Governance of GMO and non-GMO Coexistence:

Filling the Gap in the EU Regulatory Regime on Agricultural Biotechnology

Thijs F.M. Etty

Institute for Environmental Studies (IVM), Dept. of Environmental Policy Analysis;
and Faculty of Law, EU Law Unit, Dept. of International and Comparative Law;
Vrije Universiteit Amsterdam, The Netherlands
E: thijs.etty@ivm.vu.nl

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Abstract:

The dense network of EU law and policy on agricultural biotechnology and GMOs is now widely considered to be the world's most comprehensive and stringent regulatory regime. Yet, upon closer inspection a regulatory gap can be identified at the heart of the regime. Contrary to the overall trend of growing centralization and increasingly exhaustive harmonization in EU GMO regulation generally, the cultivation of GM-crops has been left largely un-regulated at EU-level. This legislative lacuna creates the anomaly of a regime that allows for authorization of GM crops for EU-wide cultivation, and sets harmonized, qualitative end-of-cycle requirements for the final cultivated products, yet which fails to provide any substantive prescriptions for how the cultivation of these GM crops alongside existing non-GM counterparts should be operationalized in order to meet these very objectives or, vitally, for who will bear responsibility in the event of adversities.

In the EU GMO-regulation discourse, these issues have come to be referred to with the policy term '*coexistence'*. The definition and interpretation of this important concept are contentious. Sparse references in EU legislation are worded vaguely and ambiguously enough to allow both agbiotech proponents and critics to rely on coexistence to buttress their arguments for either restrictive or permissive legal contexts for the cultivation of GM-crops. As a result of GM-labelling requirements and prevailing public opposition to GMOs in the EU, there is both a regulatory need and a market demand for segregation between the GM and non-GM (including organic) agriculture/food production and supply-chains. However, it is now widely accepted that total isolation of transgenic material is practically impossible, and that some level of admixture will inevitably occur. A crucial aspect of coexistence is therefore the formulation of agronomic-technical isolation measures to minimize such unwanted admixtures, and legal/liability provisions to address their (socio-)economic impacts. In view of the novel complexities raised by the concurrent cultivation of GM and non-GM agricultural-crops, against the background of the EU's guiding principles of safeguarding the freedom of choice for farmers and consumers and the ability to produce and consume both GMO and GMO-free products without compromising intra-community free trade, it is now broadly accepted that coexistence is not an issue that can simply be left to the market, but that it requires some form of organization, if not government regulation. Distinctly less consensual and straightforward, however, are the questions of *who* should regulate coexistence, and *how*.

Against this backdrop, this paper focuses on how the central regulatory gap of coexistence policy is currently being filled in the EU. A particular focus is on the steering role assumed by the Commission, in the absence of formal competence and in the face of a statutory affirmation of Member States' national autonomy in this field. Notwithstanding the ostensibly straightforward, *formal* 'subsidiarity-based' approach, in practice a notable degree of conflict and competition over regulatory authority for coexistence is ongoing. This power struggle has been transformed by the statutory subsidiarity provision from a process of political bargaining and formal negotiations toward 'hard law' regulatory interventions to a more subtle and less transparent process of influence and pressure resembling 'new', networked multi-level governance, which amounts to *de facto* 'hard' harmonization through 'soft law' instruments in the shadow of hierarchy.

This paper analyses how the Commission, in this explicitly decentralized and politically contentious policy area for which it previously resisted any type of formal EU-level harmonization, appears to have succeeded in achieving a substantial degree of *de facto* harmonization at its own terms through the proverbial 'backdoor'; outside the contours of democratically legitimized EU-integration procedures and bypassing the EU legislative institutions, advisory bodies, Member States, and civil-society/stakeholders. Following an analysis of procedural and substantive aspects of this emerging coexistence governance framework, this paper discusses how the Commission's approach of unilateral '(re-)Europeanization' through 'soft law' blurs the lines of autonomy, authority, and accountability, and raises serious questions about its transparency, proportionality, and legitimacy. Given the politically highly sensitive policy context, the potential implications surpass the coexistence debate alone and threaten to affect the legitimacy and efficacy of the overall GMO-regime, and contribute to well-entrenched critiques of democratic deficit and legitimacy crisis of the EU-integration project generally, exacerbated by recent constitutional struggles. The paper concludes by making recommendations towards policy revisions to overcome these pressing dilemmas.

1. INTRODUCTION

The spectacular speed and efficiency at which the science and commercialization of agricultural biotechnology developed in the last few decades have presented complex legal and political challenges to regulators worldwide. The European Union (EU)[1] legal order is a case in point. Despite longstanding priority status on European political agendas for genetically modified organisms (GMOs) in the food and agriculture sectors, and notwithstanding a longstanding commitment to a 'precautious' approach, nearly two decades of efforts to formulate a framework of adequately comprehensive and effective regulatory oversight have failed to produce the desired results; both in terms of the uptake of GM-crops, and in terms of appeasing the considerable opposition to GMOs that prevails throughout Europe. Complexities including persistent political divergence among Member States and EU bodies, public distrust and consumer resistance fuelled by sensationalist media, and a struggling global competitiveness position, have frustrated the EU's regulatory efforts since their inception (e.g. Meins 2003; Bernauer 2003; Toke 2004).

Under these pressures, the initial EU regulatory framework collapsed in the late-1990s, in a process which culminated in the *de facto* moratorium on new GMO-authorizations. In the wake of this disintegration, major legislative revisions were undertaken. By 2004, the European Commission declared regime overhaul completed and proceeded to unilaterally lift the moratorium. Moreover, it resumed the authorization-process for the controversial *cultivation* of GM-crops, despite unrelenting political divide between Member States. Under the comitology procedure, the Commission is empowered to break the impasse in GMO authorizations by legal default.

With this re-opening of the EU internal market to GMOs, the agbiotech regulatory regime will be put to the test once again. The question thereby emerges whether this time the revised regime will indeed, as the Commission has proclaimed, prove to be 'complete and effective', so that a repeat of the events leading to the political stalemate of the 1990s, with major global trade and diplomatic fall-out up to the present, can be avoided. Indeed, the dense network of EU law and policy on

[1] Anticipating the succession by the European Union of the European Community's legal capacity following the entry into force of the Lisbon Reform Treaty (Article1(3)), for simplicity this paper refers only to EU rather than EC.

agricultural biotechnology and GMOs is now widely considered to be the world's most comprehensive and stringent regulatory regime. Yet, upon closer inspection a regulatory gap can be identified at the heart of the regime, in respect of the cultivation of GM crops. No EU-level legislation exists for this crucial production stage, contrasting the high degree of centralization and detailed harmonization in other areas of the EU's regulation of agricultural biotechnology and its products. This creates the anomaly of a regime that allows for authorization of GM crops for EU-wide cultivation, and sets harmonized, qualitative end-of-cycle requirements for the final cultivated products, yet which fails to provide any substantive prescriptions for how the cultivation of these GM crops alongside existing non-GM counterparts should be operationalized in order to meet these very objectives or, vitally, for who will bear responsibility in the event of adversities. The now more imminent than ever commercial-scale cultivation of GM-crops on EU soil emphasizes this legislative lacuna. As a result of GM-labelling requirements and the prevailing public opposition to GMOs in the EU, there is both a regulatory need and a market demand for differentiation and segregation between the GM and various non-GM (including organic) agriculture/food production and supply-chains. The type of measures required to attain this objective are known within the EU GMO-regulation discourse as 'coexistence' measures; essentially entailing *ex ante* technical-agronomic isolation and segregation measures and *ex post* liability and redress regulations to ensure that GM-crop cultivation will be able to 'peacefully coexist' with established non-GMO practices of, mainly, conventional and organic farming.[2]

