Poland*,[111] where ethics and public morality were raised as a justification for national restrictions.[112] Although the CJEU did not decide on this particular issue,[113] the Commission dismissed this as a legitimate basis for the restrictions, as Directive 2001/18 provided for ethical issues to be taken into account in the authorisation process.[114] It is likely that the Court would have agreed with the Commission on this point, if it had been necessary to do so, or at least placed a further burden on Poland to indicate that the authorisation procedure failed to deal with the issue of ethics and religion adequately and hence why the prohibition was

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[106] However the second and third aspects are similar in content and are frequently dealt with together.

[107] TRIDIMAS, *supra* note 47, at 139; Case 11/70, Internationale Handelsgesellschaft, 1970 E.C.R. 1125.

[108] Case C-110/05, Commission v. Italy, 2009 E.C.R. I-519, para. 65.

[109] *See supra* note 96 and note 97.

[110] Unless legally challenged, the EU measure will be presumed to be in conformity with the Treaties. Further if challenged, any EU measures must comply with the principle of proportionality in achieving their objectives (e.g., Case 137/85, Maizena 1987 E.C.R. 4587, para. 15) and the institution will be granted a wide margin of discretion in deciding upon these measures; the usual test being whether the measures were "manifestly inappropriate" (e.g., Case C-84/94, United Kingdom v Council, 1996 E.C.R. I-5755, para. 58). Therefore the burden will be substantial for a Member State if the EU measure claims to have already dealt with the objective in question.

[111] Case C-165/08, *supra* note 98.

[112] *Id.* at paras. 19 and 21.

[113] *Id.* at para 51.

[114] *Id.* at para. 34 (referring to Article 29 of Directive 2001/18).

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necessary. This assessment is supported by analogy with the *Greenpeace* case[115] where the CJEU decided that as the safeguard clause embodied the precautionary principle, the legislation as a whole was compliant with the precautionary principle. Likewise, it could be argued that the risk authorisation procedures, the option of coexistence measures within Directive 2001/18, and labelling in Regulation 1830/2003 amongst other provisions already take into consideration such issues as consumer protection and agrarian interests in a proportional manner.

Consequently, Member States will have to provide strong evidence to support their arguments that more general prohibitions are required and proportional within their country. This is particularly the case considering that the Commission has indicated in the 2010 Recommendation that regional prohibitions and targeting below 0.9% admixture may be permissible due to these considerations. While prohibition might be proportional in relation to protecting "quality" produce and farming, this would seem more difficult to establish for conventional farming. In this respect, through indicating acceptance of more stringent coexistence measures, the Commission may in effect have limited the options for Member States under the new proposed Article 26b.

However, it could be argued that if, as the Commission continuously states, the coexistence measures are merely intended to focus on the economic aspects of those issues, then that only these aspects should be discounted in considering whether the objectives are adequately protected. While coexistence measures acceptable to the Commission might protect the economic interests of various farmers, the social, cultural or ethical aspects of their agricultural type may not be protected sufficiently. Taking into account that zone-by–zone segregation, whilst an effective option in the short-term, is unfeasible for the long-term[116] and other coexistence measures may not suffice depending on the weight given to the values at stake, it may be possible to establish proportionality. This is strengthened by the Commission specifically recognising that States may wish to exclude cultivation locally via coexistence measures, or nationally via the proposed Article 26b.

Overall, the proposed Article 26b provides for a strong possibility for Member States to legally prohibit the cultivation of GMOs within their territory on the basis of suitable mandatory requirements, with the exception of environmental or health protection. Further, the discussion above relates to the legal consequences if the Member States' prohibitions are challenged. Taking into consideration the Commission's response to Portugal's prohibitions within Madeira this year, along with the loosening of control in July and the desire to see Member States willing to authorise further GMOs, it would seem

[115] Case C-6/99, *supra* note 45.

[116] M. Demont & Y. Devos, *Regulating coexistence of GM and non GM crops without jeopardizing economic incentives*, 26 TRENDS IN BIOTECHNOLOGY 353 (2008); and Levidow & Boschert, *supra* note 35.

