



No. 36

The EU and Transnational Regulation of GMO Risks

University of Warsaw and European University Institute

Patrycja Dąbrowska-Kłosińska



Dr Patrycja Dąbrowska-Kłosińska
Assistant Professor
Centre for Europe
University of Warsaw
Al. Niepodległości 22
02-653 Warszawa, Poland
+48 22 553 33 01
p.dabrowska@uw.edu.pl

Academic year 2012/2013:
Jean Monnet Fellow in Global Governance
Robert Schuman Center for Advanced Studies
European University Institute
Villa Raimondi, VR028
Via Boccaccio 121/111, I-50133 Firenze, Italy
+39.055.4685 985/ int. 2985
Patrycja.Dabrowska@eui.eu

Please cite this working paper as:

Dąbrowska-Kłosińska, Patrycja, 'The EU and Transnational Regulation of GMO Risks', *GR:EEN Working Paper No. 36*

www.greenfp7.eu/papers/workingpapers

Short bio

Patrycja Dąbrowska-Kłosińska – Jean Monnet Fellow in Global Governance, Robert Schuman Centre for Advanced Studies, European University Institute, Florence & Assistant Professor, Centre for Europe, University of Warsaw

Abstract

This paper explores the role of the EU in shaping transnational regulation of GMOs and attempts to establish whether the EU's system of governance prompts experimentalist solutions at the international level in this field. In order to accomplish this aim the paper analyses the relationship between the EU policy on GMOs and the growth of the international regulatory framework which addresses risks associated with modern biotechnology products. More specifically, it examines the means through which the EU has attempted to extend its own norms, standards and governance of GMO risks to third countries and at the international level. It addresses the questions. What are the distinctive features of these processes and the characteristics of the regulatory systems created? In what way does the EU participate in the development of transnational regimes on GMOs, and do the latter regimes resemble the experimentalist architecture? Does EU policy in this area have repercussions on its domestic policy?

'EXTENDED VERSION OF A CHAPTER FORTHCOMING IN JONATHAN ZEITLIN (ED.),
EXTENDING EXPERIMENTALIST GOVERNANCE? THE EU AND TRANSNATIONAL
REGULATION'

This research acknowledges the support of the FP7 large-scale integrated research project **GR:EEN - *Global Re-ordering: Evolution through European Networks***
European Commission Project Number: 266809

EU AND TRANSNATIONAL REGULATION OF GMO RISKS*

Introduction

The application of modern biotechnology in various sectors, from medicine to food and agriculture, has been growing continuously over the last decades (Ceddia and Cerezo 2008; ISAAA 2011). Simultaneously, the use, especially in food and agriculture, and cultivation of genetically modified organisms are the subject of never-ending controversies in relation to scientific uncertainty of products' safety, possible risks to human health and the environment, and potential benefits to societies.ⁱ Moreover, the scholarship continues investigation into the adequacy of varying approaches to GMO regulation in the EU and the US against the global governance context, the relationship between the environmental concerns and trade, and the application of the precautionary principle (Vogel 2012; Bodiguel and Cardwell 2010; Everson and Vos 2009; Ansell and Vogel 2006). The claim that transnational discourses on GMO politics and legislation ought to be 'resolved' seems to be beyond dispute, but when it comes to finding a common solution on how this should be done, matters become much more complicated.

The risks and uncertainties surrounding modern biotechnology have triggered numerous regulatory developments at the regional and international levels and efforts have been undertaken to regulate GMOs through international treaties and within international institutions, but the proliferation of divergent interests, beliefs, and values among various stakeholders has led to the co-existence of overlapping regimes and organisations. As a result, it has been observed by many authors that there is currently (2013) no single, unified, coherent and consistent international regulatory regime applicable to GMOs and bio-safety, and the relationship between the environmental and trade international frameworks is not clear (e.g. the UN Convention on Biological Diversity and the GATT system; see the WTO Panel Report on Biotech Dispute 2006 and e.g. Krisch 2010; Pollack and Shaffer 2009a; Oberthuer and Gehring 2006). Thus this field, like many other areas of international law, including environmental law, provides a prominent example of international law fragmentation and regime complexity (Keohane and Victor 2011; Raustiala and Victor 2004; see also de Búrca, Keohane, and Sabel 2013; Gruszczynski 2012).

There are two main trends in the professional literature dealing with the effects and functioning of this phenomenon in the area of GM products. In particular, the interpretations of the various scholars differ on the issue whether the regime complex for GMOs leads to disruptive effects on governance aimed at linking the risks of modern biotechnology with food and environmental safety, and undermines the effectiveness of transnational regulation; or on the contrary is capable of producing positive interactions between parallel institutions, elements of convergence concerning GMOs, and successful co-operation. The former argumentation is often used by authors who perceive the transnational regulation and disputes over GMOs as one of regulatory conflict, mainly between two powerful actors, that is the EU and US, both of which pursue their self-interests, as well as between two sets of norms and rules, namely the WTO framework and the UN bio-diversity regime (Pollack and Shaffer 2009a; see also Poli 2004; Oberthuer and Gehring 2006, note 5; Lyster 2008, note 134). The second group of authors focus on the mutually reinforcing and converging effects of the GMO regime complexity, emphasising the positive sides of legal pluralism (Krisch 2010) and possible common interests of states involved in the institutional interaction between the WTO and the Cartagena Protocol (Oberthuer and Gehring 2006); or on overcoming interpretative differences through legal reasoning (French 2010: 356ff) and regulatory co-operation (Alemanno 2011: 217-220 where he proposes 6 ways to improve regulatory co-operation across the Atlantic), or pleading for an all-embracing international consensus on GMOs through

the establishment of the epistemic community in the form of a transnational biotechnology forum (Mariani 2007; Murphy 2001), or proposing to follow the example of the Forest Stewardship Council in the forest sector (Murphy 2001: 124; see also Overdevest and Zeitlin 2012).

In light of the divergences in viewpoints, it is useful to engage in the discussion from the experimentalist governance perspective (C. Sabel and J. Zeitlin 2012, 2010, 2008), and consider it in the context of the EU's influence on the transnational regime. Moreover, in view of the tension between the promises of experimentalism and those recent scholarly findings, which perceive the international politics of GMOs as a constant battlefield of conflicting state-powers, bargaining between interest groups, and lack of co-operation, it will be useful to engage in a discussion which can revitalise somewhat the pessimism surrounding the debates and enrich the current picture of EU policy in relation to the transnational regime for regulating GMO risks.

The use of the experimentalist architecture approach for risk regulation in the transnational context is vital for several reasons. First, experimentalist governance is useful precisely for the analysis of deeply contested fields like the biotechnology sector, with actors pursuing diverging interests, lack of common vision toward the precise goals to be achieved, and a multi-polar distribution of power (Overdevest and Zeitlin 2012: 5). Second, experimentalist governance is perfectly suited for risk regulation in the post-national era, characterized by the scientific uncertainty of its effects and safety, the incapacity of a single state to manage and react to emerging and uncertain risks (van Asselt and Vos 2008) and rapid technological development, both in terms of its scope, conditions and features as well as institutional structures (Dąbrowska 2010; also Murphy 2001: 120ff; Spina 2009: 200-202). Finally, elements of experimentalist architecture are present in the EU internal regulatory system on GMOs and although its implementation has constantly been challenged by national opposition, political bargaining, and public concerns, the EU has also successfully managed to modernise its outdated regulatory regime of the 1990s, control GMO risks and avoid the materialisation of any GMO hazard, which is the overall aim of the system (Dąbrowska-Kłosińska 2012).

The EU regulatory regime on GMOs, including GM food and feed, is based on the pre-market approval system, incorporating the precautionary principle and reflecting the social theory of regulation (an authorisation procedure with case-by-case and step-by-step risk assessment for the marketing and release of GMOs) and post-market control, which includes labelling and traceability obligations. This system conditions the market access of any transgenic products on their general compliance with the level of risk, standards and procedures that are chosen by the EU. Thus, from the perspective of international trade, the acceptance of and compliance with the GMO regulatory system is always required in case of marketing products within the EU. This system was adopted in response to the first 1990s regulatory crisis on GMOs in Europe, which emerged owing to the inadequacy of the EU regulatory regime, including lack of trust in scientific expertise and science-based decisions, outdated solutions on health and environmental safety, as well as both internal and international conflicts surrounding the costs and benefits and the safety aspects of biotechnology.

At the same time, the new EU governance in this policy domain has transformed it into a regime embodying numerous experimentalist solutions typical of the new EU emerging architecture (Sabel and Zeitlin 2008), and my earlier research of the field demonstrates that these experimentalist features are combined with regulatory measures that can be classified as a more traditional approach (Dąbrowska 2010).

The institutional forms and features typical of experimentalist governance which are evidenced in the EU GMO regime include: the increase of soft regulation and regulation by information (e.g. guidelines, private standards, the OMC-type and networked Internet tools); the co-operation of the networked administration of comitology committees, national authorities/bodies and EU agencies, above all the

European Food Safety Authority, in rule making and rule application; the participation of civil society in policy-making; the proceduralisation of regulatory solutions, combined with the revisability of regulation, flexibility in implementation, and mechanisms that foster horizontal cooperation, participation, learning and accountability (Dąbrowska 2010).

In view of the above, the principal aim of this chapter is to explore the role of the EU in shaping transnational regulation of GMO risks (and to establish whether the EU's system of governance prompts experimentalist solutions at the international level in this field). In order to accomplish this aim the paper analyses the relationship between the EU policy on GMOs and the growth of the international regulatory framework which addresses risks associated with modern biotechnology products. More specifically, it examines the means through which the EU has attempted to extend its own norms, standards and governance of GMO risks to third countries and at the international level. It addresses the questions. What are the distinctive features of these processes and the characteristics of the regulatory systems created? In what way does the EU participate in the development of transnational regimes on GMOs, and do the latter regimes resemble the experimentalist architecture? Does EU policy in this area have repercussions on its domestic policy?

The structure of the text is built on the chronological expansion of GMO rules, both within the EU and internationally. That is, it begins with a presentation of the relationship between the internal EU regime and a parallel, emerging transnational regime aimed at establishing a coherent system of international rules addressing GMO risks. It will be demonstrated that, on the one hand, this has resulted in the development of a fragmented and complex transnational order which has produced international conflicts in the period of the 1990s and extending until 2006 where the WTO case was decided, but on the other hand it has networked co-operation and increased the exchange of information and adoption of common standards (development of international standards on GM products, the signature of the Cartagena Protocol, and bilateral co-operation between the main trading partners). The second part of the paper investigates the post-2006 EU and international regulatory developments in order to determine whether they reveal more experimentalist features than previously, and if so, what the possible reasons lying behind the change might be. It uses of a short case study of the co-operation between the EU and the US on the release of the unauthorised GM LL Rice, where experimentalist characteristics are discovered and analyses the EU's current revision of its GMO policy in relation to the WTO decision and other influences.

Linking internal and external governance through experimentalism: internationalisation of the EU GMO regime by external standards

From the standpoint of international trade, the EU appears as an unilateral standard-setter for GMO risks because the compliance with the GMO regulatory system is always required in case of market access. This perspective is challenged by the 'internationalisation of European GMO laws' through external standards which demonstrates that the EU regime must accommodate some global developments. While the EU regulatory framework on pre-market authorization and post-market risk control of GM products – which was developed between 2001 and 2003 and since then has been undergoing repeated reforms – contains direct references to internationally developed product standards (environmental and food safety) and recommends their applicability in legislation, compliance there with remains voluntary and the final choice of content is the result of intensive collaboration in international standard bodies and expert groups (cf. Scott 2004). It also explains why the EU pursues its interests at the transnational level, but also why the process must generate certain degree of reciprocal influence and collaboration (Vos and Weimer, forthcoming).

The standards referred to include:

(a) external private standards. When one scrutinises the EU GMO rules, several acts contain references to private standards of the European Standardisation Committee, i.e. the CEN, the International Standards Organisation, i.e. ISO, or ISTA (International Seed Testing Association) (generally Schepel 2005). This reliance on transnational regulation is necessary and important in standards relating to: (i) the release into the environment of GMOs, mainly standards ensuring the implementation of quality control procedures; (ii) in the food sector, the standards belonging primarily to the category of 'sampling and detection methods,' which allow for the quantitative and qualitative detection and therefore for an effective post-market monitoring of products.