However, despite its pivotal importance and role in the overall EU agbiotech regime, the definition and interpretation of the policy concept of 'coexistence' remain complex and contentious. The sparse references to it in EU legislation are worded vaguely and ambiguously enough to allow both proponents and critics of agbiotech to rely on coexistence to buttress their arguments for either restrictive or permissive legal contexts for the cultivation of GM-crops. However, notwithstanding the high degree of polarization in the GMO discourse, both proponents and critics now widely accept that total isolation of transgenic material is practically impossible, and that some level of admixture will inevitably occur. Moreover, in view of the novel complexities raised by the concurrent cultivation of GM and non-GM agricultural-

[2] Other examples include various identity-preserved and specialty crops, either with voluntary certification or with protected status under EU law.

crops, against the background of the EU's guiding principles of safeguarding the freedom of choice for farmers and consumers and the ability to produce and consume both GMO and GMO-free products without compromising intra-community free trade, it is now broadly agreed that coexistence is 'not an issue that can simply be left to the market, but that it requires some form of organization, if not government regulation' (Lee 2008a: 196). Distinctly less consensual and straightforward, however, are the questions of *who* should regulate coexistence, and *how*.

This paper will analyze how these two questions are being answered in the EU at present, and how the central regulatory gap of coexistence policy is currently being filled. The aim of this paper is to deliver a constructive critique of the emerging policy framework, with a particular focus on the principles of legitimacy and proportionality.

These issues will be explored in this paper in the following structure: following this introduction, Section 2 will succinctly frame the regulatory context and elucidate the centrality of the regulatory gap of coexistence. Section 3 will briefly outline the type of issues and measures that coexistence policy involves, and illustrate why it forms a vital missing element in the current EU regulatory framework. Section 4 will examine how the regulatory gap of coexistence is currently being filled in the EU, characterized by an ongoing struggle between the fundamentally competing EU-policy paradigms of subsidiarity and harmonization. In the concluding section, the paper makes recommendations towards policy revisions to overcome these pressing dilemmas.

2. REGULATORY CONTEXT: THE EU AGBIOTECH REGIME

The body of EU law and policy on agbiotech has been gradually expanding since the adoption of the first legislative framework acts in 1990. Yet, this expansion has occurred in a rather piecemeal fashion, lacking a forward-looking, strategic approach towards a comprehensive, integral regime (Etty 2007b; Etty 2007c). The result has been a patchwork of laws, requiring continuous updating and revision, both to fill loopholes and to catch-up with the rapid developments in the science and commercialization of agbiotech. Following the collapse of this patchwork by the end of the 1990s, a rigorous regime-overhaul was undertaken in the early 2000's. Although the resulting dense network of EU legislative acts is now widely considered

to be the world's most comprehensive and stringent regulatory agbiotech regime, upon closer inspection a selective legislative focus can be identified that has pervaded the EU's regulatory interventions since their inception over two decades ago.

This selective focus may be elucidated by illustrating the product cycle for agricultural biotechnology commodities (seeds, crops, consumer produce) as a three-stage chain, with a concomitant three-prong system of regulatory oversight. Within the EU legal context, three major regulatory stages may be distinguished in this product-cycle: (i) *Authorization*, (ii) *Cultivation*, and (iii) *Market Distribution* (Etty 2007a).[3] Since applications of biotechnology span across all these stages, from seedling to final (consumer) product, it would appear logical that any legal regime with the objective of regulating this technology should equally span this entire product-cycle. Moreover, since authorized agbiotech products can circulate freely throughout the entire EU internal market, the scope of regulatory control should, ideally, match the scope of the respective market in all its stages (Bernauer 2003: 174). However, an analysis of past, present and pending EU laws and policies demonstrates that the current regime is principally directed at regulating the initial (*Authorization*) and final (*Distribution*) stages of this cycle (Etty 2007b). Whereas a detailed discussion of the legislative framework would exceed the scope of the present paper, a brief summary is useful to exemplify the EU's regulatory focus to date on the initial and final stages of the product cycle (there is now a large body of literature on the EU regulatory regime, including notably: Lee 2008b; Christoforou 2004; Poli 2004). The initial *Authorization* stage involves the regulatory oversight of the application and authorization process that is a precondition for any GMO or derived products to enter the EU internal market and for GM crops to be released into the environment. The regulatory involvement in this stage entails, *inter alia*, provisions on *ex ante* scientific risk assessment, public consultation and information,

[3] It should be noted that this is a simplified product cycle, which omits specific (sub)stages which can occur for certain types of GMO commodities. For example, the product cycle for processed or derived GM foodstuffs might involve, firstly, authorization of the seed for the GM crop used to produce the GM food ingredient, secondly, cultivation of this crop, thirdly, distribution (including labelling, traceability, etc.) of the GM crop harvest, fourthly, authorization of the GMO ingredient for use in food, fifthly, processing of the food product including the GMO ingredient, and finally, distribution (including labelling, traceability, etc.) of the final consumer food product. It is also important to note that this simplified product cycle excludes the inceptive research and development stages. Obviously, before an application can be filed for an authorization to place a GMO on the market, this GMO must first have been developed by molecular scientist in a lab. However, until the GMO is ready for (authorization for) market introduction, it is not yet considered as a 'product' from a regulatory perspective.

conditions for authorization, and *ex ante* and *ex post* risk management controls including monitoring and registration requirements. The main regulatory instruments for this initial stage are the Deliberate Release Directive of 2001,[4] and the GM Food and Feed Regulation of 2003.[5] The final *Market Distribution* stage involves the regulatory oversight of the distribution and circulation of the GMO commodities for final retail or further processing, depending on the type of GMO product concerned and its intended use. The legislation in this stage prescribes various further *ex ante* and *ex post* risk management measures, most notably identification, labelling, traceability, and monitoring provisions. The main instruments for this stage are the GMO Traceability and Labelling Regulation[6] and again the GM Food and Feed Regulation, adopted jointly in September 2003.

The bulk of the EU's legislative efforts in this area have throughout the past two decades been directed towards fine-tuning and increasingly harmonizing across all EU Member States the regulations in these *initial* and *final* stages of the product cycle, much to the exclusion of the *central* stage of Cultivation, which has been left largely un- or under-regulated at the EU level; thereby leaving a regulatory gap at the heart of the regime. This has created the anomaly of a regime that allows for authorization of GM crops for EU-wide cultivation, and sets harmonized, qualitative end-of-cycle requirements for the final cultivated products (including purity standards and labelling thresholds),, yet which fails to provide any substantive prescriptions for how the cultivation of these GM crops alongside existing non-GM counterparts should be operationalized in order to meet these very objectives or, vitally, for who will bear responsibility in the event of adversities. In the EU GMO regulation discourse, such dilemmas have come to be referred to with the policy term 'coexistence'.

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[4] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC [2001] *Official Journal* L106/1.

[5] Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed [2003] *Official Journal* L268/1.

