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Differentiated Integration or Uniform Regime?

National Derogations from EU
Internal Market Measures

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Edited by ELLEN VOS, Maastricht University
and
MARIA WEIMER, University of Amsterdam

Faculty of Law

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Differentiated Integration or Uniform Regime?

National Derogations from EU Internal Market Measures

Ellen Vos^{*} and Maria Weimer^{**1}

Abstract

The EU has most frequently resorted to harmonisation as a model to achieve its internal market. This contribution examines the dynamics of legal differentiation in EU's internal market law laid down in Article 114 TFEU and secondary laws. It concludes that there has been a modest number of invocations of the derogation possibilities under Article 114 (4) and (5) TFEU and the safeguard clauses. The low number may be due to the fact that may both the Commission and the Courts have a very rigid reading of the procedure whilst the grounds for invocation are very limited. This low number nevertheless does not automatically imply that Member States agree with the level of protection laid down in the EU's harmonisation measures or that the opt out mechanisms are not relevant. Derogation mechanisms may play an important role in the negotiations of the level of protection in the draft legislative acts. This study moreover reveals that the derogation mechanisms may be important devices of regulatory adjustment and learning in the fields of public health and environmental protection in the EU. They ultimately may rather strengthen the uniformity of regulatory requirements in the EU internal market instead of leading to regulatory diversity.

Key words:

EU law; differentiation; harmonisation; opt out; safeguard clauses; Article 114 TFEU

1. INTRODUCTION

The creation of one internal market in which products may freely circulate has been central in the EU's integration project from its very start. Article 26(2) TFEU thus stipulates that this internal market will embrace 'an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured'. Over the

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¹ We would like to thank Giulia Giardi (Maastricht University) for helping us with the empirical research carried out. An elaborated version of this article will appear in B. de Witte, A. Ott and E. Vos (eds.) 'Between Flexibility and Disintegration: The Trajectory of Differentiation in EU Law', Edward Elgar Publishing forthcoming 2017.

years, this internal market has evolved on the basis of various features of different integration models such as host country control, home country control and harmonisation.² The latter relates particularly to the rules established with regard to the creation of the internal market. The attractiveness of harmonisation lies in the fact that EU rules can also take into account other interests than purely economic ones, such as the protection of human health and the environment, as is expressly stipulated in Article 114(3) TFEU.³ Inevitably, however, there is a tension between harmonised rules and respect for diversity. In politically sensitive matters, it may therefore appear difficult to find a compromise and to adopt EU-wide measures. Moreover it may appear difficult within the internal market measures to offer the appropriate level of protection of, for example, environment and human health.⁴

On the other hand, it is also true that the possibility for Member States to create and/or maintain diverse conditions has for a long time been part of the EU integration process. Accordingly, EU law provides for several mechanisms of legal differentiation and flexibility. These mechanisms allow Member States to derogate from the harmonised European rules under certain circumstances in order to respond to new health or environmental risks or other individual national or regional policy needs at the national level. Examples are the ‘opt-out’ clauses of Article 114(4) and (5) TFEU as well as various so-called ‘safeguard clauses’ laid down in EU secondary legislation in the fields of EU environmental and health and safety policy.⁵ The use of these mechanisms by the Member States, however, has often created difficulties in the past as well as disagreement between the invoking Member State and the EU institutions

² Jukka Snell, ‘The Internal Market and the Philosophies on Market Integration’ in Catharine Barnard and Steve Peers (eds), *European Union Law* (Oxford University Press 2014) 304-305.

³ See Bruno De Witte, ‘The Competence to Protect. The Pursuit of Non-market Aims through Internal Market Legislation’, in Philip Syrpis (ed), *The Judiciary, the Legislature and the Internal Market* (Cambridge University Press 2012) 25-46.

⁴ Moreover the EU measures may prove inflexible, rigid and difficult to change. Snell (n 2) 304.

⁵ See art 114(10) TFEU. See section 6 of this contribution.

with regard to the interpretation of the legal conditions and their fulfilment in each and every particular case. Especially in the field of consumer health and environmental protection, the bone of contention has often been the availability and interpretation of the scientific data with regard to the existence of health and environmental risks at the national level. Hence, the authority of scientific expertise in the use of legal differentiation mechanisms, together with the question in how far scientific evidence should be an exclusive factor in granting more regulatory flexibility at the national level, are key issues to be considered.

This contribution will take stock of these developments examining dynamics of legal differentiation in EU's internal market law in an empirically informed way. In particular, it will address the question in how far the actual use of the different available derogation mechanisms of Article 114 TFEU and secondary law safeguard clauses points to the existence of processes of differentiated integration or whether it triggers follow-up regulatory developments at the EU level. In other words, we aim to analyse whether, considering both the way EU law frames and approves of national derogation and safeguard clauses and the way scientific evidence is being used in this process, we can today observe a trend towards more harmonisation and less flexibility in the use of these mechanisms or whether, on the contrary, more legal differentiation is provided for. Before examining the current derogation practice under the mechanisms provided for in Article 114 TFEU and the safeguard clauses (sections 5 and 6), we will first discuss the origins of these mechanisms (section 2) and briefly delineate their requirements (sections 3 and 4).

2. INTERNAL MARKET LAW IN THE FACE OF DIVERSITY

Already at the end of the 1960s the EU envisaged the use of harmonisation to achieve

its internal market ambition with the adoption of its harmonisation programme of 1969.⁶ At the same time, it pursued the home country control model. Importantly, the Treaty requires Member States to refrain from creating barriers to trade. Article 34 TFEU thus prohibits Member States from imposing quantitative restrictions on imports or measures having equivalent effect. It was however particularly in the 1980s, when the landmark ruling of the Court of Justice of the EU (CJEU) in *Cassis de Dijon* highlighted the mutual recognition principle,⁷ that the home state control model gained in importance. Cumbersome and slow decision making by the EU institutions, together with the development of the mutual recognition principle by the Court, pushed the European Commission, endorsed by the Council,⁸ to adopt a New Approach to harmonisation and technical standards in 1985.⁹

This approach took mutual recognition as its main principle while identifying approximately 300 measures to be adopted in line with the harmonisation model, particularly on issues involving health and safety. Over the years, the Court had always been careful to avoid situations in which regulatory gaps would arise. It had been quite tolerant in allowing Member States, in line with the justification grounds of Article 36 TFEU, to derogate from the obligation to allow foreign products on their markets which would not conform to their own strict health and safety standards, particularly in cases of scientific uncertainty. This led to a surge of the host state control model in cases of health protection measures, which led in turn to situations of justified trade barriers blocking the free movement of products. To lift such trade barriers

⁶ Council resolution drawing up a programme for the elimination of technical barriers to trade, (1969) OJ C76/1.

⁷ Case C-120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein* [1979] ECLI:EU:C:1979:42.

⁸ Council Resolution on a New Approach to Technical Harmonisation and Standards (1985) OJ C136/1.

⁹ COM(85) 19 final, 31 January 1985.

resorting to harmonisation was indispensable.¹⁰

The introduction of a new Treaty provision, then Article 100A EEC, now Article 114 TFEU, allowed for internal market measures to be adopted by qualified majority voting and this was essential for the success of the 1985 New Approach. It was also clear that in order to get agreement on the introduction of qualified majority voting for internal market measures by the Single Act, Member States needed to be assured that they would not be outvoted on measures that would reduce existing levels of health and environmental protection.¹¹ In that manner, the former Article 100A(4), now Article 114(4 and 5) TFEU, provided for the possibility for Member States to opt out of harmonisation measures in order to adhere to stricter levels of protection.¹² While some welcomed this provision as establishing, within the Treaty, the legitimate importance of national regulatory measures and the concept of shared competences,¹³ others expressed their fears that opt-outs would damage the uniformity of the EU legal order and that it would compartmentalise the single market.¹⁴

After the failure of the application of the mutual recognition principle in the manner the New Approach had envisaged,¹⁵ the harmonisation model has become increasingly popular. Although the Single Act also embraced the concept of diversity in oth-

¹⁰ See e.g. Ellen Vos, 'Differentiation, Harmonisation and Governance', in Bruno De Witte, Dominik Hanf and Ellen Vos (eds), *The Many Faces of Differentiation in EU Law* (Intersentia 2001) 145-179.

