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## **How to get out of the Transatlantic Regulatory deadlock over GMOs?**

### **This is Time for Regulatory Cooperation**



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## **Abstract**

The aim of this paper is to identify some possible ways out of the current transatlantic deadlock over GMOs, by focusing in particular on the regulatory cooperation option. After providing an account of the most important initiatives undertaken to reconcile the EU and US regulatory divergence in the past, it explores whether there is a case for transatlantic regulatory cooperation in the GMO sector. It argues that the current inability of the WTO/SPS framework to govern genetic engineering combined with the rise of emerging economies as new actors of the global GMO industry as well as the increasing unsustainability of the EU GM framework provide both the US and the EU valuable incentives to engage into an effective regulatory cooperation exercise. Unlike previous experiences of transatlantic cooperation, the two sides should not aim at harmonisation or mutual recognition of standards, but rather promote mutual understanding of their existing regimes and different regulatory approaches. Although the final aim of the cooperation exercise should be the identification of a basic set of common transatlantic risk analysis principles, the focus of cooperation should be on risk assessment, by far the most suitable procedural stage for engaging into a comparative scrutiny. Several recommendations are formulated on how to conduct an effective dialogue aimed at identifying divergence before trying to overcome them.

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## Introduction

Taking on the famous Robert Kagan's dictum, one may say that the US is from Mars and Europe is from Venus when it comes to the regulation of genetically modified organisms, notably GM food and crops<sup>1</sup>.

Although the spreading of GM foods and crops has been posing to the EU and the US common regulatory challenges, they have developed two very different approaches vis-à-vis agricultural technology<sup>2</sup>.

While the US boasts a welcoming regulatory framework, the EU has implemented a strict and scientifically demanding regulatory regime based on a pre-market approval system, which is largely inspired by the highly controversial precautionary principle. Moreover, unlike the US regime, the EU regulatory system also provides for mandatory rules for traceability and labelling of GM products<sup>3</sup>. As a result, the US biotech industry is flourishing whereas the European's is struggling<sup>4</sup>. Yet, this outcome cannot entirely be ascribed to the different regulatory approaches, but rather to a multitude of factors related to consumers' preferences, cultural configurations as well as different risk perceptions.

Most of the attempts made at explaining the reasons for these distinctive regulatory approaches tend to stress deep cultural (notably, social and philosophical)<sup>5</sup> and institutional differences<sup>6</sup>

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<sup>1</sup> R. Kagan, *Of Paradise and Power: America and Europe in the New World Order* (2003).

<sup>2</sup> See G. Shaffer and M. Pollack, *Regulating Risk in a Global Economy: Law, Politics and the Struggle to Govern Genetically Modified Foods*, (on file with the Author), p. 35, who argue that the stark differences in the US and the EU regulatory systems were not necessarily pre-ordained by the interest-group, institutional or cultural attitudes of the two sides, but that the differences are real and that the two systems, once in a place, have proven increasingly resistant to change.

<sup>3</sup> On the occasion of the adoption of the food and feed as well as traceability and labelling regulations, the Environment Commissioner Margaret Wallström and the Health and Consumer Protection David Byrne said that: “[...] European consumers can now have confidence that any GM food and feed marketed in Europe has been subject to the most rigorous pre-marketing assessment in the world”. Commission Press Release, *European Legislative Framework for GMOs in Place* (IP/03/1056, 22 July 2003).

<sup>4</sup> See D. Vogel, *Can it be done? Suggestions for better regulatory cooperation between the US and Europe*, *Transatlantic Thinkers* n. 7, Bertelsmann Stiftung, p. 8. For some data on the impact of the EU framework on research activities in the GMOs sector, see *Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee, Life Sciences and Biotechnology – A Strategy for Europe. Progress Report and Future Orientations*, SEC(2003) 248 as well as the *Second Progress Report*, sec(2004) 438, pp. 6-8.

<sup>5</sup> According to a prominent viewpoint, Europeans would be more risk-averse than the Americans because of their previous exposure to thalidomide, nuclear energy and mad cow disease. According to a more recent approach, Europeans would not be more risk-averse than Americans, but would simply worry about different things. See D. Lynch and D. Vogel, *The Regulation of GMOs in Europe and the United States: A Case-study of contemporary European Regulatory Politics*, Council of Foreign Relations Press, 2001; T. Bernauer, *Genes, Trade and Regulation: The Seeds of Conflict in Food Biotechnology*, Princeton University Press, 2003; D. Vogel, *Can it be done? Suggestions for better regulatory cooperation between the US and Europe*, *Transatlantic Thinkers* n. 7, Bertelsmann Stiftung, p. 6 and J. Wiener, *Convergence, Divergence, and Complexity in US and European Risk Regulation*, in N.J. Vig and M. Faure, *Green Giants? Environmental Policies of the United States and the European Union*, MIT Press, 2004, p. 73 ss.

existing between the two sides of the Atlantic vis-à-vis new technologies<sup>7</sup> as well as recent changes in politics of risk regulation in Europe<sup>8</sup>.

Whatever their causes, the persisting different regulatory policies vis-à-vis the GM foods and crops, after having culminated in the recent *Biotech* dispute before the WTO<sup>9</sup>, carry the potential to escalate into a transatlantic war capable of, by turning global in scope, affecting also developing countries. Indeed, the threat of being denied access to highly lucrative developed-country markets is largely shaping developing countries' approach to GMOs<sup>10</sup>. Moreover, most of these countries, when setting up their own regulatory frameworks, tend to choose – as it occurred with the design of competition policy regimes<sup>11</sup> – between the US or the EU approaches to GM foods and crops<sup>12</sup>. Yet this phenomenon of legal borrowing might be temporary. With the rise of China, India and Brasil as new actors of the world economy and as major producers of GM products, it is more likely that the future of biotechnology will be defined by their regulatory responses rather than by those developed across the Atlantic.

In the light of all the above, rather than examining the roots of Transatlantic regulatory divergence, this paper focuses on the possible ways out from the current regulatory deadlock on GMOs between these two powers.

After a brief illustration of the EU and US GM regulatory frameworks, this paper sets the scene for the subsequent analysis by providing a detailed examination of the existing international trade framework for GM products. It then offers a brief account of the most important transatlantic regulatory initiatives undertaken to reconcile these diverging regulatory approaches. Although the

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<sup>6</sup> It is generally argued that the EU, lacking a regulatory independent agency such as the FDA, would be more easily captured by the vetoes of its Member States. See, e.g., L.A. Patterson and T. Josling, *Regulating Biotechnology: Comparing EU and US approaches*, paper presented at the Western Economic Association International 76<sup>th</sup> annual conference, available at <http://www.ucis.pitt.edu/euce/pub/policypapers/2002-TransatlanticBiotech.pdf>

<sup>7</sup> For an insightful analysis of these differences, see N. Zerbe (2007) *Risking Regulation, Regulating Risk: Lessons from the Transatlantic Biotech Dispute*, *Review of Policy Research* 24 (5), 407–423.

<sup>8</sup> D. Lynch and D. Vogel, *The Regulation of GMOs in Europe and the United States: A Case-study of contemporary European Regulatory Politics*, Council of Foreign Relations Press, 2001.

<sup>9</sup> In May 2003, the US, Canada, and Argentina filed a complaint at the WTO, alleging that European restrictions (notably, the EC general moratoria, the product specific moratoria and the national bans) on the importation of GMOs violate WTO rules, notably several SPS provisions. See *EC-Measures Affecting the Approval and Marketing of Biotech Products*, Panel Report, available at [http://www.wto.org/english/news\\_e/news06\\_e/291r\\_e.htm](http://www.wto.org/english/news_e/news06_e/291r_e.htm) To know more on the genesis and nature of this dispute, see G.C. Shaffer and M.A. Pollack, “Reconciling Regulatory Differences: The Ongoing Transatlantic Dispute over the Regulation of Biotechnology,” in *The Future of Transatlantic Economic Relations*, edited by D.M. Andrews, M.A. Pollack, G.C. Shaffer, and H. Wallace, Robert Schuman Centre for Advanced Studies, 2005, pp. 220-221 and also R. Quick, “Transatlantic Regulatory Cooperation on Chemicals — An Idealist’s Dream?,” German Marshall Fund Academic Research Conference, Ford School, University of Michigan.