[6] Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC [2003] *Official Journal* L268/24. Adopted for GMO-identification was Commission Regulation (EC) No. 65/2004 establishing a System for the Development and Assignment of Unique Identifiers for Genetically Modified Organisms [2004] *Official Journal* L10/5; and for the international context Regulation (EC) No. 1946/2003 of the European Parliament and of the Council of 15 July 2003 on Transboundary Movements of Genetically Modified Organisms [2003] *Official Journal* L287/1.

3. REGULATORY GAP: COEXISTENCE POLICY

The previous section has pointed out that the missing link in the regulatory chain is so-called coexistence policy. However, straightforward as the term 'coexistence' may appear on the face of it, its interpretation in the context of agricultural biotechnology is all but consensual, lacking a clear definition in EU legislation. Essentially, the starting point for coexistence policy in the EU is the guiding principle of safeguarding the freedom of choice for farmers and consumers and the ability to produce and consume both GM or GM-free products, without compromising intra-community free trade (Commission 2003: Recitals 2 and 3). In order to safeguard and facilitate the practical choice between GM and non-GM, the EU has introduced relatively stringent GM labelling and traceability requirements, which necessitate differentiation and segregation between the respective supply chains. This is a crucial difference between the European approach to coexistence and its manifestation in most other jurisdictions; not only is there a *market demand* for products designated as 'non-GM' or 'GM-free' due to consumer scepticism that prevails in most of Europe, the EU's labelling requirements in conjunction with the principle that the various farming methods must not be mutually exclusive have also created a *regulatory need* for differentiation and segregation between the GM and various non-GM (including organic) agriculture/food production and supply-chains, for which coexistence policy is a prerequisite. Another major difference between the EU and other major jurisdictions is that, to date, Europe has not had any meaningful experience with wide-scale commercial cultivation of GM-crops, making most of the European territory a *de facto* 'GMO-free zone'. Evidently, this stands in stark contrast with the longstanding agricultural reality in, e.g., North America, where the uptake of GM crops has long been widespread and where, as a corollary, the 'coexistence' between GMO and non-GMO farming has been a *fait accompli* for nearly two decades.[7] Herein lays one of the reasons that coexistence policy has only recently been thrust to

[7] Note that, albeit in a different context and to a much lesser extent, coexistence is also on the political agendas in other jurisdictions, including notably the US. See, e.g. the ongoing deliberations on a policy paper on coexistence measures in US agriculture, undertaken by the Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) of the US Department of Agriculture (USDA). See also Endres (2006), Pew AgBiotech Inititiave (2006), and specifically with respect to the various state and county level initiatives to enact coexistence measures or even GMO-free zones (e.g. seed purity district planning), the state legislative initiative database on website of the Pew Initiative on Food and Biotechnology: http://www.pewtrusts.org.

the fore of the political debate in the EU, having previously been largely overlooked and underestimated; due to a combination of factors, including the resumption of GMO authorizations after the longstanding moratorium, as well as the fact that several of the GM crops now pending authorization are by their nature more agronomically and commercially relevant to European farmers,[8] it is now more likely than ever that large-scale commercial cultivation of GM crops on European soils is becoming imminent.

As discussed above, the EU has put in place a relatively stringent and extensive system of regulatory controls for pre- and post-authorization risk assessment and risk management of GMOs. If all GM crops were to be (re)produced in contained environments, such as laboratories or secured greenhouses, these post-introduction risk management measures and identification, labelling, and product tracing systems might work perfectly to mitigate any (residual) risks, as there would be little or no possibility for the GMO crops to be mixed or interact with nearby (non-GMO) crops or other elements of their surrounding environment. However, the characteristic for most farming is that it occurs in an open-environment setting with minimal, if any, opportunity for physical containment. Therefore, some level of commingling or admixture is an inherent part of the everyday reality of farming. The only plausible way to *minimize* such unwanted admixture is through the implementation of spatial and/or temporal isolation measures, to mitigate out-crossing or natural cross-pollination by wind or insects, or comingling as a result of so-called GM 'volunteers' surviving into subsequent growing seasons. Such isolation measures might take the form of, *inter alia*, minimum growing distances and buffer zones between GMO and non- GMO field plots (spatial), or coordinating and diversifying growing schedules, pollination times, and crop rotations between sexually compatible plants (temporal). In addition, measures would need to be taken to ensure the segregation and monitoring of the different product flows and supply chains, throughout all stages of sowing, harvesting, storage, transport, processing, and distribution. One further potentially effective measure, which is increasingly discussed, is (highly) restrictive

[8] Most of the initial GMOs to receive authorization for cultivation in the EU (between 1996 and 1998, prior to the *de facto* moratorium) were only of marginal relevance (both agronomically and economically) to European agriculture. Soybean production is minimal in the EU due to unfavourable climatic conditions. *Bt* maize is also of low interest to most European farmers because of the absence of the cornborer; the pest insect which the *Bacillus Thuringiensis* that is built into this crop was designed to combat (with the exception of some Mediterranean regions including Spain).

zoning, involving bans on certain types of agricultural practices or specific crops in designated areas, most commonly referred to as GM-free zoning although the reverse zoning destination might just as well be feasible.

However, notwithstanding the potential mitigating effects of such isolation and segregation measures, it is now widely accepted that *total* isolation of transgenic material is impossible, certainly once GM crop cultivation is widespread in the EU. Though the actual probability and extent of admixture are highly crop-specific, some level of admixture between GM and non-GM material will inevitably occur (JRC 2002). There are various conceivable consequences of such admixtures, the scope and nature of which are a topic of heated debate. Most agreement appears to exist about the potential economic consequences. most notably that non-GM farmers might incur damages in the form of product depreciation by the loss of market value or of speciality premiums due to the inadvertent presence of transgenic material in products with non-GMO designation (resulting from either mandatory or voluntary labelling requirements), or even the loss of certification for organic or identity-preserved and specialty crops;[9] additional expenses incurred for the implementation of farm-scale isolation measures and changes to existing farm-management practices and machinery, as well as the cost of inspection and enforcement.[10]

Therefore, in addition to *ex ante* technical-agronomic isolation and segregation measures, effective coexistence policy also foresees in *ex post* liability and redress regulations to address these inevitable residual economic impacts. While, again, a detailed discussion of liability issues would detract from the main focus of this paper, it is useful to make some basic observations.[11] Whilst some traditional civil liability, tort and neighbourhood (nuisance) liability regimes may in theory be applicable to GMO damages, in practice they will tend to be ill-equipped to address the unique complexities raised by coexistence scenarios. A particular challenge for GMO liability is be the exceptional difficulty for the injured party to establish the causal link between the GMO cultivation/release and the damage suffered.[12] Identification of

[9] There are various identity-preserved and specialty crops, either with voluntary certification or with protected status under EU law.

[10] In future, the reverse may just as well be conceivable: GMO farmers incurring costs or damages as a result of inadvertent 'impurities' in their specialty crops, as a result of admixture with non-GM material.

[11] For a more in-depth discussion of liability for GMO-damage, see e.g.: Koch 2008; Lee 2008: 127-41; Lee 2003.