¹¹ See Claus Gulmann, 'The Single European Act - Some Remarks from a Danish Perspective' (1987) 24(1) CML Rev. 31-40 and Ludwig Krämer, 'The Single European Act and Environmental Protection: Reflections on Several New Provisions in Community Law' (1987) 24 CML Rev. 659-688, at 681.

¹² See Claus-Dieter Ehlerman, 'Increased Differentiation or Stronger Uniformity?' EUI Working Paper RSC 95/21, Florence 1995 at 389 ff. See also AG Saggio in Case 319/97, para 17.

¹³ Stephen Weatherill, 'Beyond Preemption? Shared Competence and Constitutional Change in the European Community', in David O'Keeffe and Patrick M. Twomey (eds), *Legal Issues of the Maastricht Treaty* (Chancery Law Publishing 1994) 23.

¹⁴ See Pierre Pescatore, 'Some Critical Remarks on the "Single European Act"' (1987) 24 CML Rev. 9-18.

¹⁵ See e.g. Case C-188/84 *Commission v France* [1986] ECLI:EU:C:1986:43. See special issue of the *Hanse Law Review* Gert Brüggemeier, Josef Falke, Christian Joerges and Hans-W. Micklitz, 'European Product Safety, Completion of the Internal Market and the New Approach to Technical Harmonisation and Standards – Reissued' (2010) 6(2) *Hanse Law Review* 107-114.

er provisions,¹⁶ for the purpose of this contribution we will look at the derogation mechanisms provided for in Article 114 TFEU to see how they have impacted the internal market.¹⁷

3. DEROGATION THROUGH THE ‘OPT-OUT’ CLAUSES: ARTICLE 114(4) AND (5) TFEU

The anchoring of opt-out clauses in Article 114 TFEU seems to reflect a diversity principle even within harmonised areas of EU law, which therefore enjoy a constitutional status. As pointed out above, this mechanism was a political/strategic reply to Member States that were unwilling to reduce their health and safety protection levels within the EU framework. Opting out of harmonisation measures under Article 114(4) and (5) TFEU comes close to what has been termed ‘variable geometry’, in which unattainable or unavoidable differences are admitted and which allows a separation between a ‘hard core’ and lesser developed integrative units.¹⁸ Article 114(4) TFEU gives a limited minimum harmonisation facility for internal market measures that, in the opinion of the opting-out Member State, fail to provide for appropriately stringent levels of protection.¹⁹

Yet, this constitutional principle of diversity is not unlimited. It must fulfil various requirements; most notably national rules may not constitute arbitrary discrimination or distort the functioning of the internal market and, as such, they are subjected to the Commission’s technocratic oversight. Paragraphs (4) and (5) of Article 114 TFEU

¹⁶ Such as then art 8c EEC that expressly obliged the Commission to take account of the differences in the development of certain economies and then art 130t EEC that introduced the concept of minimum harmonisation techniques relating to environmental policy.

¹⁷ See, already, James Flynn, ‘How Will Article 100A (4) Work? A Comparison with Article 93’ (1987) 24(4) CML Rev. 689-707; Kay Hailbronner, ‘Der “nationale Alleingang” im Gemeinschaftsrecht am Beispiel der Abgasstandards für Pkw’ (1989) 16 EuGRZ 101-122; Pierre Pescatore, ‘Die ‘Einheitliche Europäische Akte’. Eine ernste Gefahr für den Gemeinsamen Markt’ (1986) 21(2) EuR 153-169.

¹⁸ See Ehlerman (n 12).

¹⁹ On different models of differentiation in harmonised areas see Vos (n 10).

distinguish between national measures which exist at the moment of the adoption of a harmonisation measure (paragraph (4)) and national measures which are introduced after the adoption of a harmonisation measure (paragraph (5)). Paragraph (4) lists the criteria for the possibility of maintaining the already existing national measures, namely, the protection of the interests laid down in Article 36 TFEU and the protection of the environment or working environment. Importantly, under Article 114 (4) TFEU, it is not possible to maintain national provisions that are less protective than the provisions laid down in the relevant EU harmonisation measure.²⁰

Stricter limitations are applied to the introduction of national measures after harmonisation. Paragraph (5) only allows Member States to adopt new national measures based on new scientific evidence due to a problem that has arisen after the adoption of a harmonisation measure and is specific to that Member State. The justification grounds are more restrictive than those that may be resorted to under paragraph 4: only the protection of the environment or the working environment. The introduction of new measures for reasons of health protection is therefore not allowed.²¹ Where a problem relating to health protection is signalled by a Member State in a field regulated by harmonisation measures, that Member State needs to bring this matter to the attention of the Commission. The Commission in turn has to examine immediately whether it is necessary to propose appropriate measures to the Council (paragraph (8)). This seems to suggest that after harmonisation health protection is a matter for the EU institutions.

The notification procedure to the Commission is laid down in paragraphs (6)-(7). Where a Member State deems it necessary to apply its national measure based on one

²⁰ Commission Decision 1999/835/EC on the Danish derogation concerning the limitation to the placing on the market and use of creosote, (1999) OJ L329/82, para 112.

²¹ Nicolas De Sadeleer, *EU Environmental Law and the Internal Market* (Oxford University Press 2014) 364-365 and 374; Isidora Maletić, *The Law and Policy of Harmonisation in Europe's Internal Market* (Edward Elgar 2013) 75.

of the justification grounds, it must notify the Commission before the time-limit for the implementation of the Community measures involved expires. Paragraph (6) stipulates that the Commission must ‘approve’ or ‘reject’ the national provisions, after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade and whether or not they constitute an obstacle to the functioning of the internal market. The Commission must fully satisfy the obligation to state reasons. It cannot merely state that the national derogation is compatible with the requirements for opting out laid down in Article 114 TFEU without stating the reasons on the basis of which the Commission considered that all conditions are fulfilled.²² Where the Commission fails to adopt a decision within six months, the national provisions are deemed to have been approved.²³ A decision that has been adopted by the Commission but not notified to the derogating Member State does not interrupt the time limit.²⁴ The six-month period may be formally extended with another six months if the complexity of the risk assessment so requires.²⁵

The Commission has a wide discretion to make complex technical evaluations in the Article 114 procedures. The evidence relied upon must be factually accurate, reliable and consistent; that evidence must contain all the relevant information and must be capable of substantiating the conclusions drawn from it;²⁶ and it must observe the fundamental guarantees of an administrative procedure, in particular ‘the obligations to examine carefully and impartially all the relevant elements of the individual case and to give an adequate statement of the reasons for its decision.’²⁷ Quite remarkably,

²² As the Court held in Case C-41/93 *Commission v France* [1994] ECLI:EU:C:1994:196, para 36, now codified in art 114(6) TFEU.

²³ Case T-69/08 *Poland v Commission* [2010] ECLI:EU:T:2010:504, para 71. See Maletić (n 21) 81 and De Sadeleer (n 21) 369.

²⁴ Case T-69/08 *Poland v Commission* [2010] ECLI:EU:T:2010:504, para 62.

²⁵ See e.g. Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* [2010] ECLI:EU:C:2007:510, para 40 and Case T-69/08 *Poland v Commission*, para 60.

²⁶ Case C-405/07 *Netherlands v Commission (Dutch emissions)* [2008] ECLI:EU:C:2008:613, para 55.

²⁷ Case C-405/07 *Netherlands v Commission (Dutch emissions)* [2008] ECLI:EU:C:2008:613, para 56

within this procedure, Member States do not have a right to be heard.²⁸ In *Danish Additives*²⁹ and in *Upper Austria*³⁰ the CJEU found that the Commission is not obliged to grant the Member State a right to be heard before adopting its decision under either paragraph (4) or (5). Hereby the Court emphasised the intention of the drafters of the Treaty to conclude the derogation procedure swiftly in the interest of the notifying Member States and the proper functioning of the internal market.³¹

As rightly observed by Maletić, such a reading of the Article 114 procedures requires an extensive degree of diligence and foresight on the part of the notifying Member State. Not only does it oblige the Member State to anticipate all possible counter-arguments to its notification, Member States are also prevented from commenting on the observations submitted to the Commission by other Member States as a reaction to the notification. It should be added that a denial of the right to be heard might in some cases be counter-productive to the purpose of speeding up the opt-out procedure.³² It follows, moreover, that the rejection of the right to be heard seems to

with reference to Case C-269/90 *Technische Universität München* [1991] ECR I-5469, para 14; Joined Cases C-258/90 and C-259/90 *Pesqueras De Bermeo and Naviera Laida v Commission* [1992] ECLI:EU:C:1992:199, para 26; and Case C-525/04 P *Spain v Lenzing* [2007] ECLI:EU:C:2007:689, para 58.