<sup>10</sup> G. Shaffer, *A Structural Theory of WTO Dispute Settlement: Why Institutional Choice Lies at the Center of the GMO Case*, *New York University Journal of Law and Politics*, forthcoming, p. 35.

<sup>11</sup> For an account of this phenomenon, see W.E. Kovacic, “Getting Started: Creating New Competition Policy Institutions in Transition Economics” 23 *Brooklyn Journal of International Law* 403-453 (1997) and W.E. Kovacic, “Lessons of Competition Policy Reform in Transition Economies for U.S. Antitrust Policy” 74 *St. John’s Law Review* 361-405 (2000).

<sup>12</sup> See, for instance, on the attitude taken by Brasil and India vis-à-vis GM products, “Soya on rice to go”, *The Economist*, November 20<sup>th</sup> 2004, p. 68.

cooperative efforts carried out so far have fallen short of providing clear answers to the fundamental differences between these two opposing regulatory policies, this paper examines whether transatlantic regulatory cooperation over GMOs may be a viable option to overcome to the current stalemate. In particular, in the light of the newly found dynamism in transatlantic regulatory co-operation, following the launch of the Transatlantic Economic Council (TEC), the paper analyses what kind of regulatory cooperation in GM products can realistically be envisaged today<sup>13</sup>, before formulating a set of recommendations.

## **Part I - Introduction to EU and US legal regulatory frameworks for GM products**

Before investigating the current deadlock over GMOs between the two sides of the Atlantic and discussing the possible ways out of it, it is imperative to briefly describe the existing EU and US legal regulatory frameworks for GM products.

### **1. The EU regulatory framework for GMOs**

In the EU, an *ad hoc* regulatory framework for GMOs has been in place since the early 1990s<sup>14</sup>. Like all other EU legislations adopted in the food sector, it pursues the dual, though conflicting, goal to protect the health and the environment and to ensure the free movement of GM products in Europe. The entire corpus of EU legislation dealing with GMOs has been entirely reformed following the so-called GM maize impasse which eventually led to a *de facto moratorium* of the EU's GM authorisation process in 1999<sup>15</sup>. This blocking of the GMOs authorisation process brought to light the main flaws of the existing regulatory regime which was considered insufficient to cope with the risks associated with GM products by an increasing number of Member States. As a result, the EU, which was in the meantime facing the criticisms of some WTO members with commercial interests in biotech products<sup>16</sup>, engaged into a reform aimed at redesigning its regulatory framework for GM products in order to meet Member States' concerns and possibly bringing its policy in conformity with WTO rules.

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<sup>13</sup> This should occur according to the U.S.-EU Guidelines for Regulatory Cooperation and Transparency, and the U.S.-EU Regulatory Cooperation Roadmap launched at the Dromoland Summit in June 2004 ([http://ustr.gov/World\\_Regions/Europe\\_Mediterranean/Europe/U.S.\\_EU\\_Regulatory\\_Cooperation/Roadmap\\_for\\_E\\_U-U.S.\\_Regulatory\\_Cooperation\\_Transparency](http://ustr.gov/World_Regions/Europe_Mediterranean/Europe/U.S._EU_Regulatory_Cooperation/Roadmap_for_E_U-U.S._Regulatory_Cooperation_Transparency)).

<sup>14</sup> For an account of the origin of the EU regulation of biotechnology, see T. Christoforou, *The Regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics*, *Common Market Law Review*, 2004, 41 (3) and 651 ss and D. Lynch and D. Vogel, *The Regulation of GMOs in Europe and the United States: A Case-study of contemporary European Regulatory Politics*, Council of Foreign Relations Press, 2001, p. 6-7.

<sup>15</sup> Shortly after the approval of a specific variety of GM maize (the Zea Mays L.), which occurred despite Member States' concerns, the Council of the EU suspended the authorisation procedure to place GMOs on the market, by giving rise to the so-called *de facto moratorium* on GMOs which, in turn, has triggered the WTO Biotech dispute. The moratorium had effectively replaced the first EC regulation on GMOs, of which Directive 90/220/EEC and Regulation 258/97 (novel food) were the most prominent texts.

<sup>16</sup> These criticisms triggered later on the WTO Biotech dispute.

The resulting GM regulatory framework consists of different regulations, which apply for different types of intended use<sup>17</sup>. The most important regulations concerning GMO use are:

- Directive 2001/18/EC and the various national acts which transpose the directive in Member States<sup>18</sup>. This directive covers “living” GMOs. As a result, it regulates the deliberate release of GMOs into the environment and the placing on the market of GMOs (e.g. the cultivation, importation or transformation of GMOs into industrial products)<sup>19</sup>. Under this regime, once a GM food or feed is authorised by the Commission, according to a comitology procedure following a risk assessment conducted by the Competent Authority of a Member State, this product is considered “safe for its intended use”, and is appropriately labelled, this may be grown, sold, or consumed in any Member State.
- Regulation 1829/2003 which covers GMOs for food and feed<sup>20</sup> use as well as food and feed containing, consisting of, or produced from GMOs<sup>21</sup>.

This last regulation is based on the "one door-one key" principle. Thus, for products containing/consisting of GMOs, it is possible to file a single application for obtaining both the authorisation for the deliberate release of a GMO into the environment, under the criteria laid down in Directive 2001/18, and the authorisation for use of this GMO in food and/or feed under the criteria laid down in Regulation 1829/2003<sup>22</sup>. This authorisation, valid throughout the EU, is granted subject to a single risk assessment process under the responsibility of the European Food Safety Authority and a single risk management process involving the Commission and the Member States through a regulatory committee procedure.

Moreover, GMOs and food products derived from GMOs which are placed on the market are also subject to labelling and traceability requirements, as provided for by Regulation 1830/2003<sup>23</sup>.

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<sup>17</sup> Besides Directive 2001/18 and Regulation 1829/2003, it is also worth mentioning Regulation (EC) No 1946/2003 which regulates intentional and unintentional movements of GMOs between Member States of the European Union and third countries.

<sup>18</sup> This directive has been fully applicable since 17 October 2002. OJ L 106, 17.4.2001, p.1.

<sup>19</sup> This directive also covers the experimental release of GMOs into the environment, i.e. the introduction of GMOs into the environment for experimental purposes.

<sup>20</sup> This is an important feature of the regulation as feed produced from GMOs was not previously included within the scope of any piece of legislation on GMOs.

<sup>21</sup> Regulation (EC) No 1829/2003 of the EP and of the Council of 22.9.2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p.1; Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p.24). Following the Starlink problem in the US, Article 27 of Reg. 1829 provides that “Where a product is likely to be used as both food and feed, a single application under Articles 5 and 17 shall be submitted and shall give rise to a single opinion from the Authority and a single Community decision”.

<sup>22</sup> It is also possible to split the application and submit both under the two instruments.

<sup>23</sup> These conditions are laid down in Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Moreover, unintentional movements of GMOs between Member States and exports of GMOs to third countries are governed by Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms.

Although this set of measures was originally conceived to persuade Member States to resume the approval procedure to market GMOs in the EU, it failed to achieve its declared goal. Indeed, not only several Member States did not correctly transpose Directive 2001/18 into their legal orders<sup>24</sup>, but some of them even blocked the marketing (and/or the use) of some GM authorised products into their territory<sup>25</sup>. Although some of these measures have been found illegal by both EU Courts<sup>26</sup> and the WTO Dispute Settlement Body, the Austrian authorities, for instance, maintain their safeguards in place and the French government has recently banned the cultivation of MON810, a maize developed by U.S. biotech giant Monsanto.

