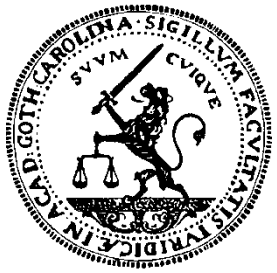

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Opting out of GM agriculture

-

The scope for EU Member States to restrict cultivation of genetically modified crops

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Summary

Cultivation of genetically modified organisms (GMOs) has for a long time been a disputed and politically sensitive topic in the EU. To many European citizens such cultivation raises concerns, ranging from safety and socioeconomic questions to ethical issues. This thesis examines the possibilities for Member States to respond to such concerns by imposing national GM cultivation restrictions.

This in an area of regulation that is part of a larger internal market context. The EU legal framework on GMOs has since it was put into place been characterised by a high degree of harmonisation and centralisation. Following this, a GMO that has been authorised for cultivation purposes may in principle be cultivated throughout the entire Union. National restriction after such authorisation has been granted has in large been limited to explicit derogation provisions in secondary and primary EU law. Until recently, these mainly science-based provisions have mostly provided for health and environmental concerns to be invoked by Member States. In 2015, the possibilities for Member States to limit GM cultivation were amended by partial "de-harmonisation" of the GMO framework.

The article enshrined in the amendment also comes with some innovative procedural changes. It holds that before authorisation Member States can reach agreements with the economic operators applying for authorisation on restricting the geographical scope of where the GMO can be cultivated. On paper the mentioned de-harmonisation means that where such agreements are not reached, a wide range of concerns can form the basis for Member State restrictions after authorisation, if the measures in question are in conformity with Union law.

In the thesis the scope for Member States to "opt out" of GM cultivation under the original still-existing provisions and the amendment are put under scrutiny.

By looking back at their historical use, the examination shows that the central institutions such as the Commission and the EU Courts have interpreted the substantive conditions of the original provisions strictly. As such Member States have been unsuccessful in fulfilling their substantive conditions, which in theory makes environmental considerations hard to pursue under them. However, much to the dismay of the Commission, procedural rules have often allowed Member States to keep their national restrictions. In other cases, the Commission itself has had a rather lax approach to restricting measures, making restrictions possible.

Regarding the amendment, it is found that many questions arise as to its actual scope and how it changes the overall possibilities to adopt restrictions. First, there is no guarantee that Member States will succeed in negotiations with companies seeking authorisation. Second, the partial de-harmonisation comes along with questions as to if this at all changes the possibilities to invoke environmental concerns. Moreover, requirements on the restrictive measures' compliance with general rules and principles of internal market law could limit the scope of the new article. A number of potential hurdles are identified in light of the case law on free movement provisions. In this regard, the future of restricting GM cultivation by relying on the new derogation grounds will depend on the approach taken by the Commission and the EU courts to the new article.

Sammanfattning

Odling av genetiskt modifierade organismer (GMO) har länge varit ett omdebatterat och politiskt känsligt ämne i EU. Sådan odling väcker en mängd olika betänksamheter och frågor hos europeiska medborgare. I spektrumet återfinns bland annat frågor om risker för miljön och hälsa till socioekonomiska och etiska betänkligheter. Den här uppsatsen undersöker medlemstaters möjligheter att svara upp mot sådana betänkligheter genom att införa nationella begränsningar mot odling av GM grödor.

Det EU-rättsliga ramverket för GMO har sedan dess tillkomst kännetecknats av en hög grad av harmonisering och centralisering. På detta följer att en GMO som har beviljats odlingstillstånd via regelverkets tillståndsförfarande i princip kan odlas i hela Unionen. Utrymmet för nationella begränsningar efter beviljat tillstånd har i stort sett varit begränsat till explicita undantagsbestämmelser i EU:s primär- och sekundärrätt. Fram tills nyligen har dessa undantagsregler främst bestått av vetenskapsinriktade sådana, vilka föreskriver att miljö- och hälsobetänkligheter kan åberopas. 2015 kom GMO- ramverket att delvis revideras genom en partiell ”av-harmonisering” av medlemsstaters möjligheter att begränsa av odling.

Artikeln som återfinns i tilläggsdirektivet innehåller även en innovativ processuell förändring. Den innebär att medlemsstater kan ingå överenskommelser med företag som söker odlingsstillstånd under tillståndsprocessen så att det geografiska området där odling får ske begränsas. På pappret innebär den ovan nämnda av-harmoniseringen att i de fall där sådana överenskommelser inte kan nås så kan medlemsstaterna nu åberopa en mängd nya grunder till stöd för restriktiva åtgärder efter beviljat odlingstillstånd. Detta förutsätter dock att åtgärderna står i överensstämmelse med unionsrätten. I uppsatsen utreds utrymmet under de ursprungliga, ännu gällande bestämmelserna och tilläggsdirektivet för medlemsstaterna att begränsa odling av GM grödor.

Genom en granskning av rättspraxis och det tidigare bruket av de ursprungliga bestämmelserna framgår i uppsatsen att centrala institutioner, såsom Kommissionen och EU-domstolarna har tolkat dessas materiella rekvisit restriktivt. Medlemsstaterna har genomgående misslyckats med att bevisa att kraven är uppfyllda, vilket i teorin gör att miljömässiga betänkligheter juridiskt sett är svåra att framföra under dessa bestämmelser. Till Kommissionens förtret har dock processuella regler i många fall möjliggjort att medlemsstater kunnat behålla sina nationella odlingsbegränsande bestämmelser. I andra fall har Kommissionen själv visat på en relativt återhållsam inställning till restriktiva åtgärder, vilket har möjliggjort för deras införande och bibehållande.

Gällande artikeln i tilläggsdirektivet finner uppsatsen att en mängd frågor uppenbarar sig rörande vilket utrymme den faktiskt ger medlemsstaterna och hur den ändrar de övergripande möjligheterna att införa nationella begränsningar. Till att börja med finns det ingen garanti att medlemsstaterna lyckas i förhandlingarna med tillståndssökare. För det andra medför den partiella av-harmoniseringen frågor gällande om den alls ändrar möjligheterna att åberopa miljöskäl. Därtill innebär krav på de restriktiva åtgärdernas förenlighet med generella regler och principer för inre marknaden att utrymmet i praktiken kan komma att vara begränsat. Flera potentiella hinder identifieras i ljuset av rättspraxis gällande reglerna för fri rörlighet. I detta avseende kommer eventuell framgång vid åberopande av de nya grunderna som stöd för begränsning av GM odling i stor utsträckning bero på Kommissionens och EU-domstolarnas förhållningssätt till den nya artikeln.

Preface

Jag vill rikta ett stort tack till min handledare Sanja Bogojević. Hon har genomgående varit hjälpsam, tålmodig och upplyftande. Tack även till Lund, med allt vad det innebär. På återseende! SFGD.

1 Introduction

1.1 Introduction

Genetically modified organisms (GMOs) have been controversial ever since the birth of genetic engineering. Debates on the benefits and concerns of GMOs range from questions of their safety to their socioeconomic and ethical implications.[1] Positions on these issues differ widely within and between given political entities. Regulation of GMOs is "deeply embedded in its social context"[2] and there are a number of interests and concerns for decision-makers to take account of.

Whereas genetic engineering applies to different areas, history shows that one of the most heated aspects of this modern technique is the cultivation of GM crops.[3] Since such cultivation first became commercialised in the USA in the mid 1990s, the total global area covered by GM agriculture has now passed 180 million hectares, or 1,8 million km2. As for now, commercial cultivation of a wide array of GM crops takes place in some twenty countries.[4]

Within the EU only one GM crop is currently authorised to be commercially cultivated. That is the MON810, a variety of GM maize that has been modified to protect it from the European corn borer.[5] Today, commercial cultivation of MON810 takes place in five Member States on a total area of 1430 km2.[6]

As these modest numbers suggest, GM agriculture has not been uncontroversial in the Union. On the contrary, many Member States have been sceptical towards it. Out of 27 Member States, only eight have experienced commercial transgenic agriculture.[7] GM cultivation is an emotive issue to many EU citizens and has met strong public opposition in many Member States.[8] With various stakeholders, such as the biotechnology industry, farmers' organisations and environmental groups also making themselves heard, GM cultivation is and has for a long time been a politically sensitive issue in the EU. The economic importance of GMOs, the social controversies surrounding them, as well as the high levels of uncertainty as to their long-term effects, have all contributed to various political and regulatory troubles.[9] Indeed, the functioning of the EU legal framework on GMOs has since it was put in place been troubled by political disagreement. This has resulted in deadlocks in decision-making and significant delays in the process of authorisation of GM products on the internal market of the EU.[10]

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[1] See chapter 2.1.
[2] Lee 2008, p. 19.
[3] Especially so in the EU. Dobbs 2011, p. 180; Lee 2014, p. 235f.
[4] The top five countries are the USA, Brazil, Argentina, India and Canada. The most common GM crops are soybean, cotton, maize and canola. ISAAA, *Brief 49-2014: Top Ten Facts:* http://www.isaaa.org/resources/publications/briefs/49/toptenfacts/default.asp
[5] This is an insect native to Europe that is a pest of grain, particularly maize.
[6] Spain, Czech Republic, Portugal, Romania and Slovakia. The vast majority, 1315 km2, is cultivated in Spain. In addition field trials takes place in many Member States. ISAAA, *Brief 49-2014: Top Ten Facts:* http://www.isaaa.org/resources/publications/briefs/49/ toptenfacts/default.asp
[7] See Poli 2013, p. 143, who holds that Member States wishing to cultivate GMOs have always been a minority.
[8] As an illustrative example, between 2000 and 2010 there were over 70 serious attacks of vandalism on GM experimental field trials across the EU. This resulted in experimental trials of GM crops being relocated outside the EU. Morris and Spillane 2010, p. 363.
[9] Zurek 2011, p. 241.
[10] Weimer 2010, p. 345. See chapter 2.2.

As such, regulation of - and Member States' ability to respond to public concerns regarding – GM cultivation is largely set within the context of the internal market, which to a large extent provides a backdrop and limits to the extent that Member States can pursue individual polices.[11] In that context lays the GMO framework. At its core is a centralised authorisation system with case-by-case risk assessments, where an approval is needed for cultivation of each individual GMO. Overall, this framework is characterised by a high degree of harmonisation, where a GM crop that has been authorised in principle can be cultivated throughout the entire Union.[12] Also following the harmonised nature of the legal framework, the Member States have historically been afforded a rather limited discretion to regulate GM cultivation within their territories.[13] Yet, a number of Member States[14] have introduced national measures to restrict or prohibit GM cultivation. The Commission[15] have considered many of these bans unlawful, still, most of them have been kept.

Drawing on this, the subject of this thesis is to examine Member States' legal and practical possibilities to adopt such restrictive measures in response to their citizens' concerns. Following years of negotiations within and between the legislative institutions, these possibilities were amended as late as this spring by partially de-harmonising the GMO framework.

1.2 Aim and research questions

The overarching purpose of the thesis is to examine the legal possibilities for EU Member States to restrict cultivation of GM crops within their territories. In doing so, some additional focus is given to the substantive requirements regarding what concerns that are deemed legally legitimate for Member States to invoke when introducing restrictive measures. However, a complete picture of Member States' possibilities to opt out[16] from GM cultivation also requires an understanding of the actors[17] that shape these legitimate concerns and the processes through which they do so. Put differently, procedural rules are key to fully apprehend the issue. Hence, examining these also fall under the aim.

In this regard the thesis aims at examining the previous and potential future use of the original[18] derogation possibilities under the Deliberate Release Directive,[19] the Food and Feed Regulation (FFR),[20] and Article 114.5 TFEU.[21] The latter provision is part of the internal market rules, allowing

[11] See chapter 2.2.
[12] See chapter 2.2.2.
[13] As will be shown in chapter 2.2.3, this has also had consequences for the functioning of the authorisation scheme as such.
[14] For instance Austria, Hungary, Luxemburg, Italy and France.
[15] See chapter 3. Others have also considered them questionable, see The Farmers Scientist Network, *National GM bans scientifically unfounded and legally questionable:* http://greenbiotech.eu/2013/08/12/national-gm-bans-scientifically-unfounded-and-legally-questionable/
[16] This is a term found in documents from the Commission that is synonymous to the word restricting.
[17] Important actors in the GMO legislation context are the EU Courts, i.e. the Court of Justice of the European Union (CJEU), the Commission and the European Food Safety Authority (EFSA). See chapter 1.4.
[18] They are original in the sense that they existed before, and remain unchanged by the amendment through Directive 2015/412.
[19] 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. Hereafter "Deliberate Release Directive".
[20] REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed. Hereafter "FFR".

for general derogations in harmonised areas, such as the one before us. The two former legislative acts are central[22] parts in the regulation of GM cultivation and allow for so-called safeguard measures, emergency measures and coexistence measures. The provision dealing with coexistence stands out from the others as it de-harmonises specific issues of socioeconomic character and provides for restrictive measures to be adopted on those grounds. In contrast, the three other original derogation provisions are concerned with safety issues, meaning science is an important part of their invocation.

The aim is also to scrutinise the scope of the new Article 26b of Directive 2015/412[23] - which amends the Deliberate Release Directive and partly de-harmonises the GMO regime - and to see how this changes the overall opt out possibilities. On paper the amendment opens up for a way out of GM cultivation through agreements with biotech companies and/or through invoking one or more of the new derogation grounds it provides for. In this regard, general Treaty law, such as the provisions on free movement, may restrict future reliance on this article. Hence, another objective is to examine the derogation possibilities in light of those general limitations in order to look closer on potential hurdles as to the new article's actual scope.

In line with this I seek to answer the following questions;

-What is the scope for Member States to restrict cultivation of GM crops in response to the concerns that such cultivation raises?

This question is in turn divided into a couple of sub-questions;

- What is the scope for Member States to restrict cultivation of GM crops in their territories under the original opt out possibilities?

- What is the scope for Member States to restrict cultivation of GM crops in their territories under the new Article 26b and in what way will the overall scope change through this amendment?

1.3 Delimitation

Some delimitation is warranted here. Firstly, GMOs do not only come as seeds that can be cultivated. They also come as finished products or as part of products, such as in food or animal feed. Although it might already be implied by the aim and research questions I should clarify that the thesis is not concerned with derogations from the marketing and free circulation of authorised GMOs in general. It is explicitly concerned with the restrictions on cultivation of GM crops.[24]

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[21] The numbering of this article was changed from 95.5 after the agreement on the Lisbon Treaty. The new numbering on this and other Treaty articles are used throughout the thesis.
[22] See chapter 2.2.
[23] DIRECTIVE (EU) 2015/412 OF THE EURPEAN PARLIAMENT AND OF THE COUNCIL of March 2015 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. Hereafter "Directive 2015/412".
[24] However some of the examined derogation possibilities are of relevance to restrictions in general on GMOs, i.e. not only on their cultivation. These are Article 23 of the Deliberate Release Directive, Article 34 FFR and Article 114.5 TFEU.

Secondly, restricting research on GM plants is not covered. It should be clarified that laboratory testing and so-called field trials[25] are important aspects in approvals for future cultivation of GM crops and have raised opposition among the European public.[26] However, spatially such research is of marginal importance.

Thirdly, coexistence measures are not fully addressed.[27] At least in theory coexistence measures provide a less stringent way for Member States to opt out of GM cultivation. Many Member States have adopted such measures, although their restrictive effects are not intended to be as far-reaching as those that are offered under the other opt out possibilities. As stated this area has already originally been expressly de-harmonised and it is concerned with certain socioeconomic impacts of GM cultivation. Being outside the harmonised area of the GMO regime this means that general Union law restrictions apply. As the overarching legal limitations under this law are somewhat the same for coexistence measures as for those applying to the new Article 26b, these are treated on a principle level in that context instead. Hence, coexistence is covered only to the extent that it shows that such measures allow for a different sort of concern to be taken into account when Member States want to restrict GM cultivation and to show that their over-use has not been challenged by the Commission.[28]

Fourthly, and perhaps most importantly, the issue of WTO compatibility is left out in the thesis. The new Article 26b does not only come with questions about restrictive measures' conformity with EU law, but also with international trade law, which may affect the scope of national autonomy. Unfortunately there is no room in here to explore that issue,[29] though it could be said shortly that WTO-law in principle allows for some space for pursuing certain legitimate values. However, it has been suggested that this space will not be simple to use.[30] As such, non-EU states and the judicial bodies of the WTO could also come to determine the scope of EU Member States possibilities to opt out of GM cultivation. Whether non-EU states will be ready to challenge the legality of Member States' national restrictions is unsure.

Finally, I want to make clear that I do not have any normative ambitions with this thesis, as I only seek to examine the actual legal existing possibilities. Hence, de lege ferenda discussions about any desired state of affairs are left out.[31]

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[25] Field trials play an important role in the authorisation procedure to place GMOs on the market. Without them, a GMO can not obtain an authorisation to circulate within the internal market. See Poli 2010, p. 344. The possibilities to restrict field trials is not affected by the new Article 26b, Recital 19 Directive 2015/412.

[26] See Morris and Spillane 2010, p. 363.

[27] See Varela 2010 and Dobbs 2011 for more thorough examinations of coexistence measures .

[28] In addition they provide a fruitful background to understanding some of the case law in relation to other derogation possibilities, as well as the new Article 26b.

[29] For a contribution on WTO law compatibility of the new Article 26b as it stood in the 2010 Commission proposal, see Dobbs 2010. See also more generally, Pollack and Schaffer: *When Cooperation Fails: International Law and Politics of Genetically Modified Foods,* Oxford 2009.

[30] Lee 2013, p. 378; Lee 2014, p.244; Dobbs 2010, p. 1370ff.

[31] Lee writes somewhat critically about the narrow interpretation of coexistence measures in 'The Governance of Coexistence Between GMOs and Other Forms of Agriculture: a Purely Economic Issue?". In: *Journal of Environmental Law* Vol 20(2) 2008. For a critical perspective on the other original opt out possibilities see Lee 2014, p. 224-247. For a critical perspective on the not final finalised version of Article 26b, see Poli 2013.

1.4 Method

The thesis draws on legal dogmatic method in that de lege lata is examined regarding Member States' different derogation possibilities. For current purposes, this means that the derogation possibilities are scrutinised from primary and secondary EU law in light of the case law from the EU Courts (CJEU) and legal literature. Furthermore, interpretations and decisions and guidelines from the Commission and the European Food Safety Authority (EFSA) are also of relevance to get a clear picture of the scope of opting out, especially so where there is an absence of case law from the CJEU on specific GMO provisions.

This of course implies that these EU institutions are of importance when it comes to studying national restrictions on GM cultivation. The CJEU - in this context the European Court of Justice (ECJ) and the General Court[32]- ensures the final interpretation and application of EU law, including the legislation on GMOs.[33] The Commission oversees the implementation of Union law[34] and has the power to bring Member States to the CJEU if it considers that Member State action is in breach of their legal duties.[35] As will be shown it also has important procedural roles to play in the contexts of authorising GMOs to be cultivated and in determining if national derogations are justified. Furthermore, as one of the potential[36] actors to make Member States answer for breaches of Union obligations, its views - as represented in its guidelines and decisions - are of importance when predicting the prospect of Member States succeeding in adopting GM cultivation restrictions.[37]

The EFSA has a central part in the scientific assessments of risk to health and the environment under the GMO legislation. As will be shown in chapter 2 and 3 their opinions matter a great deal in the authorisation process and when it comes to establishing that national derogations are justified.

In accordance with this, the thesis examines the different legal documents produced by these institutional actors to better understand the legal possibilities and practical reality of opting out.

Notwithstanding the thesis's lack of normative aspirations, a critical perspective is applied. This is so particularly in 4.3 where the actual scope of the new Article 26b is examined in light of the internal market rules, in order to see the possible legal limits that this amendment has for Member States' say on GM cultivation.

1.5 Research status and materials

Issues that stir up emotions tend to be well-covered by scholars. Legal and political questions surrounding GMOs are no exception to this.[38] However, when it comes to the possibilities for Member States to opt out of GM cultivation not that much has been written. Thus far, among the

[32] The General Court was pre-Lisbon called Court of First Instance (CFI).
[33] Article 19.1 TEU.
[34] Article 17 ibid..
[35] Article 258 TFEU.
[36] Member States have the same possibility under Article 259 TFEU. Private actors, i.e the biotech industry also have the (restricted) possibility under Article 263(4) TFEU, or through making a preliminary reference under Article 267 TFEU.
[37] In my view this is particularly important in the context of the new Article 26b, where the legal position is uncertain.
[38] For a good general overview of EU regulation of GMOs, see Lee 2008. For a comparative analysis see Jasanoff, Sheila *Designs on Nature: Science and Democracy in Europe and the United States*, Princeton 2005.

contributions of legal and political science scholars, nothing[39] has been published since the content in the new Article 26b took its current form in December 2014. This does of course not imply that the subject of this thesis is not relevant, instead I would like to claim the opposite; the issue is important to investigate further!

In any case, among the legal scholars whose' contributions are referred to in this thesis we find the likes of Pr. Marie Lee who is worth mentioning here. Being the author of "one of the most comprehensive scholarly analyses of EU regulation of GMOs",[40] her works are referred to in larger extent than any other authors'. As such, legal literature and peer-reviewed articles have been used mainly in relation to the background chapter (2), but also to some extent that it reflects relevant parts of the early versions of Article 26b.

As mentioned above I mainly depart from primary and secondary EU law of relevance to Member States' derogation possibilities when examining these. In this regard the Deliberate Release Directive and the FFR stand out, apart from the amending Directive 2015/412 that contains Article 26b. However, excursion to appurtenant procedural rules[41] has also been necessary to understand the Member States' autonomy on GMOs. In addition, case law from the CJEU and decisions and guidelines from the Commission has provided valuable material.

1.6 Outline

This introductionary part is followed by four main chapters. In order to set the scene for the reader a background chapter (2) is provided. This offers a brief presentation of GMOs and some common promises and concerns that come along with GM agriculture, which is useful for understanding the grounds on which Member States base their restrictions. The chapter also includes a historical and contemporary overview of the EU's GMO regime and its part in the internal market context. The authorisation procedure, through which GMOs need to be approved in order to be cultivated within the EU is the starting point of Member States' opt out possibilities. As such this procedure and its functioning in practise is quite thoroughly described.

