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Divided We Stand: The EU as Dissonant Player in the Global Governance of Agro-Food Biotechnology*

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Abstract

The European consumer reaction to agro-food biotechnology led to a tightening of the EU's regulatory framework and a lengthy legal row between the EU and a group of agro-exporting countries led by the Untied States. This essay aims at rendering transparent the EU's policy rationale in this transatlantic and, in its implications, global controversy. Taking a close look at the EU's biotechnology policy both from a domestic and a global perspective the study stresses the link between the ongoing internal dissension on agro-food biotechnology within the EU, the EU's efforts to manage this conflict, and its involvement in the building of an emerging system for the global governance of biotechnology. It will be demonstrated that, within this system of global governance, comprising international institutions and agreements like the World Trade Organisation, the Biosafety Protocol and the Codex Alimenatrius, the EU, for the most part the European Commission on its behalf, acts as a strategic promoter of its precautionary and consumer oriented approach. The study concludes with pointing at various ironies brought about by the EU's engagement at both the domestic and global level and sets the stage for tentative forecasts on future trends in the global biotech arena.

Anything but a smooth success story, the global advance of agro-food biotechnology has been hampered by consumer backlashes and regulatory disputes around the world. (e.g. Paarlberg 2001) Most effectual was undoubtedly the European controversy. Public pressure against Genetically Modified Organisms (GMOs) in food and agriculture, along with a series of food crises, led to a five year embargo on product approvals and imports imposed by a number of member states, induced a profound overhaul of the European Union's (EU) biotechnology regulation which resulted in a stringent regulatory framework, and eventually, provoked a trade conflict with the U.S., Canada and Argentina. The transatlantic trade conflict and the imminent resolution of this conflict through the WTO's dispute settlement system is widely regarded as key in shaping agro-food biotechnology's global governance. Beyond the impact of these changes on European agro-food biotechnology itself, and beyond the charged relations with the major GM-exporting countries, Europe's peculiar stance on agro-food biotechnology also has consequences for the rest of the world, particularly the developing world. (e.g. Meijer/Steward 2004) As one of the world's most potent markets for agricultural and food products, and the world's most pronounced forerunner of a precautionary and consumer choice-oriented biotechnology regulation, these consequences for an emerging system of global governance of agro-food biotechnology must be considerable. In analysing the logic underlying the Union's behaviour in the conflict over agro-food biotechnology's global governance, this study aims at contributing to a better understanding of the rationales driving the EU's engagement as a player in the global biotech field and, in turn, to improve our ability to estimate future developments in biotechnology's global governance.

To this end, the study will, in a first step, give an account of the Union's current biotechnology policy, emphasizing its mediative - albeit controversial - character. It proceeds to set up an analytical framework for the global governance of agro-food biotechnology and identifies the Union's rationales and strategies to shape it according to its own regulatory preferences. The central claim of the article is to explain these global strategies as resulting from the mediative policy style the EU has adopted domestically in order to cope with a crisis of trust and internal dissension. Against the backdrop of recent key decisions - the issuing of the WTO dispute settlement panel's (WTO panel) report in February 2006 anticipating the ruling on the conflict, and the agreement reached in March 2006 at the Conference of the Parties (COP) 3 on the labelling of internationally traded GM commodities - the analysis will

conclude in pointing at various ironies brought about by the EU's engagement at both the domestic and global level.

The EU's Regulatory System: Coping with Opposition without Appeasing It

In the course of an extended reform process reaching from the late 1990s to April 2004, the EU has built up one of the most stringent legislations on agro-food biotechnology in the world.[1] The normative centrepiece of this legislations is consumers' *freedom of choice*, which is upheld *regardless* of any proven risk of a particular product which lays the normative ground for a costly and highly complex labelling system. This principle is accompanied by the *precautionary principle* (PP) which allows - in certain situations commands - "to err on the side of safety," that is to act preventively, if there are reasonable grounds for concern even if they cannot draw on scientific certainty. (Christoforou 2002) The labelling regime and the PP further correspond with the *traceability*-principle, which requires that any GM product-component is identifiable at each stage of the food chain and aims at both providing the base for a consistent labelling regime and enabling to prohibit or remove a product from the market in case of an emergency. (Van der Meulen 2005a,b) The administrative and technical requirements following from its provisions, together with the fact that member states enjoy major prerogatives in the approval process, makes the marketing of GM products and, even more, the cultivation of GMOs in agriculture, a rather difficult task for potential applicants and will considerably encumber the introduction of agro-food biotechnology in years to come.

[1] As to food biotechnology reforms started in June 1997 when the Commission adopted Commission Directive 97/35, overturning the rules on GM labelling in the Novel Foods Regulation. In September of the same year, Commission Regulation (EC) 1813/97, requiring labelling of foods produced from GM soy and maize varieties, which had been approved prior to the Novel Foods Regulation having taken effect. In May 1998, the Council passed Regulation 1139/98 ratifying an unambiguous label for GM food. In January 2000, the Commission enacted Regulation (EC) 50/2000 on food and food additives, and Commission Regulation (EC) 49/2000, established a threshold of 1 % above which food containing GM ingredients due to adventitious admixture had to be labelled. Cornerstones of the amended framework for the regulation of agricultural biotechnology were put up in 2001 with Deliberate Release Directive 2001/18 /EC which repeals Directive 90/220/EEC and sets up a series of new hurdles to the approval process as mandatory post-market monitoring, a requirement to ensure labelling and traceability at all stages of the placing on the market, a restriction to approvals to a maximum of ten years, an obligation to consult the European Parliament on authorizations, and the possibility for the Council of Ministers to adopt or reject a Commission proposal by qualified majority. The framework was completed in 2003 by Regulations 1829/2003/EC on GM food and feed and 1830/2003 concerning the traceability and labelling of GMOs in food and feed products.

Mediating Countervailing Pressures

Asking for the major forces which have shaped this regulatory framework we find them to be the result of countervailing pressures, operating from "below" and "above" on the framework's designer, the European Commission (hereafter "Commission"). (Pollack/Shaffer 2005) The Commission copes with these pressures by acting "as a policy entrepreneur, leveraging the two arenas - the domestic and global - to expedite policy reforms." (Skogal 2001: 485)

As to the forces from below, the upgrading of regulatory standards in the EU can be regarded as a "trading up" of biotechnology regulation in the wake of recent years' dramatic public protests against agro-food biotechnology. Trading up is a common mechanism in EU market integration: In order to avert the negative impact that divergent national rules have on trade within the EU common rules are frequently set close to those of the most risk-averse member state. (Vogel 1997) The setting up of new, considerably stricter regulations for agro-food biotechnology was catalyzed by the Commission's mishandling of the BSE crisis in the mid 1990's, a cascade of subsequent food scares, and a powerful wave of opposition to agro-food biotechnology, decisively enhanced by the recalcitrant postures of a group of EU member states who, domestically, adopted biotechnology-aversive policies, and, from 1999 to 2004, imposed a *de facto moratorium* [2] on GMO approvals as well as individual safeguard bans on certain, already approved GMOs. [3] The legal basis for these bans is provided by the "safeguard clauses" in the respective EU directives,[4] which derive from a principle enshrined in the Treaties allowing for national bans, in case of a perceived threat to human health and the environment. This claim must be based on new scientific findings, but in no case scientific evidence delivered by member sates to warrant the measures was deemed convincing by Commission's scientific committees. [5] By nevertheless maintaining their safeguard bans and, until April 2004, the de facto moratorium, biotechnology-aversive member states pressurized the Commission to ratchet up the reform process.

[2] The "political moratorium" was set up in summer 1999 by France, Greece, Denmark, Italy and Luxembourg. In 2000 and 2001 respectively, Austria and Belgium joined the blockade group.

[3] Between 1997 and 2000, national safeguard bans had been decreed on 13 occasions by Austria (3), France (2), Germany (1), Italy (4), Luxembourg (1), Greece (1) and the United Kingdom (1) - the only country to later withdraw its ban.

[4] Article 16 of the Deliberate Release Directive 90/220 and Article 23 of its successor 2001/18 and, in the case of Italy, Article 12 in the Novel Food Directive 258/97.

[5] Even so, in January 2005, Hungary, and in March 2005, Poland invoked safeguard measures on their behalf.

The stringent features of the EU biotechnology regulation have also to be regarded against the backdrop of the broader crisis of trust in the EU's food safety system in general which prompted the latter's general overhaul in the late 1990s. Biotechnology policy evolved along with European consumer policy. In fact, consumer demands - for product safety and the "right to know" - provided biotechnology opponents with a major political lever as consumer advocates can base their claims on a maximum of popular support. The salience of consumer concerns in affluent West European societies further extended the oppositional camp to include, for example, retailers and segments of the food industry. In response, retailers in some member countries imposed their own labelling rules. Since disparate labelling criteria threatened to undermine the internal market, the Commission, in 1997 gave up its long standing rejection of GM labelling, and set up new rules based on the detectability of DNA. (Levidow 2006 forthc.)