For example, resort to private and international standards (CEN standards, OECD-methods, ISO norms) can be found in the following described EU pieces of legislation on GMOs: Regulation 641/2004 and Regulation 619/2011, which implement GM Food Regulation, and in the numerous guidance documents supplementing both GM Food Regulation and Deliberate Release Directive on the analysis and sampling of GMOs, on detection, interpretation and reporting on the presence of unauthorised genetically modified materials or on post-market monitoring of GMOs or validation process.ⁱⁱ The use of these standards is recommended in the relevant market applications. Not only is this evidence of a certain privatisation of GMO regulation in the EU, but also of its internationalisation, as it makes direct reference to norms which are external to EU law.

(b) identification standards. For example, the EU system of unique identifiers (Regulation 65/2004) was established taking into due account international developments, which include works on formats of unique identification carried out by the Organisation for Economic Cooperation and Development (OECD) for use in the context of its BioTrack product database; within the framework of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity; and the *Codex Alimentarius* Commission, the most important international organisation setting food standards (Mason-Matthee 2007). This improves the global recognition and traceability of GM products by following the same identification standards, and facilitates the availability and exchange of appropriate information on products in the event a hazard emerges.

(c) standards of judicial review. In its risk regulation case-lawⁱⁱⁱ, the European Courts very often refer to the results of international research, scientific evidence and findings of other international organisations, as OECD, which additionally amplifies the significance of transnational GMO regulation for the EU system (Dąbrowska-Kłosińska 2013; Alemanno 2008). The reasoning of the EU Courts is science-based and does not accept 'purely hypothetical risk' what highly resonates with the wording and justifications of the WTO Panel reports (Scott 2009a: 299). It indicates a will to maintain consistency between the EU rules and transnational standards of review as well as attempts to ensure convergence with the results of the research conducted within international bodies and organisations (Dąbrowska-Kłosińska 2013).

As can be seen, the content of EU GMO rules and standards applied in judicial review has not been created in isolation, but has resulted from processes of norm-generation within the framework of non-hierarchical, complex transnational co-operation, private and public, in which the EU authorities took part. The effective market and risk regulation of GMOs in the EU required both ascertainment of their consistency with international standards and avoidance of the duplication of standards (e.g. the duplication of product identification methods as developed by the OECD). Moreover, several incidents involving the trans-boundary movement of unapproved GMOs between states and continents demonstrated the urgent need to develop a framework for the international identification of GMOs which would be based on common principles, identification of products, controls, detection methods, etc. In effect, the reformed European regime provides evidence of the experimentalist

linkage between internal (EU) and external governance of GMOs. The above developments demonstrate that the EU has been engaged in the construction and reform of GMO regulation at the international level, and that the underlying premise of this involvement was not solely based on self-interest (cf. Pollack and Shaffer 2009a), but also on awareness of the need for compatibility between the EU rules and external developments, and openness towards standards worked out at the international level. Finally, it is not surprising: environmental protection has been characterised as the richest area of interplay between EU instruments and international regimes involving lots of ‘co-evolution’ of regimes (de Witte and Thies 2012: 36-37).

EU and the first phase of transnational GMO regulation (1990s-2006)

The first phase in the creation of transnational regulation of GMO risks can be identified between the 1990s and 2006, when the first major dispute over GMOs was decided by the WTO Panel. The beginning of this first phase is marked by the growing awareness of the importance of regulatory measures, rapid advancements in the application and use of modern biotechnology, above all in food and agriculture, and the first attempts of economic and environmental interests and organisations to occupy the newly emerging regulatory field (Oberthuer and Gehring 2006: 11; Jendroška *et al.* 2004: 17-20). From the perspective of experimentalist governance it can be perceived as the first attempts to establish framework goals regarding biotechnology products at the international level (cf. Morris and Spillane 2010; see also Gottweiss 1999; Cantley 1995, for historical background).

Experimentalism declared in EU external governance on GMOs

Before advancing to the analysis of the EU’s participation in the creation of the transnational GMO regime, it is important to review the EU vision of its external governance of GMOs that was presented by the Commission in its strategic document in 2002 published by DG SANCO, where the objectives of the proposed actions and the language describing them largely accords with and resembles the premises of experimentalism (Commission 2002). The ideas and views which are contained in the chapter ‘Europe in the world – responding to global challenges’ suggest that policy-makers were well-aware of the global reality, whereby policies cannot ‘be developed in isolation’ (Commission 2002: 25). It is claimed there that there is a need for international dialogue, which promotes mutual understanding of concerns and objectives of different countries and regions, on regulatory issues to develop reciprocal knowledge of basic principles and values underlying regulatory developments. Moreover, it is stated that periodic review of solutions, discussions and early policy dialogue within international bodies (e.g. OECD, Ad Hoc Intergovernmental Task-Force on Biotechnology of the Codex Alimentarius, EU/US Biotechnology Forum) ‘may reduce the potential for international friction.’ (Commission 2002: 26-27).

It stems from the Strategy that the EU clearly recognised the need for extending transnational regulation in the GMO field to include various international forums, the institutional structures of which promoted experimentalist governance. In addition it emphasized that this process of norm-generation should be based on periodic review, discussions and dialogue, mutual understanding of the concerns of different states, and support for third (developing) countries. Informal bilateral co-operation was additionally endorsed, facilitated by and institutionalized at the Commission premises. Moreover, the EU seemed to understand that precisely these methods could avoid international conflicts, especially with big trading partners such as the US.

Further relevant declarations and intended activities, based on the same principles and using similar language, can be found in the listing of planned actions (Commission 2002: 43-44). The emphasis in the text on the ‘leading role’ of the

Commission indicates the European wish to extend its vision of the substantive and procedural aspect of GMO regulation to the international level through ‘international scientific consensus’, ‘autonomous choices’ and ‘taking into account conditions prevailing in developing countries’ in order to achieve an ‘inclusive and integrated GMO system.’

It is clear from the analysed document that EU wished to assist in the development of regulatory strategies and approaches which highlight international co-operation, transparency, the involvement of local units through capacity-building of developing countries, public-private research collaboration, and scientific consensus. This prompts an assumption that the objectives of the external European policy regarding GMOs was originally shaped by ideas and concepts in accordance with the features of experimentalist governance. On the other hand, after the elapse of a decade one can find scholarly works (Pollack and Shaffer 2009a) which posit that EU participation in the creation of transnational norms has been mostly limited to political bargaining, governmental negotiations aiming at the unilateral imposition of EU governance and following its interests and strict requirements for market-access. The latter argumentation largely contradicts the Commission’s declarations and prompts the question whether these declarations were paper-based only; and if so, what is the reason for such a disparity between the formulated strategic objectives and the reality of international regime creation. The negotiations of the Cartagena Protocol on Biosafety (CPB) is the first example where answers to these queries will be sought.

Attempts to establish framework goals through multilateral agreements: WTO or Cartagena Protocol on Biosafety?

The Convention on Biological Diversity (CBD)^{iv}, which was opened for signature at the Rio ‘Earth Summit’ in 1992, has now 193 parties (2013) and entered into force on 29 December 1993. It was the first international instrument to contain provisions specifically addressing genetically engineered organisms (see Art. 8(g) and Art. 19 points 3-4). The CBD tackles biosafety through the obligations of the parties to share information on GM products, and a further competence to conclude Protocols ‘*setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.*’ This later constituted the basis for the negotiation of the supplementary agreement to the framework Convention, the Cartagena Protocol on Biosafety (CPB),^v adopted in 2000 (Eggers and Mackenzie 2000; Bail *et al.* 2002).

The CPB, which entered into force in 2003 and has now 163 parties (2013), regulates international trade of genetically modified products and incorporates the precautionary principle, the objectives of human health and environmental protection, and socio-economic considerations. The process of its adoption has been characterised as an example of political bargaining by states or groups of states with strongly defined self-preferences, and their unwillingness to deliberate on a common interest (Pollack and Shaffer 2009a). The EU was strongly supported by the developing countries (the so-called G77, e.g. African States, China) in negotiating the Protocol, demonstrating their will and interest to regulate GMOs within an international environmental agreement. This was done against the so-called Miami Group (e.g. Argentina, US, Canada and Australia) which has contested the CPB, and either refused to sign or ratify the Protocol because of their position, entrenched in their economic interest, that the GATT/ WTO system should apply to GM products (as of 2013 WTO has 159 members).^{vi} The latter group of states has preferred to regulate biotechnology within the system of WTO trade agreements adopted in 1994 – the Agreement on the Application of the Sanitary and Phytosanitary Measures, SPS and Agreement on Technical Barriers to Trade, TBT – which require that

measures possibly restricting international trade in GMOs are based on sufficient scientific evidence, risk assessment, and in principle exclude measures based on the precautionary principle or socio-economic considerations (see Art 5.7 SPS; Scott 2007). There were initiatives undertaken to specifically regulate GMOs under the WTO, but the changes were proposed too late, in 1999, when negotiations concerning the Cartagena Protocol were already well-advanced (between 1995 and 2000), and in particular this approach was rejected by the developing countries (Oberthuer and Gehring 2006: 13; von Homeyer 2006: 278). One of the most prominent and obvious agitators for trade rules regulating GMOs has been the US, both within the WTO regime and the Cartagena negotiations. In the latter however it has participated only as an observer, partly for economic reasons, and partly for formal obstacles, inasmuch as the US has not ratified the CBD and thus is neither a party to the Convention nor can it participate in the Protocol.

In this context, S. Oberthuer and T. Gehring (2006: 13-14) have observed that the WTO lost its ability to elaborate detailed rules for the sub-area of trade in GMOs, which was shifted to the biosafety regime, and which in their view demonstrates, rather surprisingly, the strength of the seemingly weaker environmental measure vis-à-vis the supposedly much stronger trade regime. At the same time, these authors claim that the WTO regime had a great influence on the design of the Cartagena Protocol because many of its parties are likewise parties to the WTO. Thus it was in the common interest of these states to maintain compatibility with their WTO obligations, but the relationship of both frameworks and the scope of potentially conflicting provisions remains unclear (Jendrośka *et al.* 2004: 26-30). Neither political initiatives nor interpretative means through the dispute settlement procedure of the WTO (the Biotech case) have so far made much progress towards the clarification of the relationship between the Biosafety Protocol and the SPS Agreement (Homeyer 2006: 278; French 2010; McMahon 2010).