After setting the scene, the thesis moves on to examine the legal provisions that Member States may rely on when it comes to restricting GM cultivation. Chapter 3 examines the legal scope and - due to the procedural rules –interesting practical implications of the original opt out provisions. As stated above, these provisions allow for safeguard measures under the Deliberate Release Directive, emergency measures under the FFR and measures under Article 114.5 TFEU. In addition, the scope and practice of coexistence measures, which are also provided for under the GMO legislation is (briefly) examined.

Next, the new Article 26b, which was adopted in 2015, is treated in chapter 4. This is a provision that is exclusively concerned with cultivation restrictions. The chapter includes key aspects of the long-drawn legislative process that formed its final contents. This helps understanding its scope,

[39] To be sure, this is to the best of the knowledge of the undersigned.
[40] Weimer 2014, p. 17.
[41] See e.g. the so-called "Comitology rules". COUNCIL DECISION 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission; REGULATION (EU) 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. Hereafter "Comoitology Decision" and "Comitology Regulation" respectively.

which is also thoroughly examined. The chapter's final part puts the new derogation possibilities to test against possible hurdles under internal market law in order to estimate their actual scope in light of these potential limitations.

Comments are made and conclusions are drawn of the findings throughout these chapters. In addition chapter 5 provides for some final considerations as to Member States' derogation possibilities.

2 Setting the scene

This chapter starts by introducing the concept of GMOs and some promises and concerns that are commonly associated them when it comes to GM agriculture (2.1). After this, a brief overview of the EU's regulatory framework on GMOs is given (2.2). This overview introduces the internal market context, provides for a historical background and explains the logic and cornerstones of the framework as it stands today in light of GM cultivation. Finally, the structure and implications of the authorisation procedure for GMOs are examined. Altogether, this sets the scene for examining Member States' autonomy regarding cultivation of GM crops in their territories. This provides valuable background information in order to better understand Member States' opt out possibilities.

The chapter shows that there is a wide range of concerns for Member States with regards to GM cultivation, which could be categorised as safety concerns, i.e. as concerns for risks to health and environment, various socioeconomic and ethical concerns. Moreover, it is shown that the GMO framework is built on the logic of creating an internal market for GMOs, where at the same time risks to the environment and health are assessed before a GM variety can be authorised for cultivation purposes. In practice, the authorisation process takes little account of concerns other than those regarding risks for health and the environment. By drawing on the EFSA's positive opinions as regards the safety of all GMOs that have passed the authorisation procedure, the Commission has pushed through authorisations in spite of the objections of many Member States. Being a sensitive political issue, there has also been substantial delays regarding authorisations of GMOs for cultivation purposes, which runs counter to the very idea of the scheme.

2.1 GMOs – a brief introduction to a diversity of prospects and concerns

Mankind has been occupied with manipulation of plant and animal genes for anthropocentric purposes for millennia.[42] However, until fairly recently, such undertakings were done in ignorance of the existence of the gene. The manipulation of living organisms at the level of the gene can be traced back the 19th century discovery by Mendel of the inheritability of the characteristics of living organisms. As knowledge accumulated regarding DNA being the carrier of genetic information during the mid 1900s, the practical step to genetic engineering was attainable. By 1973, the first GMO was created in the USA by inserting toad DNA into a bacterial cell. Inherent to genetic engineering is that it is not restricted by laws of sexual compatibility, something that had thus far always meant that a bacterium could not be "crossed" with, for instance, a toad. Instead, this technology can isolate the DNA fragments responsible for a desired trait, manipulate that gene in a laboratory, and potentially insert it into any other living organism.[43] As for today, a wide array of GMOs with different traits exists. Among those that are cultivated, GM crops with traits ranging from herbicide tolerance to improved nutritional value are now commonplace in some parts of the world.[44]

[42] For example, traditional breeding has for a long time involved 'crossing' animals or plants in search of preferred traits, such as enhanced productivity. See Lee 2008, p. 11f.
[43] Ibid, p. 11f.
[44] For a closer look, see ISAAA, *GM Approval Database*: http://www.isaaa.org/gmapprovaldatabase/default.asp

Genetic engineering can astonish in its ingenuity and its potential. However, regulating GMOs is not a simple task as disagreement about the appropriate role of GMOs in agriculture and food production is not seldom intense and bad-tempered.[45] Whereas some think that it offers a never before experienced change in human relationships with the environment, others view the technology as simply the next step in our constant efforts to control it.[46]

But what is it that GMOs promise and what are the concerns that they raise?[47] We now turn to a short examination of some typically held benefits of GM agriculture and some commonly raised concerns by its opponents. Notably, these concerns have in one way or another been put forward by Member States in attempts to derogate from the harmonised framework.[48]

First, as part of the post-industrial hope of the 'knowledge-economy', genetic engineering is often held to deliver substantial economic promise.[49] However, the potential benefits seem to be limited only by imagination. They are additionally claimed to include advantages with regards to the environment, health as well as socioeconomic, political and ethical benefits.[50]

Regarding the environment, hoped-for benefits address a myriad of problems often associated with conventional farming. Examples include or could include GM plants constructed to cope without the need of fertilisers, something that would spare water sources from being polluted by them.[51] Genetic modifications that address various health issues, for both the wealthy and the poor, are another promise. For instance the "golden rice" is modified to contain higher levels of vitamin A, which is often deficient among children with a diet heavily dependent on rice, leading to diseases and blindness.[52]

On the other hand, GMOs also come with a set of safety concerns, notably in relation to the environment and human and animal health. Examples of common concerns include increased herbicide and pesticide tolerance. Other worries include those of crops that are modified to kill particular pests also may be toxic to non-target species and uncontrolled contamination of the natural environment through, for instance, cross-pollination.[53] Safety concerns also include potentially serious risks to human health from the cultivation or consumption of GMOs.[54]

It shall be noted that negative environmental and health impacts are often disputed.[55] Many of the safety risks are surrounded with scientific uncertainty, and GM-opponents often point at limitations

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[45] Lee 2008, p. 11f.
[46] Ibid, p. 22.
[47] For a detailed examination of the main concerns, see UK Science Review, *GM Science Review: First Report: An open review of the science relevant to GM crops and food based on the interests and concerns of the public*: http://image.guardian.co.uk/sys-files/Guardian/documents/2003/07/21/gmsci-report1-full.pdf . For a discussion and an overview of the applications of genetic engineering in other areas than agriculture, see Zika, Eleni et al. *Consequences, Opportunities and Challenges of Modern Biotechnology for Europe:* https://ec.europa.eu/jrc/sites/default/files/jrc_reference_report_200704_biotech.pdf .
[48] See chapters 3 and 4.
[49] In the EU context, see Commission, COM (2002) 27 final, p. 7.
[50] Lee 2008, p. 23.
[51] Another example is crops carefully modified to be pest resistant, which could hinder loss of biodiversity associated with use of chemical pesticides. Yet another one is modifications to improve yields, which would allow for less land use, implying both environmental economic benefits. See Lee 2008, p. 23f.
[52] ibid, p. 25f
[53] UK Science Review, p. 210.
[54] Examples of worries are that modified genes could enter cells in the human gut, or that GM food or GM pollen might cause allergic reactions. See Lee 2008, p. 28.
[55] See e.g. chapter 3 on the differences between Member States and the EFSA.

of knowledge derived from laboratory testing, which they hold is not valid in relation to complex ecological and behavioural real-world conditions.[56]

There are also concerns about agricultural biotechnology that are not directly linked to the safety concerns just mentioned. These concerns could be categorised as being of socioeconomic or ethical nature, although, many of them could be seen as interrelated with each other and safety concerns and are not easily put into distinct categories. As will be shown in chapters 3 and 4 such interrelation can be difficult when Member States try to prove that that they are pursuing legitimate concerns for opting out.[57]

Many fears about socioeconomic impacts of GM agriculture are tied to underlying concerns regarding unwanted contamination of non-GM seed and crops. Apart from the possible environmental questions this might raise, this is also linked with concerns about consumer choice and difficulties for farmers wishing to market their crop as being free of GMOs. Such aspects are often held to be to the economical detriment of small-scale and ecological farmers and as such affecting social, environmental and rural development benefits associated with those types of agriculture.[58] These are issues that coexistence measures are explicitly concerned with.[59]

There is also an array of ethical questions and concerns in relation to GMOs. Perhaps most notable are those of a religious character, with certain approaches to the intrinsic value of nature and reluctance to playing "God" through technology.[60] However, safety questions also raise ethical issues, such as the level of acceptability of risk to the environment or producers, and responsibilities for future generations.

This brief overview has shown that cultivation of GM crops is accompanied with many promises, but also raises an extensive range of concerns, not all of which have been covered here. The scope of opting out of GM cultivation on the grounds of such concerns will be examined after the following introduction to the EU framework on GMOs.

2.2 The EU Framework on GMOs

Before moving on to the development and content of the EU legislative framework on GMOs, something needs to be said about the logic and context this regime exists in. In order to apprehend the expositions and discussions that follow in the thesis, the role and significance of internal market in the GMOs legislative context is to be particularly stressed here. The internal market is of central importance to the purposes of the EU.[61] If it were not for concerns about barriers to trade, there would be "little reason" why regulation of GMOs is not left completely to Member States to decide on. Free movement of goods, including those produced by genetic engineering, is not just seen as important in its own right or as simply a means of reaching economic prosperity. Instead, economic

[56] Lee 2008, p. 29f.
[57] This was the case in the cases of *Land Oberösterreich* and *Commission v Poland*. See chapter 3.2 and 4.3.
[58] Lee 2014, p. 236f. Another example is that commercial cultivation of GM crops is often accompanied with worries of enhanced large corporate control over agriculture. Enhanced corporate control is for example held to be enhanced by intellectual property protection, which might enable greater control by single suppliers over different elements of agriculture, such as when the same company supplies herbicide-resistant seed and the herbicide. See Hughes 2007, p. 318, 325 ff.
[59] See chapter 3.3.
[60] Kirkham, 2006, p. 176. See chapter 4 regarding Member States possibilities to opt out on such grounds.
[61] See Preamble to TEU and Article 3.3 TEU and Article 26 TFEU; See also chapter 4.

integration has been the symbol and a foundation of political integration ever since the birth of the EU.[62] As such, different national approaches to regulation of GMOs could raise barriers to the completion of the completion of the internal market, and in turn threaten the Union's core ambitions. On a more specific level the competitive implications following market fragmentation is that Member States that restrict cultivation put their farmers at a disadvantage when confronted with more cheaply produced products derived from authorised GMOs than can still circulate freely on the market.[63]

The GMO framework is largely built and adopted on the basis of the *a priori* shared competence of Article 114 TFEU, which forms the legal basis for harmonising measures that have as their objective to establish and further the functioning of the internal market.[64] In principle the harmonisation and connection to Article 114 means that national derogations are limited to the grounds explicit in the provisions provided for in the GMO legislation or the Treaties. As stated above,[65] these grounds have mainly[66] been related to protection of the environment and health, i.e. safety concerns. However, as will be shown in chapter 4, the new Article 26b explicitly de-harmonises some aspects of the GMO framework. This makes a broader list of concerns available for the Member States to base derogating measures on, which however may conflict with still-applicable free movement obligations.

2.2.1 Historical background

As genetic engineering first entered the scene in Europe, its potential risks were only partly regulated at national levels across the Member States and coincidentally through various EU agricultural and food safety regulations. The Member States' divergent stances regarding the value of certain agricultural and food safety practices, acceptable level of risks and the benefits of GMOs, are reflected in their regulatory models at the time. For instance, Germany and Denmark had quite restrictive laws, whereas the UK had rather permissive ones.[67]

The EU initially focused heavily on research to explore and exploit the full potential of this new technology.[68] Realising however that GMOs potentially posed risks to the environment and health and that such a regulatory fragmentation threatened to undermine the benefits of GMOs by allowing competitive distortions and hindering trade,[69] the Commission soon proposed for a union-wide framework regulating biotechnology.[70] In 1990, this proposal took the form of two old

[62] With the ultimate goal of promoting peace. See for instance Article 3 TEU. Cf, Lee 2008, p. 93ff.
[63] See Smith 2012, p. 866 and Geelhoed 2014, p. 25. See chapter 2.2.1 on the driving forces behind establishing the regime in the first place.
[64] Article 114.1 TFEU. In addition Article 114.3 holds that harmonising measures concerned with health, and environmental protection shall "take as a base a high level of protection", when proposed by the Commission. This is something that the EP and the Council shall only "seek to achieve".
[65] See chapter 1.2.
[66] Economical risks for farmers from contamination of GMOs are explicitly recognised to be falling outside the scope of the harmonised GMO regime and can to a certain extent be regulated on Member State level through coexistence measures. See chapter 3.3.
[67] See Geelhoed 2014, p. 8; Schaffer and Pollack 2004, p. 8.
[68] The Commission has continuously emphasised the economic value of biotechnology. See e.g. Commission, COM (2002) 27 final., p.7.
[69] Geelhoed 2014, p. 3.
[70] Commission, COM (1986) 573.

directives applicable to the contained use[71] and deliberate release of GMOs.[72] Since this time, the deliberate release into the environment of GMOs has required authorisation throughout the EU, following a case-by-case assessment of risks to the environment and health.[73]

During this early period, a number of GM seeds were authorised for the purpose of cultivation within the EU. However, the old framework soon came to be perceived as inadequate for the regulation of agricultural biotechnology. Instead of imposing uniform standards, the old directives relied on mutual recognition of very discretionary national risk assessment, which was only to be forwarded to an EU level-procedure in case of reasoned objections.[74] The lack of uniform standards in the risk assessment area was followed by a reluctance to accept "foreign science" much due to the fact that public opinion had come to turn against[75] genetic engineering in some Member States.[76]

During a time of heavy public opposition, the Commission decided to authorise yet another GM crop variety, despite angry objections from a number of Member States. When the new millennium approached, twelve Member States vocalised their opposition to further authorisations of GMOs.[77]

This inaugurated the notorious "de facto moratorium" on new authorisations between 1998 and 2004. Furthermore, with doubtful legality, a number of Member States banned from their territory GMOs that had already been approved at EU level.[78] The Commission, however, restrained from taking enforcing action in spite of the questionable legality of these measures, and used the period for negotiating new legislation. Among other things,[79] the group of dissatisfied Member States insisted on stricter risk assessments of the safety of GMOs. This standstill period somewhat hushed the internal disapproval.[80]

The EU soon came to adopt a more centralised "new" GMO regime that remains in place today.[81] It has been held that "there was never a clear and unified EU decision" regarding this new regime. Hence, the conflicts after the moratorium have not decreased.[82] Anyhow, this second set of EU GMO legislation is the starting point for the further analysis of this thesis.

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[71] COUNCIL DIRECTIVE 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms.
[72] COUNCIL DIRECTIVE 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. Hereafter Old Deliberate Release Directive. Herafter "Old Deliberate Release Directive".
[73] Ever since the establishment of the GMO regime, the authorisation scheme has been underpinned by the premise that the process of genetic engineering is a novel one, meaning that GMOs cannot be assumed to be equivalent to their traditional counterparts in their safety. This is in sharp contrast to their regulation in the USA. See Skogstad 2011, p. 901.
[74] Article 13.3 Old Deliberate Release Directive.
[75] In some cases GMO trial fields were destroyed by groups in front of both media and the police. These events were widely reported in media. Lee 2008, p. 19f.
[76] Geelhoed 2014, p. 3f. This is commonly attributed to the poor management of the BSE crisis and the 'mad cow' scandal. Moreover the EU was experiencing extensive legitimacy problems at the time. See e.g. Falkner 2007, p. 517f. This implies that safety concerns seems to have been the main driving force behind the change in public opinion.
[77] Lee 2008 p. 2f, 62.
[78] The safeguard clause in Article 16 of the Old Deliberate Release Directive was used to impose nine national bans. Austria, Italy and Luxemburg were among the ones to invoke this original safeguard clause. See Skogstad 2011, p. 902 and Dobbs 2010, p. 1388.
[79] They also required rules on labelling, traceability and liability, rules that to a large extent came into place with the new regime. See Lee 2008, s. 62f
[80] However, the situation also lead up to international trade trials before the WTO, See Geelhoed 2014, p. 3f.
[81] Ibid.
[82] Lee 2008, p. 63.

2.2.2 The EU framework on GMOs in light of cultivation

As for today, the EU has put in place a rather complex legal framework covering nearly all aspects of GMOs. In the words of the Commission this framework "pursues the global objective of ensuring a high level of protection of human life and health and welfare, environment and consumer interests", while at the same time "ensuring that the internal market works effectively".[83] 2001 saw the adoption of the "new" Deliberate Release Directive applying to all GMOs for release into the environment or placing on the market. By 2003, two other major pieces of legislation were put in place. These are the Food and Feed Regulation (FFR), applying special rules to GM food and feed, and the Traceability and Labelling Regulation (TLR), [84] putting in place rules on labelling and traceability for all GMOs.[85]

Whereas the TLR is outside the scope of this thesis, the Deliberate Release Directive and the FFR are of immediate relevance for cultivation of GMOs. The former regulates the deliberate release into the environment of GMOs i.e. their cultivation.. This Directive has its legal basis in Article 114 TFEU. It pursues the double objective of approximating laws of the Member States and to protect human health and the environment when releasing GMOs into the environment (or placing them on the market).[86]. With regards to legal basis and objectives of the FFR, these are somewhat broader than for the Deliberate Release Directive.[87] The regulation is based on the provisions for the common agricultural policy and public health,[88] in addition to Article 114. Thus, ensuring the effective functioning of the market is not the only objective the FFR seeks to pursue, as it also shall ensure a high level of protection of human life and health, animal health and welfare, environment and consumer interests.

These two, occasionally overlapping, pieces of legislation are built on a precautionary logic,[89] and provide that no GMO shall be cultivated (or marketed) within the Union unless previously notified and authorised after undergoing an environmental risk assessment.[90] A GM crop, like any other GMO, may only be authorised if it is found not to constitute a risk to human health or the environment.[91] The authorisation process occurs mainly at the EU level and an authorisation applies

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[83] Commission, *Biotechnology:* http://ec.europa.eu/food/food/biotechnology/index_en.htm

[84] REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

[85] Labelling is intended to guarantee consumer choice, and the traceability provisions are intended to track and recall GM products in the event of safety issues, Skogstad 2011, p 903.

[86] Article 1, Recitals 5 and 7 Deliberate Release Directive.

[87] Article 1a FFR.

[88] Articles 43 and 168.4(b) TFEU, respectively.

[89] See Article 1 and Recital 8 Deliberate Release Directive. Article 1 FFR refers to 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. Hereafter Regulation 178/2002. In this regard, see Article 7.

[90] Recital 32 and Article 4(1) Deliberate Release Directive; Article 4(2) FFR. The precautionary principle plays a role in two different contexts of the GMO framework. The first being an institutional and procedural principle that guided the drafting of the legislation, influencing the authorisation process provided therein. The second being that it has been defined as a decision rule that shall guide the case-by-case decision making in single authorisation procedures. Weimer 2010(b), p. 637. See Weimer 2010(b) in full for a critical examination on the application of the precautionary principle in this context.

[91] Additionally, a GM seed should not be harmful from the point of view of plant health to cultivation of other varieties or species. See Article 18 COUNCIL DIRECTIVE 2002/53 of 13 June 2002 on the common catalogue of varieties of agricultural plant species.

to all Member States, meaning that in principle the effect of an authorisation is that an authorised GM seed can be grown anywhere in the EU.[92]

Contingent on the scope of the biotech company's authorisation application, cultivation of a GM crop is subject to either the procedure in the Deliberate Release Directive or the FFR. Somewhat simplified, the former is applicable when the applicant intends for the GM crop to be placed on the market for the purpose of cultivation without an intention for the crops to be used in food or animal feed.[93] The FFR applies if the applicant wishes to cultivate the GM crop and also sell it on the market as food or animal feed.[94] In that case the applicant has the possibility to submit a single application for authorisation under the FFR.[95] The authorisation procedure itself is also governed by Comitology rules,[96] the effect of which will be explored below.

Furthermore, the legislation that governed the authorisation also determines to a certain degree what original opt out measures Member States may rely on if they wish to restrict or prohibit cultivation of GM crops. This will be elaborated with more in chapter 3, but first the authorisation procedure will be shortly described in theory and practise. This is done in order to shed light on the Member States' saying in the authorisation process on allowing specific GM crops to be cultivated in their respective territories in the first place. It should be noted that the amendments to the Deliberate Release Directive somewhat changes Member States' autonomy in this regard. However, this change will be treated in chapter 4.

2.2.3 Authorisation of GMOs – a centralised approach

While the procedural rules under the Deliberate Release Directive and the FFR are not identical,[97] the common pattern and reality of the authorisation process will be explained here.[98]

In the initial risk assessment stage, the economic operator (the applicant) submits an application including a risk assessment of its GMO to the competent authority in the Member State where it first wishes to market the GMO. The competent national authority thereafter sends the application to the EFSA that oversees the risk assessment regarding the GMO in relation to risks to the environment, human and animal health.[99] Based on the assessment, the EFSA delivers a risk assessment opinion to the Commission,[100] which is the first actor in the risk-management phase. Following this, the Commission formulates a draft decision, where it shall take into consideration both the possible scientific uncertainties and "other legitimate factors".[101] The draft decision is later

[92] Lee 2014, p. 227.
[93] Article 1 Deliberate Release Directive. Examples could be GM cotton or flowers.
[94] Article 3 FFR.
[95] Article 17.5 FFR. Then subject to an environmental risk assessment under the Deliberate Release Directive.
[96] The Comitology Decision and the Comitology Regulation..
[97] Cf. Articles 13-18 Deliberate Release Directive and Articles 5-6 FFR.
[98] This is done since the applications under the Deliberate Release Directive in practice invariably turn into a similar EU-level procedure to the one described, due to lack of mutual agreement of national risk assessments. Cf. Weimer 2010, p. 635.
[99] Article 28 Deliberate Release Directive and Article 5.1-2 and 17.1-2 FFR. However EFSA does not perform their own safety tests.
[100] Article 18.6 FFR and Article 28 Deliberate Release Directive.
[101] The Commission is allowed to adopt a different stance on motivated grounds, see Article 19.1 FFR and Article 28 Deliberate Release Directive. As for "other legitimate factors", see below.

submitted to either the Regulatory Committee or the Standing Committee on Food Chain and Animal Health (SCFAH), consisting of expert Member State representatives.[102]

In order for the Committees to approve or reject the draft authorisation decision a qualified majority (QM) is necessary.[103] If a QM is not possible to reach - or if the vote, in contrast to the Commission's draft decision, results in a disapproval of authorisation - the Commission refers the issue to an Appeal Committee.[104] The Appeal Committee, which has the position that was previously afforded the Council,[105] consists of representatives selected by the Member States.[106] A QM decision is also required from the Appeal Committee for either approval or rejection of the draft decision. However, when a QM is not reached here, the Commission owns the question again. Whereas earlier Comitology rules put the Commission under an obligation to adopt its initial decision in such cases, the Commission now has the possibility to do so.[107]

The functioning of the authorisation procedure in practice reveals some important insights as to why Member States have had recourse to the original derogation possibilities and why the Commission brought forth its proposal for the new Article 26b.