[12] National liability regimes are likely to provide remedies through fault-based principles of negligence or nuisance

the source of damage will be particularly onerous in GMO cases involving multiple potential sources (e.g. where more than one neighbouring field is planted with the same GM crop), and long time-lapses (with long-term effects potentially materializing only years or decades after the cultivation/release), cumulative effects, and lack of baseline data of the state of the damaged properties, environment, and biodiversity. Moreover, the GMO-operators, producers, and distributors are typically much better placed and informed to assess and control the potential damaging effects than would be the injured parties. Possible solutions to these challenges include the relaxation or even reversal of the burden of proof, presumption of causation or fault, and joint-and-several liability, meaning that each potential source of the damage, e.g. several neighbouring GMO farmers, can be held individually *and/or* jointly liable for the full amount. This can be a crucial benefit to injured parties in the event of difficulties to isolate a single source, or where not all of the potential sources offer sufficient financial resources to provide full compensation. By contrast, with proportionate liability, each defendant is only responsible for its own damage, or the proportionate share of the total damage. *Stricto sensu*, proportionate liability appears to be the most consistent with the polluter-pays principle,[13] but joint-and-several liability offers crucial additional protection for injured parties that might be warranted by the unique complexities involved in cases of GMO-damage. Another solution, in the absence of insurance coverage for GMO damages, could be the establishment of collective funds to compensate or remediate (collective) damages.

Hence, it is clear that liability and redress provisions are closely linked to various aspects of the coexistence conundrum. Their relevance might range from *ex ante* preventive and *ex post* remedial functions. Aside from their potential to mitigate and redistribute the possible costs and damages caused by coexistence problems, liability provisions could also promote responsible and prudent behaviour by all stakeholders involved and provide powerful incentives for adherence to agreed 'good agricultural practices', since non-compliance with such (formally established) norms will normally be considered faulty or negligent conduct, giving grounds to liability.

In view of these complex dilemmas raised by the concurrent cultivation of GM and non-GM agricultural crops, in conjunction with the EU's guiding principles of

[13] Article 174(2) EC Treaty.

safeguarding the freedom of choice for farmers and consumers and the ability to produce and consume both GMO or GMO-free products (Commission 2003: Recitals 2 and 3), without compromising intra-community free trade, it is now broadly accepted that coexistence is 'not an issue that can simply be left to the market, but that it requires some form of organization, if not government regulation' (Lee 2008a: 196). Distinctly less consensual and straightforward, however, is the question of *who* should regulate coexistence, and *how*.

4. FILLING THE GAP OF COEXISTENCE

4.1 What Level of Regulatory Intervention?

The answer to these questions, of *how* coexistence should be regulated and by *whom*, has to date largely revolved around the classic EU-polity dichotomy of subsidiarity *versus* harmonization. The EU coexistence policy-design debate has from the outset been pervaded with conflict and competition over legislative competence and responsibility. The determination of the appropriate forum for regulatory intervention for coexistence is not straightforward, and is giving rise to much confusion and contention.

Solid arguments can be made in favour of either of the fundamentally competing paradigms of subsidiarity *versus* harmonization, or decentralization or 'Europeanization'. For example, one the one hand, as an element of agricultural policy, and having potential for substantial internal market implications, to regulate coexistence at EU-level appears logical, if not necessary. With the political attitudes towards GM crops diverging so widely among the Member States, a significant degree of variation is to be expected. In other policy areas such fragmentation often rationalizes an EU-level approach, with a view to safeguarding the internal market. Conversely, these divergent views on GM crops are particularly strongly held because coexistence tends to be seen as closely connected to, if not an element of, risk regulation and the politically contentious issue of GMO governance generally. For these sensitive policy sectors Member States tend to feel more passionate about retaining a degree of national control than for the also connected more ethically and emotionally neutral areas of internal market and agricultural policy. Concomitantly, given how fraught with conflict and delays the past decision-making on GMOs has

been, a highly centralized EU-level approach to coexistence might be difficult, if not impossible to attain. Practically speaking, a national, regional, or even local approach to at least the technical agronomic aspects of coexistence could offer tailor-made solutions to fit the widely diverging conditions throughout the European geography, in terms of climate, ecology, and differences in farm sizes and structures (ranging from very small family farms to large, industrial-type agri-businesses), etc. Then again, such agronomic differences do not necessarily rationalize a decentralized approach to other aspects of coexistence, including purity standards, baseline 'best practices' for segregation and monitoring different product flows and supply chains at least in the post-harvest stage, liability and redress provisions, etc. Also from an internal market perspective, such issues might be best addressed in concert, creating at least an EU-level regulatory *floor*. From a policy-coherence and consistency perspective, there is also much to be said for a harmonized, EU-level approach. As argued above, coexistence policy is a crucial missing link in the EU's regulatory regime for agricultural biotechnology, and forms a central regulatory gap in the context of a highly centralized and increasingly exhaustively harmonized framework. Also, coexistence policy is closely linked to pivotal legal concepts in the overall regime (of which some examples are elaborated below), that risk becoming unenforceability or even redundant in the absence of harmonized coexistence policy; therefore, a failure to fill the regulatory gap of coexistence within the context of and coherent with the extensively harmonized and centralized overall framework would threaten to undermine the effectiveness and legitimacy of the EU's overall agbiotech regime (Etty 2007b). Regulatory consistency arguments also support concerted action, given that a subsidiarity-based approach to coexistence would constitute a considerable departure from prior policy design, both in substance and in form. Prior to the emergence of coexistence on the political agenda, there was a clear and increasing trend of 'Europeanization' and centralization in the EU's governance of GMOs. After a brief initial period of relatively minimal harmonization (creating a regulatory 'floor' but no 'ceiling'), the regulatory mode quickly shifted to increasingly exhaustive harmonization, with almost complete pre-emptive effect on national regulation. The same trend can be observed in procedural terms, as the regulatory instrument of choice in the area of biotechnology has shifted from (framework) Directives to Regulations, the most direct and true form of 'European' legislation.

All of these (and other) considerations are feeding into a complex and confusing composition of coexistence policy in the EU.

4.2 Subsidiarity *versus* Harmonization

During the negotiations for the EU's major agbiotech regime reform, in the early 2000s, the EU institutions and advisory bodies, the Member States, and a diverse range of stakeholders, held widely diverging views on the appropriate site, level, and extent of regulatory intervention for coexistence. In particular the EP and the Commission clashed over coexistence in the context of the co-decision procedures on the reform regulations package (Levidow & Boschert 2008: 181). The EP argued that a harmonized and stringent EU-level coexistence policy was vital to completing the EU's legislative framework for GMOs. The Commission rebutted that coexistence provisions could not be accommodated within the existing legislative framework since the cultivation of GM crops was not considered to present environmental or health concerns. It deemed coexistence a 'purely economic issue' that should be kept separate from the GMO authorization and risk management regime under revision (Fischler 2003). However, this distinction soon became blurred by the political compromise that was ultimately struck. A provision was adopted *within* the context of the regime, in the Deliberate Release Directive, providing an explicit statutory division of competences for coexistence policy, stipulating that:[14]

1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.
2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.

On the face of this legislation, the division of competence appears quite straightforward. Coexistence is to be a fully decentralized policy-matter, based on the principle of subsidiarity. Out of step with the trend of centralization and 'Europeanization' that had increasingly pervaded the overall EU regulatory regime for agricultural biotechnology until then (Dabrowska 2010: 180-2; Lee 2010;

[14] Article 26a of Directive 2001/18/EC, n. 4 above, introduced by Article 43(2) of Reg. (EC) No. 1829/2003, n. 5 above.

Commission 2004: 8, 13), as the last remaining component of this regime coexistence was explicitly made a matter to be regulated by the Member States rather than by the EU institutions.

4.3 *De Jure* Subsidiarity, yet *de facto* Harmonization?