²⁸ See e.g. Case C-3/00 *Denmark v Commission* [2003] ECLI:EU:C:2003:167, para 49.

²⁹ Case C-3/00 *Denmark v Commission* [2003] ECLI:EU:C:2003:167, para 50.

³⁰ Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* [2007] ECR I-7141, para 44.

³¹ Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* [2007] ECLI:EU:C:2007:510, paras 37-41. See also Advocate General Sharpston's opinion in Joined Cases C-439/05 P and C-454/05 P, para 137.

³² For example, a lengthy judicial procedure before the EU courts could in some cases be avoided if the Member State is given the right to be heard and thereby to correct a mistake made by the Commission in its assessment. As Wennerås observes on the *Danish Additives* case, 'if Denmark has been allowed to comment on the flawed interpretation of the SCF's 1995 opinion, there is a possibility that the Commission would have recognized its error and instead have approved the Danish provisions.' Pål Wennerås, 'Fog and Acid Rain Drifting from Luxembourg over Art. 95(4) EC: Case C-3/0 Kingdom of Denmark v. the Commission of the European Communities Danish Food Case' (2003) 12(6) *European Energy and Environmental Law Review* 169-178, at 175. Similarly, one could argue that in the *Dutch Emissions* case an action for annulment could have been avoided if the Netherlands was given the right to comment on the Commission decision, which erroneously stated that the 2004 air quality assessment report was not submitted to it.

be in conflict with an understanding of the Article 114 opt-out procedures as a mechanism for regulatory learning.

When a Member State is authorised to maintain or introduce derogating national provisions, the Commission must immediately examine whether the relevant harmonisation measure should be adapted accordingly (paragraph (7)). If the Commission or a Member State considers that another Member State is making improper use of this provision, it may bring the matter directly before the CJEU (paragraph (9)).

4. DEROGATION THROUGH THE ‘OPT-OUT’ CLAUSES: NUMBER OF APPLICATIONS, APPROVALS AND REJECTIONS

Overall we can conclude that the notification procedure is being interpreted strictly and is in fact ‘narrowly construed’.³³ Our analysis of the derogation practice reveals a rather modest application of the derogation mechanisms. From 1987 until 2014, a total number of 34 derogations were sought by various Member States under both Article 114(4) and (5) TFEU (see Table 1). A close examination of the derogation requests reveals that there are considerable differences in the derogation practices under Article 114 paragraphs 4 and 5. Until today, derogations under paragraph (4) were sought in 22 cases,³⁴ 16 of which were approved by the Commission. Four notifications were rejected, one was withdrawn and one was declared inadmissible. In contrast, under Article 114(5), derogations were sought in 12 cases, only one of which was approved. Eight notifications were rejected, one was withdrawn and one was declared inadmissible. It shows that the Commission is more willing to approve pre-existing measures than to allow for new measures to be introduced after harmonisa-

³³ Case C-319/97 *Kortas* [1999] ECLI:EU:C:1999:272, para 23.

³⁴ The three requests that were made under the old art 100A EEC also considered the requests to maintain legislation and therefore, for the purpose of our statistical analysis, we have added these three requests to the number of requests made under the new art 114(4) EEC post Amsterdam.

tion. Overall, our analysis reveals a varied picture in terms of the functioning of opt-outs as mechanisms of differentiation in EU internal market law. Importantly, in its decision making the Commission, following established EU case law,³⁵ has always stressed the necessity to interpret the legal requirements for derogation narrowly, given the exceptional nature of the opt-out clauses and the fact that they challenge the attainment of a fundamental Treaty objective, the integration of the market for goods. The practice followed by both the Commission and the Court shows that derogation from EU harmonisation measures will not be permitted easily.³⁶

³⁵ See Case C-41/93 *France v Commission* [1994] ECLI:EU:C:1994:196, paras 23-30 and Case C-319/97 *Kortas* [1999] ECLI:EU:C:1999:272.

³⁶ See Stephen Weatherill, *Cases and Materials on EU Law*, 9th edition (Oxford University Press 2010) at 587; Maletić (n 21) 118.

Member State	Old Article 100a (4)			Article 114 Paragraph 4					Article 114 Paragraph 5				
	A	R	Total	A	R	W	I	Total	A	R	W	I	Total
Austria	-	-	-	2	-	-	-	2	-	1*	1	-	2
Belgium	-	-	-	-	-	-	-	-	-	1	-	-	1
Cyprus	-	-	-	-	-	-	-	-	-	-	-	1	1
Czech Republic	-	-	-	-	-	1	-	1	-	-	-	-	-
Denmark	1	-	1	3	1*	-	-	4	-	-	-	-	-
Finland	-	-	-	1	-	-	-	1	-	-	-	-	-
France	-	-	-	-	-	-	-	-	-	1	-	-	1
Germany	1*	-	1	2	2	-	-	4	-	2*	-	-	2
Poland	-	-	-	-	-	-	-	-	-	1*	-	-	1
Portugal	-	-	-	-	-	-	-	-	-	-	-	-	1 [†]
Sweden	-	1 [‡]	1	2	-	-	-	2	-	1	-	-	1
The Netherlands	-	-	-	4*	-	-	-	4	1	1*	-	-	2
United	-	-	-	-	-	-	1	1	-	-	-	-	-

A -Approved
R- Rejected
W- withdrawn
I- Declared inadmissible
 *Matter taken before CJEU (See Table 2)
[†]Pending before Commission
[‡] Case before CJEU related to the matter, but not seeking annulment of Commission Decision (See Table 2)

Kingdom													
	A	R		A	R	W	I		A	R	W	I	
	2	1		14	3	1	1		1	8	1	1	
Total n. derogations sought**	3			19					12				

**Where same measures notified twice or renewal of already notified derogation sought, calculated as single instance.

Total disaggregated number of Commission Decisions: 39

Total derogations sought (aggregated): 34

Total approved: 17

Total rejected: 12

Total withdrawn: 2

Total declared inadmissible: 2

Pending: 1

Table 1: Overview of the number of Member State notifications and Commission decisions made under Article 114 (4) and (5) TFEU between 1987 and 2014

5. DEROGATION THROUGH THE ‘OPT-OUT’ CLAUSES IN PRACTICE: MAIN FINDINGS

Our findings reveal important insights into the way the derogation mechanisms under Article 114 TFEU work. We would like to highlight six important findings of our analysis of the derogations practice in relation to *i)* the role of science, *ii)* the precautionary principle, *iii)* the relevance of international developments, *iv)* proportionality, *v)* burden of proof, and *vi)* the level of risk management. The consequences of the derogation mechanisms for the internal market as a whole will be discussed in section 7.

5.1. The Role of Science

The role that scientific evidence plays in the derogation procedure is crucial. As the Court phrased it in the *Upper Austria* cases: ‘First of all, it should be pointed out that the lawfulness of national measures notified under Article 95(5) EC is closely linked to the assessment of the scientific evidence put forward by the notifying Member State’.³⁷ The same holds true for measures notified under paragraph 4, although it does not formally refer to scientific evidence. The Court’s observation indicates that science plays a dual role in the notification procedure: first scientific evidence must be produced at the national level in order to demonstrate that the derogation is justified; and second this evidence is reviewed at the EU level by a scientific committee or EU agency as requested by the Commission.