The most important single actor forcing the general turn in food policy on the Commission was probably the European Parliament, acting as an advocate of consumers' interests. In the wake of the 1996 BSE crisis, for example, the European Parliament threatened the Commission with a no-confidence vote that could force its resignation. In response, the then new Commission under Romano Prodi prioritized the introduction of new and comprehensive food safety legislation. At any rate, the fact that the Commission, in an attempt to cope with a series of legitimacy crises, significantly traded up its consumer policy inevitably had consequences for its stance towards agro-food biotechnology so that, today, the main pillars of the new regulatory regime - precaution, labelling, traceability - are all consistent with this upgraded policy.

It must be stressed, however, that the resulting regulatory regime is not a one-to-one representation of oppositional demands, which, in many instances, aim at barring agro-food biotechnology altogether. (Ansell et al. 2003) Still, it is designed to render the introduction of GMOs into the European food chain *possible*. In fact, in crucial respects, the new regulatory framework assumed elements which even *facilitate* GMO-approvals by centralizing the approval procedure. Case in point is the key role assigned to the European Food Safety Authority (EFSA). Created under a 2002 food law, the EFSA is supposed to function as an independent body conducting science-based standards for risk assessment. If applicants notify GM-products under the 2003 Food and Feed Directive instead of the beforehand crucial Deliberate Release Directive, which they are entitled to do if these products are to be

processed to food and feed only as is the case for the bulk of imported GM-materials, EFSA figures as *central risk assessor*. In so doing, EFSA virtually replaces national expert agencies in the risk assessment part of the approval procedure.[6] (Levidow et al. 2005: 264-266, 272-274) Moreover, stressing EFSA's scientific and objective advice, EU regulatory policy is brought more into line with the science-based regulations in Canada and the United States. (Skogstad 2006: 235)

The major reason for the Commission's determination to recover and enhance the approval process emanates from the forces, brought to bear on it "from above" - the pressures from agro-exporting countries, in particular the U.S., to gain market access for GM-products, which are exercised through international trade agreements under the WTO: Since the setting up of the political ban on GMO approvals, the government had warned the EU to take legal action against the moratorium at the WTO, which, in 2003, was finally supported by Canada and Argentina.[7] Caught between the looming lawsuit and member states stubbornly clinging to their moratorium and safeguard bans, the Commission hurried to do whatever possible to regain consumer confidence and appease ecological critique by elaborating a stringent regulatory regime while, at the same time, working as swiftly as possible to restore the approval process.

The European regulation is thus marked by a *mediative* policy style which has an *internal* and an *external* dimension. Internally, its burdensome regulatory framework "reflects a more than decade-long effort to resolve the high degree of political contestation that has surrounded GM products since the mid-1980s. The controversy over the terms under which GM products should be regulated has put member states at odds with one another, driven a line of cleavage through the Commission, and cast biotechnology companies against consumers and environmentalists. The various plant biotechnology legislative initiatives are efforts to

[6] Deliberate Release Directives 90/220 and its successor 2001/18 give national experts, the so called "Competent Authorities" of the EU's approval procedure or "Comitology," an important voice in the approval process. They thus had played a major part in the standstill of GMO approvals even before the political moratorium had officially been declared in summer 1999. Already in autumn 1998, the expert committees stopped to issue further approvals due to protracted scientific differences. For countries, adhering to a biotechnology aversive policy, national expertise proved as an indispensable justification, as positions of national experts on the whole correspond to those at the ministerial and government level. To deprive national experts from their influence onto the approval process through a central agency, therefore, implies a considerable streamlining of the process by "circumventing" expectable national dissent.

[7] Since late 2004, the decision has been repeatedly postponed. An intermediary report of the WTO Panel has been leaked in February 2006 and was made official in May 2006. The Appellate Body's ruling can be expected for later in 2006 or 2007.

resolve this conflict, even while promoting treaty goals of establishing an internal common market free of interstate barriers." (Skogdal 2006: 232) Externally, i.e. with regard to the EU's international environment, the regulation provides a set of doctrines abiding by global free trade principles. "Even while internal developments are the primary driving force behind policy innovations underway, these reforms are being designed to fit with the WTO model and thereby ward off trade retaliation." (Skogstad 2001: 498)

Lasting Tensions

The Commission, in its attempt to settle the conflict and get the approval process going, succeeded to some extent only. Although, in May 2004, finally an end was put to the *de facto* moratorium by approving a first GM maize variety, the introduction of agro-food biotechnology into the European market dragged on grudgingly. [8] Tensions between oppositional member states and the Commission were not mitigated either. Indicative of the still hesitant pace of the approval process is the fact that all approvals since July 2004 apply only to the importation and consumption of products as food and feed, but not to their cultivation. While accommodating importers' demands for market access, the Commission has obviously avoided to touch upon the - internally - most controversial issue, the *cultivation* of GM crops on Europe's fields.[9] Furthermore, *none* of the approvals is based on a majority decision of member states. Indeed, the Commission has granted all approvals by using a legal default procedure as member states' governments did not reach qualified majorities required to take decisions in favour of or against the proposal. As a consequence, all approvals were issued by the Commission against the will of a considerable portion of countries, only conjuring up further tensions.

In summer 2005, the Commission suffered a decisive defeat in a conflict with member states, highlighting the lasting deadlock. In July 2005, the Council of Environment Ministers foiled the Commission's attempt to initiate legal action against Austria, France, Germany, Greece

[8] After the maize variety BT-11, marketed by the Swiss firm Syngenta, seven further approvals of GM plants - now under the amended Deliberate Release directive 2001/18/EC - followed until today (early 2006). On 19. July 2004 Monsanto's herbicide resistant maize NK 603, on 8 August 2005 Monsanto's insect resistant maize MON 863, on 31. August 2005 Monsanto's herbicide resistant oil seed rape GT 73, on 3. November 2005 Pioneer's herbicide and insect resistant maize 1507, and on 13. January 2006 Monsanto's maize lines GA21, MON863, and MON 863x810.

[9] Yet, as the Commission wont abandon its objective to enable GMO-cultivation in the long term, in June 2006, at the instigation of the Austrian Presidency, experts from EFSA, the Commission and member states met to discuss the first pending GM crop applications for cultivation, and also the Council of Environmental ministers on June 27th debated the issue - without, however, arriving at any commonly agreed scheme on how to move ahead.

and Luxembourg, who, disregarding the disapproving opinion of EFSA scientists, had maintained their safeguard bans. Apart from sustaining the quandary for the Commission, the voting demonstrated the widespread support for the noncompliant countries and exposed the continuing weakness of the regulatory framework which had been amended throughout more than eight years in order to cope with opposition.

Recently, the conflict went into a new round as Austria, taking over the rotating EU presidency, seized the opportunity to move forwards its critical biotechnology agenda.[10] Besides hosting high level conferences on ongoing policy issues,[11] Austria initiated a critical debate at the Council of Environment Ministers in March 2006 to question the EFSA's role as central risk assessing agency vis-à-vis national experts and reconsider the practice of approving GMOs when no qualified majority in favour or against is reached in the Council. Responding to criticism in April 2006 the Commission announced a policy change aiming at mitigating disagreements on the EFSA's procedures and advice by improving its scientific consistency and transparency. (Levidow 2006: 12)

The - Partial - Expulsion of Agro-food Biotechnology by Pre-market Forces

It should be added that the fact that Europe is an unwelcoming place for agro-food biotechnology is not only due to its strict regulatory framework, its lengthy and still unsure approval procedures and its, in some countries, extremely hostile attitude on the part of public and governments alike.[12] It is not due to the regulatory environment alone, for instance, that, in spite of clear labelling rules, it is very hard to find products actually labelled as GM-food. Since the late 1990s big food retailers all over Europe have begun to push food industry for virtually banning GM ingredients from production in order to keep their shelves free of widely detested GM food. (Schurman 2004) Thus, GM importers today face not only substantial regulatory burdens, forcing them to offer properly segregated and labelled produce, they are also unable to market it as food for human consumption. Conversely, as

[10] Austria is one of the most GM aversive countries in the EU which, for ten years, has taken pains to prevent the highly unpopular agriculture technology from being used on Austrian soil, thus pursuing a NIMBY - Not In My Back Yard - policy at national level. (Seifert 2005b, 2006b)

[11] "Co-existence of genetically modified, conventional and organic crops - Freedom of choice," 4-6 April 2006, Vienna (http://europa.eu.int/comm/agriculture/events/vienna2006/index_en.htm)
"The role of precaution in GMO policy", 18 - 19 April 2006, Vienna.
(http://www.umweltbundesamt.at/en/umweltschutz/gentechnik/gtveranstaltungen/precautionandgmos/)

[12] It is important to note that this holds only for agricultural biotechnology - not for biotechnology in general. (see OECD 2006: 50-54) Also public hostility is directed against "green", or agro-food biotechnology, while the medical applications of "red" biotechnology meet with much feebler, and rather dispersed criticism. (Bauer 2005)

human food derived from animals fed with GM feedstuff is not required to be labelled, the only remaining European market for maize and soy is therefore the feed market, which, however, does not spare GM traders from labelling their cargos.

