

Faculteit Rechtsgeleerdheid
Universiteit Gent

Academiejaar 2013-2014

Regulating Biotechnology in the European Union

Towards more possibilities for Member States to regulate GMO cultivation



Masterproef van de opleiding
'Master in de rechten'

Ingediend door

Vanreenterghem Zanna

(studentennr: 00804806)

Promotor: Prof. Dr. Piet Van Der Meer

Co-promotor: Prof. Dr. Luc Lavrysen

TABLE OF CONTENTS

INTRODUCTION	5
PART I: THE LEGISLATIVE ROAD TO MORE POSSIBILITIES FOR MEMBER STATES TO REGULATE THE CULTIVATION OF GMOS	7
CHAPTER 1. STATUS OF CULTIVATION OF GMOs IN THE EU	7
SECTION A. LATEST DEVELOPMENTS ON A NEW DRAFT LEGISLATION REGARDING CULTIVATION	7
SECTION B. CULTIVATION IN PRACTICE	8
SECTION C. KEY PRINCIPLES OF THE LEGAL FRAMEWORK FOR CULTIVATION	8
2. A Centralised authorisation procedure	8
3. Possibilities for Member States to regulate the cultivation of GMOs	9
4. A high level of harmonisation	10
SECTION D. SOME MEMBER STATES' REVOLT	10
1. National cultivation bans	10
2. Joint Member States' call for action	10
CHAPTER 2. THE 2010 'CULTIVATION PROPOSAL'	11
SECTION A. THE COMMISSION'S APPROACH	11
1. Partial re-nationalisation	11
1.1 A variety of motives	12
1.2 Art 26b: a simplistic legal design	12
1.3 Based on the principles of subsidiarity and proportionality	13
2. Choice of legal basis and legal instrument	13
SECTION B. THE PROPOSAL'S EVOLUTION THROUGH THE ORDINARY LEGISLATIVE PROCEDURE	14
1. Opinion of the European Economic and Social Committee	14
2. The Parliamentary Committees' Opinions	14
2.1 Draft Report of the Committee on Environment, Public Health and Food Safety	14
2.2 Opinion of the Committee of the Regions	15
3. The Commission's indicative list of derogation grounds	16
3.1 Patchwork and inclusion of environmental policy objectives	16
3.2 Opinion of the Committee on Agricultural and Rural Development	17
4. The Council's proceedings: part one	17
4.1 Compromise proposals under the Hungarian Presidency	17
5. Parliament's first reading	18
5.1 Art 26b: a thinning line between EFSA and the Member States	19
5.2 Emphasis on the principle of subsidiarity and proportionality	20
5.3 Other technical elements	20
6. The Council's proceedings: part two	21
6.1 A third compromise proposal under the Danish presidency	21
6.2 Impasse due to a blocking minority	22
6.3 A fourth compromise proposal under the Greek Presidency	23
6.4 Political Agreement	23
7. Adoption at Council's First Reading	24
7.1 Article 26b	24
7.2 An expanded list of derogation grounds	26
7.3 A new role for the Commission	26
7.4 Transitional measures	27
7.5 Choice of legal instrument	27
SECTION C: CONCLUSIONS ON THE EVOLUTION OF THE 2010 PROPOSAL AND FUTURE PROSPECTS	27
1. A political agenda item under the Italian Presidency	27
2. Will the Council and European Parliament be able to meet in the middle?	28
2.1 Same goals	28

	3
2.2 Different approaches	28
3. Remaining issues	29
<u>PART II: POSSIBILITIES FOR MEMBER STATES TO RESTRICT OR PROHIBIT THE CULTIVATION OF GMOS UNDER THE EXISTING LEGISLATIVE FRAMEWORK(S)</u>	30
CHAPTER 1. A HIGH LEVEL OF HARMONISATION, A LOW LEVEL OF DEROGATION?	30
CHAPTER 2. THE SCIENCE-BASED APPROACH	31
SECTION A. UNDER THE GMO LEGISLATION: DIRECTIVE 2001/18 AND REGULATION 1829/2003	31
1. Safeguard clause and Emergency measures in theory	31
1.1 Common ground: a science-based risk approach	31
1.2 Informing the Commission and Member States	34
1.3 Union control procedure	34
2. National safeguard and emergency measures in practice	35
2.1 National measures based on Article 23 of Directive 2001/18	36
2.2 National measures based on Article 34 of Regulation 1829/2003	37
2.3 The Commission's infringement action	38
SECTION B. UNDER THE GMO LEGISLATION: DIRECTIVE 2002/53	40
1. Article 16 in theory	40
2. Article 16 in practice	41
SECTION C. INTERNAL MARKET RULES: ART 114 (5) TFEU	42
1. Article 114 (4) vs 114 (5) TFEU	42
2. Substantive requirements of Article 114 (5) TFEU	43
2.1 The novelty requirement	43
2.2 The specificity requirement	45
3. Comparison to the safeguard measures under the GMO legislative framework	47
3.1 Similarities	47
3.2 Differences	47
SECTION D. THE SCIENCE-BASED APPROACH: IS THE STRAITJACKET TOO TIGHT?	48
CHAPTER 3: A SOCIO-ECONOMIC APPROACH?	49
SECTION A. IS THERE ROOM FOR NATIONAL MEASURES BASED ON SOCIO-ECONOMIC JUSTIFICATIONS	49
1. <i>Land Oberösterreich</i>	49
2. Lessons learned from <i>Commission vs. Poland</i>	50
CHAPTER 4: COEXISTENCE	51
SECTION A. COEXISTENCE MEASURES TO OPT-OUT OF CULTIVATION?	51
1. Legal framework for coexistence	52
2. A purely economical approach	53
3. Limits of coexistence measures	53
SECTION B. GM-FREE REGIONS	54
CHAPTER 5: CONCLUSIONS	55
<u>PART III: POSSIBILITIES FOR MEMBER STATES TO RESTRICT OR PROHIBIT THE CULTIVATION OF GMOS UNDER THE NEW REGIME</u>	57
CHAPTER 1: WHEN AND HOW CAN MEMBER STATES OPT OUT OF CULTIVATION?	57
SECTION A. THE NEW PROCEDURAL MODEL	57
1. First step: Selective applications	57
2. Second step: National measures based on a list of derogation grounds	57
	57

	4
CHAPTER 2. NEW DEROGATION GROUNDS	58
SECTION A. SOCIO-ECONOMICAL AND NON-ECONOMICAL FACTORS	58
1. Scope of the new derogation grounds	58
1.1 Environmental policy objectives	58
1.2 Land use, town and country planning	59
1.3 Socio-economic impacts	59
1.4 Avoidance of GMO presence in other products without prejudice to Article 26a	59
1.5 Agricultural policy objectives	60
1.6 Public policy	60
2. Mandatory requirements	60
2.1 Proportionality	61
2.2 Compatibility with Article 34 – 36 TFEU	61
SECTION B. POSSIBLE IMPLICATIONS FOR THE INTERNAL MARKET	62
PART IV: THE NEW REGIME AS AN EXAMPLE OF DE-HARMONISATION	63
CHAPTER 1: RE-APPROPRIATION OF NATIONAL SOVEREIGNTY?	63
CHAPTER 2: THE CHOICE OF THE LEGAL BASIS	63
SECTION A. THE INTER-INSTITUTIONAL DEBATE ON THE LEGAL BASIS	63
SECTION B. IS ARTICLE 114 TFEU THE APPROPRIATE LEGAL BASIS?	65
CONCLUSION	66
BIBLIOGRAPHY	68

INTRODUCTION

It is virtually impossible to have never heard of GMOs. Fierce debates have surrounded this subject for such a long time that by now everyone knows that ‘GMO’ stands for Genetically Modified Organism. A GMO is an organism whose genetic material has been altered using genetic engineering techniques. GMOs are the source of genetically modified foods and are also widely used in scientific research and to produce goods other than food. The most common types of GMOs that have been developed and commercialised are genetically modified crop plant species, such as genetically modified maize, soybean, oil-seed rape and cotton varieties. Such varieties have, in the main, been genetically modified to provide resistance to certain insect pests or tolerance to herbicides.

The situation in the EU with respect to GMOs is very diverse. Many member states have field trials, but only some states have commercial cultivation. Moreover, the views of member states on GMOs differ widely. Some states are positive to GMOs, and some are negative. In addition, many stakeholders with different points of view are engaged in the debate, such as the biotechnology industry, consumers, environmental NGOs, and farmers’ organizations. Therefore, regulation of GMOs in the EU is a difficult and sensitive issue.

Currently only one GM crop, MON 810, is commercially cultivated in the EU. This product's genetic modification aims to protect the crop against a harmful pest – the European corn borer. It was authorized in 1999. In 2013 MON 810 was cultivated in five Member States, with Spain covering 137,000 out of 150,000 cultivated hectares in total.

The European Union has passed legislation covering all aspects of GMOs, from research to commercialization. The legislative framework is based on a cautious approach. The core elements of the legislation are the centralised approval procedure for bringing GMOs on the market or releasing them into the environment, the case-by-case approach, and the compulsory risk assessment. The legislative framework is characterised by its high level of harmonisation, which has its roots in the nature of the subject, for which the EU has chosen to set a high level of protection of human health and the environment.

From the high level of harmonisation follows that Member States have limited possibilities to regulate aspects of GMOs, in particular cultivation. Under the existing legislative framework, Member States are allowed to install safeguard measures against the cultivation of a GM crop on a national level, if sufficient concerns exist. However, Member States have been taken advantage of these possibilities and have installed legally questionable bans against GMOs. In 2014, nine Member States have banned MON 810.

In 2009, 13 Member States asked the European Commission for more flexibility to decide not to cultivate GMOs on their territory. This is why, in 2010, the Commission presented a Proposal to the European Parliament and to the Council to offer additional possibilities to Member States to ban or restrict the cultivation of GMOs on part of or all their territory, based on their national circumstances. In July 2011, the European Parliament issued a positive first reading opinion with amendments. Three years later, in July 2014, the Council adopted the Proposal, with new amendments, at first reading.

The 2010 Cultivation Proposal from the Commission is the inspiration for this thesis. The legislative changes proposed within marked a fundamental change for the GMO policy in the EU. The aim was to grant Member States more freedom with regards to the cultivation of GMOs, in the form of national “opt-outs”, which was considered as “of particular importance for the self-determination of Member States” by the European Parliament.

This thesis will examine how the Commission designed its Cultivation Proposal initially and how the design and content changed during the ordinary legislative procedure. In Part II, the possibilities for Member States to “opt-out” of cultivation under the existing framework will be examined. In Part III the technical and substantive changes of the new regime are addressed, in particular the scope and content of the newly introduced grounds for derogation from the harmonised rules. The possible impacts for the internal market are examined as well. Part IV will address why the new regime could be considered an example of de-harmonisation within the European Union.

PART I: The legislative road to more possibilities for Member States to regulate the cultivation of GMOs

CHAPTER 1. Status of cultivation of GMOs in the EU

Section A. Latest developments on a new draft legislation regarding cultivation

On July 23th 2014 the Council adopted its first reading position regarding a draft legislation that moves towards a new legal basis giving Member States more discretionary authority to restrict or prohibit the cultivation of GMOs in their territories.¹ The 28 ministers almost unanimously voted in favour, with Luxembourg and Belgium abstaining.²

This outcome had been long on its way. It was preceded by a series of consultations under different presidencies that finally resulted in a political agreement, adopted by the Environment Council on May 28th under the Greek Presidency, laying down almost the exact same outline as the recently adopted position.³

Nevertheless this recent event officially marks a breakthrough in the development of new legislation regarding cultivation the GMOs in the European Union. According to Commissioner Tonio Borg, the political agreement answered to “Member States’ consistent calls since 2009 to have more flexibility and legal certainty for national decisions on cultivation on their territory or part of their territory.”⁴

The proposal recently adopted by the Council, has come a long way. In June 2010, the Commission presented its Cultivation Proposal, consisting of a new recommendation on coexistence and a draft proposal giving Member States more discretionary authority to take restrictive measures against the cultivation of authorised GM crops. In addition to its aim to keep the existing framework for cultivation authorisations intact, the proposed regime change also “unveiled a shift in EU policy”⁵, by opting wholeheartedly for a renationalisation of some of the key elements of the cultivation regulation, namely the Member States’ possibilities for “opting-out” of cultivation.

The proposal adopted by the Council in July 2014, stays true to the roots of its origin. In a nutshell, this entails allowing Member States to invoke grounds other than those related to the protection of the environment or human health to justify a ban on GMOs, in addition to the science-based safeguard clauses embedded in the existing legislative framework.⁶ However, the Council also added its own touch, by fundamentally modifying the dynamics between the Member States and the applicants for cultivation authorisations.⁷ In the Council’s version, based on the aforementioned grounds, an opt-out can be invoked either after an authorisation has been granted or before it is granted, with an explicit or tacit agreement from the applicant to the Member States’ request to adjust the geographical scope of his application.

¹ COUNCIL doc. n° 10972/3/14, Proposal for a regulation of the European Parliament and of the Council, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory - Adopted by the Council, 23 July 2014.

² K.R. LEWIS, Mixed reaction to Council’s agreement on GMO cultivation, *The Parliament Magazine*, <https://www.theparliamentmagazine.eu/articles/news/mixed-reaction-councils-agreement-gmo-cultivation>

³ COUNCIL doc. n° 10271/14, Proposal for a regulation of the European Parliament and of the Council, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory – Political Agreement, 28 May 2014

⁴ Statement by Commissioner Borg following Council’s political agreement to allow the prohibition of GMO cultivation, European Commission - MEMO/14/415, 12/06/2014, http://europa.eu/rapid/press-release_MEMO-14-415_en.htm

⁵ T.F.M. ETTY, “Brussels cunningly paves the way for genetically modified crops”, *De Volkskrant*, 18 July 2010, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1725440

⁶ GMO agreement gives EU opt-out right, *Euranet Plus*, <http://euranetplus-inside.eu/agreement-on-gmos-gives-an-opt-out-right-in-the-eu/>

⁷ *Infra*, see Part IV

The evolution of the cultivation proposal from its presentation by the Commission in 2010 to its adoption by the Council in 2014, as well as the events leading up to it, represent the bumpy road to accommodating more national diversity in the stringent and heavily harmonised legislative framework for GMO cultivation in the EU.

Before describing this evolution in Chapter 2, a brief overview is given hereafter of the cultivation practice of GM crops in the Member States and the key features of the existing legislative framework.

Section B. Cultivation in practice

Presently, there is only one genetically modified organism, hereafter GMO authorised for cultivation: GM maize MON 810⁸. The cultivation of MON 810 covered a total of almost 150.000 hectares in five Member States in 2013, thereby representing 1.56% of the 9.6 million hectares of maize cultivated in the EU.⁹ With only eight out of twenty-eight having experienced cultivation on their territories, Member States “wishing to cultivate GM crops have always been a minority”.¹⁰

Section C. Key Principles of the legal framework for cultivation

There are two tenet principles in the existing legal framework for cultivation that are of key importance for this thesis, namely the harmonised nature of the framework and the restricted possibilities for Member States to regulate cultivation of authorised GMOs within their territories.

1. Legislation applicable to the cultivation of GMOs.

Depending on the scope of an application for authorisation, the cultivation of a GM crop is subject to the procedure described by Directive 2001/18¹¹ or by Regulation 1829/2003¹². The former applies if the GM crop is placed on the market for the exclusive purpose of cultivation whilst the latter applies if the applicant not only wants to cultivate but also sell the crop on the market as food or animal feed, whereby the applicant has the option to submit both requests under Regulation 1829/2003.

2. A Centralised authorisation procedure

The first key principle concerns the harmonised nature of the authorisation process: the process is carried out at EU level and the resulting decision applies to all Member States.

Although the procedural rules under the Regulation¹³ and Directive¹⁴ differ, the common pattern for an application is the following.¹⁵ A company submits its application to the competent national authority of the Member State, within whose territory the product is to be marketed for the first time. The application is then forwarded to the European Food Safety Agency (EFSA), which will

⁸ EU register of genetically modified food and feed, MON 810, http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=11

⁹ Are GMOs already cultivated in the EU?, European Commission, Health and Consumers, http://ec.europa.eu/food/plant/gmo/legislation/future_rules_en.htm

¹⁰ S. POLI, “The Member States’ long and winding road to partial regulatory autonomy in cultivating genetically modified crops in the EU”, *European Journal of Risk Regulation*, 2013, vol 2, p. 143.

¹¹ 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.

¹² REGULATION 1829/2003/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed.

¹³ Art. 5-6 Regulation 1829/2003/EC.

¹⁴ Art. 13-18 Directive 2001/18/EC.

¹⁵ Under the Directive, the standard authorisation procedure entails the national authority deciding upon a GMO application, but in cases where objections to an application are raised and upheld by a national authority from other Member States or the Commission, the application procedure is elevated to the central level, see art 18.

subsequently carry out a risk assessment governing risks related the environment, human health and animal safety. After receiving EFSA's opinion, the Commission prepares a draft authorisation decision, which is submitted to the Committee¹⁶ for a decision to be approved by qualified majority. If the poll delivers a negative opinion, the Commission may summon an Appeal Committee¹⁷, that serves not as "a permanent body, but rather a procedural tool which gives EU countries the opportunity to have a second discussion at a higher level of representation"¹⁸. It is up to the Member States' representatives in the Committee to adopt or reject the draft authorisation with qualified majority as well.¹⁹ If that majority is not reached, the Commission has the final say in adopting the proposal and granting the authorisation.²⁰

It has to be noted that in the pre-Lisbon era²¹, the Comitology-procedure did not provide a role for an Appeal Committee and it was the Council that had the "call-back right"²² in the event that the Committee failed to reach a qualified majority neither for nor against the authorisation. If the Council in turn could not reach a qualified majority, the Commission adopted its draft decision.

The GMO authorisation Comitology practice has definitely put the 'central' in 'centralised authorisation procedure'. So far, every²³ authorisation decision has ended up in the hands of the Commission, who is "supposed to be the decision-maker of last resort in a process that is supposed to be unusual but now is the norm in this area"²⁴. With the final decisions being referred to the 'centre', the Commission is now the central midfielder in the authorisation process.

Albeit the authorisation procedure is centralised, it doesn't mean that Member States are excluded from the process.²⁵ They are invited to submit their own evaluations regarding the assessment reports and by representation in the Committees they are an integral part of the decision-making process.

3. Possibilities for Member States to regulate the cultivation of GMOs

With authorisation decisions being made at the central EU level, the second key feature concerns the scope of the Member States margin to decide on limiting the cultivation of an authorized GM crop within their territory.²⁶

Within the legislative framework, Member States may, provisionally, prohibit or restrict cultivation of a GM crop only if there are "detailed grounds for considering that the GMO in question constitutes a risk to human health or the environment"²⁷ or where the GMO in question is "likely to constitute a serious risk to human health, animal health or the environment"²⁸. The relevant provisions are Article 34 of Regulation 1829/2003 and Article 23 of Directive 2001/8.

¹⁶ The Regulatory Committee under the Directive and the Standing Committee on Food Chain and Animal Health under the Regulation.

¹⁷ Implementing Lisbon: what's new in Comitology? Policy Brief april 2011, *European Policy Centre*, http://www.epc.eu/documents/uploads/pub_1258_implementing_lisbon_-_what_s_new_in_comitology.pdf

¹⁸ Comitology in brief, *European Commission*, <http://ec.europa.eu/transparency/regcomitology/index.cfm?do=implementing.home>

¹⁹ Rules of procedure for the appeal committee (Regulation (EU) No 182/2011), adopted by the appeal committee on 29 March 2011.

²⁰ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers

²¹ Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

²² Comitology in brief, op.cit.

²³ V. PASKALEV, "Can Science Tame Politics: The collapse of the new GMO regime in the EU", *European Journal of Risk Regulation*, 2012, vol. 2, p. 193.

²⁴ M. LEE., "Multilevel Governance of GMOs in the EU: ambiguity and hierarchy" in L. BODIGUEL, M. CARDWELL, *The Regulation of Genetically Modified Organisms: Comparative Approaches*, Oxford, Oxford University Press, 2008, p. 110

²⁵ V. PASKALEV, op.cit., p. 193

²⁶ Infra Part II

²⁷ Safeguard clause of art. 23 Dir. 2001/18/EC.

²⁸ Emergency measures in art. 34 Regulation EC 2003/1829.

In principle²⁹, this science-based approach does not offer the possibility to enact restrictions on factors other than science, such as socio-economic reasons, for example the aversion of some farmers to GM crops.³⁰ In part II, this issue is thoroughly addressed.

4. A high level of harmonisation

The legislative framework for GMO cultivation, and GMOs tout court, achieves such a high degree of harmonisation that one could argue it is “almost exhaustive”³¹. It might be due to “the principle of the pre-emption of national power because of the occupation of the field”³², that little scope is left for Member States to adopt measures restricting or prohibiting the cultivation of a GM crop.

Section D. Some Member States’ revolt

1. National cultivation bans

For years, some Member States have been working around their limited discretionary authority by introducing national bans and adopting national legislation to keep GMOs out of their territory.³³

Albeit that the era of the so called ‘de facto moratorium’ on authorisations of GMOs came to an end ten years ago³⁴, there is still undeniably a deadlock when it comes to the cultivation of the approved crops. MON 810 is the only GM crop that is presently being cultivated.

Status of MON 810	EU Member States ³⁵
(partially) Banned	Austria, Bulgaria, France, Germany, Greece, Hungary, Italy, Luxembourg, Poland, Belgium, Cyprus, Estonia, Croatia, Ireland, United Kingdom.
Allowed but not Cultivated	Denmark, Sweden, Netherlands, Malta, Slovenia, Latvia, Lithuania, Finland.
Cultivated	Czech Republic, Portugal, Spain, Romania, Slovakia.

2. Joint Member States’ call for action

In 2009, led by Austria, thirteen Member States³⁶ joined forces and adopted a declaration³⁷ that clearly voiced their demand that the individual countries should be granted more freedom regarding cultivation. They stated believing that the “way forward” meant that “options should be considered which could allow Member States to decide for themselves as regards cultivation, without changing the general authorisation procedure for placing GMOs and products thereof on the market”.

²⁹ Infra Part II, art 114 TFEU

³⁰ S. POLI, *op.cit.*, p. 145

³¹ M. WEIMER, “Legitimacy through precaution in European Regulation of GMOs”, in C. JOERGES, P.F. KJAER, *Transnational Standards of Social Protection Contrasting European and International Governance*, vol. 5, ARENA report n° 5/08.

³² T. CHRISTOFOROU, “The regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics”, (2004) 41 *Common Law Review*, p 671- 672,

³³ S.H. MORRIS, C. SPILLANE, “EU GM crop regulation: a road to resolution or a regulatory roundabout?”, *European Journal of Risk Regulation*, 2010, vol. 2, p. 359-361.

³⁴ Between 1998 and 2004 no applications for authorization reached the end of the decision-making process.

³⁵ Information gathered from <http://greenbiotech.eu/eu-gm-crops/> and <http://www.gmo-free-regions.org/gmo-free-regions/bans.html>.

³⁶ Bulgaria, Ireland, Greece, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, The Netherlands, Poland, Slovenia

³⁷ COUNCIL doc. n° 11226/2/09, Declaration from the Austrian Delegation, 24 June 2009

According to the statement, this change could be integrated in the existing framework, by “a set of minor amendments” based on the subsidiarity principle or the principle of unanimity for decisions on land use. Although the proposed legal solution might have seem rather simple, the declaration brought to the fore the widespread frustration of some Member States with the existing legislative options. The Commission was explicitly urged to put forward a proposal on the discussion.

CHAPTER 2. The 2010 ‘Cultivation Proposal’

In September 2009 when President of the Commission José Manuel Barroso outlined his political guidelines, he explicitly addressed the issue of GMO cultivation: “I want to be rigorous about where we need to have common rules and where we need only a common framework. We have not always got the balance right, and we have not always thought through the consequences of diversity in a EU of twenty-seven Member States.”³⁸

In March 2010 it was announced that Health and Consumer Policy Commissioner John Dalli had been asked to come forward with a proposal by the summer of 2010 “setting out how a Community authorisation system, based on science, can be combined with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory”³⁹.

On 13 July 2010, the Commission launched what could be called a 3-package-deal. The reform package included new guidelines on national coexistence measures,⁴⁰ a Communication⁴¹ and a Proposal for a Regulation to amend Directive 2001/18/EC⁴². The next chapter will focus primarily on the latter.

It is the aim of this chapter to examine to what extent the Member States’ call for action was answered by the Commission and how the Commission’s initial approach evolved through the ordinary legislative procedure(s).

Section A. The Commission’s approach

1. Partial re-nationalisation

The Commission had the hard task of finding a new balance in the trade-off between the science-based authorisation system and the practice of some Member States objecting GMOs on non-scientifically justified grounds⁴³. That balancing exercise resulted in a proposal for what can be called ‘partial renationalisation’.

This term may occur strange given that the common understanding of ‘nationalisation’ refers to “the process of taking a private industry or private assets into public ownership by a national government or state”⁴⁴ however in the EU-context it implies “a shift of competence back from EU institutions to national ones”⁴⁵.

³⁸ My Vision – Political Guidelines, President of the European Commission, 3 September 2009, http://ec.europa.eu/commission_2010-2014/president/about/political/index_en.htm

³⁹ European Commission press release IP/10/222, 2 March 2010, <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/222>

⁴⁰ COMMISSION Recommendation of 13 July 2010 on guidelines for the development for coexistence measures to avoid the unintended presence of GMOs in conventional and organic crops. See Part II.

⁴¹ COMMISSION Communication of 13 July 2010 on the freedom for Member States to decide on the cultivation of genetically modified crop, http://ec.europa.eu/food/food/biotechnology/docs/proposal_en.pdf

⁴² Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 13 July 2010.

⁴³ So far, EFSA has rejected every scientific argumentation provided by Member States to justify a national bans.