That it is crucial for the Commission to have scientific evidence produced by national authorities reviewed by another (EU) body flows from the Court’s case law in *France v Commission*. In this case, the Commission had merely confined itself to in-

³⁷ Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* [2007] ECLI:EU:C:2007:510, para 56.

dicating to the content of the German provisions, taking notice of the evidence submitted by the German authorities, and referring to the dangers of PCP as revealed by these authorities. The Court however reprimanded the Commission for not having properly explained ‘the reasons of fact and law on account of which the Commission considered that all the conditions contained in Article 100a(4) were to be regarded as fulfilled in the case in point’³⁸ and annulled the Commission’s approval for lack of argumentation. Subsequently the Commission resorted to an internationally recognised expert, Prof. Rappe of the Swedish Institute of Environmental Chemistry, who confirmed that the German derogation was justified by the specific circumstances relating to health protection and the environment in Germany. This led the Commission to approve again of the German derogation.³⁹

The reproach by the Court in *PCP* has been key for the Commission’s practice and its reliance on an assessment by scientific bodies created at the EU level. Soon after the *PCP* case, the Commission thus started to involve its own scientific bodies in reviewing scientific evidence submitted by national authorities. In general, the outcome of that re-evaluation determined the further outcome of the procedure. Our analysis thus confirms the authoritative role played by EU bodies and their scientific opinions as observed in other areas of risk regulation.⁴⁰ In the creosote cases, the Commission resorted to the Scientific Committee for Toxicology, Ecotoxicology and the Environment (CSTEE) (now renamed as SCHER: Scientific Committee on Health and Environmental Risks), that it had already created in the 1980s.⁴¹ In all derogations that

³⁸ Case C-41/93 *France v Commission* [1994] ECLI:EU:C:1994:196, para 36.

³⁹ Commission Decision 94/783/EC concerning the prohibition of PCP notified by the Federal Republic of Germany (1994) OJ L316/43-48.

⁴⁰ See e.g. Michelle Everson and Ellen Vos (eds), *Uncertain Risks Regulated* (Cavendish 2009).

⁴¹ The Scientific Advisory Committee examined the toxicity and ecotoxicity of chemical compounds established by Commission Decision 78/618/EEC, as last amended by the Act of Accession of Austria, Finland and Sweden (1978 OJ L198/17) was replaced by the Scientific Committee on Toxicity, Ecotoxicity and the Environment, Commission Decision of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety, OJ L237 of 28.08.97.

were notified by the various Member States in those cases, this Committee confirmed the evidence submitted by the Member States that these substances were harmful to human health or the environment. This subsequently led the Commission to approve of all derogations⁴² and to amend the relevant EU legislation (see section). A similar situation occurred in relation to the Austrian, Finnish and Swedish derogations to the EU legislation on cadmium in fertilisers which were approved by the Commission on the basis of an opinion by the Committee highlighting risks to the environment and public health resulting from the use of cadmium-containing fertilizers.⁴³

The Commission is not formally bound by the scientific opinion produced by the EU bodies. Yet it must take sufficient account of such opinions. In the *Danish additives* case of 2003, the Court thus found that the Commission had failed to take sufficient account of the EU's former Scientific Committee on Food (SCF) (now EFSA) opinion; an opinion the Danish authorities had referred to in order to support their derogation request.⁴⁴ Subsequently, in the *Dutch Emissions* case, the Court reaffirmed the Commission's obligation to take account of all available scientific evidence. In this case, the Court stressed the obligation of the Commission, in its decisions in the field of the environment, to take into account *all* available new scientific and technical data based on the first indent of what is now Article 191(3) TFEU. This seems to imply that the Commission can base its assessment under Article 114 (4) *et seq* on various scientific sources including national and international studies.

⁴² See Commission Decision on the Danish derogation 1999/835/EC (1999) OJ L329/82; Commission Decision on the Dutch derogation 1999/832/EC (1999) OJ L329/25 and Commission Decision 1999/834/EC on the Swedish derogation (1999) OJ L329/63.

⁴³ Commission Decision 2006/349/EC for Austria (2006) OJ L 129/31 ; Commission Decision 2006/348/EC for Finland (2006) OJ L 129/25; Commission Decision 2006/347/EC for Sweden, (2006) OJ L 129/19. ok

⁴⁴ Case C-405/07 *Netherlands v Commission (Dutch emissions)* [2008] ECLI:EU:C:2008:613, paras 63-64.

In the *Danish Additives* case the Court moreover opened up a degree of flexibility for Member States that seek to derogate on the basis of different standards than those adopted at the EU level.⁴⁵ The Court took an ‘unusually expansive approach’⁴⁶ to the scientific evidence that may be submitted by a derogating Member States and ruled that

‘in the light of the uncertainty inherent in assessing the public health risks posed by, inter alia, the use of food additives, divergent assessments of those risks can legitimately be made, without necessarily being based on new or different scientific evidence’.⁴⁷

This flexibility was however somewhat neutralised by the Court’s strong emphasis on the burden of proof placed on Germany (see section //) and its strict interpretation of the requirements. Moreover, the Court’s lenient approach does not cover requests for derogations under Article 114 (5). In the *Upper Austria* case the Court confirmed that the Commission had discretion in choosing experts in order to assess whether the evidence submitted complied with the prerequisite of ‘new scientific evidence’ under paragraph (5). In this case the Commission had asked EFSA to assess the scientific evidence that Austria had submitted. Where EFSA came to the conclusion that the evidence in the so-called Müller report, which the Austrian authorities relied on, did not contain ‘new or uniquely local scientific information on the environmental or human health impacts of existing or future GM crops or animals’,⁴⁸ the Commission

⁴⁵ See Maletić (n 21) 115.

⁴⁶ *Id.*

⁴⁷ Case C-3/00 *Denmark v Commission* [2003] ECLI:EU:C:2003:167, paras 63-64.

⁴⁸ Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* [2007] ECLI:EU:C:2007:510, para 65.

subsequently rejected the request.⁴⁹ The approval of this practice by the Court again confirms the predominant role of scientific opinions adopted by EU committees or agencies and will make it difficult for Member States to fulfil the criteria posed by this provision.⁵⁰

5.2. The Precautionary Principle

Closely linked with the role of science is the application of the precautionary principle in the notification procedure. As indicated above, in the *Danish additives* case the Court appeared to be quite favourable towards a certain degree of respect for regulatory diversity within the derogation procedure of Article 114 (4) and alluded to the relevance of the precautionary principle and scientific uncertainty.⁵¹ Also, various Commission decisions contain precautionary language in response to the invocation of the principle by the derogating Member States.⁵² Hereby we can observe that when scientific evidence, assessed by an EU scientific committee or agency, confirms scientific uncertainty, the Commission tends to refer to the precautionary principle when approving the national derogations.

Yet, at the same time, both the Commission and the Court have been very restrictive in allowing the precautionary principle to be applied in the context of the deroga-

⁴⁹ Commission Decision 2003/653/EC relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty, 2003, L230/34.

⁵⁰ See also Maletić (n 21) 130.

⁵¹ Case C-3/00 *Denmark v Commission* [2003] ECLI:EU:C:2003:167, paras 63-64.

⁵² See in the 'creosote' cases, e.g. Commission Decision 1999/835/EC on the Danish derogation, 1999 OJ L329/82 stating at para 110 that 'national measures aiming at reducing the probability of prolonged dermal exposure to creosote, either through direct contact with creosote or wood treated with creosote, are justified in the light of the precautionary principle.' The three other decisions on derogation requests for creosote contain similar statements. See Commission Decision on the Dutch derogation 1999/832/EC (1999) OJ L329/25 and Commission Decision 1999/834/EC on the Swedish derogation (1999) OJ L329/63. See also Commission Decision 2006/372/EC on a Dutch derogation request on the regulation of limit values for the emissions of particulate matter by diesel vehicles, (2006) OJ L142/16 para 25-31; Commission Decision 2007/395/EC approving a Dutch derogation aiming to maintain more stringent national provisions on short-chain chlorinated paraffins, (2007) OJ L 148/17, paras 36-45. Is ok

tion mechanisms of Article 114(5) TFEU, in particular in relation to the criteria of new scientific evidence and new problems. Hence recourse to the precautionary principle does not appear to mitigate the stringent criteria of Article 114(5).⁵³ In the *Upper Austria* cases, Advocate General Sharpston expressed this by stressing that, however pertinent the precautionary principle may be in relation to new evidence concerning a new situation, ‘no amount of precaution’ could make that evidence or situation new and that in this manner the novelty of the situation and the evidence was a ‘dual criterion which must be satisfied before the precautionary principle comes into play’.⁵⁴

5.3 The Relevance of International Developments

The assessment of scientific evidence submitted by the derogating Member States by the Commission seems less important when there are clear international obligations that Member States (and the EU) need to adhere to. In several cases, the Commission allowed for differentiated regimes to be maintained, taking into account obligations from international agreements, without submitting the national derogation to review by EU bodies. For example, in the case of the EU framework aiming to achieve the Union’s targets under the Kyoto Protocol for the reduction of greenhouse gases, Austria⁵⁵ and Denmark⁵⁶ were allowed, for the purposes of environmental protection, to maintain lower targets for the level of so-called fluorinated gases than those set out in an EU regulation.⁵⁷ In these cases, the Commission found that both the Danish and Austrian measures were already contributing to the overall objective of the Kyoto

⁵³ See Maletić (n 21) 128.