The Freedom of Choice II: The EU's Contentious Co-existence Policy

Labelling rules, a strong demand for "GM-free" food and producers' avoidance of the technology as there is no market for GM produce, all combined to the quest for "GM-free zones." From 2000 on, conventional crops in various countries were found "contaminated" with GM admixtures,[13] raising doubts as to whether biotechnological, conventional and non-GM production types could exist side by side. The problem gained economic pertinence as the viability of production types like organic farming rests on their capacity to comply with their GM-free guarantee. Coping with this essentially economic problem, in 2003, the Commission finally decided to issue guidelines on the "co-existence" of GM and conventional crops and organic farming. (CEC 2003) As the guideline (in contrast to a regulation) delineates not more than a general framework for suitable co-existence policies, both the implementation and the elaboration of which is left to member states, the Commission's step opened up a new and highly complex policy arena which currently busies policy-makers in most member states. (Levidow/Boschert 2006) Again, the unfolding co-existence arena is beset with tensions between the Commission's liberal agenda and local actors' fundamental opposition to agricultural biotechnology. The Commission's objective is - analogous to the Union's labelling policy - to defend the freedom of choice, in this case, however, farmers' choice for a production type either involving or excluding GM crops. The guidelines invoke a number of regulatory principles which, again, reflect the Commission's objective to comply with international trade disciplines. (see also Herdegen 2005) As a general rationale the coexistence approach, again, aims at *rendering possible* the use of GM crops and guard against the erection of new obstacles in view of widespread opposition and attempts to create GM-free zones.[14] Therefore, in response to the Commission's co-existence policy, a contrasting development set in, driven by a set of policy-protagonists, hitherto only

[13] Episodes are documented for Austria (Seifert 2003: 203-204), France (Marris et al. 2004: 31-32), Germany (Boschert and Gill 2004: 31-32) and Spain. (Tàbara et al. 2004: 58, 67-68)

[14] The Commission charged a small expert group with managing the coexistence agenda and coordinating regional, national, and supranational coexistence policies. (CEC 2005) March 2006, it delivered a report to the Council and the EP on the experience gained in the member states and announced a further progress report for 2008. (CEC 2006) The report can only refer to a limited number of national models as, by early 2006, only Germany, Austria, Denmark, Portugal, and the Czech Republic had notified their national coexistence regimes, while in the Netherlands, Great Britain and Spain regulations were about to materialize.

marginally involved: By late 2003, a growing group of regions aligned to embark on a campaign aiming at banning the cultivation of GMOs altogether on their territories. (Seifert 2005b, 2006b) Led by Upper Austria and Tuscany, the movement proved considerably skilful in rallying like-minded regions, growing from 10 in late 2003 to 33 by early 2006.[15] In addition, there is a similar NGO-driven network fostering "GM free zones."[16] In contrast to this campaign pulling together any local initiative to ban GM cultivation from a given territory - and therefore attaining a much higher number of "GM-free zones" - the network of European regions acts on the basis of its legal authority.

To summarize, it is a logic of conflict, compromise and mediation which governs EU biotechnology policy. This policy conforms to both pressures operating "from above," i.e. international free trade disciplines, and forces "from below," i.e. powerful social opposition to agro-food biotechnology and recalcitrant member states. The undiminished strength of this opposition must not be underestimated. The most significant part in the EU's trading up of its biotechnology regulation played the bloc of national governments which, through the moratorium on GMO approvals managed to ratchet up the European regulatory framework.[17] (Seifert 2006a) Taken together with forces operating on European markets, these factors make the marketing of such GM products and, even more, the cultivation of GMOs in agriculture, a highly difficult task for potential applicants and will considerably encumber the introduction of agro-alimentary biotechnology in years to come. At the same time, the forces "from above" make sure that there is a price to pay for the EU's dissonant response to the challenge of agro-food biotechnology. It has been the moratorium and national safeguard bans, both resulting from unresolved *internal* opposition to agro-food biotechnology, which have been targeted in the WTO complaint against the EU, and in fact, in a recently leaked intermediary report by the WTO Panel, found to cause an "undue delay" of GMO approvals and thus to be inconsistent with WTO agreements.

[15] The regional movement largely coincides with the countries mobilized against agro-food biotechnology in the late 1990s: By January 2006, the alliance comprised 12 French, 8 Italian, 8 Austrian regions, two regions in the UK (Wales and the Highlands and Islands) and all Greek regions.

[16] http://www.gmofree-europe.org

[17] "The informal moratorium on GM crop approvals and the subsequent revision of the directive on the intentional release of genetically modified organisms illustrate how escape clauses can provide opportunities for trading up even after common rules have been agreed." (Young/Holmes 2006: 289)

Effects on an Emerging System of Global Governance

And yet, apparently the EU is more than a receiver of instructions emanating from an international free trade regime, more than just responding to external pressures. Being a global policy recipient, the EU is also a global policymaker. The set of global rules and standards agreed upon with the participation of the EU in various fora pertaining to agro-food biotechnology's global governance are incorporated in the Union's legal framework. As will be shown in the following passages, the EU is seeking to move these standards as close as possible toward its own legal framework. Its coping with internal dissension thus translates into global rule making. To demonstrate this we will first, take a look at the emerging system of Agro-food biotechnology's global governance, in a subsequent step we will examine the EU's strategic approach to this system.

Agro-Food Biotechnology's Emerging Global Governance

Already in the 1970s and 1980s, debates regarding the safe use and regulation of modern biotechnology were international in reach. (Cantley 1995) While individual states acted as regulators, regulatory standards widely diffused across national boundaries as, for example, the guidelines of the U.S. National Institute of Health (NIH) for the safe laboratory use of recombinant DNA technology, or the recommendations of Organisation for Economic Cooperation and Development (OECD 1986). In the late 1980s, a tendency of regulatory regionalism began with the passing of the two European Community (EC) Biotechnology Directives, with the first regulating the use of modern biotechnology within research facilities, the other one the environmental release of GMOs.

The major push for a *global* regime regulating the trans-boundary movement of transgenic organisms and commodities came in the early 1990s and was driven by the anticipation of an imminent rise in international trade with such products. Since then, a - still evolving - structure of multilateral agreements (MAs) and international institutions has emerged that shapes the global governance of agro-food biotechnology in matters of international trade as well as food and environmental safety. Major MAs are the Cartagena Protocol on Biosafety, and the Agreement on Sanitary and Phytosanitary Measures (SPS), major international

organisations are the World Trade Organisation (WTO), and the standard-setting Codex Alimentarius Commission (Codex).[18]

The Cartagena Protocol on Biosafety was adopted in early 2000 as a supplement to the Convention on Biological Diversity (CBD). The Protocol sets up a legally binding framework allowing member states to make informed decisions on - by consequence to eventually reject - the import of Living Modified Organisms (LMOs) into their country.[19] While the Protocol is an environmental treaty, in seeking to regulate the movement of LMOs from one country to another it has major implications for international trade. Indeed, these trade concerns, particularly among developing countries worried to become testing grounds of an unexplored technology, constituted the major rationale to start negotiations on the Protocol. (Falkner 2002)

The SPS Agreement has been negotiated in the GATT Uruguay Round with the objective of minimizing trade barriers created by national standards to protect human, plant, and animal life and health. It thus commits WTO members to eliminate those standards which result in arbitrary discrimination and harmonize them to a level that distorts trade to a minimal extent. Measures should not create disguised trade barriers and, except for interim measures, must be based on scientific risk assessment. Like the Cartagena Protocol, the SPS Agreement thus affects trade with biotechnology products. In contrast to the Protocol, the enforcement mechanism of which is still under discussion, the SPS Agreement is based on the powerful dispute settlement mechanism of the WTO.

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[18] The above sketch on agro-food biotechnology's global governance is not exhaustive but focuses on its major constituents. Further free trade agreements impinging on trade with GMOs are the General Agreement on Tariffs and Trade (GATT) and, as part of it, the Agreement on Technical Barriers on Trade (TBT) promoting the development of international technical standards. Further international organisations closely observing and, to some extent, co-shaping governance are the World Bank, the UN Food and Agriculture Organization (FAO), the Consultative Group on International Agricultural Research (CGIAR), both promoting agricultural technologies, the World Health Organization (WHO), and the United Nations Environment Programme (UNEP). (Paarlberg 2003: 87-88) As technical standard-setting bodies, one can further mention the Office International des Epozooites (OIE), the International Plant Protection Convention (IPPC) and the OECD. In preparing its ruling on the EC Biotech Products case the WTO panel, for example, sought information from the secretariats of the CBD, the Codex, FAO, IPPC, OIE, UNEP and the WHO. (WTO 2006: 255)

[19] Article 19.3 of the CBD obliged Parties to the CBD to consider the modalities of a protocol defining procedures for the safe use of (comprising and trade with) LMOs that may have adverse effects on biodiversity. The Protocol became effective in September 2003 and, until now (June 2006), has been ratified or accessed by 132 states. (http://www.biodiv.org) Subsequent negotiations addressing the protocol's further interpretation and translation into appropriate domestic laws took place in the course of three "meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol" (COP-MOP 1-3) in February 2004 (Kuala Lumpur), in May-June 2005 (Montreal), and in March 2006 (Curitiba).

It is this outstanding enforcement power of the SPS Agreement that adds weight to a number of international standard-setting bodies, as the Agreement explicitly recognizes the standards and recommendations of three international organizations; of the Codex in the area of food safety, of the IPPC in the area of plant health, and of the OIE for animal health. (Wolff 2003: 1) While these international standards are not legally binding, WTO members have a strong incentive for harmonizing their SPS measures on their basis since, in 1995, the WTO declared Codex norms to the reference point for evaluating the legitimacy of food regulatory measures within its free trade framework. Countries maintaining stricter measures without scientific justification therefore run the risk of colliding with free trade disciplines that might eventually be enforced by WTO dispute settlement.