⁴⁴ Definition of ‘nationalisation’, *Larousse Dictionnary*, <http://www.larousse.fr/dictionnaires/francais/nationalisation/53865>

⁴⁵ Y. NIEMI, J. KOLA, “Gradual renationalisation of the Common Agricultural Policy: a way forward?”, 2004, <http://www.smts.fi/MTP%20julkaisu%202004/esi04/ma15.pdf>

1.1 A variety of motives

In the guiding Communication⁴⁶ and Explanatory Memorandum, the Commission comprehensively explains its reasoning behind the proposed modification to the existing legislative framework. Its motives can be divided into four types.

Firstly, the Commission refers to the fact that Member States have currently “no margin of appreciation”. The existing framework “does not fully address the need to give more freedom to Member States on cultivation of GMOs”⁴⁷

Secondly, the Commission is aware that the limited derogation margin gives rise to arbitrary opt-outs. They argue that the new approach is “expected to reduce the recourse of Member States to safeguard measures”, that “Member States would not invoke the procedure of Article 114(5)” and that it will “reduce the institutional burdens on the Commission as well as on EFSA”.⁴⁸

The third motive type concerns the decision-making process of cultivation authorisations. According to the Commission, under the existing framework Member States “vote on the basis of non-scientific grounds”. The new article 26b would “facilitate decision making” and “possibly increase the predictability of the decision-making process”.⁴⁹

Fourthly, the Commission believes that the change will “offer greater clarity to affected stakeholders”, e.g. GMO farmers, organic farmers, conventional farmers, seed producers/exporters/importers, livestock breeders, feed processors and consumers and biotechnology companies.⁵⁰

The Commission’s “accommodating attitude is understandable from a political point of view”⁵¹, when taking in account the reality of the aforementioned difficulties under the existing framework

1.2 Art 26b: a simplistic legal design

The Commission shaped its approach of the intended renationalisation in a rather simplistic way. It proposed to insert a new art 26b in Directive 2001/18, stating that:

“Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs (...) 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.”

The scope of “other grounds” is minimally specified in the guiding recital⁵², where it states that it concerns “ground relating to the public interest”. On the contrary, what would not be legitimate grounds is clearer: national measures would have to be based on grounds other than those covered by the risk assessment conducted at EU level during the authorisation process.

As practice shows that Member States attempting to invoke the safeguard clauses never succeeded in providing new scientifically valid information, this new article symbolises the Commission’s reality-check.⁵³

⁴⁶ COMMISSION Communication of 13 July 2010, op.cit.

⁴⁷ Proposal for a REGULATION, op.cit., p.3

⁴⁸ Proposal for a REGULATION, op.cit. p.4

⁴⁹ Proposal for a REGULATION, op.cit. p.3 - 4

⁵⁰ Proposal for a REGULATION, op.cit. p.4

⁵¹ S. POLI, op.cit. p. 144

⁵² Proposal for a REGULATION, op.cit. recital 8.

⁵³ J. DAVISON, “Commissioner John Dalli’s GM-crop-non-coexistence Proposals”, 2010, <http://ddata.over-blog.com/xxxyyy/1/39/38/37/Dalli-proposal-Davison-review-en.pdf>

Moreover, the new approach abandoned the requirement of provisionality, which applies to safeguard measures under article 23 of Directive 2001/18:

“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.”

With this mere information duty, national measures would no longer have to undergo the Comitology procedure for approval. This addition definitely meets reality as well, where Member States in the past either never communicated their national measures or the Comitology procedure failed to impose legal compliance.⁵⁴

1.3 Based on the principles of subsidiarity and proportionality

The Commission refers to the principle of subsidiarity to found the competence shift from the EU level back to the Member States. According to article 5(3) TFEU⁵⁵, “the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States”. Moreover the Treaties provide an explicit basis for partial renationalisation in article 2(2) TFEU⁵⁶: “Member States shall again exercise their competence to the extent that the Union decides to cease its competence”.

Contrary to the safety assessment of GMOs, the Commission believes that cultivation is “an issue with a strong local/regional dimension”.⁵⁷ They refer to the “requirements of local agricultural structures, separate production chains and consumers’ demands”⁵⁸, and the linkage between cultivation and land use. Therefore the Commission considers national, regional or local levels of decision making to be the most appropriate frameworks to address the particularities linked to GMO cultivation.

Furthermore the Commission also refers to article 5(4) TFEU under the proportionality principle. The Commission argues that the content of the Union action in the proposal is limited but that it should not prevent the EU to achieve the objectives of the Treaties because “measures adopted by Member States could refer to the cultivation of GMOs only and not to the free circulation”.⁵⁹

2. Choice of legal basis and legal instrument

Since the Commission aimed at modifying Directive 2001/18/EC by inserting a new article, one would expect the legal instrument to be a Directive as well. Instead the Commission choose to make a proposal for a Regulation, stating that does “it not contain in substance any provision that would require transposition as it only provides to the Member States a legal base to adopt measures.”⁶⁰

The legal basis for the proposal is art. 114 TFEU, namely the approximation of internal market rules. The Commission does not comment on this choice, since it seems to be self-evident when the Directive has the same legal basis. Part IV will address the issue of the legal basis.

⁵⁴ *Infra*.

⁵⁵ Art. 5(3), Treaty of the Functioning of the European Union (hereafter TFEU)

⁵⁶ Art. 2(2) last sentence, TFEU

⁵⁷ Proposal for a REGULATION, op.cit., p.8

⁵⁸ *Ibidem*.

⁵⁹ Proposal for a REGULATION, op.cit., p.9

⁶⁰ Proposal for a REGULATION, op.cit., p.8

Section B. The Proposal's evolution through the ordinary legislative procedure

1. Opinion of the European Economic and Social Committee

In its opinion of 9 December 2010⁶¹ the EESC welcomes the Commission's intention to address the "sensitive issue" of GMO cultivation "with a view to reaching a practicable solution", however not with open arms.⁶² The EESC criticises the Commission's minimalistic approach stating that it "creates more vagueness than certainty and could in practice result in a proliferation of (legally unstable) measures" since it is "mainly based on ethical and moral criteria".⁶³

The EESC's main concern is legal certainty in regards to the Proposal's criteria for a prohibition or restriction of cultivation. They argue that the weak legal design "could affect the operation of the EU's internal market".⁶⁴ Since the Commission does not specify the new derogation grounds - other than stating the relation with "public interest" - the EESC questions to which extent a national ban could be "exempted from the area of harmonised law and does not run counter to the general legal principles of the single market."⁶⁵ Therefore the EESC urges for a clarification of the Commission's (other) grounds. As a solution, the EESC proposes to include in art 26b a non-exhaustive, indicative list of concrete grounds, including, in addition to ethical, moral and religious arguments, also socio-economic concerns.⁶⁶

The EESC Opinion is very valuable because it pinpoints the main deficit of the Commission's Proposal: the vagueness of possible derogation grounds.

2. The Parliamentary Committees' Opinions

2.1 Draft Report of the Committee on Environment, Public Health and Food Safety

On 27 January 2011, the Committee on Environment, Public Health and Food Safety delivers a draft report on the Commission's Proposal.⁶⁷ Like the EESC, the Committee welcomes the objective of the Proposal but expresses concerns about the compatibility with internal market rules. However, their main concern regards the implementation of the 2008 Council Conclusions on the centralised risk assessment procedure.

a) Art. 26b: inclusion of grounds related to environmental impacts

Possibly inspired by the EESC, the Committee members propose different amendments to include an indicative list of derogation grounds, since they believe that "the wording should not be limited to a negative definition of the grounds".⁶⁸

⁶¹ EESC, doc. n° NAT/480 - CESE 1623/2010, OPINION of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 9 December 2010.

⁶² EESC Opinion, op.cit., par. 1.1

⁶³ Ibidem

⁶⁴ Ibidem

⁶⁵ EESC Opinion, op.cit., par. 5.1.2

⁶⁶ EESC Opinion, op.cit., par. 5.1.3

⁶⁷ COMMITTEE Environment, Public Health and Food Safety, doc. n° C7-0178/2010, Draft Report on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, Rapporteur Corinne Lepage, 27 January 2011.

⁶⁸ COMMITTEE Environment, Public Health and Food Safety Opinion, op.cit., p.17.

The draft introduces three categories of grounds. The first is inspired by the EESC “socio-economic concerns” and entails references to “changes in agricultural practices, land use, town and country planning, socio-economic impacts, or other legitimate factors”.⁶⁹ The second category refers to “the absence or lack of data on the potential negative impacts of the release of GMOs on the territory or biodiversity of the Member State” and has to be understood in the light of the third category.⁷⁰

As regards the latter, the Committee introduces a new type of derogation grounds. The Committee believes that Member States should be able to rely on “grounds relating to environmental impacts which might arise from the deliberate release or the placing on the market of GMOs, and which are complementary to the environmental impacts examined during the (risk) assessment”.⁷¹ This perspective is fundamentally different from the Commission’s, whose approach entails a strict separation between derogation grounds that Member States may rely upon to opt-out of cultivation and “grounds related to the assessment of the adverse effect on health and environment”, since the Commission believes that the risk assessment conducted by EFSA already considers these adverse effects.

The Committee’s vision exposes the Member States’ frustrations with the risk assessment conducted at EU-level. Because of strong local and regional diversity within the Union, the Committee believes that the risk assessment can never be exhaustive when it comes to taking into account regional and local characteristics. Even more, the Committee states that “the distinction made by the Commission between a ‘scientific’ assessment conducted at Community level on the one hand, and grounds that have nothing to do with the scientific debate on the environmental impact on the other, is simplistic and takes no account of the complexity of the link between risk assessment and risk management.”⁷² It is even argued that “the consideration of environmental grounds is also the aspect which gives the Member States the soundest legal bases for taking national measures”.⁷³

Thus the Committee’s view sets the tone for a fierce debate between supporters of the initial Commission’s approach that derogation grounds in any case should stay outside the centralised risk assessment scope and those who support the Committee in granting Member States the freedom to go beyond the central risk assessment and act upon their own (scientific) findings.

2.2 Opinion of the Committee of the Regions

The Regions Committee delivered its opinion on the same day as the Committee on Environment, Public Health and Food Safety. They share the view that the welcome possibility for Member States to restrict or prohibit the cultivation of GMOs in their territory should not be curtailed by excluding reasons pertaining to either human/animal health or environmental protection.

Moreover the Regions Committee justifies this approach by referring to the subsidiarity principle. It argues that a consistent implementation of the subsidiarity principle “also means taking into account particular national or regional circumstances with regard to human/animal health or environmental protection as justification for prohibiting or restricting GMO crops”.⁷⁴

Furthermore, the Opinion particularly addresses the issue of the “inadequacy of risk assessment procedures” and underscores the criticisms levelled at the scientific analysis conducted by EFSA. The Regions Committee believes that “local and regional authorities are the most appropriate level for assessing the impact of the introduction of GM crops”.⁷⁵

⁶⁹ COMMITTEE Environment, Public Health and Food Safety Opinion, op.cit., amendment 3,4,5,6,8.

⁷⁰ COMMITTEE Environment, Public Health and Food Safety Opinion, op.cit., amendment 8 and p.18

⁷¹ COMMITTEE Environment, Public Health and Food Safety Opinion, op.cit., p.17.

⁷² Ibidem.

⁷³ COMMITTEE Environment, Public Health and Food Safety Opinion, op.cit., amendment 5.

⁷⁴ COMMITTEE of the Regions, doc. n° NAT-V-006, Opinion on the freedom of Member States to decide on the cultivation of genetically modified organisms on their territory, 27-28 January 2011.

⁷⁵ COMMISSION, doc. n° 16826/10, Complementary Considerations: Indicative list of grounds to restrict or prohibit GMO cultivation, 8 February 2011.

3. The Commission's indicative list of derogation grounds

By February 2011 the Commission had identified an open list of reasons⁷⁶ relating to the public interest, thereby trying to satisfy the demand of the aforementioned Committees. As the Commission states that these reasons “are either already foreseen in the Treaty or in the existing case-law of the Court of Justice of the European Union or could be inferred from the terms of the existing secondary legislation”, it becomes clear why the Commission might not have bothered to further clarify its approach beyond “other grounds related to the public interest” in the first instance.

3.1 Patchwork and inclusion of environmental policy objectives

The list reads as following⁷⁷: “

1. Public morals (including religious, philosophical and ethical concerns);
2. Public order;
3. Avoiding GMO presence in other products, i.e. contributing to:
 - Preservation of organic and conventional farming systems;
 - Avoiding the presence of GMOs in other products such as particular food products under GM-free schemes;
4. Social policy objectives, e.g.:
 - Keeping certain type of rural development in given areas to maintain current levels of occupation (such as specific policy for mountain regions);
5. Town and country planning/land use;
6. Cultural policy; e.g.:
 - preservation of societal traditions in terms of traditional farming methods;
 - preservation of cultural heritage linked to territorial production processes with particular characteristics;
7. General environmental policy objectives, other than assessment of the adverse effects of GMOs on environment; e.g.:
 - Maintenance of certain type of natural and landscape features;
 - Maintenance of certain habitats and ecosystems (i.e. preservation of the conservation status quo);
 - Maintenance of specific ecosystem functions and services (e.g. preservation of nature-oriented regions of particular natural and recreational value to citizens);”

This list is the patchwork result of the different Committees' opinions. Moreover, a brand new category of derogation grounds is introduced, namely “cultural policy”. The most surprising addition however is the reference to “general environmental objectives”. Albeit the Commission keeps the strict segregation with grounds addressed in the centralised risk assessment, this reference seems to be the Commission's way of meeting the Environmental Committee's demand.

Furthermore the Commission seems to anticipate concerns regarding compatibility with market rules and adds that the concerned Member State “shall ensure that its measure is justified by one of the exceptions to the principle of free circulation of goods referred to in Article 36 TFUE.” This proves that the Commission is well aware that the envisaged restrictive measures might have an effect on the free circulation of goods, in casu GM seed. Moreover, “to meet the scrutiny of the Court, the measure should also be justified, proportionate and non discriminatory.”⁷⁸

⁷⁶ COMMISSION Opinion, op.cit., p.2.

⁷⁷ Ibidem.

⁷⁸ COMMISSION Opinion, op.cit., p.3.

With this list the Commission definitely shows that it took the criticism from the different Committees seriously and was willing to address the lacunas in its technical design of art 26b. By comprehensively explaining almost every listed item, the Commission gives a valuable insight in the scope it might have had in mind when drawing up the original proposal.

3.2 Opinion of the Committee on Agricultural and Rural Development

Contrary to the Committee on Environment, Public Health and Food Safety, the Agricultural Committee seconds the Commission's approach that the derogation grounds Member States may invoke should be "different from those covered by the harmonised scientific assessment".⁷⁹

This Committee recaptures some of the grounds of the Commission's indicative list, like "territorial management", "land use planning" and "wider policy objectives". Furthermore, according to the Regions Committee "the impossibility to implement coexistence due to specific geographical conditions" should also be a ground for derogation.⁸⁰

Albeit with references to "the need to preserve specific types of agriculture such as organic or high nature value farming, as well as traditional types of farming" and grounds "related to the protection of the diversity of agricultural production", the agricultural inspired touch is undeniably present.⁸¹

Last on their list are "other legitimate grounds in the public interest or addressing public concerns, duly justified, proportionate and non-discriminatory", which gives it an open ending though at the same time it leaves nothing to the chance.⁸²

Although the Agricultural Committee has a very similar take on things, it does not copy the Commission's Proposal and indicative grounds blindly. The Committee introduces an additional requirement for Member States to invoke the derogation grounds, by obliging a "prior impact assessment showing them to be necessary and proportional."⁸³ The Committee argues that if a dispute rises, "such assessment would make it easier to defend the measure adopted."

4. The Council's proceedings: part one

Parallel to the Parliamentary Committees working on the proposal, the Council established an Ad-Hoc Working Party to allow an integrated examination of the Commission's Proposal.

4.1 Compromise proposals under the Hungarian Presidency

By submitting a first compromise proposal on March 25 2011⁸⁴ and a second one three months later⁸⁵, the Hungarian Presidency went ahead of itself as it was clearly to soon to reach a qualified majority and, as one delegation stated, "a robust progress report would be more appropriate"⁸⁶. However the Presidency's suggestions were considered a good basis for further work and important progress was made.

Moreover, the Presidency's approach revealed common ground with the position of the

⁷⁹ COMMITTEE on Agricultural and Rural Development, Opinion for the Committee on the Environment, Public Health and Food Safety on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 15 March 2011.

⁸⁰ COMMITTEE on Agricultural and Rural Development, op.cit., amendment 5, 11.

⁸¹ Ibidem.

⁸² Ibidem.

⁸³ COMMITTEE on Agricultural and Rural Development, op.cit., amendment 4, 13.

⁸⁴ COUNCIL doc. n°8259/11, Compromise proposal, 25 March 2011.

⁸⁵ COUNCIL doc. n°10532/11, Compromise proposal, 25 May 2011.

⁸⁶ COUNCIL doc. n°11326/11, Progress Report from the Presidency to COREPER/Council, 10 June 2011.

Committee on the Environment, Public Health and Food safety. In the last Hungarian compromise proposal, the list of derogation grounds reads as following: “

1. Public morals;
2. Avoiding GMO presence in other products, without prejudice to Art 26a;
3. Social policy;
4. Town and country planning/land use;
5. Cultural policy;
6. Complementary environmental policy objectives, distinct from those concretely assessed according Directive 2001/18/EC and Regulation (EC) no 1829/2003.”

The compromise proposal clearly states the Committee’s position to allow Member States to rely upon grounds relating to environmental impacts which are complementary to those examined during the risk assessment, is not acceptable. However by integrating “complementary environmental policy objectives” in the list, the Council expresses to share the view that there should be margin to invoke environmental related grounds. Nevertheless, this wording is still very ‘distinct’ from the Environmental, Health and Safety Committee’s

The other grounds are almost identical to those in the Commission’s indicative list, with the exception of “public order” which seems to have been abandoned.

Furthermore the Council’s proposal introduces an explicit reference to the difficulties regarding the authorisation procedure “in the light of the expression of national concerns which do not only relate to issues associated with the safety of GMOs on health or the environment” and the practice of national bans on cultivated GMOs. Similarly to the Commission’s statements in the original Proposal’s explanatory memorandum, the Council believes that granting more freedom to Member States will “facilitate the decision-making process” and ease “the smooth functioning of the internal market”.⁸⁷

As regards the issues raised by the Parliamentary Committees on the centralised risk assessment procedure, one could argue that the Council seems far less bothered with them as the Environmental Committee, since their compromise proposals do not refer to the risk assessment procedure at all.⁸⁸ However, in the following progress report, the Council states that a majority of delegations does support the need for continuing the implementation of the 2008 Council Conclusions in parallel and not as a prerequisite.⁸⁹

It is to be noted that the Council proposes to change the legal instrument from a Regulation to a Directive in its second proposal, however it does not provide a reason.

It can be concluded that the compromise proposal seems to be a good start for the informal dialogue with the European Parliament in order to reach a political agreement.

5. Parliament’s first reading

On 5 July 2011, the European Parliament adopts the draft legislation at first reading.⁹⁰ The text integrates most of the amendments from the Committee on Environment, Public Health and Food Safety as adopted on April 12th 2011.⁹¹

⁸⁷ COUNCIL 2nd Compromise Proposal, op.cit., amendment 6.

⁸⁸ The Council does not stand by the Committee’s reference to the 2008 Environmental Council Conclusions and states that the Committee’s view does not reflect correctly the content of the 2008 Conclusions, see COUNCIL 2nd Compromise Proposal, op.cit., amendment 3.

⁸⁹ COUNCIL Progress report, op.cit. p 6.

⁹⁰ EUROPEAN PARLIAMENT, doc. n° P7_TA(2011)0314, Legislative resolution of 5 July 2011 on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict

5.1 Art 26b: a thinning line between EFSA and the Member States

The Parliament designs Article 26b in a comprehensive way. Since the derogation measures are described in detail, it seems as if the Parliament does not want to leave anything to the chance. The new article reads as following: “Those measures are based on

1. “duly justified grounds relating to local or regional environmental impacts which might arise from the deliberate release or the placing on the market of GMOs and which are complementary to the environmental impacts examined during the scientific assessment of the grounds relating to risk management. Those grounds may include:
 - the prevention of the development of pesticide resistance amongst weeds and pests;
 - the invasiveness or persistence of a GM variety, or the possibility of interbreeding with domestic cultivated or wild plants;
 - the prevention of negative impacts on the local environment caused by changes in agricultural practices linked to the cultivation of GMOs;
 - the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability;
 - the maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features;
 - the absence or lack of adequate data concerning the potential negative impacts of the release of GMOs on the local or regional environment of a Member State, including on biodiversity;
2. grounds relating to socio-economic impacts. Those grounds may include:
 - the impracticability or the high costs of coexistence measures or the impossibility of implementing coexistence measures due to specific geographical conditions such as small islands or mountain zones;
 - the need to protect the diversity of agricultural production;
 - the need to ensure seed purity; or
3. other grounds that may include land use, town and country planning, or other legitimate factors.”⁹²

The Parliament categorizes the measures in three groups. The third group seems to be a rest category, with mentioning of a rather vague “other legitimate factors”. The second group, relating to socio-economic impacts, is nothing new, although it now houses the reference to coexistence measures instead of those being regarded as a category in itself - as in the Commission’s indicative list. It also integrates the agricultural related grounds raised in the opinion of the Agricultural Committee.

As regards the first category, Parliament has adopted the Environmental, Health & Food Committee’s initial view that Member States should be able to rely on “grounds relating to environmental impacts” which might arise from the deliberate release or the placing on the market of GMOs and which are “complementary” to those examined by EFSA, entailing “those factors (that) have not been addressed as part of the harmonized procedure”.⁹³ Furthermore “grounds relating to risk management” can now also be invoked.

As regards the scientific foundation of environmental related measures, the new text refers to “duly justified grounds”. Whereas the original amendment from the Committee referred to “scientifically justified grounds”, according to the new text Member States are not obliged to justify measures on scientific grounds, but can also refer to “grounds relating to risk management” and even

or prohibit the cultivation of GMOs in their territory, 5 July 2011.

⁹¹ COMMITTEE Environment, Public Health and Food Safety, doc. n° A7-0170/2011, Amendments to the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 12 March 2011.

⁹² EUROPEAN PARLIAMENT, Legislative resolution, op.cit., art. 26b.

⁹³ EUROPEAN PARLIAMENT, Legislative resolution, op.cit., recital 8.

“other legitimate factors”. Moreover, according to the Parliament, “persisting scientific uncertainty” should be a sufficient reason to allow Member States to ban cultivation.⁹⁴

It is clear that the Parliament remains convinced that EFSA assessments cannot be exhaustive. Therefore, *inter alia*, the Parliament allows Member States to interfere with EFSA’s competences regarding the assessment of environmental impacts. An *a-contrario* reading of “without these grounds necessarily challenging the assessment conducted at Community level”⁹⁵, leads to conclude that Parliament realizes and does not find it problematic that Member States might invoke grounds relating to environmental impacts that are contrary to EFSA’s findings. This inevitably also leads to conclude that that EFSA’s authority might be undermined by Member States’ measures.

Whilst the Commission and Council have showed an open-minded approach to the inclusion of environmental related grounds from the beginning, the adoption of the text by the the Parliament confirms that it continues to have a very different approach and that it is either not ready or not willing to concede. Moreover, Parliament’s frustration with the risk assessment procedures brings them to navigate tricky waters, balancing on the thinning line between EFSA’s competences and Member States extensive margin to rely upon environmental related derogation grounds.

5.2 Emphasis on the principle of subsidiarity and proportionality

The Parliament’s text makes multiple references to the principle of subsidiarity. Parliament believes that, contrary to issues related to the placing on the market and import of GMO’s, cultivation is an issue with a strong local, regional or territorial dimension and therefore requires more flexibility. Stating that “cultivation is closely linked to land use and the conservation of fauna and flora, areas in which the Member States retain significant powers”, Parliament describes the extended possibility to opt-out of cultivation as “of particular importance for the self-determination of Member States.”⁹⁶ According to Parliament, the subsidiarity principle justifies granting Member States the possibility to invoke grounds relating to environmental impacts.

Furthermore, the text explicitly refers to principle of proportionality as a requirement for national measures.⁹⁷

5.3 Other technical elements

Apart from an elaborated Article 26b, the Parliament’s resolution also contains some new technical elements. Firstly, before measures can be taken on the basis of the previous article, an independent cost-benefit analysis has to be conducted, taking in account alternatives.⁹⁸ Moreover possible measures should also be preceded by a prior public consultation.⁹⁹ The Member State has to make the measures publicly available to “all operators concerned” and has to communicate them to other Member States and the Commission. Once the measures are adopted, they can stay in place for five years but need to be reviewed when the authorization is renewed.

As regards the choice of legal instrument, unlike the Council’s approach, Parliament adopts a Regulation.

⁹⁴ *Ibidem*.

⁹⁵ COMMITTEE Environment, Public Health and Food Safety, *op.cit.*, amendment 6.

⁹⁶ EUROPEAN PARLIAMENT, Legislative resolution, *op.cit.*, recital 5.

⁹⁷ EUROPEAN PARLIAMENT, Legislative resolution, *op.cit.*, art. 26b (b) and amendment 8.

⁹⁸ EUROPEAN PARLIAMENT, Legislative resolution, *op.cit.*, art. 26b (ab)

⁹⁹ EUROPEAN PARLIAMENT, Legislative resolution, *op.cit.*, art. 26b (ac)

6. The Council's proceedings: part two

6.1 A third compromise proposal under the Danish presidency

At the beginning of February 2012, the Danish Presidency submits a new compromise proposal.¹⁰⁰ After a first revision¹⁰¹ the third version is presented in March.¹⁰² This new proposal, in the form of a Directive, laid the foundations for the text adopted by the Council at first reading on July 23rd 2014.

a) Art. 26b: a two-way opt-out model

The Danish presidency takes the proposal to a whole other level compared to the minimalistic and uninspired approach of the Hungarian Presidency.