To begin with, research has shown that the Commission's draft authorisation decisions are overwhelmingly based on the EFSA's positive[108] scientific opinions rather than on competing evidence from the Member States or other stakeholders such as environmental groups.[109] Secondly, Member States' representatives in different stages of the procedure have struggled to reach a QM to reject or adopt the Commissions draft decisions on authorisation of GMOs. The ultimate decision has therefore in practise frequently landed on the Commissions table where it has been "the sole force" behind post-moratorium GMO[110] authorisations in the absence of QM decisions in comitology.[111]

The authorisation regime envisions a strict division between risk assessment and risk management. This division relies on the idea of quantifying the likelihood of harm caused by (cultivation of) GMOs on the basis of scientific evidence. Geelhoed points out that such an idea, or presumption is undermined by the many uncertainties that exist in debates on the safety of GMOs.[112] In contrast to the worries of some Member States, the EFSA has almost exclusively adopted positive opinions by unanimity on submitted applications, signalling a confident view on the safety of GMOs.[113] Furthermore it has been shown that the centralised risk assessment approach tends to disregard national risk assessments,[114] and some hold that they neglect the diversity and particularity of

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[102] Under the Deliberate Release Directive and FFR respectively. See Articles 3 and 5 Comitology Regulation 182/2011; and Article 35.1-2 FFR and Article 30 Deliberate Release Directive.
[103] Art 5 Comitology Regulation 182/2011.
[104] Pre March 2011 the application was referred to the Council in such cases.
[105] Lee 2013, p. 365.
[106] The pattern is that these representatives vote in line with stances of the Member States that have appointed them. See Weimer 2014, p. 6ff.
[107] Cf. Article 6.3 the Comitology Regulation 182/2011 and Article 5.6 Comitology Decision 1999/468/EC.
[108] In the sense of the safety of the GMOs assessed.
[109] Lee 2014 p. 226 and Geelhoed 2014, p. 6.
[110] Note that this overwhelmingly concerns authorisation for purposes other than cultivation, as explored below.
[111] Geelhoed, 2014 p. 6. Authorisation decisions can be found on; Commission, *EU Register of Authorised GMOs:* http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
[112] Geelhoed 2014, p. 7f.
[113] Weimer 2014, p. 8.
[114] Instead research has shown that EFSA relies heavily on the information provides by the applicant. See Geelhoed 2014, p. 7.

environmental conditions in the different Member States.[115] The consequences being that some Member States have felt unheard of their divergent scientific outlooks on the risk assessments.[116]

Neither the EFSA, nor the Commission have to this date accounted for non-scientific concerns, such as societal concerns of a socioeconomic or ethical character, in their opinions and draft decisions.[117] The EFSA has concluded that it is not in their position to integrate social and ethical considerations into its work.[118] As for the Commission it is allowed to consult an ethical committee before it drafts its decision,[119] and rely on "other legitimate factors" than science to base its decisions on.[120]

The central role that the EFSA and the Commission has come to play has raised questions about the legitimacy of the authorisation process among Member States.[121] Criticism has concerned both the quality of the EFSA's risk assessment, as well as the absence of taking into account of the other legitimate factors in the Commission's risk management decisions.[122] While the authorisation procedure in theory provides for taking into account different Member States' views, in practice it has not done so. As such the authorisation practice shows a purely science-based approach to GMO authorisation[123] and critics point at the "procedure's disregard for diversity in and beyond science".[124]

However, this science-based approach, where GMOs are authorised in spite of relatively strong Member State opposition is only part of the picture. Public and Member State opposition against the authorisation scheme has resulted in quite a dysfunctional authorisation system.[125] With regards to cultivation of GM crops, this whole process has in the last two decades resulted in merely one currently valid and one recently annulled authorisation. These concern the insect resistant MON810 Maize[126] and Amflora Potato,[127] respectively. Yet, there are a number of cases where the Commission, despite positive EFSA opinions, have not taken action for a long time, and hence delayed the authorisation process.[128]

The authorisation process concerning cultivation of the above-mentioned Amflora Potato serves as an illustrative case here. In that case it took five years, and the threat of legal action by the applicant, between the final EFSA opinion and the final authorisation.[129] As for today a number of authorisations for GM cultivation purposes decisions are pending final decisions after long delays,

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115 Ibid.
116 Ibid.
117 Weimer 2010, p. 646; Geelhoed 2014, p. 9.
118 Poli 2013, p. 143, 149.
119 Article 29 Deliberate Release Directive and Article 33 FFR.
120 Recital 32 and Article 7 and 19.1 FFR.
121 Many changes in the authorisation process have suggested in the doctrine. Klika et al, 2013, suggest outsourcing of the risk assessment to an independent agency to enhance the credibility of the Commission's proposal. Skogstad 2011, has suggested that democratic legitimacy would increase by giving government representatives in principle the final say.
122 Weimer 2010, p. 647. With regards to MON810 the EFSA was criticised for underestimating the level of uncertainty surrounding its effects on the environment. See Poli 2013, p. 147.
123 Weimer 2010, p. 647.
124 Geelhoed, 2014 p. 5ff.
125 Already in 2008 a review of the framework pointed out the delays that the procedure caused. See, COUNCIL. 2912th Council meeting, , 4 December 2008.
126 See Commission, Decision 98/294/EC.
127 See Commission, Decision 2010/135/EU and Case T-240/10 *Hungary v Commission* .
128 Weimer 2010, p. 647.
129 The time from application to final consent was thirteen years. The final decision was taken by the Commission in the absence of a QM decision in comitology, Lee, 2014, p. 227.

including another insect-resistant maize, GM Maize 1507.[130] Also the procedure of Maize 1507 has been marked by delay. This has resulted in the CFI finding a breach of the Commission's procedural obligations as it had not submitted its proposal to the Council after the comitology committee had failed to reach a QM.[131] All in all this process has taken more than a decade from the time of the submission of the application.[132] These massive delays could be seen as going against the objective of an effective internal market in GMOs.[133]

Thinking of the legal effect[134] of an authorisation of a GM crop there are high stakes in the authorisation process and the difficulties with finding compromises between the involved actors are quite understandable. However, the authorisation of GM crops has led some Member States to shield and preserve their non-cultivation stances after authorisation. The legal possibilities and the actual practise of doing so will be examined next.

[130] Weimer 2014, p. 27; Commission, *EU Register of auhorisaed GMOs:* http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
[131] Case T-164/10, *Pioneer Hi-Bred International v Commission*.
[132] Weimer and Pisani 2014, p. 211.
[133] It is probable that the delays are the main reason for why the Commission put forth the proposal for the new Article 26b. See chapter 4.
[134] As stated above, as a starting point it can be cultivated throughout the Union.

3 The original opt out possibilites – science as key

With the lack of recognition of Member States' diverse concerns in the authorisation process in mind, this chapter explores the original, still existing possibilities for Member States to adopt restrictive post-authorisation measures on cultivation of GM crops. In doing so this chapter seeks to examine the scope for opting out on of GM cultivation through reliance on these original provisions, thus answering the first subquestion.

As mentioned above, the Deliberate Release Directive and the FFR[135] were both adopted on the basis of the equivalent to Article 114 TFEU, with a view to harmonise national laws in order to ensure the effective functioning of the internal market. To the extent that the GMO regime is harmonised,[136] Member States seeking partially or fully to limit cultivation in their territories can only do so through the explicit derogation provisions offered by EU law, of which the GMO framework is part.

The chapter begins by examining the legal possibilities and the reality of opting out under the specific derogation provisions of the GMO legislation, namely Article 23 of the Deliberate Release Directive, Article 34 of the FFR (3.1). This is followed by an examination of the opt out possibilities under the TFEU's internal market rules, where the so-called "environmental guarantee" in Article 114.5 TFEU provides for an alternative route to derogate from harmonised measures (3.2). In one way or another, these three provisions hold protection of the environment and/or health as the only legitimate grounds of concern, meaning that scientific evidence is of great importance when Member States seek to justify restrictions on GM cultivation under them. In addition, a less stringent form of opting out is provided for in Article 26a of the Deliberate Release Directive is introduced. This article allows for coexistence measures, on grounds to hinder economical losses for conventional and organic farmers due to contamination from GMOs (3.3).

It will be shown that in theory the legal scope for Member States to rely on the first three "science-based" provisions is narrow. This is especially due to restrictive interpretations of the substantive conditions made by the EU Courts, the Commission and the EFSA. However, the procedural Comitology rules and a rather lax approach from the Commission in other cases has allowed for Member States to keep their national restrictions.. This means that to a certain degree, the legal scope of these opt out possibilities has been widened in practice, arguably against the intended use of the derogation possibilities.

As for coexistence measures their scope was somewhat increased by Commission guidelines in 2010, in connection to its proposal of the new Article 26b. However, their scope has not been tested by the CJEU. It is likely that general principles of EU law, such as proportionality, should hinder them from being used to impose larger territorial bans. This runs opposite to how they have been used in some cases. These latter issues are indirectly elaborated with further in chapter 4.3.

135 In this case partially, see chapter 2.2.
136 Note that in the context of derogation, the new Article 26b de-harmonises areas that are not covered by the EFSA's environmental risk assessment. See chapter 4.

3.1 Under the GMO legislation - Safeguard and Emergency measures on specific GMOs

Article 114.10 TFEU provides that Union measures based on Article 114, in appropriate cases shall include "safeguard" clauses. These safeguard clauses authorise Member States to take "provisional" restrictive measures subject to Union control procedures.[137] In the GMO framework Article 23 of the Deliberate Release Directive and Article 34 FFR include such provisions, allowing for safeguard and emergency measures respectively on specific GM crops. Which one of these two articles a Member State should rely on when restricting cultivation depends on what piece of legislation the GMO in question was authorised under. Restrictions on GMOs authorised under the FFR may for instance only be undertaken on the basis of Article 34 and not Article 23 of the Deliberate Release Directive.[138]

3.1.1 Article 23 Deliberate Release Directive and Article 34 FFR – in theory

3.1.1.1 Substantive conditions

The safeguard clause in Article 23 of the Deliberate Release Directive allows for a Member State to employ provisional safeguard measures to restrict or prohibit cultivation of specific authorised GM crops in its territory on a case-by-case basis.

This requires the Member State to have "detailed grounds for considering" that the GMO in question "constitutes a risk to human health or the environment".[139] These grounds for consideration shall be a result of "new or additional information" made available *after* the date of authorisation and affect the environmental risk assessment or be the result of a "reassessment of existing information on the basis of new or additional scientific knowledge".[140]

Under the FFR, Article 34 allows for "urgently" needed national emergency measures to restrict cultivation of specific GM crops where it is "evident" that the authorisation of the GMO is "likely to constitute a serious risk to human health, animal health or the environment".[141]

The two provisions share a science-based approach, although a number of differences appear between the two articles when reading them side by side. Similarly to Article 23, legitimate concerns of Article 34 FFR are risks to human health and the environment, although with the addition that risk relating to animal health has been included in the latter. Whereas Article 23 requires Member States to demonstrate a "risk", turning to emergency measures under Article 34 increases the threshold in that it requires demonstration of "serious risk". Another difference is the standard of proof required. The safeguard clause in Article 23 requires "detailed grounds", while Article 34

[137] There is a similar provision for measures adopted under the "Environment Title" in Article 191.2 TFEU.
[138] This issue was not entirely clear until 2011, see Joined Cases C-58/10 to C-68/10, Joined Cases C-58/10 to C-68/10 *Monsanto SAS and Others v Ministre de l'Agriculture et de la Peche,*, para 59-63.
[139] Article 16 of the Old Deliberate Release Directive required that Member States put forward "justifiable reasons" to consider that a GMO constituted a risk. What would had constituted justifiable reason was not entirely clear, Lee 2008, p. 89.
[140] Article 23.1 Deliberate Release Directive. Note that Article 20 ibid provides for Union action if new information becomes available that applies to the whole of EU.
[141] Emergency measures can also be triggered by an opinion by the EFSA, Article 34 FFR.

reads "where it is evident" that the GMO is "likely to constitute a risk". The use of the wording "evident" indicates a higher standard of proof.

The further meaning of these and similar conditions has been subject to interpretation by the ECJ.

As for Article 23, the meaning of "detailed grounds" for considering that a GMO constitutes a "risk" to human health or the environment has not been directly up for interpretation by the EU courts. However, in 2003 in Case C-236/01 *Monsanto (Italy)*,[142] the ECJ interpreted an essentially identical safeguard clause of Regulation 258/97 concerning novel foods and novel food ingredient.[143]

The Court held that in order to not adversely affect the functioning of the internal market and protection of public health, i.e. the objectives of that legislation, the following conditions had to be fulfilled. First, restrictive measures adopted under the safeguard clause may not be based on a "purely hypothetical approach to risk [to health (or the environment)], founded on mere suppositions which are not yet scientifically verified".[144] Such measures may, regardless of their temporary character and preventative nature, be adopted only if they are based on a risk assessment "which is as complete as possible in the particular circumstances of an individual case". Furthermore, the results of this risk assessment shall indicate that the measure is "necessary" in order to ensure the safety of the protected interest.[145]

In the joined cases C-58/10 to C-68/10*, Monsanto (France)*,[146] the conditions "likely" to constitute a "serious risk" in Article 34 FFR were interpreted. These expressions were understood as being equivalent to a "significant risk which clearly jeopardises human health, animal health or the environment". It was held that the risk in question must be established on the basis of new evidence based on reliable scientific data.[147] The Court then went on to reiterate the conditions set forth in *Monsanto (Italy)*, including that a purely hypothetical approach to risks founded on not scientifically verified assumptions is excluded.[148] Hence, the same underlying conditions as for the evidence apply to Article 34 FFR. Furthermore, it was emphasised that in the light of the scheme provided for by FFR and its objective of avoiding "artificial treatment of serious risk", the assessment and management of such risks ultimately come under the responsibility of the Commission and the Council, subject to review by the Union courts.[149]

In *Monsanto (Italy)* the ECJ held that the safeguard clause had to be understood as giving specific expression to the precautionary principle and that its conditions must be interpreted in light of it. Drawing on earlier case law the court stated that uncertainties regarding the existence or extent of risk to the human health, could allow for protective measures from Member States "without having to wait until the reality and seriousness of those risks to become fully apparent".[150] Hence, safeguard

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142 Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others*. Hereafter "*Monsanto (Italy)*".
143 See Article 12.1 REGULATION (EC) NO 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 1997 concerning novel foods and novel food ingredients. The CJEU has not dealt with a Member State relying on Article 23 directly.
144Case C-236/01, *Monsanto (Italy)***,** para 106.
145 Ibid, para 107. This indicates proportionality, which is elaborated with in chapter 4.
146 Case C-58/10 to C-68/10, *Monsanto v Ministre de l'Agriculture et de la peche* [2011]. Hereafter "*Monsanto (France)*"
147 Ibid*,* para 76.
148 Ibid, para 77.
149 Ibid, para 78.
150 Case C-236/01, *Monsanto (Italy)***,** para 110-114.

measures may be taken "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". Still, such measures are only allowed if the Member State has carried out a risk assessment which is as complete as possible "given the particular circumstances of the particular case" and where, in the light of the precautionary principle, it is apparent that such measures are necessary. In such cases the Member State needs to provide "the most reliable scientific evidence available and the most recent results of international research" which makes it reasonably possible to conclude that the measures are necessary in order to avoid the risk.[151]

However, in practice such a theoretical relaxation of Member States' evidentiary burden has not been afforded the Member States relying on these two provisions when restricting GM agriculture. As will be shown in 3.1.2 Member States have invariably been unable to convince the EFSA and the Commission that the substantive requirements and their evidential thresholds have been fulfilled.

We now turn to introducing the procedural conditions of the two provisions and the rules that govern their invocation. As such, these rules and the Commission's treatment of them have been of greater importance for the Member States derogation possibilities under these two provisions.

3.1.1.2 Procedural rules

Recourse to the safeguard clause in Article 23 requires the Member State to immediately notify the Commission and other Member States of its actions. In addition it has to motivate its decision and present a reviewed environmental risk assessment, indicating if and how the conditions of the authorisation should be amended or terminated.[152]

Similarly, employing emergency measures under Article 34 FFR also demands that Member States make its actions known to the Commission and other Member States.[153] The CJEU has made it clear that notification is to take place and the information about the content of the measures has to be provided as soon as possible when there is a need to take emergency measures.[154]

After the information has been forwarded the Union control procedure takes place. It was mentioned above in 3.1, that Article 114.10 TFEU permits for harmonised measures to include safeguard clauses of a *provisional* nature. Accordingly, Article 23 of the Deliberate Release Directive states that Member States may "provisionally" invoke safeguard measures.[155] Likewise, Article 34 of the FFR allows for "interim protective measures".[156] As also stated in the Treaty article, these provisional measures are to be governed by a Union control procedure.[157] This procedure, which is also governed by Comitology rules, bares resemblance to the one in the authorisation process.

The procedure governing safeguard measures taken under Article 23 is the following. After the Member State has forwarded its information about the safeguard measure, the Commission has 60

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151 Ibid, para 110-114. In relation to emergency measures, see Case C-58/10 to C-68/10*, Monsanto (France)*, para 71.
152 Article 23.1(3) Deliberate Release Directive.
153 By reference to Articles 53 and 54 Regulation 178/2002.
154 Case C-58/10 to C-68/10, *Monsanto (France),* para 72-73.
155 Article 23.1(1) Deliberate Release Directive. The measure is to be provisional but effective immediately upon notification to the Commission.
156 Article 34 FFR by reference to Article 54 Regulation 178/2002.
157 Article 114.10 TFEU.

days to make a draft decision on the restrictive measures.[158] During this time the Commission shall consult the EFSA regarding the Member State's scientific evidence. Upon this, the draft approving or rejecting decision is handed over to the Scientific Committee, which has 90 days to provide an opinion by QM. If the safeguard measure is in line with the Scientific Committee's opinion, the measures shall be approved and adopted by the Commission. In case the scientific opinion is unsupportive of the Member State's stance, or when an opinion is not provided, the measure is up to the Council to decide upon. As with the Scientific Committee, the Council has 90 days to find a QM, this time to adopt or reject the safeguard measure. If the Member States' representatives cannot reach the necessary majority in the Council the safeguard measure is to be decided upon by the Commission.[159]

The control procedure in relation to Article 34 is very much alike the one just described. One notable difference is that consultation with the EFSA regarding the Member State's scientific evidence is not mandatory. Furthermore, due to the "urgency" of emergency measures, the Commission submits its draft decision within only ten days after notification from the Member State. This is then followed by the same procedure as for safeguard measures.[160]

With this examination of how the two provisions are to be used in "theory" in mind, we now turn to Member States' use of Article 23 of the Deliberate Release Directive and Article 34 of the FFR in practice.

3.1.2 Article 23 Deliberate Release Directive and Article 34 FFR – in practice

In practice several Member States have made use of the opt out possibilities offered by these two provisions to restrict or completely ban cultivation of GM crops in their respective territories.[161]

A handful of Member States have made recourse to the safeguard clause in Article 23, with a number of national and regional bans on GMOs authorised for cultivation purposes currently in place.[162] Bans on the use for cultivation purposes have since the Deliberate Release Directive came in place concerned the GM maize varieties MON810 and T25,[163] and the Amflora Potato. It should be reiterated, though that MON810 is the only GM crop that is currently cultivated for commercial purposes.

Article 34 of the FFR has thus far when it comes to cultivation, only been used in relation to MON810. It was stated earlier[164] that safeguard measures under Article 23 are not applicable in case the authorisation of the GMO was granted under the FFR. This has had practical implications since the renewal of the authorisation of MON810 was submitted under the latter. Therefore, since early

158 Articles 23.2 and 30.2 Deliberate Release Directive and Article 5 Comitology Decision 1999/468/EC.
159 Article 5.6 Comitology Decision 1999/468/EC.
160 Article 34 FFR and Articles 54, 58.1-2 Regulation 178/2002 by reference to Article 5 Comitology Decision 1999/468/EC.
161 For an overview that also covers more restrictions on GMOs than cultivation, see The Farmers Scientist Network, *Europe: GM crop cultivation and bans*: http://greenbiotech.eu/eu-gm-crops/
162 Note that recourse has been made to Article 23 Deliberate Release Directive also outside the context of restricting cultivation of GMOs. See ibid and Hristova, 2013, p. 116.
163 T25 never came to be marketed by their company for cultivation purposes, Hristova, 2013, p. 113.
164 See chapter 3.1

2007 notifications regarding national measures restricting or prohibiting cultivation of this specific GM crop have been viewed against Article 34.[165]

As will be demonstrated next, Member States has had a hard time convincing the EFSA and the Commission that they meet the substantive conditions in these two articles.

3.1.2.1 Fulfilling the substantive conditions in practice

We begin by considering invocation of Article 23 of the Deliberate Release.