Therefore, while the compatibility of the existing EU regulatory regime with WTO law still remains an open question<sup>27</sup>, what makes it even more susceptible of being declared WTO-incompatible is its (internal) inconsistent application and delays<sup>28</sup>. This is the lesson learned from the WTO Biotech dispute.

## 2. The US regulatory framework for GMOs

Unlike the EU, the United States has not issued any new legislation for genetically modified organisms<sup>29</sup> and uses health and safety laws written prior to the advent of modern biotechnology to regulate genetically engineered products<sup>30</sup>. As a result, several (non *ad hoc*) federal laws and regulations<sup>31</sup> govern today the production and use of genetically modified organisms<sup>32</sup>. Several

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<sup>24</sup> See, for instance, Cases C-296/01, Commission/France [2003] ECR and C-121/07, Commission/France [2008] not yet reported in which the European Court of Justice has condemned France to pay a lump sum of EUR 10 million.

<sup>25</sup> The legal basis for the adoption of safeguard measures can be found in the Deliberate Release Directive, notably in Article 23 (1). A Member States may “provisionally restrict or prohibit the use and/or sale” of an authorised GMO in its territory provided that it “has detailed grounds for considering that a GMO [...] constitutes a risk to human health or the environment” on the basis of “new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information”.

<sup>26</sup> Joined Cases T-366/03 and T-235/04, Land Oberösterreich and Republic of Austria v. Commission [ECR]

<sup>27</sup> This might be *prima facie* surprising since the EU regime for GMOs has already been at the centre of dispute within the WTO. However, it must be pointed out that the Biotech dispute, which began when the United States, Argentina and Canada requested consultation at the WTO, revolved around the *de facto* moratorium of the previous authorisation system instead of examining the legality of the EU pre-market approval system for GMOs. Indeed, according to the plaintiffs, the *de facto* moratorium on imports of GMOs, that had taken place since 1999, found its origin in trade protectionism rather than from concerns for consumer health or for the protection of the environment. As a result, there is no assessment in the Biotech panel report of the compatibility of biotechnology regulations with the WTO Agreements. For a speculative examination of this assessment, see L. Boisson de Chazournes and M.M. Mbengue, Trade, Environment and Biotechnology, in D. Wüger and T. Cottier, Genetic Engineering and the World Trade System, Cambridge University Press, 2008, p. 237-245.

<sup>28</sup> See on this point, D. Wüger, introduction, in D. Wüger and T. Cottier, Genetic Engineering and the World Trade System, Cambridge University Press, 2008, p. 7. To know more, see *infra* section on Why it is time for regulatory cooperation.

<sup>29</sup> In the US, the terms genetically engineered or bioengineered are used instead of the terms genetically modified products or organisms commonly employed in the EU.

<sup>30</sup> For a detailed presentation of the US regulatory framework applicable to GM, see, P. Barton Hutt, R.A. Merrill and L. Grossman, Food & Drug Law, Cases and Materials, III<sup>ed.</sup>, New York, Foundation Press, 2007, pp. 453-464.

<sup>31</sup> The laws currently used to regulate the products of modern biotechnology are the Plant Protection Act (PPA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA). Available at <http://usbiotechreg.nbio.gov/lawsregsguidance.asp> These laws are product-specific because they regulate certain product uses, such as foods or pesticides.

agencies share the implementation of this complex regulatory framework. In general, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS) determines whether GMOs are safe to grow, the Environmental Protection Agency (EPA) oversees their impact on the environment and the Department of Health and Human Services' Food and Drug Administration (FDA) determines whether they are safe to eat. Depending on its characteristics, a product may be subject to review by one or more of these agencies<sup>33</sup>. Thus, for instance, a food crop plant developed using genetic engineering to produce a pesticide in its own tissue, such as a bt corn<sup>34</sup>, provides an example of GM product that is reviewed by all three regulatory agencies. For such a product, the regulatory process would take place as follows. Following a petition, USDA-APHIS, acting under the Plant Protection Act (PPA), may authorize field tests and subsequently grant "non-regulated status" for the plant where data demonstrate that "the new crop variety is not a plant pest and should no longer be regulated by APHIS". If the petition is granted, that organism will no longer be considered a "regulated article" and will no longer be subject to oversight by USDA-APHIS. However, in order to legally sell or distribute the resulting pesticide in commerce, the company must register the pesticide with EPA. Through the registration, EPA can establish the conditions of commercial use and is also responsible for setting the amounts or levels of pesticide residue that may safely be in food or feed (i.e., establish a tolerance). EPA may allow an exemption from the requirement to set such a tolerance if it can be shown there are no food or feed safety issues associated with the pesticide. Finally, developers of Bt crops *may* consult with FDA about possible other, unintended, changes to the food or feed, for example possible changes in nutritional composition or levels of native toxicants. Although this consultation is voluntary, it seems that all of the food/feed products marketed to date have gone through the consultation process. Indeed, under the Federal Food, Drug, and Cosmetic Act, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. In addition, any food additive, including one introduced into food or feed by way of plant breeding, must receive FDA approval before marketing<sup>35</sup>. The consultation with FDA serves to ensure that safety or other regulatory issues that fall within the agency's jurisdiction, including appropriate labeling of the food, are resolved prior to commercial distribution. The current system was delineated under the 1986 Coordinated Framework for Regulation of Biotechnology in which "The Administration, recognizing its responsibility to confront these [GM-related] concerns, formed in 1984 an interagency working group [...] which sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry". Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately. In their view, the existing health and safety laws had the

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<sup>32</sup> For a detailed description of the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products, see Coordinated Framework for Regulation of Biotechnology, published in the Federal Register December 31, 1984 (49 FR 50856).

<sup>33</sup> The first two types of genetically engineered products are referred to as plant-incorporated protectants, or PIPs.

<sup>34</sup> This is corn into which scientists have inserted a gene isolated from the soil bacterium, *Bacillus thuringiensis* (Bt). The Bt gene encodes a pesticide and when this gene is inserted into the plant, the plant can then produce the Bt pesticidal substance.

<sup>35</sup> The term "food additive" refers to substances introduced into food that are not pesticides and are not generally recognized as safe by qualified scientific experts.

advantage that they could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation.

This welcoming regulatory regime for GM products has not, unlike the European's, raised any particular compatibility issue with the WTO regime.

## **Part II – The Regulatory deadlock over GMOs**

### **1. Setting the scene: the international regime for GM products**

Since the regulation of biotechnology belongs to domestic law, it should not cause surprise – at least *prima facie* – the resulting regulatory divergence existing among countries, such as the EU and the US, when it comes to regulate genetic engineering or, in particular, biotech products. Indeed, each country's regulatory response is the product of its democratic system which tends to reflect the attitudes and beliefs of society vis-à-vis genetic engineering. This process inevitably translates into different regulatory answers to similar or identical normative questions.

Yet, since regulatory divergence may lead to the creation of obstacles to the free movement of factors of production and of unfair conditions of competition for likely products, international law, notably international trade law, is expected to step in to ensure market access. Indeed, the principle of comparative advantage, which underpins the existing trade regime, relies on the assumption that commonly accepted products be traded widely and universally used. Under such an approach, which – as is well known – dominates our current system of international trade, the operation of this principle would be at stake as soon as a product is limited in its access to another market, with the inevitable result of reduction in global growth.

This explains why international trade law is “the prime area where such divergences are truly felt in international law, and serious conflicts are emerging”<sup>36</sup>. In particular, it is the WTO that, consisting in the most articulated legal framework for global international trade<sup>37</sup>, is expected to provide some answers to this emerging regulatory divergence problem.

The challenge for international trade law is to address - and try to reconcile - the demand for ensuring the free movement of GM products among countries on the one hand, and the demand for trade restrictions on these products on the basis of non-economic grounds, such as public health or the environment, on the other hand.