The Danish Presidency fundamentally changes the opt-out procedure for a Member State. Up till now, the compromise proposals and even the text adopted by the Parliament have focused on describing the derogation grounds, each more elaborate than the other, and have introduced only minor technical changes to the opt-out procedure.¹⁰³ However, this is not surprising since the core of the debate revolved around the question of what kind of measures Member States should be able to invoke in addition to the existing science-based safeguard clause and emergency measures.¹⁰⁴

In this new proposal, the focus is not so much on the type of derogation grounds but rather on how and when Member States can rely invoke them.

The new Article 26b foresees in a two-way model by introducing an opt-out right during the GMO authorisation procedure in addition to the existing opt-out right after the GM crop has been authorised.¹⁰⁵ This new model is very innovative because it involves directly the economic operators.

In the first stage, during the authorisation procedure, a Member State may request the applicant company applying for an authorisation to adjust the geographical scope of its application. The effect being that part or all of the territory of that Member State is excluded from cultivation. Following this request, the notifier/applicant shall then notify the Commission and the other Member States of the adjustment, which shall take place from the moment of notification. Moreover the authorisation decision, if granted, is adapted to the new geographical scope.

Secondly, Member States may also adopt restricting measures after the authorisation procedure, thus against authorised GMOs. This opt-out is independent from the possibility to ask the notifier/applicant to adjust its the geographical scope.

b) A short list of derogation grounds

Surprisingly, the new Article 26b does not contain a list of derogation grounds. The grounds are to be found in the guiding recital. Measures may be invoked:¹⁰⁶ “

1. On the on the basis of grounds distinct from those assessed according to the harmonized set of Union rules (i.e. Directive 2001/18/EC and Regulation (EC) No 1829/2003);

¹⁰⁰ COUNCIL doc. n° 6152/12, Revised compromise proposals in view of a Council Political Agreement, 5 February 2012.

¹⁰¹ COUNCIL doc. n° 6761/12, Revised compromise proposals in view of a Council Political Agreement, 23 February 2012.

¹⁰² COUNCIL doc. n° 7153/12, Revised compromise proposals in view of a Council Political Agreement, 2 March 2012.

¹⁰³ For example, Parliament introduced a prior public consultation and cost-benefit analysis.

¹⁰⁴ See art. 23 Directive 2001/18/EC and art. 34 Regulation 1829/2003/EC.

¹⁰⁵ COUNCIL 3rd Revised compromise proposal, op.cit., art. 26b (1) – (3).

¹⁰⁶ COUNCIL 3rd Revised compromise proposal, op.cit., recital 10.

2. These grounds may be related to
 - environmental policy objectives,
 - or other legitimate grounds such as land use, town and country planning, socio-economic impacts, and coexistence.”

This list is also surprisingly short, as the references to “public morals, “social policy” and “cultural policy” from the previous compromise proposals have been omitted.

The recital further refers to grounds relating to socio-economic impacts which may relate “to the impracticability or the impossibility of implementing coexistence measures due to specific geographical conditions or the need to avoid GMO presence in other products such as specific or particular products or the need to protect the diversity of agricultural production or the need to ensure seed and plant propagating material purity.”¹⁰⁷ The socio-economic concerns mentioned seem to refer mainly to coexistence related issues.

Furthermore, the Danish Presidency proposal resumes the view that derogation grounds should be distinct from those assessed by EFSA and even explicitly states that this is to “to avoid any interference with the competences which are granted to the risk assessors and risk managers”. Therefore there is no room for grounds based on “the maintenance of certain type of natural and landscape features, certain habitats and ecosystems as well as specific ecosystem functions and services”, since these elements are considered already in the centralised risk assessment.¹⁰⁸

c) Revival of the provisionality requirement?

Up till now, every proposal imposed only a minor communication requirement for Member States when taking national measures against GMOs, which is very different from the Commission’s existing supervising powers under the safeguard clause of Directive 2001/18 and emergency measures under Regulation 1829/2003.¹⁰⁹ The Danish Presidency however, partially restores the Commission’s involvement. Albeit this compromise proposal does not bring back the original provisional character of the measures, Member States have to submit to the Commission a draft of the measures three months prior to their adoption. During these three months, a standstill period applies and the Member State has to refrain from adopting and implementing the measures. If the Commission considers that the Member State is making an improper use of the powers provided to it, it shall communicate this to the Member State. The Commission may make suggestions on how these measures should be amended to meet the conditions of this Directive. After the standstill period, the Member State can adopt the measures as intended or as altered by the Commission’s remarks.¹¹⁰

6.2 Impasse due to a blocking minority

The above described proposal was submitted to the Environment Council on 9 March 2012 with a view to reaching a Political Agreement. However a blocking minority of delegations opposed. Germany, France, Belgium and the United Kingdom found the proposal in conflict with the single market, and had concerns regarding the compatibility with WTO. The blocking minority also argued that the proposal did not sufficiently address the 2008 Council Conclusions.¹¹¹

Between March and June, the Presidency held informal consultations with delegations, in particular the blocking minority, in order to examine if and how a change in delegations’ positions could be achieved. This examination showed that it wasn’t possible to dissolve the blocking minority.

¹⁰⁷ COUNCIL 3rd Revised compromise proposal, op.cit., recital 12.

¹⁰⁸ COUNCIL 3rd Revised compromise proposal, op.cit., recital 11.

¹⁰⁹ These supervising powers are mainly theoretical.

¹¹⁰ COUNCIL 3rd Revised compromise proposal, op.cit., recital 15 and art. 26b (4).

¹¹¹ COUNCIL doc. n° 10883/1/12, Progress report, 6 June 2012.

It wasn't until February 2014 that the proposal came back on the political agenda. When the General Affairs Council held a policy debate in the context of a Commission proposal for a Council Decision regarding an authorisation for cultivation of a GM maize product¹¹² a significant number of Ministers expressed their willingness to revisit the EU legislative framework governing this kind of authorisations and in particular, those relating to cultivation.¹¹³

6.3 A fourth compromise proposal under the Greek Presidency

When Greece drew up a fourth compromise proposal at the beginning of its Presidency in February 2014¹¹⁴, the Council's proceedings on the proposal finally approached, after almost a year and a half on hold, the finish line. The new text almost entirely copied the previous proposal. However there are some interesting changes to be noted.

Firstly, the Danish two-way model is slightly altered into a one-way model with two possible exits. From now on a Member State can only invoke an opt-out after an authorisation has been granted in the case where that Member State has previously requested the notifier/applicant during the authorisation procedure to adjust the geographical scope and the latter has refused to do so.¹¹⁵

Secondly, Member States can no longer take restrictive measures against "a group of GMO's" or "where appropriate, all GMO's"¹¹⁶, but can only take measures against the GM crop that was the subject of the authorisation procedure for which the Member States had requested an opt-out.

Thirdly, it is the notifier/applicant's task to notify the Commission and Member States of an adjustment of the geographical scope as well as of his disagreement.

The compromise proposal also explicitly urges to foresee specific transitional measures.¹¹⁷ It is proposed to give the Member States a certain amount of time after the Directive enters into force to request adjustment of the geographical scope of an application lodged or an authorisation granted.

Interestingly, the Proposal also foresees the possibility to opt back in to cultivation after a previous opt-out. A Member State can request to re-adjust the geographical scope so that its territory is re-included in the authorisation.

Lastly the proposal states that the new procedure may not affect the cultivation of any authorised varieties which were planted before the Directive enters into force.¹¹⁸

6.4 Political Agreement

After the Greek presidency submitted its proposal, three months of intensive negotiations followed.¹¹⁹ At its meeting on 28 May 2014, the COREPER agreed, in principle, on the said Presidency's text and invited the Environment Council to adopt a Political Agreement, under a "B" Agenda Item, at its meeting on 12 June 2014.¹²⁰ And so it happened.

In comparison to the last compromise proposal, the content of the Agreement is very similar, with some technical elements further established.

¹¹² It concerned the GM crop known by the name Pioneer 1507, see Cultivation of unpopular GM maize in Europe hangs in the balance, *Science Insider*, <http://news.sciencemag.org/environment/2014/02/cultivation-unpopular-gm-maize-europe-hangs-balance>.

¹¹³ COUNCIL doc. n° 6528/14, Preparation for the Environment Council of 3 March 2014, 17 February 2014.

¹¹⁴ *Ibidem*.

¹¹⁵ COUNCIL 4rd Revised compromise proposal, *op.cit.*, art. 26b (3).

¹¹⁶ COUNCIL 3rd Revised compromise proposal, *op.cit.*, art. 26b (3).

¹¹⁷ COUNCIL 4rd Revised compromise proposal, *op.cit.*, art. 26b (5).

¹¹⁸ *Ibidem*.

¹¹⁹ Council documents for this period are not accessible to the public via the Register of the of the Council..

¹²⁰ COUNCIL doc. n° 1027/14, Political Agreement, 28 May 2014.

7. Adoption at Council's First Reading

The Council adopted, based on the Political Agreement, its position at first reading on 23 July 2014, with the Belgian and Luxembourg delegations abstaining from a positive vote.¹²¹

With regard to the text adopted by the European Parliament in July 2011, it can be noted that the general direction of the Parliament's amendments to the original Commission's Proposal was followed by the Council in certain key respects, namely the introduction of specific grounds on which to base national restrictions. However, in other respects the Council took a different approach. The text adopted will be described in detail hereafter.

7.1 Article 26b

a) Procedural model inspired by the proposals of the Greek and Danish Presidency

The procedural model adopted at first reading is inspired by the work of the Danish and Greek Presidencies. The Council agreed on the mechanism whereby Member States can accord on restrictions with economic operators. According to the Council, "such a mechanism is likely to provide the greatest possible legal certainty, both to operators and to Member States."¹²²

In the original proposal from the Danish Presidency, Member States wishing to oppose the cultivation of a GMO crop, could go two ways. Firstly, during the authorisation procedure they could request the applicant to adjust the geographical scope of the application. Secondly, after the authorisation procedure, the Member State could invoke derogation grounds to ban the GMO. These two exits of cultivation were "without prejudice" to, and thus independent from, one another.

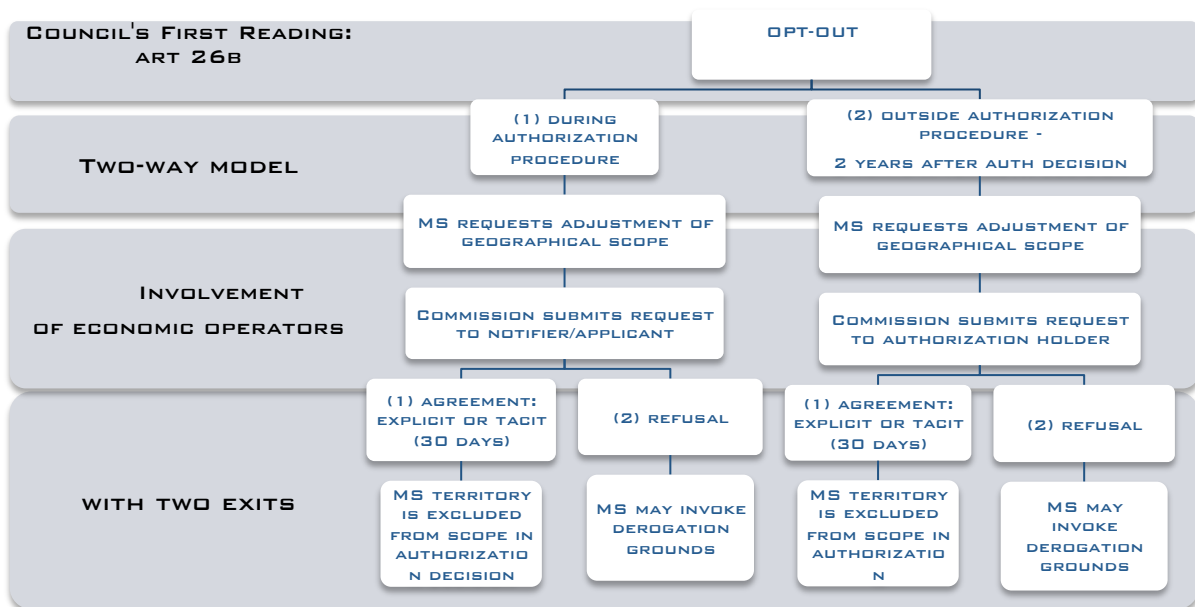
The Greek proposal however made the second exit option interdependent from the first. This introduced a one-way model with two exits out of cultivation. The first exit applies when a Member State has requested the applicant to adjust the geographical scope and the latter agreed. The second exit applies when a Member State had made the request but an adjustment had not been notified – in the case of a refusal from the applicant. Only in the latter case and only after the GMO had been authorised, the Member State could invoke the derogation grounds.

b) A two-way model with two exits

The model adopted by the Council at first reading is as following:

¹²¹ COUNCIL doc. n° 10972/3/14, Proposal for a regulation of the European Parliament and of the Council, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory - Adopted by the Council, 23 July 2014.

¹²² COUNCIL Statement of reasons, op.cit., par. 2.



During the authorisation procedure, a Member State can make a request for adjustment of the geographical scope to the applicant. If the applicant agrees, the adjustment is implemented in the authorization. The applicant has a time-frame of thirty days to answer the request. If the applicant does not explicitly oppose within this period, the adjustment is considered agreed upon tacitly.¹²³ In the event that an agreement with the economic operator cannot be reached, the notifier/applicant has to notify the Commission and the Member States of its opposition.¹²⁴ Once the authorisation has been granted, the Member State that had requested the adjustment is then entitled to adopt measures restricting or prohibiting cultivation on the basis of a non-indicative list of derogation grounds. Either way, the restrictive measures envisaged have to be taken within two years after the date that the authorisation is granted.¹²⁵

This part of the procedural model is copied from the Greek one-way model (during the authorisation procedure the Member State requests an adjustment of the scope) with two exits (either the applicant explicitly or tacitly agrees to the request, or he refuses and the Member State may take restrictive measures) but is complemented with a timeframe of two years.

The new model however also introduces an additional way out of cultivation in the case where an authorisation has been granted for at least two years and the Member State considers that new objective circumstances justify an adjustment of the geographical scope.¹²⁶ The Member State may then make a request to the consent/authorisation holder, which can result either in exclusion of the Member State's territory if the authorization holder agrees or restrictive measures if the latter opposes.

Furthermore the Council adds an explicit reference to the Commission's powers to make and adjustment of the geographical scope itself in the context of its decisional authority regarding authorisation applications, and "in the light of the environmental risk assessment" carried out by EFSA.¹²⁷

The opt-back-in possibility from the Danish proposal is also present. Where a Member State wishes all or part of its territory to be reintegrated into the geographical scope of the consent/authorisation from which it was previously excluded, it may make a request to that effect to

¹²³ COUNCIL First reading, op.cit., art. 26b, par. 1.

¹²⁴ COUNCIL First reading, op.cit., art. 26b, par. 2.

¹²⁵ COUNCIL First reading, op.cit., art. 26b, par. 3.

¹²⁶ COUNCIL First reading, op.cit., art. 26b, par. 5.

¹²⁷ COUNCIL First reading, op.cit., recital 9.

the competent authority which has issued the authorisation. It must be noted that the economic operator has no part in a possible opt-back-in request.

7.2 An expanded list of derogation grounds

Unlike in the last two compromise proposals, a non-indicative list of derogation grounds is re-inserted in Article 26b. In comparison to the Parliament's text, the main differences are in terms of emphasis and the level of detail.¹²⁸ The most important difference however, is that the Council excludes grounds that interfere with EFSA's risk assessment competences. The new list reads as following¹²⁹: “

- (a) environmental policy objectives distinct from the elements assessed according to this Directive and Regulation (EC) No 1829/2003;
- (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.”

This list is almost identical to the list proposed by the Hungarian Presidency in 2011. The Council still considers it essential to ensure that the grounds invoked to restrict cultivation do not conflict with the centralised scientific risk assessment.¹³⁰

As regards to the conditions, these measures need to be “in conformity with Union law, reasoned, proportional and non-discriminatory.”¹³¹ The grounds may be invoked individually or in combination. Interestingly, “public policy” cannot be invoked on its own.

Furthermore it is emphasised that when invoked, these grounds may in no case be in conflict with the environmental risk assessment.

7.3 A new role for the Commission

The Commission is involved in the opt-out process in two ways. Firstly, the Commission is the go-between the Member State and the notifier/applicant to whom it is submitting a request for geographical adjustment. The request is communicated to the Commission at the latest 30 days from the date of the circulation of the assessment report¹³² or from receiving the scientific opinion of EFSA¹³³ and is then passed on to the notifier/applicant and to the other Member States “without delay”¹³⁴.

Secondly, the new text resumes the view of the Danish Presidency proposal that derogation measures should be subject to a procedure of scrutiny and information at Union level. A Member State intending to adopt restrictive measures shall first communicate a draft of those measures and the corresponding grounds invoked to the Commission. A standstill period follows during which the Member State may not adopt or implement the measures and during which Commission has the opportunity to make comments. The standstill applies for 75 days, which is slightly more than the Danish proposal of three months. After this period the Member State can adopt the measures as intended or whilst taking in account the Commission's comments.

¹²⁸ COUNCIL Statement of reasons, op.cit., p. 3.

¹²⁹ COUNCIL First reading, op.cit., art. 26b, par. 4.

¹³⁰ COUNCIL Statement of reasons, op.cit., p. 3.

¹³¹ COUNCIL First reading, op.cit., art. 26b, par. 4.

¹³² under Article 14(2) of Directive 2001/18/EC.

¹³³ under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003.

¹³⁴ COUNCIL First reading, op.cit., art. 26b, par. 1.

This new level of involvement, however small, is a step further than the pure information obligation as adopted by the European Parliament. Surprisingly, even the Commission did not provide for the possibility to make comments in its own proposal of 2010. An information obligation is the bare minimum, “in light of Union scrutiny and information”¹³⁵.

7.4 Transitional measures

In view of the fact that authorisation procedures may reasonably be expected to be underway when the proposal is finally adopted, the Council introduces appropriate transitional provisions.¹³⁶ The Council believes that this is “necessary to respect the legitimate expectations of farmers who have already planted GM crops prior to the adoption of national measures.”¹³⁷ Moreover, “transitional measures are also justified by the need to avoid creating potential distortions of competition by treating existing authorisation holders differently from future applicants for authorisation.”¹³⁸

A new Article 26c is inserted and specifically applies to these transitional measures. The new Article entails that the aforementioned procedural model applies during the transition period.

The Council does not stipulate the period¹³⁹ during which such transitional measures may be adopted but states that it “should be limited to that which is strictly necessary in order to ensure a smooth transition to the new regime”.¹⁴⁰

7.5 Choice of legal instrument

The Commission’s proposal was initially in the form of a Regulation and the Parliament also adopted a Regulation at first reading. Whereas the Council first two compromise proposals supported this choice of legal basis, the text adopted is now a Directive. The Council explains that “the legal form of a regulation would have been appropriate if it had been the intention to create rights and impose obligations directly on economic operators, whereas the logic of the proposal is to give Member States the right to decide on cultivation, without actually requiring them to take any decisions restricting cultivation at all”¹⁴¹ Given the optional nature of the provisions the Council does not provide a transposition period.¹⁴²

SECTION C: Conclusions on the evolution of the 2010 Proposal and future prospects

1. A political agenda item under the Italian Presidency

In its program¹⁴³, the Italian presidency¹⁴⁴ has declared that it will give particular attention to continuing work on the draft legislation with view to concluding a second-reading agreement with the

¹³⁵ COUNCIL First reading, op.cit., recital 13.

¹³⁶ COUNCIL First reading, op.cit., art. 26c

¹³⁷ COUNCIL Statement of reasons, op.cit., p. 4.

¹³⁸ COUNCIL First reading, op.cit., recital 21.

¹³⁹ Article 26c indeed does not provide with a timeframe but a period up till six months has been mentioned, see Council Press Release of 23 July 2014, http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/144116.pdf

¹⁴⁰ Ibidem.

¹⁴¹ COUNCIL Statement of reasons, op.cit., par. 2.

¹⁴² Ibidem.

¹⁴³ Europe, a fresh start; Programme of the Italian Presidency of the Council of the European Union, p.66; http://italia2014.eu/media/1349/programma_en1_def.pdf

¹⁴⁴ Presidency from 1 July 2014 – 31 December 2014.

European Parliament. Furthermore the Commission has indicated that it can accept the Council's position at first reading.¹⁴⁵

2. Will the Council and European Parliament be able to meet in the middle?

“Whilst the Council is conscious of the fact that it has taken a different approach from the approach taken by the European Parliament, the overall direction of the two institutions is broadly the same. The Council therefore looks forward to constructive discussions with the European Parliament at second reading with a view to the early adoption of the directive.” The Council seems to be feel that there is more than enough common ground to adopt the legislation. But is there really?

2.1 Same goals

From the beginning, the Council, Parliament and Commission agreed upon the same incentives. The two main goals of the draft legislation, that have been repeated in each (compromise) proposal, were and are: the smooth functioning of the internal market and freedom for Member States to make their own decisions regarding the cultivation of authorised GMOs.

As regards the first goal, it is undeniable that the Commission’s proposal was - to say the least - inspired by the deadlock on GMO authorisations. It was believed that if Member States would have more freedom to opt-out of cultivation, they would be more willing to agree to cultivation applications in the Comitology procedure. The Council’s latest procedural model is designed to, “with a view to ensuring the least possible disturbance to the internal market”¹⁴⁶, facilitate the decision-making process on authorisations. With the two-way model and the two exits, that can always result in a cultivation ban, the Council’s proposal definitely gives Member States a lot of margin to say “no”. However it is currently not possible to say with certainty that this will indeed lead to more “yes”.

Moreover, during the legislative procedure, numerous concerns have been raised regarding the impact the draft legislation would have on the internal market and the compatibility with the internal market rules as well as other general principles. This issue is discussed in Part III and IV.

As regards the second goal, shaping the Member States’ freedom has proven to be an intensive process, particularly in the Council. The European Parliament was able to decide rather smoothly on the issue at first reading. Both institutions contributed significantly yet differently to the design and technical development. It can be argued that as regards most of the elements constituting the “freedom”, Parliament and Council have comparable approaches.

We can refer to the emphasis on the principle of subsidiarity and proportionality, the need for transitional measures and the information obligation to the Commission and Member States in case of restrictive measures. As regards the derogation grounds, both have embraced socio-economic concerns such as land use, town and country planning and agricultural policy objectives.

2.2 Different approaches

So when the Council believes that there is a sound common ground, why should we have to take this with a grain of salt?

Firstly, it is to be noted that the Council has ignored some of the Parliament’s additions to the draft legislation, such as a public consultation and cost-benefit analysis prior to adopting restrictive measures, as well as a limited timeframe of five years.

¹⁴⁵ COUNCIL Statement of reasons, op.cit., par. 1.

¹⁴⁶ COUNCIL Statement of reasons, op.cit., p. 3.

Secondly, It is undeniable that some key elements have been approached in very different manners. The main stumbling block remains the possibility to invoke derogation grounds that strictly speaking belong to EFSA's risk assessment competences. It concerns grounds relating to local or regional environmental impacts which might arise from the deliberate release or the placing on the market of GMOs and which are complementary to the environmental impacts examined during the scientific assessment.

As regards this issue, Council and Parliament have undeniably opposite views. The European Parliament desperately wants to give Member States margin to invoke grounds that might interfere with the risk assessment. The Council consistently works on keeping these kinds of grounds outside the list of derogation measures. The European Parliament believes that the risk assessment conducted at EU level can never be exhaustive in taking in account local and regional characteristics. The Council believes that in no case Member States should be able to interfere on this level to accomplish national restrictions against GMOs. It can be argued that the Council has made a concession towards the Parliament by proposing "environmental policy objectives" as a possible derogation ground, however this is far from what the Parliament actually wants.

It is obvious that this discussion will not be resolved easily and we will have to wait and see if, how and where the Parliament and Council are going to meet in the middle on this issue.

3. Remaining issues

There are some other substantive topics that need further examination. Firstly we will need to examine the scope of the new derogation grounds. To fully apprehend this, we will examine the derogation measures under the existing legislative framework, in particular the science-based approach of article 23 of Directive 2001/18 and article 34 of Regulation 1829/2003. We will also examine whether the existing framework already provides for measures based on socio-economic grounds and if so, to what extent. The relation with the concept of coexistence will also be addressed.

Secondly, the question whether the new approach is compatible with internal market rules has been raised multiple times and will be examined as well.

Lastly the choice of the legal basis will be discussed in the context of de-harmonisation.

PART II: Possibilities for Member States to restrict or prohibit the cultivation of GMOs under the existing legislative framework(s)

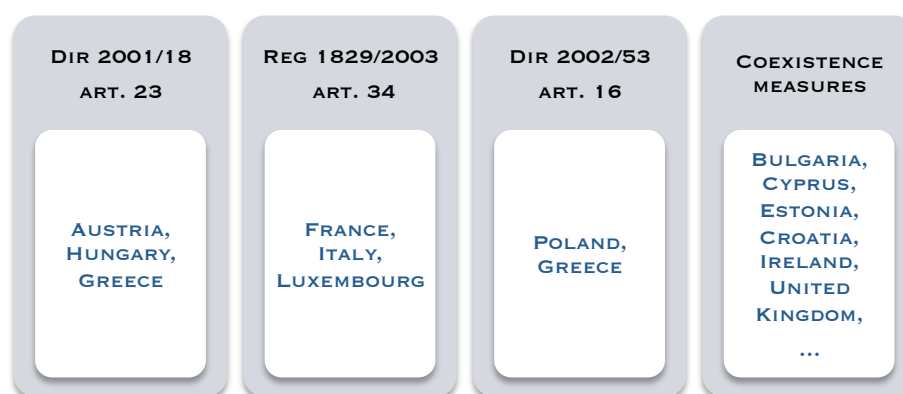
CHAPTER 1. A high level of harmonisation, a low level of derogation?

In the first Part it was demonstrated how the new draft legislation giving Member States more freedom as regards GMO cultivation, has evolved, with a list of new derogation grounds at its core.