Lasting Tensions

Neither is this governance system complete nor can it be expected to work frictionless in the future. The SPS Agreement backed up by the WTO dispute settlement mechanism appears well consolidated at first glance. It depends, however, on the standard-setting bodies pointed out above, whose approach to legitimate hurdles to trade might diverge from the Agreement's provision. As to the Biosafety Protocol, the actual meaning of some of its rules and procedures are still being negotiated. In the ongoing implementation phase, negotiations are controversial. Major agro-biotech exporters, particularly the U.S. and Canada, who are reluctant to ratify the CBD or the Protocol respectively, effectively influence decision-making processes in both passive and active ways; passively, since parties to the Protocol need to be considerate of the positions of major exporters, and actively as non-parties can intervene in negotiations through allied member countries. Similar gulfs operate among members, depending on whether and to what extent they belong to the agro-exporting or importing side.[20]

Most important are the *structural* contradictions inherent in this governance regime, which result from the different rationales of its components. Whereas the SPS Agreement is designed to minimize obstacles to international trade, the Biosafety Protocol's principal objective is to watch over ecological diversity and human health, and the Codex Alimentarius

[20] For the Protocol's history see Bail et al. 2002, for past progress in implementation see: Falkner/Gupta 2004, MacKenzie 2004, Secretariat of the Convention on Biological Diversity 2003.

attaches importance to both consumer safety and consumer rights. As the effects of these rule types potentially work against each other, their relationship is still unsettled.[21]

Risk, Science, Precaution

For the most part, these contradictions play out in the form of scientific disputes over real or hypothetical *physical risks* emanating from modern biotechnology. Physical risk, i.e. threats to human health and the environment, figures as central criterion in the global governance of biotechnology. In theory, alternative criteria for restricting trade in GMOs, e.g. socio-economic or ethical concerns, are conceivable. (e.g. Gupta 2001) Developing countries and NGOs in particular have been pushing for the inclusion of socio-economic criteria into the Biosafety Protocol. The consideration of these factors, however, has been granted only insofar as these factors "are linked to impacts on a country's biodiversity and are consistent with other international obligations (such as those of the WTO)." (Gupta/Falkner 2006: 3) In practice, therefore, *physical*, in this case ecological, risk remains the central argument against the introduction of GM products or LMOs respectively, while recurrent attempts undertaken by various sides to include *other* criteria than physical risk as grounds for legitimately restricting international trade in GMOs have been systematically rebutted in the past. This holds even more for the SPS Agreement, in which Jaqueline Peel, based on an analysis of recent rulings, clearly identifies: "a move away from recognizing the legitimacy of Members' risk management policies motivated by domestic social considerations towards the seemingly more neutral and universal criterion of science." (ibid. 2004: 3) With minor variations, however, the supremacy of physical risk also holds for the Biosafety regime. (Seifert 2005a: 376-378)

As a result, *science* plays a central part in governing agro-food biotechnology. First of all, this is due to the SPS Agreement which, aiming at ruling out disguised trade barriers, requests that national safety measures be based on scientific risk assessment procedures in order to demonstrate the need for these measures. (Noiville 2006: 311) The SPS Agreement thus elevates science to the arbiter over the legality of national SPS measures, treating it not

[21] Paragraph 10 of the preamble to the Cartagena Protocol states that it "shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement", which is qualified by the subsequent paragraph stating that "the above recital is not intended to subordinate this protocol to other international agreement." Whether the Protocol's thus stated objective of an equal standing with "other international agreements" provides the ground for an harmonious coexistence of Protocol and WTO-backed free trade disciplines or will have to be played out by means of the WTO dispute settlement procedure is open to future developments.

only "as a sufficient but - at least in practice - also a necessary criterion for establishing the legitimacy of relevant trade restrictions."[22] (Hormeyer 2006: 272, Skogal 2001: 495) In the same vein, the Cartagena Protocol requires that risk assessment "shall be carried out in a scientifically-sound manner." (Article 15 (1)) The emphasis on scientific risk assessment thus appears to create common ground between the Biosafety and WTO regime, particularly if one believes that science is able to deliver positive knowledge as to the risks emanating from GMOs.

Then again, we might ask whether the *concepts* of science in the risk-based approach of the SPS Agreement and the Cartagena Protocol enshrining the PP respectively are the same. As to the PP, while there is no single, generally agreed on definition, as a general rule, "precaution justifies uncertainty."(Levidow 2001: 868) Neither is the existence of a risk to be scientifically ascertained nor is its causal nature to be fully understood. The hypothetical proposition of a risk, a plausible supposition as to its causal pathways may suffice to warrant restrictive action. Further, the Biosafety Protocol does not provide a definition of what constitutes a "scientifically sound" risk assessment. Hence, "identifying what constitutes a 'scientifically sound manner' may give rise to disagreement between States." (MacKenzie et al. 2003: 108) The SPS Agreement, conversely, strongly relies on science which it tends to regard as a source of unambiguous knowledge. Thus, WTO Panel interpretations of the SPS Agreement confirm that risk assessment must be based on scientific principles, and are not to be maintained without sufficient scientific evidence. Also, in making Codex the benchmark for food standards countries are allowed to adopt stricter standards only if they are scientifically justified.

Beyond scientific differences, the PP entails a more general regulatory gulf. The SPS Agreement's strong reliance on science "is essentially in harmony with the focus on use-related experience at the base of sectoral legislation because such experience can often be transformed into scientific knowledge." (Hormeyer 2006: 279) The framework chosen by the U.S. is a sectoral regulation too. The horizontal Biosafety Protocol, by contrast, is *in itself* precautionary as it is based on the mere assumption of potential dangers caused by modern biotechnology: "Unlike other multilateral environmental agreements, the Cartagena Protocol was negotiated without evidence of concrete environmental damage resulting from the

[22] As stipulated in Articles 2 (2) (Basic Rights and Obligations) and 5 (Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection of the SPS Agreement)

release of LMOs into the environment. What is more, the scientific community was deeply divided over the potential risks involved. Thus the biosafety agreement is a truly precautionary instrument, setting rules for decision-making that seek to minimize the risk of future, potential, damage." (Falkner 2002: 4) Such a horizontal approach corresponds with the European regulation which, already in early 90s, was set up on the base of two Biotechnology Directives (on "deliberate releases" and use in "contained systems") which both treat the characteristics of the production process - i.e. use of modern biotechnology - as regulatory trigger, and in prescribing protective health measures even in the absence of clear scientific proof of harm.

Labelling

The Biosafety Protocol requires exporters to identify through accompanying documentation any LMO intended for direct use as food, feed or for processing (LMO-FFP) which - actually or supposedly - contains LMOs. It further entitles importing countries to enforce this identification requirement. (Article 18) It is clear that, in spite of the Protocol's stated aim of protecting human health and biological diversity, by burdening exporters with extra transaction costs, the labelling requirement affects international trade in the first place, and thus the capability of importing countries to set up food labelling regimes designed to guarantee consumers' freedom of choice. The split on this issue between GMO exporters and importers in general, and the EU and the U.S, in particular, is obvious. Already in the early 1990s, U.S. regulators decided not to label GM food, the EU, by contrast, since then set up the most exhausting labelling system in the world. Also, in the weave of global free trade rules, the Protocol's labelling provision might lead to conflicts once becoming mandatory. Taken together these differences explain why the labelling clause remained contentious throughout the negotiations on the Protocol's implementation. (MacKenzie 2004: 274-275, Falkner/Gupta 2004: 4-7, CBD 2005: 57)

Precautionary Non-Interference

There is an ongoing debate as to whether and to what extent the regimes of the Biosafety Protocol and the SPS Agreement are bound for collision. To be sure, both regimes contain features designed to avoid conflict. The Biosafety Protocol, for example, contains careful wording ruling out either its overriding of or subordination to other international agreements. The Preamble of the Biosafety Protocol emphasizes that the Protocol "shall not be interpreted as implying change in the rights and obligations of a Party under any existing international

agreements" which, as is clear from the Protocol's negotiation history, primarily implies the Party's obligations under the WTO. At the same time the Preamble clarifies that this provision "does not subordinate the Protocol to other international agreements." (MacKenzie et al. 2003: 27-29)

The SPS Agreement, in turn, contains "elements of precaution." (Shaw/Schwartz 2005: 6, Noiville 2006: 311) In spite of the Agreement's strong reliance on science, for instance, previous WTO Panel interpretations neither insisted on a certain standardized manner in which risk assessment had to be carried out nor that science relied on had to be based on a mainstream scientific opinion. It thus proved flexible as to scientific uncertainty. What is more, the Agreement entitles members to take provisional SPS measures "in cases where relevant scientific evidence is insufficient." (Art. 5.7) This provision appears to correspond to the PP as it deviates from the requirement of a risk to be demonstrable.

The right to take such precautionary steps, however, is circumscribed by a number of further provisions: the measure is thought to be only provisional and must be adopted on the basis of available pertinent information, members are obliged to obtain additional scientific information for a more objective risk assessment and to review the measure within a reasonable period of time. In comparison to the Biosafety Protocol, which does not include such obligations, the Agreement's precautionary options are therefore to be considered as a rather weak version of the PP.