It seems also uncontested that the EU played a key role in the elaboration and entry into force of the Protocol (Commission 2007; Delreux 2012: 214-231) given that the environment represent a central policy area for EU external action (Wouters *et al.* 2012: 9; Vogel 2012) and although the 'behaviour' of the EU was not necessarily experimental, it was indeed successful in 'uploading' its regulatory model to the international arena. The reasons for this success was also the US refusal to accept any compromise on the precautionary principle as well as the EU's internal capabilities for pragmatic co-operation and co-ordination leading to the convergence of preferences between Member States, enabling them to adjust quickly and responsively to the changing progress of international negotiations and facing the challenge that the issue will be 'taken over' by the WTO (Delreux 2012: 219-227; Rhinard and Kaeding 2006; Kritikos 2004). In effect, the premises of this transnational system are similar to the European ones (although generally less demanding in terms of regulatory requirements) and also reflect the features of experimentalism. In this case the outcome of the political and inter-governmental negotiation process seems to have produced an international system for the protection of biodiversity (the Cartagena Protocol) embodying experimentalist solutions. The specific objective of the Protocol is to ensure an adequate level of protection in the safe transfer, handling and use of living modified organisms (LMOs = GMOs) and to establish a system of GMO trade and movement controls, based on Advanced Information Agreements of importing countries (Lyster 2008 critically). Key aspects of the Protocol, as reflected in its provisions, include: assessment and review, capacity building, compliance, information sharing, monitoring and reporting, public awareness and participation, collaboration of experts, and recently, following adoption in 2010 of the Nagoya-Kuala Lumpur Supplementary Protocol to the Cartagena Protocol on Biosafety, liability and redress as well. Parties have a discretion in implementation in line with considerable flexibility and proceduralisation of provisions, and they need to report on their performance and participate in

assessment and monitoring exercises (Eggers & Mackenzie 2000: 529-531). Besides regular meetings of the Conference of the Parties (COP) (Falkner & Gupta 2004: 8-11), the Biosafety Clearing-House (BCH) is a mechanism set up by the Cartagena Protocol on Biosafety to facilitate the exchange of scientific, technical, environmental and legal information on GMOs, including risk assessments, and enable the parties to better comply with their obligations under the Protocol, taking into account the special needs of developing countries. BCH operates through multi-platform Internet mechanisms which enable collaboration of the parties, either through specific forums devoted to e.g. informal networking of national focal points and experts or portals, e.g. on capacity-building. Strategic Plan of the Clearing-House Mechanism identifies three major goals: the promotion and facilitation of technical and scientific cooperation; the promotion and facilitation of information exchange among Parties, other Governments and stakeholders; a fully operational mechanism with the participation of all Parties, and an expanded network of partners. Its mission is to contribute significantly to the implementation of the Convention through the promotion and facilitation of technical and scientific cooperation among Parties, other Governments and stakeholders.^{vii} Further, the provisions of the Protocol institute the following mechanisms for assessment and review and monitoring and reporting. Once a year a Quarterly Report must be prepared by the Secretariat of the Convention. In addition, parties and other users of the BCH are encouraged to provide the Secretariat with feedback on their experiences with its operation. Such feedback should be made available to the COP, and may serve as a basis for further development of the Biosafety Clearing-House. Therefore, the implementation and operation of the BCH shall be subject to periodic review every five years, which should aim to include consultation with a wide variety of countries and participating organizations. Finally, the Protocol requires parties to monitor the implementation of their obligations under the Protocol and to report to the COP, serving as the meeting of the parties to the Protocol (COP-MOP) on measures taken to implement the Protocol (see also Gupta & Falkner 2006: 28-31, 49-52; Gupta 2000).

10

This attempt to establish common framework goals by the international community through multilateral agreements has given rise to two contrasting interpretations. First, the adoption of the Cartagena Protocol to regulate biosafety of GMOs, together with the WTO system, has resulted in the fragmentation of international law in this area, creating a regime complex where effective transnational regulation is impossible and where conflicts are likely to arise between actors with divergent interests, leading finally to a continuous regulatory conflict (Pollack and Shaffer 2009a). In particular, fears are expressed that trade agreements may undermine the efficiency of the Protocol and the attempts of nation states to regulate GMOs in accordance with their democratic mandates and principles of sustainable development (Lyster 2008: 519).

In the second interpretation, and in a more optimistic and proactive vein, the Cartagena Protocol can be understood as a specific *de facto lex specialis* to the WTO system, especially to the SPS Agreement, which regulates a sub-area of trade in GMOs (Oberthuer and Gehring 2006: 20; Bevilaqua 2007: 336). In this sense, there are two sets of rules, environment-focused and trade-focused, which set different framework goals in the two inter-related domains of environmental and trade regulation of GMOs, realising different objectives and allocating divergent interests. To the extent they do not cause further conflicts between states regarding GMO trade and WTO restrictions, their co-existence is plausible. Authors emphasise that the two instruments can be interpreted in mutually supportive and consistent ways, but this issue, has not yet been settled either politically, judicially, or informal/quasi-judicial interactions between the regimes in the long term.

Collaboration on product safety standards in international public and private Bodies

The second regulatory domain where common goals and metrics are created relating to food and product safety world-wide in the face of GMO risks is that of the creation of standards within international private and public bodies. The EU participates in these structures, where applicable standards are debated and reviewed. In this area it once again aims at playing 'a lead technical role' while pushing for international scientific consensus and an integrated system (Commission 2007). The relevant, key platforms include: the Codex Alimentarius Commission (the "CAC", established within the UN Framework of FAO and WHO), the OECD structures, and International Organization for Standardization.

(a) The CAC Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology was a fixed-term subsidiary body which operated between 1999-2008 (Mason-Mathee 2007). The work of the Task Force concerned preparation of a guidance document for the food safety assessment of recombinant DNA animals and plants modified for nutritional or health benefit. Moreover, the Task Force produced guidelines for the food safety assessment of plants and micro-organisms derived from modern biotechnology (Mason-Mathee 2007: 42; Poli 2004).^{viii} The EU took an active part in the meetings of the Codex Task Force on Biotechnology (Commission 2007; Mason-Mathee 2007: 129-133). European experts additionally participated in the scientific expert groups which assisted the work of various task forces, e.g. at Joint FAO/ WHO Expert consultations on Food Safety Assessment for Foods Derived from Biotechnology (Mason-Mathee 2007: 42). Moreover, informal but structured contacts between scientists, which have a great influence on the institutional relationships between the EU (EFSA) and the Codex Alimentarius, had already been established and they seemed to intensify and tighten the mutual co-operation (Mason-Mathee 2007: 129-130).

The evaluation of the work of the Codex Task Force against the experimentalist governance architecture induces a mixed interpretation. On the one hand, the authors emphasise that since Codex standards create a presumption of compliance with the SPS Agreement and have a harmonising capacity at the global level (Mason-Mathee 2007: 135-197), the work of the CAC has undergone a process of politicisation and became a forum for intergovernmental bargaining, especially between the EU and US, the two most powerful actors in the field (Pollack and Shaffer 2009a: 162-174; Poli 2004). And indeed it seems to affect some of the Codex discussions relating to biotechnology, e.g. labelling of GM products.^{ix} On the other hand, however, it is admitted that the very structure of Codex, with its functioning based on exchange of information and reporting according to pragmatic needs, deriving its legitimacy based on transparency, broad participation, and consensual decision-making, generally makes it an adequate forum for deliberative problem-solving and revision of created standards (Krisch 2010: 27; Mason-Mathee 2007: 279-284). Even authors critical of the work of the Task Force point out that the first phase of its operation was a success, creating a working deliberation towards consensus (Pollack and Shaffer 2009a: 167), and that only the second phase of its work was affected by political interests. Finally, it is submitted that Codex has constantly been working on reforming itself to improve its legitimacy through the enhancement of transparency, participation, and consensus in decision-making (Mason-Mathee 2009: 337-341). In fact, it was the EU who was constantly advocating transparency and a system based on sharing information and detection of GMO products in case of risk of contamination within the present context (Krisch 2010: 27, who cites a positive report of the US Delegate; Pollack and Shaffer 2009a: 168 for an entirely different interpretation).

(b) The OECD setting with its Working Group on Harmonization of Regulatory Oversight in Biotechnology^x, founded in 1995, is the next example which needs to be mentioned in the present context. The primary goal of the Working Group is to promote international regulatory harmonisation for transgenic crops (Mason-Mathee 2007). The Coding System for the development of unique identifiers of GM products

is the most prominent example of a standard developed by the Working Group and now used world-wide.^{xi} Moreover, the Working Group produces compilations of information i.e. *Biosafety Consensus Documents*, that can be used in the risk/safety procedures. Consensus documents comprise technical information for use during the regulatory assessment of products of biotechnology. They are intended to be mutually recognised among OECD Member countries. These documents are updated to take into account new knowledge on a topic. In order to assist in this, stakeholders can also make comments to the OECD on the Biotechnology Consensus Documents. This decision-making process makes the Working Group a good example of experimentalism in transnational governance of biotechnology. And again, its operation demonstrates that it was a forum of deliberative problem-solving (Pollack and Shaffer 2009a: 142) although primarily related to risk assessment issues.

(c) Finally, the International Organization for Standardization (ISO)^{xii} is the third forum – and a private body – where the development of international standards relating to the use of GMOs takes place (Buethe and Mattli 2011). The ISO Committees which work in the field of biotechnology are above all the Committee on reference materials (REMCO) and Committee on conformity assessment (CASCO).^{xiii} Although, the Members of ISO are primarily national standards institutes and industry associations, the European Commission Joint Research Centre (JRC), who at the EU level works closely with the European Network of GMO Laboratories, is able to participate in the work of the ISO because it has an agreement with CEN (European Committee for Standardisation). CEN and ISO entered into an Agreement on technical cooperation and standards to be developed in parallel, e.g. when ISO and CEN agree to submit relevant and approved work items within the same scope to parallel procedures, with agreement on leadership (the Vienna Agreement^{xiv}). Accordingly, the JRC has made significant contributions to the development of international guidelines and standards for bioanalysis (Commission 2007; IHPC Annual Report 2004).

To summarise, the relevant institutional channels and mechanisms in this domain take the form of transnational networks of various types (intergovernmental task forces, working groups, inclusion of private stakeholders) which can be said to generally follow the experimentalist approach. In the aim of establishing and revision of scientific and technical common goals related to GM risks and metrics to measure their accomplishment, they allow for broad participation of stakeholders at various levels of governance and in different international configurations, the exchange of information on GMO risk-related issues, and the review of agreed-upon standards in view of national experience. This input of various lower-level units and plurality of international institutional structures and participating actors and states also seem to stimulate the correct implementation of multinational agreements in the long-term (e.g. the implementation of the Cartagena Protocol) and accommodate diverging preferences which excluded the adoption of one, unified GMO-related international treaty. Although periodically political bargaining over particular interests has become visible within the decision-making processes in some of these networks, they were also able to work out effectively guidance documents, recommendations, or private standards relating to various aspects of the use of GM products.

Co-operation of EU and US civil society stakeholders

When analysing the first phase of the creation of the GMO transnational regulations, the informal co-operation of scientists and stakeholders should also be addressed. Informal and bilateral dialogue platforms with trading partners, especially the US in the form of EU-US Transatlantic Consumer Dialogue^{xv} ('TACD'), and EU-US Biotechnology Consultative Forum, have been specifically established by the EU to foster co-operation between the EU and the US and in order to facilitate the resolution of potentially conflicting issues (see Alemanno 2011: 211; Murphy 2001:

127ff for a positive assessment; and Pollack and Shaffer 2009a: 107-108 for a contrasting one).

TACD has been a forum of US and EU consumer organizations which develops and agrees upon joint consumer policy recommendations to the US government and the European Commission related to food, electronic commerce, trade, health and intellectual property issues, and aims at increasing the involvement of civil society in transatlantic policy-making at annual conferences.^{xvi} They have submitted five specific recommendations regarding pro-consumer and EU-supported GMO policy (1999, 2002, 2003, 2004, 2006),^{xvii} although they were largely ignored by the US government at that time. Interestingly, members of TACD also submit comments to Codex Alimentarius, attempting to influence the outcome of work in that body. This body is also enumerated as ‘advisory group’ to guide the work of Transatlantic Economic Council which has recently recommended the negotiation of a bilateral trade and investment agreement between the EU and the US.^{xviii}

The initiative known as the EU/US Biotechnology Forum constitutes another good example of informal co-operation and dialogue between the two sides of the Atlantic (Alemanno 2011: 210-211). It operated throughout the year 2000 as a group of experts (ten from each side), drawn from different areas related to biotechnology (including scientists, lawyers, consumer representatives, specialists on ethics, farmers, environmentalists and people in business). The dynamic created by the Forum’s broad range of stakeholders resulted in a constructive dialogue that permitted it to address the most immediate issues related to agricultural biotechnology, which were included in the Forum’s mandate.^{xix} Alemanno emphasises that ‘(...) *they managed to agree on a core set of common principles that could have inspired their respective regulatory frameworks.*’ (Alemanno 2011: 211; see Pollack and Shaffer 2009a for a critical assessment). After 2000, the Forum exercise was not repeated, but it can be argued that this was due to the establishment of the European Food Safety Authority, which overtook the organization of both informal and more institutionalized contact between the EU, US and other third countries’ scientists, as well as the creation of the Joint Research Centre, which manages EU research on GMOs.