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likely that the Commission would be willing to accept the Member States' justifications even where the legitimate objectives or proportionality might be questionable, at least initially, thereby avoiding legal confrontations before the Court of Justice of the EU (CJEU).

However, considering the impact of the Biotech Dispute, the Commission's approach to national measures may well alter depending on whether Article 26b and national measures are found to be in compliance or breach of the WTO legal instruments.

**D. Permissible under the WTO?[117]**

Much like Member States under the TFEU, the EU has contractual obligations under the WTO not to negatively discriminate or impose trade restrictions on imports, except under certain circumstances. Within the Biotech Dispute, the Dispute Panel condemned the *de facto* moratorium, extensive delays and national bans, refusing the EU's defence on the precautionary principle as they deemed a satisfactory risk assessment could be carried out and the measures were not justified even under Article 5.7 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

In the context of Article 26b, with the exclusion of environmental and human health protection, it appears that the SPS Agreement would be excluded. It could be argued that the Technical Barriers to Trade (TBT) Agreement applies, however this relates to technical regulations relating to labelling, packaging, product requirements, etc. Further, due to the non-exhaustive justifications possible under Article 2 TBT, it would seem probable that complainants would bring an action under alternative relevant agreements.

The core basis for action would appear to be under the General Agreement on Tariffs and Trade (GATT),[118] which prohibits quantitative restrictions in Article XI and discriminatory measures under Article III. For the latter, the complainant State must first establish that there exists a "like product" which is receiving more favourable treatment than the one being discriminated against (i.e., that a non-GM product is "like" the GM equivalent). This is a complex issue, especially where GMOs are no longer detectable in the product, as proponents see little difference while opponents consider them as substantially different to goods created in a "conventional" manner.

Although raised within the Biotech Dispute, the Panel did not find it necessary to decide upon the issue[119]. Consequently there is no ruling on this question yet. The jurisprudence

[117] An exhaustive analysis is beyond the scope of this article, and this section only provides a brief overview of some of the issues that might arise if the proposed Article26b were challenged before the WTO.

[118] The Trade-Related Aspects of Intellectual Property Rights Agreement is a further option.

[119] Panel Report , *supra* note 13, para. 7.2418.

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of the WTO provides several general criteria in establishing whether a good is a "like product."[120] These include, *inter alia*, consumers' tastes and habits which would seem to raise the likelihood that the WTO would reject GMOs as "like products," thereby removing restrictions on them from the scope of GATT III:4. However, consumer tastes are merely one of a number of criteria, and difficult to establish as any positive or restrictive legislation will have an impact on the consumer tastes. There is the risk that the current regime may "crystallise" consumer tastes[121] and thereby justify itself by circuitous logic. Other criteria include the properties and end-uses of the products. Consequently, it is possible that GMOs would be considered a "like product" for the purposes of GATT.[122] Either way, a complainant State could still raise the issue of a quantitative restriction.

Although a number of justifications exist in Article XI, and elsewhere within GATT,[123] most are of little relevance for the purpose of justifying Article 26b and Member States' measures. The provision of greatest relevance is the General Exceptions Clause, Article XX of GATT. To avail of the exceptions therein, the EU must establish that the measures relate to and are necessary to protect a listed public interest,[124] and are not arbitrarily or unjustifiably discriminatory or a disguised restriction on trade or services.[125]

As the public interests within Article XX are exhaustive, and Article 26b would exclude the possibility of environmental and health protection, the most relevant interest remaining would be that of public morality in Article XX (a). Public morality however is an ethereal concept and begs the question of whose morality, both within the relevant State and of how many States internationally. There is minimal jurisprudence on the exception of public morality[126] in GATT XX (a), and consequently what it covers will be difficult to assess.