The harmonised nature of the existing legislative framework for cultivation and the nature of the EU internal market, whereby barriers to the free movement of goods are to be removed, fundamentally limit the competence and discretion of the Member States to restrict or prohibit cultivation on their territories. Thus, Member States wishing to opt-out may only do so within the framework provided for by EU law.

Derogations are provided for under the GMO legislation in Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003 as well as in other relevant secondary legislation such as Directive 2002/53 on the common seed catalogue. The TFEU itself also provides for Member States to derogate from harmonised measures in Article 114. It mentions an “environmental clause” in paragraph 4 and 5 and a “safeguard clause” in paragraph 10. In the latter it is stipulated that “harmonisation measures (...) shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non- economic reasons referred to in Article 36, provisional measures subject to Union control procedure”.

Whereas the applicable rules provide for limited margin, the practice of GMO cultivation throughout the European Union has shown a significant trend, namely Member States banning GMOs within their territory. As regards MON810, the only GM crop commercially cultivated, the Member States who are not in favour of GM crops have invoked every ground available to justify national bans, as demonstrated by this chart:



It is the aim of this Chapter to examine, on the basis of case law, how Member States can invoke – and have invoked – the aforementioned legal bases to ban GMOs. In Chapter two and three, we will examine to what extent Member States can rely upon (socio-) economic grounds. Lastly we will address the concept of coexistence as a less stringent way out of cultivation.

A thorough understanding of these opt-out ‘options’ in the existing legislative framework will then lead us to a detailed analysis in Part III of the derogation grounds in the new draft legislation.

CHAPTER 2. The science-based approach

Section A. Under the GMO legislation: Directive 2001/18 and Regulation 1829/2003

1. Safeguard clause and Emergency measures in theory

1.1 Common ground: a science-based risk approach

Under Article 23 of Directive 2001/18/EC, a Member State may invoke a safeguard clause to restrict or prohibit cultivation of an authorised¹⁴⁷ GM crop “when it has detailed grounds for considering that a GMO (...) constitutes a risk to human health or the environment”.

The science-based approach of this safeguard clause has its roots in the fact that reconsideration grounds should be “a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge”¹⁴⁸.

Under Regulation 1829/2003, Member States may take emergency measures thereby restricting the cultivation of a GM crop “where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment”.¹⁴⁹

Like in Article 23 of the Directive, at the core is an occurring risk to human health or the environment. A risk relating to animal health has been added to the areas of interest.

By analogy, it can be mentioned that this science-based approach is also at the core of the Novel Foods Regulation of 1997¹⁵⁰. Article 12 of this Regulation is very similar to Article 23 of Directive 2001/18: “where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory”.

This science-based approach is to be seen in the light of the achievement of a high level of protection of the environment¹⁵¹ and a high level of human health protection¹⁵² as one of the objectives of Union action. In order to achieve the latter, the General Food Law Regulation¹⁵³ lays down that EU food legislation shall be based on risk analysis.¹⁵⁴ Risk assessment shall be based on the available scientific evidence and undertaken in an objective, independent manner.¹⁵⁵

In *Monsanto vs. Others*, the European Court of Justice emphasised that “the assessment and management of a serious and evident risk ultimately come under the sole responsibility of the

¹⁴⁷ This refers to “a GMO as or in a product which has been properly notified and has received written consent under this Directive”.

¹⁴⁸ Art. 23, par. 1, (1), Directive 2001/18/EC.

¹⁴⁹ Art. 34 Regulation EC N° 1829/2003.

¹⁵⁰ REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 1997 concerning novel foods and novel food ingredients. This regulation does not apply to GMOs under Regulation 1829/2003.

¹⁵¹ Art. 3 (3) TFEU.

¹⁵² Art. 152 (1) TFEU.

¹⁵³ REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

¹⁵⁴ Regulation 178/2002, op. cit., art. 6 (1), recital 16.

¹⁵⁵ Regulation 178/2002, op. cit., art. 6 (2), recital 18-19.

Commission and the Council, subject to review by the European Union Courts” since the harmonised legislative framework has as objective to avoid artificial disparities in the treatment of risks.¹⁵⁶

a) Level of risk to human health or the environment

There is a small but significant difference in formulation between Article 34 and Article 23 as regards the “risk to human health and environment”. To restrict cultivation under the Directive, the Member State must demonstrate a “risk” whereas under Article 34 of the Regulation a “serious risk” is to be demonstrated. This nuances the scope of Article 34 in that it might heighten the standard. However, it can be argued that it is “impossible and unnecessary”¹⁵⁷ to define exactly what level of risk is required for the adoption of emergency measures since it will be determined by a case-on-case basis.

Furthermore there is a more notable difference between the two Articles as regards to the wording of the burden of proof. Where the safeguard clause of Directive 2001/18 refers to “detailed grounds” for considering a risk, Article 34 of Regulation 1829/2003 refers to “where it is evident ... are likely to constitute a risk”. ‘Evident’ seems to assume a high level of proof¹⁵⁸ but it can be expected that under both clauses the burden of proof is heavy.

The European Court of Justice has indirectly addressed the difference between the Article 23 and Article 34 in *Monsanto vs. Others* where it examined what degree of requirement Article 34 imposes on the Member States in so far as it makes restrictive measures subject to the existence of a situation which is ‘likely’ to constitute a ‘serious risk’ to human health, animal health or the environment.¹⁵⁹ According to the Court, these expressions must be understood as referring to a significant risk which clearly jeopardises human health, animal health or the environment.¹⁶⁰ Thus, there is a need to establish both urgency as well as a clear and serious risk when invoking emergency measures.¹⁶¹

b) Substantive conditions for invoking a risk to human health or the environment

In its 2003 *Monsanto Judgment*¹⁶² the Court of Justice addressed the Member States’ power to invoke restrictive measures under a safeguard clause. It concerned Article 12 of the Novel Foods Regulation, which is almost identical to Article 23 of Directive 2001/18.¹⁶³

In this judgment, the Court went some way to stipulate the substantive conditions of the safeguard clause. Firstly, a risk to public health or the environment is to be demonstrated. Secondly, the measure “may not properly be based on a purely hypothetical approach to risk” or “founded on mere suppositions, which are not yet scientifically verified”.¹⁶⁴ Thirdly, the measure must be “based on a risk assessment which is as complete as possible in the particular circumstances of an individual case.”¹⁶⁵ Lastly the outcome of this risk assessment must indicate that those protective measures are “necessary” in order to ensure that the products do not present a danger for human health or the environment.¹⁶⁶

Furthermore, the Court expressed that if the national protective measures adopted under the safeguard clause did not meet these conditions, they would adversely affect the twofold objective of the

¹⁵⁶ ECJ, Joined cases C-58/11 to C-68/11, *Monsanto SAS vs. Others*, 8 September 2011, paragraph 72.

¹⁵⁷ S. NELSON, “ Summary of the ruling in Joined Cases C-58/10 to C-69/10, *Monsanto SAS and Others*”, *KentLaw*, vol. 13 n° 1, 2012-2013, <http://studentorgs.kentlaw.iit.edu/jicl/wp-content/uploads/sites/5/2014/01/Case-of-Monsanto-SAS-and-Others.pdf>

¹⁵⁸ M. LEE, *EU Regulation of GMOs: Law and decision-making for a new technology*, Cheltenham, Edward Elgar Publishing Limited, 2008, p. 92.

¹⁵⁹ C-58/11 to C- 68/11, op.cit., paragraph 75.

¹⁶⁰ C-58/11 to C- 68/11, op.cit., paragraph 76 and 81.

¹⁶¹ C-58/11 to C- 68/11, op.cit., paragraph 76 and 81.

¹⁶² ECJ, Case C-236/01, *Monsanto Agricoltura Italia SpA and Others vs. Presidenza del Consiglio dei Ministri and Others*, 9 September 2003.

¹⁶³ *Supra*.

¹⁶⁴ C-236/01, op.cit., par. 106.

¹⁶⁵ C-236/01, op.cit., par. 107.

¹⁶⁶ *Ibidem*.

Novel Foods Regulation, that is “the functioning of the internal market in novel foods and protecting public health against the risks to which those foods may give rise”.¹⁶⁷ The Court’s reasoning in the *Monsanto Judgement* has been confirmed repeatedly as regards safeguard clauses in other food legislation.¹⁶⁸

In the joined *Monsanto vs. Others* cases, the Court resumed the four substantive conditions as set out in its judgement of 2003 and applied them to Article 34 of Regulation 1829/2003. With regard to these conditions, under which the adoption of emergency measures is subject to the existence of a situation which is ‘likely to constitute a clear and serious risk to human health, animal health or the environment’, the Court specified that that risk must be established on the basis of new evidence based on reliable scientific data, which cannot be purely hypothetical.¹⁶⁹

c) Expression of the precautionary principle

The precautionary principle is of importance for restrictive measures under Article 23 and Article 34 since it provides a mechanism for determining risk management measures in those specific circumstances where a risk to life or health exists but scientific uncertainty persists.¹⁷⁰

According to *Greenpeace France vs. Others* the precautionary principle is reflected in the right of a Member State to restrict or prohibit the use and/or sale on its territory of a GMO.¹⁷¹ By analogy this applies to cultivation as well.

In this case the Court of Justice interpreted Directive 90/220¹⁷², which preceded Directive 2001/18, in the light of the precautionary principle. The case concerned preliminary questions raised by the French Conseil d’Etat in an appeal brought by Association Greenpeace France seeking the annulment of a French Decree amending the official list of plant species and varieties grown in France so as to include in that list a species of genetically modified maize. The Court considered that observance of the precautionary principle was assured through risk assessments at national and Community level. Furthermore the Court enabled a national authority to refuse its consent to place a GMO on the market, after the Commission had already adopted an authorisation decision, if it received new information that revealed that the concerned GMO posed a risk to human health or the environment.¹⁷³ The Court’s ruling was transposed in Directive 2001/18.¹⁷⁴

Article 23 and Article 34 differ as regards the expression of the precautionary principle. In Directive 2001/18 the precautionary principle is mentioned multiple times.¹⁷⁵ On the contrary, Regulation 1829/2003 does not mention the principle at all. However Regulation 1829/2003 refers to the General Food Law Regulation in which the principle is comprehensively addressed.¹⁷⁶ As a result, a narrow reading of the precautionary principle also applies to GM food and feed under the Regulation.¹⁷⁷

¹⁶⁷ C-236/01, op.cit., par. 106.

¹⁶⁸ See ECJ, Case C-192/01, *Commission v. Denmark*, 23 September 2003, par. 49-51 for a confirmation of the Court’s substantive conditions outside the context of GMO case-law.

¹⁶⁹ C-58/11 to C- 68/11, op.cit., par. 106 – 107.

¹⁷⁰ COMMISSION doc. (2000)1, Communication from the Commission on the precautionary principle. Brussels, 2 February 2000.

¹⁷¹ ECJ, Case C-6/99, *Association Greenpeace France and Others v Ministère de l’Agriculture et de la Pêche and Others*, 21 March 2000, par. 44.

¹⁷² COUNCIL DIRECTIVE 90/220/EEC on the deliberate release into the environment of genetically modified organisms, 23 April 1990.

¹⁷³ Directive 90/220/EEC op.cit., par. 45.

¹⁷⁴ S. POLI, “The Member States’ long and winding road to partial regulatory autonomy in cultivating genetically modified crops in the EU”, *European Journal of Risk Regulation*, 2013, vol 2, p. 148.

¹⁷⁵ Directive 2001/18/EC, op.cit., recital 8; article 1; article 4; Annex II General Principles.

¹⁷⁶ Regulation 178/2002, op.cit. recital 20 – 21; article 6 (1); article 7.

¹⁷⁷ H.T. ANKER and M.R. GROSSMAN, “Authorization of Genetically Modified Organisms : Precaution in US and EC Law”, *European Food and Feed Law Review*, 2009, vol. 1, p.14.

In the 2003 *Monsanto Judgment* the Court directly invoked the precautionary principle regarding Member States' powers to adopt restrictive measures under a safeguard clause. The Court repeated *Greenpeace France vs. Others* in that the safeguard clause must be understood as giving specific expression to the precautionary principle. Therefore, "the conditions for the application of that clause must be interpreted having due regard to this principle"¹⁷⁸

According to the case-law of the Court¹⁷⁹, it follows from the precautionary principle that where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent.¹⁸⁰

Furthermore, protective measures may be taken pursuant to a safeguard clause even if it proves impossible to carry out as full a risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data.¹⁸¹

Thus, it follows from Courts' interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken.¹⁸²

It can be concluded that through the precautionary principle, the Court allows a "certain relaxation"¹⁸³ of the previously described substantive conditions of the safeguard clause.

1.2 Informing the Commission and Member States

If a Member State wants to invoke the safeguard clause of Directive 2001/17, it has to immediately inform the Commission and the other Member States. Moreover it has to provide the "reasons for the decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based."¹⁸⁴

If a Member State wants to take emergency measures against a GM crop under Regulation 1829/2003, there is also an information obligation. Article 34 does not explicitly make mention of it but refers to Directive 178/2002 laying down the general principles and requirements of food law: "where a Member State officially informs the Commission of the need to take emergency measures (...) In this event, it shall immediately inform the other Member States and the Commission."¹⁸⁵

Unlike in article 23 it is not specified if and what kind of information is to be provided by the Member State. However the Court of Justice has ruled that "the Member State concerned must inform the Commission as quickly as possible both of the need to take emergency measures and, as necessary, of the content of the measures adopted."¹⁸⁶

1.3 Union control procedure

As provided for in article 114 TFEU (10), the safeguard clause of Directive 2001/18 has a 'provisional' nature. According to the reference to the General Food Law Regulation, the emergency measures taken under Regulation 1829/2003 are 'interim protective measures'. Thus article 23 and

¹⁷⁸ C-58/11 to C- 68/11, op.cit., par. 110.

¹⁷⁹ See Case C-157/96, *National Farmers' Union and Others*, 5 May 1998, par. 63; and Case C-180/96, *United Kingdom v Commission*, 12 July 1996, par. 99.

¹⁸⁰ C-58/11 to C- 68/11, op.cit., par. 112.

¹⁸¹ See CFI, T-13/99, *Pfizer Animal Health v Council*, 11 September 2002, par. 160 and 162; and Case T-70/99, *Alpharma v Council*, 11 September 2002, par. 173 and 175).

¹⁸² See in particular judgments in cases T-13/99 and T-70/99 of the Court of First Instance, (2002) ECR-II, p. 3305.

¹⁸³ P. DABROWSKA, "GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the Day in the recent Judgment of the European Court of Justice?", *German Law Journal*, 2004, vol. 5 n° 2, p. 160.

¹⁸⁴ Art. 23, par. 1, (3), Directive 2001/18/EC.

¹⁸⁵ Regulation 178/2002, op. cit., art. 54.

¹⁸⁶ C-58/11 to C-68/11, op.cit., paragraph 78.

article 34 have in common that if a Member State undertakes measures in execution of these articles, those measures shall be subject to a kind of ‘Union control procedure’.

The control procedure under Directive 2001/18 is a regulatory Committee procedure.¹⁸⁷ Within 60 days¹⁸⁸ of the date of receipt of the information transmitted by the Member State, the Commission draws up a draft decision with view to the extension, amendment or abrogation of the restrictive measures. The Directive makes consultation with the European Food Safety Authority on the national scientific evidence obligatory.¹⁸⁹ It is to be noted that no such obligation is established under Regulation 1829/2003. The Commission’s draft decision is submitted to a Scientific Committee which has to deliver an opinion by qualified majority within three months. If the measures envisaged are in accordance with the Committee opinion then the Commission has to adopt the measures. If the measures are not supported by the scientific opinion or if no opinion is delivered, then the Commission shall submit to the Council a proposal regarding the measures. Within a period of three months, the Council must find a qualified majority to either adopt or reject the measures. If such vote is not reached, the measures are adopted by the Commission.¹⁹⁰

In case of emergency measures under Regulation 1829/2003, the control procedure is almost exactly the same. Given the ‘urgent’ nature of the situation, the Commission puts the matter before the Standing Committee on the Food Chain and Animal Health within 10 working days after being informed by the Member State. Subsequently, the regulatory procedure as under Article 23 applies.¹⁹¹

It is clear that the European level has a firm hand in the execution of restrictive measures taken under the Directive and Regulation. Nevertheless, Member States may maintain their protective measures until a decision has been made at EU level.¹⁹²

Albeit the stringent Union control procedure, it will be demonstrated that Member States who have invoked emergency measures or the safeguard clause to ban GMO cultivation on their territory, have not been abiding by the rules.

2. National safeguard and emergency measures in practice

It has been established that in the context of the GMO legislative framework, Member States can take unilateral measures against GMOs on the basis of either Article 23 of Directive 2001/18 or Article 34 of Regulation 1829/2003.

¹⁸⁷ Art. 23, par. 2 and art. 30 Directive 2001/18/EC with reference to art. 5 of the COUNCIL DECISION of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

¹⁸⁸ For the purpose of calculating the 60-day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee or Committees which has or have been consulted shall not be taken into account. The period of time during which the Commission is awaiting the opinion of the Scientific Committee or Committees consulted shall not exceed 60 days.

¹⁸⁹ Art. 28 Directive 2001/18/EC.

¹⁹⁰ Art. 5, par. 6 (3) of COUNCIL DECISION of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, (1999/468/EC).

¹⁹¹ Art. 34 Regulation EC N° 1829/2003, art. 54 and art. 58 (1-2) General Food Law Regulation, op.cit., with reference to art. 5 of the COUNCIL DECISION of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

¹⁹² Regulation, 178/2002 op.cit. art. 54.



The chart¹⁹³ above might lead to conclude that only few Member States have banned the cultivation of GMOs but nothing could be less true. Apart from the safeguard clause of Directive 2001/18 and the emergency measures under Regulation 1829/2003, Member States have also invoked article 16 of Directive 2002/53 on the common catalogue to ban GMOs¹⁹⁴. Furthermore Member States have invoked national rulings¹⁹⁵ and have made eagerly use of coexistence measures.¹⁹⁶

With regards to the two first opt-out modalities, practice shows that a number of Member States have made extensive use of their discretionary authority.¹⁹⁷

2.1 National measures based on Article 23 of Directive 2001/18

Austria¹⁹⁸ has invoked the safeguard clause on two occasions, in June 1999 and in May 2000.¹⁹⁹ In February 2004 and November 2007, Austria provided additional information to support their national safeguard measure to be considered under Article 23. On request of the Commission, the European Food Safety Authority delivered its opinion in December 2008 and rejected Austria's recourse to the safeguard clause due to a lack of new scientific evidence justifying the measure.²⁰⁰

Hungary²⁰¹ invoked the safeguard clause in 2005. After a first rejection by EFSA of the scientific documentation provided, Hungary presented additional studies to EFSA in April 2008. However the conclusion remained that no new scientific evidence was presented that would justify a cultivation prohibition.²⁰²

In 2011, Greece²⁰³ provided to the European Commission new scientific argumentation in support of its request for the prohibition of the placing on the market of MON 810. This request was preceded by two previous ones in 2006 and 2007. EFSA repeated its opinion in response to the two previous requests and concluded that the scientific evidence currently available did not sustain the arguments provided by Greece and that the cultivation of MON 810 was unlikely to have an adverse effect on human and animal health and the environment.²⁰⁴

In all of these Member States, the bans remain in place.

¹⁹³ This chart is composed with information derived from <http://greenbiotech.eu/eu-gm-crops/> and <http://www.gmo-free-regions.org/>

¹⁹⁴ Ban of MON810 under the Seed Directive: Poland.

¹⁹⁵ Ban of MON810 under Ministry announcement (Germany) or Ministerial Circular (Italy).

¹⁹⁶ *Infra*

¹⁹⁷ S. POLLI, "The Member States powers to adopt emergency measures in the context of the Genetically Modified Food/Feed Regulation" in *European Union Law for the twenty-first century: Internal market and free movement of goods*, Oxford, Hart Publishing, 2004, p. 131.

¹⁹⁸ Austria: National GM crop situation, *Greenbiotech.eu*, <http://greenbiotech.eu/eu-gm-crops/austria/>

¹⁹⁹ At that time, under Article 16 of Directive 90/220/EEC.

²⁰⁰ EFSA Scientific Opinion, *EFSA Journal* 2008, 891.

²⁰¹ Hungary: National GM crop situation, *Greenbiotech.eu*, <http://greenbiotech.eu/eu-gm-crops/hungary/>

²⁰² EFSA Scientific Opinion, *EFSA Journal* 2008, 756.

²⁰³ Greece: National GM crop situation, *Greenbiotech.eu*, <http://greenbiotech.eu/eu-gm-crops/greece/>

²⁰⁴ EFSA Scientific Opinion, *EFSA Journal* 2012, 2877.

2.2 National measures based on Article 34 of Regulation 1829/2003

Since Regulation 1829/2003 provides that the safeguard clause of Directive 2001/18 does not apply to authorisations granted under the Regulation²⁰⁵, it is to be noted that any measures restricting the cultivation of MON 810 notified after April 2007 are handled under Article 34 of the Regulation, the time since the renewal of MON 810 was submitted and is processed under Regulation 1829/2003.²⁰⁶

So far, Article 34 has only been invoked by three Member States, both times in relation to the cultivation of MON 810.

In Italy,²⁰⁷ a national ruling has banned the cultivation of MON 819 on the basis of Article 34 since 12 July 2013. Before adopting the ban, Italy provided to the European Commission a scientific argumentation in support of the request. The Commission requested EFSA to assess the supporting documentation, which concluded in September 2013 that there was no specific scientific evidence, in terms of risk to human and animal health or the environment that would support the notification of an emergency measure.²⁰⁸ However, up to the present day the Italian ban remains in place.

France²⁰⁹ has invoked emergency measures on two occasions. In February 2008 France informed the Commission of the adoption of a Ministerial Order²¹⁰ prohibiting the cultivation in view of the placing on the market of varieties of seeds derived from GM maize MON810 until a decision had been taken on the renewal of the authorisation to place this GM crop on the market. The Commission submitted the documentation to EFSA, which decided that there was no new scientific evidence that would invalidate the previous risk assessments.²¹¹ It is to be noted that France only informed the Commission after the adoption of the emergency measure and thus did not abide by Article 54 of the General Food Law Regulation.

In 2012, France communicated a new emergency measure to the Commission²¹² The communication was followed by the publication in March 2012 of a National Decree banning MON 810. The EFSA GMO Panel again did not support the scientific documentation provided by France and concluded that MON 810 was as safe as conventional maize.²¹³ As in Italy, the ban remains in place.

Luxembourg²¹⁴ adopted a National Decree in March 2009 to prohibit the cultivation of MON 810 on its territory. In June 2012 Luxembourg provided to the European Commission scientific argumentation in support of its request for the prohibition of the placing on the market of the genetically modified maize MON 810. The EFSA GMO Panel concluded that, based on the documentation submitted by Luxembourg, there was no specific scientific evidence that would invalidate its previous risk assessments of the maize crop.²¹⁵ The ban has been in place since 2009.

²⁰⁵ Regulation 1829/2003, op.cit., art. 5(5).

²⁰⁶ The renewal of authorisation is still ongoing, see http://ec.europa.eu/food/dyna/gm_register/index_en.cfm - latest update: 12 August 2014.

²⁰⁷ Italy: National GM crop situation, *Greenbiotech.eu*, <http://greenbiotech.eu/eu-gm-crops/italy/>

²⁰⁸ EFSA Scientific Opinion, EFSA Journal 2013, 11(9).

²⁰⁹ France: National GM crop situation, *Greenbiotech.eu*, <http://greenbiotech.eu/eu-gm-crops/france/>

²¹⁰ Arrêté du 5 décembre 2007 suspendant la cession et l'utilisation des semences de maïs MON 810; art. 1 : "La cession à l'utilisateur final et l'utilisation des semences de maïs issues de la lignée de maïs génétiquement modifié MON 810 mentionnées dans l'arrêté du 3 août 1998 susvisé sont suspendues sur le territoire national jusqu'à la publication d'une loi relative aux organismes génétiquement modifiés et au plus tard jusqu'au 9 février 2008."

²¹¹ EFSA Scientific Opinion, EFSA Journal 2008, 850(45).

²¹² For a translation of the document that was sent by France to the Commission, see <http://www.nature.com/nbt/journal/v31/n6/extref/nbt.2613-S1.pdf>.

²¹³ EFSA Scientific Opinion, EFSA Journal 2012, 10(5).

²¹⁴ Luxembourg: National GM crop situation, *Greenbiotech.eu*, <http://greenbiotech.eu/eu-gm-crops/luxembourg/>

²¹⁵ EFSA Scientific Opinion, EFSA Journal 2013, 3372.

With regards to Article 34 concerns have been raised regarding its appropriateness as a mechanism to invoke unilateral measures against the cultivation of a GM crop.²¹⁶ Originally, the Article was designed to be used in the case of genuine emergencies such as mad cow disease (BSE) and Creutzfeldt–Jakob disease (CJD).²¹⁷ This explains why the Commission has a strict time limit of ten days to decide if the emergency measures are lawful.

It is arguable that the use of the Regulation's emergency measure as a safeguard against cultivation is less appropriate than the use of Article 23 under Directive 2001/18 since the latter is much more detailed and is based much more clearly on the precautionary principle. Moreover, the Regulation only provides for an authorisation to be suspended or modified when the need is urgent whereas the Directive, in contrast, allows a product to be provisionally restricted or prohibited. Moreover under Article 34 the Commission is not obliged to consult the European Food Safety Authority, contrary to this obligation under Directive 2001/18.²¹⁸ Furthermore it can be argued that the concept of 'emergency' stands in contrast to the nature of the scientific arguments that have been invoked by Italy and France to support the emergency measures, referring namely to long term impacts of MON 810.²¹⁹

2.3 The Commission's infringement action

As previously described, the measures Member States may invoke under Article 23 of Directive 2001/18 are 'provisional' and the emergency measures under Article 34 of Regulation 1829/2003 are 'interim'. In both cases a Union control procedure applies and the final decision on the appropriateness and lawfulness of the measures is taken at EU level.