Austria[166] twice invoked the Article 16 of the old Deliberate Release Directive to provisionally prohibit cultivation of the authorised GM maize variants MON810 and T25 respectively. By the time the new regime was in place, Austria was asked by the Commission to reconsider its position and Austria provided additional information for their measures to be adopted under Article 23. The EFSA concluded in their scientific opinion in 2008 that there was no new evidence in terms of risk to human health and the environment suggesting that the previous risk assessments in the authorisation procedure should be invalidated.[167] The same answer was given by the EFSA on the evidence provided by Austria in 2010 with regards to the Amflora Potato.[168]

Likewise, Luxemburg,[169] Hungary[170] and Greece[171] have invoked Article 23 to ban cultivation within their territories. For Luxemburg the ban concerned the Amflora Potato. For Hungary the bans have concerned the Amflora Potato and MON810, and for Greece only the latter. As was the case for Austria, neither one of these Member States managed to convince the EFSA with their scientific evidence.[172] However, all restrictions remain in place.

Regarding emergency measures a total of three Member States - France, Luxemburg and Italy -have invoked Article 34 in order to ban cultivation of MON810.

The most recent emergency measure was adopted by Italy.[173] In March 2013 Italy notified and provided the Commission with scientific evidence in support of its coming prohibition. By July the same year the ban was put in place by a national decree. The EFSA was soon requested by the Commission to evaluate the documentation provided by Italy. The EFSA held in the end of 2013 that there was "no specific scientific evidence, in terms of risk to human and animal health or the environment" supporting the notification of an emergency measure that would "invalidate the EFSA's previous risk assessments of the GM maize in question".[174] This national ban on MON810 is still in effect.

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165 Commission. *Evaluation of the EU legislative framework in the field of GM food and feed.* Final Report 2010, p. 82.
166 The Farmers Scientist Network, *Austria*: http://greenbiotech.eu/eu-gm-crops/austria/
167 EFSA, (891) 2008, p.1-2.
168 EFSA, (2627) 2012, p. 3.
169 The Farmers Scientist Network, *Luxemburg:* http://greenbiotech.eu/eu-gm-crops/luxemburg/
170 The Farmers Scientist Network, *Hungary:* http://greenbiotech.eu/eu-gm-crops/hungary/
171 The Farmers Scientist Network, *Greece* http://greenbiotech.eu/eu-gm-crops/greece/
172 Regarding Luxemburg, EFSA,(2874) 2012; Regarding Hungary, EFSA, (756) 2008; Regarding Greece, EFSA, (757) 2008.
173 The Farmers Scientist Network, *Italy:* http://greenbiotech.eu/eu-gm-crops/italy/
174 EFSA, (3371) 2013-

Luxemburg[175] prohibited cultivation of the MON810 in 2009. By 2012 its scientific argumentation in supporting the measures was submitted to the Commission. The scientific evidence subsequently came under the scrutiny of the EFSA, which reached the same conclusion as it did on the Italian evidence. It also added that Luxemburg's remaining concerns related to socioeconomic aspects of coexistence and thus fell outside its remits.[176] This ban also remains in place.

France[177] has twice turned to emergency measures to ban cultivation of MON810 by invoking Article 34. Apart from the EFSA reaching the same conclusion regarding the provided evidence,[178] it is notable that France ignored the procedural rules, as it did not inform the Commission prior to its adoption of the measures. The first French ban was in place until 2013 when it was annulled by the Conseil d'Etat,[179] in the aftermath of the preliminary ruling in Monsanto (France). The second one remains in place.

This brief overview shows that these Member States have invariably been unable to convince the EFSA that the substantive requirements and their evidential thresholds have been fulfilled. The EFSA has consistently held that no scientific evidence has been forwarded regarding risk to health or the environment so as to invalidate its previous risk assessments of the GM crop in question. Notably, in practice no precautionary relaxation of Member States' evidentiary burden has been afforded the Member States relying on these two provisions when restricting GM agriculture.

However, all bans under Article 23 concerning MON810 remain in place today.[180] The same goes for most of the bans under Article 34. The explanation of this is found in the procedural reality surrounding these two provisions. We will now turn to the practical procedural interplay between the Commission, the EFSA the Member States' representatives in the Council in these cases. This is of importance to understand the actual scope and reality of derogating under these provisions. In addition it shows how the provisions have arguably been misused by Member States against the will of the Commission.

3.1.2.2 The procedural reality

The practical pattern of the control procedure when it comes to Member States prohibiting cultivation under these two provisions reveals some interesting insights in terms of understanding their potential scope.

To begin with, as shown by the review above, the Commission has invariably consulted the EFSA for a scientific opinion on the documentation provided by the Member States in support of their measures. This has been the case also under Article 34 of the FFR when such requests from the Commission are not mandatory.

Furthermore, according to the control procedure described in 3.1.1.1, the Commission is to deliver a draft proposal on the restrictive measures and forward it to the Scientific Committee for an opinion. The draft proposal is to be submitted within 60 or 10 days depending on the measure.

175 The Farmers Scientist Network, *Luxemburg*: http://greenbiotech.eu/eu-gm-crops/luxemburg/
176 EFSA, (3372) 2013.
177 The Farmers Scientist Network, *France*: http://greenbiotech.eu/eu-gm-crops/france/
178 EFSA, (2705) 2012.
179 The highest administrative court in France.
180 As stated earlier, T25 and the Amflora Potato are no longer authorised for cultivation.

However, this was not done by the Commission concerning the emergency measures taken by Italy and Luxemburg.[181] These measures remain unchallenged by the Commission, and, as stated above, are still in place. Somewhat lax approaches to the procedural rules seem to have been the case for both the Commission and the Member States. With regards to the Member States, France's omission to inform the Commission in advance of its adoption of its measures is one example. Others include mere translations of scientific evidence handed in by other Member States that have earlier been rejected.[182] Notably, at the time of adoption of the Italian decree under Article 34 the Italian Ministry of Agriculture held that the Italian measure could be inconsistent with EU law, but that based on earlier experience it was unlikely that the Commission would open an infringement procedure.[183]

Regarding Article 23 measures, the Commission has repeatedly sought to overturn the bans by drawing on the EFSA's conclusions.[184] As the EFSA has found no risk to health or the environment, the Commission has simply held that the measures ought to be repealed.[185] This suggests that the Commission has put great trust in the EFSA findings and that it has not wanted the internal market to be fragmented needlessly.

However, the Commission's proposals for upheaval of these measures have constantly met opposition in the Council. As opposed to when it comes to authorisation decisions, the Council has not had problems with reaching QM[186] in favour of the cultivation bans.[187] Hence, enough Member States seem to agree that the Commission should not be entitled to lift the restrictive measures against the will and concerns of the Member State and its citizens.[188]

It has been stated in evaluations of the GMO regime that there has been a general understanding between Member States that the use of national safeguard and emergency measures, while presented as having a scientific justification, has instead at times been expressions of "frustrations with the current risk assessment practice, of non-scientific objections to GMO cultivation and of political circumstances".[189] One example here is Luxemburg's reference to the socioeconomic impact of GM cultivation which was held to fall outside the scope of the safeguard clause.

As Member States' restrictions based on the provisions have been kept contrary to the EFSA's

[181] See The Farmers Scientist Network, *Italy*: http://greenbiotech.eu/eu-gm-crops/italy/and The Farmers Scientist Network, *Luxemburg*: http://greenbiotech.eu/eu-gm-crops/luxemburg/

[182] The scientific information provided by Italy under Article 34 has been held to have been a "simple translation of the scientific dossier submitted by France", The Farmers Scientist Network, *Italy*: http://greenbiotech.eu/eu-gm-crops/italy/

[183] See ibid.

[184] See e.g, Commission, COM (2009) 56 final.

[185] See e.g., ibid, para 22 and Commission, COM (2009) 12 final, para 10.

[186] The Council has only failed to reach a qualified majority in two cases on safeguard bans. Both with regards to Austrian bans and these have not been concerned with GMOs for cultivation purposes. See Geelhoed, 2014, p. 12. On this note Zurek holds that the accession to the EU of more Eastern European states, where traditional and organic agriculture remain of great economic and social importance, has resulted in a power-shift, strengthening the opposition against GMOs considerably, Zurek 2011, p. 241.

[187] The logic behind this seems to differ between Member States. Even if being pro-GMO, some Member States' representatives in the Council have voted against the Commission's repealing proposals because they believe Member States should have the capacity to impose restrictions on their territories. As such, this group of countries vote for preserving national competences rather than on substantive grounds concerning the actual safety of the crop in question, Pollack and Schaffer 2010, p. 352 and Hristova, 2013, p. 116f. The latter also concludes that Member States that have wished to keep their bans have actively lobbied other Member States to secure QM against Commission proposals.

[188] Weimer 2014, p. 7.

[189] Commission, *EPEC Final Report,* 2011, p. 52.

scientific opinions and the Commission's proposals, it is possible to conclude that the practical use of safeguard measures have partly reflected Member States' non-scientific considerations and partly because of dismay with the centralised risk assessments. As for the latter, the Council held on the Hungarian measure that the assessments fail to systematically take into account the diversity of agricultural structures and ecological characteristics of the Member States in the EU.[190]

The quite stringent interpretations of the substantive conditions thus have had little practical implications as the procedural rules have de facto helped Member States to maintain national discretion on cultivation of GM crops. Alternatively, the Commission has not taken action pursuant to notifications.

However, the appropriateness and pratice of invoking these measures against cultivation of GM crops is questionable. For one thing, with basically all national measures on the MON810 still in place, the "provisional" nature of them is debatable, as some have been in place for quite some time. Furthermore, in theory, rather than being used to accommodate national differences, Article 23 and, especially Article 34 are intended for situations of emergency and crisis where prompt action is needed to prevent harm to human health or the environment.[191] As for Article 34 it was incorporated in the FFR with emergencies such as the "mad cow disease" and "Creutzfeld-Jakob disease" in mind. Therefore it is not surprising that the aptness of Member States' use of the article in relation to GM cultivation has been questioned. And arguably, the idea of an "emergency" does not fit well with the scientific arguments used by for instance France, when referring to uncertainties over long term impacts of the MON810.[192]

It may be concluded that the limited theoretical scope to invoke environmental and health concerns towards specific GM crops under these two provision in the GMO legislation has thus far not had practical limiting effects. This is so due to the procedural rules and somewhat lax approach from the Commission regarding emergency measures. It is also clear that emergency and safeguard measures have not been used as intended. In any case, it remains to be seen how this practice will develop in light of the new possibilities offered under Article 26b. As will be shown in chapter 4, it is unclear to what extent the possibilities to invoke environmental concerns will increase in the future. However, at least it should be able to better accommodate non-safety concerns.

Next we turn to the derogation possibilities offered by Article 114.5 TFEU. As with the just examined provisions, this so called "environmental guarantee" is also concerned safety concerns. However, as potentially having more restrictive and general effects on GM cultivation – and in turn on the internal market-, its substantive conditions are and have been interpreted even stricter.

3.2 Under Article 114.5 TFEU – general measures on GMOs

Article 114 TFEU does not only provide for safeguard clauses in secondary EU law. It also provides an alternative route for banning cultivation of authorised GM crops on grounds related to environmental protection. Whereas the provisions in the GMO-legislation (in theory) only permit

[190] See e.g., COUNCIL. 2785th Council meeting, 6272/07 (Presse 25), 20 February 2007.

[191] Hristova, 2013, p. 117.

[192] Commission. *Evaluation of the EU legislative framework in the field of GM food and feed.* Final Report 2010, p. 81f.

provisional bans on a case-by-case basis, Article 114.5 TFEU allows for permanent and general opt outs from the harmonisation provided by the authorisation procedure in the Deliberate Release Directive and the FFR. However, as will be demonstrated, in the very limited number of cases that Member States have sought to rely on this provision in relation to GMOs it has shown to provide limited scope for autonomy.

Article 114.5 states that:

> […] if, *after* the adoption of a harmonisation measure […] 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.[193]

The provision contains five cumulative substantive conditions,[194] which must all be fulfilled for the national measure to be accepted. The essence of these, are that it is for the Member State in question to demonstrate on the basis of new scientific evidence that the level of protection for the (working) environment) afforded by the harmonising measure, i.e. the Deliberate Release Directive and the FFR, was not acceptable having regard to a problem specific to that Member State which arose after the adoption of these legislative acts.[195]

The protected interests of Article 114.5 are the environment and the working environment. This can be compared with Article 114.4 TFEU,[196] which allows Member States to invoke any of the grounds of Article 36 TFEU when *maintaining* stricter national measures. The logic of this limited[197] number of grounds that can be invoked is that new national measures are more likely to threaten harmonisation, than keeping existing measures that will already have been taken intro account in the harmonisation. As such, it is in line with the EU's restrained attitude towards giving Member States too much manoeuvrability to derogate from harmonised rules.[198]

Furthermore, the notification requirement explicit in Article 114.5 means that national measures must be notified to the Commission, and that they are not effective until the Commission has accepted them. The Commission has six months to approve or reject the national measures after assessing if they are a means of arbitrary discrimination, disguised trade restrictions or constitute an obstacle to the functioning of the internal market.[199] This timeframe can be extended in complex of cases.[200] Article 114.6(2) holds that in the absence of a decision form the Commission within the time limit, the national measure shall be deemed to have been approved, whereby it can take effect.

It is worth mentioning here that Portugal managed to get a cultivation ban on the island of Madeira approved in this way. Portugal's evidence relating to environmental protection was considered

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193 My italics.
194 Joined cases C-439/05 P and C-454/05 P, *Land Oberösterreich and Republic of Austria v Commission*, para 58-59.
195 Cf., Case C-3/00, *Kingdom of Denmark v Commission*, para 57.
196 This article is not of immediate relevance to this thesis since national measures on GMOs have so far been dealt with as *new* measures under Article 114.5.
197 Article 36 TFEU allows for invocation of grounds of for example public morality, public policy, the protection of health and life of humans, animals or plants. See below in chapter 4.3 where these grounds can be used in the context of non-harmonised areas.
198 Case C-512/99, *Federal Republic of Germany v Commission*, para, 41; Lee 2008, p. 93.
199 See Article 114.6 TFEU. These conditions that essentially have to do with proportionality will be examined in Chapter 4 as they are of relevance also for the new Article 26b. It could be argued that they are not of much relevance in the context of GMOs and Article 114.5 as national measures have not been able to pass the cumulative conditions.
200 Article 114.6(3) TFEU.

complicated, whereby the Commission found an EFSA opinion on the scientific risk assessment necessary and extended its decision period.[201] However, no decision was given within the extended timeframe, notwithstanding a conclusion by the EFSA that the provided evidence was insufficient to justify a prohibition on GM cultivation in Madeira.[202] This tacit approval is likely to have been the result of that the Commission was soon to present its proposal on the new Article 26b.

The cumulative substantive conditions that are italicized above act very restrictive on Member States possibilities to act pursuant to this provision. This is especially so for what amounts to new scientific evidence and a problem specific to a Member State. These are the so-called "novelty" and "specificity" conditions. In addition, the legitimate grounds for concern limit Member States justification grounds in the context of GM cultivation. This is all evidenced by a closer look on the how they have been treated by the EFSA, the Commission's and the EU courts.

3.2.1 Substantive conditions

The joined Cases C-439/05 P and C-454/05 P, *Land Oberösterreich*,[203] provide the main backdrop against which the substantive conditions of Article 114.5 are examined here.

In this case Austria notified the Commission of its plans to adopt an act banning all uses – including cultivation - of GMOs in the Land Oberösterreich region in derogation of the Deliberate Release Directive. Austria held that its measures aimed at protecting the natural environment's biodiversity. It also put forward that the act aimed at keeping the region's small-structured and mainly organic farming systems GM free, which it held would be practically impossible alongside GM cultivation in the long term and further worsen environmental impacts. Under these premises Austria held that general GMO restrictions were justified.[204] However, these claims were rejected by the Commission on the ground of failure to provide new scientific evidence or demonstrate that a problem specific in the region had arisen following the adoption of the Deliberate Release Directive. The Austrian measure was subsequently rejected also by the CFI,[205] as well as by the ECJ.

3.2.1.1 "New scientific evidence" – novelty

The novelty requirement of Article 114.5 holds that the national measure must be based on "new scientific evidence". The meaning of the requirement was up for interpretation in the case before us.

As evidence in support of their measures, Austria relied on a report that was published after the adoption of the Deliberate Release Directive. The report pointed towards long term negative impacts of GM crops on naturally occurring crop formations and GM free agricultural production. After requesting the EFSA's opinion, the Commission rejected the report as the data it included "were for a large part available prior to the adoption" of the Union measure. The Commission rejected an argument put forward by Austria that the report it relied on was released almost a year

[201] Commission, Decision 2009/828/EC, para 21-22.
[202] EFSA, (1500) 2010.
[203] Joined cases C-439/05 P and C-454/05 P, Land Oberösterreich and Republic of Austria v Commission. Hereafter "*Land Oberösterreich*".
[204] Commission, Decision 2003/653/EC, para 31-36.
[205] Joined Cases T-366/03 and T-235/04, *Land Oberösterreich and Republic of Austria v Commission.* Hereafter "*Land Oberösterreich*".

after the adoption of the Deliberate Release Directive, as most of the sources it referred to "were published prior to the adoption" of the directive.[206]

This issue never came under the test of the ECJ as the appeal was rejected on the grounds of there being a lack of a specific problem.[207] However, the Commission's stance is in line with previous case law on what amounts to new evidence.[208] AG Sharpston's opinion, can serve to illustrate the implications of this approach to newness. Her view was that "new conclusions drawn from existing data *may* constitute new scientific evidence" within the meaning of the article.[209]

An approach similar to the AG's on new evidence has not been pursued by the Union courts. Hence, there is a demand of new data under the provision, whereby evidence that existed before the EU adopted its harmonised measure, but was not taken into account is excluded. This means that it does not seem to be possible to reassess previous data with "new glasses" that may throw new light on the nature or degree of risk to the environment. Instead new evidence is literally required. This is also in itself a stricter approach than under Article 23 of the Deliberate Release Directive,[210] under which Member States have also not been able to satisfy the evidentiary demands.

3.2.1.2 "Problem specific to the Member State" – specificity

Article 114.5 furthermore states that the new evidence shows an environmental problem *specific* to the Member State, arising after the adoption of the harmonisation measure.

In *Land Oberösterreich* Austria fruitlessly argued, and that its "small-structured farming systems" were specific to the region in question. By leaning on the opinion of EFSA, the Commission held that the scientific evidence did not suggest anything else than that such systems exist in every Member State. Therefore they were "certainly" not specific to this region. Furthermore, Austria had not provided scientific evidence establishing that the area in question had "unusual or unique ecosystems", necessitating distinct risk assessments from those conducted for the country as a whole, or for similar areas of the EU.[211]

Both the CFI and the ECJ were of the same opinion regarding the specificity. They quite shortly stated that there was no scientific evidence in the report demonstrating the existence of a specific problem.[212]

The ECJ also stated that the requirement is not that the problem needs to be "unique" to the Member State, but that it should be "specific".[213] The meaning of this was not further defined by

[206] Commission, Decision 2003/653/EC, para 65. The CFI did not go into detail regarding this, other this requirement, see Joined Cases T-366/03 and T-235/04, *Land Oberösterreich,* para 65f.
[207] Ibid, para 63-64.
[208] See Lee 2008, p. 94 with reference to 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 and Others v Commission,* para 194.
[209] Opinion of AG Sharpston – Joined Cases C-439/05 P and C-454/05 P, para 124.
[210] Article 23 Deliberate Release Directive allows for new interpretation of earlier data.
[211] Commission, Decision 2003/653/EC, para 70-71.
[212] Joined Cases T-366/03 and T-235/04, *Land Oberösterreich,* para 65-68; Joined cases C-439/05 P and C-454/05 P, *Land Oberösterreich*, para 61-64.
[213] Joined cases C-439/05 P and C-454/05 P, *Land Oberösterreich*, para 65-68.

the ECJ. However, AG Sharpston held in her opinion that a specific problem is located somewhere between a unique one and one that is "common, generalised or widespread".[214]

The specificity requirement was elaborated with by the CFI in another case the same year, but in the context of air pollution. Apart from stating that the problem does not need to be unique to the Member State,[215] the CFI held that that the problem in question needs to be "so acute as to distinguish them significantly from those observed in other Member States".[216] This judgment treated specificity in relation to harmonisation. The CFI held that the issue of a specific problem relates in particular to "cases where a new phenomenon arises in all or part of a Member State's territory, which has negative effects on the environment and which could not be taken into account in the preparation of the harmonised rules".[217] Drawing on this it stated that a problem that arises which on the whole is comparable to those of other Member Stats lends itself to harmonised solutions at the EU level, is to be seen as "general in nature" and does not constitute a specific one. Thus, it held that national specificity of a problem is essentially to be envisaged "from the angle of the aptness or inaptness of the harmonisation of the applicable [EU measure]" to adequately confront difficulties encountered locally, "since the established inaptness of those rules justify the introduction of national measures".[218]

It is however still not very clear as to what exactly amounts to a specific problem. But it is not a wild guess that it takes substantial effort to convince the Commission and the CJEU that the GMO regime does not take into account regional and local environmental aspects, as the Commission continuously states that such aspects are taken into account in the central risk assessments.[219]

3.2.1.3 Protection of the (working) environment

Furthermore the only interests that a Member State can legitimately pursue under Article 114.5 are the protection of the environment or the working environment.[220] As stated above Austria held in *Land Oberösterreich* that the general ban was justified in light of the impossibilities for GM cultivation to coexist with the region's own organic agriculture. The argument was that extensive use of GM farming would result in contamination and in the long run displace GM-free agriculture.[221]

The Commission, drew on the EFSA's conclusions and held that no evidence was presented in the Austria's report "to show that coexistence is an environmental or human health risk issue". Instead the Commission was of the opinion that Austria's concerns of avoiding negative impacts on its organic farming from GM crops related more to concerns of a socioeconomic character.[222] Consequently, Austria's concerns in this regard were held to fall outside the scope of the article.[223]

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214 Opinion of AG Sharpston – Joined Cases C-439/05 P and C-454/05 P, para 110.
215 Case T-182/06, *Kingdom of Netherlands v Commission*, para 65.
216 Ibid, para 53.
217 Ibid, para 62.
218 Ibid, para 61-64.
219 See also chapter 4.3 on environment and EFSAs guidelines.
220 Emphasised in Joined Cases T-366/03 and T-235/04, *Land Oberösterreich*, para 62 and Joined cases C-439/05 P and C-454/05 P, *Land Oberösterreich*, para 31.
221 Commission, Decision 2003/653/EC, para. 34.
222 Ibid, para 66-67.
223 The EU Courts did not deal with this question, as the specificity condition was not fulfilled.