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[120] *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, 2001:VII, 3243. The criteria listed are: "(i) the properties, nature and quality of the products; (ii) the end-uses of the products; (iii) consumers' tastes and habits - more comprehensively termed consumers' perceptions and behaviour - in respect of the products; and (iv) the tariff classification of the products," at para. 101.

[121] Condemned within the EU in Case 178/84, Commission v Germany, 1987 E.C.R. 1227, para. 32.

[122] For more in-depth discussion, see J. Wong, *Are Biotech Crops and Conventional Crops Like Products? An Analysis under GATT*, 2003 DUKE L. & TECH. REV. 0027; and D. Morgan & G. Goh, *Genetically Modified Food Labelling and the WTO Agreements*, 13 RECIEL 306, 315-317 (2004).

[123] For example in Articles XII, XVIII, XIX, and XXI.

[124] *United States - Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R DSR 1996:I.

[125] In accordance with the good faith requirement of the *chapeau* of Article XX.

[126] The first instance of the AB addressing the exception of 'public morality' under the scope of any WTO Agreements was within *United States – Measures affecting the cross-border supply of gambling and betting services*, WT/DS285/AB/R, DSR 2005:XII, 5663; fn 351 of the Report of the Appellate Body of the WTO. M. Wu, *Free Trade and the Protection of Public Morals: An Analysis of the Newly Emerging Public Morals Clause Doctrine*, 33 YALE J. INT'L. L. 215 (2008).

In *US-Gambling*, the WTO examined public morality in conjunction with public order in the context of the General Agreement on Trade in Services (GATS) Article XIV(a),[127] albeit without detailing what it involved. The Panel resorted to a dictionary definition and stated that the term "public morals" "denotes standards of right and wrong conduct maintained by or on behalf of a community or nation."[128] It is apparent from the case that the morals to be protected need not be held by all States (i.e., universal), but nor should they generally be just held one State (i.e., unilateral).[129] It appears that, although not absolutely required, where a number of States are of the same viewpoint, this will be of aid in establishing that the issue is one of public morality[130] and also in examining the issue of necessity.

Since *US-Gambling*, the WTO has had occasion to examine Article XX(a) public morality in *China-Audiovisual Services*,[131] where the WTO approved a similar approach. In both cases the WTO provided the States with some leeway in deciding what issues fell within public morality, similarly to within the EU, as the content of the concepts for States "can vary in time and space, depending upon a range of factors, including prevailing social, cultural, ethical and religious values."[132] Taking the leeway provided in these two disputes and the focus of the parties' arguments upon the issues of necessity and discrimination instead,[133] it appears that the content of public morality will prove sufficiently flexible to encapsulate a wide range of issues, including that of GMOs. Instead the control and limitation is seen through ensuring compliance with the *chapeau* and, in particular, necessity.

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[127] See the AB's Report, *id.* at para 327 (restrictive measures taken by the USA were necessary for the protection of public morality and the maintenance of public order).

[128] *United States - Measures Affecting the Cross-Border Supply of Gambling and Betting Services* - Report of the Panel, WT/DS285/R at para. 6.465.

[129] J.C. Marwell, *Trade and Morality: The WTO Public Morals Exception After* Gambling, 81 NYU Law Review 802 (2006); and Wu, *supra* note 126, at 231-233.

[130] For further discussion on the impact of *US-Gambling* on the development of the public morality exception, see N.F. Diebold, *The Morals and Order Exceptions in WTO Law: Balancing the Toothless Tiger and the Undermining Mole*, 11 J. INT'L ECON. L. 43 (2008).

[131] *China — Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*- WT/DS363/AB/R.

[132] Panel Report in *US-Gambling*, *supra* note 128, at para. 6.461, where they refer to the discretion traditionally granted by the AB to States in deciding upon the level of protection, and then apply it to the content of what may be protected, similarly to the approach within the EU; the Panel continued this approach in *China-Audiovisual Services*-see WT/DS363/R at para. 7.759.

[133] Panel Report in *China-Audiovisual Services, id.* at paras. 7.762-3 (the relevance to morality was not specifically contested).