When one thinks about the bilateral scientific co-operation, it is clear that they offered an opportunity for meetings, discussions, and exchanges of information and experience. They importantly broadened the circle of stakeholders whose views could assist in revision of contentious policy issues. There is no evidence that the views expressed have been directly reflected in the revision of policy objectives (Pollack and Shaffer 2009a: 107-108), but this may have been the result, at least

partially, of the unwillingness of the US Bush administration to give an ear to non-industry stakeholders. Moreover, a direct translation of policy recommendations into immediate governmental actions were not the objective of these initiatives. Yet, they offer evidence that bringing stakeholders together in policy-making processes regarding GMOs can nevertheless boost the future regulatory co-operation in the long term and enhance the revision processes, and we do not know how many further conflicts may have been avoided owing to their establishment. '*This experience, by going beyond the model of pure regulatory co-operation among government agencies, proved a valuable tool for exploring broad public consensus in biotechnologies*' (Alemanno 2011: 211).

In appraising the first phase of the transnational regulation of GMO risks against experimentalism, the following observations should be made.

First, when one considers both trade and environment regulations and policy fields, there has been a regime complex and fragmentation of international law resulting from a failure to establish uniform framework goals through one international, universal treaty or agree on shared, identical values in one regulatory public domain. Political visions and interests have affected the understanding of preferences, and their underpinning values (e.g. precaution vs. solely science-based regulation), which in turn shaped actors' (i.e. states') positions in various international institutions. In effect, outcomes of decision-making processes were based on political bargaining with fixed positions of the parties rather than on ideal-typical Habermasian deliberation leading to an immediate reshaping of actors' positions. There seemed to be also a certain degree of adversarial attitude between the actors in long-term negotiations over GMO risks which escalated the 'conflicting atmosphere'. The institutionalisation of disagreement took place in May 2003 through the WTO when US joined by Argentina and Canada filed complained against certain EU measures on GMOs.

Second, the EU has made various attempts to extend its governance of GMO risks. It used market access conditions as a means to influence transnational GMO regime and aspired to convince the rest of the world of its 'political' vision of risk, precautionary principle and environmentally-oriented regulation (as opposed to trade-oriented) as the best solution for shaping the future, international GMO regime. In this sense, it can be seen as pursuing its own political interest, and, at least to some extent, there was a disparity between the declared need for experimentalism in the external governance of biotechnology and actual behaviour (e.g. during negotiations of the Cartagena Protocol). But to claim that EU was acting in a strictly unilateral manner is somehow over-simplistic, especially because the internal EU governance on GMOs and external regime were 'linked' through experimentalist features and the EU rules were not created solely for a later 'unilateral uploading'. In addition, the assessment of the EU's actions on GMOs needs to relate to the role EU plays in the forming of standards of global environmental regulation which mirror its regulatory stringency (Vogel 2012) and its preference for multilateral mode of governance (Wouters *et al.* 2012: 4; de Búrca 2012).

Finally, while the contestation over GMOs signalled the difficulties involved in transnational regulation, it was also 'evidence of how much co-operation can be achieved in spite of deep-seated disagreement' (Krisch 2010:21). Thus we can observe institutional structures which offer a great deal of room for consensus building to agree on common goals and metrics in technical and scientific circles

(although not always through entirely deliberative processes, at least, in the short term analysis), sharing of experience from regional and local contexts, and revision of agreed terms in view of this experience. Some political processes lead nevertheless to the establishment of experimentalist regulatory structures (like the Cartagena Protocol). So while there was a relative failure in the first phase to definitively establish common framework goals (such as ‘precautionary trade of GMOs’) within one multilateral treaty, partial success was achieved in the establishment of common objectives relating to GMO risk analysis and safety assessment, common metrics, in view of national experience and fragmented revision of practices.

After the WTO decision: EU and the transnational regulation of GMOs post-2006

The second phase of the transnational GMO regime can be identified after the GMO dispute was decided by the WTO Panel in 2006.

WTO case: failure, destabilisation and a new reality – different approaches but common interests?

The WTO complaint, filed in May 2003, came as a relative surprise to the European Commission, which at that time was convinced that bilateral co-operation with the US through means of institutionalized civil society structures and negotiations would allow to avoid the dispute.^{xx} This seemed true especially in light of the constant updating the US authorities provided of legislative developments that were in the pipeline. In fact it was just about this time when the European Parliament tabled a report after the second reading of the new GM Food and Feed Regulation, with numerous amendments, posing the threat of a conciliation procedure and of possibly lengthening the legislative process for another year. The Commission feared that the WTO complaint would firm up the position of the EP and the non-adoption of the regulation. Yet, the shadow of the WTO complaint fostered the horizontal deliberation between the EU institutions and the informal dialogue during the legislative process allowed for the adoption of GM Food and Feed Regulation by the Council on 22 July 2003.

15

On the other side of the conflict, the US authorities had been observing the widespread acceptance of the precautionary principle following the ratification of the Cartagena Protocol. When their GM food aid was rejected by some African States on the precautionary grounds, they decided to move on the case with, it has been argued, the actual hope of discouraging the third-world and developing countries from following the EU approach, which involved real economic losses (von Homeyer 2006). Finally, the WTO Panel report of 29 September 2006 decided that the EU de facto moratorium on product approvals, and national bans on GMOs, were unlawful under the SPS Agreements, but it is also noted that the Panel took the procedural approach in addressing the conflict, either not being able to or not wishing to

evaluate the substantive issues of scientific uncertainty, GMO risks, and political preferences (Scott 2009; Gruszczynski 2011).

The later factual developments of the WTO case may be summed up as follows: Disputes were settled with Canada and Argentina in 2009 and 2010 respectively after some GM approvals in the EU (Vogel 2012) and through mutually agreed solutions, which provide for the establishment of a regular dialogue on issues regarding Agriculture Biotechnology.^{xxi} The US and the EU first turned to the litigation strategy (Poli 2010a: 134) through requesting an arbitration procedure under Article 21.5 of the Dispute Settlement Understanding of the WTO, which has aimed at the examination of compliance of the panel report by the EU, but agreed to suspend it in February 2008. Since then technical discussions have been continuing with the goal of resolving the dispute and related issues (the last technical meeting was held in March 2012).^{xxii} In view of the launch of negotiations of the Transatlantic Trade and Investment Partnership between the EU and the US in February 2013, it might be that the procedure will not be resumed.^{xxiii}

There are two interpretations of the WTO case which are relevant for the present context.

First, it can be seen as a ‘failure’ in the sense that its outcome has led to neither an immediate discontinuity of the GMO conflict nor its definite solution through the rapid policy redirection or evidently more effective market access for GM products in the EU (WTO has not imposed authorisations, Poli 2007). Several scholars criticised the content of the Panel’s report for taking a legally-literal position on the non-application of multilateral environmental agreements not ratified by all parties in the WTO framework (i.e. neither the Cartagena Protocol, nor the Montreal Convention on Biodiversity) (Joerges 2009; French 2010; McMahon 2010), and not recognising the precautionary principle as a principle of international law (Provost 2004). By doing so, the Panel arguably missed an opportunity to assemble the fragmented international regime on GMOs, although such an interpretative possibility through an application of the proceduralised version of the precautionary principle was not excluded by the Panel report (Gruszczynski 2008). It also did not address the socio-economic concerns of GMOs which are crucial for some EU Member States, as advocated by the *amicus curiae* brief (Winickoff *et al.* 2005).

Second and more importantly, the significance of the WTO case can be explained as providing a crucial destabilisation mechanism to unblock the relative regulatory impasse in co-operation and framework rule-making on GMOs (Sabel and Zeitlin 2012: 176-177). It happened through the obligation to explicate the EU unilateral conditions for GMO market access in a multilateral WTO setting and opening up a forum for participation by states who are not involved in the transnational environmental GMO regime (Cartagena). In this sense, it afforded an external reflexive discipline for the EU (although it might also have intensified Member States’ national opposition towards GM approvals). In the long-term, it also prompted amicable settlements between the parties and promoted regulatory co-operation between the EU and the US as an alternative institutional mechanism (e.g. Transatlantic Risk Assessment Dialogue established in 2008, Alemano 2011: 213-14). As a result, the post-WTO era seems to have brought about a new reality where the parties to the conflict tempered somewhat their willingness to escalate it further.

Oberthuer and Gehring (2006: 26) have observed that the joint membership of many parties in the WTO system and the Cartagena Protocol in fact created a shared interest in avoiding conflicts and incompatible commitments, owing to the accepted regulatory objectives of both regimes concerned. They further submit that (...)'despite the diverging interest of member states as to the appropriate balance' between the environment and trade aspects 'features of international governance drive the institutions towards an accommodation' and so 'there is a good chance that both regimes will develop further in consistent ways in the future'.

EU-US co-operation on emergency measures against unauthorised GMO release^{xxiv}

The release of the 2006 WTO Panel Report on GMOs coincided with the adoption of the European Commission Decision 2006/601/EC concerning emergency measures on non-authorised genetically modified LL Rice 601.^{xxv} On 18 August 2006 the US authorities informed the Commission that rice samples taken from the US 2005 crop market proved to be contaminated with the GM rice called 'LL RICE', which were authorised neither in the EU nor in the US. As emergency measures, the EU decided to require each consignment of relevant US rice products to be accompanied by a certified report of an accredited laboratory attesting that the product does not contain 'GM LL RICE 601', and to carry out systematic official sampling and analysis of each US consignment of products concerned before their placement on the market (FVO 2008a).

In response the USDA submitted a proposal for a protocol to the Commission that would ensure that the products concerned are subject to official sampling by the US Grain Inspection, Packers and Stockyards Administration (GIPSA) and analysed using the 'P35S:BAR' method, which was verified both by the US (GIPSA) and EU (JRC) authorities. In the text of the proposal the US authorities explicitly referred to the EU Sampling and Detection Recommendation as an appropriate guidance for seed testing, and agreed to the EU level of GM traces detection (set at 0.01 %).^{xxvi} This protocol became a part of the Commission Decision reviewing the emergency measures provisions.^{xxvii} In parallel the USA Rice Federation of industry (growers, merchants, millers and exporters), developed and implemented a 'seed plan' in response to the LL rice contamination. The aim of this plan was to eliminate LL rice traits from the US commercial market, which affected US exports to many rice customers as EU, Japan, Iraq, Cuba, Korea, Philippines, Taiwan and Russia. This 'seed plan' was a US rice industry recommendation to the rice growing state authorities and included: seed testing, certification for mills, and education and training programmes to ensure that all sectors of the industry understood the requirements (FVO 2008a; see also Strauss 2012: 307-308 for industry's role in reshaping US public policy).

Moreover, EU's Food and Veterinary Office carried out a mission in the US in 2008 to evaluate the US Government's and industry's actions related to the EU emergency decision. The initiative concerning the involvement of public authorities (GIPSA) and the evaluation of the US control system by the FVO reassured the EU which removed the requirement of official testing of each consignment. Finally, as a result of the co-operation process aimed at the avoidance of admixture of the contested GM rice with rice exported from the US to the EU, the Commission Decision on emergency measures was repealed.^{xxviii}

During the aftermath of the 'LL RICE 601' problem in October 2007, the USDA-APHIS informed the Commission of revisions under consideration for the Biotechnology Regulatory Framework to strengthen its oversight of field trials. The published document identified up to ten areas under consideration to enhance the regulatory framework (e.g. a requirement to create and retain additional reports for quality and completeness: requiring applicants seeking the experimental release of GMO to submit a contingency plan and a written corrective action plans; a

requirement for business agreements between GM technology researchers to be in writing, taking into consideration the sufficiency of isolation distances between experimental crops and nearby field crops; encouraging the use of quality management systems throughout the biotechnology research community; and electronic storage of all information associated with permits and notifications, FVO 2008a). As part of this review, an interagency memorandum was signed to strengthen the collaboration and information flow between APHIS, AMS and GIPSA when responding to incidents of low-level presence of regulated, GM material in commerce (USDA 2008: 15).

The development of state laws to address the contamination also took place: Arkansas adopted state legislation ensuring that contaminated rice will not enter the food chain and establishing a system of inspection, controls, sampling and testing. Both California and Louisiana issued regulations similar to the one adopted in Arkansas. The USA Rice Federation recommended the extension of the industry 'seed plan' into 2008, and states of both Arkansas and Louisiana extended seed testing regulations into 2008 (FVO 2008a; see also Strauss 2012: 304).