At any rate, in spite of some common ground between the Biosafety and SPS regimes, their legal compatibility remains an unresolved issue. More specifically, it remains unclear whether the pre-established harmony between the Biosafety and WTO regime as laid down in the Cartagena Protocol's preamble will hold in the longer term. The WTO also contains a clause stating that no other MA can take precedence over it. Who is to win if precautionary measures are justified under reference to the Biosafety Protocol which are then challenged by contenders under WTO law or vice versa?

What can be said so far is that, on the part of the WTO, no need has been identified to alter existing rules to accommodate environmental MAs like the Biosafety Protocol. The "status quo" is thus upheld. (Shaw/Schwartz 2005: 9) On the part of the proponents of the Biosafety

Protocol and the PP respectively, attempts are being made to establish the PP as a recognized principle of international customary law. (ibid: 4-5)

The EU's Global Strategy and Its Outcomes

The assertion argued for in this article is that the EU, while domestically coping with dissension, acts as a shaper of agro-food biotechnology's governance in the international environment. We accordingly expect the EU to systematically seek to improve its bargaining position in international fora which entails attempts to speak with one voice in negotiations in order to enhance negotiating power. From the sketch of agro-food biotechnology's global governance system follow the focal points of investigation. First, we expect conflicts over the shape of biotechnology's global governance to play out as conflicts over regulatory and scientific approaches to risk assessment. Secondly, given that the EU's regulatory approach is mainly designed to cope with consumer concerns, we expect the Union to pursue the core principle of its food policy, the consumers' right to chose, at the international level, or if that proves unworkable, to create international regulatory conditions favourable to its own strict labelling requirements.

Precautionary Entrepreneurship

As regards the Union's position with respect to the Cartagena Protocol there is unambiguous evidence for the EU acting in the way predicted. This becomes clear in hindsight. In the course of the biosafety negotiations from the mid to the late 1990s the EU, firstly, became a clear supporter of an legally binding, international instrument and, secondly, progressively channelled its negotiating power in order to speak with one voice and so increase its negotiation leverage.

"The negotiations began with little political visibility, as the EU engaged mainly in responding to the demands of the developing countries. In the end, the negotiations had important political stakes for the EU itself." (Bail et al. 2002: 166) A combination of endogenous and exogenous reasons accounts for the fact that, by the end, a successful outcome had become so important for the EU. (ibid. 167) Domestically, it was the consumer crisis of the late 1990's, which pushed the EU to present itself as an advocate of global action for safety in biotechnology. In the international environment, by the late 1990s, the EU faced

the challenge of trade sanctions as GMO approvals had ground to a halt under its Biotechnology Directive 90/220.

This threat appeared very real because, at about the same time, the Union suffered a defeat in the trade conflict over its ban on hormone-fed meat. In 1989 the EU, after protracted debates since the early 1980s, had issued a ban on the production and importation of meat derived from animals treated with growth hormones, and in 1991, it outlawed the use of hormones to increase milk production. Since the Union justified its ban with safety concerns (as was shown above, the only viable route for legitimising such a ban) the U.S. and Canada, after a Codex ruling had declared the products safe, filed a complaint against the ban at the WTO. Since the EU failed to provide a positive risk assessment supporting the ban the WTO Appellate Body ruled it illegal and granted the USA and Canada the right to issue trade sanctions.

Punitive tariffs hit European producers in summer 1999, just at the same time as anti-biotechnology groups in major member countries like France or the United Kingdom attained maximum media attention, pushing governments to take action at European level. (Seifert 2006a) Thus, at the Environmental Council in summer 1999, France, Greece, Denmark, Italy and Luxembourg set up their "political moratorium" on future GMO approvals until amendment of the regulatory framework was completed. Yet again, the EU found itself in the awkward position of blocking a technology considered safe by major trade partners and international standards. The thus looming trade conflict over agro-food biotechnology resembled the hormone conflict in crucial respects; again a strategic agricultural technology was at issue, again the EU, against long odds, needed to demonstrate it to be unsafe, and conflict resolution would hinge on pretty much the same set of international regulations and institutions. It differed only in that the embargo on GMO approvals, and thus imports, was not the result of a Community policy proper but of recalcitrant member states' alliance building. The EU was nevertheless well-advised to work towards a system of global governance allowing for a more favourable outcome of an eventual trade conflict.

This suggested intensified engagement in favour of the PP and for the Biosafety Protocol, as it now seemed possible that the Protocol might be a vehicle for introducing the PP firmly into an international legally binding agreement. Even though, under the "status quo," it was unlikely that the Protocol would be recognized as a relevant international standard-setting

body under the SPS Agreement, it nevertheless could be expected to form part of the wider legal context in which the Agreement operates.

Furthermore, "it was felt that adopting the protocol would bolster the EU's defences in the event of a WTO challenge to its regulatory framework for safety in biotechnology and how it was applied, a concern that had arisen with the grinding to halt of approvals under Directive 90/220." (Bail 2002: 167) In contrast to the regulatory approach of the U.S., both the EU Directive on Deliberate Releases and the prospective Protocol are based on the PP and, perhaps more important, use characteristics of the production process as regulatory trigger. With the Protocol the EU therefore could envisage the chance to universalise its regulatory approach.

The biosafety negotiations also provide evidence for a gradual concentration of negotiation leverage on the part of the EU. First, this was due to changes in member states' positions regarding the Protocol which were brought about by the pan-European anti-GM mobilization. While a bloc of critical countries - mainly Scandinavian countries and Austria - consistently had supported the PP and Protocol respectively, other important members, in particular the UK, France, the Netherlands and Germany, who had been sceptical at the outset, shifted to a promotional position in the late 1990s. Thus, "views of member states had largely converged by the time of the Cartagena meeting, which greatly facilitated the tasks of the EU's negotiators and strengthened its negotiating leverage." (ibid.)

Furthermore, the Commission succeeded in extending its negotiation mandate. In 1994, it was neither clear on whether to give priority to an international, legally binding instrument nor justified in issuing a negotiation mandate as it was still to be decided whether to open negotiations at all. Prior to the official onset of biosafety negotiations in 1995, however, the Commission sought to ensure that the EU's position would be prepared, as it now considered the implications for the EU's legislative framework for biotechnology and its respective trade interests significant. "It would be essential from the outset, indeed from the stage of deciding whether to launch negotiations and what their scope would be, to arrive at a unified internal position and a coherent outward presentation of views." (ibid.: 169)

Unlike the other actors in international negotiations, either single states or loose groupings of states formed in an ad hoc manner on the basis of common interest, the EU is required to

adopt a common position, which is mostly represented by the Commission. To act as negotiator in international negotiations, however, the Commission depends on member states' support, as the treaty establishing the EC lays down that the Council, in areas of EU competence, decides the line for the EU via negotiation directives, while the Commission negotiates on behalf of the EU based on these directives. Whereas, in the early years, a considerable amount of energy went into discussions on who did what, when and how, and member states proved reluctant to allow the Commission to negotiate on its own, in the final meeting of the extraordinary meeting of the Conference of the Parties (ExCOP) in Cartagena, the Commission managed to assume the role of sole EU negotiator.

The EU as Player in Codex Negotiations

In recent Codex negotiations, the Commission displayed virtually the same pattern of targeted, strategic behaviour, seeking to obtain a negotiation mandate from member states, promoting the PP and, implicitly, the consumer's right to choose and, specifically regarding biotechnology, promoting its labelling and traceability agenda. Again, it was the trade conflict over the EU's ban on "hormones in beef" which both lent significance to Codex food standards and appeared to constitute a precedence to the looming transatlantic confrontation on agro-food biotechnology. It had been a vote in the Codex in 1995 which – by a majority of 152 country members approving the use of the hormones and against the opposition of the EU - had rubberstamped the U.S.' and Canada's appeal to the WTO to rule the EU ban illegal. (Skogstad 2001: 496) The existence of harmonised standards disallowed the EC to justify measures resulting in a higher level of health protection. In view of future disputes, it suggested itself to the EU to strongly defend its interests within this standard setting organisation. As can indeed be shown, in recent years this actor has both considerably strengthened its position as a policymaker within the Codex and sought to shape standards so that they reflect as much as possible its own food policy objectives.

First, the EU strove to strengthen its position as a policymaker within the Codex Commission. In 2001, the Commission sought full membership status, justifying the step with the necessity to ensure that the interests of the EU were taken into consideration in the negotiation of Codex standards and to reinforce their coherence with EU regulations. (Poli 2004: 618) This implied a role for the EU not solely as recipient but also maker of Codex rules. Until then, while the EU as regional organisation had enjoyed observer status, only individual European countries had been Codex members. Its defeat in the hormones case clearly revealed the

strategic importance of the Codex and enhanced the Commission's determination to fully participate in its negotiations. Although, due to the still valid principle of 'one state-one vote', Codex membership did not result in having a greater number of votes, speaking with a single voice would nevertheless augment the bargaining power of the EU now perceived as stronger than the mere sum of its members. Against the opposition of particularly the U.S. and some Latin American States, the EU lobbied intensely for its membership which was eventually granted in 2003.