Necessity[134] is very similar to the notion of proportionality within the EU, involving a process of "weighing and balancing a series of factors". These factors include: the importance of the public interest, the contribution of the measure to this interest, and the degree of restrictiveness on trade. The defendant State must demonstrate that the measures are somewhere between "indispensable to" and "contributing to" the legitimate objective being protected. Where a prima facie case of necessity has been established, the complainant State may challenge this through providing evidence of less trade restrictive alternatives; however, these alternatives should be reasonable and available rather than hypothetical.[135] The Panel and Appellate Body (AB) have closely scrutinised the national measures in assessing whether truly necessary.

In *US-Gambling*, the AB reversed the findings by the Panel that the measures were not necessary due to failure to participate in meetings with Antigua, as this was not a reasonable alternative.[136] Similarly, in *China-Audiovisual Services*, the Panel and the AB examined China's measures minutely[137]; however, in this case, they both found the measures unnecessary, as either China failed to establish sufficient evidence of *prima facie* necessity[138] or else to displace the burden once the USA demonstrated reasonably available alternatives.[139]

Although it is likely that the WTO would accept that GMOs could raise the issue of public morality, the EU and the Member States must then establish that GMOs raise the issue of public morality within the relevant Member State(s), that they were necessary to protect this public interest and that this was the reason for the restrictions. Similar difficulties to those discussed in the context of the EU regime above would arise. However, this does not necessitate that the responses by the EU Commission or CJEU would parallel those of the WTO; within the EU, the Commission's Communication accompanying the Proposal and the Preamble of the Proposal itself explicitly provide for the possibility of Member States unilaterally imposing prohibitions on cultivation for legitimate objectives beyond health or environmental risks, thereby implying that such measures could be considered proportional. No such provisions exist within the WTO relating to GMOs, and the

[134] *Id.* at paras. 7.782-7.793.

[135] AB's Report in *US-Gambling, supra* note 126, at paras. 103-109.

[136] *Id.* at paras 126-7. The AB did however find against the USA on the basis that they had not demonstrated that the measures did not discriminate against foreign gambling service providers.

[137] Panel Report, *supra* note 132, at paras. 7.794-7.909, and AB Report, *supra* note 131, paras. 234-335.

[138] Panel Report, *supra* note 132, at paras 7.848, 7.863 and 7.868; The AB upheld the Panel's conclusions generally, however believed that China had failed to establish even necessity conditional on no reasonable alternatives being available, AB Report, *supra* note 131, at para. 336.

[139] Panel Report., *supra* note 132, at paras 7.869-7.909, and AB Report, *supra* note 131, at paras 336-7.

complainant State could discharge its burden by proposing reasonable and available alternatives such as accurate labelling, or reasonably stringent coexistence measures, which the EU and its Member States would then have to demonstrate were insufficient. In particular, where a Member State has raised an alternative objective acceptable under EU law, it will be exceedingly difficult to then claim necessity to protect public morality as the basis similarly to in *Commission v Poland*[140] before the CJEU.

If the WTO should reject the necessity/proportionality of these measures or as protecting an objective not provided for by WTO law, the Commission would once again be in the position where it would be obliged to take measures to lift national restrictions. Nonetheless, politically if the Coexistence Recommendation and the incorporation of Article 26b do achieve the Commission's goal of increasing authorisations, and reducing delays and what the Commission considers are insupportable applications of safeguard clauses, then other nations such as the USA may not challenge individual Member States' restrictions.

**E. Conclusion**

The proposed Article 26b is both intriguing and innovative within the EU, as it attempts to encourage harmonisation of the overall EU GM cultivation regime via post-authorisation de-harmonisation. It provides the potential for Member States to exclude GM cultivation nationally where desired in order to resolve national concerns, without resorting to the safeguard clauses, in a manner legally compliant with EU and WTO law. However, stakeholders on each side are remaining suspicious of the proposals, approving of some aspects, disapproving of others, and generally unsure as to their impact,[141] as the legal and practical consequences are unclear. These consequences will depend on approaches by the Commission, the CJEU, non-EU States and the WTO, as well as on the nature of the actual concerns of the Member States imposing the ban rather than merely the declared concerns.