⁵⁴ Opinion of AG Sharpston in Joined Cases C-439/05 P and C-454/05 P, para 134.

⁵⁵ Commission Decision 2008/80/EC concerning national provisions notified by the Republic of Austria on certain fluorinated greenhouse gases, 2008 OJ L24/45.

⁵⁶ Commission Decision 2007/62/EC concerning national provisions notified by Denmark on certain industrial greenhouse gases, 2007 OJ L32/130.

⁵⁷ Regulation (EC) No 842/2006, 2006, OJ L161/1.

Protocol to reduce greenhouse gases and went further than the EU regulation which aimed to result in significant F-gases emission reductions throughout the EU, principally in those Member States where appropriate measures for reducing F-gases emissions were not yet in place. In this manner, the EU would adopt more stringent measures at a later stage. To this end, Regulation 842/2006 had already recognised that Member States would be able to maintain more stringent national measures until 2012.⁵⁸ Denmark, for example, already had strict measures in place since 50 years earlier and applied for a derogation. The Commission examined the Danish order and concluded that it met needs based on grounds of environmental protection proportionality and did not constitute an arbitrary discrimination or disguised restriction on trade. Herewith the Commission allowed Denmark to be a forerunner in fulfilling international obligations. In 2014 the EU adopted new more stringent requirements in Regulation No 517/2014.⁵⁹

Also, in the case of so-called short-chain chlorinated paraffins (SCCPs), the Commission approved a Dutch derogation aiming to maintain more stringent national provisions on the SCCPs than laid down in Directive 76/769/EEC,⁶⁰ in particular taking account of new developments at the EU and international level. When assessing the Dutch notification of 2006,⁶¹ the Commission was well aware of novel scientific insights. First, a UK risk assessment had indicated new risks for certain applications of SCCP, which the Commission intended to send to the SCHER committee for review.

⁵⁸ See art 9(3)(a) of Regulation (EC) No 842/2006, 2006, OJ L161/1.

⁵⁹ European Parliament and Council Regulation No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006, 2014, OJ L150/195.

⁶⁰ Directive 76/769/EEC, this was repealed by Regulation (EC) No 1907/2006 of the European the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

⁶¹ A first Dutch notification of 2003 was approved only insofar as they did not apply to the use of SCCPs as constituents of other substances and preparations in concentrations lower than 1% intended for use as plasticisers in paints, coatings or sealants, and flame retardants in rubber or textiles. See Commission Decision 2004/1/EC concerning national provisions on the use of short-chain chlorinated paraffins notified by the Kingdom of the Netherlands under Article 95(4) of the EC Treaty, 2004 OJ L1/20.

Second, the EU had notified SCCPs as candidates under the UNECE Protocol and the Stockholm Convention on Persistent Organic Pollutants (POPs) respectively. Given that the outcomes of these processes could lead to further restrictions at the EU level and that the precise scope of any such further restrictions was unclear at that moment, the Commission considered it necessary to apply the precautionary principle. It thus authorised the Dutch provisions this time in their entirety without further review until new EU measures taking full account of the latest scientific data would be adopted.⁶² In 2010 the Commission decided that the Netherlands could maintain its legislation until 1 June 2013 and called for a re-examination of the restriction of SCCPs laid down in the REACH regulation.⁶³ Finally, pushed by new international obligations flowing from the Stockholm Convention, the Commission amended its rules on persistent organic pollutants in 2012 and widened the scope of the restriction on the use of SCCPs by prohibiting their production, placing on the market, and use, except for two exempted uses.⁶⁴

5.4 Burden of Proof

Our analysis reveals a strong emphasis by both the Commission and the Court on the burden of proof that is being placed on the Member States that wish to derogate when faced with challenges to Commission's rejections of derogations. We already set forth above that in the *Danish additives* case the Court's lenient approach towards the permissible scientific data that could be submitted by the derogating Member State was

⁶² Commission Decision 2007/395/EC concerning national provisions on the use of short-chain chlorinated paraffins notified by the Kingdom of the Netherlands under Article 95(4) of the EC Treaty 2007 OJ L148/17, paras 36-45.

⁶³ Commission Decision 2010/226/EU on the re-examination of the restriction concerning short-chain chlorinated paraffins (SCCPs) listed in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

⁶⁴ Commission Regulation 519/2012 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I, 2014, OJ L363/67.

counterbalanced by its strict adherence to the burden of proof placed on that State. The latter had to prove that the national provisions ensure a level of health protection which is higher than the EU harmonisation measure and that they do not go beyond what is necessary to achieve that objective.⁶⁵ In *Toys*, the General Court again emphasised the burden of proof on Germany that wished to maintain its existing legislation upholding stricter limits on values for lead, barium, arsenic, antimony, mercury, nitrosamines, and nitrosatable substances in toys. The Court ruled that Germany had failed to demonstrate that the national measure provided a higher level of protection than the EU harmonising measure and that it did so in a proportionate manner.⁶⁶

5.5. Proportionality

Member States that wish to derogate must prove that their provisions are not a means of arbitrary discrimination or a disguised restriction on trade between the Member States and do not constitute an obstacle to the functioning of the internal market (Article 114 (6) TFEU). An important aspect of the procedure of national derogations therefore has been for the Commission to analyse whether the national derogating measures go beyond what is necessary to attain the objective foreseen and hence to apply the proportionality principle.

A good example is the Commission's assessment of the German derogation request on pharmacovigilance under Directive 2000/38 introducing a new EU-wide electronic data system of pharmacovigilance.⁶⁷ According to the German authorities, their existing stricter obligation requirements would attain the highest possible level

⁶⁵ Case C-3/00 *Denmark v Commission* [2003] ECLI:EU:C:2003:167, para 64.

⁶⁶ Case T-198/12 *Germany v Commission* ECLI:EU:T:2014:251. In this case Germany challenged Commission Decision 2012/160/EU that only in part and temporarily approved the derogation.

⁶⁷ Commission Directive 2000/38/EC amending Chapter Va (Pharmacovigilance) of Council Directive 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products 2000 OJ L139/28.

of protection for the population in their use of medicinal products. The Commission, however, rejected the notification, emphasising that the system of information sharing chosen under the EU Directive would adequately protect public health. It stated that ‘maintaining the previous obligations to report would place an unnecessary and unjustifiable burden on the respective marketing authorization holders.’⁶⁸ Moreover, the Commission deemed its assessment of the appropriateness of the EU system to be supported by the fact that Germany ‘is the only Member State which does not restrict the obligation to report adverse reactions occurring in non-member countries to those which are unexpected, but extends this obligation to adverse reactions which are expected.’⁶⁹

In the *Dutch emissions* case, the Commission carried out a similar strict analysis. Here it recognised the need for further reductions of emissions but emphasised the grave consequences for the vehicle manufacturers who would have to adapt their production or restrict the models on the Dutch market.⁷⁰ It concluded that the envisaged national measure was not the least restrictive to achieve the desired environmental and health protection and would constitute a disproportionate barrier to the functioning of the internal market.⁷¹ Hence, in this case, the Commission gave more weight to the disruption of the internal market than the potential benefits of the measure. This suggests the application of the most onerous version of the proportionality principle.⁷²

5.6. EU RATHER THAN NATIONAL NORMS AND PROVISIONS

⁶⁸ Commission Decision 2001/571/EC, on the national provisions notified by Germany in the field of pharmacovigilance, 2001, L202/46, para 24.