The theory of the applicable Comitology procedure seems rather straightforward. To repeat briefly, it starts with a draft proposal from the Commission²²⁰ regarding the national measure that is subsequently submitted to a Scientific Committee. Within three months, the Committee has to deliver an opinion on the matter by qualified majority. If no such vote is reached or if no opinion is delivered, the proposal is forwarded to the Council which also has to find a qualified majority within three months to adopt or reject the Commission's proposal. If again a qualified majority is nowhere to be found, the Commission is obliged to adopt the decision, in accordance with Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission.

The practice of national bans invoked under Directive 2001/18 and Regulation 1829/2003 has shown that when it comes to GMOs, putting Comitology to practice is not so straightforward. The Union's reaction pattern to national safeguard measures shows the following trends.

Firstly, the Commission has requested the opinion from the European Food Safety Authority to assess the scientific grounds of the national measures each time a Member State provided scientific documentation with the communication of its national measure. The Commission even consulted EFSA when those measures were invoked under Article 34 of Regulation 1829/200 and under which this consultation is not obligatory.

Secondly, the GMO Panel of the Food Safety Authority has on every occasion so far rejected the scientific argumentation provided by the Member States. Time after time, EFSA concluded that there was no new scientific evidence that would invalidate previous risk assessments and justify the safeguard measures.

²¹⁶ COMMISSION, *Report on the evolution of the EU legislative framework in the field of GM Food and Feed*, Directorate-General for Health and Consumers, Food Chain Evaluation Consortium, 2010, p. 81.

²¹⁷ S. POLLI, *op.cit.*, p. 129.

²¹⁸ European Policy Evaluation Consortium (EPEC) for DG SANCO, European Commission, *Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003, and the placing on the market of GMOs as or in Products under Directive 2001/18/EC*, 2011, p. 52 – 53.

²¹⁹ EPEC Report on the evolution of the EU legislative framework in the field of GM Food and Feed, p. 82.

²²⁰ If measures are taken under Directive 2001/18, the Commission has to consult the European Food Safety on the matter.

The third trend is the Commission has not been very bold in its action against national bans. As regards the safeguard measures invoked by Luxembourg and Italy, the Commission renounced from further action after EFSA delivered its opinion. However, according to the regulatory procedure, the Commission should draw up a draft proposal on the national measures and submit it to a Scientific Committee for an opinion. This should be done after the measures have been communicated and within a time-limit of 60 days for safeguard measures under Directive 2001/18 and 10 days for emergency measures under Regulation 1829/2003.

The Commission has only taken this step against the national bans in Austria, Hungary, France and Greece. In the case of the French²²¹ and Greek²²² national bans, the Commission's draft stranded in the Standing Committee since France and Greece, supported by nine other Member States, requested a postponement of the vote on until a decision on the renewal of the authorisation of maize MON810 was adopted, underlining that EFSA had not yet finalised the risk assessment of MON810 in the context of this renewal procedure.²²³

As regards the Commission's proposals to repeal the national bans in Hungary²²⁴ and Austria²²⁵, the Scientific Committee did not deliver an opinion. Therefore the proposals were submitted to the Environment Council, who supported the Member States measures and rejected the Commission's proposals with a qualified majority.²²⁶

In Luxembourg and Italy the bans remain in place, unchallenged by the Commission. France and Greece are awaiting the decision on the authorisation renewal of MON 810. It is to be noted that France originally invoked Article 34, which means that its 'emergency measures' have been in place for a very long time. The Hungarian and Austrian bans are the only national measures that have undergone the Comitology procedure. Albeit not in accordance with EFSA's opinion and the Commission's proposal to repeal, these measures were in the end considered justified by the Environment Council.

As a matter of exception, the issue of national bans has made it to the European Court of Justice. The *Pioneer Hi Bred* case²²⁷ concerned a de facto moratorium on GM crops through an additional national authorisation procedure. The Court ruled that Member States are not entitled to make the cultivation of GMOs authorised under Regulation No 1829/2003 and listed in the common catalogue pursuant to Directive 2002/53 conditional on national authorisation based on considerations of protection of health or the environment.

In *Monsanto vs. Others*²²⁸ the Court of Justice described the substantive conditions for the use of Article 34 of Regulation 1829/2003. With regard to procedural conditions, the Court gave France a tap on the knuckles since it had adopted its emergency measures before informing the Commission.

This concise overview of the practice of national bans under the GMO legislative framework shows that the EU has a significant problem when it comes to Member States abiding by the rules.

Moreover it is argued that the Commission, despite of its role as "guardian"²²⁹ of the correct implementation of the European law, "has failed to ensure legal compliance with EU legislation, in full knowledge of non-compliant practices by several Member States."²³⁰

²²¹ COMMISSION DECISION concerning the provisional prohibition in France of the cultivation of seeds of genetically modified maize, http://www.saveourseeds.org/downloads/COM_draft_french_ban_Mon810_D003704-01-00-EN.pdf.

²²² COMMISSION DECISION concerning the provisional prohibition in Greece of the cultivation of seeds of genetically modified maize, http://www.saveourseeds.org/downloads/COM_draft_greek_ban_Mon810_D003703-01-00-EN.pdf.

²²³ COMMISSION, Report on the evolution of the EU legislative framework, p. 81.

²²⁴ Proposal for a Council Decision concerning the provisional prohibition of the use and sale in Hungary of genetically modified maize, 21 January 2009 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0012:FIN:EN:PDF>

²²⁵ Proposal for a Council Decision concerning the provisional prohibition of the use and sale in Austria of genetically modified maize, 10 February 2009, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0056:FIN:EN:PDF>.

²²⁶ For Hungary: COUNCIL Decision of 20 February 2007,

http://www.saveourseeds.org/downloads/Council_HU_ban_20_feb_2007.pdf;

For Austria: COUNCIL Decision of 18 December 2006,

http://www.saveourseeds.org/downloads/Council_decision_Austrian_ban_2006.pdf.

²²⁷ ECJ, Case C-36/11, *Pioneer Hi Bred Italia Sri v. Ministero delle Politiche agricole alimentari e forestali*, 2012.

²²⁸ C-58/10 to C-68/10, op.cit.

The statement of the Italian Ministry of Agriculture, when it adopted a national ruling to ban the cultivation of MON 810 is exemplary for the situation. The Ministry admitted that its national ruling might be inconsistent with the European law but also added that it would be unlikely that the European Commission would open an infringement procedure against Italy since in previous alike cases the European Commission did not take any action.²³¹

According to a Report from the European PPP Expertise Centre, “there is a general understanding that the use of national safeguard measures, while presented as having a scientific justification, is sometimes an expression of frustrations with the current risk assessment practice.”²³²

This finding is proven by the practice of national bans and the Union action pattern. In its Decisions addressing the Austrian and Hungarian national measures, the Environment Council referred to the environmental risk assessment as provided in Directive 2001/18/EC and indicated that “the different agricultural structures and regional ecological characteristics in the European Union need to be taken into account in a more systematic manner in the environmental risk assessment”.²³³

Section B. Under the GMO legislation: Directive 2002/53

1. Article 16 in theory

To be cultivated in the EU, a GM seed variety, like any other seed variety, needs to be registered in the European Union’s common seed catalogue of agricultural plant varieties. This common catalogue is established by Directive 2002/53²³⁴. The catalogue is composed on the basis of Member States’ national catalogues. The aim of this Directive was to lay down uniform quality requirements for plant varieties, in the light of the common agricultural policy.²³⁵

Recital 11 states that seed covered by this Directive should be freely marketable within the Community once it has been published in the common catalogue. Consequently, Member States may not make a seed variety subject to marketing restrictions.²³⁶ Directive 2002/53 explicitly addresses genetically modified varieties in numerous places.

A Member State may prohibit the use of the variety in all or in part of its territory when it is established “that the cultivation of the variety could be harmful from the point of view of plant health to the cultivation of other varieties or species”.²³⁷ A Member State may also prohibit the use of a variety or lay down appropriate conditions for its cultivation when the Member States provides “valid reasons for considering that the variety presents a risk for human health or the environment”.²³⁸

The wording of Article 16 under Directive 2002/35 bears resemblance to the safeguard measures under Directive 2001/18 and Regulation 1829/2003. It also refers to a risk for human health and the environment. The reference to plant health seems evident.

²²⁹ T.A. BORZEL, M. KNOLL, “Quantifying non-compliance in the EU – A database on EU infringement procedures”, *Berlin Working Paper on European Integration*, n° 15, 2012, p.8, http://www.polsoz.fu-berlin.de/polwiss/forschung/international/europa/arbeitspapiere/2012-15_BoerzelKnoll_Non-Compliance.pdf?1367709772

²³⁰ “National bans scientifically unfounded and legally questionable”, *Greenbiotech.eu*, <http://greenbiotech.eu/2013/08/12/national-gm-bans-scientifically-unfounded-and-legally-questionable/>

²³¹ Decreto del Presidente del Consiglio dei Ministri 4 agosto 2000 Sospensione cautelativa della commercializzazione e dell'utilizzazione di taluni prodotti transgenici sul territorio nazionale, http://www.arpa.emr.it/cms3/documenti/alimenti/normativa/DPCM_04ago2000.pdf.

²³² EPEC Report on the evolution of the EU legislative framework in the field of GM Food and Feed, p 52.

²³³ COUNCIL Decision of 20 February 2007 and 18 December 2006, op.cit.

²³⁴ COUNCIL DIRECTIVE 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species.

²³⁵ The legal basis for Directive 2002/53 is Article 37 of the EC Treaty, which was replaced by Article 43 TFEU.

²³⁶ DIRECTIVE 2002/53/EC, op.cit., art. 16 (1).

²³⁷ DIRECTIVE 2002/53/EC, op.cit., art. 16 (2)a.

²³⁸ DIRECTIVE 2002/53/EC, op.cit., art. 16 (2)c.

Article 16 lacks an explicit reference to a need for scientific evidence to support the prohibiting measures, although it might be “expected that these problems are scientifically established”²³⁹.

It is to be noted that, in comparison to Directive 2001/18 and Regulation 1829/2003, Article 16 has a more explicit wording in that it states that a Member State “may, upon application (...) be authorised to prohibit the use of a variety”. This implies a Union control procedure, and reference is made to the regulatory committee procedure under article 5 and 7 of Council Decision 1999/468/EC.²⁴⁰

Since restrictive measures are subject to an authorisation, Member States may not adopt them before a final decision is reached according to the regulatory procedure. However, Article 18 provides for Member States to impose such measures as soon as the application is lodged, when “there is imminent danger of the spread of harmful organisms or imminent danger for human health or for the environment”.²⁴¹

2. Article 16 in practice

Article 16 as a safeguard clause has not been as popular with Member States as Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003. Only two Member States have made recourse to the Article.

Greece has attempted to prohibit a number of GM seeds under this provision. In March 2005 Greece asked the Commission to authorise a national measure based on Article 18 of Directive 2002/53 to prohibit, amongst other seeds for marketing, the cultivation of MON810.²⁴² The Greek authorities claimed that the prohibition measure was necessary because the cultivation of MON810 might cause adverse effects to the Greek rural environment. Since no supporting information was supplied, the Commission asked for clarifications. The Greek authorities replied that the adverse effects it was concerned about were of an economic nature and did not concern the environment in general or human health. Thus the Commission denied authorisation of the measure arguing that none of the specific provisions of Article 18 were applicable.²⁴³

Poland has been more successful in relying on the safeguard clause of Directive 2002/53. In March 2005 the Polish authorities made a request to the Commission for the adoption of a restrictive measure under Article 16. Since it was “well known” that the maturity class of the varieties concerned was too high to be suitable for cultivation in Poland, the Commission found the climatic and agricultural factors invoked to “provide a permanent obstacle to cultivating these varieties”. The Commission therefore granted the application of the prohibition.²⁴⁴ It is to be noted that this is the first (and so far last) time the Commission did not oppose a Member States’ recourse to a safeguard clause.

²³⁹ M. LEE, *EU Regulation of GMOs: Law and decision-making for a new technology*, Cheltenham, Edward Elgar Publishing Limited, 2008, p. 91.

²⁴⁰ DIRECTIVE 2002/53/EC, op.cit., art. 23 (2).

²⁴¹ DIRECTIVE 2002/53/EC, op.cit., art. 18.

²⁴² It concerned a Ministerial Order prohibiting for the growing seasons of 2005 and 2006 the marketing of 17 genetically modified varieties.

²⁴³ COMMISSION DECISION 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, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:007:0027:0028:EN:PDF>

²⁴⁴ COMMISSION DECISION of 8 May 2006 authorising the Republic of Poland to prohibit on its territory the use of 16 genetically modified varieties of maize with the genetic modification MON 810 0 listed in the Common catalogue of varieties of agricultural plant species, pursuant to Council Directive 2002/53/EC, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:124:0026:0028:EN:PDF>

Section C. Internal Market rules: Art 114 (5) TFEU

It is established that under the GMO legislative framework, namely under Directive 1001/18 and Regulation 1829/2003, as well as under the adjacent seed legislation of Directive 2002/53, Member States have discretionary authority, although very restricted, to invoke safeguard measures against the cultivation of GM crops.

It will be examined hereafter how the Treaty of the Functioning of the European Union provides Member States another possibility to prohibit or restrict cultivation. As an alternative route for autonomous action from Member States²⁴⁵, the main question of interest is to what extent Member States can exercise their discretionary authority under the TFEU provision.

Article 114 (5) TFEU allows derogations from measures adopted on the basis of Article 114 (1) which provides for the harmonisation of internal market laws. Member States can invoke Article 114 (5) to (attempt to) justify the introduction of new measures in conflict with Directive 2001/18 and Regulation 1829/2003. Since Article 114 (5) relates to the protection of the (working) environment, it is considered as an environmental safeguard clause.

Article 114 (5) reads as following: “If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence, relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.”

It is noted that the Article in itself seems rather straightforward. New, scientific evidence is to be presented, demonstrating a problem specific to a Member State’s territory, which has arisen after the adoption of the harmonising act. These requirements are cumulative.

However, Article 114 (5) is anything but straightforward. To fully grasp a Member State’s discretionary authority under this provision, it is therefore necessary to thoroughly look into the relating case law.

1. Article 114 (4) vs 114 (5) TFEU

Article 114 does not only provide for Member States to introduce new measures derogating from harmonised law. Via Article 114 (4), after the adoption of a harmonisation act on EU level, Member States may also maintain national provisions, when they are deemed necessary on grounds of major needs referred to in Article 36 TFEU. Since paragraph (4) covers the preservation of existing national measures and since this is less relevant in the light of this thesis, this Section will primarily focus on paragraph (5).

However, the difference between these two consecutive paragraphs does reveal some of the characteristics of Article 114. Whereas paragraph (4) allows Member States to invoke grounds such as public morality, public policy, the protection of health and life of humans, animals or plants,²⁴⁶ paragraph (5) is limited to the protection of the environment or the working environment. This difference was addressed by the Court of Justice and explained by the logical consequence of the fact that the adoption of new national legislation is more likely to jeopardise the internal market²⁴⁷ than stricter measures which existed before and which the EU institutions already knew of but chose not to

²⁴⁵ M. LEE, *EU Regulation of GMOs: Law and decision-making for a new technology*, Cheltenham, Edward Elgar Publishing Limited, 2008, p. 92.

²⁴⁶ TFEU art. 36. Other grounds are: public security, the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property.

²⁴⁷ M. LEE, *op.cit.*, p. 93.

take in account when adopting the harmonisation act.²⁴⁸ Thus national measures under paragraph (5) allow the pursuit of a very limited range of objectives, namely solely the protection of the (working) environment. This demonstrates the EU's cautious approach towards giving Member States margin to derogate from harmonised rules.

2. Substantive requirements of Article 114 (5) TFEU

With regards to its substantive requirements, Article 114 (5) has been a much debated subject. The provisions have proven to be in need of further interpretation. Jurisprudence from the Court of Justice has contributed to, and - for the most part - established the now generalised understanding of the novelty and specificity requirement. However, this has also contributed to the view that the substantive provisions to be complied with to obtain Commission approval for a new national measure, are very hard to meet.²⁴⁹ On the basis of the existing case law it will be demonstrated that indeed the interpretation of 'new scientific evidence', in addition to the 'specific problem', limits the Member States' discretionary authority to a minimum.

The case central to this examination is *Land Oberösterreich and Republic of Austria vs. Commission*. The case concerned a notification to the Commission from Austria pursuant to Article 95 (5) EC²⁵⁰, the former Article 114 (5) TFEU. Under their 2002 draft Act on the prohibition of Genetic Engineering²⁵¹, Austria planned to ban the use of all GMOs in the province of Upper Austria, in derogation from the provisions of Directive 2001/18. The Austrian Act was aimed at protecting the organic agriculture in the region as well as at the protection of nature, natural biodiversity and the environment.

The Commission requested an opinion on the matter from the - at that time newly established - European Food Safety Authority. EFSA concluded that Austria's request lacked of new scientific evidence. The Commission decided to deny Austria the application of Article 114 (5).²⁵² Austria brought its case for the Court because it was convinced that the notified measure was intended to protect the environment, that it was based on new scientific evidence, justified by a problem specific to Austria and that it complied with the principle of proportionality. The Court however dismissed Austria's action as well.²⁵³ Subsequently Austria made an appeal to the European Court of Justice to have set aside the first judgement. The Court of Justice ruled that Austria did not fulfil the requirements under Article 95 (5) EC and dismissed its plea as well.²⁵⁴

2.1 The novelty requirement

Article 114 (5) requires that Member States must refer to "new scientific evidence" as the basis for introducing restrictive national measures. There are two possible interpretations of this requirement: broad and narrow.²⁵⁵

²⁴⁸ CJEU, Case C-512/99, *Germany vs. Commission*, 21 January 2003, par. 41.

²⁴⁹ M. ONIDA, "The practical application of Article 95 (4) and 95 (5) EC Treaty: What lessons can we learn about the division of competences between the EC and the Member States in product-related matters?", in *EU and WTO Law: How tight is the legal straitjacket for environmental product regulation?*, Brussels, University Press, 2006, p. 101.

²⁵⁰ Art. 95 (5) Treaty Establishing the European Community. This article has the same wording as Art. 114 (5) TFEU.

²⁵¹ Provincial Act, prohibiting the cultivation of genetically modified seed and planting material and the use of transgenic animals for breeding purposes as well as the release of transgenic animals especially for the purposes of hunting and fishing (Upper Austrian Act prohibiting genetic engineering 2002).

²⁵² 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, 2 September 2003, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:230:0034:0043:EN:PDF>.

²⁵³ CFI, Joined Cases T-366/03 and T-235/04, *Land Oberösterreich and Republic of Austria vs. Commission*, 5 October 2005.

²⁵⁴ CJEU, Joined cases C-439/05 P and C-454/05 P, *Land Oberösterreich and Republic of Austria vs. Commission*, 13 September 2007.

²⁵⁵ See F. FLEURKE, "What use for Article 95 (5) EC", *Journal of Environmental Law*, 2008, vol. 20 n° 8, p. 269.

The narrow approach refers to the text of paragraph (5) which states that only scientific data “arising after the adoption of harmonisation measure” are taken into account. This implies that a brand new problem must have emerged. On the contrary, the broad approach takes into account all relevant knowledge, including information available at the time of adoption of a measure.

It will now be demonstrated how the Commission and the Court of Justice have adopted the narrow approach.

In *Land Oberösterreich*, Austria advanced the ‘Müller Study’²⁵⁶ as new scientific evidence. The study invoked long-term negative effects of GMOs on GM-free agricultural production and naturally occurring crop formations. EFSA answered the ‘scientific evidence’ requirement by concluding that no evidence was presented in the report to show that coexistence was an environmental or human health risk issue. The Commission contributed to the ‘novelty’ requirement and argued that the data invoked in the report “were for a large part available prior to the adoption of Directive 2001/18”. Furthermore the Commission dismissed Austria’s argument that the report was released about a year after the date of adoption of Directive 2001/18, since it found that the vast majority of the sources referred to in the bibliography were published prior to the adoption of the Directive.²⁵⁷ The Court of First Instance did not enter into detail regarding the novelty requirement and merely stated that Austria “failed to provide convincing evidence such as to cast doubt on the merits of those (risk) assessments”.

It can be concluded that in this case the Commission set the bar very high. Not only did it literally require new evidence, it also rejected existing scientific evidence “that might throw new light on the nature or degree of risk”.²⁵⁸ Furthermore it is noted that the judgements of the Court of First Instance and Court of Justice did not make any contributions in this case to the interpretation of the novelty requirement.

The narrow approach has been confirmed in *Artegodan vs. Others*²⁵⁹. This case concerned a withdrawal by the EU of a marketing authorisation for diet pills. Albeit Article 114 (5) TFEU was not invoked, the judgement is relevant since it took a similar narrow approach to the interpretation of the novelty requirement. In this case the Court of First Instance stated that “only where a new potential risk is substantiated (...) by new objective scientific data (...), the application of a new assessment criterion is justifiable (...) only if that development is based on new data or information”.²⁶⁰ Unlike in *Land Oberösterreich*, the Court did address the issue of newness. From the Court’s statement it can be concluded that a ‘new criterion’ is not enough, it must also be based on “new data”, thereby rejecting again the possibility to shed a new light on existing data with a new assessment criterion.

Does this mean that there is no room at all for the broad approach? When delivering her opinion on *Land Oberösterreich*, Advocate General Sharpston did not reject the broad approach and stated: “I do not think it necessary to look further in order to reach the view that new conclusions drawn from existing data may constitute new scientific evidence”.²⁶¹ This approach can be considered more “generous”²⁶².

²⁵⁶ “Genetically modified-free areas of farming: conception and analysis of scenarios and steps for realisation”, Werner Müller, 28 April 2002 (carried out on behalf of the department for environment of the region of Upper Austria and of the Federal Ministry for social security and generations).

²⁵⁷ COMMISSION Decision 2003/653/EC, op.cit., par. 64 -67.

²⁵⁸ F. FLEURKE, op.cit., p. 270.

²⁵⁹ CFI, Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan GmbH vs. Others*, 26 November 2002.

²⁶⁰ For the full text, see CFI T-74/00, op.cit., in par. 194: “withdrawal of a marketing authorisation must in principle be regarded as justified only where a new potential risk or the lack of efficacy is substantiated by new, objective, scientific and/or medical data or information. In particular, it is entirely logical that the application of a new assessment criterion, which reflects a current consensus in the medical community, is justifiable during the period of the authorisation’s validity only if that development is based on new data or information.”

²⁶¹ CFI, Joined Cases T-366/03 and T-235/04, op.cit., Opinion of AG Sharpston, 15 May 2007, par. 194.

²⁶² M. LEE, op.cit., p. 95.

Furthermore, in this context a reference to Article 114 (4) should be made. Although this provision does not require new scientific evidence, it is interesting to note that the Court of Justice, in *Denmark vs. Commission*, ruled that Member States can legitimately rely upon a national risk assessment diverging from that made by the Community legislature in the harmonisation measure without having to base the assessment on new or different scientific evidence.²⁶³ The Court of Justice's approach under Article 114 (4) demonstrates that the broad approach can be accepted but only in the case where Member States plan to maintain existing national measures, as opposed introducing new measures.

2.2 The specificity requirement

Cumulative to the novelty requirement, Article 114 (5) requires that a new national measure has to be concerned with the protection of the (working) environment “on grounds of a problem specific to that Member State”. The timing of the emergence of the new scientific data and the awakening of an environmental problem are thus inherently linked. The interpretation of ‘specific’ has been a debated topic as well.

In *Land Oberösterreich*, Austria unsuccessfully claimed that the issue of coexistence of GMOs and natural crops was a problem specific to Austria. It argued that its small structured agricultural sector and the importance of organic agriculture were specific to the region of Upper Austria. The European Food Safety Authority however did not corroborate this justification and stated that Austria had failed to present evidence that this area of Austria had indeed “unusual or unique ecosystems” that required separate risk assessments from those conducted for Austria as a whole or for other similar areas of Europe.²⁶⁴ The Commission stood with EFSA's opinion: “small-structured farming systems are certainly not specific to this region and exist in all Member States”.²⁶⁵

When the case was brought to the Court of First Instance and later the Court of Justice, the issue was simply not assessed since the Court had already found Austria failing to fulfil the other cumulative requirement of ‘new scientific evidence’. Thus, the requirement of ‘specific to the Member State’ criterion was left unresolved in this case.

The question remained: what does ‘specific problem’ mean? Does it refer to a problem that is unique to a Member State's territory? And do Member States have to prove that it concerns a new phenomenon?

In *Netherlands vs. Commission*,²⁶⁶ the Netherlands Government invoked Article 114 (5) to derogate from the Air Quality Directive²⁶⁷ and argued that it was confronted with a specific problem of air quality because of its geographical situation. As regards the meaning of ‘a problem’, the Court of First Instance referred to “a new phenomenon (that) arises in all or part of a Member State's territory, which has negative effects on the (working) environment and which could not be taken into account in the preparation of the harmonised rules”.²⁶⁸

As regards the interpretation of ‘specific’, AG Tizzano took a strict approach in *Germany vs. Commission*. He claimed that there is either a real country-specific problem, that was not known at the time of adoption of the harmonisation measure, or nothing justifies allowing a Member State to introduce a stricter measure because in that case there is no reason why the measure would not apply to all the Member States.²⁶⁹ However, in *Netherlands vs. Commission*, the Court of First Instance observed that for a problem to be considered “specific” it was not necessary that it was the result of an

²⁶³ CJEU, C-3/00, *Denmark vs. Commission*, 20 March 2003, par. 63.

²⁶⁴ COMMISSION Decision 2003/653/EC, op.cit., par. 71.

²⁶⁵ COMMISSION Decision 2003/653/EC, op.cit., par. 70.

²⁶⁶ CFI, C-182/06, *Netherlands vs. Commission*, 27 June 2007.