Regarding legitimate objectives, Article 26b is unlikely to prove as legally substantive as it might first appear, in particular omitting environmental and health protection; the current demanding conditions posed by the safeguard clauses would continue to exist, as would the exclusion of new interpretations of existing data. The scope is narrower within WTO law, where likely restricted to public morality. Consequently, Member State bans under

[140] *Supra* note 98.

[141] *E.g.*, *EU makes decision on approval, countries on cultivation*, *GMO-Safety News*, June 8, 2010, *available at* http://www.gmo-safety.eu/news/1182.makes-decision-approval-countries-cultivation.html (accessed Dec. 8, 2010); J. Riss, M. Stoczkiewicz, & R. Gouveia, *Barroso's empty GM deal*, EUROPEAN VOICE, July 8, 2010, available at http://www.europeanvoice.com/article/imported/barroso-s-empty-gm-deal/68451.aspx. The authors of this letter respectively are Director of the European Unit of Greenpeace, Director of Friends of the Earth Europe, and Secretary General of Euro Coop Brussels.

Article 26b may be legally compliant with EU law, while in breach of GATT as not related to the acceptable objectives therein. The legal status of a ban will depend on whether its objectives are regarding the environment/human health (excluded by Article 26b), other mandatory restrictions excluding morality (irrelevant to GATT) or morality (potentially compliant with both Article 26b and GATT).

Although the *status quo* encourages Member States to disguise actions based on ulterior concerns within the ambits of safeguard clauses, it would instead become possible that Member States would attempt to disguise concerns over the environmental/human health risks behind other objectives such as consumer choice/protection or ethics in order to comply with Article 26b. Likewise, morality may be raised as the ultimate "get out of jail free" card, subsuming all other relevant concerns in order to appear legally compliant with EU and WTO law. Member States which believe that the crops pose a threat may restrain themselves from raising the issue in the first place, as seeing it as simpler to utilise an alternative legitimate objective under Article 26b to justify their prohibition instead. Although the Proposal would resolve many of the Member States' concerns, while not posing the same difficult legal questions regarding risks and precaution as raised in the Biotech Dispute, the desirability of encouraging Member States to raise alternative issues rather than risks as legitimate objectives should be considered. In particular, whether Member States should be limited in their choice of level of protection regarding the environment and health, compared to other values, and whether the EU should interpret newness and specificity so narrowly or instead should follow Advocate General Sharpston's more recent flexible suggestions.

If the Commission follows a lenient approach to national restrictions, then it may achieve a more positive approach to authorisations and consequently satisfy non-EU States. However, if non-EU States challenge the prohibitions before the WTO, it is likely that some Member States would fail to establish the necessity of their measures to protect public morality; although potentially still legal within the EU as protecting other objectives, the Commission may treat applications more restrictively and even attempt to exclude other objectives on the basis that they are already protected by GM legislation. Although the CJEU would presumably uphold a broader approach regarding the range of legitimate objectives, they may accept a more restrictive interpretation of the proportionality of the measures. In such a case, Member States may once again turn to Article 23 safeguard clauses and the help of the Council in upholding national prohibitions, if unable to justify Article 26b bans before the CJEU.

For the moment, Article 26b is merely at the Proposal stage; however it would seem likely that it will be adopted in a substantively similar form in the next few years, as the Parliament and Council are unlikely to object to Member States having a national veto on GM cultivation. It is also a somewhat inevitable step to take considering the current safeguard clause stalemate. It would be interesting to see whether other Member States, who have not availed of the safeguard clauses but who have not shown a strong positive

stance towards national GM cultivation, would also avail of Article 26b as a method approved by the Commission for general, national prohibitions. It remains to be seen whether these proposals will clear a passage through the mountainous GMO regime for the infamous Sherpa, or alternatively lead to one more dead end.

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