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<sup>36</sup> T. Cottier, Genetic Engineering , trade and human rights, in D. Wüger and T. Cottier, Genetic Engineering and the World Trade System, (Cambridge University Press, 2008), p. 17.

<sup>37</sup> The WTO, established on 1 January 1995, is subsumed and expanded upon the GATT, an international agreement that had regulated international trade since 1947. See, e.g., G. Sacerdoti, La trasformazione del GATT nell'organizzazione mondiale del commercio, *Diritto del commercio internazionale*, 1995, pp. 73-90; P. Demaret, Les métamorphose du GATT: de la Charte de La Havane à l'Organisation mondiale du commerce, *Journal des tribunaux - Droit européen*, no. 13, 1994, pp. 174-178 and J. Wouters and B. De Meester, *The World Trade Organisation*, (Intersentia, 2007), pp. 6-13.

Although harmonisation of principles and rules among countries would represent the most effective answer to address this challenge<sup>38</sup>, regulatory harmonisation has not occurred yet in the GM sector and, given the existing differences between the two sides of the Atlantic, is not likely to occur in the near future. Indeed, the existence of largely different views and approaches, being essentially based on beliefs rather scientific evidence<sup>39</sup>, vis-à-vis GM products is difficult to overcome.

Since no agreement specifically addressing GM products exists in WTO law, domestic regulations on biotechnology are subject to the rules of the GATT, the SPS and the TBT Agreements<sup>40</sup>.

### *The international trade regime for GMOs*

The 1994 GATT agreement – like the original GATT agreement of 1947 – leaves countries free to establish whatever level of protection they deem appropriate when introducing regulations. The only constraints on the exercise of their legislative autonomy are set by Article III:<sup>41</sup>, which requires that these regulations have to be applied in a non-discriminatory way on imported and domestic goods, and Article XI<sup>42</sup>, prohibiting all restrictions “instituted or maintained on the importation or exportation of any product”. Similar to the EC<sup>43</sup>, the WTO maintains general exceptions which enable a Member to justify a violation of the general prohibition of quantitative restrictions. In particular, Article XX GATT<sup>44</sup> allows any Contracting Party to depart from GATT

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<sup>38</sup> E.U. Petersmann, *Biotechnology, Human Rights and International Economic Law*, in F. Francioni (ed.), *Biotechnologies and International Human Rights* (Oxford: Hart Publishing, 2007), pp. 229-274.

<sup>39</sup> T. Cottier, *Genetic Engineering, trade and human rights*, in D. Wüger and T. Cottier, *Genetic Engineering and the World Trade System*, (Cambridge University Press, 2008), p. 22.

<sup>40</sup> Also other WTO agreements may be relevant such as that on agricultural products and the TRIPS. The SPS and TBT Agreements are designed to prevent technical legislation, which is intended for the protection of human health or safety, the protection of the health or life of humans animals or plants, consumer protection against deceptive practices and environmental protection, being used to create or resulting in unjustified barriers to international trade. Since sanitary and phytosanitary measures introduce specific concerns for trade in goods, a separate Agreement, the SPS, was ‘carved out’ of the TBT. As a result the two agreements differ in scope. While the TBT covers all technical regulations and voluntary standards, and the procedures to ensure that these are met, the SPS agreement applies to all measures to protect human, animal and plant life and health. While both the SPS and the TBT apply to food, the TBT is more relevant to labelling requirements than to safety

<sup>41</sup> According to this provisions: "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product".

<sup>42</sup> This provision establishes that: "No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party".

<sup>43</sup> Article 30 EC has clearly been formulated with Article XX in mind. See J. Scott, *Mandatory or Imperative Requirements in the EU and the WTO*, in C. Barnard and J. Scott, *The Law of the Single European Market: Unpacking the Premises* (Oxford, Hart Publishing, 2002), p. 286.

<sup>44</sup> Article XX states: "[s]ubject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail,

obligations by adopting restrictions on imports and exports justified *inter alia* for the protection of health and life of humans, animals and plants (Article XX letter b)<sup>45</sup>.

The GATT regime though, by merely requiring Member States not to discriminate between domestic and imported products and recognising them to exceptionally depart from this principle, falls short in addressing the underlying issues related to the GM phenomenon, such its food safety, environmental and public perceptions implications. This explains why the rules governing public health measures and standards are specifically expressed, as *lex specialis*, in the SPS and TBT agreements, which were adopted during the Uruguay Round. In particular, the SPS Agreement, which aims at balancing health concerns against the goal of free trade, may be seen as an extension of Article XX GATT<sup>46</sup>. In fact, it expands the scientific and procedural requirements that Member States have to abide by when adopting an SPS measure (which must be based on scientific evidence), by, in particular, urging them to develop and to adopt international standards (as set up by Codex Alimentarius, the International Plant Protection Commission (IPPC) and the International Office of Epizootics (OIE)<sup>47</sup>). As a result, under the WTO/SPS legal framework, WTO members' regulations implementing these international standards are presumed to be legitimate<sup>48</sup>.

If the purpose of the SPS agreement is to minimize the negative effects on trade stemming from SPS measures, such as health regulations<sup>49</sup>, by encouraging harmonization of SPS measures through the adoption of international standards, guidelines and recommendations where they exist<sup>50</sup>, this outcome could not be easily achieved in the GM sector due to the absence of international standards. This shows how the SPS negotiators' decision to invest the standard-setting organisations, such as the Codex Alimentarius, the IPPC and the OIE<sup>51</sup>, with the task of adopting international standards, in order to keep their elaboration far from political tensions, did

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or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: [...] (b) necessary to protect human, animal or plant life or health.

<sup>45</sup> Already in 1969 John Jackson noted that in theory all GATT obligations may be rendered subject to the exceptions of Article XX, because of the wording "nothing in this Agreement shall [...] prevent". See J.H. Jackson, *World Trade and the law of GATT: A Legal Analysis of the General Agreement on Tariffs and Trade*, Bobbs-Merrill Company, Indianapolis, 1969.

<sup>46</sup> Although building upon Article XX GATT, the SPS scientific and procedural obligations are independent from GATT, so that Members are obliged to comply with the SPS Agreement regardless of whether their SPS measure is otherwise consistent with a provision of GATT<sup>46</sup>. Should, then, an SPS measure be in conformity with the SPS Agreement, that measure is presumed to be consistent with GATT<sup>46</sup>.

<sup>47</sup> To know more on these standard-setting organisations and their roles in international trade, see A. Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO*, Cameron May, 2007, pp. 263-274.

<sup>48</sup> See Article 3 of the SPS Agreement.

<sup>49</sup> That's why the SPS Agreement applies to all measures adopted by WTO Members to protect human, animal or plant life or health "which, directly or indirectly, may affect international trade". Notably, SPS measures – as defined in Annex A of the Agreement – are those aimed at protecting animal or plant life or health arising from food-borne risks, pests, diseases, disease-carrying organisms, additives, contaminants, toxins or disease-causing organisms in foods. More precisely, SPS measures can take the form of inspection of products, permission to use only certain additives in food, designation of disease-free areas, determination of maximum levels of pesticide residues, quarantine requirements, import bans, etc.

<sup>50</sup> The SPS has indeed been defined a "refined system of applied subsidiarity, subtly allowing national autonomy subject to certain constraints", see J.P. Trachtman, *The World Trading System, the International Legal System and Multilevel Choice*, in 12 *European Law Journal* 469, p. 480 (2006).

<sup>51</sup> To know more on these standard-setting organisations and their roles in international trade, see Alemanno, *Trade in Food*, pp. 263-274.

not prove wise. Indeed, the increasing number of scientific controversies surrounding new technologies, such as GMOs, and also the diverging economic interests of its Members, are rendering increasingly difficult the adoption of standards, notably in areas characterised by scientific uncertainty, within Codex<sup>52</sup>.