Secondly, the EU's strategic regulatory aims are reflected in the way in which it defended a number of principles in recent Codex negotiations that are all embedded in EU food and biotechnology law. Thus, the EU pushed for the consideration of the PP, as well as "factors other than science" in Codex in risk management and decision-making processes. As to food derived from biotechnology in particular, the EU insisted on the need to label and impose traceability requirements. Consistently, in Codex negotiations these views clashed with those of the U.S. holding a fundamentally different view on the issue.

The PP became a subject of regulatory dispute in the debates on Codex working principles for risk analysis held from 1997 to 2003. (ibid.: 619-622) At issue was whether the Codex should lay down guidelines for products carrying potentially severe though scientifically unverified health risks which inevitably brought the PP into play. As expected, the Europeans advocated the elaboration of guidelines and the inclusion of the PP arguing this was necessary to restore consumer confidence in risk analysis. The U.S. fervently opposed the idea on grounds of a lack of an internationally accepted definition of the principle. In their view, existing provisions under the SPS Agreement sufficiently and adequately dealt with scientific uncertainty over risk.

A like constellation occurred in the debates over the inclusion of "factors other than science" into Codex standards, notably the Statements of Principle of the Codex Procedural Manual on the "Role of Science in the Codex Decision-Making Process" (ibid.: 623-625) While the precise meaning of these "other factors" remained vague throughout the debate, it pitted EU against U.S., with the former as their principal promoter, the latter as their major adversary. For the U.S. the "principle of sound scientific analysis and evidence" hitherto keystone of the Codex food standards (and normative fence against arbitrary barriers to trade) was watered down by the provision which, in turn, appealed to the EU, as it allowed for the consideration

of additional restrictive criteria, in particular environmental and consumer concerns. In past debates on bovine growth hormone within the Codex Commission, for example, members of the EC had attempted to invoke these factors to encumber the hormones' approval procedure. In 2001, eventually the Codex Procedural Manual was amended in a way which, albeit in a highly qualified and restricted form, took "factors other than science" into consideration.

Finally, Codex discussions centring on risk management options concerning food derived from biotechnology fit the predicted pattern. In various Codex committees which, for over 10 years, negotiate food standards in this sector the divergent views of the EU and of the U.S. overshadowed debates.[23] Ongoing is the conflict between two options on food labelling. The one advocated by the EU calls for the labelling of all GM foods, the other, which is supported by the U.S. and its agro-exporting allies, has GM food only labelled in case its product composition is no longer "substantially equivalent" to a conventional counterpart. According to the U.S., only "scientific," thus "objective," information on health risks is to be conveyed to consumers, who otherwise would be misled into stigmatising GM food. For the EU, conversely, consumers' unqualified "freedom of choice" makes the selling of any unlabelled GM foods, regardless of their product properties, a deceptive practice. While the U.S. categorically oppose any approach based on the production process and consent but to voluntary labelling arrangements, the Europeans have to defend mandatory labelling, that is even coupled with a cumbersome traceability regime. It is thus no wonder that, up to now, differences in protracted Codex negotiations have not been resolved and, indeed, are unlikely to be resolved in the foreseeable future. What the above paragraphs nevertheless clearly illustrate is the EU's determination and systematic effort to shape food standards negotiated in an institutional system satellite to the WTO and pivotal to the agro-biotechnology's global governance.

Conclusions: Ironies and Outlook

The analysis in point aims at explaining the EU's biotechnology policy rationale both in its domestic and global dimensions. Domestically, the policy can be interpreted as an attempt to cope with the highly influential opposition to agro-food biotechnology, due to contingent circumstances (BSE crisis, the ongoing project of European integration). The main

[23] Even though the Codex Alimentarius Commission in 2003 adopted Principles and Guidelines on foods derived from biotechnology specifying principles on the risk analysis and guidelines for food safety assessment, the debate, particularly on food labelling, is yet far from conclusion. (Codex Alimentarius Commission 2004)

ingredients of this coping strategy comprise two normative principles - consumers' "freedom of choice" and the PP - as well as an organisational approach; traceability. While the legal framework that rests on these pillows is probably the world's most stringent and best policed regulation of agro-food biotechnology, it is nevertheless designed and - since the lifting of the moratorium in 2004 - actively employed by the Commission to *render possible* the introduction of GMOs into the European production-chain. The major reason for this trade-off between restrictive and enabling features is the EU's integration into a global system of free trade law under the aegis of the WTO, and the pressure brought to bear on the EU through this system by agro-exporting countries. The EU policy can be conceived as mediating between internal dissension and global free trade imperatives.

Having said this, it needs to be stressed that the EU's policy goes beyond a merely inward-looking, mediative response to external and internal pressures. The EU also acts as *global* policy maker seeking to align features of an emergent system of global governance entailing trans-boundary information sharing, practices of risk assessment, food standards and labelling etc. to its own regulatory principles and norms. Main arenas of its engagement have been shown to be the negotiations preceding the endorsement of the Cartagena Protocol, and still are the negotiations on the terms of its implementation. Certainly less momentous but featuring the same combination of focussed and strategic behaviour is the EU's pursuit of its regulatory goals in various Codex fora. Domestic policy mediation between both member states, some of whom responded exceedingly hostile to agro-food biotechnology, and supranational and global levels of governance is thus linked to global policy entrepreneurship.

The pivotal part in this "multi-level game" is played by the Commission who, internally, figures as architect and executor of domestic policy, and on the exterior, as policy entrepreneur; Domestically, EU biotechnology policy making is characterised by a standard interplay of European institutions, with the Commission acting as designer and defender of regulatory objectives, member states impinging on the harmonization process through the Council of Ministers, and the European Parliament, backed by co-decisional powers, mostly attempting to influence the policy process in favour of non-market criteria. Most leverage, after the Commission, have member states; member states, collectively able to control the approval process through the Council of Ministers, imposed the moratorium on the Commission, persistently thwarted its attempts to restore the approval process, and thus urged

the framework's tightening. Still, most significant in the policy process is the Commission as designer and enforcer of EU policies.

The same holds for the global level. As has been shown for two critical fields in the global governance of agro-food biotechnology, the Biosafety and Codex negotiations, the Commission resolutely acquired and extended its negotiation mandate in order to speak with one voice on behalf of the Union's member states, and it strategically attempted to establish principles and standards in international agreements - the precaution, process-based regulation, labelling - that are part and parcel of its own system. Figure 1 depicts this double role of the Commission.

Fig. 1: The EU as dissonant player in the global governance of agro-food biotechnology; the Commission's role.