This case exemplifies the following positive aspects of EU-US collaboration: (i) the satisfactory results of public investigation and control (pursued by US authorities and EU's FVO); (ii) the existence of the US Rice Federation plan for seed testing and products' control; (iii) the implementation of the industrial plan, which allowed for negative tests results for the presence of 'LL RICE 601'; and (iv) regulatory developments in five rice growing states: Arkansas, Mississippi, Louisiana, Texas and Missouri (FVO 2008a).

Arguably, this example of co-operation was much more experimental than some of the previous EU-US collaborative initiatives. In support of this postulate the following features should be taken into account. First, the co-operation occurred in view of a pragmatic need for concrete problem-solving related to risk of GMOs, and was not based on any earlier negotiated legislative measure. There was an agreement on the goals to be achieved, and the methods for their achievement and the metrics for measuring them were worked out during the course of the co-operation process. Second, regarding the institutional arrangements of the co-operation, there were direct meetings between public officials and stakeholders at various levels of governance (FVO with US authorities; FVO with US Rice Federation and American Seed Trade Association; US representatives with SCFCAH; Commission officials with US authorities, US Rice Federation with the Commission and MS Representatives, US industry and officials presenting their position directly to the SCFCAH), and parallel and co-ordinated private and public actions in the US and EU to resolve the problem. Moreover, the relevant private and public actors participated in a 'peer-review' exercise aimed at achieving the agreed-upon objectives, i.e. the FVO mission to the US where the inspections carried out were undertaken in collaboration with and employing the assistance of the USDA, EPA and FDA officials, and USA Rice Federation. This mission included visits to central and regional authorities, public and private laboratories, and three different food establishments (e.g. rice miller, food sampling point).

The processes of decision-making (as compared to previous experiences) seemed to be based on broadening the circle of actors involved in problem-solving, goal-setting, and revision. It included not only federal public officials, but also incorporated the input of 'lower-level units', such as local-state US authorities, industries, and industry federations. In addition, the exchange of information and experience between actors was critical to achievement of the traceability of the unauthorised GM rice and seed testing. The reporting by actors within their local settings and to each other also occurred (MS – review obligations and RASFF and US state authorities). In light of these reports and the efforts undertaken by the actors to curtail GMO risks, timely reviews of the necessary steps and emergency measures took place (the EU Decision was reviewed four times between 2006 and 2010, based

on the information provided by EU Member States and US partners). The private actors (the seed industry) also declared the need and their will to undergo further voluntary monitoring, GMO testing, and review of their policy in order to avoid further risks and in view of market needs (FVO 2008a; see also Strauss 2012: 304-312).

As a result, a process took place whereby the technical and scientific aspects of the transnational regime, the EU GMO regime, the US state regulatory measures, and private practices gradually influenced each other (a kind of a bottom-up policy change). For example, international private standards, especially of testing and sampling methods (endorsed also in the EU regulatory framework), were applied and followed, which at the same time, raised awareness of the need to establish tools for monitoring both risks and the unauthorised presence of GM materials in products in the US. It seems that systems developed in US to deal with this particular case of GM rice contamination followed in part the EU regulatory examples (laboratory testing, detection methods, the traceability concept). To a certain extent, there was also a mutual influence of regulatory actions: the US referred to EU recommendations on sampling and testing in its state laws, and the EU accepted the private certification scheme established by US Rice Federation. Finally, specific legislation on the low level presence of unauthorised materials in feed when authorization is pending or expired was later adopted in the EU.

In addition, USDA officials declared to the Commission that there was a need for an in-depth review of the existing US Biotechnology framework on the basis of the lessons learned from these incidents, and its recommendations for reforms greatly resemble the current EU approach. It appears that the EU rules empowered US domestic actors concerned about the weaknesses of the national segregation regime with arguments for reforms (see also Strauss, 2012: 268-272; 2006). The co-operative handling of this case also differed significantly from a similar GM contamination case which occurred in 2005 (Pollack and Shaffer 2009b: 287).

Similar two cases and emergency measures concerned EU's finding the presence of unauthorised CDC Triffid FP967 in linseed originating from Canada and of unauthorised Bt63 rice from China. The co-operative outcome seemed to depend on the performance and capacity of the partner state. While the control system presented by the Canadian authorities to the SCFCAG (comitology committee) was considered sufficient not to take emergency measures, the collaboration with Chinese authorities appeared as more difficult in terms of reciprocal communication and their willingness to provide GMO samples (FVO 2008b). All the three described events were also communicated through and included co-operation via RASFF (Vos and Weimer, forthcoming).

A momentum toward co-operation in transnational GMO regulation?

When one analyses the developments over the second phase of the transnational regulation of GMO risks in various regulatory and governance settings, which were investigated in part 3 of this chapter, they seem to differ from the pre-WTO period. The conflict, especially between the EU and US, that culminated in the 2006 in the WTO dispute has recently, and especially somewhere in between 2008-2010, lost its pace. More generally, in the post-2006 era a spirit of co-operation may have been re-emerging in the field of GMO risk regulation together with the tendency either to include more participants in the policy-making, or to re-shape horizontally the circles where exchange of information and collaboration on GMO safety takes place, or to diminish political bargaining based on narrowly defined states' interests. Against the experimentalist features, one can see the post-WTO period as a phase when local units have been 'applying and testing' the partially-established framework objectives/metrics to measure their implementation within their domestic settings and international circles where they belonged. In parallel, there have been processes indicating partial revision of goals and broadening groups of actors to address problems in view of the transnational experience.

These views can be supported by several manifestations. First, the international arena appears to be characterised by intensified attempts to achieve reconciliation on the basis of technical co-operation and exchange of information and best practice, and not by the conflict-escalation between the trade and environment regulatory domains. For example, the Codex Task Force on Biotechnology completed its work one year ahead its schedule, *inter alia*, on the low-level presence of recombinant-DNA material in food as proposed by the US (Pollack and Shaffer 2009a: 168), which was adopted by consensus^{xxix} and on the modification of guidelines for the food safety assessment of plants and micro-organisms derived from modern biotechnology (revision in 2008).^{xxx} In 2010, the Global Biotechnology Forum was founded to assist the OECD Committees working in the field of biotechnology in hearing the views of non-Members and other stakeholders of multidisciplinary, multi-regional, and multi-cultural background and to foster partnerships with other intergovernmental organisations (OECD 2012: 4). The OECD Bio-track database was also reformed in 2010 to provide a more user-friendly public access to GMO product information, but also to the outcomes of work of the OECD bodies active in the field of biotechnology (e.g. consensus documents). In addition, the OECD coding system of unique identifiers for GM products, also implemented in the EU, can now be said to function universally (OECD 2012: 8). There is also growing evidence of continuous external collaboration through research workshops, GMO analysis training courses, scientific exchange and capacity-building initiated by the EU bodies: EFSA and Joint Research Centre (Vos and Weimer, forthcoming). JRC is the main channel through which the EU promotes standards for GMO traceability, sampling, and validation of detection methods world-wide (which are simultaneously a result of international and EU-national, public-private network co-operation) and institutional practice of networked laboratory collaboration (following the example of ENGL) on these standards.^{xxxi}

Second, there are monitoring, assessment and peer-review processes taking place in the framework of the EU-third countries co-operation under the FVO controlling and reporting powers (Vos and Weimer, forthcoming) and within international settings of the Cartagena Protocol. The latter regulatory instrument is expanding its significance and territorial scope; and its systemic, normative build-up and established structure of governance resemble clearly the features of experimentalist architecture.^{xxxii}

Third, there was some evidence of mutual regulatory adjustment and learning between the EU and the US in the face of a concrete GMO risk (and an experimental process was involved in the resolution of the problem). The events disclosed that the differences between the US and the EU in regulatory approaches towards environment and trade does not prevent collaboration on risks arising from biotechnology. In addition, there is some indication of convergence of US and EU practices in the context of the application of private standards in food safety. It is argued that new public regulations in US will have consequences similar to those arising from the widespread adoption of private standards in Europe (Humphrey 2012: 1000-3).

Fourth, there has been an internal 'greening' change occurring in the US recently offering perhaps a potential for more co-operation in the transnational risk regime on GMOs (Strauss 2012; 2011; Humphrey 2012: 1000-3; Endres 2012) although it is difficult to predict its future development (Vogel 2012: 234-235). The new Food Safety Modernisation Act was adopted in 2010 and in 2011 US Congress passed legislation prohibiting FDA from approving GM salmon and requiring labelling in case a GM fish is approved following an earlier Californian initiative (Strauss 2012: 298-

306). Moreover, state-level initiatives, private associations and the general public seems to begin to mobilise towards a more stringent regulatory requirements for food (e.g. labelling), including GM products in the US. A recent ABC News survey (2011) reports that 92% of American public wants federal government to require mandatory labelling of GM foods and 55% says it would avoid such products if they were labelled (after Strauss 2012: 270). Farmers' private litigation against seed practices of biotechnology corporations might also play a role in evolution of approach by regulatory agencies if courts pursue a more restrictive judicial review (Strauss 2012; Endres 2012). In the light of Vogel's conditions allowing for the policy discontinuity (intensity of public pressure, political preferences of influential policy-makers and the policy criteria used to assess and manage risks, Vogel 2012: 294), the above events may make a good start.

Finally, the on-going internal political disagreements over GMO approvals in the EU can also be a good moment for the intensification of the regulatory co-operation with the US (Alemanno 2011: 216). The next section returns to the developments of EU domestic regime on GMOs to complete the analysis.

Reshaping the EU domestic regime on GMO risks post-2006 – responsiveness to internal and external factors

21

The EU GMO regime, like many other areas of European policies, functions between external and internal reality (Pollack and Shaffer 2004). This forces the EU to be more open and accommodative for a diversity of problems at various levels of national/ international governance and requires more adapting capacity to changing political and scientific environment of risks. That is, EU has to follow global disciplines as WTO and the Cartagena Protocol, but also accommodate its internal political reality, constitutional structure of comitology decision-making and judicial developments^{xxxiii}. The general EU architecture is well designed to cope with these tasks (Sabel and Zeitlin 2010).

Analysis of how transnational developments have been feeding back to the EU domestic regime on GMOs in the post-WTO period reveals Moreover, two types of effects of transnational processes can be captured: (i) a visible adaptation of regime through statutory/ institutional developments; (ii) indirect responsiveness in the long-term through recursive revision of policy in view of identifying, monitoring and assessing problems determined by experience of lower-level units and on the basis of performed peer-reviews. It must be also emphasised that each of these effects has been equally influenced by EU internal factors.

One possible example of the first type of effect is the adoption in the EU of the so-called Regulation on Low Level Presence (LLP).^{xxxiv} LLP problem means adventitious presence of non-approved GM material in non-GM or approved GM products and it is connected with asynchronous authorisations world-wide. The issue was first debated in the Codex and OECD settings around 2006/2007 as advocated by the US and it was then adopted as an annex to CAC standard in 2008. Later it reappeared as a general issue in the EU-US co-operation on LL Rice 601 in 2006-2010, and finally entered EU legislation on feed. The act is a pragmatic solution, which is based on strict EU requirements of 0.1% threshold and EU-advocated standards for detection, to meet the reality of international trade, possible risk, and the EU need for

import of certain (GM) products. The Commission after the impact assessment feedback from the industry and discussion in the SCFCAH considers the extension of its scope also to food and seeds.^{xxxv} Other examples include the regulatory developments stemming from the Cartagena obligations or the revisable emergency measures adopted to deal with risks of unauthorised GM products communicated through RASFF. Finally, the WTO Biotech case, as an external, deliberative discipline (Sabel and Zeitlin 2012: 178), prompted the change of institutional practice in the EU, that is a re-start of GMO authorisations already in 2004 (Poli 2007; 2010). All these examples demonstrate that the EU internal GMO regime has been modified and mitigated, at least in part, to take account of external developments within multilateral foras or bilateral relationships (e.g. co-operation on imports of products from a third country where GMO adventitious admixture took place Vos and Weimer, forthcoming). The need for regulatory modifications also reinforce d two central, experimentalist features of the EU internal regime, that is: (a) constant attempts made by EU actors to respond to GMO risks under conditions of uncertainty and in view of experience (b) on-going recursive revision of goals and reflective approach to the GMO policy.