Whereas the issue of coexistence will be dealt with more thoroughly just below, it can be stated already now that this approach from the Commission has been criticised. Lee holds that this understanding of the values of organic farming is "contentiously narrow", as it neglects its environmental merits.[224] What she means seems to be that organic farming comes along with benefits for biodiversity and that in that sense, protecting organic farming could be interpreted as "environmental protection". Indeed there are studies that point to the environmental benefits from organic farming compared to other methods.[225] While this is not the place for a normative analysis, this shows that not all considerations that by some are considered to fall in under the scope do so. In this context however, coexistence has been addressed in Article 26a of the Deliberate Release Directive and the possbile insufficiencies of such measures in the new Article 26b.

It has now been demonstrated that the scope for derogating under Article 114.5 is limited by the substantive conditions of the article and the strict interpretations made by the central Union institutions. As opposed to the opt out possibilities afforded under Article 23 of the Deliberate Release Directive and Article 34 FFR there is not really any procedural safety net for Member States to rely on. This is in sharp contrast to the procedure governing safeguard and emergency measures as under Article 114.5 the Member States are not represented in comitology. Instead the Commission has the final saying, subject to review of the Courts.

What happened in the Portugal case is very likely to be a one-time incident on behalf of the Commission. Together this probably goes a long way in explaining why the "environmental guarantee" clauses has been invoked so few times by Member States in comparison to the earlier examined provisions also concerned with safety issues.

Moreover, it was mentioned in passing that the Commission, and ultimately the CJEU, are to assess if the restriction are means of arbitrary discrimination, disguised trade restrictions or constitute an obstacle to the functioning of the internal market. These typical internal market restrictions are explicit in Article 114.6 and have to do with proportionality..[226] As is obvious from the *Land Oberösterreich* case these tests were not undertaken as the other substantive conditions were not fulfilled. Nonetheless, these controls are of great importance to Member States' derogation possibilities in general (and apply equally to coexistence measures) and are elaborated with in chapter 4 in the context of the new Article 26b.

Before we move on to the new derogation possibilities however, we look a little closer at the issue of coexistence, which is explicitly addressed and de-harmonised in the Deliberate Release Directive.

3.3 Coexistence measures – Article 26a Deliberate Release Directive

Apart from the original "scientific" opt out possibilities explored above, coexistence measures offer another, leaner way out of GM cultivation for Member States, as this mechanism is intended to target local and individual situations rather than providing for national prohibitions.[227] Yet, coexistence measures have an important role to play for Member States and in this thesis, as they

[224] Lee 2014, p. 230.
[225] Bengtsson et al 2005, p. 261-269.
[226] See Lee 2014, p. 230.
[227] Dobbs 2010, p, 1353.

potentially offer a way out of GM cultivation for different reasons than the science-based provisions.[228] Certain economic risks of GM agriculture have since the second framework came into place expressly been left outside the scope of the harmonisation of the GMO regime. As such these concerns have been allowed to be regulated on Member State level through coexistence measures under the conditions that apply to these.

This chapter briefly demonstrates how the concept of coexistence is subject to a largely economical logic and limitations of general EU law requirements such as proportionality. However, the Commission has not challenged any national coexistence measures, whereby their actual use is likely to exceed their intended one.

3.3.1 Introduction

The coexistence provision is found in Article 26a of the Deliberate Release Directive.[229] According to that article "Member States may take appropriate measures to avoid the unintended presence of GMOs in other products".[230] This applies in particular to avoiding the presence of GMOs in other crops, such as conventional or organic ones.[231]

As indicated from the article itself, the concept of coexistence is based on the recognition that cultivation of GM crops may have consequences for conventional and organic agriculture and vice versa due the possibility of adventitious mixture of crops.[232] In line with this, coexistence measures are envisioned to smoothen harmonious cultivation of these three agritypes, without excluding any of them.

Article 26a foresees that national coexistence measures should be coordinated by the Commission. Hence, the Commission has provided guidelines at two times, in 2003 and 2010, to provide guidance to the Member States in implementing appropriate measures under the article.[233] Notably the 2010 guidelines were issued at the same time as the Commission's proposal on the new Article 26b, which might explain their somewhat more flexible approach in comparison to the older ones'.

According to the guidelines, coexistence is the idea that famers should be able to choose between conventional, organic and GM-crop production in practice..[234] The idea is to allow Member States to set up binding or non-binding good practices of isolation in order to guarantee farmers' right of choice and compliance with labelling and traceability standards set out in the GMO framework.[235]

Measures to ensure coexistence of different forms of agriculture include technical measures, such as weed management and careful cleaning and maintenance of equipment. Another common measure

[228] Moreover, in practice, more than half of the Member States have at some point adopted coexistence legislation to limit or prevent the presence of GMOs within non-GM crops**.**
[229] The insertion of the Article 26a into the Deliberate Release Diretive in 2003 was an attempt to lift the bans and the moratorium under the Old Deliberate Release Directive, see Dobbs 2011, p. 181.
[230] Article 26a.1 Deliberate Release Directive.
[231] Recital 1. Commission Recommendation 2010/C 200/01.
[232] Commission Recommendation 2003/556/EC, para 1.1.
[233] In 2003 the Commission Recommendation 2003/556/EC and in 2010 the Commission Recommendation 2010/C 200/01.
[234]Recital 3 Commission Recommendation 2003/556/EC.
[235] Varela 2010 p. 353.

is that Member States prescribe a fixed buffer-zone of up to a few hundred meters between GM crop fields and fields where conventional or organic crops are grown.[236]

Whereas the technical measures are of lesser importance in the view of actually restricting GM cultivation, it should be pointed out that the 2010 Guidelines introduced the concept of "GM-free areas". This permits Member States to exclude GMO cultivation from larger areas under certain economic and natural conditions to avoid unintended GMO presence.[237] As such, these buffer and GM free zones can be of various scales and are the strictest of the legal coexistence measures in light of the Commission's guidelines.[238]

3.3.2 The logic of coexistence

The logic of coexistence under Article 26a is largely economical. The Commission has held that admixture of GM crops and conventional or organic ones might amount to potential economical losses and impacts for farmers, for example through the possibility of losing organic certification due to unintended presence of GMOs for organic farmers.[239] This is to be understood in light of the 0.9 % threshold in the GMO legislation that requires farmers to label their products as containing GMOs if the threshold is altered.[240] If measures are not adopted to avoid admixture above that threshold, farmers' investments in keeping crops organic or traditional may be seriously affected as economic benefits from being able to advertise their products as GMO-free are lost.

The Commission's guidelines underline the importance of making a "clear distinction between the economic aspects of GMO cultivation and the environmental risk assessment aspect dealt with under the authorisation procedure". Since only authorised GMOs can be cultivated in the Union and the environmental and health aspects are already covered by the environmental risk assessment of the authorisation process, "the pending issues still to be addressed in the context of co-existence concern the economic aspects associated with the admixture of GM and non-GM crops".[241]

3.3.3 The limitations and control of coexistence measures

In the 2003 guidelines GMO-free and GMO exclusive productions zones could only be established by private agreements between farmers, which proved to be difficult in practice. This "highly restrictive approach" did not allow for any larger areas to be GM free.[242] As such, the 2010 guidelines which were issued together in a package with the Commissions proposal on the new Article 26b, are somewhat more permitting. This is so for example in regards to the 0.9% threshold. Although Member States can still not eliminate cultivation of GM crops in their whole territory by relying on this provision.[243] The discretion that Member States are allowed under Article 26a is

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[236] These include familiar countries like Austria and Hungary. Others include Denmark, Romania and the Netherlands. See Commission, COM (2009) 153 final. See also for a recent overview IFOAM, *Preventing GMO Contamination – An Overview of National "Coexistence" Measures in the EU*: http://www.ifoam-eu.org/sites/default/files/ifoameu_policy_gmos_dossier_201412.pdf
[237] Commission Recommendation 2010/C 200/01, Para 2.4.
[238] Varela 2010, p. 356.
[239] Recital 5 Commission Recommendation 2003/556/EC.
[240] See Article 12 FFR.
[241] Commission Recommendation 2010/C 200/01, para 1.2
[242] Varela 2010, p. 353f.
[243] Dobbs 2010, p, 1353.

subject to a number of limitations.

To begin with, the economical understanding of the article sets limitations, as Member States cannot invoke other grounds than these specific socioeconomical ones. Focusing on the economical implications of coexistence, not only excludes environmental and health protection, but also other aspects like consumer protection, ethics and cultural traditions when Member States adopt measures under the provision.[244]

Next, by being outside the harmonised scope of the GMO regime coexistence measures are subject to general rules of internal market law.[245] Specifically, it is likely that any GM free zone will need to be justified under Article 36 of the TFEU or the mandatory requirements[246] and already the wording "appropriate" in the article suggests that the measures have to be proportional. This is also made clear in the in the 2010 Guidelines, where measures on large areas are to be "proportionate to the objective pursued" and necessity needs to be demonstrated by the Member State in the sense that "other measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops".[247] Thus while the Commission recognises that "appropriate" restrictions *could* involve GM-free areas all measures need to be proportionate to the protection of the needs of the farmer, which would normally only require the determination of the above-mentioned isolation distances.[248]

These limitations are more thoroughly addressed in Chapter 4.3. What can be said here is that national coexistence measures have sometimes taken extreme forms. In some European regions full prohibitions to plant GM crops have been enacted. These bans have been based on agronomic justifications, political and economic reasons, for instance meeting the market demands for GM-free products or the need to preserve biodiversity and the natural environment in general.[249] Not surprisingly some of these restrictions have been considered legally questionable.[250]

Notwithstanding this, and that a majority of the Member States have enacted coexistence measures, the Union courts have not yet ruled on the legality of any of them in light of the limitations yet, as none have been challenged by the Commission for infringement of EU law.[251] Notably, the Commission has put the issue aside, holding that the relatively small effects of the measures prevents them from hindering trade.[252] However, on a preliminary reference it was held by the CJEU that Article 26a allows for coexistence measures that give rise to restrictions, but not to general bans on GM cultivation.[253]

As such the scope to avoid unintended contamination under Article 26a is limited, but it is possible

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[244] Dobbs, 2011, p. 189ff.
[245] These issues will be explored in chapter 4.3. This is also emphasised in Article 22 Deliberate Release Directive.
[246] Lee 2014, p. 246.
[247] Commission Recommendation 2010/C 200/01, Para 2.2, 2.4.
[248] Geelhoed 2014, p. 10.
[249] Poli 2010, p. 340.
[250] Lee 2013, p. 368.
[251] It should also be noted that coexistence has been relied on by Member States in attempts to justify measures under Article 114.5 TFEU. See e.g. Joined cases C-439/05 P and C-454/05 P, *Land Oberösterreich*.
[252] Commission, COM (2010) 1454, p. 11. On this note Geelhoed holds that the Commission has invented a *de minimis*-type exception to Article 34 TFEU. However, stating also that the CJEU has rejected such an exception in the context of the free movement of goods, even when the measures would only concern as little as 0,3 percent of a Member State's territory, Geelhoed 2014, p. 18 with reference to Case C-67/97, *Criminal Proceeding against Ditlev Bluhme* and Joined Cases 177/82 and 178/82, *Criminal proceedings against Jan van de Haar and Kaveka de Meern BV*, para 14.
[253] Case C-36/11, *Pioneer Hi Bred Italia Srl v Ministero delle Politiche Agricole Alimentari e Forestali*.

that the controls of these restrictions will continue to be weak in relation to GM-reluctant Member States. Mainly since they have the new opt out clause in Article 26b to base restrictive measures on.[254]

3.4 Concluding remarks on the original opt out possibilites

This chapter has sought to examine the Member States' original possibilities to restrict or prohibit cultivation of authorised GM crops in their respective territories. In doing so the provisions in Article 23 of the Deliberate Release Directive and Article 34 of the FFR and Article 114.5 TFEU were examined. Additionally, coexistence measures, which are allowed for under Article 26a of the Deliberate Release Directive, were treated.

Regarding the first three of these original provisions it has been shown that they share common ground in that they are all concerned with safety, i.e. risks to either the environment or the health.[255] As such the provisions are all founded on a science-based approach, as national measures are to be based on new[256] scientific evidence regarding these risks. The provisions also share that their respective substantive conditions have been interpreted strictly by the Commission, the EFSA and the EU Courts. This has been the case for the degree and existence of risk for Article 23 and Article 34, as well as for the requirements on "new" evidence and specificity in Article 114.5 TFEU.

It appears that the mentioned institutions stringently control the use of these provisions, and that divergent stances with regards to scientific uncertainty and varying views on existing data between Member States and the central institutions have been hard to accommodate. The Commission also relies heavily on the opinions of the EFSA in its decision-making.

Indisputably, a significant evidential burden lies upon Member States that want to invoke measures under these articles. In the context of authorised GM crops, thus far, not a single Member State has successfully provided new scientific evidence showing risk to environment or human health under Article 23 or Article 34. The same goes for Article 114.5 TFEU in the very limited number of cases it has been invoked to restrict GMO cultivation, as the cumulative substantive conditions have been interpreted so stringently.

However, in spite of the strict understandings of the substantive conditions and almost continual opposition from the Commission, several Member States have not hesitated to adopt restrictions on GM cultivation. With regards to the only commercially cultivated GM crop, the MON810, six Member States currently have safeguard and emergency measures[257] in place. Notwithstanding the Commission's and EFSA's constant opinions that Member States have not met the substantive

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254 Varela 2010, p. 358.

255 However, the scope of their respective protected interests differ somewhat. Notably safeguard and emergency measures under the GMO legislation are broader in their scope than Article 114.5, as the former two also cover protection of human health and in the case of Article 34 FFR, animal health.

256 It was shown that "newness" regarding the presented evidence is treated somewhat differently between for example Article 23 of the Deliberate Release Directive and Article 114.5 TFEU, as the former explicitly allows for reassessment of existing information, though with the restriction that this is to be done on the "basis of new or additional scientific knowledge". This essentially entails that Member States that rely on these provisions must put forward evidence for a new element to the original risk assessment regarding the risk.

257 Reminder: Austria, Hungary and Greece under Article 23 Deliberate Release Directive. Italy, Luxemburg and France under Article 34 FFR.

requirements in Article 23 and Article 34, the decision-making structure that accompany these provisions has permitted the same states to maintain them. The Commission has held that these measures, since they are not based on new or additional scientific information are not justified from a legal point of view.[258]Alternatively the Commission has not acted upon the notifications on the measures. Or as is the case for coexistence measures the Commission has deemed the measures to be too small to actually conflict with trade. As will be shown in chapter 4.3 such an approach to ceoxistence measures is questionable in light of the CJEU's case law on the free movement.

Thus, it can be concluded that in theory, the theoretical scope for Member States to derogate under these provisions is narrow. However, procedural rules and a lax approach from the Commission in some cases has allowed for Member States to keep many restrictions although being legally questionable through not fulfilling the substantive conditions. This means that to a certain degree, the scope of the opt out possibilities is widened in practice, much against their intended use.

The restrictions to the areas of environmental or human health protection mean that other concerns raised by GM cultivation are excluded under the safety provisions. As such, the legal possibilities to accommodate other national concerns post-authorisation under them are basically non-existent if they are deemed to be concerns regarding health or the environment. This was evidenced by *Land Oberösterreich* where concerns about coexistence of organic agriculture and GM cultivation was deemed to be concerns of a socioeconomic character, thus falling outside the scope of Article 114.5. One could of course hold that the this is only valid with regards to the substantive requirements, as for instance the Comitology rules in practice allow for other (or any) considerations to uphold restrictions.

Here coexistence measures under Article 26a has had and will have a role to play in terms of substance of the concerns, albeit also coming with limitations to their scope. As such they allow for socioeconomic concerns to be used as reason that potentially restrict GM cultivation. The specific economical logic behind them and the fact that they are not intended to exclude GM cultivation, but rather facilitate harmonious coexistence between the three types of agriculture are important limitations. Furthermore, the general requirements on proportionality in the context of GM-free areas are also of great importance as will be shown further in 4.3. It is not certain that the Commission's lax approach in this regard would be shared by the CJEU if a Member State's extensive use of coexistence measures were challenged.

Overall, the narrowness of the scope of these provisions and the fact that national derogation measures could be kept thanks to procedural rules instead of what was allowed on substantial grounds were two of the reasons why the Commission came to propose the new Article 26b in 2010. We now turn to this new article to looks into the scope of it and see how it changes Member States' overall scope to opt out of GM cultivation.

[258] Commission, COM (2010) 380 final, p. 2f

4 The new Article 26b – what is key?

In March 2015 the Council formally adopted Directive 2015/412 that amends the Deliberate Release Directive. Enshrined within it is Article 26b, which intends to extend the possibilities for Member States to restrict or prohibit the cultivation of GMOs.[259] The original derogation possibilities just examined will continue to exist after this amendment.

Article 26b applies to GMOs authorised for cultivation purposed either under the Deliberate Release Directive or the FFR and offers two stages for Member States to opt out. One is offered during the (re-) authorisation procedure and requires consent from the applicant. The other possibility - like the original ones - is after the GMO has been authorised for cultivation. In that case a non-exhaustive list of new derogation grounds are provided for the Member States to justify their measures on. However, the invoked grounds cannot conflict with the environmental risk assessment carried out under the Deliberate Release Directive or the FFR. In addition to the requirement that the measure is based one of the new grounds, the measure has to be in "conformity with Union law".[260]

With the previous chapters in mind, the legislative process regarding the article unsurprisingly turned out to be prolonged and challenging. The final text was welcomed by Commissioner Andriukaitis, who held that the agreed text gives Member States "the final say" on GM cultivation on their territory, allowing them "to better take into account their national context and, above all, the views of their citizens".[261] However, not all stakeholders were as satisfied with the outcome. Some has held that "it grants biotech companies the power to negotiate with elected governments and excludes the strongest legal argument to ban GM crops – evidence of environmental harm".[262] Others hold that the real purpose of the new article "is to make it easier to wave through EU authorisations of GM crops" and that it is not a "legally-watertight basis" for opting out, but a Trojan horse "riddled with loopholes".[263] The biotech industry association EuropaBio, on the other hand called it "a stop sign for innovation in Europe", enabling Member States to "reject safe EU approved products based on arbitrary and non-scientific reasons",[264] i.e. on grounds of concerns other than safety.

In accordance with the second subquestion, this chapter seeks to examine the scope of the new possibilities that Article 26b offers for Member States to restrict GM cultivation and how this amendment affects the overall scope to opt out. First a brief overview of the bumpy legislative development is given, where the Commission's original proposal is highlighted (4.1). This is followed by an examination of the content of the article itself, divided into the two different stages

[259] Note that the provision is concerned only with restrictions and prohibitions on *cultivation* of GMOs. Measures under it cannot otherwise restrict the free circulation and import of GMOs as products or harvest from GM crops, Article 26b.8 and Recital 16 Directive 2015/412
[260] Article 26b.3(1) Directive 2015/412.
[261] Commission, Statement/14/2363, 4 December 2014.
[262] Greenpeace, *EU Parliament to adopt new GM crop national opt-out law*: http://www.greenpeace.org/eu-unit/Global/eu-unit/reports-briefings/2015/GMOs%20briefing%2012012015%20%20FINAL.pdf
[263] EurActiv, *MEPs approve national ban on GM crops cultivation*: http://www.euractiv.com/sections/agriculture-food/meps-approve-national-ban-gm-crops-cultivation-311221
[264] EuropaBio, *GMO Agreement: A Stop for Innovation:* http://www.europabio.org/press/gmo-agreement-stop-sign-innovation

of opting out (4.2). Lastly the possible limits to the scope of the article and the implications of that Member States' measures are to be in conformity with Union law are examined (4.3).

It is found that Article 26b might not increase Member States' scope to adopt restrictive measures as much as it first appears. Opting out in the authorisation stage will depend on the outcome of negotiations with the biotech companies seeking authorisation. As for opting out post-authorisation the de-harmonisation entailed by the amendment allows for a very wide range of concerns to be invoked. However, environmental concerns still appear to be harmonised to a large extent. Furthermore the actual scope under the new derogation grounds will depend on the approaches and interpretations of the Commission and the CJEU of compatibility with rules governing the free movement of goods. In this regard, establishing genuineness and proportionality could pose real hurdles depending on the circumstances and conditions under which the measures are invoked.

4.1 An overview of the legislative development

By June 2009 Austria and twelve[265] fellow Member States at opposite ends of the GMO debate,[266] came together and signed a declaration[267] that urged the Commission to put forward a proposal for an amendment allowing for greater national autonomy as regards the cultivation of GM crops. Later that year, the then President of the Commission José Manuel Barroso addressed the issue in his political guidelines of the new Commission. He did so by referring to the principle of subsidiarity and stated that the GMO framework might not have been considerate enough of "the consequences of diversity in a EU of twenty-seven Member States". Barroso's view was that it should be possible to combine a science based EU authorisation system, with freedom for Member States to decide whether they wish to cultivate GM crops on their territory.[268]

In mid 2010, the Commission put forward a GM cultivation reform package, including a proposal to amend the Deliberate Release Directive to implement the political guidelines.[269].

The overarching purpose of the Commission proposal was to, "in accordance with the principle of subsidiarity" grant the Member States more freedom to decide on GMO cultivation, "without changing the system of Union authorisations of GMOs".[270] In its explanatory memorandum several underlying motives behind the Commission's proposal appear. Regarding safeguard and emergency measures, it explicitly stated that the Member States' limited margin of appreciation on cultivation of authorised GMOs had in many cases led them to act on the basis of non-scientific grounds.[271] Thus an amendment was "necessary to facilitate decision making and take into account all relevant

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[265] Bulgaria, Cyprus, Greece, Hungary, Ireland, Latvia, Lithuania, Luxemburg, Malta, The Netherlands, Poland and Slovenia.