As the *EC - Hormones*, *Australia - Salmon* and *Japan - Agricultural Products* cases have shown, the outcome of many international trade disputes may revolve around the conformity by a WTO Member's SPS measure with international standards. This explains the increasing involvement of WTO Members in these standard-setting international organizations. (Developed) Countries try to protect their current or possible future SPS measures by promoting their approaches to risk analysis through the work of the organization. This trend is likely to lead to less consensus within these standard/setting bodies, thus inevitably harming the final objective of harmonization.

When harmonisation may not be attained, the WTO/SPS framework relies on science as the main organising principle enabling the WTO to distinguish between legitimate and illegitimate SPS measures. According to the traditional structured risk analysis framework, this scientific requirement is procedurally translated into the risk assessment stage as opposed to the risk management stage.

However, in a scientifically controversial area such as biotechnology, scientific evidence cannot *per se* provide definitive answers. That's where may enter into play Article 5.7 SPS, which allows the adoption of "provisional measures" where scientific evidence is "insufficient". Unfortunately, following the DSB's judicial interpretations given so far to this provision, the scope of this provision remains controversial<sup>53</sup>.

The recently-decided panel report in the *Biotech* case, having "decided not to decide" on the legality of a pre-market approval for GM products implemented by the EU<sup>54</sup>, has confirmed what already emerged from the *Hormones* dispute<sup>55</sup>: the inadequate character of the WTO/SPS

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<sup>52</sup> The internal rules of procedures governing the adoption of standards by these standard-setting bodies provide for a simple majority vote, in the case of Codex and OIE, or a qualified majority vote for plant protection standards under the IPPC. To know more on the standard-setting activity conducted within these bodies, A. Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO*, Cameron May (2007), pp. 261-274 and S. Poli, *The European Community and the Adoption of International Food Standards within the Codex Alimentarius Commission*, *European Law Journal*, Vol. 10, No. 5, September 2004.

<sup>53</sup> This is especially true after the *Biotech* panel report's confusing analysis of the relationship between the duty of risk assessment, as enshrined in Article 5.1 SPS, and the invocation of Article 5.7. See on this point T. Broude, *Genetically Modified Rules: the Akward Rule-Exception-Right Distinction in EC-Biotech*, 6 *World Trade Rev.* 215 (2007). For an analysis of the scope of Article 5.7 SPS and its main differences with the Precautionary principles as enshrined in EC law, see A. Alemanno, *Trade in Food*, p. 280 ss. and 407 ss.

<sup>54</sup> Indeed, the panel avoided addressing the SPS substantive provisions by considering the EU *de facto* moratorium being outside of the category of "SPS measures". In so doing, it did not have to examine whether the moratoria complied with Article 5.1 risk assessment requirement, with Article 5.5 consistent application requirement and 5.6 least-trade restrictive requirement. By adopting a rather procedural approach, the panel merely found that the EU had breached its procedural obligations under the SPS Agreement, by engaging in "undue delay" in the authorisation process.

<sup>55</sup> This dispute, one of the longest running trade disputes in the modern trading system, involved a complaint by the United States and Canada against an EC regulatory regime prohibiting the administration of growth hormones (such as estrogen, progesterone and testosterone) to cattle. This prohibition, although not discriminatory *per se* (being addressed also to the use of these hormones domestically) was found in breach of WTO rules, notably Article 5.1, risk assessment requirement. On this dispute, see, e.g., T. Christoforou, *Settlement of Science-Based Trade Disputes*

framework to handle controversial transnational regulatory disputes arising out in the SPS area<sup>56</sup>. Indeed, the only requirements imposed by the SPS Agreement relating to risk analysis boil down to a detailed risk assessment obligation that Member States should satisfy when adopting SPS measures<sup>57</sup>. In other words, risk assessment is the only formalized risk analysis step expressly recognized and defined by the SPS Agreement. However, risk assessment does not provide the decision-makers with a definitive regulatory answer; it rather offers them some information upon which to take regulatory action. Thus, it follows that while expressly recognizing and regulating in great detail the risk assessment stage of risk analysis<sup>58</sup>, the SPS does not even mention the risk management stage, i.e. the process, distinct from risk assessment, of weighing policy alternatives and selecting appropriate measures and control options<sup>59</sup>. In particular, this vacuum in the WTO/SPS risk regulatory discipline gives rise to the following questions: How Member States, once they have conducted the risk assessment of a particular stressor, should manage the risk stemming from its consumption? Which factors should they take into account? What should Member States decide in case of scientific uncertainty about the safety of a certain product? These questions, relating to the risk management stage of risk analysis, do not find a direct answer in the SPS text<sup>60</sup>. In fact, as SPS negotiators considered it inappropriate for the WTO to be more prescriptive about risk management, they considered Codex as a better forum for the elaboration of guidelines for regulatory action. Unfortunately, although the model of risk analysis

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*in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty*, (2000) 8 N.Y.U. Environmental Law Journal, pp. 622 ss.; J. Scott, *Of Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO* in J.H.H. Weiler (ed.), *The EU, NAFTA and the WTO: Towards a Common Law of International Trade*, Oxford: OUP, 2000; S. Pardo Quintillán, *Free Trade, Public Health Protection and Consumer Information in the European and WTO Context*, 33 Journal of World Trade p. 147 (1999) and R. Howse, *Democracy, science and Free Trade: Risk Regulation on Trial at the WTO* (2000) 98 Mich.L.R. 2329.

<sup>56</sup> The *Biotech* dispute took place between the US, Canada, Argentina and the EC in relation to the European alleged general moratoria (the product specific moratoria and the national bans) on the importation of genetically modified organisms. Being a procedural decision, the moratorium could not be considered an SPS measures, but still could not escape the requirement of Article 8 providing that WTO Members must ensure that approval procedures are undertaken and completed without undue delay” (Annexe C(1)(a), first clause.

<sup>57</sup> For analysis of the incomplete risk analysis framework within the WTO, see A. Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO*, p. 387 ss.

<sup>58</sup> As to the risk assessment procedural obligations, Article 5 tells Member States to rely on the risk assessment techniques developed by the “relevant international organizations”, which presumably include the Codex, IPPC and OIE, and also to take in due account the following factors: available scientific evidence, relevant process and production methods; relevant inspections, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine and other treatment.

<sup>59</sup> It may be recalled that in the *Hormones* case the AB explicitly rejected the Panel’s effort to distinguish between risk assessment and risk management within the SPS Agreement, by stating that “Article 5 and Annex A of the SPS Agreement speak of “risk assessment” only and that the term “risk management” is not to be found either in Article 5 or in any other provision of the SPS Agreement”. See *EC – Hormones*, AB Report, at para 181.

<sup>60</sup> Unlike the EC risk analysis model, the WTO regulatory framework does not specify the extent to which ‘other factors’, such as social values and consumer preferences, may be taken into account in national regulatory decision-making processes. Its exclusively scientific-oriented approach would seem to suggest that the risk management phase should focus solely on the rational, science-driven data stemming from risk assessment, by thus ruling out all ‘other factors’ from consideration. That basis for law-making would seem to exclude, or at least marginalize, other public concerns or other forms of knowledge from consideration as part of the process of regulating food safety risk. The only risk management requirements imposed by the SPS, the ‘consistency’ and ‘proportionality’ tests, contained as they are in open-textured provisions, fail to offer useful guidance to Member States when establishing the appropriate level of protection and choosing the measure designed to achieve that level

which is developing within Codex is gradually becoming, by virtue of the bridge offered by the SPS harmonization requirements, a “de facto” WTO risk analysis model<sup>61</sup>, Codex has been unable to solve at the regulatory level the long-standing issues of the role of the precautionary principle and that of “other factors” in risk management. Despite some progress on the definition of the role of the precautionary principle and other factors in risk analysis having been made, the extent to which Members may rely on this principle and the other factors in SPS risk management policy is not yet clear. Until this debate is resolved, the question arises as to what happens if countries invoke the precautionary principle or rely on “other factors” when developing their food safety policies.