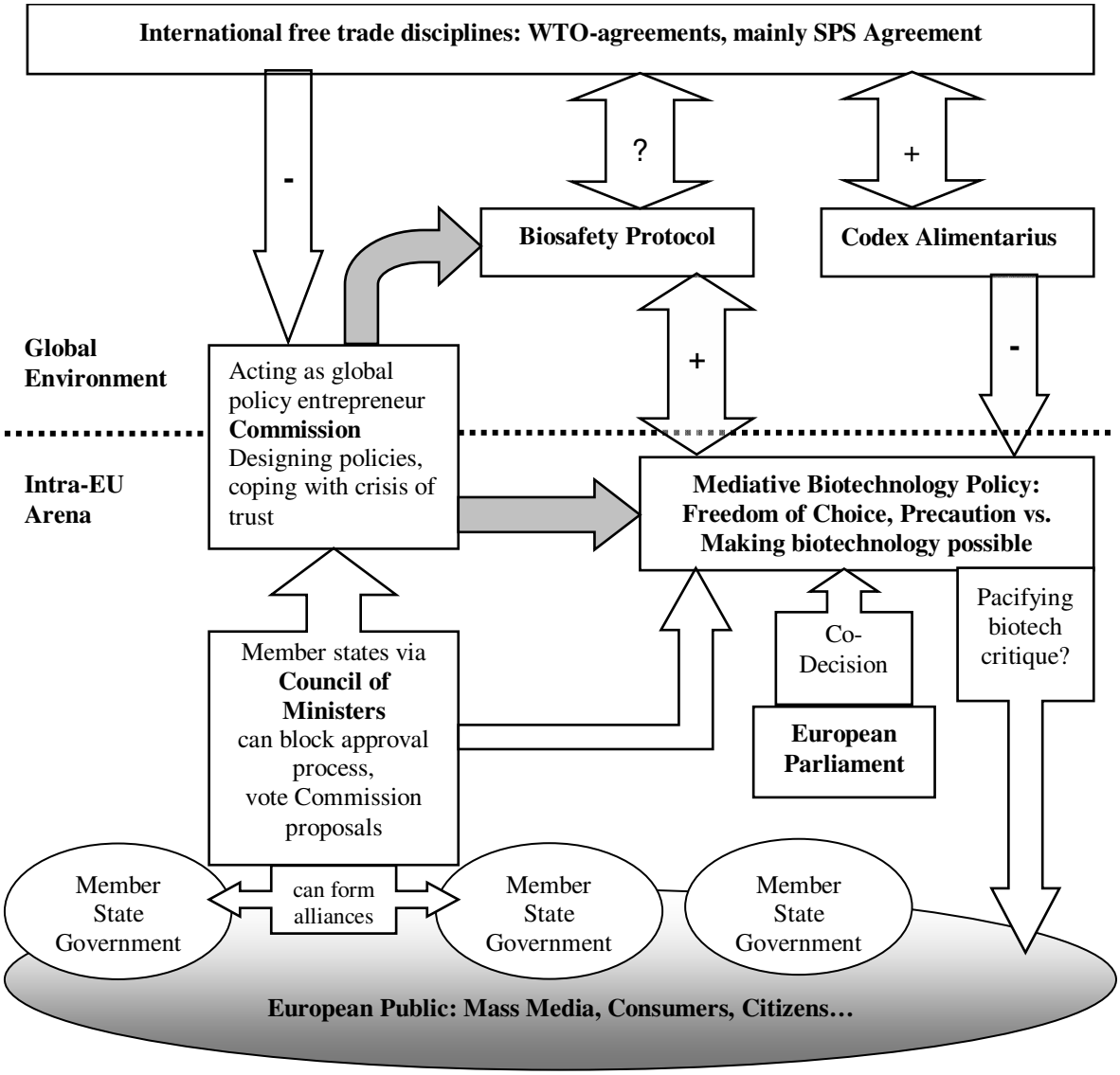

Fig. 1 condenses the EU's biotechnology policy rationale at both the supranational and the global level and highlights the pivotal role of the Commission in interlinking these levels. In an attempt to cope with a crisis of trust and pressurized by a fraction of member states, the Commission designed the EU's mediative biotechnology policy combining restricting and enabling elements with the former meant to restore trust in food authorities, and the latter to align EU regulations with WTO trade disciplines. At the same time, the EU, again to a major part represented by the Commission, seeks to shape an emerging system of global governance in order to assimilate it to its own regulatory goals. Most effective has been its involvement in the Biosafety negotiations, the significance of which for matters of global trade, however, is still unclear. Another, less effective, focus has been on Codex negotiations which have a direct bearing on WTO decisions. WTO law, the SPS Agreement in particular, clearly is the decisive legal corpus, which itself is affected only to the extent it is clarified by the appellate body in the ongoing case. The "+" symbol inside double-arrows stands for a positive correspondence between supranational and global legal frameworks and institutions respectively. The "-" symbol indicates a constraining effect from one international actor or legal corpus onto another.

Ironies

A number of ironies spring from these insights. First, there is an ironic note to the fact that the EU's internal dividedness over GMOs begot a unified position and strategy in the global arena. In order to come to terms with biotech opposition decisively augmented by an alliance of recalcitrant members states, as well as drawing lessons from the previously lost hormones case, the Commission sought to universalize elements of a biotechnology policy it had designed to cope with internal dissension. Internally divided, the Union stands its ground - or, at any rate, struggles to do so - in the global, particularly transatlantic arena.

Second irony: one of the major goals of the Union's mediative policy, to assuage public unease and to manage internal division over agro-food biotechnology, has *not* been achieved, and, in fact, is most unlikely to be in years ahead. A number of member countries are still unconvinced by the EU's regulatory framework and keep up their unremitting opposition to agro-food biotechnology. Recently European regions came to enter the stage as new critical actors, and vocal critical groups keep denouncing GMOs which apparently strings a chord with the European public.[24] Opposition is here to stay and keeps constituting a driving - or rather blocking - force within EU biotechnology policy. In spite of its highly restrictive regulatory system holding "consumer sovereignty" in highest regard a secure remedy against politically effective opposition still seems wanting.

Why? The answer lies in the ultimate subordination of the EU's biotechnology policy, equally designed to constrain and *render possible* the use of agro-food biotechnology, to the WTO free trade regime. In this respect, the Commission acts as agent of the liberal and scientific doctrines embodied in this regime. In the years of the "political moratorium," for example, the Commission again and again requested that member states lift the "political" ban which, in May 2004, it finally did by itself, unsupported by the consent of a majority of EU members, relying on the EFSA risk assessment only. Likewise, the bolstering of the EFSA as central, "objective" risk assessment agency is, to some extent, intended to put an end to the intractable disputes among national experts, which had ushered in the moratorium

[24] A recent Eurobarometer survey found "widespread support for medical and industrial biotechnologies, but general opposition to agricultural biotechnologies in all but a few countries" (Gaskell et al. 2006: 3) and, as to the latter, arrives at the conclusion that ""the introduction of the new regulations on the commercialisation of GM crops and the labelling of GM food appears to have done little to allay the European public's anxieties about agro-food biotechnology." (ibid.: 19)

in the late 1990s.[25] The reasons for the Commission's eagerness to reinvigorate the approval process are not to be found in the technology's utility for Europe's agriculture which, in fact, for the most part has come to avoid its use out of concern over hostile consumer and retailer reactions. Rather the Commission, beleaguered by the U.S. and agro-exporters insisting on WTO dispute settlement, needs to prove the feasibility of the European approval procedure, at least as far as the import of GM products is concerned. In turn, the Commission is seen as, once more, forcing GMOs on European consumers and agriculture. Hence, NGO alarmism is stirred alone by the fact that GMOs are still around, the technical and ecological viability of the co-existence regime envisioned by the Commission to give producers "the freedom of choice" is - perhaps rightly - questioned, and a number of member state governments is determined to uphold their anti-GM stance adopted in the late 1990s.

A similar irony suggests itself as we look at the efficacy of the EU's *external* coping strategy. While the EU was partly successful in its endeavour to install key elements of its regulatory system in an emerging structure of agro-biotechnology's global governance, particularly the PP enshrined in the Cartagena Protocol (which is not to imply the EU was mainly responsible for this outcome), the strategy - at least in the WTO case on biotech products and until now - seems not to have paid off.

Thus, the EU, in its defence in the WTO case, has heavily banked on the CBD, the Biosafety Protocol and the PP, arguing these agreements should be taken into account when interpreting the relevant WTO rules. Conversely, the Panel, similar to the plaintiffs' rebuttal of the suggestion, found that there was no obligation to take these MAs into account when interpreting WTO rules as the complainants were not parties to them.[26] As to the PP, the Panel found the principle to be too controversial to serve as a basis for Panel rulings. As precedent to the point, the Panel quoted the WTO ruling on the hormones case, which had come to the same conclusions. (WTO 2006: 249-307, Suppan 2006) A similar conclusion holds for the EU's engagement in Codex negotiations on food safety standards. The Codex had played a decisive role in the hormones case as it has been a vote in the Codex which had paved the way for the U.S.' and Canada's to appeal to the WTO to rule the EU ban illegal. In

[25] In fact, the new centralisation of scientific risk expertise in the EFSA, together with a more complex regulatory framework, now allows applicants to bypass member states' risk assessment. This could smoothen and accelerate the GMO approval process in years to come.

[26] The U.S. have signed but not ratified the CBD, nor have they signed the Biosafety Protocol. Canada and Argentina are members of the CBD and have signed the Biosafety Protocol which, however, they are reluctant to ratify.

the biotech products case the WTO panel, while often falling back on Codex definitional groundwork, ruled on both the moratorium and national bans primarily on procedural grounds so that the Codex never attained as much significance as in the hormones case. Hence, at least for the time being, the political caution the EU has exercised with so much determination in the realms of global governance has as yet proved futile.

A forth irony which comes to mind, when dealing with the European case, concerns *the role of science* in decision making. As has been pointed out, in both the global and the European governance of agro-food biotechnology, scientific risk assessment is assigned a key role in the GMO approval process. As physical (rather than socio-economic, therefore "political," and therefore "protectionist") risk is the only legitimate restrictive criterion allowed into biotechnology's global governance and, since to clear a product as safe for use and consumption is a genuinely scientific task, the "soundness" of scientific risk assessment is stressed in all pertinent inter- and supranational prescriptions. Nevertheless, one of the EU's major quandaries, incriminated in the WTO biotech case and ultimately found to contravene free trade law - the national safeguard bans - apparently testifies to the *inability* of science to play its role as a neutral, objective arbiter, at least not to the satisfaction of those envisioning an integrated approval mechanism functioning smoothly under a free trade regime.

Member states' governments issued their product bans by invoking a safeguard clause in the respective biotechnology regulations allowing them to provisionally prohibit GMOs on their territory provided new information or a "reassessment of existing information on the basis of new or additional scientific knowledge" has led them to the conclusion that a GMO already cleared for marketing constitutes a risk to human health or the environment. Regardless of their "soundness," it has to be recognized that the arguments brought forward by member states' experts to justify these bans constitute *scientific* arguments. As such they can only be countered by other scientific arguments. After EU committees and, from 2002, EFSA had refuted these arguments, national experts insisted on their validity. Who is to settle this disagreement?

The WTO Panel, in ruling that the national bans go against the SPS Agreement and recognizing the inconsistency of a European situation with its sustained national bans in spite of contrary EU assessments, formally has taken a purely legal decision, in effect however, it

has privileged one over another scientific opinion:[27] In its preliminary findings, the WTO Dispute Settlement Panel concludes that the national safeguard bans do not meet the SPS requirement for a science-based risk assessment - violation of SPS article 5.1 - nor can member states demonstrate that they applied provisional SPS measures because of inadequate scientific information - violation of SPS article 5.7. The panel found that national safeguards failed to meet the requirements stipulated in these articles as the arguments in their defence did not did not include risk assessments. According to SPS Annex A(4), risk assessments need to entail an evaluation of the likelihood of entry of a potential for adverse effect, which, in the panel's opinion, none of the member states were able to demonstrate. Conversely, the relevant EC scientific committees, who had assessed the products as safe, had later refuted member states' risk assessments and their contention of insufficient scientific evidence. In other words, the product bans by EC member states, which are allowed in SPS article 5.7 only in case of insufficient scientific evidence, were judged unlawful by the panel because the EC scientific committees had stuck to their original assessments and turned down member states' attempts to demonstrate their insufficiency. (WTO 2006: 920-1016) Obviously, the panel's conclusions relies on one corpus of expert opinion and discounts another. (Suppan 2006) Undoubtedly, the Panel's opinion will back up the Commission in future attempts to compel member states to lift their safeguard bans, but it cannot *resolve* the scientific dispute over possible harms to human health and environment from GMOs. Currently, the conclusion and the expert opinion on which it is based is being hotly debated. Only science could resolve this dispute, but today we are simply not able to make out any such resolution.