However, despite this ostensibly clear statutory division of competences on the basis of subsidiarity and underlining Member States' national autonomy, the competition over authority appears to be ongoing. Although it was a political compromise between (mainly) the EP and the Commission, intended to resolve the conflict between subsidiarity *versus* harmonization, the statutory division seems to have merely transformed the nature and appearance of the ongoing power struggle. The former process of political bargaining and formal negotiations towards 'hard law' regulatory competences for coexistence has transformed into a more subtle and less transparent process of influence and pressure involving 'soft law' instruments in the shadow of hierarchy. As a result, the previously clear and marked contrast between the regulatory paradigms of 'subsidiarity' and 'harmonization' now appears to be blurring or even eroding; effectively melding into a rather ambiguous and confused construction of networked multi-level governance, using a blend of 'soft' and 'new' governance techniques, with distinctly 'hard' and 'classic' undertones.

Alongside the official (statutory) framing of subsidiarity, a multi-level governance framework is emerging for coexistence policy. Multi-level governance constitutes an attempt to compromise or even bypass the dichotomy between subsidiarity and harmonization by moving beyond clear delimitations of national and European/central competence, avoiding single-sites of authority, and diffusing regulatory responsibility. The ideal-type involves non-hierarchical or heterarchical collaboration by various levels of government (European/central, national, regional, or even local), and often also engaging non-state bodies, public and private, in a reflexive process of problem-solving through deliberation, information, learning, and persuasion (cf. de Búrca & Scott 2006; Lee 2008a: 196-7). In this way, by moving beyond traditional, hierarchical lawmaking procedures and command-style regulation, multi-level governance can be instrumental to breaking longstanding impasses in contentious and politically deadlocked policy fields like agricultural biotechnology.

However, as with other notions of 'new governance', multi-level governance is an open and flexible concept, without established criteria or procedures. Therefore,

particularly in contentious and deadlocked policy sectors like agbiotech, there is a risk of multi-level governance being reduced to mere rhetoric, or employed as a euphemism for ongoing competition over 'hard', exclusive authority (cf. Lee 2010). Indeed, these risks appear to be materializing in the emerging multi-level governance constellation for coexistence policy in the EU.

A leading role in this process has been assumed by the Commission, though not attributed by the legislation. The impetus for the Commission's alternative governance approach was the dilemma it faced of having concrete and explicit conceptions of how coexistence should be regulated and how detrimental effects for the internal market of wide-ranging diversity in Member States' policies should be avoided, yet at the same time lacking the formal competence to undertake such regulation unilaterally, while the EU legislative route of co-decision was also blocked by the obstacles of political stalemate in the Council and a relatively GMO-critical Parliament. To overcome this dilemma, it appears that in the absence of formal (and (politically usable) rule-making powers the Commission has turned to more flexible and informal governance modes, seeking to attain the same objectives. While maintaining its *de jure* resistance to accept legislative responsibility for initiating harmonization of coexistence at EU-level through the 'classic' Community Method, at the same time, *de facto*, the Commission nonetheless appears to be employing a more subtle, 'softer' and less direct method of influence towards convergence, at its own terms, yet with the appearance of 'multi-level/new' governance.

4.4 Open Method of Coordination?

On the face of it, this EU governance framework for coexistence most resembles an 'Open Method of Coordination' (OMC) procedure. However, upon closer inspection this semblance may prove deceiving. In ideal-type, the OMC is a 'new', multi-level governance mode *par excellence*, with its experimental 'soft' governance approach based on iterative benchmarking of national progress towards common (European) objectives through a bottom-up process of mutual information, feedback and peer review, monitoring and benchmarking, allowing comparison and adjustment; but meanwhile allowing the main competences to be retained by the Member States (e.g. Zeitlin 2005: 3; Trubek *et al.* 2005: 18-20). Since its inception as a tool for the coordination of national economic and especially employment policies, the OMC has been embraced as a new and broadly applicable EU governance instrument by the

2000 Lisbon European summit, as a 'third way' between regulatory harmonization and fragmentation, and extended to cover an enormous range of policy fields. In theory, the contentious policy issue of coexistence could be one of those fields for which an OMC-type governance might be ideally suited (cf. Sabel & Zeitlin 2007). By providing a multi-level, non-hierarchical, reflexive, 'soft' framework that facilitates mutual learning, spreads good practices and, perhaps most importantly, by accommodating diversity while at the same time fostering convergence toward commonly agreed EU goals, it could bridge, or at least narrow, the gap between subsidiarity and harmonization.

However, a closer examination of the EU coexistence governance framework reveals that fundamental anomalies in the practical arrangements and the application of this OMC-type process stand in the way of it attaining its reconciliatory potential.

4.5 Networked Multi-level Governance?

A vital element for a successful OMC-process is a forum for deliberation and mutual learning and adjustment, and to develop best practices. In the EU coexistence governance context, such a forum is provided by the Network Group for the Exchange and Coordination of Information concerning Coexistence of Genetically Modified, Conventional and Organic Crops (COEX-NET). The Network was established and is administered and chaired by the Commission, and consists of national coexistence experts representing their Member States (Commission 2005). It is open to *ad hoc* experts by invitation of the Commission. The official aim of COEX-NET is to facilitate the exchange of Member States' experiences and information about scientific research projects and best practices for national coexistence strategies. In addition, based on a mandate by the May 2006 Agriculture Council, a European Coexistence Bureau (ECoB) has been set up under the auspices of the Commission's Joint Research Centre (JRC), to organize the exchange of technical-scientific information on best agricultural management practices, with a view to developing consensus-agreed crop-specific coexistence guidelines. The Commission and JRC administer the Bureau, with Member States represented by technical-experts in crop-specific Technical Working-Groups. Stakeholders are consulted via Advisory Groups established by the Commission (Commission 2008). Networks and expert committees are classic tools of multi-level and 'new' governance; so much so that some forms

(comitology)[15] are sometimes referred to as 'new old governance' (Scott & Trubek 2002: 2).

A prerequisite for the effective functioning of such networks and expert bodies within the OMC-context are common goals, guidelines and benchmarks. According to the OMC ideal-type, and consistent with the principles of multi-level governance, the mutual learning and convergence in this network or forum should work towards, and on the basis of, commonly and consultatively agreed objectives for collaboration towards common 'European' goals. This is where the anomalies of the OMC-type process in coexistence governance become evident: EU legislation does not provide any democratically adopted objectives specific to coexistence, nor have any such goals been agreed by the Member States in a more 'soft', informal setting (e.g. at the non-legislative level of the European Council). As for the possible agreement of common objectives by the COEX-NET itself, the Commission has stressed explicitly that the network is *not* intended to develop a harmonized approach to coexistence or to scrutinize individual domestic measures.

4.6 'Soft' *De Facto* Harmonization

Instead, the 'common' goals have been formulated in a top-down, quasi-hierarchical manner, unilaterally by the Commission. This has taken the form of a Commission Recommendation on Guidelines for the Development of National Coexistence Strategies and Best Practices (Commission 2003). The Recommendation is the centrepiece of the EU coexistence governance strategy. It has from the outset fundamentally shaped the coexistence policy-design debate (and hence the OMC-type process), by providing a narrow conceptualization of coexistence as a 'purely economic issue'. This unilaterally restored the Commission's strict distinction between the economic impacts of GM crop cultivation and possible environmental or health concerns and other socio-economic factors, despite the dissenting positions of the EP and Council (and a variety of stakeholders), which defined coexistence issues more broadly. The Commission's strict distinction had become blurred by the statutory compromise with the EP and Council, of introducing the coexistence mandate Article 26a *within* the context of the risk-oriented Deliberate Release

[15] Though it should be noted that comitology is a different type of networking than here discussed in the OMC/multi-level governance context, in that it is a mechanism through which the Member States can supervise the Commission's exercise of its implementing powers.