As argued elsewhere, this shows how the original decision not to delineate a well-defined management policy within the SPS Agreement is producing the effect of transferring the responsibility of shaping a WTO risk analysis model from the decision-making dimension to the dispute-settlement level; in other words, from the ‘executive-legislative’ powers to the ‘judiciary’, who, as a result, cannot but require strict compliance with the only regulatory requirement textually provided for: risk assessment.

The inability of the WTO legal system to offer clear answers to the regulation of GMOs lies behind the current deadlock over the regulation of genetic engineering and explains the multitude of initiatives undertaken since the early 1990s to provide some credible solutions to the impending conundrum.

### **Part III – Regulatory Cooperation**

Before venturing to suggest some possible ways out of the existing regulatory deadlock over GMOs, it might be crucial to provide a narrative, as well as critical, account of the regulatory cooperation efforts undertaken at bilateral level during the last two decades.

#### **1. An introduction to the Transatlantic Regulatory Cooperation**

Because of the potential for trade conflicts over GMOs and the serious impact that such conflicts could have for the multilateral systems of trade rules and, in particular, upon the Transatlantic relationship, several attempts have made to reconcile differences<sup>62</sup>.

By facing growing economic interdependence, several initiatives have been launched, since the early 1990s, to dismantle existing regulatory barriers and to prevent new ones from emerging. Thus, both sides have engaged in extensive cooperation in order to overcome their divergent regulatory approaches. These efforts fall under the rubric of transatlantic regulatory cooperation (TRC) and are at the heart of today’s U.S.-EU economic relationship. As shown below, the issue of GMO appeared quite early in the Transatlantic agenda.

#### **2. The genesis and evolution of the regulatory cooperation efforts**

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<sup>61</sup> See A. Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO*, p. 387 ss.

<sup>62</sup> For a very recent account of the transatlantic regulatory cooperation, see R.J. Ahearn *Transatlantic Regulatory Cooperation: Background and Analysis*, CRS Report for Congress, October 22, 2008.

Since the early 1990s, the US and the EU have engaged in significant efforts to achieve deep integration by focusing on regulatory cooperation. In particular, the roots of the existing US-EU regulatory cooperation can be found in the Transatlantic Declaration of 1990 which paved the way for the institutionalisation of the mutual commitment to common political and economic values in the 1995 New Transatlantic Agenda. The interactions at the official level helped to advance discussions in view of the conclusion of the Uruguay Round and led in turn to the launch of the ambitious Action Plan that promised action on economics (the term “New Transatlantic Marketplace” was coined and entered into the policy-makers’ vocabulary) as well as security issues. At the very origin of these efforts to deepen economic integration between the two sides of the Atlantic there was the recognition that the most significant impediment to trade and investment is represented by regulatory barriers and that the GATT/WTO framework was inadequate to effectively tackle those measures. Indeed, following the lowering of tariffs and the phasing out of other border measures induced by the GATT/WTO agreements, regulatory divergence was likely to affect producers on the other side of the Atlantic. Indeed, redundant standards, testing, and certification procedures were increasingly being seen by US and EU economic operators as far more costly and harmful than any trade barriers imposed at the border, such as tariffs or quotas<sup>63</sup>. In particular, while the purpose of many regulations is to protect consumers and the environment, divergent domestic regulations and standards can affect the competitive position of firms, helping some and disadvantaging others by affecting the importation of products not manufactured or grown according to those requirements<sup>64</sup>.

Against this backdrop, at the London Summit of May 1998, the US and EU launched the Transatlantic Economic Partnership (TEP) with an Action Plan focusing mainly on regulatory cooperation and mutual recognition in the following sectors: services, intellectual property rights, government procurement, food safety, biotechnology and competition law. In particular, the Action Plan called on both sides to take action to address technical barriers in goods, including improving the dialogue between the US and EU regulators<sup>65</sup>. Indeed, there was a growing belief that until the respective regulatory approaches converge or are re-aligned, a transatlantic gap in regulatory policies was likely to persist. At the Bonn Summit in June 1999, a Joint Statement on

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<sup>63</sup> D.C. Esty, “Regulatory Competition in Focus,” *Journal of International Economic Law* (2000), pp. 215-217.

<sup>64</sup> Among the most well-known examples, European winemakers intending to sell in the U.S. market must label their bottles according to U.S. requirements, which are different than EU requirements. Similarly, U.S. exports to the EU of poultry washed with antimicrobial treatments have been blocked for years by different health and safety standards. The most widely known example of transatlantic regulatory divergence is that occurring in the automotive sector where there are even multiple crash test dummies of the same or similar size and purpose. See V.H. Wilber and P.T. Eichbrecht, “Transatlantic Trade, the Automotive Sector: The Role of Regulation in a Global Industry, Where We Have Been and Where We Need To Go, How Far Can EU-US Cooperation Go Toward Achieving Regulatory Harmonization,” German Marshall Fund Academic Policy Research Conference, Ford School, University of Michigan, p. 7.

<sup>65</sup> Pursuant to the NTA, the two sides focused particular attention on problems posed by divergent standards and certification systems. In addition to promoting the convergence in regulatory systems, efforts were undertaken to negotiate MRAs covering several sectors. In 1998, Mutual Recognition Agreements affecting sectors such as electrical equipment, pharmaceutical products, telecommunications and information technology equipment were reached. For an analysis of the MRAs concluded by the EC, see A. Alemanno, *Le principe de la reconnaissance mutuelle au delà du marché intérieur. Phénomène d'exportation normative ou stratégie de 'colonialisme' réglementaire?*, in *Revue du droit de l'Union européenne*, 2/2006, p. 273 ss.

*Early Warning and Problem Prevention Mechanisms* was adopted. The warning system was designed to identify regulations, preferably still in draft form, that might contribute to non-tariff barriers to trade. Finally, by turning into operational terms the rather vague commitment towards enhanced cooperation, the *Guidelines on Regulatory Cooperation and Transparency* were adopted in 2002. These sought to develop a step further the idea of an early warning system by encouraging U.S. and EU regulatory agencies to consult on a voluntary basis, sharing work plans that identify areas of anticipated regulatory action for the coming year and offering opportunities for reaction before regulations are finalised<sup>66</sup>. Under these *Guidelines*, each party should minimise divergences in the development of new rules and strive for regulatory convergence through harmonisation, compatible solutions or mutual recognition. This document identified as the main cooperation tools: regular consultation aimed at between US and EU regulators in the development of technical regulations. The idea behind these initiatives is that the transatlantic partnership could encourage a spirit of cooperation rather than confrontation among regulatory agencies.

Although legally non-binding, these guidelines have been challenged by France who argued that, by constituting an agreement between the EU and the United States, they should have been adopted by the Council and not by the Commission<sup>67</sup>. The European Court of Justice rejected this action for annulment, after denying any legally binding character and noting that the Guidelines were no agreement under Article 300 EC.

Besides these initiatives involving intergovernmental structures, several private sector and civil society structures have been set up. Thus, since 1995, the Transatlantic Business Dialogue (TABD) has emerged as a private sector initiative aimed at facilitating commerce and investment between the two sides. Then, in response to the TABD' activities, the Transatlantic Consumer Dialogue (TACD) was established as a forum of EU and US consumer organisations committed to make "consumer friendly" policy recommendations to their respective legislators. Finally, in 1998, in response to a request by the EU Commission and the US government to have a platform for an ongoing discussion between officials and environmentalists, the Transatlantic Environmental Dialogue (TAED) was launched to gather EU and US environmental organisations.

While each of these initiatives has made some progress towards reducing regulatory burdens, many U.S. and European companies heavily engaged in the transatlantic marketplace maintain that the results have not been materially significant. Indeed, as most observers agree, none of these attempts have altered the regulatory divergence between the two sides of the Atlantic<sup>68</sup>.