[266] The group included GMO-sceptical Member States like Poland and Hungary, but also the Netherlands who has been more supportive of genetic engineering, Geelhoed 2014 p. 15. However, Member States that are generally opposed to GM crop cultivation, such as France was not part. The latter has been described to have been concerned that that the reform would "divert attention from the problems of the environmental risk assessment by the EFSA, as well as from the need to reform the EU authorisation procedure", Weimer 2014, p. 35.

[267] COUNCIL, doc nr. 11226/2/09, 24 June 2009.

[268] José Manuel Barroso, *Political guidelines for the next Commission*: http://ec.europa.eu/archives/commission_2010-2014/president/pdf/press_20090903_en.pdf

[269] Commission, COM (2010) 375 final. The Commission simultaneously issued the new guidelines on coexistence measures, see chapter 3.3.

[270] Recital 6 Commission, COM (2010) 375 final.

[271] There is substance in this statement. However it also disregards divergent interpretations of science and estimations of acceptable risks.

factors".[272] In addition, recourse to Article 114.5 on the basis of considerations other than health and environmental protection could be avoided. Hence, resort to the original opt out possibilities were expected to be reduced, and only be used in line with their intended purposes. As a result, the institutional burdens on the Commission and the EFSA could decrease.[273]

Finally, this solution would provide for increased legal certainty for Member States wishing to restrict or prohibit cultivation of GM crops, and increase predictability of the decision-making process for affected stakeholders.[274]

The proposal was held by some as being a "substantial policy turn" in comparison to previous Commissions policy on national restrictions on GMOs,[275] and as such being a "pragmatic"[276] compromise attempting also to remedy the delays of the authorisation procedure, allowing for more authorisations and reinforcing trade and the internal market.[277] As Lee states, for the Commission a "divided market in GMOs might be a price to pay for cultivation in favourable Member States"[278] of more GM varieties.

While the functioning of the authorisation scheme is not really the main subject of the thesis, these are still some interesting observations, as they highlight that the Commission seems to have found a compromise necessary between getting more authorisations through and allowing for greater national autonomy with potential fragmentation of the internal market in GMOs as a consequence. Time will tell if GMOs will be approved faster given the new possibilities to opt out.

In any case, the material content of the Commission's proposed Article 26b was rather basic in comparison with the final product. It stated that:

> Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties placed on the market in accordance with relevant EU legislation on the marketing of seed and plant propagating material, in all or part of their territory, provided that:
>
> (a) those measures are based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs; and,
>
> (b) that they are in conformity with the Treaties.[279]

[272] Commission, COM (2010) 375 final, p. 3f.
[273] Ibid, p. 3f.
[274] Among the affected stakeholders GMO farmers, organic and conventional farmers, seed producers/exporters/importers and biotechnology companies are mentioned, see ibid, p. 4.
[275] Weimer 2010, p. 346.
[276] Weimer called the proposal pragmatic as it recognized that the EU authorisation regime, enforced against the opposition of a majority of Member States, cannot be sustainable in the long term. An additional pragmatic element was the hopes to avoid that in the future Member States continue to base their decision-making in the comitology on whatever concerns they have undermining the scientific authority of EFSA's risk assessments, ibid, p. 350ff.
[277] Poli 2010, p 339, 343; Weimer 2010, p. 346.
[278] Lee 2014, p. 235.
[279] Article 26b Commission, COM (2010) 375 final.

Notably, the "other grounds" that national measures could be based on were not specified. What was clearer was that restricting measures would have to be based on different grounds than those related to the risk assessment performed under the authorisation procedure.

As will be shown below this proposal differs in several aspects from the final outcome. However, it laid the foundation for further discussions between the legislative institutions. The exact content of the new opt out clause came to be intensively debated within and between the different institutions. Before the time that the final version was agreed on in a political agreement between the EP and the Council in late 2014, the legislative development saw several compromise Council proposals under different presidencies.[280] It also saw a two-year deadlock in the Council from 2012 to June 2014, where no agreement could be reached between the different government representatives.[281] The deadlock did not end until the Commission proposed for a positive authorisation decision for cultivation of the GM maize Pioneer 1507. That seem to have sparked the change in attitude amongst enough ministers in the Council that was needed to reopen the discussions.[282]

Several aspects of the content and implications regarding Article 26b were debated during the legislative procedure. The discussions concerned everything from the appropriate legal basis for the amendment to the form of it.[283] Although more important for current purposes were discussions regarding some other features and implications of the amendment. As is apparent from the Commission's proposal it only included the possibility for Member States to opt out post-authorisation. This is another aspect that was debated and it will be shown below how the final outcome provides additional possibilities for Member States. Also at the centre of the debates in the legislative process was the issue of derogation grounds for opting out. The outcome of these latter discussions will now be further examined as we turn to the content of the final version of Article 26b.

4.2 The outcome – two stages for opting out

As stated above, the new Article 26b provides for two ways of opting out for a Member State that opposes cultivation of GM crops. First, this can be done against a given GMO during the authorisation procedure or during the renewal of an authorisation by a Member State demanding the applicant to adjusting its geographical scope of its application on a given GMO. Secondly, the Member State in question can rely on the grounds in a non-exhaustive list of derogation grounds to restrict or prohibit cultivation of a given GMO or a group of GMOs after authorisation. These two stages will now be examined closer.

4.2.1 During authorisation – Article 26b.1-2

Article 26b introduces a whole new way of restricting GM cultivation by allowing for Member States to opt out during the authorisation procedure. It is also "new" in that this first stage includes the economic operator in the process.

[280] See e.g. the Danish and Greek Presidencies' compromise proposals; COUNCIL, doc nr. 7153/12, 2 March 2012 and COUNCIL, doc nr. 6528/14, 17 February 2014.
[281] A group of Member States, including France, the UK, Germany and Slovakia blocked a compromise as they had concerns regarding, in particular, the compatibility of WTO law and the EU internal market provisions. Poli 2013, p. 147.
[282] Cf. Geelhoed 2014, p. 8.
[283] The Commission's proposal suggested a regulation, but the final outcome was a directive.

The attentive reader sees that this new possibility was not provided for in the Commission's proposal from 2010. Until 2012 the focus of the legislative debate had mainly focused on the different derogation grounds and not on how and when Member States might actually invoke them. Under the Danish Council Presidency in 2012, a compromise proposal was put on the table that envisioned a two-way opt out model. In addition to the right to restrict or prohibit cultivation after authorisation, the Danish proposal suggested an independent possibility to opt out from cultivation of a specific GMO during the authorisation procedure.[284]

As for the adopted version, Article 26b.1 states that, during the authorisation procedure or during the renewal process a Member State may demand that the geographical scope of the authorisation of a given GMO is adjusted to the effect that all or part of its territory is to be excluded from cultivation from that crop. Such a demand has to be communicated to the Commission within 45 days, whereby the Commission is to present the demand to the applicant and to the other Member States.[285] No motivations from the Member State seems to be necessary here, which means that whatever concerns the Member State might have regarding GM cultivation is valid.

Upon this, the applicant has 30 days to either adjust - i.e. accept the demand - or confirm -i.e. reject the demand - the geographical scope of its initial application.[286]

If the applicant decides to accept the Member State's request, the adjustment of the geographical scope is to be implemented under the Deliberate Release Directive or the FFR depending on the scope of the application. As a result, cultivation in the whole or part of the Member State's territory is excluded from the authorisation of the specific GMO.[287]

However, the applicant has the option to decline adjusting the geographical scope of the application. In that case three possible scenarios can take place. First, the Member State that made the demand may simply accept the applicant's stance. This seems rather unlikely given the historical persistence of Member States on the issue. Another possibility is that the Commission opposes the applicant's confirmation of the original scope in accordance with its powers under the Deliberate Release and the FFR in light of the environmental risk assessment carried out by the EFSA.[288] More likely however, the opt out process moves on to stage two, where the applicant is excluded from the procedure, but the Member State has to make use of one of the new derogation grounds.[289]

A Member State that manages to get the economic operator to adjust its geographical scope may later wish to include all or parts of its territory into the scope of the authorisation from which it was first excluded. Such "reintegration" is expressly permitted and does not require the consent of the authorisation holder.[290]

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[284] COUNCIL, doc nr. 7153/12, 2 March 2012, p. 9f.
[285] This shall be done by the Commission "without delay". Furthermore the Commission shall make the demand publicly available by electronic means, Article 26b.1 Directive 2015/412.
[286] Article 26b.2(1) ibid.
[287] Article 26b.2(2) ibid.
[288] Article 19 Deliberate Release Directive, and Articles 7 and 19 FFR. See Recital 12 Directive 2015/412.
[289] Article 26b.3(1) Directive 2015/412. See 4.2.2..
[290] Article 26b.5-6 and Recital 21 Directive 2015/412.

It is stated in the preambular text of Directive 2015/412 that it is expected that most restrictions or prohibitions adopted pursuant to the new article will be implanted at this stage.[291] The Council stated that a solution of this kind is appropriate to ensure the least possible disturbance to the internal market while at the same time facilitating the authorisation process of GMOs. Furthermore it held that this stage one possibility is "likely to provide the greatest possible legal certainty" to operators as well as to Member States.[292]

In reality, successful recourse to this stage-one opt out will be up to the outcome of negotiations between Member State representatives and negotiators from the biotechnology companies. As mentioned above, this state of affairs has been criticised, for granting biotech companies the power to negotiate with elected governments. However, the solution seems straightforward from a legal perspective. Greater legal questions await where agreements cannot be reached.

4.2.2 Post-authorisation – Article 26b.3

4.2.2.1 Introduction

If no demand was made by the Member State to the applicant or if the applicant denied adjusting its geographical scope, the post-authorisation opt out stage starts.

In that case, Article 26b.3 allows for Member States to adopt measures restricting or prohibiting the cultivation in all or part of its territory of a specific GMO or of a group of GMOs under the conditions that the measures adopted are based on "compelling grounds" and otherwise are "in conformity with Union law".[293] Before we venture into what these requirements mean, some initial remarks are in place..

The provision allows for restrictive measures on "a GMO" or of a group of GMOs defined by "crop"[294] or "trait".[295] Although being wider than what stage one opt out provides for, this seems to be a rather big limitation in comparison to the Commission's proposal that allowed for measures on "all or particular GMOs".[296]

The procedural requirements regarding *when* a Member State may rely on post-authorisation measures have been quite disputed during the legislative procedure. Whereas the Danish model allowed for two ways out of cultivation that were "independent" from each other, the Greek Presidency proposed more stringent rules. The Greek proposal stated that restrictions after authorisation would only be available for those Member States that had unsuccessfully demanded that the applicant adjusted its geographical scope during the authorisation procedure.[297] This limitation does not seem to be the case for the final version,[298] and therefore any Member State seem to be able to use this possibility irrespective of previous negotiations with the economic operator.

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[291] Recital 13 ibid.
[292] COUNCIL doc nr. 10972/3/14 REV 3 ADD 1, 23 July 2014, p.3.
[293] Article 26b.3(1) Directive 2015/412.
[294] E.g. maize.
[295] E.g. herbicide-resistant crops.
[296] See Article 26b Commission, COM (2010) 375 final. In line with what is said in chapter 4.3 about proportionality the commission's suggestion seems extreme in this regard.
[297] COUNCIL, doc nr. 6528/14, 17 February 2014.., p. 4.
[298] See the wording "Where no demand was made pursuant to paragraph 1" in Article 26b.3(1) and the use of the wording "in addition also be the possibility for Member States to adopt […] in Recital 13. Both in Directive 2015/412.

When a Member State intends to adopt measures under Article 26b.3 it first needs to communicate a draft of those measures to the Commission. That draft is to include the corresponding grounds that the Member State invokes as the basis for their measures. During a timeframe of 75 days after the communication to the Commission the Member State in question is not allowed to adopt and implement the restricting measures. Furthermore, the Member State shall ensure that no plantation of the GMO or GMOs concerned takes place within its territory in this time. The Commission may make any comments it considers appropriate on the draft during this period.[299]

When the period of 75 days has expired, the measures may be adopted either in the form the Member State originally proposed or in a different form if it has taken account of the Commission's non-binding comments. The restriction or prohibition time corresponds to the authorisation period of the GMO(s) in question.[300] Thus, bans on cultivation under this new provision does not have the same provisional character as is intended for safeguard and emergency measures under the GMO legislation.[301]

But what are the grounds that that can be invoked in the new article? We will now have a closer look at the outcome in this regard from the legislative process. This will also be compared to what the Commission envisioned as justifiable grounds, as this might give further understanding of their future use and acceptance on behalf of the EU's executive body. Thereafter we turn to possible conflicts with the internal market rules when invoking measures under Article 26b.3.

4.2.2.2 The new derogation grounds

As mentioned above, measures may be adopted by Member States under Article 26b.3 given that they are based on "compelling grounds".[302] This is the first substantive limitation to the use of the new opt out clause.

It was stated earlier that the Commission's 2010 proposal did not specify what grounds Member States could rely on when restricting or prohibiting GMO cultivation under the article. Except for ruling out grounds related to the risk assessment carried out at the EU level during the authorisation procedure, the recital of the proposal vaguely explained that the "other grounds" were grounds relating to the "public interest".[303]

The vagueness in this regard came to be criticised in the beginning of the ordinary legislative procedure. For instance, the European Economic and Social Committee held that inclusion of specific derogation grounds would increase legal certainty for those concerned.[304] In response, the

[299] Article 26b.4(1) Directive 2015/412.
[300] Article 26b.4(2) ibid.
[301] As is the case for measures under Article 26b.1, Member States may revoke these bans. Revoked measures shall be notified to the Commission and the other Member States without delay, Article 26b.7 ibid.
[302] Article 26b.3(1) ibid. In addition Recital 16 states that conformity with the Treaties necessitates compatibility with 216.2 TFEU. The latter means that measures cannot breach international agreements, such as those under WTO law.
[303] Recital 8 Commission, COM (2010) 375 final. Public interest is likely to refer the interests that can be pursued under Article 36 TFEU and the mandatory requirements.
[304] EESC, doc nr. NAT/480, Para 1.2.

Commission soon provided for an open list of legitimate grounds relating to the public interest in order to satisfy the co-legislators. On the whole, these grounds are quite similar to the ones that were finally explicitly incorporated into the final text.

In line with the above, the now adopted Article 26b states that measures that Member States adopt have to be based on "compelling grounds such as" the following:

> (a) environmental policy objectives;
> (b) town and country planning;
> (c) land use;
> (d) socioeconomic impacts;
> (e) avoidance of GMO presence in other products without prejudice to Article 26a;
> (f) agricultural policy objectives;
> (g) public policy.[305]

The use of the wording "such as" emphasises that this is a non-exhaustive list of grounds that may be invoked by the Member States and the recitals also hold that "other legitimate factors" may be relied on.[306] These grounds may be invoked individually or in combination depending on the particular circumstances of the Member State, region or area in which the measures will apply. One exception is "public policy", which cannot be invoked separately.[307]

Similarly to the Commission's version the adopted article makes holds that the invoked grounds "shall, in no case, conflict with the environmental risk assessment" carried out pursuant to the Deliberate Release Directive or to the FFR.[308] This is another substantial limitation of the article.[309]

We now turn to have a look at what the legislators have envisioned as being the new derogation grounds, before we start at looking their possible limitations.

4.2.2.2.1 "Environmental policy objectives"

The new article states that Member States can rely on environmental policy objectives when adopting its cultivation bans. It also came to be included in the Commission's indicative list,[310] possibly to increase the chances for final approval. As mentioned the article also states that the grounds invoked are not to conflict with the environmental risk assessment performed under the GMO legislative framework. This is so with regards to all derogation grounds, but in reality it should mostly be relevant with regards to this ground as the EFSA only has the competence to consider environmental (and health) impacts in its assessment of risks.

The recitals of Directive 2015/412 hold that the level of protection of human and animal health and the environment chosen in the EU allows for a "uniform scientific assessment throughout the Union" and that the amendment should not alter this.[311] Further, they state that the certain competences granted to risk assessors, i.e. the EFSA and risk managers under the Deliberate

[305] Article 26b.3(1) Directive 2015/412.
[306] Recital 15 ibid.
[307] Article 26b.3(2) ibid.
[308] Article 26b.3(2) ibid.
[309] See chapter 4.3.1.
[310] Commission, SEC (2011) 184 final,, p. 3.
[311] Recital 14 Directive 2015/412.

Release Directive and the FFR are not to be "interfered with".[312] The recitals further hold that Member States may only rely on grounds with respect to environmental policy objectives relating to impacts that are "distinct from and complementary to the assessment of risks to health and the environment which are assessed in the context of the authorisation procedure".[313]

Distinct and complementary grounds in this regard are exemplified with maintenance and development of agricultural practices "which offer greater potential to reconcile production with ecosystem sustainability". Maintenance of local biodiversity is also mentioned. This is suggested to include maintenance of "certain" habitats, ecosystems, or certain types of natural and landscape features, in addition to "specific" ecosystem functions and services.[314] The Commission clarified these examples in its 2011 indicative list by stating that maintenance of certain habitats and ecosystems means "preservation of the conservation status quo". Moreover, it specified the meaning of maintenance of specific ecosystem functions and services. This could for example entail "preservation of nature-oriented regions of particular natural and recreational value to citizens".[315]

We return to questions of the scope to rely on environmental policy objectives in 4.2.2.3, where it is questioned if the inclusion of this ground is meaningful at all.

4.2.2.2.2 "Town and country planning" and "land use"

Other justification grounds that Member States may rely on according to the article are town and country planning and land use.[316] The meanings of these grounds are not clarified anywhere in the directive, although they were included by the Commission in its indicative list in 2011. Some examples were given in that list that might give some indications on their intended use, at least in the eyes of the Commission. For example, as for general environmental policy objectives, maintenance of certain types of natural and landscape features can by justified under the these grounds "depending on the circumstances".[317] What these circumstances are is not elaborated with further by the Commission and remains unclear.

In addition preservation of organic and conventional farming systems is suggested to fall in under this category.[318] It is not clear in the indicative list if the latter should be achieved only by designing a restrictive national measure so as to avoid GMO presence in the crops in these farming systems. If so, that specific ground is already covered by 26b.3(1)(e), as it concerns the impossibility to achieve coexistence of the three agricultural types in a given area.[319] However, it could also mean that preservation is envisioned for reasons other than the economic implications of farmers from adventitious admixture.

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[312] Recital 14 Directive 2015/412.
[313] Ibid.
[314] Ibid.
[315] Commission, SEC (2011) 184 final, p. 3.
[316] Article 26b.3(1)(b)-(c) Directive 2015/412.
[317] Commission, SEC (2011) 184 final, p. 3.
[318] Ibid.
[319] Ibid, especially footnotes 7 and 8; Poli 2013, p. 150 is of this opinion, and rules out the necessity of this ground since it is already covered.

4.2.2.2.3 "Socioeconomic impacts" and "avoidance of GMO presence in other products without prejudice to Article 26a"

Other explicit legitimate concerns embedded in the article are "socioeconomic impacts"[320] and "avoidance of GMO presence in other products without prejudice to Article 26a".[321] The latter is concerned with insufficiencies of coexistence measures. However, separation of these two justification grounds is not obvious when looking at the recitals.

Recital 15 holds that a Member State should be able to base its restrictive measures "on grounds concerning socioeconomic impacts which might arise from the cultivation of a GMO" on its territory. These socioeconomic grounds may be related to the "high cost, impracticability or impossibility of implementing coexistence measures". The impracticability or impossibility to implement coexistence measures might be attributed to specific "geographical conditions, such as small islands or mountain zones, or the need to avoid GMO presence in other products such as specific or particular products".[322]

In this context the recital text recognises that coexistence measures have been addressed by the Commission in its guidelines, but that there should be the additional possibility for Member States to adopt measures against cultivation of authorised GMOs through the amendment.[323] The idea seems to be that Member States can implement restrictions relating to coexistence, but that these are not to be considered as coexistence measures under Article 26b.3 nor the Commission's 2010 coexistence guidelines. The inclusion of avoidance of GMO presence in other products is line with the Commission's indicative list. In the list it was stated that restriction or prohibition measures may be justified under this ground when "other less restrictive measures are not sufficient to avoid the unintended presence of GMOs in other products".[324] How this relates to the concept of GM-free areas under Article 26a is not straightforward as such areas are to be established under the same circumstances.

The recital states that these socioeconomic impacts "may" be related to the troubles adopting coexistence measures. This suggests that the Council and the EP has envisioned other aspects to fall in under this potentially broad derogation ground. At the moment it is not entirely clear what these other socioeconomic impacts could be, although a reference is made in the recitals to a forthcoming report from the Commission on such impacts.[325] Notably, a separate category with "socioeconomic impacts" was not in the Commission's indicative list.

4.2.2.2.4 "Agricultural policy objectives"

Furthermore measures could be based on grounds relating to "agricultural policy objectives".[326] This was not explicitly included among the grounds in the Commission's indicative list but was added later in the legislative process. An indication of what this may include is "the need to protect the diversity of agricultural production and the need to ensure seed and plant propagating material

[320] Article 26b.3(1)(d) Directive 2015/412.
[321] Article 26b.3(1)(e) ibid.
[322] Recital 15 ibid.
[323] Ibid.
[324] Commission, SEC (2011) 184 final, p. 3, especially footnote 6.
[325] Recital 15 Directive 2015/412.
[326] Article 26b.3(1)(f) ibid.

purity".[327] This exemplification also suggest a relationship to the concept of coexistence, although other agricultural policy objectives might be possible to pursue.