⁶⁹ *Id.*, para 29.

⁷⁰ Commission Decision 2006/372/EC concerning draft national provisions notified by the Kingdom of the Netherlands under Article 95(5) of the EC Treaty laying down limits on the emissions of particulate matter by diesel-powered vehicles (OJ 2006 L142, p. 16).

⁷¹ *Id.*, para 62.

⁷² Maletić (n 21) 145.

Closely linked to the above is our, rather unsurprising, finding that both the Commission and the Court seem to prefer the EU harmonisation measures to the notified national derogation measures. Therefore, an important aspect in the assessment of derogation requests has been the question whether the national measure was based on evidence already available prior to EU harmonisation and whether the EU took this evidence into account in the preparation of the EU harmonising measure. Hence, all notifications rejected under Article 114 (4) suggest a presumption in favour of the risk management choice made at EU level by both the Commission and the Court.⁷³

The central role assigned to the Commission as the risk manager within Article 114 opt-outs by the Court in its case law is crucial. In the *PCP* case the Court held that Member States cannot unilaterally apply national measures which deviate from the norm set by harmonisation measures adopted in the field concerned.⁷⁴ The centrality of the Commission's role as a risk manager was further underlined by the Court in the *Kortas* case⁷⁵ and was confirmed in the *Dutch Emissions* case of 2008. In the latter case, the Court held that the primary responsibility for the assessment of the merits of a request for derogation rests on the Commission, which must itself properly take account of all the relevant evidence and explain the essential considerations that led to adopting its decision.⁷⁶

It thus seems that, in cases of divergent risk management choices regarding differences in the appropriate level of protection based on the same risk assessment, there is a clear preference for the EU norms adopted either by the legislator or, in the case of new evidence, the Commission. This conclusion is substantiated by the Commission's

⁷³ See also Maletić (n 21) 139 ff.

⁷⁴ Case C-41/93 *France v Commission* [1994] ECLI:EU:C:1994:196, para 30.

⁷⁵ Case C-319/97 *Kortas* [1999] ECLI:EU:C:1999:272.

⁷⁶ Case C-405/07 *Netherlands v Commission* [2008] ECLI:EU:C:2008:613, para 67.

assessment in 2003 of the German derogation request on the use of azodyes,⁷⁷ which sought to impose a higher level of protection by also banning azodyes in materials other than textiles and leather. To support its notification, Germany relied on the same SCTEE scientific opinions but interpreted them differently with regard to the risks posed by the use of azodyes in other materials. The Commission held that the new EU legislation already took these opinions into account and had opted for a regime to impose restrictions only where sufficient data has clearly shown the existence of risks (namely for textiles and leather).⁷⁸ Since Germany failed to prove ‘the existence of a known risk to human health going beyond the risk already identified by the Community legislature’,⁷⁹ the Commission rejected the request, even considering the lack of scientific data with regard to the use of azodyes in other materials than textiles and leather. Hence, the risk management choice taken by the EU legislature seems to have been decisive in this case.

Also the Commission’s scrutiny of Denmark’s request to derogate from the EU additives directive⁸⁰ relied on a similar reasoning. In this case, Denmark relied in particular on the risks pointed out by several scientific opinions of the EU’s former Scientific Committee on Food (SCF) (now EFSA). The Commission, while acknowledging these risks, stressed that the EU Directive already took into consideration all the questions raised by the SCF and rejected the request. Hereby it stressed the ‘responsibility incumbent on a legislator, whether Community or national, with regard to risk management.’⁸¹ Hence, according to the Commission, Denmark’s responsibility as a

⁷⁷ European Parliament and Council Directive 2002/61/EC amending for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (azocolourants), 2002, OJ L243/15.

⁷⁸ Commission Decision 2003/829, concerning national provisions on the use of azodyes notified by Germany under Article 95(4) of the EC Treaty 2003 OJ L311/46, para 41.

⁷⁹ *Id.*, para 46.

⁸⁰ European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners, 1995, OJ L61/1.

⁸¹ Commission Decision 1999/830/EC on national provisions notified by Denmark concerning the use

risk manager in this case was much more restricted than the responsibility of the EU legislature. Yet, in 2003, the Commission's decision was annulled by the Court for having failed to duly take into account an opinion of the EU Scientific Committee for Food, which affected the scientific basis of the EU harmonisation measure and which was favourable to Denmark's submission.⁸²

This judgment influenced the subsequent Commission approach to a new Danish derogation request for nitrites in meat. Here Denmark wished to derogate from Directive 2006/52/EC, which amended the previous EU framework in the light of a new EFSA opinion and the Court's *Danish additives* judgment.⁸³ This time, although still considering that the EU Directive provided for an adequate response to the challenge of reconciling two health risks,⁸⁴ the Commission acknowledged the possibility for Denmark to choose a different level of protection for a limited period of time. It submitted that it was necessary 'to evaluate the specific choices made by the Danish regulator and the experience made with these rules, which have been in force for a considerable period of time' and that 'the Danish legislation is compatible with the relevant scientific opinions of the Union's scientific bodies.'⁸⁵ Subsequently, the Commission has continued to extend its approval of the Danish derogation for its provisions on nitrates in meat,⁸⁶ while requiring EFSA to re-evaluate the use of nitres by

of sulphites, nitrites and nitrates in foodstuffs, 1999 OJ L329/1.

⁸² Case C-3/00 *Denmark v Commission* [2003] ECLI:EU:C:2003:167, para 114.

⁸³ See para 10 of Commission Decision 2010/561/EC concerning national provisions notified by Denmark on the addition of nitrite to certain meat products, 2010, OJ L247/55.

⁸⁴ Namely, the presence of nitrosamines in meat products, on the one hand, and the microbiological safety of meat products, on the other hand, see paras 49-50 of Commission Decision 2010/561/EC, *supra* note 84. Is ok

⁸⁵ Commission Decision 2008/448/EC, paras 51-52.

⁸⁶ Commission Decision 2008/448/EC (2008) OJ L157/98 allowed first for a derogation of two years. Subsequently the Commission, in its Decision 2010/561/EC, approved of the Danish derogation for a period of five years, most recently, Commission Decision (EU) 2015/826 approved the provisions until 22 May 2018, 20105 OJ L130/10.

the end of 2015.⁸⁷ It is likely that after such a re-evaluation of these substances, the Commission will either adjust the EU legislation or ensure that the Danish provisions will be in line with the EU rules. Therefore, the Court's lenient ruling and the Commission's cooperative practice towards the Danish provisions on nitrates in meat seem to be rather an exception to the practice of derogations under Article 114 (4) and are rooted in the complexities and uncertainties as to the use of nitrates in meat. It seems therefore very likely that after 22 May 2018 -- the date until which the Danish derogating provisions have been approved -- and EFSA's opinion -- due by the end of 2015-- either the EU or Danish legislation will be amended.

6. DIFFERENTIATION THROUGH SAFEGUARD CLAUSES

6.1. Article 114(10) and Safeguard Clauses in EU Legislation

In addition, the Treaty instructs the European institutions to provide for safeguard clauses in measures that deal with the protection of human health and safety and the environment. Member States may thus derogate from the obligation to ensure free movement of goods that comply with the rules laid down in EU harmonisation measures if a specific product legitimately produced in accordance with the EU rules causes a danger to *inter alia* human health or the environment. Thus paragraph (10) of Article 114 TFEU stipulates that harmonisation measures shall, in appropriate cases, include a safeguard clause which enables the Member States to take provisional measures for one or more of the non-economic reasons referred to in Article 34 TFEU, which are subjected to an EU control procedure.⁸⁸

⁸⁷ Commission Regulation 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives, 2010 OJ L80/19.

⁸⁸ In practice, the inclusion of such clauses in directives was already common prior to the Single European Act, which introduced this possibility into the Treaty. See the survey carried out by Ludwig Krämer, *EEC Consumer Law* (Story-Scientia 1986) points 242-246.