The Commission has attempted to make EFSA both the institutional gateway to a faster approval procedure, virtually circumventing potentially dissenting, national experts, and the authoritative voice in scientific risk assessment. Yet, as has turned out, the dissenting voices of national experts keep on challenging EFSA's scientific verdicts. A dilemma becomes apparent: "regulators depend on expert advice but cannot credibly delegate responsibility for adjudicating disagreements among experts." (Levidow 2006: 12) The dilemma pertains to the European as well as to the global governance of agro-food-biotechnology since both the European and the global governance of agro-food biotechnology depend on a scientific

[27] In general, the WTO Panel conspicuously refrained from making factual statements reserved for a scientific assessment. Thus, for example, its outspoken denial of giving any judgement on the general safety of GM food and products.

judgment over the safety of GMOs but, since scientific evidence is always disputable, science is far from delivering any such judgement.

Outlook

Since, in the early 1970s, a number of molecular techniques have converged to form what came to be called modern biotechnology, speculation about the future scientific, industrial and political evolution of this technology are marked by an excess of often exaggerated and mostly wrong predictions. If therefore this essay concludes with a number of forecasts these are to be taken with a grain of salt. Events, coincidental and unpredictable as they are, may and will impinge on the emergent field of agro-biotechnology's global governance, as they already have when, for example, the BSE crisis shook and ultimately rearranged the fundaments of the EU's food and biotechnology policy.

Nevertheless, a first prediction regarding just this policy claims to be plausible if not obvious; it suggests that the EU's current regulatory framework is here to stay. Not the regulatory framework but rather its malfunctioning has been at issue in the legal case, and the Commission has invested considerable energy into cleverly working out a policy design that strikes a balance between internal consumer concerns and external free trade disciplines. Likewise, the Commission was instrumental in restarting the approval machinery and is still determined to keep trying to eliminate residual frictions with free trade disciplines, which chiefly means bringing down national safeguard bans. Moreover, agro-exporting countries by now have understood that Europe's biotechnology backlash for the most part represents an independent market response, rather than resulting from a revised policy framework. Its dismantling in the medium term by external pressures from agro-exporting countries therefore seems highly improbable.

Things might be different with the domestic functioning of this framework and the problems which might be prompted by its own normative standards. It has been pointed out that the normative centrepiece of the European regulation - consumers' freedom of choice - inevitably leads to a claim for producers' freedom of choice; if consumers ought to enjoy the freedom of choice between GM and GM-free products, farmers must be granted the right - and technical prerequisites - to offer GM-free certified produce. It is this option which is currently at stake in the European "co-existence" debate. The final shape and - more important - the very achievability of this emerging policy is far from being established. (Levidow/Boschert 2006,

Seifert 2005b, 2006b) Too unmanageable are the ecological and logistical pathways of a possible GM admixture, too divergent the many alternative views on how to achieve co-existence, to warrant optimism.[28] If, however, the orderly co-existence of agro-biotech and GM-free crop growing proves unworkable, this might, in the long run, jeopardize the Union's entire consumer-centred framework as food products which could constitute a trustworthy alternative to "GM-food" turn out beyond reach. At any rate, more controversy on this matter is to be expected for years to come.

Which leads to a second conjecture: As the European GMO controversy is very likely to keep occupying media, stakeholders and policy-makers, so is the global debate. While the final resolution of the transatlantic biotechnology trade row is still uncertain, its further escalation or any noteworthy impact on one of the contestants' regulatory frameworks seem rather unlikely since neither side is willing nor, as matters stand, actually required to back down. The global controversy, however, might still be outstanding.

Important regions which are rather recipients than exporters of agro-food biotechnology, like most of sub-Saharan Africa and East- and South Asia, still have to come to consistent positions in the struggle for biotechnology's global governance. As far as these developing countries have a stake in retaining control over GMO imports they would be well advised to take advantage of the opportunities the emerging system of global governance offers. While, for instance, the consideration of restrictive criteria based on socio-economic harm goes against the grain of its liberal core principles, its focus on physical risk provides a much more promising route for managing GMO trade.

Precondition for it to be applied is the appropriate use of scientific risk assessment. Scientific arguments as to physical, i.e. sanitary and environmental, harm emanating from GMOs pass for admissible grounds to impose restrictions. Meanwhile the workings of risk assessment are much less clear cut as its "objective" and "neutral" status in biotech governance would have it. In fact, risk assessment leaves ample scope for stressing unknowns and scientific

[28] "A resolution to the debate on co-existence will be a long and rocky road," as George Gaskell recently encapsulated prospects in this policy field. ("Co-existence of genetically modified, conventional and organic crops - Freedom of choice," 4-6 April 2006)

disagreements, for raising questions or revising tacit normative standards.[29] Still, to make use of the argumentative possibilities inherent in risk assessment, regulatory agencies must dispose of the requisite scientific expertise. Here developing countries can benefit from capacity building efforts arranged under the Biosafety Protocol and, to a considerable extent, supported by European countries. The expectation therefore is that future global conflicts over the trade in GMOs involving developing countries will, as it has been the case in the transatlantic controversy, assume the shape of conflicts over risk assessment or, more concretely, over particular product decisions based on risk assessment.

The latter does not necessarily imply the formal application of the PP. After all, as illustrated by the European case, the embracing of a particular normative approach to risk assessment is not likely to be incriminated under WTO rules, but the (arguable) fact that risk assessment has been corrupted by non-scientific factors. Like in the hormones case, the PP was not a subject in the current Panel interpretation. This does not rule out, however, that the ruling will have an impact on the admissible *interpretation* of the PP and, as seems most likely, constrain its application to a narrow version of the PP. (Levidow et al. 2005) As noted, the panel dismissed member states' risk assessments for their failure to evaluate the *likelihood* of a potential adverse effect. Instead, they typically pointed at a *possibility* of harm and often identified uncertainties and the need for further scientific research. In refusing this type of arguments based on uncertainty and ignorance, the panel seems to have drawn a line between legitimate an undue interpretations of precautionary reasoning: undemonstrated and thus hypothetical risks, even if based on scientific arguments, are ruled out in the liberal WTO framework. Furthermore, what is likely as regards the prospects of the further spread of the PP in international regulations, is signalling effect which this ruling might have on the changing status of the principle. The ruling will not, however, directly impact on, or change the "status quo" for the time being. At any rate, whether this is to discourage the PP's further gaining currency or will change in the long term, remains open.

Finally, a last prediction, or rather projection of current trends: What, in recent years, clearly gained salience, not only in Europe but in many other parts of the world, is the role of consumer politics in the shaping of biotechnology's global governance. While the EU

[29] For a recent case study illustrating the operation of risk assessment in the transatlantic expert controversy over Bt Maize see Murphy et al. 2006, for the interpretative scope still opened up by the PP see Levidow et al 2006.

maintains the most stringent and, for producers and importers, most burdensome labelling regime, many countries have likewise introduced mandatory GM labelling, often in an attempt to cope with public opposition. Even though its ambitious European stipulation reflects the worries of an affluent society and is unlikely to be emulated by developing countries, consumers' "freedom of choice" is clearly gaining currency as a general principle in its own right, decoupling labelling from health risk.

The worldwide emergence of labelling regimes has not only had a chilling effect on the global expansion of agro-food biotechnology, it also creates a complex dynamic in the production of and trade with agricultural goods. As consumers ought to have the choice between GM and GM-free products, these products also must be provided which implies both the logistical and geographical segregation of biotechnology-based and GM-free production types. In order to prevent GM admixture, the establishment of "GM-free zones" of yet undetermined dimension - ranging from provinces to grander regions - could become necessary. That this quest for a feasible "co-existence" of production types is not a European peculiarity but also pursued in other parts of the world is currently exemplified by the case of Brazil.

After having expanded its soy cultivation in the 1990s, Brazil has become the largest soy producer after the , and after years of hesitation, in 2003, legalised the cultivation of GM soy. However, even within Brazil the genetic technology is not embraced uniformly across regions. While the state *Rio Grande do Sul* was among the driving forces of the federal approval of GM crops, the state of *Paraná* decided to bank on GM-free production. Promoting the initiative is a network of farmers, government officials, food industry, trade corporations and retailing chains from the Brazilian State and the EU, particularly EU regions. If successful, the initiative marks the expansion of the current European debate on coexistence and GM-free zones beyond Europe. It could serve as a case to explore the possible further evolution in an ongoing conflict which ultimately is to be decided by the world's consumers.

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