4.2.2.2.5 "Public policy"

The last of the derogation grounds that are included in Article 26b itself is "public policy".[328] This ground has to be invoked in combination with another compelling ground.[329] Public policy is thus listed as a secondary ground. This differs from the CJEU's general stance towards public policy as an explicit justification under Article 36 TFEU that can be used on its own terms.[330]

What public policy entails in this context is not made clear by Directive 2015/412. In general it has been interpreted by the CJEU as to do with protecting the machinery of government, rather than underlying public values that the government seeks to serve. As such it can justify measures against dangers of civil disturbances.[331] In relation to this, the Commission's legal considerations found that public order could be relied on for example "to avoid social unrest due to the destructions of GMOs affecting the public order of the country".[332]

4.2.2.2.6 "Other legitimate factors"

Last but not least, the non-exhaustive character of Article 26b.3 allows for Member States to base their measures on other compelling concerns. An example of such other legitimate factors includes those relating to safeguarding "cultural traditions".[333] The Commission has held that this could include preservation of societal traditions in terms of traditional farming methods and "preservation of cultural heritage" that is linked to "territorial production processes with particular characteristics".[334]

Apart from factors relating to cultural traditions "social policy objectives" have also been proposed by the Commission. An example of a national measure pursuing such objectives could be one that seeks to keep a certain type of rural development in a given area to maintain occupational levels.[335]

Last but not least, "public morals" was previously suggested by the Commission, but not included in the Directive 2015/412. The indicative list held that this includes "religious, philosophical and ethical concerns".[336]

4.2.2.2.7 Preliminary conclusions on the new derogation grounds

This has been an overview of what the new derogation grounds entail, seen through what was included in Article 26b.3 and what the Commission has envisioned.

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[327] Recital 15 Directive 2015/412.
[328] Article 26b.3(1)(g) ibid.
[329] Article 26b.3(2) ibid.
[330] Geelhoed 2014, p. 20.
[331] See ibid, p. 19 with reference to Case 231/83 *Cullet v Centre Leclerc*. In this case the French Government failed to show that it was unable to meet the threat with the means at its disposal.
[332] Commission, SEC (2010) 1454 final, p. 9.
[333] Recital 15 Directive 2015/412.
[334] Commission, SEC (2011) 184 final, p. 3.
[335] Ibid.
[336] Ibid, p. 2.

Several of the grounds, are either directly or indirectly concerned with the socioeconomic impacts of adventitious admixture of GM crops with non-GM ones. This includes Article 26b.3(b-f). As such they are concerned with problems adopting coexistence measures and preserving certain conventional and organic forms of agriculture. It should be reiterated that the impossibility to adopt coexistence measures to ensure farmers' freedom of choice has been invoked by for example Austria to justify national restrictions.[337] This inclusion seems to be a response to such concerns.

Also other grounds such as ethical concerns and preservation of cultural traditions are included explicitly or have been envisioned by the Commission. Such concerns have also been invoked earlier.[338]

Concerns regarding the environment is another common theme for Member States. In this regard it is unclear what the scope will be for Member States to rely on environmental policy objectives that do not conflict with the EU level environmental risk assessment. We turn to this issue next before we have a closer look at the legal significance of this non-exhaustive list of possible derogation grounds in light of the requirement that the national measures are to be "in conformity with Union law". As will be shown, the real scope to rely on these new derogation grounds to restrict GM cultivation might not be as big in reality.

4.3 The limits of Article 26b.3

4.3.1 The limits of "environmental policy objectives"

It was stated above that the "common consensus" is that the legislation on GMOs has provided exhaustive harmonisation when it comes to environmental protection and human health.[339]

It appears clear from the inclusion of the restriction in Article 26b.3(2) and the preamble of the amending directive that with regards to environmental protection this will to a large extent still be the case. The question then becomes as to what extent the inclusion of "environmental policy objectives" is really meaningful, in the sense of extending Member States' scope to derogate on grounds of environmental concerns?

Where the exact line is drawn between such environmental concerns and those covered in the centralised risk assessment is hard to say. The interpretation of what amounts to "distinct" and "complementary" in this regard will be important.

It is possible that the inclusion of "environmental policy objectives" might actually be rendered insignificant in light of that such objectives have to be distinct from those assessed under the EU's risk assessment. For instance, Annex II of the Deliberate Release Directive requires that a comprehensive assessment is to be conducted, which includes the examples that have been provided in the recitals that are suggested to be "distinct", such as "maintenance of habitats, ecosystems and landscapes".[340] Moreover, as regards local and regional impacts, the EFSA

[337] See Commission Decision 2003/653/EC. It was rejected as a basis for derogation under Article 114(5) TFEU as a socioeconomic, rather than an environmental concern. See chapter 3.
[338] See chapter 4.3.3.2.
[339] Lee 2014 ,p. 237. Hence the need to turn to the safeguard and emergency clauses or Article 114.5 TFEU.
[340] See Annex II para D and Annex III A, para III.B Deliberate Release Directive, on which Geelhoed 2014 p. 22.

Guidelines already explicitly hold that such environmental characteristics are to be taken into account in the centralised risk assessment.[341]

One could ask what amounts to already have been "assessed" in the context of the authorisation procedure? Is it only those aspects actually covered by the EFSA or is it also aspects that should have been covered, but were not? It is not sure if the EFSA's failure to take "regional-specific" environmental characteristics into account, despite its formal commitment to do so, is a sufficient ground for national derogations here.[342]

Even if it is accepted that regional environmental conditions can be invoked under Article 26b.3(a), the CJEU would have to decide whether this should offer more extensive opt out possibilities than those offered under Article 114.5. Here the high judicial thresholds set in the case law regarding for example the specificity requirement should be recalled.[343] In addition, the requirements elaborated with in 4.3 will apply, which means that proportionality problems could arise with respect to geographically wide bans in Member States. This means that it is likely that only local bans can be pursued.[344]

Thus it could be that Article 26b will not give Member States extended possibilities to invoke environmental grounds to restrict GM cultivation.[345] Instead, Member States might still have to rely on the original science-based opt out possibilities, which were established to be very hard to use as a means to derogate. At least when it comes to fulfilling the substantive requirements.

In any case, for those environmental policy objectives that fall outside of the harmonised scope, additional requirements will apply in order the be in conformity with Union Law. This in an issue we turn to next.

4.3.2 The main limit – "Conformity with Union law"

Apart from stating that national measures restricting GM cultivation are to be based on one or more "compelling grounds", Article 26b also holds that the measures are to be "in conformity with Union law, reasoned, proportional and non-discriminatory".[346] Since secondary legislation cannot amend the Treaties, these restrictions would apply whether or not explicitly stated, as these conditions apply automatically in also in areas that are not harmonised,[347] such as the now de-harmonised ones and those within the realms of coexistence.

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[341] See EFSA (1879) 2010, p. 24, on which Geelhoed 2014, p. 22.
[342] Geelhoed holds that this does not seem to be the case, ibid. Lee holds that it is arguable "that because art 26b [of the Commission's proposal] refers to the "assessment" of environment and health, anything not covered by the EFSA risk assessment could be revisited", Lee 2013, p. 373f.
[343] Geelhoed 2014 p. 22.
[344] Larger areas of a Member States are unlikely to be entirely characterised by unique elements that demand preferential treatment. Hence necessity and if required, proportionality in stricto sensu, will be hard to establish. See Geelhoed 2014, p. 23 and similarly Poli 2013, p. 150.
[345] In fact Member States must proof that other concerns relied on are not invoked to conceal (harmonised) environmental aims. See below 4.3.2.2, especially *Commission v Poland* par 52-55.
[346] Article 26b.3(1) Directive 2015/412. In addition Recital 16 states that conformity with the Treaties necessitates compatibility with 216.2 TFEU. The latter means that measures cannot breach international agreements, such as those under WTO law. Compatibility with WTO law is outside the scope of this thesis.
[347] Lee 2014, p. 237.

As such the explicit inclusion of these restrictions in Article 26b.3 could be considered to merely serve as a reminder that even though Member States are granted more flexibility on their competence to restrict GMO cultivation, they are still bound by their legal obligations under general EU law. It is to be recalled that the Commission is only to be notified before the restrictions can take effect. This means that they can go on prohibiting cultivation of GM crops, but they might have to answer later before national and European courts when doing so.

Whereas the likelihood of this happening is treated further below, the following discussions relate to possible legal implications *if* a Member State's restrictions were to be challenged. Indeed the Commission pointed out in its indicative list that "the sole invocation of one or several of [the derogations grounds] in abstract terms will not be sufficient to meet the scrutiny of the Court of Justice of the European Union".[348] As such, the national measure should be "carefully designed to withstand the Court scrutiny and not be contradictory", whereby "substantive, persuasive and unequivocal evidence" is required.[349] The Commission also underlined that only the CJEU is entitled to provide for the final interpretation of the article.[350]

The implications of these restrictions on restrictive measures adopted under Article 26b.3 will be examined next. This is done in the light of the case law and doctrine on the internal market rules that are of relevance to the examined grounds in order to see what their actual legal scope might be. We start by looking at the relationship between the derogation grounds and the internal market provisions in the TFEU together with an introduction of the latter.

4.3.2.1 Introduction – Article 34 and Article 36 TFEU

It may be asked what the legal significance of the derogation grounds listed in Article 26b is? As evidenced by the reference to Article 2.2 TFEU,[351] Directive 2015/412 explicitly de-harmonises issues that fall outside the EFSA's risk assessment, which now allows for Member States to rely on derogation grounds such as the ones examined above.[352] As such, there is no obvious legal effect to this non-exhaustive list of grounds itself, as national measures in any event have to comply with the Treaties.[353] The meaning that national measures must be based on "compelling grounds", is thus to be understood in relation to the EU rules on the internal market. In this regard the free movement provisions are the most relevant, namely Article 34 and 36 TFEU.[354]

In the internal market "goods", like those derived from biotechnology, are entitled free movement, one of the fundamental freedoms in Union law.[355] Article 34 TFEU forbids quantitative restrictions on imports and measures having equivalent effect. The case law on this provision has clarified that all measures enacted by Member States which are "capable of hindering, directly or indirectly, actually or potentially" the trade in the EU are to be considered as measures having an equivalent

[348] Commission, SEC (2011) 184 final, p. 3.
[349] Commission, SEC (2010) 1454 final, p. 10.
[350] Commission, SEC (2011) 184 final, p. 3.
[351] Recital 6 Directive 2015/412. Article 2.2 TFEU holds that Member States "shall again exercise their competence to the extent that the Union had decided to cease exercising its competence".
[352] It is possible that issues other than environment and health were never harmonised at all, so that Article 36 and mandatory requirements applied in any event, Lee 2014, p. 237.
[353] Lee 2014, p. 238. The article does not give Member States an enforceable right to ban GMOs. Instead it reallocates competences in this regard, see Geelhoed 2014 p. 16f.
[354] See Weimer 2010, p. 347.
[355] See chapter 2.2.

effect to quantitative restrictions.[356] It is not at all unlikely that national restrictions or complete bans on cultivation would have considerable restricting effects on consumer behaviour regarding the use of GM seeds. On the contrary, demand of such seeds would likely completely disappear in the whole or part of the affected territory in that Member State among farmers who are potentially interested in GM cultivation. Hence, a cultivation ban may fall within Article 34 as a "measure having equivalent effect", which has also been noted by the Commission.[357]

In order to justify measures having equivalent effect, Member States can only rely on the derogation grounds provided for in Article 36 TFEU,[358] or the mandatory requirements as established by the EU Courts' case law.[359] In that sense the grounds explicit in Article 26b.3 mirrors these available justifications to restrict trade.[360]

The case law from the EU Courts shows that a wide range of social and ethical objectives has historically been relied on successfully by Member States outside the context of GMOs.[361] However, within the context of GMOs the outcome might be different. In addition, research points to increasing reluctance from the courts to accept justifications for internal market derogations.[362]

A first potential hurdle in this regard is establishing genuineness. According to settled case law from the CJEU, Member States bare the burden of showing that the conditions permitting derogation from Article 34 TFEU are satisfied.[363] When a Member State relies in its defence on a legitimate aim, the Court is required to examine if the restrictive national legislation concerned does in fact pursue the purposes that the defendant Member State attributes to it.[364] Put differently, the Court examines if the Member State genuinely seeks to pursue the interest it claims it does. In establishing genuineness of the Member State's motivation a consistent approach to the specific issue in question is important.[365]

Establishing the pursuit of a legitimate objective might not be the only problem for Member States when justifying their future GM cultivation restrictions. As is explicit from Article 26b and Article

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356 Case C-8/74 *Procureur du Roi v Benoit and Gustave Dassonville*, para 5.
357 Commission, SEC (2011) 184 final, p. 2. For an illustration of how easily measures fall in under Article 34 TFEU, see e.g. Case C-142/05, *Åklagaren v Percy Mickelsson and Joakim Roos*.
358 Article 36 TFEU states that "The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property".
359 Case 120/78, *Rewe-Zentral AG v Bundesmonopolverwaltung fur Branntwein* (Cassis de Dijon) and Case 302/86 Commission v Denmark (Danish Bottles).The Commission's indicative list was an attempt to identify possible grounds under Article 36 TFEU and the mandatory requirements doctrine.
360 Whereas in theory the justifications under the mandatory requirements are only available for Member States with respect to non-discriminatory measures, the EU Courts do not always distinguish clearly between Article 36 justification grounds and mandatory requirements, Lee 2014 p. 238. Determining if bans on GMOs are discriminatory could raise questions of whether restricted, "foreign" GM seeds are "like" unrestricted, national conventional seeds. Lee holds that Given that EU law regulates GMOs as if they are meaningfully different from conventional seeds, it is likely that national measures applying equally to domestic and imported GM seeds are indistinctly applicable, Lee 2013, p. 376. However, the CJEU applies the requirement for non-discrimination inconsistently and often avoid it, Jacobs, 2006, p. 185.
361 Lee 2014, p. 239.
362 Barnard 2009, p. 280.
363 Case C-110/05, *Commission v Italian Republic*, para 62.
364 Case 124/81, *Commission v United Kingdom of Great Britain and Northern Ireland*, para 35; Case C-320/03, *Commission v Republic of Austria,* para 71; Case C-141/07, *Commission v Federal Republic of Germany*, para 47.
365 Lee 2014, p. 241.

36 TFEU[366] national measures may not constitute arbitrary discrimination or disguised restrictions on trade between Member States. However, the Court has not systematically addressed the question of what amounts to a disguised restriction or an arbitrary discrimination. It is even debatable, in light of the requirement of proportionality[367] whether these requirements add anything at all to the Courts' scrutiny.[368] As such establishing proportionality might be the second significant hurdle for restricting GM cultivation under the new article.

The principle of proportionality has been imposed as a requirement on trade restrictive measures by the EU Courts from an early stage.[369] The principle is often said to hold that a measure must be suitable or effective and *necessary* to achieve the legitimate aim pursued by it.[370] The former means that the Member State will be required to establish a link between the restrictive measure and the objective pursued. The latter holds that the Member State needs to establish that it is the least trade restrictive measure available to achieve this aim.[371] In addition, some argue that a third criterion applies to the proportionality test, namely proportionality in stricto sensu.[372] This means that a measure taken to protect one of the legitimate interests may be deemed unlawful if its contribution to the protective aim is too little in the light of its restrictive effect on trade. This view of proportionality implies that the interests named in Article 36 should be balanced against the free movement of goods,[373] and individual rights, such as those of producers, consumers and farmers supporting GMO cultivation.[374]

The precise content and stringency of proportionality in internal market law is not straightforward, in the sense that the EU Courts' approach to it can vary,[375] although in general the they have applied the so called necessity test restrictively.[376] Furthermore, Member States have a margin of appreciation as for the level of protection they wish to achieve in de-harmonised areas for the aim they are pursuing. This is so even when other Member States have less strict measures in place.[377] The higher the level, the more intervening the measure may be and still be proportionate.[378]

The question of course rises to what extent restrictive measures on GM cultivation under Article 26b.3 might run counter to these principles of the internal market? We will now have a look at what the case law shows on Member States' reliance on objectives such as the ones proposed by the Commission and finally included in the new article. In doing so we will have a closer look at public morality and the socioeconomic grounds. Even though these do not represent the full range of the

366 This is the case also for mandatory requirements, Jans and Vedder 2012, p. 272.
367 Explicit in Article 26b.3 and applicable to Article 36 TFEU and mandatory requirement justifications through case law.
368 See Jans and Vedder 2012, p. 273f who state that restrictions "might constitute a disguised restriction on trade, if their restrictive effect is not limited to what is necessary to protect the interest referred to by the rules" and that the "dividing line between this requirement and the proportionality principle is no a sharp one".
369 See e.g., Case C-4/75, *Rewe Zentralfinanz eGmbH v Landwirtschaftskammer*.
370 Jans and Vedder 2012, p. 282ff
371 See e.g. Case C-331/88, *The Queen v Fedesa and others*, para 13.
372 Jans and Vedder 2012, p. 285-287. These authors find some evidence from the case law for such an approach. See also Dobbs 2010, p. 1363f.
373 Jans and Vedder 2012, p. 285-287.
374 Weimer 2010, p. 349.
375 Lee 2014, p. 242f and Lee 2013, p. 377. Note that in preliminary references, national courts are ultimately to decide on the proportionality of the measures.
376 Barnard 2009, p. 282.
377 Case C-110/05, *Commission v Italian Republic*, para. 65.
378 Dobbs 2010, p. 1363f

possible derogation grounds, they illustrate some general and potential difficulties when it comes to justifying restrictions on trade in the EU.

4.3.2.2 The example of public morality

As stated above, public morality is not explicitly included in Article 26b.3. However, the Commission's indicative list included it and held that this includes "religious, philosophical and ethical concerns".[379] For some countries, like Poland, the ethical and religious concerns raised by GMOs are particularly manifested. There is plenty of case law with regards to public morality and public policy under Article 36 TFEU outside the context of GMOs. The EU Courts have been ready to accept protection of public morals in some cases, although qualitatively very different from GMO cultivation.[380] These cases have however been held to be "exceptional cases" by commentators.[381] As will be shown below, case law in the context of GMOs show that relying on ethical grounds could be difficult for Member States when seeking to opt out from GM cultivation.

In *Commission v Poland*,[382] Poland unsuccessfully tried to rely on ethical and religious grounds to justify a general national ban on placing GMOs on the market in their territory.

After receiving a letter of formal notice from the Commission of an infringement of the GMO legislation, Poland referred to the fact that Polish general public had shown itself to be strongly opposed to GMOs. Poland also refereed to the need to respect its ethical principles, claiming that not respecting the Polish concerns would be unethical.[383] Additionally, they submitted that the fact that the assemblies of the Polish administrative regions had recently adopted resolutions declaring that the Polish territory should be kept free of GM crops and GMOs, showed that the national provisions in dispute reflected public morality.[384]

The Commission brought the case to the Court and submitted that the Polish measure was incompatible with the system of free circulation established by the Deliberate Release Directive as a whole, particularly Article 22 and 23 thereof.[385] Poland then further clarified their ethical claims and held that the adoption of the ban "was inspired by the Christian and Humanist ethical principles adhered to by the majority of the Polish people". In Poland's view their "Christian conception of life" ran contrary to the manipulation and transformation of living organisms created by God, and as such this conception "urges respect for creation […] and harmony between Man and Nature". [386]

Responding on this, the Commission held that Poland had not produced any evidence capable of establishing that it was truly inspired by these ethical and religious considerations when adopting its

[379] Commission, SEC (2011) 184 final, p 2.
[380] See e.g. Case C-34/79, *Regina v Maurice DonaldHenn and John Frederick Ernest Darby* regarding the control of pornography as a legitimate question of public morality. See also Case C-447 and 448/08, *Criminal proceedings against Otto Sjöberg and Anders Gerdin* regarding restrictions on gambling which was found to pursue the legitimate objective of protection consumers, specifically by reducing gambling addiction. Finally, Case C-36/02, *Omega Spielhallen – und Automatenaufstellungs-GmbH v Oberbugermeisterin der Bundesstadt Bonn,* regarding computer games in which killing was simulated.
[381] Geelhoed 2014 p. 19, with reference to the wording in supposedly leaked Opinion of the European Parliament Legal Service.
[382] Case C-165/08, *Commission v Republic of Poland*.
[383] Ibid, para 19.
[384] Ibid, para 21.
[385] Ibid, para 34.
[386] Ibid, para 31.

restricting measure.[387] Poland then emphasized that it was well known that, at the time of the vote on their contested measure, most Polish MEPs belonged to parties for which the Roman Catholic faith is a fundamental value. Hence, it was not at all surprising that they were truly inspired by Christian and Humanist values when adopting the ban.[388]

The Court held that to the extent that the national provisions pursued ethical objectives, which were unrelated to the objectives which characterising the Deliberate Release Directive, i.e. the protection of the environment and of human health, they were outside the scope of the harmonisation and could in "some circumstances" be justified under Article 36 TFEU.[389]

However, instead of venturing into when these circumstances are at hand, the Court held that Poland, on which the burden of proof lied, had failed to establish that the "true purpose" of their ban was in fact to pursue the ethical and religious objectives that they held were relied upon.[390] As such the "relevant evidentiary burden" was not discharged by presumptions of adherence to certain social values and statements as general as those put forward by Poland.[391]

Therefore, the conclusion was drawn that public morality was not really being invoked as "a separate justification", but as an aspect of the justification relating to the harmonised elements concerned with protection of human health and the environment.[392]

In other words, Poland was unsuccessful in establishing that the true purpose of their measures were indeed ethical and religious objectives. It can be concluded from the case that the EU Courts will not simply accept any claims a Member State makes on that it is relying on public morality. More than sheer declarations that most of its population or legislators adhere to certain ethical and religious values are required to prove that public moral is genuinely pursued. Particularly, statements of a general nature will be hold to be insufficient.

But it is not clear exactly what will be required in terms of proof in order the prove that an adopted restriction is indeed based on public morality or public interest in general. Would for example a referendum or some sort of large survey suffice showing factual existence of value-based concerns? Some sort of reliance on public participation expressing ethical concerns might be able to establish a genuine connection between the cultivation restriction and public morality. However, exactly what is required in terms of evidence is unclear.

The question also arises to what extent a consistent approach to the claimed ethical concerns will matter in order establish genuineness of the Member State's motivation. A problem of contradiction might arise if for instance GM products are otherwise allowed and consumed as food and feed in the Member State and their only objection is on GM cultivation.[393] That could make it difficult to convince the EU Courts that ethical concerns genuinely lay at the root of a cultivation ban of a GM seed.