### *EU-US Biotechnology Consultative Forum*

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<sup>66</sup> The Atlantic Council of the United States, *Risk and Reward: U.S.-EU Regulatory Cooperation on Food Safety and the Environment*, Policy Paper, November 2002, p. 7.

<sup>67</sup> Case C-233/02, *French Republic v Commission of the European Communities* [ECR]. For a review of this judgment, see E. Baroncini, *La Cour de Justice et le treaty-making power de la Commission européenne*, 2 *Revue du Droit de l'Union européenne* (2006), 369.

<sup>68</sup> L.A. Patterson and T. Josling, *Regulating Biotechnology: Comparing EU and US approaches*, paper presented at the Western Economic Association International 76<sup>th</sup> annual conference, available at <http://www.ucis.pitt.edu/euce/pub/policypapers/2002-TransatlanticBiotech.pdf>, p. 11.

In the meanwhile, a more specific initiative aimed at tackling the GM conflict was authoritatively launched by President Prodi of the European Commission and President Clinton of the United States in May 2000: the EU-U.S. Biotechnology Consultative Forum.

This was an “independent group of experts representing diverse views on the two sides of the Atlantic”. The Forum, comprised of 10 experts from the U.S. and 10 experts from the EU drawn from different areas related to biotechnology (including scientists, lawyers, consumer representatives, specialists on ethics, farmers, environmentalists and people in business), met four times and produced a report to the EU-U.S. Summit meeting in December 2000.

The mission of the Forum was: “[to] consider the full range of issues of concern in biotechnology in the United States and the European Union, most of which relate to the use of modern biotechnology in food and agriculture”. The group decided to focus on the use of biotechnology in food and agriculture.

Although the report was a collective effort which had to represent most sides of the argument, it had the merit to reach, after some rhetoric statements<sup>69</sup>, some concrete recommendations, showing the existence of some common grounds for a shared regulatory approach<sup>70</sup>.

By highlighting the shared goals of ensuring human and environmental safety, the US and EU authorities agreed that “regulatory processes on both sides of the Atlantic should meet basic, minimum standards”. Therefore, although the U.S. and EU differ in the particulars of how they approach regulation for agricultural biotechnology products, they managed to agree on a common core of principles which could have inspired their respective regulatory frameworks. In particular, this experience, by going beyond the model of pure regulatory cooperation among government agencies, proved a valuable tool to explore broad public consensus in biotechnologies.

Although no significant action has followed after since, this list of substantive recommendations might be a valuable tool for future cooperation. There is, indeed, no doubt that the EU-US Biotechnology Consultative Forum has been one of the most ambitious and promising initiatives ever undertaken in the ongoing Transatlantic dialogue concerning genetic engineering.

### **3. Transatlantic Regulatory Cooperation : where do we stand?**

Albeit the annual summits, the transatlantic regulatory cooperation did not advance any further. As recently observed, “it almost seemed as if political-institutional integration was no longer

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<sup>69</sup> “Modern biotechnology holds the promise of dramatic and useful advances in some of the areas of greatest challenge for humankind during the 21st Century”. See Final Report of the EU-US Biotechnology Consultative Forum, p. 5.

<sup>70</sup> Among the numerous recommendations, the following are worth mentioning: “that all products should be subject to mandatory pre-market approval (recommendation 1); that “substantial equivalence” should not be used as relieving new foods from additional testing (recommendation 5); Risk/benefit considerations should not be introduced until the basic threshold of reasonable certainty of no harm to human health has been reached (Recommendation 6); Governments should undertake to develop and implement processes and mechanisms that will make it possible to trace all foods, derived from GMOs (Recommendation 7); that when substantive uncertainties prevent accurate risk assessment, governments should act protectively on the side of safety. (Recommendation 12); that regulatory procedures, including risk assessment, should include, *inter alia*, representatives of civil society (recommendation 14); that the EU and U.S. should establish content-based mandatory labelling requirements for finished products containing novel genetic material (Recommendation 15).

necessary, because – in the boom phase of the late 1990s – the transatlantic market was also growing without political support”<sup>71</sup>. Moreover, during this time, both the US and the EU have departed from the 2002 *Guidelines on Regulatory Cooperation and Transparency* and brought forward regulatory proposals, such as REACH, that were strongly opposed by the other side. This process of stagnation in the transatlantic relations seemed to show all the limits inherent to a non-legally binding process that is maintained in life by annual declarations of political will rather than being advanced by mandatory commitment aiming at positive integration and involving the respective Parliaments.

However, in 2004, the US-EU annual summit revived the TRC by launching the *Roadmap for EU-U.S. Regulatory Cooperation and Transparency*, which subsequently expanded to cover 15 sector-specific projects. This represented a significant move towards a more systematic cooperative approach and paved the way to the establishment of new dialogues:

- 1) One between the European Commission and Office of Management and Budget (OMB) on transparency and methodologies for impact and risk assessment, in order to improve understanding of each other’s regulatory systems.
- 2) A second, a *High-Level Regulatory Cooperation Forum*, was tasked to develop a joint regulatory work plan based on mutual best practices<sup>72</sup>.
- 3) A third one, between the FDA and Directorate General SANCO of the European Commission, called regulatory dialogue<sup>73</sup>.

Building upon this momentum, at the 2007 U.S. — EU Summit, leaders of the EU and U.S. launched the Trans-Atlantic Economic Council (the “TEC”), a political body entrusted of overseeing and accelerating government-to-government cooperation with the aim of advancing economic integration between the EU and the US. In particular, they committed their governments to increasing the efficiency and transparency of transatlantic economic cooperation and to accelerating the reduction and elimination of barriers to international trade and investment with the ultimate objective of achieving a barrier free transatlantic market. The TEC brings together those members of the European Commission and the US Cabinet Members who carry the political responsibility for the policy areas covered by the “Framework for advancing Transatlantic Economic Integration”<sup>74</sup>: regulatory cooperation; intellectual property rights; secure trade; financial markets; innovation and investments.

Although the TEC will intensify sector-by-sector regulatory cooperation and encourages “further cooperation in the areas of agriculture, sanitary and phytosanitary measures and food safety”, the biotechnology’s sector, by not appearing among the Lighthouse Priority Projects, won’t deserve the most immediate TEC’s efforts. However, by acknowledging the importance of research and

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<sup>71</sup> R. Quick, *Regulatory Cooperation – A Subject of Bilateral Trade Negotiations or Even for the WTO?*, 3 *Journal of World Trade* 42, 391-406, p. 399.

<sup>72</sup> Its members include senior U.S. and European Commission officials, academics, business executives, and other officials.

<sup>73</sup> See *Roadmap for EU-US Regulatory Cooperation and Transparency*, June 2004, p. 3.

<sup>74</sup> On the EU side, the permanent TEC members are the Commissioner for External Relations (Benita Ferrero-Walder), for Trade and for Internal Market and Services. In addition, other Commissioners can attend the meetings upon invitation by Co-chairs (EU Commission Vice-President Günter Verheugen and Assistant to the US President for International Economic Affairs Daniel M. Price).

innovation in promoting competitiveness and quality of life, the framework provides for an “exchange of views on policy option for emerging technologies [...] in particular in the field of nanotechnologies, cloning or biotechnologies”<sup>75</sup>.

As most observers agree, none of the abovementioned attempts have altered the regulatory divergence between the two sides of the Atlantic<sup>76</sup>. Despite hopes for a new type of bilateral cooperation characterised by flexible and informal structures of governmental representatives, the revamped TRC has not delivered yet.