But the causal relations also run in the opposite direction. Transnational developments can support EU internal experimentalism, but they can also cause increased political tension and bargaining between actors. The latter may often lead in the longer-term to the need for more co-operation and further revision of agreed objectives (type ii effect above). The initiation of the WTO biotech case and the later implementation of the Panel ruling in the EU can serve as an example.

First, the WTO dispute prompted resuming of GMO authorisations in the EU and offered a legitimising argument for the Commission to apply strictly the procedural steps in GMO approvals (in line with comitology rules, see also Poli 2007). The Commission has been authorising GMOs through its final decision since almost 10 years and the imposition of its hierarchical power in the lack of Member States qualified majority or consensus did not foster more deliberation in the shadow of hierarchy (Dąbrowska-Kłosińska 2012; cf. Boerzel 2012: 378-384). It means that the Commission's behaviour implementing the WTO ruling through legal formalism and procedural efficiency might have intensified the firmness of national positions on GMOs or national opposition against individual GM products approvals.^{xxxvi} Moreover, the safeguard clauses which were found WTO-incompatible remained in place thanks to Member States' QMV decisions and the new ones were also accepted (Poli 2007: 724-5). WTO's requirements for a strict scientific discipline could also cause the Commission's unwillingness to recognise national public concerns and socio-economic factors as legitimate obstacles to GMO approvals (although it would be possible under the EU GM Food and Feed Regulation). In sum, it can be said that in relation to the EU GMO approvals the WTO dispute 'favoured' statutory proceduralisation and structured, institutional decision-making, but at the same time gave reasons to more political bargaining.

From this perspective, the WTO did not help, but also could not help to resolve the main EU internal problem with GMOs: political conflicts over GMO authorisations, especially for cultivation, and disagreements over EFSA scientific decisions and its authority (Dąbrowska-Kłosińska 2012; Poli 2010a: 147-48). Put another way, the WTO external discipline assisted reinforcement of the legal and institutional EU governance on GMOs, but it could not remove the structural obstacles in the functioning of the regime, that is the political stalemate and the problem with democratic legitimacy of Commission's decisions for product approvals against the inability of Member States to reach qualified majority of votes in favour or against a GMO concerned (Dąbrowska-Kłosińska 2012; Poli 2010b; cf. also Navah 2013).

On the other hand, the efforts of the Commission and EFSA to implement the WTO ruling effectively have also brought about more experimentalist practices (Dąbrowska 2010: 209-10). Especially, between 2006-2010 (as compared to 2001-

2004), there was a tendency to increase co-operation, and reciprocal understanding in decision-making processes, and also transparency of GMO websites of the Commission (Poli 2007: 725-6). For example, informal EU-MS co-operation outside normatively prescribed steps and time-limits in the aim of building a wider consensus took place through: referring questions back to EFSA by the Commission, direct meetings between EFSA officials and national authorities in SCFCAH to address MS concerns on applications directly. EFSA also attempted to improve on several issues where it was subject of criticism or sanctioned (Poli 2007: 725) what included networking and consultation with Member States: it has been slowly evolving from a sole Internet-based networking to a regular meetings and personal contact policy (since 2008).^{xxxvii}

But personnel changes could also throw these developments into reverse. For example, just after taking his office, in March 2010, new Commissioner John Dalli proceeded with approval for cultivation of GM potato causing surprise and disappointment in many Members States, who believed that the process of scientific and administrative co-operation on this file was not over. In 2012 the European Parliament refused to grant discharge to the agency's budget for 2010 due to claims on the lack of independence, among other problems, when it came out that the chief of EFSA Management Board worked simultaneously for a biotech-sponsored Institute and went to work there directly after resignation.^{xxxviii} It caused national distrust in the EU's practices and made settling deliberative practices more difficult for the future,^{xxxix} but also re-emergence of the need for further revision of the GMO regime objectives.

In the post-WTO era, several review exercises were undertaken at various levels of governance to unblock the political deadlock. The Commission held two 'orientation debates' already in 2004-5 (Pollack and Shaffer 2009b: 285-86). In 2008, President of the Commission Manuel Barroso and the French Council Presidency proposed initiatives to find solutions in view of national and public reservations to the GMO regime (Carau 2009). Finally, in addition to regular report on the implementation of GMO legislative measures, a general evaluation process was launched by the Commission and conducted by two independent consultancies on the basis of input provided by Member States and broadly involved stakeholders (EPEC 2011). The results were published in 2011 and 2012 and analysed deeply the problems associated with the functioning of GMO approval procedures in the EU with the conclusion that '*The 'dysfunction' in the system arises as a consequence of a complex set of factors, both external and internal to the authorisation process.*' These evaluation exercises should be interpreted as an evidence of experimentalist dynamic accountability in the regime. They offered independent assessments and peer-review exercise based on broad participation of lower-level units, their knowledge and experience. The reports also openly acknowledged 'complexity and ambiguity' of problems (Sabel and Zeitlin 2012: 173) and the need for the policy revision which has been currently taking place in form of statutory developments and proposals. The principal aspects of the proposed reform provide for a modification which should be welcomed from the perspective of experimentalist governance (cf. Weimer 2010).

First, there is an institutional revision. A new EFSA policy on independence and transparency towards the public after the EP heavy censure proposed together with a modification of approach towards direct meetings between scientists and the public (EFSA 2012ab). After years of hesitation EFSA decided to open Panel meeting to the public, for which it had long had the competence, but refrained from its application (EFSA 2012cd). It is accompanied by an internal process of competence simplification within the Commission (unifying the GMO responsibilities under the competence of DG SANCO).

Second, the Commission proposed re-nationalisation of GMO cultivation to allow Member States to decide individually on the restriction of GMO cultivation on the

basis of socio-economic concerns. The proposal was accompanied by the maintenance of the soft national co-ordination on co-existence of GM and non-GM products. By doing so, the Commission implemented the recommendations of the evaluation reports and attempted to respond to the 13 Member States growing demand to have the possibility to opt-out from GMO cultivation (Commission 2010a; Commission 2010b). So the proposal responds to national demands, as it increases flexibility of GMO provisions, further decentralises EU powers, and allows for differentiated integration, but it can be equally advantageous for international trade through offering a potential of resolving the regulatory deadlock (Poli 2010b: 344). Yet, it is also not entirely clear whether this solution will be WTO-compatible as not following a strict scientific discipline (Poli 2010b: 342).

Third, the new Regulation for comitology contains several provisions which are highly relevant to the decision-making processes in the Standing Committee for Food Chain and Animal Health that debate and determine GMO authorisations (Weimer 2012: 160-162). First, when no opinion is delivered in the committee, the Commission shall not adopt a measure if it concerns the protection of the health or safety of humans, animals or plants (here decision for a GMO approval) or a simple majority of the committee members (14 out of 27 Member States) oppose (it unless it is deemed *necessary*). Second, there is a newly set appeal committee which replaces the Council meetings within the comitology structure and allows for a second discussion on a matter at a higher level but without a necessity of levering the case to the Council level, which is perceived as a more effective and less politicised solution. Its role is to deliberate and resolve contentious issues. It is composed of higher-level national officials and chaired by the Commission (Deputy Director of the DG instead of the Head of Unit who chairs committees' meetings). Third, which is a significant change as compared to old rules where procedural structure of the regulatory comitology procedure (art. 5 of Council Decision 1999/468 as amended in 2006). This means, , the Commission can refrain from making a decision in the light of inequality of weight of votes in GMO cases and in view of improving the democratic legitimacy of its action. It however remains an unsettled question whether the Commission will use its new competence to refrain from adopting controversial decisions on the basis of e.g. minority scientific views included in EFSA opinions (Poli 2010b).

Arguably, the reform of comitology and the new procedural rules aim at facilitating deliberation and consensus-based decision-making which constitute a crucial step to improve the functioning of the GMO governance. It also introduces means for better decision-making on GMO approvals in terms of less politicisation, more flexibility and simplification as compared to old comitology decision (Weimer 2012: 160-162). On the other hand, as stated above, the implementation of the reform will much depend on the Commission's behaviour and its understanding of its role.

Conclusions

The analysis of the EU role in the creation and transformation of the transnational GMO regime provokes the following conclusion. It generally aimed at 'uploading' its own regulatory regime to the global level, but the regime's normative content is often a result of international collaboration, includes direct references to external standards, remains the subject of multilateral, deliberative disciplines, and is sometimes adopted under the direct influence of transnational developments. The latter often feed back into the European system through recursive process of policy reforms. EU prefers to act collectively and multilaterally rather than through unilateral means to advance its goals (de Búrca 2012: 42, 58; Wouters *et al.* 2012: 4, 275-277), and it turns to bilateral channels when it is forced by pragmatic need for more co-operation or risk reality. EU's mode of action at the international level was determined by political

bargaining or pursuing of self-interests, but it seemed to have intensified when other parties are averse to co-operation and deliberation. Moreover, while seeking to replicate its GMO regime it promotes the experimentalists modes of governance that it has developed for the internal policy. For example, it encourages both including lower-level units knowledge and experience in the transnational field and strengthening scientific networked co-operation and external capacity-building. Further, EU supports horizontal collaboration on GMO tracing and identification based on the extension of monitoring, information exchange and reporting to avoid risks; and the world-wide consistency and transparency of Internet tools on GMOs for maximum coherence in the regulatory domains (e.g. OECD, Codex and Cartagena). In case of risk materialisation, EU becomes a front-runner in offering solutions for traceability, sampling, and detection methods for non-authorised products on the basis of its experience within ENGL.

The general dynamics of the GMO transnational regulation through the lens of experimentalism can be interpreted as follows. The first attempt to establish framework goals/ metrics at the international level were characterised by the division between trade and environmental regulatory domains of multilateral treaties, underpinned by a disagreement of two powerful actors EU and the US, their political bargaining and attempts to extend their regulatory visions transnationally. The first implementation and reporting phase (1990-2006) witnessed flourishing of various national experiences within both trade and environmental ‘circles’ (WTO and Cartagena) and the existence of different transnational forums with overlapping parties, where technical and scientific knowledges, including pluralist views on GMO risk assessment and risk management, were monitored, exchanged and debated. It offered a richness of approaches for comparison, but created further obstacles to agree on regulatory collaboration and common understanding of objectives. There seemed to be no will to engage in mediating solutions, but rather to escalate conflicts. The WTO Biotech case provided a destabilisation mechanism which unblocked the conflicting tendency. It coincided with the materialisation of some GMO risks and had implications for both EU and US regulatory regimes. In the post-2006 times, there was a parallel continuation of implementation of objectives in diverse local settings and a revision of goals to respond to new problems (unauthorised GMO releases; financial crisis, growing AGRO-food global actors in China, Brazil, India). In addition, experimentalist problem-solving occurred in the process of addressing GMO risks between EU and US together with a more general turn towards co-operation in international bodies. Account taken of transnational developments and the WTO ruling, EU launched the reform of its internal policy embodying many experimentalist characteristics both in relation to processes and content of rules.

Now, we can now observe the second attempt to establish framework goals through alternative means which can modify the current trade-environment division of regulatory domains (the planned bilateral EU-US trade partnership; the extension of scope of the Cartagena Protocol).^{xi} The on-going reforms in the EU and the US internal change can produce new experience and knowledge, which will later feed back to the transnational level, but also more room for regulatory co-operation. These trends for revision and factual developments offer a potential for the prospective extension of experimentalism. The overall picture suggests that experimentalism in transnational GMO governance emerges through a combination of some elements of several pathways (Sabel and Zeitlin 2012): unilateral agenda setting subject to multilateral deliberative constraints (EU against WTO/ Cartagena Protocol), gradual joining up of regimes through benchmarking and public comparison (EU-US co-operation on risk) and possibly cross-national convergence through mutual influence (if US internal change leads to a broader change and regulatory convergence, cf. Scott 2009b).

The possible scenario for the future is a gradual regulatory accommodation of the existing regimes based on a complementing effect with the diverse international

forums performing a role of ‘bridging’ bodies to exchange of information, best practices, experience and monitoring of emerging risk problems. It will depend on the performance of actors in these institutional settings, including developing economies, the progress of scientific knowledge and the reality of GMO risks.