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[387] Ibid, para 35.
[388] Ibid, para 41
[389] Ibid, para 50.
[390] Ibid, para 52.
[391] Ibid, para 54-59.
[392] Ibid, para 55.
[393] This issue was raised by the Council Legal Service, see Commission, SEC (2010) 1454 final, p. 9.

In this regard Poland is actually likely to be the most consistent Member State, as it has also attempted to ban the use of GMOs for animal feed.[394] In contrast, France has argued on both sides of the GMO debate over the last decade.[395] Although public morality is not a static notion, changes across fields and over time could make it difficult to demonstrate a sincere public morality objective for many Member States.

Although the Court in *Commission v Poland* did not touch upon the issue of consistency, inconsistency has been the reason for Member States failing the Court's scrutiny in relation to public morality in other cases.[396]

As for proportionality, suitability is probably not that hard to establish. However, necessity could be harder to demonstrate. For example, ethical concerns could be sheltered by labelling requirements of products derived from GM cultivation, which leaves moral choices to consumers. This is arguably less restrictive than a complete ban on GM cultivation itself.[397] As the more extensive the restrictions are the harder it will be to claim that it is proportionate to the pursuit of ethical concerns, which means that it will be unlikely that nation-wide bans are accepted. With regards to the extent of the ban, a regional ban could also be easier to accept for the CJEU than a national one, as it could be somewhat more feasible to establish genuineness and consistency.

Next up are some considerations on potential hurdles when invoking the various socioeconomic grounds included in Article 26b.3.

4.3.2.3 The example of socioeconomic concerns

As for the various socioeconomic concerns that are envisioned in Directive 2015/412 it has for long been established in the case law of the EU Courts that a Member State cannot rely on purely economic arguments to justify interference with free movement of goods.[398] In this regard restrictions on the cultivation of GMOs enacted for economic purposes for example to avoid economic damage to conventional and organic farmers might be problematic, as they could be deemed to hinder free movement of goods for economic reasons.[399]

As shown previously, the Commission itself has treated coexistence as being only about protecting farmers from economic losses.[400] Moreover, the Commission has held that the relative size of the measures prevents them from hindering trade.[401] By doing so it has in practice created something similar to a "de minimis-type exception"[402] to Article 34 TFEU. However, in other cases the CJEU

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394 The ban was the subject of Case C-313/11, *Commission v Republic of Poland.*
395 This is of course a natural consequence of change of governments, which in turn is inherent to democracy. France has had a very wide range of field trials, but has also banned cultivation of MON810, see chapter 3.3.
396 For instance in relation to gambling in Joined Cases C-316/07, C-358/07 to C-360/07, C-409/07 and C-410/07, *Markus Stoβ and others v Land Baden-Wurttemberg*, para 101.
397 See Geelhoed 2014, p. 20, drawing an analogy with case law regarding proportionality and the objective of consumer protection. Case C-178/84, *Commission v Federal Republic of Germany* and Case 120/78, *Rewe-Zentral AG v Bundesmonopolverwaltung fur Branntwein*.
398 See e.g. Case C-120/95, *Nicolas Decker v Caisse de Maladie des employés privés*, para 39 and Case C-203/96, *Chemische Afvalstoffen Dusseldorp BV and Others v Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer*, para 44.
399 Cf., Poli 2013 p. 152.
400 See chapter 3.3.
401 Commission, SEC (2010) 1454 final, p. 11.
402 Geelhoed 2014 p. 18.

has rejected such exceptions to the free movement of goods, even when the measures would only concern as little as 0,3 % of a Member State's territory.[403] This could mean that the Courts might not share the same view as the Commission, even when it comes territorially relative small restrictions. Hence, the restriction will indeed have to be justified.

In such cases, it should be clarified that problems would only arise to the extent that a Member State fails to establish that it pursues something else than a purely economic purpose with its cultivation restriction. Alternatively, the CJEU would have to create an exception to the rule of non-reliance on purely economic objectives.

With regard to more far-reaching bans than which in any case could not be considered to fall under de minimis exception, Member States will thus have to argue that their pursuit of "purely" economic objectives contributes to the achievement of other underlying, yet compelling non-economical aims. As for measures explicitly concerning problems with coexistence measures Member States could try to link the contamination risk from GM cultivation to the social value of organic or small-scale farming practices. As for protection of organic farming such objectives could be that such farming also delivers important public goods such as rural development and animal welfare.

In doing this the Member State could try to rely on a case regarding Austrian land ownership restrictions where aims like "preserving agricultural communities, [...] the sympathetic management of the country side as well as encouraging the reasonable use of land" were acknowledged as legitimate aims to impede on the free movement of capital.[404] These aims could perhaps be categorised under the grounds of "socioeconomic impacts", "agricultural policy objectives", "land use" and "town and country planning" of Article 26b.3 of Directive 2015/412.

When it comes to establishing the true purpose of the measure questions arises also here on how to establish this. Namely, what evidence is required and how consistent must the approach be to demonstrate that the measure really seeks to protect for example small-scale farming and the animal welfare that comes with it? Evidence in this regard could perhaps be long-term consistent support of small-scale farming and animal welfare, together with evidence on the economic impacts of GMOs showing the vulnerability of this particular approach to farming that it argues is valued nationally.[405] With *Commission v Poland* in mind, sweeping arguments and presumptions are not sufficient. Needless to say, not all Member States will be able to show consistency for example in support of particular farming structures.[406]

As regards proportionality it was mentioned above that necessity has been interpreted rather restrictively in general CJEU case law. In a preliminary reference regarding coexistence measures AG Bot held that under the special circumstances that technical measures do not suffice to ensure coexistence, it was not "inconceivable" that Article 26a of the Deliberate Release Directive could be interpreted as allowing Member States to prohibit GM cultivation in specific areas of its territory.[407] However, Bot pointed out that the principle of proportionality required that such a possibility

[403] Case C-67/97, *Criminal Proceeding against Ditlev Bluhme.*. See also Joined Cases C- 177/82 and C-178/82, *Criminal proceedings against Jan van de Haar and Kaveka de Meern BV*, para 14.
[404] Case C-452/01, *Margarethe Ospelt and Schlössle Weissenberg Familienstiftung*, para 39.
[405] Cf., Lee 2014, p. 241f.
[406] Austria could provide one example of a Member State that could be able to do so.
[407] Opinion of AG Bot – Case C-36/11, para 61.

would be "subject to the provision of strict proof" that less stringent measures would not suffice.[408] It is not unbelievable that such an approach would be adopted by the CJEU in the context of Article 26b.3. If that was the case, technical measures might still have to do rather than actual GM-free areas and smaller GM-free areas instead of larger ones where these suffice.

It has been argued that the necessity test might give different results depending on the dominant forms of agricultural structures in the Member States. Necessity of restrictions might be easier to establish to prevent contamination in Member States like Poland and Austria where agriculture is dominated by small-scale or organic farming, than it is for Member States like Germany and Hungary that have transitioned to large-scale conventional farming Germany and Hungary.[409] This could be so since it is easier to connect restrictions to the former structures of "quality" produce and farming to economical losses for such farmers and additional legitimate objectives than for conventional farmers, as the latter do not run the same risks from GM agriculture.

In any case it would be hard to establish the necessity of national-wide bans. Local or regional ones are more likely to survive a scrutiny from the Courts.

As regards specifically the ground relating to the inability to enact coexistence measures it should be noted that an absolute reliance on this ground would lead to the imperialism of conventional /organic agriculture over GM agriculture. As this situation would be contrary to the idea of coexistence between the three forms of agriculture, it is likely that opting out on the basis of that or similar considerations could come to be interpreted strictly.

As such there is no guarantee of succeeding in convincing the CJEU of the legality of restrictions on socioeconomic grounds. Earlier case law on social values has indeed condemned national measures because of their impact on treaty economic freedoms.[410]

We now move on to some concluding remarks as to the scope of Article 26b and its effect on the overall opt out possibilities.

4.4 Concluding remarks on Aricle 26b

This chapter has sought to scrutinize the scope to restrict GM cultivation under the new Article 26b and see how it changes the overall possibilities for Member States to do so. Following the exposé above it is not easy to give a straightforward answer to these questions. As is common among (soon-to-be) lawyers, the answer is, "it depends". In fact, it depends on a number of factors. Will Member States succeed in negotiations with biotech companies to adjust the geographical scope during authorisation? If not, will measures adopted under Article 26b.3 be challenged? If they are challenged, how will they be motivated and how will the scope be interpreted by the CJEU in the context of the rules on free movement? Time will tell how exactly how these issues will settle, but some considerations and conclusions are provided already now.

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[408] Ibid.. Note that the CJEU did not rule on the proportionality of the Italian measure in the case as it was a preliminary reference, and left to the national court to decide on.
[409] See Geelhoed 2014, p. 19 and Dobbs 2010 p. 1363ff.
[410] Drawing on Lee 2014, p. 243 with reference to cases C-438/05, *International Transport Workers' Federation and Finnish Seamen's Union v Viking Line* and Case C-341/05, *Laval un Parneri Ltd v Svenska Byggnadsarbetareförbundet*.

The amendment sets out a legal context for GM cultivation that clearly departs from some of the fundamental principles of the GMO framework. First, Member States may introduce restrictions before authorisations to cultivate GM crops is granted. Since this does not require explicit motivations nor approval at EU level this offers great potential to opt out of cultivation as nation-wide bans could be introduced for the GMO in question following a mere notification to the Commission. This is very different from the original authorisation procedure as it does not require reaching a qualified majority with other Member States.[411] Instead "simply" an agreement with the applicant is required. The legislators seem confident or at least hopeful in that this is how most restrictions will materialise in the future.[412] I must say that it is quite innovative by EU parliamentarians and the ministers in the Council to include this possibility since it does not come with any future legal concerns and provides for legal certainty. As such, it could be understood as a novel and consensus-oriented way to avoid impeding the freedom of free movement of goods provision. Yet its success depends on the extent that biotech companies are willing to agree to the requests made by Member States. This represents a possible hurdle in itself.[413] In any case, this shows again that procedural rules are important regarding national autonomy on GMOs.

The second fundamental change is the partial de-harmonisation or re-nationalisation that comes with the amendment. Where the applicant rejects an adjustment of the geographical scope the Member States can now rely on a number of new derogation grounds in order to restrict cultivation post-authorisation. This shift allows for restrictive measures on cultivation to be handled as a matter of national competence, as if they were adopted before harmonisation. In essence this has the "de facto effect of narrowing down the scope ratione materiae" of the EU GMO regime.[414] This is in sharp contrast to the original state of affairs where the reasons that could be invoked to justify restrictive measures were strongly constrained, [415] and predominantly subject to a science-based risk approach.

However, as shown above, Article 26b.3 comes with some possible limitations. One concerns the extent that environmental policy objectives can be invoked. Others concern the possible hurdles identified in light of the (general) requirement of Union law conformity.

As for the environmental aspects there are some serious doubts as to if the inclusion of "environmental policy objectives" adds anything at all in light of that the grounds invoked cannot conflict with the central risk assessment. The Commission did not originally envision environmental policy objectives as a derogation ground. It's concise version of the then proposed Article 26b rather implied a clear division of responsibility where the risk assessment stays with the EU, whilst other (legitimate) factors to rely on go to the Member States.[416]

Notably this goes against some Member States' view of the impossibility for the EFSA to analyse the whole range of impact on the different national ecosystems. In the legislative process on the new article Member States such as France - that are mainly concerned about the environmental impacts of GMOs - were anxious to get a change in this regard as they are generally dissatisfied with

411 Which they have thus far always failed to reach. See chapter 2.
412 See Recital 13 Directive 2015/412.
413 As stated in 4.1., for some this is a moral hurdle.
414 Poli 2010, p. 339. Ratione materiae means subject matter.
415 At least explicitly, as evidenced by *Commission v Poland*, where ethical concerns were not ruled out to fall outside of the harmonised parts of the GMO regime.
416 See chapter 4.1.

the EFSA's risk assessments and the authorisation procedure as a whole.[417] However, the Commission and the Council majority[418] have throughout the legislative process been of the view that such grounds may not conflict with the risk assessment conducted by the EFSA. In the eyes of the Commission the risk assessment already takes into account the adverse effects in health and the environment throughout the Union. The Commission apparently does not want the Member States' new derogation possibilities to undermine the EFSA's authority. This fact seems to haven been agreed on by the majorities of the Council and the EP, as a compromise to get the other derogation grounds.

Overall it is likely that the assessments in the authorisation procedure and the original opt-out clauses will have to suffice with regards to risks to health and the environment. Whereas the original derogation possibilities themselves remain unaffected, the new article does not seem to change the issues of diversity of scientific interpretations and disagreement over different valuation of environmental risk between Member States, the EFSA and the Commission However, in order to address conflicting views on how to deal with the scientific uncertainty surrounding long-term environmental impacts of GMOs and take more account of local-/regions specific environmental and health aspects, it seems that a modification of the harmonised risk assessment would be required. Until this is done, it could be that conflicts regarding the safety aspects of GM cultivation will remain.

If environmental policy objectives may at all fall outside the harmonised scope, measures invoked under that ground, or any other of the new ones, are subject to further concerns.

As for the limitations imposed by conformity with Union law and its general principles and free movement obligations it is clear that Member States are not afforded a carte blanche with regards to post-authorisation restrictions. On the contrary, as suggested by the case law, establishing genuineness and proportionality might be difficult for Member States. I say, "might", because we are on an unexplored and unpaved path here.

Whereas decisions to restrict cannot be adopted immediately by Member States, they are not bound by the Commission's opinion and can enact them in due time. However, in theory, national measures under Article 26b.3 could be subject to an infringement procedure brought by the Commission or proceedings brought by the GMO producer in national courts.[419] Considering the Commission's occassional lack of action on GM cultivation derogations and that it is keen on getting the authorisation procedure to function better, it is possible that the Commission will not confront Member States' measures legally. Besides it is not sure that the Commission will enforce Union law in an area where the EU institutions has just (partially) renounced to exercise their powers in. In light of this it could be politically very difficult to plead before the Union Courts that a restriction is disproportionate.

In any case, it is completely possible that the CJEU will eventually be requested to determine EU law conformity of a Member State's measures adopted under the article. The approach from the courts regarding compatibility with Union law will be crucial for determining the actual scope under Article 26b.3.

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[417] Weimer 2014, p. 35.
[418] See for example Danish Presidency's compromise proposal, COUNCIL, doc nr. 7153/12, 2 March 2012.
[419] The former under Article 258 TFEU and the latter under Article 267 TFEU. Possibly also under Article 263(4) TFEU.

In general it could be said that we know that the outcome of a possible judicial procedure before the CJEU will depend on the circumstances of the individual case, particularly how the Member State chooses to justify its measures and the restrictiveness of it and what evidence is provides..

Whichever objective is presented as the basis for the cultivation restrictions, it must be clear that it is the actual reason behind the restriction, and that it is not concealing other illegitimate objectives, such as environmental or health concerns falling under the scope of the EFSA or purely economical ones. This will prove even more difficult to establish where national approaches are inconsistent. As such, genuineness could limit what derogation grounds that can be relied on successfully by different Member States.

In addition, in light of proportionality, I find it hard to see that any absolute measures like nation-wide cultivation bans will pass the test of Union law conformity. Rather smaller regional or local bans are likely to be accepted.

To the optimistic reader the new derogation grounds could be seen as granting Member States significant flexibility, respect for national and local differences and an acknowledgement of the validity of concerns other than those related to safety. A sceptical reading, however, might render questions about the real intentions of the Commission. Whereas measures invoked under Article 26b.3 are probably capable of interpretations that are compatible with general Union law, too narrow interpretation will render the article less significant from the perspectives of Member States that are sceptical to GM cultivation. In that case one might wonder if the Commission's proposal was just a "cynical attempt to hasten authorisations, in confident expectation that any autonomy will be meaningless in practice".[420] While research points to increasing reluctance from the CJECU to accept justifications for internal market derogations, time will tell if it will show more lenience towards Member States' non-scientific objectives against the backdrop of apparent explicit EU approval in Article 26b.

Together this allows for questioning Commissioner Andriukaitis' complacent attitude to Member States' scope for action under the article, where he held that Member States would have "the final say" on GM cultivation on their territory. As biotech industry has the final say in stage one opt outs and the CJEU has the final say as for the stage two ditto this statement is utterly wrong.

Drawing on this, it is also not clear if Article 26b will come along with the Commission's hoped for benefits. Whereas the original regime was undoubtedly underperforming it is not sure that the article will aid decision-making on GMOs at the EU level. As many questions remain open as for the possible interpretation of measures under Article 26b.3 it is not sure that this solution provides for more legal certainty[421] for involved stakeholders as the restrictions adopted under it could be legally vulnerable.

[420] See Lee 2014, p. 243.
[421] The Commission declared this as one of its objectives for its proposal of Article 26b, see chapter 4.1.

5 Final considerations

The thesis has sought to examine the scope for EU Member States to restrict commercial cultivation of GM crops within their territories. More specifically, it asked what the scope is for Member States to restrict cultivation of GM crops in response to the different concerns that this sort of cultivation raises. In order to answer that question the thesis looked into the scope and use of the original opt out provisions as well as the possible scope of the new Article 26b.

As for the scope for Member States to respond restrictively to the variety of concerns accompanied by GM cultivation it could be concluded that none are easily or straightforwardly adhered to in the EU framework governing GMOs. Be they safety concerns, socioeconomic or ethical ones. This is mainly so since this framework is part of a larger legal context where national autonomy will have to be measured against other demands, such as those of the internal market. In addition, the economical prospects of genetic engineering itself is something that has for a long time been emphasised, not least by the Commission.[422] These are underlying aspects shaping the overall scope for Member State derogations.

With specific regards to environmental concerns related to cultivation of GM crops the framework has been heavily centralised and new scientific evidence is a common denominator to allow for opt outs. It was concluded above that the new Article 26b is not likely to change the overall prospect for relying on environmental concerns. Instead, Member States with such concerns are likely to have to do with the very strictly interpreted original provisions in Article 23 of the Deliberate Release Directive, Article 34 FFR and Article 114.5 TFEU. A somewhat paradoxical consequence of the hardships in convincing the EFSA, the Commission and the CJEU that the substantive conditions are fulfilled could be that Member States that are worried about safety concerns will try to conceal these in terms of the now de-harmonised other legitimate objectives, hoping that those will be easier to pursue.

It is however not sure how the (non-environmental) de-harmonisation that comes along with the amendment of Directive 2015/412 will change the actual possibilities to pursue other concerns such as socioeconomic and ethical ones. A number of hurdles have been identified stemming from fundamental rules and principles of the internal market, including establishing genuineness and proportionality. The future for national autonomy in this field very much depends on the approach taken by the central actors in the governance of GMOs. Now these will not only be the traditional ones such as the Commission and the EU courts. The number of actors has been extended to the biotech industry itself trough institutionalisation of negotiations with national governments, allowing in practice for any concerns to be adhered to. Following, however, the uncertainties surrounding future negotiations and interpretations I dare not give a definite answer as to the question of Member States overall scope to opt out of GM cultivation.

Indeed, uncertainty and paradoxes works in many ways in the context of GMOs. It is possible that allowing for more national autonomy could increase rather than decrease the EU market for

[422] See chapter 2.

GMOs, as more GM crop varieties could be pushed through in the authorisation process.[423] If, however, we see a stringent approach to the - on paper - newfound autonomy, an increase in authorisations is likely to only be a short-term effect. Instead, we might go back to the use of the original opt out possibilities where Member States find help from the comitology procedure to uphold national prohibitions and in practice can respond to concerns of any kind. Such seems to be the politics of GM cultivation.

There appears to be no easy solutions in regulating GMOs in general, or GM cultivation specifically within the EU. At the very core of this massive institutional creation lay fundamental principles of multilateralism and free movement. Expanding the range of and finding room for objectives that can justify interruptions with free trade is indeed challenging in light of this. Allowing Member States to move forward under different policies, whatever they may be, could divide the EUs internal market and moves away from a cohesive approach. As representing the first case of de-harmonisation,[424] the German Chancellor Angela Merkel held the amendment to be "a first step at dismantling the [EU's internal] market".[425] Such a view shows that questions of national autonomy and letting Member States respond to their citizens' various concerns about GMOs is perhaps best understood in the context of the meaning of European integration. It then becomes more than a question of how to regulate GMOs or GM cultivation in itself. It becomes a matter of principle.

Finding room for Member States to express the diverse concerns of their own citizens is almost bound to lead to situations where not everyone can be content. Too much insistence on EU authority could potentially undermine the perceived legitimacy of the EU institutions and the internal market if GMOs are pushed onto reluctant Member States. This makes too narrow interpretations on behalf of the Commission and the CJEU risky in the same way as a too lenient approach is for other fundamental values. Accepting simple claims of reliance on "public opinion" when introducing restrictive measures would give Member States a free hand to avoid their obligations under the Treaties when they feel like it. Such an approach would run contrary to decades of market integration and risks undermining one of the EU's primary achievements. Whilst expanding the range of legitimate objectives that can justify interruptions to free trade has been difficult to agree on, so is the alternative with perceived illegitimacy of the legal framework and the EU itself. A consequence being that the law does not function as intended.[426]

Whereas no definite answer can be given on the scope for Member States to opt out of GM cultivation I feel more confident in stating that the controversies surrounding this debated area of regulation will continue. Indeed authority on GMOs is likely to continue to be disputed and politics matter as much as law in this fascinating area of regulation.

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[423] That is regarding the number of GM varieties on the market and in cultivation. As for the effect that the new derogation possibilities will have on the total area of GM cultivation it is hard to speculate in light of the uncertainties explored above.

[424] On the explicit basis provided by Article 2.2 TFEU.

[425] EurActiv, *EU governments seen opposing GM crop proposals:* http://www.euractiv.com/cap/eu-governments-seen-opposing-gm-news-496823.

[426] As evidenced by the use of the original opt out possibilities and that the authorisation GMOs for cultivation purposes has been filled with delays.

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