Directive 2001/18/EC.[16] According to Levidow & Boschert (2008: 181): 'Commission staff saw the outcome [of the compromise to incorporate a national coexistence mandate into the Deliberate Release Directive] as an awkwardly "mixed Directive", which could complicate the task of policing the boundary between economic and environmental issues. Article 22 requires Member States to permit any GM product which has EU approval, yet the new Article [26a] could justify restrictions: "These articles are potentially contradictory, unless regulation is done in a balanced way" (interview, Commission staff, July 2005).'

In an effort to mitigate these concerns, lacking formal legislative powers, the Commission appears to have set out to ensure that national regulation is done in an (in its view) 'balanced way', through what appears to be a 'soft' OMC-type multi-level governance framework, but with a strong underlying current of centralized control, if not command.

Although recommendations are not formally binding, they do provide a highly influential indication of the issuing institution's perspective (Snyder 1994; Senden 2005). Whereas, clearly, the Commission is not the definitive interpreter or arbiter of EU law – that role remains reserved for the European Court of Justice (ECJ) – its position as the designated 'guardian of the Treaties' does imply a significant amount of influence and authority. Consequently, by outlining the Commission's own perception of the appropriate type, scope and (crucially) the proportionality of national coexistence measures, in the form of 'steering soft law' norms promulgated against a background of hierarchical Commission authority, also given its formulation and application in practice, the Coexistence Recommendation appears clearly intended to have normative, if not binding, effect (cf. Scott 2002: 70-1; Snyder 1994; Senden 2005: 93-4).

Obviously, a certain degree of centralization is inevitable, given the powerful centralizing force of internal market law, triggered by the intra-EU trade implications which most coexistence policies will inherently entail. Typically, this is precisely the *raison d'être* of multi-level governance networking; to mitigate the inherent EU centralization by avoiding hierarchy and single sites of authority, and instead allowing collaborative problem solving through deliberation, mutual learning, and peer pressure and review. In fact, in the authorization context of the EU GMOs regime,

[16] N. 4 above.

various networks are now in place to for this purpose (e.g. comitology committees, EFSA's expert committees and consultations with national centres for cultivation dossiers, etc. Further examples in: Dabrowska 2010). However, 'in the context of coexistence, this [appears to work] in reverse, in that the network prevents the surrendering of central (and mutual, i.e. Member State on Member State) influence in a context of ostensible national control' (Lee 2008a: 197). The Commission's Recommendation applies, in addition to the 'hard' internal market law constraints, substantial and compelling 'soft law' circumscriptions to national autonomy, and to the scope of Member States' collaboration through OMC-type processes and multi-level governance networking. Moreover, the Recommendation places the 'hard law' controls in a very narrow legal context, emphasizing their most restrictive and centralizing aspects, as will be elaborated below.

The COEX-NET and the ECoB, established by and under the auspices of the Commission, operate within the narrowly defined parameters of coexistence in the Commission's Recommendation.[17] The 'bottom-up *common* goals' that form a *crucial* prerequisite basis for OMC-type multi-level networking have for coexistence in fact been formulated top-down, unilaterally by the Commission. Obviously, this constitutes a substantial departure from the appearance of non-hierarchal, deliberative collaboration between the Member States. Hence, notwithstanding the representation of Member States in these fora, there appears to be little scope for mediating de-centralization and for safeguarding national autonomy from some degree of inherent EU-centralization. In fact, as one scholar has observed: 'it is not far-fetched to anticipate that COEX-NET could be an effective way of further emphasizing the central hold on coexistence initiated by the Commission's Recommendation' (Lee 2008a: 198).

Given the high input-legitimacy of OMC-type networks (at least theoretically, according to the above ideal-type; in practice, and particularly outside the OMC-context, networking often operates in the 'shadow of hierarchical authority', can lack transparency and exclude outsider-perspectives, while network experts tend to be far-removed from national publics and civil society. Cf. Radaeilli 2003; Lee 2008a: 198), their outputs of standards or guidelines emanate an implicit authority of legitimization

[17] For example, at the very first COEX-NET meeting, the Commission explicitly reiterated 'the' definition of coexistence as a purely economic issue, see Minutes of the Meeting of COEX-NET of 22.09.2005, para. 2.

(though *stricto sensu* not in legal terms). As these outputs are currently conceived within the narrowly defined limits promulgated by the Commission, the result of this networking exercise may simply be a conversion of the Commission's unilateral, centralized standards into an seemingly 'legitimatized' form of 'soft harmonization', and hence reinforce centralization (cf. Lee 2010).

4.7 *Ex Ante* Pre-emption and *Ex Post* Correction

Aside from its role in this OMC-type, multi-level networking arrangement, the Commission's narrow conceptualization of coexistence and its strict distinction between economic and all other impacts, has had an *ex ante* pre-emptive effect on Member States' domestic coexistence policies. Since the Recommendation was adopted *after* the agreement of Article 26a, but *prior* to its formal adoption and entry into force, it served to circumscribe national autonomy from the very outset; before most Member States had even begun to define the parameters of their domestic coexistence policies, and in fact even before they had been formally mandated to do so.

In addition, the Recommendation also has an *ex post* 'corrective' function, to discipline domestic regulations after they have been drafted. Since coexistence measures constitute technical regulations concerning products, and as such have the potential to distort internal market trade, they must be notified in draft form to the Commission and the other Member States before being adopted into national law. The Technical Regulations Information System (TRIS) procedure under Directive 98/34/EC[18] envisages a dialogue between the Commission and the Member States during a standstill period. Measures that have not been duly notified prior to adoption cannot be enforced or invoked before national courts.[19]

It is in this internal market law-oriented procedure that the restrictive framing by the Commission of coexistence has its most paramount consequences for national autonomy. This autonomy appears quite vast on the face of the legislation, which provides simply that 'Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.' However, the tempering effect on national discretion of the additional proviso of 'appropriate measures' is greatly enhanced by the limitation of coexistence to pure economics, as this emphasizes the

[18] Directive 98/34/EC laying down a Procedure for the Provision of Information in the Field of Technical Standards and Regulations. [1998] *Official Journal* L204/37.
[19] Case C-194/94, *CIA Securitel* [1996] ECR I-2201.

most restrictive aspects of internal market law (Lee 2008a: 204). After all, as a basic principle of EU law, obstacles to the free movement of goods within the internal market – which most coexistence measures will inevitably entail – cannot be justified by (purely) economic arguments. By the same token, an official framing of coexistence as an issue with purely economic ambit would prohibit Member States from relying on perhaps genuinely competing public policy arguments such as protection of the environment, human health, consumer choice, etc., to warrant restrictive (let alone precautionary) coexistence prescriptions. Therefore, the introduction of a broad Member State mandate in Article 26a alongside the internal market clause of Article 22 in the Directive was intended by the EP (or at least in effect served) to provide coexistence a legal counterweight to the supremacy of the classic EU policy areas of internal market and competition law, thereby somewhat levelling the playing-field and requiring a balancing-test of competing policy objectives.