Bibliography:

- Alemanno A. (2011). 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', in D. Vogel and J.F.M. Swinnen (eds.), *Transatlantic Regulatory Co-operation The Shifting Roles of the EU, the US and California*. Cheltenham, Northampton: Edward Elgar.
- Alemanno A. (2008). 'The Shaping of European Risk Regulation by Community Courts'. *Jean Monnet Working Papers*, 18/08. Florence: European University Institute.
- Ansell C. and Vogel D. (2006). *What's the beef?: the contested governance of European food safety*. Cambridge, London: MIT Press.
- Bail C., Falkner R. and Marquard H. eds. (2002). *Cartagena Protocol on Biosafety: reconciling trade in biotechnology with environment and development?*. London: Earthscan.
- Bodiguel L. and Cardwell M. eds. (2010). *The Regulation of Genetically Modified Organisms: Comparative Approaches*. Oxford: Oxford University Press.
- Boerzel T. (2012). 'Experimentalist governance in the EU: The emperor's new clothes?'. *Regulation and Governance*, 6/3: 378-384.
- Büthe T. and Mattli W. (2011). *The new global rulers: the privatization of regulation in the world economy*. Princeton and Oxford: Princeton University Press.
- Cantley M.F. (1995). *The Regulation of Modern Biotechnology, A Historical and European Perspective* in H.J. Rehm and G. Reed (eds.), *Legal, Economic and Ethical Dimensions of the Multi-Volume Comprehensive Treatise Biotechnology*. Weinheim: VCH.
- Ceddia M.G., Cerezo E.R. (2008). 'A Descriptive Analysis of Conventional, Organic and GM Crop and Certified Seed Production in the EU'. *JRC Scientific and Technical Reports*. Luxembourg: Office for Official Publications of the European Communities.
- Carrau J. G. (2009). 'Lack of Sherpas for a GMO Escape Route in the EU'. *German Law Journal*, 10: 1169-1200.
- Dąbrowska P. (2010). 'EU Governance of GMOs: political struggles and experimentalist solutions?', in C. Sabel and J. Zeitlin (eds.), *EU Governance: Towards a New Architecture?*. Oxford: Oxford University Press.
- Dąbrowska-Kłosińska P. (2012). 'The regulation of GMOs in the EU: conflicts, problems and reforms', in L. Ammannati (ed.), *Networks. In search of a model for European and global regulation*. Torino: Giappichelli editore.
- Dąbrowska-Kłosińska P. (2013). 'Risk, Precaution and Scientific Complexity before the CJEU' in W. Werner and L. Gruszczyński (eds.), *Standard of Review in International Courts and Tribunals*. forthcoming
- de Búrca G. (2013). 'EU External Relations: The Governance Mode of Foreign Policy', in B. Van Vooren, S. Blockmans, J. Wouters (eds.), *The EU's role in global governance: the legal dimension*. Oxford: Oxford University Press.

- de Búrca G., Keohane R.O., Sabel C. (2013). 'New Modes of Pluralist Global Governance'. *New York University Journal of International Law and Politics*, 45/1.
- De Witte B. and Thies A. (2012). 'Why Choose Europe? The Place of the European Union in the Architecture of International Legal Cooperation', in Van Vooren B., Blockmans S., Wouters J. (eds.) *The EU's role in global governance: the legal dimension*. Oxford: Oxford University Press.
- Eggers B. and Mackenzie R. (2000). 'Cartagena protocol on biosafety'. *Journal of International Economic Law*, 3/3: 525-543.
- Endres A. B. (2012). 'An Evolutionary Approach to Agricultural Biotechnology: Litigation Challenges to the Regulatory and Common Law Regimes for Genetically Engineered Plants'. *Northeastern University Law Journal*, 4/1: 59-87.
- French D. (2010). 'The regulation of genetically modified organisms and international law: a call for generality', in Bodiguel L. and Cardwell M. (eds.), *The Regulation of Genetically Modified Organisms: Comparative Approaches*. Oxford: Oxford University Press.
- Falkner, R. and Gupta A. (2004). 'Implementing the Cartagena Protocol: Key Challenges'. *Sustainable Development Programme Briefing Paper* 4. London: Royal Institute of International Affairs (Chatham House).
- Gottweis H. (1999). 'Regulating genetic engineering in the European Union A post-structuralist perspective', in: B. Kohler-Koch and R. Eising (eds.), *The Transformation of Governance in the European Union*. London: Routledge.
-
- Gruszczyński L. (2012). 'Customary Rules of Interpretation in the Practice of WTO Dispute Settlement Bodies,' in A. Nollkaemper, O. K. Fauchald (eds.), *Unity or Fragmentation of International Law: the Role of International and National Tribunals*. Oxford: Hart Publishing.
- Gruszczyński L. (2008). 'SPS Measures Adopted in Case of Insufficiency of Scientific Evidence: Where Do We Stand after EC-Biotech Products Case', in J. Chaisse and T. Balmelli (eds.), *Essays on the Future of the World Trade Organisation*. Geneva: Edis.
- Gupta A. and Falkner, R. (2006). 'The Influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa'. *Global Environmental Politics*, 6:4.
- Gupta, A. (2000). 'Governing Biosafety in India: The Relevance of the Cartagena Protocol' *Discussion Paper*, 2000-24. Harvard University: Kennedy School of Government.
- Humphrey J. (2012). 'Convergence of US and EU production practices under the new FDA Food Safety Modernization Act'. *The World Economy*, 35/8: 994-1005.
- Jendrośka J., Bar M. and Bukowski Z. (2004). *The Cartagena Protocol to the Convention on Biological Diversity A Commentary* [in Polish]. Wrocław: Centrum Prawa Ekologicznego.
- Joerges C. (2009). 'Judicialisation and Transnational Governance: The Example of WTO Law and the GMo Dispute', in B. Iancu (ed.), *The Law/ Politics Distinction in Contemporary Public Law Adjudication*. Utrecht: eleven international publishing.

- Keohane R. O. and Victor D. G. (2011). 'The Regime Complex for Climate Change'. *Perspective on Politics*, 9/1: 7-23.
- Krisch N. (2010). 'Pluralism in Post-national Risk Regulation: The Dispute over GMOs and Trade'. *Transnational Legal Theory*, 1/1: 1-29.
- Kritikos M. (2004). 'Mixity and Ad Hoc Arrangements in EU Negotiating Strategies for the Biosafety Protocol', in F. Snyder (ed.), *International Food Security and Global Legal Pluralism*. Bruxelles: Brulyant.
- Lyster R. (2008). 'The Reality and Effect of "Advanced Informed Agreement" under the Cartagena Protocol', in M. I. Jeffery, J. Firestone and K. Bubna-Litic (eds.), *Biodiversity Conservation, Law + Livelihoods*. Cambridge: Cambridge University Press.
- MacMahon J. (2010). 'The EC-biotech decision: another missed opportunity?', in L. Bodiguel and M. Cardwell (eds.), *The Regulation of Genetically Modified Organisms: Comparative Approaches*. Oxford: Oxford University Press.
- Mariani M.T. (2007), *The Intersection of International Law, Agricultural Biotechnology, and Infectious Disease*. Leiden: Martinus Nijhoff Publishers.
- Mason-Matthee M. (2007). *The Codex Alimentarius Commission and Its Standards*. The Hague: TMC Asser Press.
- Matthee M.D. (2009). 'The Codex Alimentarius Commission and its food safety measures in the light of their new status', in E. Vos and M. Everson (eds.), *Uncertain Risks Regulated*. Oxon, New York: Routledge Cavendish.
- Morris S.H., Spillane C. (2010). 'EU GM Crop Regulation: A Road to Resolution or a Regulatory Roundabout?'. *European Journal of Risk Regulation*, 4: 359-369.
- Murphy S. D. (2001). 'Biotechnology and International Law'. *Harvard International Law Journal*, 42/1: 47-139.
- Navah M. (2013). 'The Politics of Risk Decision-Making: The Voting Behaviour of the EU Member States on GMOs', in M.B.A. van Asselt, E. Versluis and E. Vos (eds.), *Balancing between Trade and Risk Integrating Legal and Social Science Perspectives*. Oxon, New York: Routledge.
- Oberthuer S. and Gehring T. (2006). 'Institutional Interaction in Global Environmental Governance: The Case of the Cartagena Protocol and the World Trade Organisation'. *Global Environmental Politics*, 6/2: 1-31.
- Overdevest C. and Zeitlin J. (2012). 'Assembling an experimentalist regime: Transnational governance interactions in the forest sector', *Regulation & Governance*.
- Poli S. (2004). 'Adopting International Food Standards: Euro-American Conflicts within the Codex Alimentarius Commission', in F. Snyder (ed.), *International Food Security and Global Legal Pluralism*. Bruxelles: Brulyant.
- Poli S. (2007). 'The EC's implementation of the WTO ruling in the Biotech Dispute'. *European Law Review*, 32: 705-726.

- Poli S. (2010a). ‘Continuity and change in the EU regulatory framework on GMOs after the WTO dispute on “biotech products”’. *Legal Issues of Economic Integration*, 37/2: 133-148.
- Poli S. (2010b). ‘The Commission’s New Approach to the Cultivation of Genetically Modified Organisms’. *European Journal of Risk Regulation*, 1/4: 339-344.
- Pollack M. A. and Shaffer G. C. (2004). ‘Regulating between national Fears and Global Disciplines: Agricultural Biotechnology in the EU’, *NYU Jean Monnet Working Paper*, 10.
- Pollack M. A. and Shaffer G. C. (2009a). *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*. Oxford: Oxford University Press.
- Pollack M. A. and Shaffer G. C. (2009b). ‘The EU Regulatory system for GMOs’, in E. Vos and M. Everson (eds.), *Uncertain Risks Regulated*. Oxon, New York: Routledge Cavendish.
- Provost D. (2004). ‘Selected International Developments regarding Health and Environmental Regulation of Relevance to the European Union’. *European Environmental Law Review*, 13/2: 38-60.
- Raustiala K. and Victor D. G. (2004). ‘The Regime Complex for Plant Genetic Resources’. *International Organisations*, 58: 277-309.
- Rhinard M. and Kaeding M. (2006). ‘The international bargaining power of the European Union in “mixed” competence negotiations: the case of the 2000 Cartagena Protocol on Biosafety’. *Journal of Common Market Studies*, 44/5: 1023-1050.
-
- Sabel C. and Zeitlin J. (2008). ‘Learning from Difference: The New Architecture of Experimentalist Governance in the EU’. *European Law Journal*, 14/3: 271-327.
- Sabel C. and Zeitlin J. eds. (2010). *EU Governance: Towards a New Architecture?*. Oxford: Oxford University Press.
- Sabel C. and Zeitlin J. (2011). ‘Experimentalism in Transnational Governance: Emergent Pathways and Diffusion Mechanisms’. *GR:EEN Working paper*.
- Sabel C. and Zeitlin J. (2012). ‘Experimentalist Governance’, in D. Levi-Faur (ed.), *The Oxford Handbook of Governance*. Oxford: Oxford University Press.
- Schepel H. (2005). *The constitution of private governance: product standards in the regulation of integrating markets*. Oxford: Hart Publishing.
- Scott J. (2004). ‘International Trade and Environmental Governance: Relating Rules (and Standards) in the EU and the WTO’. *European Journal of International Law*, 15: 307-354.
- Scott J. (2007). *The WTO Agreement on Sanitary and Phytosanitary Measures A Commentary*. Oxford: Oxford University Press.
- Scott J. (2009a). ‘European Regulation of GMOs: thinking about “judicial review” in the WTO’, in E. Vos and M. Everson (eds.), *Uncertain Risks Regulated*. Oxon, New York: Routledge Cavendish.

Scott J. (2009b). 'From Brussels with Love: The Transatlantic Travels of European Law and the Chemistry of Regulatory Attraction', *American Journal of Comparative Law*, 57/4: 897-942.

Spina A. (2010). 'European Networks in the Regulation of Biotechnologies'. *European Law Review*, 35/2: 197-213.