The safeguard clause requires Member States to notify the Commission of any stricter national provision they want to maintain or adopt and complements the notification procedures for non-(fully) harmonised areas. It aims to prevent dangerous products from circulating in the EU market. At the same time, the inclusion of safeguard measures reflects a recognition of the constitutional obligation of most Member States to ensure the health and safety of their citizens.⁸⁹ Hence, where a Member State has good grounds for believing that a product which satisfies the requirements set out in a specific directive nonetheless poses a hazard to safety or health, it may temporarily prohibit this product or attach special conditions to its circulation. The final say in this procedure is left to the Commission together with a committee composed of national representatives. These cases generally lead the Commission to consider whether a revision of the relevant provisions in the harmonisation measure is necessary. Practice shows that also in situations where Member States rely on the safeguard clause, resort to science and reasoning in terms of science has become crucial. As will be discussed below (section 6.2.), in particular in relation to the authorisation of GMOs, comitology has given the Member States an instrument to enforce the maintenance of national derogations against the will of the Commission.

In addition, we also observe a recent trend of a disappearance of safeguard clauses from some of the EU food legislation. While this seems unconstitutional and in conflict with the rationale underlying Article 114 (10) TFEU, our analysis reveals that the safeguard clauses in such measures are replaced by the emergency procedures of the General Food Law that empower the Commission (and not the Member States) to take measures at once.⁹⁰ This would indicate a shift from the power of Member States to

⁸⁹ See Hans W Micklitz, Thomas Roethe and Stephen Weatherill (eds), *Federalism and Responsibility. A Study on Product Safety Law and Practice in the European Community* (Graham & Trotman 1994).

⁹⁰ Articles 50 and 53, 54 of European Parliament and Council Regulation 178/2002, 2002, OJ L31/1, as lastly amended by Regulation (EU) No 652/2014, 2014 OJ L189/1.

act as risk managers to the Commission as the central risk manager as we already signalled above. This shift may in turn cause tension in relation to the constitutional obligations of some Member States to protect the health and safety of their citizens.

6.2. From Safeguard to Opt-out Clause Laid Down in a Directive: The Case of GMOs

Our analysis reveals that it has appeared virtually impossible to find information on the use of safeguards, which has led us, for the time being, to limit our research to the food sector. Here it seems that relatively few derogations have been requested.⁹¹ Most derogation requests concerned the notifications in the framework of the safeguards clauses laid down in the GMO Deliberate Release Directive⁹² (13 notifications). These cases are exemplary in demonstrating the limits of scientific expertise when resolving politically sensitive regulatory issues. In the GMO case science, although frequently invoked by both Commission and Member States, has so far not been able to resolve the regulatory deadlock,⁹³ for which the EU was condemned by a WTO panel.⁹⁴ Rather, this deadlock led the Commission in 2010 to propose an amendment to the Deliberate Release Directive so as to include a new and highly unusual opt-out clause in this Directive.⁹⁵ After five years of discussion, the reform finally entered

⁹¹ A mere 16 invocations were done under Directives 90/220, 2001/18, 2002/53, and Regulation 178/2002.

⁹² European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2001 OJ L106/1.

⁹³ Maria Weimer, 'Applying Precaution in EU Authorization of Genetically Modified Products – Challenges and Suggestions for Reform' (2010) 16(5) *European Law Journal* 624 and Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance' (2015) 21(5) *European Law Journal* 622-640.

⁹⁴ Maria Lee, *EU Regulation of GMOs* (Edward Elgar 2008).

⁹⁵ Maria Weimer, 'What Price Flexibility? – The Recent Commission Proposal to Allow for National "Opt-outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Post-Lisbon' (2010) 1(4) *European Journal of Risk Regulation* 345; and Weimer 2015 (n 93).

into force in April 2015.⁹⁶

The new so-called ‘flexible approach’ to GMO cultivation embodied in the now amended Deliberate Release Directive is an exceptional example of a process in which a persistent invocation of both Article 114 opt-outs and safeguard clauses has resulted in a new differentiated regulatory regime. Moreover, for the first time, the Commission has proposed to give back to Member States decision rights previously exercised at the EU level and thereby to allow for less harmonisation across the Union.⁹⁷ According to the now agreed amendment of Directive 2001/18, a new Article 26b⁹⁸ entitled ‘Cultivation’ shall be inserted, laying down the procedure for the adoption by a Member State of measures restricting or prohibiting the cultivation of a GMO previously authorised at EU level in all or part of its territory. The most unusual feature of this new legal basis for GMO opt-outs consists in the nature of the grounds for ‘opting-out.’ In contrast to the traditional opt-out (Article 114) and safeguard measures discussed above, which have been provided for by the EU legislator in order to allow for a better protection of public health and the environment, the GMO ‘opt-out’ excludes these grounds from the permissible grounds on which Member States may rely when banning GMOs. Quite to the contrary, Member States have to base their opt-outs on grounds which do not conflict with the scientific risk assessment of health and environmental risks conducted by the EFSA. The new Article 26b (3) states that Member States may adopt opt-out measures

provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on compelling grounds such as

⁹⁶ European Parliament and Council Directive 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, 2015, OJ L68/1.

⁹⁷ For a more detailed discussion of the nature and problems of this reform see Weimer 2015 (n 93).

⁹⁸ Moreover, an art 26c is inserted concerning ‘Transitional measures.’

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

The amendment emphasises that the assessment of potential risks for human and animal health and the environment of the deliberate release of GMOs is fully harmonised. Therefore, the Member States should only use grounds related to environmental policy objectives which do not conflict with the EU assessment of risks.⁹⁹

The rationale behind this framing is to grant the Member States more regulatory autonomy when it comes to GMO cultivation, but only for the purpose of responding to so-called ‘other legitimate factors’ involved in GMO cultivation. The EU centralised authorisation procedure with its harmonised risk assessment and EFSA’s epistemic authority¹⁰⁰ ought to be preserved, however. This also shows that the persistent invocation of opt-out and safeguard clauses in the GMO case has *not* led to a differentiation in terms of different levels of public health and environmental protection across the Union (as was sometimes the case in other areas, see discussion above). In other words, it has not led to the acceptance by the EU, most notably the Commission, of scientific pluralism including different evaluations of scientific evidence on GMOs. Instead, national bans and restrictions on GMOs have led to an opening up the ‘scientific risk’ framing of the GMO regulatory regime by providing the Member States with a legal basis to act upon other concerns surrounding the issue of GMO cultiva-

⁹⁹ See recitals (6) and (14) of Directive 2015/412, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, 2015, OJ L68/1.

¹⁰⁰ See Maria Weimer and Gaia Pisani, ‘Expertise as Justification - The Contested Legitimation of the EU ‘Risk Administration’ in Maria Weimer and Anniek de Ruijter (eds), *Regulating Risks in the European Union - The Co-production of Expert and Executive Power* (forthcoming with Hart Publishing).

tion (e.g. agricultural, land use and even more abstract public policy¹⁰¹ concerns).

Interestingly, the GMO case also signals an important difference between Article 114 opt-outs and safeguard clauses in terms of their impact on differentiation versus harmonisation. The resistance against GMO authorisation on the part of several Member States was mainly channelled through the invocation of the safeguard clause laid down in Article 23 of the Deliberate Release Directive. This was unsurprisingly due to the fact that comitology, as the applicable procedure, provided for a forum in which Member States could voice their opposition to a Commission decision rejecting the safeguard measure. In this way comitology allowed for a certain mitigation of (EU) science as the sole basis for the Commission decision bringing both other concerns than science and divergent national evaluations of scientific evidence into the discussion surrounding GMOs. In contrast, the Article 114 opt-out procedure does not foresee comitology, but instead grants the Commission (based on the opinion of an EU agency) the sole authority to decide on opt-outs. This leads us to assume that the gradual disappearance of safeguard clauses in EU secondary legislation is likely to result in strengthening the role of the Commission as the central EU risk manager at the expense of a more multi-level approach.¹⁰²

7. CONCLUDING REMARKS AND REFLECTIONS ON THE IMPACT OF THE DEROGATION MECHANISMS ON THE INTERNAL MARKET

Overall, in the case of opt-out notifications we can observe the following pattern in

¹⁰¹ On the invocation of ethical and religious arguments against GMOs, see Case C-165/08 *Commission v Poland* [2009] ECLI:EU:C:2009:473.