Of course, Articles 22 and 26a stand on equal footing within the Directive, and in strict legal terms, this 'hard law' balance cannot be unilaterally altered through 'soft law' by the Commission. However, as often is the case, these strict legal terms do no fully capture the full complexities of reality. The above observations regarding the significant influence or even implied authority of 'soft law' norms promulgated against a background of hierarchical Commission authority are particularly relevant in the context of the TRIS-procedure. Although the procedure does not foresee in a legally binding rejection or approval by the Commission or a comitology-decision, given the internal market focus the Commission's authoritative role as 'guardian of the Treaties' is further emphasized, creating a particularly large shadow of hierarchy for soft law instruments to seize normative effect in.

The normative intent of the Coexistence Recommendation is, moreover, unambiguously confirmed in the TRIS-procedure by the Commission's consistent pattern of referring to its own conceptualizations as authoritative legal benchmarks for the proportionality and legality of Member States' proposed coexistence regulations. The most notably and recurrent substantive example is the Commission's consistent practice of objecting to national coexistence measures that apply stringent purity targets, or even an effective 'zero tolerance' to GM presence in non-GM products (setting the target for preventive measures at the 'technical zero' of 0.1% impurity). In this respect, the Commission applies a particularly restrictive proportionality-test for

coexistence measures in the TRIS procedure by directly linking its economic framing of coexistence to the labelling exception thresholds for GMOs.

Though an in-depth analysis of this practice and its problems exceeds the scope of this brief paper (for more detail see: Etty 2007b**;** Lasok & Haynes 2005**;** Lee 2008a), for present purposes it is relevant in that, as the most frequently raised objection by the Commission in the TRIS notification procedure, it provides a useful and telling illustration of how the Commission has achieved a degree of *de facto* harmonization of coexistence parameters through the 'soft' policy instrument of a Recommendation.

The Commission's definition of the proportionality benchmark for national coexistence measures based on its (re-)interpretation of the labelling threshold unilaterally transforms the threshold of 0.9% *maximum tolerable adventitious impurity* for reliance on the labelling exception into a *minimum* threshold for Member States' *regulatory intervention* on coexistence. This is questionable both in substance and in form. Substantively, it appears plainly incompatible with the intended nature of the labelling *exception* threshold, particularly in view of the additional condition that the impurity must be 'adventitious', meaning 'inadvertent or technically unavoidable'. This appears hard to collate with the use of the 0.9% threshold value as an intended *target*, or starting point for proportionate policy, since GM-presence that is 'built in' or assumed can hardly be called 'adventitious' or 'inadvertent', nor 'technically unavoidable' insofar as admixtures could have been avoided or minimized with preventive measures aiming closer to 'zero'. Reliance on the labelling exception is furthermore dependent on farmers' ability to demonstrate that 'appropriate preventive measures' were taken to avoid the *adventitious* GM presence. There is a clear circularity in the Commission's argumentation that the conditions for the labelling threshold should be assessed on the basis of compliance with coexistence measures, which in turn should themselves be defined by reference to that very labelling threshold. This would deprive the pivotal concept of 'adventitious presence' of its (intended) meaning in the overall regulatory framework, and effectively render it redundant. What is more, aside from theoretical legal rationalizations, the prevalence of 'real world' contractual obligations to deliver agricultural commodities at the 0.1% purity level would appear to negate the Commission's policy stance.

In procedural terms, this interpretation of the labelling exception and its transformation into a *de minimis* threshold for *regulatory intervention* on coexistence

and a benchmark for the proportionality of Member States' policies, does not find a basis in 'hard law', but merely in the Commission's 'soft law' framework established by Recommendation. In fact, it can be argued that the Commission's 'soft' policy stance that there is no legal basis for national coexistence measures that aim to '*avoid*' GMO-traces in non-GMO products more completely than the 0.9% trigger for the labelling requirements is in direct contradiction with (the literal wording of) the 'hard law' mandate that the EP and Council Directive has provided Member States in Article 26a.

5 CONCLUDING REMARKS: MOVING BEYOND SUBSIDIARITY *vs.* HARMONIZATION TOWARDS 'SYNERGETIC GOVERNANCE'

The above discussion of procedural and substantive aspects of the Commission's strategy to govern coexistence demonstrates a clear discrepancy between its *de jure* insistence on subsidiarity (along with its resistance to a formal EU-level harmonization of *any* aspect of coexistence), and its *de facto* practice of substantial and substantive interference in, if not command of, the formulation of Member States' domestic coexistence policies. Moreover, it has highlighted how this discrepant strategy has produced a complex, confusing and rather opaque mix of, on the one hand, ostensibly bottom-up, de-centralized, non-hierarchal/heterarchical, OMC-style deliberative, multi-level 'soft' governance modes and instruments; and on the other hand, top-down, hierarchical centralization and command and control reminiscent of classic 'hard' command regulation.

The result, if not intent, is a degree of 'competence creep', or even a *de facto* re-negotiation towards (re-)centralization and (re-)Europeanization of the legislative competence and authority in this sensitive policy field. By promulgating its own, unilateral conceptions of what constitutes appropriate and proportionate coexistence measures, in the form of a 'soft law', even policy, instrument but with implicit normative effect against a background of hierarchy, the Commission has effectively secured *ex ante* pre-emptive and *ex post* corrective control over Member States' policies.

In this way, in an explicitly decentralized and politically contentious policy area for which it previously resisted any type of formal harmonization at EU-level, the Commission appears to have succeeded in achieving an important degree of

harmonization through the proverbial 'backdoor'; outside the contours of the established and democratically legitimized EU integration procedures and bypassing the EU legislative institutions and advisory bodies, Member Stats and civil-society stakeholders. It is fair to say that, as a result, the *indirect* influence that the Commission now exercises is more autonomous than anything it might have achieved in the formal lawmaking process (cf. Lee 2010).

This approach of 're-Europeanization', blurs the lines of autonomy, authority, and accountability, and raises serious questions about its transparency and legitimacy. In fact, in its current form the Commission's approach appears to run counter both to its own official policy, ECJ case-law, and primary EU law. In its 2001 White Paper on European Governance, the Commission explicitly emphasized that the use of multi-level governance OMC-processes 'must not upset the institutional balance', 'must ensure overall accountability' and 'in particular, should not exclude the European Parliament from a European policy process' (Commission 2001: 21-2). Furthermore, the ECJ has previously condemned similar Commission practices of unilaterally rearranging the vertical and horizontal distribution of power within the EU and '*de facto* harmonization through the backdoor', as currently with coexistence (Senden 2005: 88-9, 93-5).[20] Whereas the proportionality principle generally supports the search for 'softer forms of law', this is only insofar as this does not disrupt the institutional balance (point 2 of the Amsterdam Treaty Protocol on the application of the Principles of Subsidiarity and Proportionality), which would also be contrary to the EU loyalty and faithful cooperation principle of Article 10 EC, especially given the Commission's exclusive legislative initiative (Senden 2005: 97, 86). Finally, the Commission's use the form of 'soft' instruments to establish 'hard' harmonization unilaterally, as examined above, runs counter to the fundamentals of the agreed EU good governance and Better Regulation agendas (in terms of transparency, accountability, democratic input, etc.), and may even be said to undermine the fundamental principle that the EU is governed by the rule of law. Given the politically highly sensitive policy context, the implications of this surpass the coexistence debate alone and threaten to affect the legitimacy and efficacy of the overall GMO regime (arguably already signalled in current comitology decision-making), and contributes

[20] Senden cites respective examples of cases C-303/90, *France* v. *Commission* [2004] ECR I-2759, and C-57/95, *France* v. *Commission* [1997] ECR I-1640.

to the well-known criticisms of the democratic deficit and legitimacy crisis of the EU generally, exacerbated by the recent constitutional struggles.