²⁶⁷ COUNCIL Directive 1999/30/EC relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air, 23 June 1999.

²⁶⁸ CFI, C-182/06, op.cit., par. 61.

²⁶⁹ Case C-512/99, op.cit. par. 73 – 76.

environmental danger within that State alone.²⁷⁰ The Court thus rejected that a ‘unique problem’ was to be demonstrated and ruled that in the context of the occurrence of a general, cross-border danger, local particularities might constitute a specific problem. This judgement elaborated on AG Sharpston’s opinion in *Land Oberösterreich* that “the word ‘specific’ in Article 95(5) EC cannot be equated with ‘unique’”.²⁷¹ Her opinion also stated that “a specific problem clearly lies somewhere between one which is unique and one which is common, generalised or widespread”.²⁷²

In any case, the Member State invoking a specific problem must “establish something distinctive about the impact of GMOs in its territory rather than others, and not just a different understanding of acceptable risks”.²⁷³

2.3 The precautionary principle

The question arises whether the precautionary principle can be invoked to justify a derogation measure under Article 114 (5) TFEU. A number of Member States have relied on this principle to support their national measures.²⁷⁴

In order to invoke the precautionary principle under paragraph (5), “something more than scientific uncertainty” is to be demonstrated by the Member States.²⁷⁵ Indeed, a justification based on the precautionary principle does not relieve a Member State from the obligation to fulfil the specificity and novelty requirement. Furthermore, the precautionary principle does not enable Member States to take in account other considerations than the protection of the (working) environment when taking a risk management decision in the form of a national measure. This is because it is assumed that the Community legislator has already considered these concerns in the legislative process pursuant to Article 114 (1) TFEU.²⁷⁶

Although a substantive body of case law is not available, the Commission and the Court of Justice tend to favour a narrow interpretation of the precautionary principle in the context of Article 114 (5).²⁷⁷ It is to be noted that the practice of Commission Decisions relating to national measures under paragraph (5) shows that the Commission takes a slightly more open approach than the Court. In for example the *Dutch Creosote* Decision the Commission accepted the precautionary principle as a justification for the national measure since it agreed with the Member State that the EU level of protection was not sufficiently high in the light of the Member State’s needs.²⁷⁸

In *Land Oberösterreich*, Austria invoked, amongst other arguments as described above, the precautionary principle. In its Decision, the Commission considered that the allegations made for recourse to the precautionary principle were too general and lacked substance. The Commission also referred to the fact that the Food Safety Authority had not identified a risk that would justify taking action on the basis of the precautionary principle.²⁷⁹ The Court of First Instance and the Court of Justice did not find it necessary to address the issue given the fact that the cumulative conditions of Article 95 (5) EC were not fulfilled.

²⁷⁰ CFI, C-182/06, op.cit., par. 65.

²⁷¹ CFI, Joined Cases T-366/03 and T-235/04, op.cit., Opinion of AG Sharpston, par. 110.

²⁷² Ibidem.

²⁷³ M. LEE, “Multi-level governance of GMOs in the EU: ambiguity and hierarchy”, in M. CARDWELL, L. BODIGUEL, *The Regulation of GMOs: Comparative Approaches*, Oxford, Oxford University Press, 2010, p. 19.

²⁷⁴ For a list of Commission Decisions under Article 114 (4) and (5) see . ONIDA, “The practical application of Article 95 (4) and 95 (5) EC Treaty: What lessons can we learn about the division of competences between the EC and the Member States in product-related matters?”, in *EU and WTO Law: How tight is the legal straitjacket for environmental product regulation?*, Brussels, University Press, 2006, p. 92 – 93.

²⁷⁵ J. ZANDER, *The Application of the Precautionary Principle in Practice: Comparative Dimensions*, Cambridge, Cambridge University Press, 2010, p. 132.

²⁷⁶ F. FLEURKE, op.cit., p. 273.

²⁷⁷ Ibidem. It is argued that outside the context of this provision, the European Courts have taken a more progressive approach.

²⁷⁸ COMMISSION Decision n° 2001/599 concerning draft national provisions notified by the Kingdom of the Netherlands on limitations on the marketing and use of creosote, 13 July 2001.

²⁷⁹ COMMISSION Decision 2003/653/EC, op.cit., par. 73.

3. Comparison to the safeguard measures under the GMO legislative framework

3.1 Similarities

What do Article 23 of Directive 2001/18, Article 34 of Directive 1829/2003, Article 16 of Directive 2002/53 and Article 114 (5) TFEU all have in common? They are all safeguard clauses. They provide Member States with the possibility to derogate from the harmonised rules and take unilateral measures to restrict or prohibit the cultivation of GMOs.

All of these safeguard clauses are aimed at giving Member States a possibility to take protective measures against an occurring risk related to the cultivation of a GM crop. At the core is a science-based approach, which entails that Member States must found their national measures on scientific evidence. Moreover, this evidence must be ‘new’.

Another common ground is that the substantive conditions of these safeguard clauses are interpreted very restrictively.

The requirement of ‘scientific evidence’ implies that the national measure cannot be based on a purely hypothetical approach to risk and that it should be based on suppositions that are scientifically verified.²⁸⁰ Moreover the measure must be “based on a risk assessment which is as complete as possible in the particular circumstances of an individual case”.²⁸¹ Lastly the outcome of this risk assessment must indicate that those protective measures are necessary. In essence it comes down to the fact that a Member State wishing to invoke safeguard measures must demonstrate a new element to the risk assessment, “rather than merely a risk management element.”²⁸²

The requirement that the scientific evidence must be ‘new’ - as interpreted by the case law of the Courts and Commission Decisions – implies that national measures cannot be justified by data that existed at the moment of the adoption of the harmonisation measures. A Member State wishing to invoke a safeguard clause must therefore present brand new scientific findings that prove the existence of a risk to the environment (or human health, see Differences).

3.2 Differences

Albeit very similar as regards their ultimate protection objective and substantive conditions, there are some differences to be noted between the different kinds of safeguard clauses.

Firstly, as regards the scope of their protection objectives, there is a notable difference. The scope of the safeguard clauses under the GMO legislative framework is broader than the scope under the TFEU environmental safeguard provision since the latter does not cover “human health”.

Secondly, Article 114 (5) gives to the Commission alone the authority to pass judgment on national measures, without Member State involvement through Comitology.

Thirdly, under Article 114 (5) TFEU, a Member State can issue a general ban against the cultivation of every authorised GM product.²⁸³ On the contrary, Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003 do not allow a general ban and for each GM crop a specific case-by-case risk assessment has to be conducted.

Furthermore, as regards the substantive condition of ‘new’ scientific evidence, Article 23 of Directive 2001/18 is less strict than Article 114 (5) TFEU. Article 23 allows “ a reassessment of existing information”. However it still requires that this is done “on the basis of new or additional

²⁸⁰ C-236/01, op.cit., par. 106.

²⁸¹ C-236/01, op.cit., par. 107.

²⁸² M. DOBBS, “Legalising general prohibitions on cultivation of genetically modified organisms”, *German Law Journal*, 2010, vol. 11, n° 12, p. 1355.

²⁸³ M. DOBBS, op.cit. p. 1357.

scientific knowledge”.²⁸⁴ With regards to the specificity requirement of Article 114 (5), this is not a substantive condition for the other safeguard clauses. This is a very remarkable difference because it implies that under the safeguard clauses of Regulation 1829/2003 and Directive 2001/18, a Member State can invoke new scientific evidence proving that a GM crop poses a risk to human health or the environment, without having to demonstrate that the invoked risk and the territory are inherently linked.

This leads to conclude that the safeguard provisions under the GMO legislative framework are more generous than the general internal market provisions of Article 114 (5) TFEU.²⁸⁵ Therefore it is not surprising that Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003 have been much more popular with Member States as a tool to ban GMO cultivation.

Section D. The science-based approach: is the straitjacket too tight?

It is established that Member States are granted a discretionary margin under both the GMO legislative framework and the general framework of the TFEU to restrict or prohibit the cultivation of GMOs. However it has also been demonstrated that the safeguard clauses that Member States can invoke, are of limited scope because of restrictively interpreted substantive conditions. The Commission, the European Food Safety Authority and the Courts have attempted to control their use stringently.

It is undeniable that a heavy burden of proof lies with Member States when they want to invoke safeguard measures. This can be demonstrated by the practice of national measures invoked under Article 23 of Directive 2001/18 and Article 34 Regulation 1829/2003. So far not one Member State has been successful in providing new scientific evidence that an authorised GM crop constituted a risk to human health or the environment. As regards the use of the environmental clause under Article 114 (5) TFEU, the few cases where the provision has been invoked to ban GMO cultivation, the Member States concerned were not able to pass the Courts’ scrutiny test with regard to the substantive conditions.²⁸⁶

It can be argued that these safeguard clauses are too difficult to be used, in particular in cases where risks do exist but where the required “newness” or “specificity” is either hard to prove or lacking at all. Especially in the case of Article 114 (5), where it seems impossible to fulfill all of these conditions cumulatively.

The requirement of ‘newness’ is virtually impossible to prove, or so it seems when one examines the series of Opinions from the European Food Safety Authority stating, time after time, that no new scientific evidence was demonstrated. This novelty requirement is interpreted in that Member States can rely only on scientific evidence that emerged after the adoption of the harmonisation act. This means that a Member State cannot rely on relevant information that might not have been taken into account by the EU legislator in the process of authorising a GM crop or in the process of adopting Directive 2001/18 or Regulation 1829/2003. However, this is an area of possible scientific uncertainty and it is possible to have varying interpretations of the existing data.²⁸⁷

The biggest stumbling block might be the fact that the use of safeguard clauses is limited to the protection of the environment or human health. Consequently concerns over ethics, freedom of choice, etc. are ignored. Grounds such as agricultural policy, public morality, public policy can not be

²⁸⁴ M. LEE, *EU Regulation of GMOs: Law and decision-making for a new technology*, Cheltenham, Edward Elgar Publishing Limited, 2008, p. 94.

²⁸⁵ M. LEE., “Multi-level governance of GMOs in the EU: ambiguity and hierarchy”, in M. CARDWELL, L. BODIGUEL, *The Regulation of GMOs: Comparative Approaches*, Oxford, Oxford University Press, 2010, p. 17.

²⁸⁶ At least not when it concerned GMO regulation. Article 114 (5) has been successfully invoked to derogate from other harmonised measures.

²⁸⁷ M. DOBBS, op.cit. p. 1358.

invoked to justify national measures banning GMO cultivation, although they might be affected.²⁸⁸ It is undeniable that the safeguard clauses are of limited scope compared to the wide breadth of concerns.

CHAPTER 2: A socio-economic approach?

Section A. Is there room for national measures based on socio-economic justifications?

The EU legislator has been very clear in determining the objective of a Member State's recourse to the existing safeguard measures. Nor the clauses under Article 23 of Directive 2001/18 or Article 34 of Regulation 1829/2003, nor the environmental safeguard of Article 114 (5) allow an opt-out for any other reason than the protection of human health or the environment.

In theory, this leaves no margin at all to justify a cultivation ban under the safeguard clauses on socio-economic grounds, such as agricultural policy, public morality, ethical and regional arguments, social and cultural policy objectives. However, some Member States have tried to rely on similar grounds to ban cultivation.

1. Land Oberösterreich

In *Land Oberösterreich*²⁸⁹ Austria raised concerns relating to the cultivation of EU authorised GM crops in the light of coexistence with its own organic agriculture. The Austrian authorities argued that the extensive use of GM seed would interfere with and, in the long-term, displace organic and conventional genetically modified-free production. Therefore Austria submitted a notification to the Commission pursuant to Article 95 (5) EC²⁹⁰ of a draft Act that would prohibit GMO cultivation in the province of Upper Austria.²⁹¹ The Müller study, which served to support Austria's arguments, found that genetically modified-free areas represented the only approach, which could ensure long-term security in relation to the problems of coexistence within the small structured Austrian agricultural sector.²⁹²

The question arose if Austria's arguments relating to coexistence and the agricultural sector type fell within the scope of the objective of Article 114 (5). The Commission, not surprisingly, answered that the concerns related "more to a socio-economic problem than to the protection of the environment or the working environment."²⁹³

Austria could have tried to prove that its concerns relating to coexistence fell within the scope of 'protection of the environment', although this would have been very hard to demonstrate. Yet, Austria did not even try to hide that its main objective was to safeguard organic protection.²⁹⁴

When the case came before the Courts, the issue was not (re)assessed since the Court focused on the absence of 'new scientific evidence'. However, it would have been interesting to see how the

²⁸⁸ M. DOBBS, "Legalising general prohibitions on cultivation of genetically modified organisms", *German Law Journal*, 2010, vol. 11, n° 12, p. 1351.

²⁸⁹ CFI, Joined Cases T-366/03 and T-235/04, *Land Oberösterreich and Republic of Austria vs. Commission*, 5 oktober 2005; and Joined cases C-439/05 P and C-454/05 P, *Land Oberösterreich and Republic of Austria vs. Commission*, 13 September 2007.

²⁹⁰ This provision preceded Article 114 (5) TFEU.

²⁹¹ 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, 2 September 2003, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:230:0034:0043:EN:PDF>.

²⁹² COMMISSION Decision 2003/653/EC, op.cit., par. 34.

²⁹³ COMMISSION Decision 2003/653/EC, op.cit., par. 67.

²⁹⁴ COMMISSION Decision 2003/653/EC, op.cit., par. 35, where the Müller study is quoted: "Given that the proportion of organic farmers is particularly high in Upper Austria (around 7 %), hardly any areas would be available for a GMO cultivation if the intention was to safeguard the organic production".

Courts would have ruled if the other substantive conditions of Article 95 (5) would have been fulfilled and the question came down to whether or not the ‘protection of the environment’- objective was at stake.

2. Lessons learned from *Commission vs. Poland*

In 2007, Poland notified to the Commission²⁹⁵ a provision of its Seed Law²⁹⁶ that would prohibit the cultivation of GMOs in its territory, in derogation to Directive 2001/18.²⁹⁷ In its communication to the Commission, the Polish authorities invoked “the need to fulfil the expectations of Polish society” as a ground for the derogation measure. Poland further argued that its agriculture was “fragmented to a very high degree”, which made it impossible to isolate GM crops from conventional and organic crops.²⁹⁸ The Commission declared that the Polish provision infringed both Directive 2001/18 and Seed Directive 2002/53, and concluded that Poland did not provide any new scientific argumentation to support a derogation under Article 114 (5) TFEU. Since Poland did not withdraw its restrictive measures after the Commission’s disapproval, the Commission brought Poland before the Court.²⁹⁹

In its argumentation before the Court, Poland took a new approach. It justified its derogation measures on the protection of public morality. In support, Poland relied on ethical and religious grounds. The argumentation referred to “the fact that it is well known that Polish society attaches great importance to Christian and Roman Catholic values”. Secondly, Poland stated that “the political parties with a majority in the Polish Parliament at the time when the contested national provisions were adopted, specifically called for adherence to such values”.³⁰⁰

Interestingly, public morality was not invoked as a separate justification, but as an aspect of the justification relating to protection of human health and the environment³⁰¹ Like in *Land Oberösterreich* the Court could have easily closed the case by repeating the Commission’s argument that, since Poland still did not provide any scientific evidence, the substantive conditions of the safeguard clauses were not fulfilled. However, the Court went beyond these observations and put Poland’s justification based on public morality to the test.

The Court first observed that Poland’s national measures pursued ethical objectives. Since ethical objectives are unrelated to the objectives of Directive 2001/18 and Directive 2002/53, namely the protection of the environment and of human health, the Court observed that they were outside the scope of those Directives. Consequently it was not possible to rely on the safeguard measures under this legislative framework. The Court further concluded that Poland’s restrictive measures then constituted an obstacle to the free circulation of goods, potentially in breach of Article 28 EC.³⁰² However the Court added that such a breach “in some circumstances” could be justified under Article 30 EC.³⁰³

Now, this observation could have been a turning point. It could have been the perfect opportunity for the Court to examine whether Article 30 EC was indeed applicable and to what extend Poland’s ethical reasoning could have withstood the scrutiny test of this provision. It could have been

²⁹⁵ Commission Decision 2008/62, 12 October 2007,

<http://policy.mofcom.gov.cn/english/flaw!fetch.action?libcode=flaw&id=05015B04-C167-488F-8F88-4B0B8BF8C01E>

²⁹⁶ see K. ZUREK, “When Lab results are not sufficient: on the limitations of science in tackling modern food regulatory concerns”, *Swedish Institute for European Policy Studies*, 2009, vol. 5, p. 6-8 for a further examination of the provisions of Polish Draft Act on Genetically modified Organisms, and in particular art. 172.

²⁹⁷ The provision allows the creation of zones specifically designated to the cultivation of GMOs. Such zones are assigned by the Ministry of Agriculture on the basis of an application, which has to be accompanied by written declarations from the holders of land within the area of spatial isolation from the land on which it is planned to cultivate genetically modified plants that they do not object to the intention to create a zone.

²⁹⁸ Poland stated that it has almost two million farms, and the average area of a farm is less than 8 ha. See Commission Decision 2008/62, op.cit., par. 26.

²⁹⁹ CJEU, C-165/08, *Commission vs. Poland*, 16 July 2009.

³⁰⁰ C-165/08, op.cit., par. 58.

³⁰¹ A. ANYSHCHENKO, *Role of science in EU environmental decision-making. A study of EU regulation of GMOs*, Master Thesis, Lund University, 2013, p. 34; and C-165/08, op.cit., par. 48.

³⁰² Article 28 EC, now Article 34 TFEU.

³⁰³ Article 30 EC, now Article 36 TFEU. See C-165/08, op.cit. par. 50.

the time and place to analyse a range of extension of public morality to environmental concerns.³⁰⁴ However none of this happened.

The Court concluded that “for the purposes of deciding the present case” it was not necessary to rule on these questions. The Court observed that Poland had not produced any evidence capable of establishing that, in adopting the prohibitions concerned, it was inspired by the ethical and religious considerations. Secondly the Court stated that a Member State cannot rely on the views of public opinion in order to unilaterally challenge a harmonisation measure.³⁰⁵ The Court referred to another case specifically concerning Directive 2001/18, in which it had ruled that a Member State may not plead difficulties of implementation which emerge at the stage when a Community measure is put into effect, such as difficulties relating to opposition on the part of certain individuals, to justify a failure to comply with the obligations of Community law.³⁰⁶ Thirdly the Court observed that the detailed reasons of a religious and ethical nature set out in the defence were not mentioned during the pre-litigation procedure, in the course of which Poland relied principally on considerations relating to the environment and public health.³⁰⁷ In other words, according to the Court, Poland had failed to establish that the true purpose of the contested national provisions was in fact to pursue the religious and ethical objectives relied upon.

So what lessons can be learned from *Commission vs. Poland*? Firstly it can be concluded that the Court will not easily accept ethical or religious concerns. To even be considered a justification ground for derogation measures, a Member State must go beyond a mere declaration that (a part of) its population has specific ethical values or a specific religious background. Secondly, it is noted that the Court seems willing to make examinations that go further than a pure assessment of the substantive conditions of a legal provision. However the hardest lesson to be learned is that this case did not reach its full potential, since it did not examine the margin for Member States to rely on justifications other than those relating to the ‘protection of human health or the environment’.

Nevertheless, this case does, however briefly, touches the scope of Article 34 and 36 TFEU, relating to the prohibition on quantitative restrictions in the light of the freedom of goods in the internal market. This issue will be addressed in Part III.

CHAPTER 4: Coexistence

In the light of describing a Member State’s discretionary authority to restrict or prohibit the cultivation of a GM crop under the existing GMO legislative regime, coexistence has an important role to play. It is the aim of this chapter to examine how coexistence measures provide Member States with another type of cultivation opt-out, in comparison to the science-based risk approach of the existing safeguard measures under Directive 2001/18, Regulation 1829/2003 and Article 114 (5) TFEU.

However it must be noted that a comprehensive review of the coexistence framework would go way beyond the scope of this thesis and therefore its description will be limited to what is relevant for the above described examination.

Section A. Coexistence measures to opt-out of cultivation?

³⁰⁴ A. ANYSHCHENKO, *op.cit.*, p. 50.

³⁰⁵ A. DE VEGA ALVAREZ, “Analysis of the Commission Decisions under Article 114(6) TFEU regarding the application by the Member States of Articles 114(4) and 114(5) TFEU relating to the protection of the environment or working environment: What conclusions can be made?”, 2011, p. 19, <http://dare.uva.nl/document/353347>; and C-165/08, *op.cit.* par. 59.

³⁰⁶ see CJEU, Case C-121/07, *Commission vs. France*, 9 December 2008, par. 72.

³⁰⁷ C-165/08, *op.cit.* par. 59.

1. Legal framework for coexistence

In the Commission's words, coexistence refers to "the ability of farmers to make a practical choice between conventional, organic and GM-crop production, in compliance with the legal obligations for labelling and/or purity standards"³⁰⁸ Coexistence measures are intended to facilitate the harmonious cultivation of each agritype, without excluding any.³⁰⁹ The roots of the concept lies in the recognition that the cultivation of GMOs is likely to have implications for the organisation of agricultural production. The possibility of (unintended) presence of GM crops in non-GM crops, and vice versa, raises the question as to how producer choice for the different production types can be ensured.³¹⁰ From the beginning, the Commission has recognised that an 'EU-answer' to this question, in the form of a harmonised legislative framework, would not be suitable, because of the diversity of specific regional and local agricultural factors. The Commission has always considered that measures to avoid the unintended presence of GMOs in conventional and organic crops should be developed and implemented by the Member States.³¹¹

Regulation 1829/2003 introduced this approach officially in the GMO legislative framework, by inserting a new Article 26a in Directive 2001/18:

"1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products;"³¹²

However the legislative framework for coexistence is not limited to this brief Article. The Commission adopted a guiding Recommendation in 2003³¹³, in an attempt to support Member States in the process of developing national measures to avoid that presence. The Commission's approach to coexistence management is a farm-level, crop-by-crop approach.³¹⁴

Since the Commission considered that the approach applied on the basis of the 2003 Recommendation did not exhaust the provisions of Article 26a, in 2010, the Commission issued a new Recommendation³¹⁵. This was part of the Commission's 2010 Cultivation Package, in the light of a growing need for more flexibility as regards Member States say on GMO cultivation.

With the competence lying at Member State level, a majority of Member States has developed national coexistence legislation.³¹⁶ Typical coexistence measures include a prescribed distance between fields where GM crops are being cultivated and fields where conventional or organic crops are cultivated. For example, in Germany a distance of 150 – 300 meters applies respectively.³¹⁷

³⁰⁸ COMMISSION Recommendation, doc n° 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, 23 July 2003, rec. 3 and Section 1.1 of the annexed guidelines.

³⁰⁹ M. DOBBS, "Excluding coexistence of GMOs? The Impact of the EU Commission's 2010 Recommendation on coexistence", Research Paper, Queen's University Belfast School of Law, 2013, p. 5.

³¹⁰ COMMISSION Recommendation 2003/556/EC, op.cit., rec. 1.

³¹¹ COMMISSION document, Communication from the Commission to the European Parliament, the Council, The Economic and Social Committee and the Committee of the Regions, on the freedom of Member States to decide on cultivation of genetically modified crops, 13 July 2010.

³¹² Directive 2001/18, op.cit., Article 26b. Paragraph (2) reads as following: "2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops."

³¹³ COMMISSION Recommendation 2003/556/EC, op.cit.

³¹⁴ M. WEIMER, "Risk regulation, GMOs, and the challenges to deliberation in EU Governance. Politicization and scientification as co-producing trends", Working Paper, Amsterdam Centre for European Law and Governance, 2014, p. 28.

³¹⁵ COMMISSION Recommendation, doc n° 2010/C 200/01, on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, 13 July 2010.

³¹⁶ By February 2009, 15 Member States have adopted specific legislation on coexistence (AT, BE, CZ, DE, DK, FR, HU, LT, LU, LV, NL, PT, RO, SE, and SK). In some of these Member States, the competence lies at regional level (AT, BE).

See COMMISSION REPORT on the coexistence of genetically modified crops with conventional and organic farming, 2 April 2009, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0153:FIN:en:PDF>

³¹⁷ Verordnung über die gute fachliche Praxis bei der Erzeugung gentechnisch veränderter Pflanzen (Gentechnik-Pflanzenerzeugungsverordnung – GenTPfIEV) Bundesgesetzblatt Jahrgang 2008 Teil I Nr. 13, at 658; http://www.keine-gentechnik.de/fileadmin/files/Infodienst/Dokumente/08_02_27_gfp_ausschuss_elv.pdf

2. A purely economical approach

According to the 2003 Recommendation, the issue of coexistence “concerns the potential economic loss and impact of the admixture of GM and non-GM crops”³¹⁸. The Commission reasons that, “since certain types of agriculture production such as organic production are often more costly, the possibility of losing the associated price premium due to unintended presence of GMOs may entail important economic damages to these types of production”. Therefore such production may require stricter segregation efforts. In addition, local constraints and characteristics may render these particular segregation needs very difficult and costly to be met efficiently in some regions.³¹⁹ This reasoning, in addition to the fact that “all environmental and health issues are dealt with in the authorisation process, and only authorised GMOs can be cultivated in the EU”,³²⁰ leads the Commission to consider coexistence as a purely economic issue.

This approach is repeated in the 2010 Recommendation. Surprisingly, Article 26A does not make mention of an economic objective. In fact, it doesn’t specify any other objective than “to avoid the unintended presence of GMOs in other products”.

Since the Commission’s approach of coexistence is narrowly downsized to its pure economical implications, other possible aspects such as consumer protection, morals, cultural benefits and even environmental and health protection are excluded, not only as elements that could potentially influence cultivation choices but “also as independent objectives”.³²¹

3. Limits of coexistence measures

Thus, the concept of coexistence grants Member States a discretionary authority to organise, and even exclude in certain areas, the cultivation of GM crops. However, there are some strict limitations.