Strauss, D. M. (2012). 'The Role of Courts, Agencies, and Congress in GMOs: a Multilateral Approach to Ensuring the Safety of the Food Supply'. *Idaho Law Review*, 48: 267-319.

Strauss, D. M. (2011). 'An Analysis of the FDA Food Safety Modernisation Act: Protection for Consumers and Boon for Business'. *Food and Drug Law Journal*, 66/3: 353-376.

Strauss, D.M. (2006). 'The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply'. *Food and Drug Law Journal*, 61/2: 167-196.

van Asselt M.B.A. and Vos E. (2008). 'Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox'. *Journal of Risk Research*, 11/1-2: 281-300.

Vogel D. (2012). *The Politics of Precaution Regulating Health, Safety, and Environmental Risks in Europe and the United States*. Princeton and Oxford: Princeton University Press.

von Homeyer I. (2006). 'The EU Deliberate Release Directive: Environmental Precaution versus Trade and Product Regulation', in S. Oberthuer and T. Gehring (eds.), *Institutional Interaction in Global Environmental Governance*. Cambridge and London: MIT Press.

31

Weimer M. (2010). 'What Price Flexibility? – The Recent Commission Proposal to Allow for National "Opt-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon'. *European Journal of Risk Regulation*, 1/4: 345-352.

Winickoff, D., Jasenoff, S., Busch, L., Grove-White, R. and Wynne, B. (2005). 'Adjudicating the GM food wars: Science, risk and democracy in world trade law'. *Yale Journal of International Law*, 30: 81-123.

Wouters J., Bruyninckx H., Basu S., Schunz S. eds. (2012). *The European Union and multilateral governance: assessing EU participation in United Nations human rights and environmental fora*. Basingstoke, Hampshire: palgrave macmillan.

Documents:

Cartagena Protocol on Biosafety to the Convention on Biological Diversity, as reproduced in OJ 2002 L 201/50.

Commission (European Commission) (2002). *Communication Life Sciences and Biotechnology A Strategy for Europe*. COM(2002) 27 final.

Commission (2007). *Mid-term review of the Strategy on Life Sciences and Biotechnology*. COM (2007) 175 final.

Commission (2010a). *Communication on the freedom for Member States to decide on the cultivation of genetically modified crops*. COM(2010) 380 final.

Commission (2010b). *Proposal for a Regulation amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory*. COM(2010) 375 final.

EFSA (European Food Safety Authority) (2012a). 'European Court of Auditors recognises EFSA's advanced independence policy, makes recommendations'. EFSA press release, 11.10.2012.

EFSA (2012b). *EFSA's Policy on Independence and Scientific Decision-Making Processes*. <http://www.efsa.europa.eu/en/aboutefsa/keydocs.htm>

EFSA (2012c). *Guidelines for Observers*.
<http://www.efsa.europa.eu/en/stakeholders/docs/observersguidelines.pdf>

EFSA (2012d). *Pilot Project Observers*.
<http://www.efsa.europa.eu/en/stakeholders/observers.htm>

EPEC (European Policy Evaluation Consortium) (2011). *Final report Evaluation of the EU legislative Framework in the Field of Cultivation of GMOs*.
http://ec.europa.eu/food/plant/gmo/reports_studies/docs/gmo_cultivation_report_en.pdf

FVO (2008a). Final report of a mission carried out in the US from 04 June to 11 June 2008 in order to evaluate the control activities in the US for Commission decision 2006/601/EC as amended regarding emergency measures for rice exports to the EU, doc. ref. DG(SANCO)/ 2008-7857 - MR - FINAL

32

FVO (2008b). Final report of a mission carried out in China from 27 November to 03 December 2008 in order to evaluate official control systems for Commission decision 2008/289/EC on emergency measures regarding the unauthorised GMO "Bt 63" in rice products, doc. ref. DG(SANCO)/ 2008-7834 - MR - FINAL

ISAAA (2011). 'Global Status of Commercialized Biotech/GM crops 2011'. Report available at:
<http://www.isaaa.org/resources/publications/briefs/43/executivesummary/default.asp>

OECD (2012). 'Internal Co-ordination Group for Biotechnology', *OECD Newsletter*, 23. <http://www.oecd.org/env/ehs/biotrack/49867087.pdf>

WTO (World Trade Organisation) (2006). *Panel Report (WT/DS291/R, WT/DS292/R, WT/DS293/R), European Communities – Measures Affecting the Approval and Marketing of Biotech Products*.

* I am very grateful to Jonathan Zeitlin for his invaluable comments on an earlier draft of this paper. Many thanks also to Maria Weimer and the participants in the Amsterdam GR:EEN Workshop on Extending Experimentalist Governance, May 2012 as well as the participants in the Madison workshops on experimentalist governance, 2009, for their feedback. All errors are mine. The support of the Jean Monnet Fellowship 2012/2013 in the Global Governance Programme at the Robert Schuman Center for Advanced Studies, European University Institute in Florence is acknowledged.

ⁱ See e.g. recently a controversial study by G.-E. Séralini et al, *Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize*, claiming that NK603 GM maize poses risk to health, in *Food and Chemical Toxicology*, 2012 and EFSA, *Review of the Séralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology*, in *EFSA Journal*, vol. 10(10), 2012, p.2910.

ⁱⁱ See the guidance documents at <http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm> (visited 18 march 2013) and press release of 17 October 2012 *GMO sample preparation: practical guidance under development by JRC-hosted ENGL network*, where it is announced that ‘European Network of GMO Laboratories working group shall prepare a practical guidance for sample preparation, combining information that is now scattered throughout European legislation, ISO, and other technical standards’.

ⁱⁱⁱ E.g. C-236/01 *Monsanto Agricoltura Italiana SpA and Others v. Presidenza del Consiglio dei Ministri and Others*, [2003] ECR II-8105.

^{iv} See: <http://www.cbd.int/history/> (visited 20 March 2013).

^v See <http://www.biodiv.org/biosafety/default.aspx> (visited 20 March 2013). Its implementation at the EU level is the Regulation 1046/04 on transboundary movement of GMOs.

^{vi} http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (20 March 2013).

^{vii} <http://bch.cbd.int/about/operation-modalities/> (12 January 2013).

^{viii} See: http://www.who.int/foodsafety/biotech/codex_taskforce/en/index.html (18 January 2013).

^{ix} See Summary Report of the Standing Committee for Food Chain and Animal Health (SCFCAH) meeting, GMO Section, 16.06.08.

^x See:

<http://www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnology.htm> (visited 20 March 2013).

^{xi} See: <http://www2.oecd.org/biotech/> (visited 20 March 2013).

^{xii} See: http://www.iso.org/iso/fr/actionplan_2005-en.pdf (April 2012).

^{xiii} See: http://www.iso.org/iso/about/structure/strategic_and_technical_advisory_groups.htm (April 2012).

^{xiv} http://isotc.iso.org/livelink/livelink/fetch/2000/2122/3146825/4229629/4230450/4230458/01_Agreement_on_Technical_Cooperation_between_ISO_and_CEN_Vienna_Agreement_.pdf?nodeid=423068&vernum=0 (April 2012).

^{xv} http://ec.europa.eu/consumers/cons_issue/tacd_en.htm and <http://www.tacd.org/> (visited 14 April 2012).

^{xvi} http://ec.europa.eu/consumers/cons_issue/tacd_en.htm and <http://www.tacd.org/> (visited 14 April 2012).

^{xvii}

http://tacd.org/index.php?option=com_content&task=category§ionid=5&id=24&Itemid=43 (visited 14 April 2012).

^{xviii} <http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/united-states/>

^{xix} Final Report of December 2000, at <http://64.26.159.139/docroot/articles/2001008-A.pdf> (visited 14 April 2012).

^{xx} Source: author’s own experience from the internship within the Biotechnology Unit at DG SANCO of the European Commission, March-June 2003.

^{xxi} See the documents and histories of two disputes: <http://trade.ec.europa.eu/wtodispute/show.cfm?id=190&code=2> (for Argentina, visited 22 March 2013) and <http://trade.ec.europa.eu/wtodispute/show.cfm?id=189&code=2> (for Canada, visited 22 March 2013).

^{xxii} Summary Report of the SCFCAH meeting, GMO Section, 22.07.2009; Status Report of the European Union, 13.04.2012, doc. ref. WT/DS291/37/Add.51

http://trade.ec.europa.eu/doclib/docs/2012/april/tradoc_149347.pdf and Status Report of the European Union, 15.02.2013

http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150713.pdf (both visited 22 March 2013).

^{xxiii} Commission press release, *European Union and United States to launch negotiations for a Transatlantic Trade and Investment Partnership*, doc.ref. MEMO/13/95, 13 February 2013;

Commission press release, *European Commission Fires Starting Gun for EU-US Trade Talks*, 12 March 2013.

^{xxiv} Summary Report of the SCFCAH meeting, GMO Section, 16 January 2007), Summary Report of the SCFCAH meeting, GMO Section, 2 March 2007 and Summary Report of the SCFCAH meeting, 19-20 December 2007.

^{xxv} Commission Decision 2006/601/EC of 5 September 2006 on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products, OJ 2006 L 244/27.

^{xxvi} Commission Decision 2008/162/EC and Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms or in products in the context of Regulation (EC) No 1830/2003, OJ 2004 L 348/18.

^{xxvii} Commission Decision 2006/578/EC of 23 August 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products, OJ 2006 L 230/8; and Commission Decision 2006/754/EC of 6 November 2006 amending Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products, OJ 2006 L 306/17.

^{xxviii} Commission Decision 2010/315/EU of 8 June 2010 repealing Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products, and providing for random testing for the absence of that organism in rice products, OJ 2010 L 141/10.

^{xxix} Report of the 31st session of the Codex Alimentarius Commission.

^{xxx} See: <http://www.who.int/foodsafety/publications/biotech/sept07/en/index.html> (20 January 2013).

^{xxxi} http://ihcp.jrc.ec.europa.eu/our_activities/gmo; <http://gmo-crl.jrc.ec.europa.eu/capacitybuilding/workshops.htm>; <http://gmo-crl.jrc.ec.europa.eu/capacitybuilding/training.htm> (25 March 2013).

^{xxxii} More research is still needed into the institutional practice of the Cartagena Protocol. Given its universal character and the amount of the parties, there is surprisingly little scholarship on its functioning while most of the studies focus either on the negotiation process or on the relationship with the WTO framework.

^{xxxiii} C-442/09 *Karl Heinz Bablok and Others v Freistaat Bayern* [2011] ECR, par. 92, where the CJEU decided that honey contaminated with GM pollen constitutes food containing ingredients produced from GMOs.

^{xxxiv} See Commission Regulation (EU) No 619/2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired, OJ 2011 L 166/9.

^{xxxv} Summary Report of the SCFCAH meeting, GMO Section, 16.01.07; Summary Report of the SCFCAH meeting, GMO Section, 12.12.2011.; Commission press release, *Questions and answers on the evaluation of the European Union's GMO legislation*, doc. ref. MEMO/11/742, 28 October 2011.

^{xxxvi} Interview with Polish official, Head of the Unit within Ministry of Environment responsible for GMOs, May 2010.

^{xxxvii} Summary Report of the SCFCAH meeting, GMO Section, 10.09.2012; Summary Report of the SCFCAH meeting, GMO Section, 24.09.2010., p.4. The list of bilateral and multilateral meetings of the EFSA GMO Panel with Member States authorities, at <http://www.efsa.europa.eu/en/gmo/gmomsmeetings.htm> and EFSA Scientific Network for Risk Assessment of GMOs, at:

<http://www.efsa.europa.eu/en/gmonetworks/docs/gmonetworkstor.pdf> (visited 29 September 2012).

^{xxxviii} See: *MEPs divided on whether to punish EU agencies*, EUobserver, 09.05.2012.

^{xxxix} Interview with Polish official, Head of the Unit within Ministry of Environment responsible for GMOs, May 2010; Summary Report of the SCFCAH meeting, GMO Section, 09.03.2010, p.4.

^{xl} See also: R. Zoellick, *Questions for the world's next trade chief*, FT, 01.04.2013.