In view of all this, it is clear that the Commission's experimentalist approach involving 'new' and 'multi-level' governance instruments has not succeeded in bridging the divide between the conflicting paradigms of subsidiarity and harmonization, and that competition for authority for coexistence is ongoing. Therefore, at first glance the conclusion might logically be drawn that multi-level governance has failed in the coexistence context. It would be wrong, however, to attribute this failure to the introduction of these governance techniques *per se*, and to assume (as some scholars have done) that coexistence lends itself only to centralized, 'hard' regulation.

Instead, more detailed analysis of this governance framework (as initiated in this paper) demonstrates that it is the anomalies in the *arrangement* and *application* of these governance features have undermined their potential for reconciliation as well as their legitimacy, and as a result have let coexistence fall between two regulatory stools.

Therefore, it is here submitted that the solution to the coexistence governance conundrum need not involve a complete uprooting or reinvention of the current framework, based on exclusive choices between either subsidiarity or harmonization, de-central or central oversight, and 'classic hard regulation' or 'soft new governance'. Instead, to remove the regulatory gap of coexistence policy, these competing 'regulatory stools' between which coexistence threatens to fall must be slid closely together, from the current arrangement of opposition to a juxtaposed, adjoined setting, thereby creating a more broad and stable platform for coexistence policy to rest on.

There is nothing inherently inappropriate or inadequate about Member States collaborating in multi-level governance networks or OMC-type fashion towards common European goals and best practices for coexistence. Quite the contrary; this is likely to be the only plausible way forward. But the common objectives that form the basis for this collaboration towards convergence must be truly *common*, and formulated bottom-up by the Member States in keeping with their national mandate; not unilaterally imposed, top-down by the Commission. Likewise, there is nothing principally wrong with (or uncommon about) Commission officials being involved in regulatory determinations that are ostensibly national or regional, like coexistence. In

fact, the European unity and the internal market demand this type of monitoring. However, this involvement should be based on hard law benchmarks and limitations, rather than the Commission's own, unilateral conceptions laid down in 'soft' policy instruments. This would not only boost the public perception of legitimacy and accountability, but also enhance the political ownership by Member States of their coexistence policies, which is likely to feed into the acceptability and efficacy of GMO authorizations as well. These arguments would appear to be in line with the recent suggestions (notably endorsed by Commission president Barosso in the political guidelines for 'his' newly incoming Commission: Barosso 2009) that cultivation decisions should be re/de-centralized.

In essence, then, the recommendation this papers aims to make is that the discrepancy between the Commission's formal*, de jure* position and its *de facto* practice should be removed, by legalizing and legitimizing the current *de facto* harmonization strategy through a more genuine multi-level governance approach. To be clear, the point is not whether coexistence policy should be more or less stringent than currently defined by the Commission, but rather that whatever the parameters for coexistence in the EU might be in future, they should be legitimized with a basis in law or express political commitment by the Member States. To this end, the Commission's coexistence Recommendation should be replaced as the centrepiece in the governance framework by legally established and democratically legitimized parameters agreed either intergovernmentally by the Member States in OMC-style, or through the formal EU lawmaking procedures. Likewise, the COEX-network and Bureau must be transformed from drivers of centralized Commission policy, to truly heterarchical multi-level governance fora to promote mutual learning and the development of common best practices by the Member States.

The intention of this paper is by no means to suggest exhaustive harmonization should 'cement in' a single 'best', European approach' to coexistence. Instead, the level of harmonization here proposed would – at least initially – focus on the fundamental determination of what constitutes an 'acceptable' level of GM presence in non-GM products, and *to what end* such presence may be avoided (i.e. proportionality), while still allowing for local flexibility in terms of formulating concrete preventive measures. After all, given the wide diversity of conditions throughout the European geography, at least for the technical agronomic aspects of coexistence an adequate degree of flexibility for national, regional, or even local

approaches is imperative.

Despite the rigid separation that is often suggested (as also in the Commission's Governance White Paper) between 'new/soft' governance modes like the OMC and 'classic/hard' regulation, there is a growing body of literature on the potential for 'old' and 'new' governance modes to 'coexist' or even to function as complementary and mutually reinforcing elements of a single 'hybrid' governance framework, citing empirical examples in various policy fields (de Búrca & Scott 2006; Sabel & Zeitlin 2008; Sabel & Zeitlin 2010). In fact, the EU's overall regime shows hybrid features as well (cf. Dabrowska 2010; Lee 2010). However, hybridity in and of itself is no guarantor for success, as GMO regime well illustrates. Imbalanced hybrid governance constructions can, in fact, become detrimental or dysfunctional to the regulatory objectives pursued (cf. Dabrowska 2010). 'True' and functional hybridity (aimed at creating a positive synergy rather than mere combination or merging) requires a balanced distribution of influence among the complementary regulatory modes, and a genuine legitimized platform for its multilevel governance components, removed from the shadow of hierarchy and centralization.

I therefore distinguish as 'synergetic governance' the combination of using reflexive minimum harmonization to create a legitimate basis and structure for *genuine* multi-level governance networking between the Member States, within their own-defined framework based on their subsidiarity-based national legal mandate to regulate coexistence.. This could create the positive synergy of promoting genuine and innovative policy experimentalism within a safe, defined regulatory space to protect the EU internal market (cf. Dougan 2004; Deakin 2009). A welcome side-effect of this approach of enhanced respect for national diversity might well be a decline of Member States' recalcitrance in the authorizations procedures, and a reduction of their incentives to create questionable barriers to GMO trade through safeguard provisions. This effect could be strengthened by the recently proposed de-centralization of cultivation decisions, as this would take away the current incentive for Member States to use stringent coexistence policies as a guise for *de facto* bans against GMO cultivation within their territory.

While it would certainly be naïve to suggest that the negotiation and adoption of harmonized baseline coexistence parameters will be an easy task given the persisting deep political divide on GMO-issues, clearly this cannot not *a priori* justify infringements of the basic principles of legitimacy, accountability, and consistency in

lawmaking. Likewise, an obvious criticism of the recommendations in this paper might be that renegotiation of coexistence is likely, again, to lead to delays and policy inertia, with the risk of further world trade law implications. However, it is submitted that it would be equally naïve to think that the current framework left unchanged would not produce similar ramifications. As long as coexistence is not legitimately resolved (in terms of its conceptualization and governance structure) and the competition for authority remains ongoing, with *de facto* harmonization on the basis of a 'soft' policy instrument of the Commission, this unrest will (continue to) spill-over into the troubles in the overall GMO governance in the EU, and fuel decision-making gridlock in the authorization process, as several Member States continue to directly link these issues. In this respect, it should be recalled that Member States' dissatisfaction with GMO regulation has brought the EU regime to its knees before. If conflict over coexistence continues, this risk is likely to recur.

In view of all of this, it is here submitted that the legitimate and viable regulation of coexistence in the EU requires moving beyond the dichotomy of subsidiarity *versus* harmonization towards 'synergetic governance', combining both these paradigms as mutually reinforcing components of a concerted effort to fill the regulatory gap of coexistence so as to realize a comprehensive, consistent, and viable regulatory regime for agricultural biotechnology in the EU.

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