¹⁰² See Maria Weimer, 'The Right to Adopt Post-Market Restrictions of Genetically Modified Crops in the EU – A shift from De-Centralised Multi-Level to Centralised Governance in the Case of GM Foods', Case note on Court of Justice of the European Union, Joined Cases C-58/10 to C-68/10 *Monsanto SAS and Others* (2012) 3 *European Journal of Risk Regulation* 445.

the practice of Commission decision making. First, EU scientific opinions seem to play a crucial role in determining whether or not the Commission approves a national derogation under both Article 114 (4) and (5). The Commission does not simply consider the evidence submitted to it by the notifying Member State, but it typically sends it to EFSA or a relevant EU scientific committee for re-evaluation. Where the EU scientific bodies confirm the scientific justification invoked by the notifying Member State, the Commission authorises the derogation. Hereby, in several cases, the Commission has relied on the precautionary principle or has invoked scientific uncertainty as an argument to approve the notification – only in accordance with the advice of EU scientific bodies, however. Another important factor of a successful notification seems to be whether a re-evaluation of a risk assessment with regard to a particular substance or product is already on-going at the EU level. Moreover, international developments and institutions provide an important context, which the Commission takes into account in its decisions. This was the case with the Kyoto Protocol in the fluorinated gases cases and with WHO guidelines in the short-chain chlorinated paraffins case. Finally, it can be noted that those cases in which derogations resulted in the adjustment of rules at the EU level were characterised by the fact that several (more than two) Member States filed a notification.

The modest application of the derogation possibilities under Article 114 (4) and (5) shows that the initial fears that the opt-out mechanism would lead to a fragmented internal market have not materialised.¹⁰³ Member States have only in a few cases enforced their national positions on health and safety issues notwithstanding a common approach adopted at EU level. And, of the 38 cases that were notified, 17 derogations were approved. Notably, in approximately 50% of the latter cases, the derogations

¹⁰³ See e.g. Pescatore(n 14).

have led to an adjustment of the EU framework to set a higher level of protection. In the other 50% of derogation approvals, the situation is less straightforward. In five cases the approval of derogations did not immediately lead to any further action at the EU level. The Danish provisions on nitrates in meat have been controlled by the Commission that renewed its approval of these derogation measures three times. As indicated above, currently EFSA will re-evaluate the use of these substances, which in all likelihood will subsequently lead to either an amendment of EU legislation or the discontinuation of the Danish derogation measures. The other four cases seem rather atypical cases of compliance with the Kyoto Protocol where the Commission did not submit the national derogation request for scientific review at the EU level but rather approved of the national derogation. In these cases, the derogation was approved for a limited period. Both new scientific insights at the EU and international level have led the Commission after 10 years to revise the relevant EU measures and to expand the restriction on the use of SCCPs. In the other cases, derogations were granted in the light of or until the completion of the revision of EU legislation. Hence, it seems that, where differentiation has been permitted by the Commission, the permission was of temporary nature until a revised EU framework would be established.

Therefore in the case of approved notifications, both Article 114 (4) and (5) seem to be an important mechanism of regulatory adjustment and learning in the fields of public health and environmental protection at the EU level. In some cases the successful invocation of an opt-out has ultimately triggered a process of further harmonisation at the EU level aiming to remove the regulatory disparities among the Member States. In such cases the Commission was more tolerant to allow for a derogation especially in cases in which many Member States filed a notification to derogate from the same harmonisation measure, such as in case of PCP, creosote and cadmium, thus

threatening the internal market laws on these substances. Hereby, it seems that it is not coincidental that the approval of the derogations resulted in the adjustment of the EU rules at the higher level of protection, pushed for by the derogating Member States. The Commission's line of argumentation in these cases clearly shows the importance of avoiding what is deemed as unnecessary burdens on traders.¹⁰⁴

Moreover, the emphasis on the relevance of choices made in other Member States refutes the logic of differentiation. Rather, a 'one size fits all' approach becomes apparent. Our study shows that the opt-out mechanism can be seen as failing to realise the promise of regulatory diversity and instead ultimately strengthens the uniformity of regulatory requirements in the EU internal market. Hence, the practice does not confirm the view that opt-out and safeguard clauses constitute a means of differentiated integration in EU internal market law. Rather they can be regarded as mechanisms increasing the uniformity of regulatory requirements in the EU internal market and thereby serving as means of further harmonisation. This happens mainly in two ways. Firstly, the strict interpretation by both the Commission and EU Courts of the legal requirements for a Member State to invoke an opt-out or safeguard clause successfully prevents more frequent invocation of these derogation mechanisms. Secondly, where these mechanisms are actually being invoked successfully, this ultimately triggers a process of further harmonisation at the EU level to remove the regulatory disparities among the Member States. In these cases, the derogation clauses could be characterised as a kind of learning process indicating the need to provide other EU legal solutions and could act as a catalyst for better regulation and protection at the

¹⁰⁴ For a similar reasoning see Commission Decision 2003/829 on azodyes recital 46.

EU level.¹⁰⁵ The ultimate result, however, is a uniform EU framework rather than the acceptance of regulatory differences.

An example of this is the strengthening of the role of the European Commission as a central risk manager of crisis situations and emergencies with regard to food safety. However, as the GMO case shows, persistent national derogations might also indicate the need to provide for more regulatory autonomy at the national level. The recent ‘flexible approach’ of the European Commission to GMO cultivation, which followed a yearlong national non-compliance with EU rules in this field, is a case in point. It exemplifies the tension between the creation of one internal market on which all products that conform to the EU rules may freely circulate on the one hand and the possibility and right of Member States to adhere to the values that they highly regard and wish to uphold on the other. The complexities of decision making on GMOs illustrate a strong reliance of the Commission on scientific expertise (also pushed by the WTO), which has been accompanied by a continuous ‘battle of the experts.’¹⁰⁶ Persistent invocation of derogations by several Member States has in this case led to a new differentiated regulatory regime, as well as to the creation of a novel type of opt-out to be invoked on grounds other than public health and environmental safety. Consequently, GMO derogations have *not* led to a differentiation in terms of different levels of public health and environmental protection across the Union, given that the EU-wide scientific assessment remains fully harmonised. Instead, they resulted in opening up the ‘scientific risk’ framing of the GMO regulatory regime by allowing the Member States to act upon other concerns surrounding the issue of GMO cultivation.

¹⁰⁵ See also Maletić (n 21) 186.

¹⁰⁶ See Denise Prevost, ‘The Role of Science in Mediating the Conflict between Free Trade and Health Regulation at the WTO: The EC - Biotech Products Dispute’ in Marjolein Van Asselt, Ellen Vos and Michelle Everson (eds), *Trade, Health And The Environment: The European Union Put To The Test* (Routledge Explorations in Environmental Studies 2013) 161-212.

Lastly we need to reflect on what the low number of invocations of the opt-out clauses (and the safeguard clauses) really tells us. Does this mean that Member States are satisfied with the level of protection of the non-market values and that they feel no need to opt out of the general harmonisation schemes? This is not necessarily the case. First, the opt-out procedure is important in the negotiations of a harmonisation measure and gives Member States an important tool to push for a level of protection that is satisfactory to all Member States. In addition, analysis of the practice and case law on the opt-out procedures reveals that both the Commission and the Courts have an extremely rigid reading of the procedure while the grounds for invocation are very limited. As the GMO case exemplifies, this requires a rethinking of the ways in which the paradigm of uniformity may be combined with a respect for diversity, which eventually will impact on the implementation of international legal (trade) regimes. This entails a profound reflection on what ultimately should be the inner soul of the internal market¹⁰⁷ and more generally of the EU.

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¹⁰⁷ Stephen R Weatherill, 'Maximum versus Minimum Harmonization: Choosing between Unity and Diversity in the Search for the Soul of the Internal Market' in Niamh Nic Shuibhne and Lawrence W. Gormley (eds), *From Single Market to Economic Union: Essays in Memory of John A Usher* (Oxford University Press 2012) 175.

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