Firstly, the economic understanding in itself is a limit³²², since it restrains Member States from invoking any other objectives than those of an economic nature. Secondly, the discretionary margin is also limited by the term ‘appropriate’ in Article 26a. This implies that coexistence measures must be proportionate. Furthermore coexistence is not an independent subject. National coexistence measures under Article 26a must also abide by the other provisions of Directive 2001/18, in particular Article 22 which states that the States “may not prohibit, restrict or impede the placing on the market of GMOs”.³²³

With regards to their purely economic nature, it can be argued that coexistence measures might seem peculiar, since basic internal market law in the EU prevents Member States from using economic arguments to justify an interference with the free movement of goods.³²⁴ The Courts’ case law demonstrates that economic interests are indeed not accepted as a legitimate objective to justify derogating national measures.³²⁵ However it is noted that coexistence measures are “intended to facilitate the management of cultivation rather than providing national prohibitions”.³²⁶ Thus when

³¹⁸ COMMISSION Recommendation 2003/556/EC, op.cit., rec. 5.

³¹⁹ COMMISSION Recommendation, 2010/C 200/01, op.cit., par. 2.1.

³²⁰ COMMISSION Recommendation 2003/556/EC, op.cit., par. 1.2. and M. WEIMER, op.cit., p. 30.

³²¹ M. DOBBS, op.cit., p 17.

³²² In the words of M. LEE: “an economic understanding of coexistence dramatically restricts national freedom of action.”

See “Multi-level governance of GMOs in the EU: ambiguity and hierarchy”, in M. CARDWELL, L. BODIGUEL, *The Regulation of GMOs: Comparative Approaches*, Oxford, Oxford University Press, 2010, p. 22.

³²³ Directive 2001/18, op.cit., art. 22.

³²⁴ O. INANILUR, “Derogation from the free movement of goods in the EU: Article 30 and ‘Cassis’ mandatory requirements”, *Ankara Review*, 2008, vol 2, p.1, <http://www.ankarabaru.org.tr/siteiler/AnkaraBarReview/tekmakale/2008-2/11.pdf>

³²⁵ For example see Case C-203/96 *Chemische Afvalstoffen Dusseldorp BV v Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer*, 25 June 1998, para 44.

³²⁶ M. DOBBS, “Legalising general prohibitions on cultivation of genetically modified organisms”, *German Law Journal*, 2010, vol. 11, n° 12, p. 1360

Member States adopt coexistence measures, in theory, they are not intended to be measures derogating from the harmonised legislative framework.

So far, coexistence measures have not been challenged for breach of EU law.³²⁷ Therefore the Courts have yet to rule on the acceptability of coexistence measures, including the objectives invoked by Member States and the proportionality of their measures. If a Member State would be brought for the Court, it is argued that it is unlikely that the Courts would follow the Commission's narrow interpretation of economic objectives.³²⁸ "Although unilateral action by Member States in order to protect the financial interests of farmers is seriously disapproved of by the Courts",³²⁹ such protection could be accepted by the Court as within the scope of 'appropriate measures' under Article 26. In any case, the starting point for the Court's scrutiny test would be the objective(s) chosen by the Member State for justifying their national measures.

Section B. GM-free regions

The Commission's Recommendation of 2010 made Member States able to extend coexistence beyond the restrictions of the previous guidelines.³³⁰ Moreover, it introduced the concept of "GM-free Regions", which allows Member States to exclude GMO cultivation from large areas of their territory.³³¹

This new approach seems significantly different from Recommendation 2003 which explicitly specified that no type of agriculture was to be excluded via national measures. In its 2006 report on the implementation of national coexistence measures, the Commission stated that general regional or national bans would not be legitimate coexistence measures³³² and would therefore have to be justified under Article 114 (5) TFEU or under Article 23 Directive 2001/18.

As regards the establishment of GM-free areas within their territory, Member States are not totally free. Such measures need to be "proportionate to the objective pursued", namely the protection of conventional or organic farming needs from unintended presence of GMOs, and Member States must demonstrate that "other measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops".³³³

The question arises to which extent the possibility to assign GM-free regions affects a Member State's discretionary authority to regulate cultivation. It has to be noted that the Commission recognizes more and more that differences in regional aspects, such as farm structures or climatic conditions need to be taken into account, in particular since these differences influence the degree of admixture between GM and conventional and organic crop. However the Commission still adheres to the economical approach, thus such GM-free regions can only be established in the light of economical priorities. Other motives previously cited - consumer protection, morals, cultural benefits and environmental and health protection – are still excluded. National measures under Article 26a can only be justified where the cultivation of specific GM-crops would be incompatible with ensuring coexistence.

³²⁷ However, coexistence has been invoked by Member States to justify derogation measures, see for example *Land Oberösterreich and Republic of Austria vs. Commission*, 13 September 2007 and Case C-36/11, *Pioneer Hi Bred Italia Sri v. Ministero delle Politiche agricole alimentari e forestali*, 6 September 2012.

³²⁸ M. DOBBS, "Excluding coexistence of GMOs? The Impact of the EU Commission's 2010 Recommendation on coexistence", Research Paper, Queen's University Belfast School of Law, 2013, p. 17.

³²⁹ M. DOBBS, op.cit., p. 18.

³³⁰ For instance Member States are now allowed to adopt measures ensuring the relative absence of GMOs from other products (and not just to respect the 0.9% labelling threshold).

³³¹ COMMISSION Recommendation, 2010/C 200/01, op.cit., par. 2.4.

³³² COMMISSION doc. n° 2006 (104), Report on the implementation of national measures on the coexistence of genetically modified

crops with conventional and organic farming, 9 March 2006.

³³³ COMMISSION Recommendation, 2010/C 200/01, op.cit., par. 2.4.

However criticism has been raised regarding the establishment of GM-free regions.³³⁴ It is argued that “the very existence of GMOs in several regions, or even in entire MS might lapse” and that this might possibly develop into an “abolition of the overall notion of coexistence”.³³⁵ These ‘fears’ can be supported by the fact that the GM-free movement is growing in Europe and by the fact that more and more regions are declaring themselves GM-free.³³⁶

CHAPTER 5: Conclusions

It was the aim of Part II to comprehensively describe a Member State’s discretionary authority to restrict or prohibit the cultivation of GM-crops. Both under the GMO legislative framework established by Directive 2001/18 and Regulation 1829, as well as under the general TFEU provision of Article 114 (5), Member States can invoke safeguard measures against GMO cultivation. Furthermore Member States also have discretionary authority to take coexistence measures to avoid the unintended presence of GMO’s in other crops, for instance by assigning GM-free regions within their territory.

There are some important conclusions to be drawn from this range of possibilities for Member States to ‘opt-out’ of cultivation. The most important observation is that none of the above described options constitute an opt-out at will. The safeguard measures under Directive 2001/18 and Regulation 1829/2003 are taken when a GMO constitutes a risk to human health or the environment. The environmental guarantee measures under Article 114 (5) can only be invoked when they are necessary to protect the environment. And coexistence measures need to be justified in the light of economical priorities. However, between objectives relating to the protection of the environment or human health, and economical objectives lies a whole range of other concerns.

Agricultural biotechnology in particular raises a host of social questions, which are very likely to manifest themselves differently around the Member States. But in the face of the law, the scope for engagement with national preferences after the EU-authorisation is virtually non-existent. This is demonstrated by the cases *Land Oberösterreich* and *Poland vs. Commission* where socio-economic concerns such as public morality were raised to justify cultivation bans.

Secondly it is observed that the tight legal straightjacket for national measures restricting or prohibiting cultivation, has not withheld Member States from installing bans. In 2014, eight Member States have banned the cultivation of the GM crop MON 810 based on safeguard clauses. Furthermore a majority of Member States has adopted coexistence measures and new GM-free regions are appearing everywhere.

Thirdly, Member States have successfully taken advantage of these derogation grounds, since most of the existing bans are unlawful. Either these bans have simply not been reported to the Commission³³⁷ or the European Food Safety Authority has concluded that the GM-crop did not constitute a risk to human health or the environment.³³⁸ Furthermore, the Commission has not been bold in taking infringement actions against the Member States. Most of the bans remain in place unchallenged. When the Commission did take action, the Member States’ measures were supported by the Environment Council in the Comitology procedure, which highlights again the sensitivity of national preferences.³³⁹ Even Member States who have been brought for the Courts by the Commission have upheld their bans.³⁴⁰

³³⁴ See, amongst others, M. SABALZA, “EU legitimizes GM crop exclusion zones”, *Nature Biotechnology*, 2011.

³³⁵ EPEC Report, op.cit., p. 99.

³³⁶ It is outside the scope of this thesis to examine the impact of this movement, but it demonstrates that Member States of the European Union are not in favour of GMO cultivation, see for instance the 2006 Vienna Declaration for a GM-free Europe, http://www.foeeurope.org/sites/default/files/press_releases/vienna_declaration%5B1%5D.pdf.

³³⁷ This is the case for the cultivation bans in Bulgaria, Germany and the most recent ban in Poland.

³³⁸ So far, for every national measure that has been subject to EFSA’s assessment.

³³⁹ Hungary and Austria.

³⁴⁰ Austria and Poland.

It can be concluded that the Commission has restrained from forcing Member States to abolish their unlawful national measures and it is clear that the Commission is trying to avoid a direct clash.

However, the fourth observation learns that, partially due to the Commission's lack of action, the discretionary authority that is granted to Member States as regards cultivation, has been used as a political tool to express, inter alia, frustrations with the stringency of the GMO legislative framework.

In 2010, after numerous calls from the Member States to review the existing framework, the Commission presented the Cultivation Proposal, with at its core, a non-limitative list of grounds that Member States can opt-out of cultivation. In the next Part, it will be examined what the scope and impact of these new grounds will be, in comparison to the existing framework.

PART III: Possibilities for Member States to restrict or prohibit the cultivation of GMOs under the new regime

In July 2014, the Council adopted a Proposal at first reading³⁴¹ that was the result of a lengthy ordinary legislative procedure that had started with the 2010 Commission Proposal³⁴² regarding the possibility for Member States to restrict or prohibit cultivation of GMOs in their territory.

It is the aim of this Part to examine how and when Member States can opt out of cultivation under the framework recently adopted by the Council. In particular the scope of the new derogation grounds will be addressed.

CHAPTER 1: When and how can Member States opt out of cultivation?

Section A. The new procedural model

1. First step: Selective applications

In its Proposal, the Council adopted a two-way model with two exits.³⁴³ In the pre-authorisation stage, a Member may request the economic operator applying for an authorisation to exclude the GM crop from part or all of its territory, via an adjustment of the geographical scope of the application. If the GM crop has already been authorised, the Member State can request such adjustment from the authorisation holder. This new procedural element is remarkable since it involves the economic operator. If the latter agrees to this adjustment, the scope of the application or authorisation is adjusted. If the notifier/applicant or authorisation holder opposes the requested adjustment, the geographical scope is not amended.

2. Second step: National measures based on a list of derogation grounds

If the economic operator does not agree to the adjustment of the geographical scope of the authorisation, the Member State can take a next step to restrict or prohibit the cultivation of the crop concerned. The Council Proposal inserts a new Article 26b that provides a non-limitative list of derogation grounds Member States may invoke³⁴⁴:

- “a) environmental policy objectives distinct from the elements assessed according to this Directive and Regulation (EC) No 1829/2003;
- (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.”

³⁴¹ COUNCIL Proposal for a regulation of the European Parliament and of the Council, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory - Adopted by the Council, 23 July 2014. (hereafter the Council Proposal)

³⁴² COMMISSION Proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 13 July 2010.

³⁴³ COUNCIL First Reading, op.cit., Art. 26b (1-5).

³⁴⁴ COUNCIL First Reading, op.cit., Art. 26b (3).

CHAPTER 2. New derogation grounds

Section A. Socio-economical and non-economical factors

In comparison to the existing derogation possibilities under Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003, the most notable observation is that the new grounds are non-scientific. Where the existing safeguard measures rely on a strict science-based risk approach, the new grounds allow the justification of a cultivation ban on a wide range of socio-economic and non-economic factors. The question arises what the exact scope is, or could be, of these new grounds, and to what extent Member States can invoke them to justify restrictive measures.

1. Scope of the new derogation grounds

1.1 Environmental policy objectives

According to the Council Proposal, Member States can rely on environmental policy objectives, distinct from the elements assessed according to Directive 2001/18 and Regulation 1829/2003. As an example are given: maintenance of certain type of natural and landscape features, certain habitats and ecosystems, as well as specific ecosystem functions and services.³⁴⁵ The Council Proposal imposes that the environmental grounds should be different from those assessed by the European Food Safety Authority during the risk assessment.³⁴⁶ However, the scope of this provision is still not very clear.

The provision seems to incorporate on the one hand a possibility for Member States to act upon environmental concerns relating to a specific GM crop and on the other hand the robust principle that the level of protection of human or animal health and of the environment is chosen and set at Union level. The question then arises to what extent a Member State can rely on environmental grounds? If the Food Safety Authority considers that a given GM crop is unlikely to pose a risk to human health or the environment, can a Member State still restrict the cultivation of that crop, claiming that it threatens a certain ecosystem? It would seem so, if the Member State can demonstrate that, firstly, this claim is an element that has not been part of EFSA's risk assessment and, secondly, that this claim does not conflict with the centralised scientific risk assessment.³⁴⁷

However, as regards to the burden of proof, the provision is silent. It can be argued that the burden of proof "should be a light one otherwise it would be difficult for a Member State to use this justification as the practice of negative Commission Decisions under Article 114 (5) has shown."³⁴⁸ Indeed, if, in analogy with Article 114 (5), a "newness" and "specificity" requirement apply, this provision would lose its practical sense. However, these requirements apply in the case where a Member State needs to take measures in order "to protect the environment", and this cannot be equated with the notion of "environmental policy objectives".

³⁴⁵ COUNCIL First Reading, op.cit., recital 11.

³⁴⁶ *Infra* Part I for a detailed analysis in comparison to the European Parliament's First Reading.

³⁴⁷ COUNCIL First reading, op.cit., recital 11: "to avoid any interference with the competences which are granted to the risk assessors and risk managers under Directive 2001/18/EC and Regulation (EC) No 1829/2003, a Member State should only use grounds related to environmental policy objectives which do not conflict with the assessment of risks to health and the environment which are assessed in the context of the authorisation procedures provided in Directive 2001/18/EC and in Regulation (EC) No 1829/2003."

³⁴⁸ S. POLI, "The Member States' long and winding road to partial regulatory autonomy in cultivating genetically modified crops in the EU", *European Journal of Risk Regulation*, 2013, vol 2, p. 149.

1.2 Land use, town and country planning

As regards the second and third justification, these were introduced by the Commission when presenting its indicative list of derogation grounds.³⁴⁹ According to the Commission, these grounds could include the preservation of organic and conventional farming systems as well as maintenance of certain type of natural and landscape features. The first example is interesting because it seems to refer to coexistence. This ground might thus allow Member States to take restrictive measures against the cultivation of GM crops in areas where different forms of agriculture might not be able to coexist.

1.3 Socio-economic impacts

With regards to the fourth justification, the Council states that “these grounds may be related to the impracticability or the impossibility of implementing coexistence measures due to specific geographical conditions, the need to avoid GMO presence in other products such as specific or particular products, the need to protect the diversity of agricultural production, or the need to ensure seed and plant propagating material purity”.³⁵⁰ It is to be noted that the Council limits the interpretation of socio-economic impacts to possible effects of (the impossibility of) coexistence, such as potential economic loss and admixture of GM and non-GM crops.

The justification referring to the impossibility to implement coexistence measures has in the past been invoked by Member States such as Austria and Poland.³⁵¹ The Council states that “while coexistence measures have been addressed by the Commission Recommendation of 13 July 2010, there should also be the possibility for Member States to adopt measures restricting or prohibiting cultivation of authorised GMOs in all or part of their territory under this Directive.”³⁵² It seems that the Council wants to give Member States an extended possibility to adopt measures relating to coexistence, without those measures being considered as coexistence measures under the scope of Article 26b and the guiding Recommendation. It is to be noted that reliance on this ground should have to be substantiated, since it could possibly be invoked to adopt the status of GM-free region.³⁵³

Albeit the grounds proposed by the Council are non-limitative, it is not clear if other socio-economic concerns could be considered a justification as well. A broader definition of socio-economic impacts might include requirements for education, effects on the safety of farmers, social acceptance and well-being, and sustainability issues.³⁵⁴

1.4 Avoidance of GMO presence in other products without prejudice to Article 26a

The fifth justification explicitly refers to coexistence. The aim seems to be to insert an autonomous ground to take national measures protecting against admixture outside the scope of the coexistence measures under Article 26a. “The need to avoid GMO presence in other products” is furthermore already mentioned as a possible interpretation of the previous provision relating to socio-economic impacts. Therefore the partition between this justification and justifications based on the Council’s interpretation of ‘socio-economic impacts’ is not clear.

³⁴⁹ COMMISSION, doc. n° 16826/10, Complementary Considerations: Indicative list of grounds to restrict or prohibit GMO cultivation, 8 February 2011

³⁵⁰ COUNCIL First Reading, op.cit., recital 12.

³⁵¹ See Commission Decisions 2003/653 and 2008/62.

³⁵² COUNCIL First Reading, op.cit., recital 12.

³⁵³ S. POLI, op.cit., p. 143.

³⁵⁴ GM IMPACT, “Criteria for sustainability assessment”, 2009, http://www.gm-impact.ch/documents/indicators_draft.pdf.

1.5 Agricultural policy objectives

The derogation ground related to agricultural policy objectives has its roots in the Opinion from the Agricultural Committee on the draft proposal from the Commission in 2010.³⁵⁵ The Council does not clarify this provision. However, it looks like this justification ground might also give margin to invoke grounds that relate to coexistence issues, that are not covered by the scope of Article 26a nor by the other justifications in Article 26b.

1.6 Public policy

The last ground is different from the previous justifications since it, at first glance, does not refer to coexistence issues directly or indirectly. However the Council does not give examples of what might be considered under this derogation ground. In previous versions of Article 26b, grounds such as public order, public interest, cultural policy and public morals have been mentioned. In that light, ‘public policy’ might be considered an umbrella for these possible justifications. When the Commission presented its indicative list of derogation grounds, it commented that, for example, a Member State could possibly invoke national measures to avoid social unrest due to the destructions of GMO fields, thereby affecting the public order of the country. The Commission also referred to other reasons relating to the public interest aiming at preserving cultural and social tradition or at ensuring balanced rural conditions.³⁵⁶

It is noted that justifications such as public morality and public policy have been invoked successfully by Member States to impose restrictions on the free movement of goods. Moreover, it is the only derogation ground of which the scope has been clarified through case law.³⁵⁷ If a Member State wants to rely on ‘public policy’, the Member State will have to demonstrate that the cultivation of a GM crop involves a genuine and serious threat to fundamental interests of the Member State’s society.³⁵⁸ Furthermore the Court has recognised that Member States have a certain degree of discretion when defining their own conception of public morals.³⁵⁹

However, even with some substantiated case law supporting these justifications, it remains unclear to what extent a Member State will be able to rely on this ground to justify a cultivation ban.

2. Mandatory requirements

The choice of a suitable objective justification is only the first step in the process of justifying a national measure. Some potentially suitable objectives might be undermined due to the fact that other mandatory requirements are not fulfilled. The Council Proposal states that measures taken under Article 26b should be in conformity with the Treaties, in particular as regards the principle of proportionality, and Article 34, Article 36 and Article 216(2) TFEU, which refers to the compatibility with international agreements.³⁶⁰

³⁵⁵ COMMITTEE on Agricultural and Rural Development, Opinion for the Committee on the Environment, Public Health and Food Safety on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 15 March 2011

³⁵⁶ COMMISSION, Staff Working document n° SEC(2010)1454, 5 November 2010

³⁵⁷ A. J. NOSI, “Public security, public health and public policy as potential grounds for imposing restrictions on the free movement of goods”, University of Miskolc, https://www.law.muni.cz/sborniky/cofola2008/files/pdf/evropa/janos_i_andrea.pdf

³⁵⁸ See Case C-30/77, *Régina v Pierre Bouchereau*, 27 October 1977.

³⁵⁹ CJEU, C-34/79, *Henn vs. Darby*, 14 December 1979.

³⁶⁰ COUNCIL First Reading, op.cit., recital 14.

2.1 Proportionality

The proportionality principle is considered to consist of three tests. The suitability test, or appropriateness test, refers to the relationship between the means and the end.³⁶¹ The question asked is whether the measure chosen is suitable or appropriate in order to achieve the objective invoked. The necessity test implies that the chosen measure must be necessary to achieve the proposed goal, in the meaning that the measure chosen is the one least restrictive on the given norm.³⁶² In the third test the measure's proportionality is assessed *stricto sensu*.³⁶³

Applied to a case where a Member State has adopted restrictive measures against GMO cultivation, these tests imply a rather heavy burden of proof. For example, the Member State would have to demonstrate that the centralised risk assessment procedure did not take into consideration, in a proportional manner, the need to protect the diversity of agricultural production.

An analogy can be made to *Commission vs. Poland*,³⁶⁴ where Poland invoked ethical and religious concerns to justify a national ban on GMO cultivation. If the Court would have accepted that Poland indeed pursued objectives of public morality, Poland would still have had to prove that the authorisation procedure failed to deal with the issue of ethics and religion adequately and hence why the prohibition was necessary.³⁶⁵

With regards to the issue of coexistence, proving proportionality might be feasible. If a Member State were to invoke a general cultivation ban on the ground of the need to protect the diversity of agricultural production, as part of the justification relating to socio-economic impacts, the Member State could argue that their agricultural type is not protected sufficiently since coexistence measures only pursue economical objectives. However the Member State would also have to demonstrate that the general ban is necessary and that other coexistence measures do not suffice.

The question is whether the Commission would bring Member States for the Court to plea that a ban is disproportionate. This seems very unlikely since it is the exactly the objective of the new legislation to give Member States more freedom as regards cultivation.

2.2 Compatibility with Article 34 – 36 TFEU

The Council Proposal explicitly states that measures adopted under Article 26b shall not affect the free circulation of authorised GMOs as, or in, products.³⁶⁶ By explicitly referring to the requirement that national measures under Article 26b should be in conformity with Article 34 and 36 TFEU, the Council recognises that it is not unlikely that such national measures might constitute quantitative restrictions on import, or measures of equivalent effect, which are prohibited between Member States.³⁶⁷

However, under Article 36 TFEU such restrictions can be accepted when they are justified on one of the grounds listed in the Article, such as public morality, public policy, public security and protection of the health and life.³⁶⁸ However, this last exception ground cannot be invoked.³⁶⁹ The Member State who wishes to rely on this provision must furthermore demonstrate that the measures are proportionate, that they are not intended for economic gain and that it does not concern a disguised trade restriction.³⁷⁰

³⁶¹ T.I. HARBO, "The Function of the principle of proportionality in the EU", *European Law Journal*, 2010, vol.16 n° 2, p. 167.

³⁶² *Ibidem*.

³⁶³ M. DOBBS, "Legalising general prohibitions on cultivation of genetically modified organisms", *German Law Journal*, 2010, vol. 11, n° 12, p. 1364.

³⁶⁴ C-165/08, *op.cit.*

³⁶⁵ M. DOBBS, *op.cit.*, p 1365.

³⁶⁶ COUNCIL First Reading, *op.cit.*, Art. 26b (9).

³⁶⁷ TFEU, art. 34.

³⁶⁸ TFEU, art. 36.

³⁶⁹ M. DOBBS, *op.cit.*, p 1361.

³⁷⁰ A. PHILIPSON, "Guide to the concept and practical application of Article 28-30 EC", DG Internal Market, 2001, p. 4.

Section B. Possible implications for the internal market

By adopting this Proposal, the new regime will add fundamental changes to the existing legislative framework. Whereas before it was centred around a science-based risk approach, the Member States' regulatory autonomy is now expanded to grounds that "include broader political concerns".³⁷¹ Although measures taken under the new regime still are required to be proportionate and to abide by the internal market rules such as Article 34 and 36 TFEU, it is undeniable that Member States are given much more discretionary authority to regulate cultivation of GMOs on their territory in comparison to the existing framework.

The question arises how this will affect the internal market. Some argue that this new regime will give Member States a "free hand to avoid their obligations when they feel like it"³⁷². However, it must be noted that the new derogation grounds are not unconditional and a Member State will still have to demonstrate that its national measure is justified and that it is not an arbitrary obstruction to the free movement of goods. Albeit it must also be noted that it is not clear how, and if, this will be controlled, since current practice shows that the Commission is reluctant towards forcefully taking action against national bans that are unlawful.

The new procedural model can be considered an alternative way to avoid running counter to the free movement of goods. Since a specific Member State can request to be left out of the geographical scope of an authorisation, the GM crop concerned would simply not be authorised in that specific territory. The new procedural model could therefore "diminish the scope of the internal market" and create a "smaller market".³⁷³

However, it remains unclear how the internal market would be affected by Member States opting-out of cultivation via the second step of non-scientific derogation grounds. Either way, it seems that the internal market will not remain unchanged. A certain degree of "fragmentation"³⁷⁴ can be expected. Therefore it seems that this new legislation might weaken the effective functioning of the internal market.

³⁷¹ M. LEE, *EU Regulation of GMOs: Law and decision-making for a new technology*, Cheltenham, Edward Elgar Publishing Limited, 2008, p. 97.

³⁷² *Ibidem*.

³⁷³ L. PETETIN, "The EU Proposal on GM crop cultivation: a real opportunity for consumer preferences?", University of Hull, 2012, p. 6., http://www.uaces.org/archive/papers/abstract.php?paper_id=283

³⁷⁴ L. PETETIN, *op.cit.*, p. 7.

PART IV: The new regime as an example of de-harmonisation

CHAPTER 1: Re-appropriation of national sovereignty?

When the Commission presented its Cultivation Proposal in 2010, the objectives of the proposed changes to the legislative framework were communicated very clearly: Member States need more flexibility to decide on GMO cultivation.³⁷⁵ The Cultivation Proposal aimed at giving Member States more freedom in deciding when and why they wanted to ban the cultivation of genetically modified organisms. The Commission argued that, although the existing legislative framework fully harmonised the area, “experience has shown that cultivation is an issue which is more thoroughly addressed by Member States”.³⁷⁶ As such, the regional or local levels were considered to be the most appropriate framework to address the particularities linked to GMO cultivation.

When the European Parliament adopted its text at first reading, an amendment was introduced that stated: “cultivation is an issue of particular importance for the self-determination of Member States”.³⁷⁷ This shows that the European institutions felt that there was a need for “re-appropriation of national sovereignty”³⁷⁸ that had to be answered by re-conferring some competences back to the Member States. According to the Commission, the Parliament and the Council, this de-harmonisation was justified by the principle of subsidiarity.

In the light of the aim and content of the new regime, the legal basis deserves particular attention. The Council has adopted its position at first reading on the basis of Article 114 TFEU, which was also the legal basis for the original Commission Proposal.

The question arises whether Article 114 TFEU can be used as the basis of a legal act that has as objective a partial de-harmonisation?

CHAPTER 2: The choice of the legal basis

Section A. The inter-institutional debate on the legal basis

When the Commission launched the Cultivation Proposal, the Council and Parliament’s legal services expressed serious doubts about the legal basis of the Proposal. The debate concerning the legal basis revolved around the following questions: 1) can Article 114 serve to introduce de-harmonisation measures?; 2) should the legal basis be Article 192 TFEU?

The Council³⁷⁹ argued that de-harmonisation on the basis of Article 114 would only be allowed if the purpose of the amendment aiming at such “de-harmonisation” was to improve the functioning of the internal market.³⁸⁰ To support this argument, the Council referred to *Tobacco Advertising* which states that “a measure adopted on the basis of Article 114 must genuinely have as its objective the

³⁷⁵ Commission 2010 Cultivation Proposal, op.cit., p.3.

³⁷⁶ Ibidem.

³⁷⁷ EUROPEAN PARLIAMENT, doc n° C7-0178/2010, European Parliament Legislative resolution of 5 July 2011 on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, recital 5.

³⁷⁸ S. POLI, op.cit. p. 152

³⁷⁹ COUNCIL, doc n° 15696/10, Opinion of the Legal Service, 5 November 2010. (limited acces)

³⁸⁰ COMMISSION, doc n° SANCO/13177/2010, Commission Staff Working Document – Considerations on legal issues on GMO cultivation raised in the opinion of the Legal Service of the Council of 5 November 2010, par. 10.

improvement of the conditions for the establishment and functioning of the internal market”³⁸¹. The Council further argued that it was not “apparent that any justification having to do with a problem, actual or potential, in the functioning of the internal market of the relevant products was decisive in the adoption of the Commission’s proposal”³⁸², however, according to the Council, such ‘protection element’ should be decisive in the choice on the internal market.³⁸³ In other words, the Council doubted that the intentions of the Proposal were aimed at improving the functioning of the internal market.

The Commission did not follow this reasoning. According to them, the wording of Article 114 does not refer to “improving” but only to the “establishment and functioning of the internal market.”³⁸⁴ Furthermore the Commission referred to the Council’s argument that Article 2(2) could not be used since “this provision does not set out conditions for the EU to cease exercising its competences in specific areas where competence is shared nor does it provide a legal basis for the EU to act”³⁸⁵. The Commission answered that it “would be a contradiction in terminis to always assume that the conditions set out in Article 114 for the purpose of approximation of laws at EU level have to be met when the purpose of the amendment is precisely that the EU ceases to exercise its competences and, in some cases, “give back competence to MS” in a given sector.”³⁸⁶ Thus according to the Commission, Article 114 and 2 (2) TFEU could perfectly be used as a legal basis for de-harmonisation measures.

The Parliament’s legal services³⁸⁷ were of the same opinion as the Commission, in that Article 114 TFEU was indeed to be read with Article 2 (2) and that the “improving the functioning of the internal market” was not to be considered a condition. According to the Parliament’s legal services, the proposal did not in fact pursue any objective other than introducing a certain “flexibility” into the existing centralised system of authorisation of GMOs.

In the end, the Council did not seem to contest that Article 114 could be used as a legal basis, however, justifications in the Proposal’s recital were proposed by the Council to clarify the choice.

As regards to the Union’s competence to take measures aimed at a certain degree of de-harmonisation, the *Vodafone* case explained that Article 114 can, indeed, provide the basis for an intensification of regulation in addition to deregulatory measures. In the same case, the Court held that: “Where an act based on Article 95 EC has already removed any obstacle to trade in the area that it harmonises, the Community legislature cannot be denied the possibility of adapting that act to any change in circumstances or development of knowledge having regard to its task of safeguarding the general interests recognised by the Treaty”.³⁸⁸

Although the Parliament did not contest the possible use of Article 114 TFEU for de-harmonisation measures, The Parliament proposed to use Article 192 (1) TFEU as a legal basis.³⁸⁹ This is to be seen in the light of the Parliament’s concerns about the exhaustivity of risk assessments and “the fact that arguments against the cultivation of GMOs are notably based on grounds related to environment”.³⁹⁰ The Parliament did not profoundly argue for Article 192 (1) as a legal basis but seemed to feel that measures concerning the release of GMOs into the Union environment on grounds relating to internal market seemed “inappropriate”.³⁹¹

³⁸¹ CJEU, C-491/01, *Tobacco vs United Kingdom*, 10 December 2002.

³⁸² CJEU, C-58/08, *Vodafone and Others*, 8 June 2010.

³⁸³ COUNCIL, Opinion of the Legal Service, op.cit., point 10; COMMISSION. Legal considerations, op.cit., par. 12.

³⁸⁴ COMMISSION. Legal considerations, op.cit., par. 16.

³⁸⁵ COMMISSION. Legal considerations, op.cit., par. 26-29.

³⁸⁶ COMMISSION. Legal considerations, op.cit., par. 30-31.

³⁸⁷ EUROPEAN PARLIAMENT, doc n° PE462.539v01-00, Committee on legal affairs, Legal basis of the proposal for a Regulation amending Directive 2001/18, 29 March 2010.

³⁸⁸ *Ibidem*.

³⁸⁹ EUROPEAN PARLIAMENT, Legal basis, op.cit., p 9-12.

³⁹⁰ EUROPEAN PARLIAMENT, Legal basis, op.cit., p 11.

³⁹¹ EUROPEAN PARLIAMENT, Legal basis, op.cit., p 12.

Section B. Is Article 114 TFEU the appropriate legal basis?

The objective of Directive 2001/18, in which Article 26 will be inserted, is described as following: “the objective is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment”.³⁹² Furthermore, recital 7 states that “it is necessary to approximate the laws of the Member States concerning the deliberate release into the environment of GMOs” and “it is necessary to establish harmonised procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment.”

In the light of the above, this raises the question whether Article 114 is indeed an appropriate legal basis for the de-harmonisation measures that are envisaged. How can the aim of giving Member States more flexibility to derogate from harmonised measures that have been established precisely to ensure a smooth functioning of the internal market, be considered an approximation of laws? In that view, Article 352 TFEU seems a more appropriate legal basis. This provision provides a flexibility clause with regard to the European Union's areas of competence. This clause allows the Union's competences to be adjusted to the objectives laid down by the Treaty when the latter has not provided the powers of action necessary to attain them. However, because of the procedure implied, it would be much more difficult to give back competences to the Member States and it would deprive the Parliament from its influence as co-legislator. The use of this Article would not be compatible with the principles of proportionality and subsidiarity.

It seems that Article 114 would not be sufficient to justify the proposed legislation. A possible option would be a triple legal basis of Article 2 (2), 114 and 352 TFEU. The latter would be necessary insofar as the draft legislation aims at attaining the objective of ensuring the smooth functioning of the internal market but the EU Treaty does not provide the EU institutions with the power to (only) partially cease its exercise of competence.

³⁹² Directive 2001/18, *op.cit.*.

CONCLUSION

The main objective of this thesis was to assess the scope of the changes to the legislative framework for Genetically Modified Organisms, initiated by the 2010 Cultivation Proposal from the European Commission. The main questions raised were how and to what extent Member States would be able to opt-out of GMO cultivation. In particular the technical and substantive elements of new derogation grounds were assessed in comparison to those of the safeguard clauses under the existing legislative framework.

From the evolution throughout the ordinary legislative process, it can be concluded that in some ways the Cultivation Proposal has undergone fundamental changes, and in others not so much. The objective of the Proposal was to grant Member States more freedom to decide on cultivation within their territories. Both the European Parliament and Council have been in favor of this change from the start.

The possibilities for Member States to adopt safeguard measures under the existing framework have been comprehensively described in Part II. The main tools are Article 23 of Directive 2001/18 Article 34 of Regulation 1829/2003 and Article 114 (5) TFEU. It can be concluded that they have been designed and interpreted in such way that their use is limited in practice. The requirements for new scientific evidence and, under the little used Article 114 (5) TFEU, the requirement for ‘specificity’ have demonstrated to place a heavy burden of proof on Member States. However, this legal straitjacket has not withheld Member States from invoking national bans.

An important conclusion has to be made with regards to the EU’s action against safeguard measures. The Commission has been reluctant to take forceful action against unlawful bans. It seems that the Commission has tried to avoid direct conflict with the Member States. However, this has contributed to the practice of Member States adopting cultivation bans without fulfilling the requirements, since they do not (have to) fear infringement action.

The recently adopted Proposal by the Council has introduced additional derogation grounds for Member States to adopt restrictive measures against the cultivation of GMOs. Since these grounds do not have to be based on scientific evidence that a GM crop constitutes a risk to human health or the environment, the Member States are given much more leeway to impose national bans. However, the content and scope of these grounds remain unclear. Although some conditions apply, such as compatibility with internal market rules, it is questionable if Member States would ever have to demonstrate that the requirements are fulfilled and that the derogation ground is justified. In particular questions arise as regards the proportionality of bans that are adopted under the new regime. In this regard, it must be noted that, in the text adopted at first reading, the Council did not introduce the cost-benefit analysis as proposed by the European Parliament, which could have been a tool to assess the proportionality of national restrictive measures.

In comparison to the existing safeguard measures, whose use heavily depends on stringent conditions, the new derogation grounds give Member States a free hand and might become an arbitrary tool to ban cultivation.

Furthermore, the majority of those grounds refer directly or indirectly to coexistence between GM and non-GM crops, a subject that is already regulated at the national level. It seems that Member States are given the opportunity to take measures related to coexistence issues on their territory, however outside the legislative framework for coexistence measures.

A significant stumbling block remains the different positions as regards the use of environmental derogation grounds. Where the European Parliament finds that Member States should be able to justify grounds on the basis of environmental concerns that might have already been addressed by the central risk assessor - the European Food Safety Authority - the Council has the opposite view and believes that the risk assessment, which can be contested by Member States when they invoke safeguard clauses, should not be made part of the new derogation grounds by allowing

Member States to invoke environmental concerns and findings that are possibly in conflict with EFSA's risk assessment.

The Council seems to have a strong point. The question is not if, but to what extent Member States will invoke environmental concerns to justify their bans. Practice has shown that Member States have invoked numerous scientific arguments to support their safeguard measures, which have each time been rejected by EFSA. It seems that EFSA's credibility as risk assessor will be affected when Member States can adopt safeguard measures in contradiction to EFSA's scientific findings

This inter-institutional difference of views seems to be determinative for the outcome of the Parliament's second reading and thus the possible adoption of the new legislation.

Another important issue remains, that of the legal basis. Although the Commission, Council and even the Parliament seem to find that Article 114 TFEU is the appropriate legal basis, in the light of the overall approach and design of the new legislation this has to be questioned. Is Article 114 really an appropriate provision for a Directive that aims at de-harmonisation and a re-appropriation of national sovereignty? There seems to be a conflict between the objective of the new legislation and the choice of legal basis. Therefore it is argued that a triple legal basis should be used: Article 2 (2), Article 114 and Article 352 TFEU.

To conclude it can be said that the new legislation, as adopted by the Council, is a 'first' in many ways. For the first time, Member States will have to discuss the (geographical) scope of a food product authorisation with the economic operator. For the first time, Member States will be able to exclude EU authorised products from their territories on very broad grounds that do not have to be supported by scientific arguments. For the first time, the European Union gives back some competences to the Member States.

However, this new approach raises some fundamental questions. How will this legislation affect farmers' choice to cultivate GM crops? Will the new legislation solve the deadlock on GMO authorization decisions? And if so, what use does this have if the Union's market is bisected with on the one hand Member States that have banned GMOs and on the other hand Member States that have not?

The 2010 Cultivation Proposal is ground-breaking in many ways, and we will have to wait and see if it will be referred to in the future as the "2015 Cultivation Directive".

BIBLIOGRAPHY

LEGISLATION

- Treaty of the Functioning of the EU
- REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 1997 concerning novel foods and novel food ingredients. This regulation does not apply to GMOs under Regulation 1829/2003.
- REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- COUNCIL DIRECTIVE 90/220/EEC on the deliberate release into the environment of genetically modified organisms, 23 April 1990.
- COUNCIL DIRECTIVE 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species.
- 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.
- REGULATION 1829/2003/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed.
- PROPOSAL for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 13 July 2010.

EU DOCUMENTS

- COMMITTEE on Agricultural and Rural Development, Opinion for the Committee on the Environment, Public Health and Food Safety on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 15 March 2011.
- COMMITTEE Environment, Public Health and Food Safety, doc. n° A7-0170/2011, Amendments to the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 12 March 2011
- EUROPEAN PARLIAMENT, doc. n° P7_TA(2011)0314, Legislative resolution of 5 July 2011 on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 5 July 2011.
- 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, 2 September 2003.

- COMMISSION Decision n° 2001/599 concerning draft national provisions notified by the Kingdom of the Netherlands on limitations on the marketing and use of creosote, 13 July 2001.
- COMMISSION Recommendation, doc n° 2010/C 200/01, on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, 13 July 2010
- COMMISSION DECISION concerning the provisional prohibition in France of the cultivation of seeds of genetically modified maize.
- COMMISSION DECISION 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.
- COMMISSION DECISION of 8 May 2006 authorising the Republic of Poland to prohibit on its territory the use of 16 genetically modified varieties of maize with the genetic modification MON 810 0 listed in the Common catalogue of varieties of agricultural plant species, pursuant to Council Directive 2002/53/EC.
- 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, 2 September 2003.
- COMMISSION Communication of 13 July 2010 on the freedom for Member States to decide on the cultivation of genetically modified crop,
- COUNCIL doc. n° 10972/3/14, Proposal for a regulation of the European Parliament and of the Council, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory - Adopted by the Council, 23 July 2014.
- COUNCIL doc. n° 10271/14, Proposal for a regulation of the European Parliament and of the Council, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory – Political Agreement, 28 May 2014
- COUNCIL Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.
- COUNCIL doc. n°8259/11, Compromise proposal, 25 March 2011.
- COUNCIL doc. n°10532/11, Compromise proposal, 25 May 2011.
- COUNCIL doc. n°11326/11, Progress Report from the Presidency to COREPER/Council, 10 June 2011.
- COUNCIL doc. n° 6152/12, Revised compromise proposals in view of a Council Political Agreement, 5 February 2012.
- COUNCIL doc. n° 6761/12, Revised compromise proposals in view of a Council Political Agreement, 23 February 2012.
- COUNCIL doc. n° 7153/12, Revised compromise proposals in view of a Council Political Agreement, 2 March 2012.
- COUNCIL doc. n° 10883/1/12, Progress report, 6 June 2012.
- COUNCIL doc. n° 6528/14, Preparation for the Environment Council of 3 March 2014, 17 February 2014.
- COUNCIL doc. n° 1027/14, Political Agreement, 28 May 2014.

- COUNCIL doc. n° 10972/3/14, Proposal for a regulation of the European Parliament and of the Council, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory - Adopted by the Council, 23 July 2014.

EESC, doc. n° NAT/480 - CESE 1623/2010, OPINION of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 9 December 2010.

COMMITTEE of the Regions, doc. n° NAT-V-006, Opinion on the freedom of Member States to decide on the cultivation of genetically modified organisms on their territory, 27-28 January 2011.

COMMISSION, doc. n° 16826/10, Complementary Considerations: Indicative list of grounds to restrict or prohibit GMO cultivation, 8 February 2011.

European Food Safety Authority (EFSA)

EFSA Scientific Opinion, EFSA Journal 2008, 891.

EFSA Scientific Opinion, EFSA Journal 2008, 756.

EFSA Scientific Opinion, EFSA Journal 2012, 2877.

EFSA Scientific Opinion, EFSA Journal 2013, 11(9).

EFSA Scientific Opinion, EFSA Journal 2008, 850(45).

EFSA Scientific Opinion, EFSA Journal 2012, 10(5).

EFSA Scientific Opinion, EFSA Journal 2013, 3372

JURISPRUDENCE

Court of Justice of the European Union

- C-512/99, *Germany vs. Commission*, 21 January 2003, par. 41.

- C-439/05 P and C-454/05 P, *Land Oberösterreich and Republic of Austria vs. Commission*, 13 September 2007.

- C-3/00, *Denmark vs. Commission*, 20 March 2003.

- C-165/08, *Commission vs. Poland*, 16 July 2009.

- Case C-121/07, *Commission vs. France*, 9 December 2008

- C-58/11 to C-68/11, *Monsanto SAS vs. Others*, 8 September 2011, paragraph 72.

- C-236/01, *Monsanto Agricoltura Italia SpA and Others vs. Presidenza del Consiglio dei Ministri and Others*, 9 September 2003.

- C-192/01, *Commission v. Denmark*, 23 September 2003, par. 49-51

- C-6/99, *Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others*, 21 March 2000.

- C-36/11, *Pioneer Hi Bred Italia Sri v. Ministero delle Politiche agricole alimentari e forestali*, 2012.

- C-157/96, *National Farmers' Union and Others*, 5 May 1998.

- C-180/96, *United Kingdom v Commission*, 12 July 1996.

- C-182/06, *Netherlands vs. Commission*, 27 June 2007.

- C-439/05 P and C-454/05 P, *Land Oberösterreich and Republic of Austria vs. Commission*, 13 September 2007

- C-203/96 *Chemische Afvalstoffen Dusseldorp BV v Minister van Volksbuisvesting, Ruimtelijke Ordening en Milieubeheer*, 25 June 1998

Court of First Instance

- T-366/03 and T-235/04, *Land Oberösterreich and Republic of Austria vs. Commission*, 5 oktober 2005.

- T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan GmbH vs. Others*, 26 November 2002.
- T-13/99, *Pfizer Animal Health v Council*, 11 September 2002.
- T-366/03 and T-235/04, *Land Oberösterreich and Republic of Austria vs. Commission*, 5 oktober 2005.
- T-70/99, *Alpharma v Council*, 11 September 2002.

BOOKS

- A. ANYSHCHENKO, *Role of science in EU environmental decision-making. A study of EU regulation of GMOs*, Master Thesis, Lund University, 2013
- CARDWELL M., BODIGUEL L., *The Regulation of GMOs: Comparative Approaches*, Oxford, Oxford University Press, 2010
- DE SADELEER N., *EU Environmental Law and the Internal Market*, Oxford, Oxford University Press, 2014, pp. 560.
- DERLEN M., *Multilingual Interpretation of European Union Law*, Alphen aan den Rijn, Kluwer Law International, 2009, pp. 418.
- KENT P., *Law of the European Union*, New Jersey, Pearson Education, 2008, pp. 416.
- LEE M., *EU Regulation of GMOs: Law and decision-making for a new technology*, Cheltenham, Edward Elgar Publishing Limited, 2008.
- MALETIC I., *The Law and Policy of Harmonisation in Europe's Internal Market*, Cheltenham, Edward Elgar Publishing, 2013, pp. 214.
- RAITIO J., *The Principle of Legal Certainty in EC Law*, Berlijn, Springer Science & Business Media, 2003, pp. 398.
- RUIVENKAMP G., HISANO S., JONGERDEN J., *Reconstructing Biotechnologies: Critical Social Analyses*, Wageningen, Wageningen Academic Pub, 2008, pp. 367.
- SZAJKOWSKA A., *Regulating Food Law: Risk Analysis and the Precautionary Principle as General Principles of EU Food Law*, Wageningen, Wageningen Academic Pub, 2012, pp. 155.
- ZANDER J., *The Application of the Precautionary Principle in Practice: Comparative Dimensions*, Cambridge, Cambridge University Press, 2010.
- ŻUREK K., *European Food Regulation After Enlargement*, Leiden/Boston, Martinus Nijhoff Publishers, 2011, pp. 275.

ARTICLES

- ONIDA M., “The practical application of Article 95 (4) and 95 (5) EC Treaty: What lessons can we learn about the division of competences between the EC and the Member States in product-related matters?”, in *EU and WTO Law: How tight is the legal straitjacket for environmental product regulation?*, Brussels, University Press, 2006.
- FLEURKE F., “What use for Article 95 (5) EC”, *Journal of Environmental Law*, 2008, vol. 20 n° 8.
- DOBBS M., “Legalising general prohibitions on cultivation of genetically modified organisms”, *German Law Journal*, 2010, vol. 11, n° 12
- LEE M., “Multi-level governance of GMOs in the EU: ambiguity and hierarchy”, in M. CARDWELL, L. BODIGUEL, *The Regulation of GMOs: Comparative Approaches*, Oxford, Oxford University Press, 2010

NELSON S., “Summary of the ruling in Joined Cases C-58/10 to C-69/10, Monsanto SAS and Others”, *KentLaw*, vol. 13 n° 1, 2012-2013

POLI S., “The Member States’ long and winding road to partial regulatory autonomy in cultivating genetically modified crops in the EU”, *European Journal of Risk Regulation*, 2013, vol 2

ANKER H.T. and GROSSMAN M.R., “Authorization of Genetically Modified Organisms : Precaution in US and EC Law”, *European Food and Feed Law Review*, 2009, vol. 1.

DABROWSKA P., “GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the Day in the recent Judgment of the European Court of Justice?”, *German Law Journal*, 2004, vol. 5 n° 2

POLLI S., “The Member States powers to adopt emergency measures in the context of the Genetically Modified Food/Feed Regulation” in *European Union Law for the twenty-first century: Internal market and free movement of goods*, Oxford, Hart Publishing, 2004

BORZEL T.A., KNOLL M., “Quantifying non-compliance in the EU – A database on EU infringement procedures”, *Berlin Working Paper on European Integration*, n° 15, 2012, p.8

ETTY T.F.M., “Brussels cunningly paves the way for genetically modified crops”, *De Volkskrant*, 18 July 2010, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1725440

PASKALEV V., “Can Science Tame Politics: The collapse of the new GMO regime in the EU”, *European Journal of Risk Regulation*, 2012, vol. 2.

CHRISTOFOROU T., “The regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics”, (2004) 41 *Common Law Review*.

FORSMAN Z.K., “Community Regulation of Genetically Modified Organisms: a Difficult Relationship Between Law and Science”, *European Law Journal*, 2004, vol. 10.

MORRIS S.H., SPILLANE C., “EU GM crop regulation: a road to resolution or a regulatory roundabout?”, *European Journal of Risk Regulation*, 2010, vol. 2

K. ZUREK, “When Lab results are not sufficient: on the limitations of science in tackling modern food regulatory concerns”, *Swedish Institute for European Policy Studies*, 2009, vol. 5, p. 6-8 for a further examination of the provisions of Polish Draft Act on Genetically modified Organisms

A. DE VEGA ALVAREZ, “Analysis of the Commission Decisions under Article 114(6) TFEU regarding the application by the Member States of Articles 114(4)

M. DOBBS, “Excluding coexistence of GMOs? The Impact of the EU Commission’s 2010 Recommendation on coexistence”, Research Paper, Queen’s University Belfast School of Law, 2013

M. WEIMER, “Risk regulation, GMOs, and the challenges to deliberation in EU Governance. Politicization and scientification as co-producing trends”, Working Paper, Amsterdam Centre for European Law and Governance, 2014

O. INANILUR, “Derogation from the free movement of goods in the EU: Article 30 and ‘Cassis’ mandatory requirements”, *Ankara Review*, 2008, vol 2

M. DOBBS, “Legalising general prohibitions on cultivation of genetically modified organisms”, *German Law Journal*, 2010, vol. 11, n° 12

M. DOBBS, “Excluding coexistence of GMOs? The Impact of the EU Commission’s 2010 Recommendation on coexistence”, Research Paper, Queen’s University Belfast School of Law, 2013

M. SABALZA, “EU legitimizes GM crop exclusion zones”, *Nature Biotechnology*, 2011.

INTERNET SOURCES

European Policy Evaluation Consortium (EPEC) for DG SANCO, European Commission, *Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003, and the placing on the market of GMOs as or in Products under Directive 20018/18/EC*, 2011

LEWIS K. R., Mixed reaction to Council's agreement on GMO cultivation, *The Parliament Magazine*, <https://www.theparliamentmagazine.eu/articles/news/mixed-reaction-councils-agreement-gmo-cultivation>

Information gathered from <http://greenbiotech.eu/eu-gm-crops/> and <http://www.gmo-free-regions.org/gmo-free-regions/bans.html>.

NIEMI Y., KOLA J., "Gradual renationalisation of the Common Agricultural Policy: a way forward?", 2004, <http://www.smts.fi/MTP%20julkaisu%202004/esi04/ma15.pdf>

DAVISON J., "Commissioner John Dalli's GM-crop-non-coexistence Proposals", 2010, <http://ddata.over-blog.com/xxxyyy/1/39/38/37/Dalli-proposal-Davison-review-en.pdf>

Implementing Lisbon: what's new in Comoitology? Policy Brief april 2011, *European Policy Centre*, http://www.epc.eu/documents/uploads/pub_1258_implementing_lisbon_-_what_s_new_in_comitology.pdf

My Vision – Political Guidelines, President of the European Commission, 3 September 2009, http://ec.europa.eu/commission_2010-2014/president/about/political/index_en.htm

European Commission press release IP/10/222, 2 March 2010, <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/222>