#### **Part IV – How to get out of the regulatory deadlock?**

In the light of the above, there are at least three different ways that might be followed to get out of the current regulatory deadlock. The easiest, though probably the least effective, would be to leave the market play under the existing and incomplete regulatory framework offered by the WTO Agreements. This will inevitably bring about trade disputes and will produce the effect of shifting responsibility from the executive to the judicial. Courts will then have to find (uneasy) answers into the WTO legal texts in order to accommodate genetic engineering within their scope. Another possible way, though antithetical to the former, would be to try to engage into multilateral cooperation in order to agree upon an *ad hoc* regulation for biotechnology. A WTO Agreement on GMOs might inject some more certainty on the existing legal framework by providing clear answer to the growing demand for minimum standards to comply with when marketing GM products. However, the difficulties surrounding the negotiation of such an agreement are self-evident and a look at the current stall on the Doha round makes appear such an option not viable for the time being.

##### **1. Why is it time for regulatory cooperation?**

In the light of the newly found dynamism in transatlantic regulatory co-operation, this paper finds it particularly tempting to explore a third way to get out of the regulatory deadlock over GMOs: regulatory cooperation between the two sides of the Atlantic.

After showing that there is clearly a case for regulatory cooperation today, the paper will try to sketch out some possible mechanisms and strategies that might be followed to implement such cooperative efforts. In so doing, it will refer to some of the previous, or even actual, cooperation exercises.

#### *The inability of the WTO/SPS framework to provide effective solutions*

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<sup>75</sup> See Annex 7 to the Framework for advancing Transatlantic Economic Integration between the European Union and the United States of America, available at <http://www.whitehouse.gov/news/releases/2007/04/20070430-4.html>

<sup>76</sup> L.A. Patterson and T. Josling, *Regulating Biotechnology: Comparing EU and US approaches*, paper presented at the Western Economic Association International 76<sup>th</sup> annual conference, available at <http://www.ucis.pitt.edu/euce/pub/policypapers/2002-TransatlanticBiotech.pdf>, p. 11.

The shortcomings of the WTO/SPS regime combined with those of Codex Alimentarius mean that the EU and the US must develop alternative institutional mechanisms to promote regulatory cooperation in the GM arena. Indeed, in parallel with the WTO regulatory framework, both sides have been cooperating at bilateral level during recent years. As shown above, although these efforts have not led to any significant result, they have paved the way for a closer dialogue between competent authorities in order to promote mutual understanding. Officials working from the relevant competent agencies and institutions become to know each other. The recently launched Transatlantic Risk Assessment dialogue between representatives of relevant departments and bodies' scientific experts seems particularly relevant in this regard. This innovative form of dialogue shows that both sides are increasingly aware of the need to shift regulatory cooperation from the high-level *fora* leading to vague policy commitments to technical gatherings where scientific experts may discuss on their daily risk assessment tasks<sup>77</sup>.

This form of structured cooperation on real substantive work represents the most symbolic, as well as promising, initiative undertaken so far. It carries the potential to bring closer the two sides of the Atlantic on how to conduct risk assessment of emerging risks. Although the immediate focus of the dialogue is not the GM sector, but rather new hazards (such as nanotechnologies), it might be predicted that a mutual understanding on the respective risk assessment methodologies could pave the way for further cooperation also in the GM arena.

As the recently launched risk assessment dialogue illustrates, both sides have an interest in ensuring that they will have the opportunity, method, and forum for participating constructively in each other's regulatory process. Indeed, recognizing that the U.S. and the EU have become each other's most important stakeholder, and that regulatory divergence over GMOs may endanger such a privileged relationship, the relevant authorities seem ready to engage into a very different regulatory cooperation exercise.

The actual disagreement over the implementation of the *Biotech* report shows once again the inadequateness of the WTO framework to reach viable solution within the GM sector.

#### *The increasing unsustainability of the EU framework for GMOs*

The EU seems to have a further incentive in engaging in regulatory cooperation at this particular point in time. Indeed, its GM regulatory regime is not only criticised outside of the EU, but it is increasingly facing resistance within the same EU. Although it recently undertook a profound reform, this regime is all the time more showing its limits. To date, the only GM crop authorised for cultivation and grown in the EU is Bt maize (MON810)<sup>78</sup>, but there are bans on its cultivation in five EU countries and no cultivation in 16 others<sup>79</sup>. Indeed, at least five member states have made use of the safeguard clause according to the EU Directive on the deliberate release of

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<sup>77</sup> This initiative was launched in July 2008 in Washington DC. For an overview of the aims of this initiative and the outcome of the first meeting which was held in Brussels in November 2008, see [http://ec.europa.eu/health/ph\\_risk/ev\\_20081113\\_en.htm](http://ec.europa.eu/health/ph_risk/ev_20081113_en.htm)

<sup>78</sup> In reality, a total of three GM maize lines (Bt176, MON810, T25) were authorised in 1997/98 for cultivation in the EU. However, only MON810 is relevant to agricultural production. Bt maize contains a gene from a bacterium that produces a toxin to defend it from the European corn borer. An insect pest, the European corn borer is present primarily in southern and middle Europe, and is slowly making its way north.

<sup>79</sup> Until 2007, Spain, France, Portugal, the Czech Republic, and Germany were the only European countries growing GM crops, for a total of nearly 110,000 hectares.

genetically modified organisms. However, any of the safeguard measures have been found to be adequately backed by new scientific evidence<sup>80</sup>. Lastly, in January 2008, the French government issued a nationwide ban on cultivating MON810 maize because of "serious doubts" as to its safety, but the scientific studies brought forward to back up its claim were recently found by EFSA "scientifically unfounded"<sup>81</sup>.

At the same time, despite the unequivocal condemnation of its de facto moratorium of GM approval under the previous regime by the WTO DSB, the EU is still proving reluctant in granting authorisation under the new regime<sup>82</sup>. The recent Commission draft proposal not to approve two varieties of maize in the EU<sup>83</sup>, against the positive scientific advice of EFSA, has brought again the EU approval system under severe criticism<sup>84</sup>. Since, in its Commission opinion, possible long-term risks have not been sufficiently researched, and suitable research methods are not available, the Commission believes that it is necessary, in the name of the precautionary principle, not to authorise the two Bt maize lines for cultivation<sup>85</sup>. The fear is that both Bt maize lines could harm other animal species.

While since 1998 the Commission has not approved any applications for the cultivation of genetically modified crops, it has not actively rejected any applications, either, as it is the case with these GM corn products<sup>86</sup>. This is due to the existing authorisation system where if a qualified majority vote is reached neither at the Standing committee on the Food Chain and Animal Health (SCFCAH)<sup>87</sup> nor within the Council, the ball goes back to the European Commission which will have to take alone the final decision. Under the current regulatory framework, to prevent such political blockades leading to an inability to act at EU level, the European Commission has indeed a duty to adopt a decision. Until now, the Commission has approved all applications for GMO products where EFSA has concluded that they are as safe as comparable conventional products. Now, however, the political conflict surrounding plant genetic engineering is blocking the European Commission itself. The Community regime stipulates that

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<sup>80</sup> Thus, for instance, the national bans on maize MON810 by Hungary and Greece have recently been found not scientifically substantiated by EFSA (July 2008).

<sup>81</sup> Following the notification of the ban, the Commission requested EFSA to examine the scientific studies advanced by the French authorities. The EFSA GMO panel finished their evaluation on 29 October 2008 stating that the studies given to them delivered no new scientific findings which would undermine the previous safety assessment of MON810. To know more on the triggering of the safeguard clause by France [http://www.gmo-compass.org/eng/news/319.maize\\_mon\\_810\\_france\\_triggers\\_safeguard\\_clause.html](http://www.gmo-compass.org/eng/news/319.maize_mon_810_france_triggers_safeguard_clause.html)

<sup>82</sup> Seventeen applications for the use (not for cultivation) of GMOs have been approved since 2003 and four approvals are expected within the current year.

<sup>83</sup> The EU proposed, in November 2007, to reject the applications to license the Bt-11 corn seed made by Switzerland's Syngenta AG and the corn 1507 product produced by the U.S.-based Pioneer Hi-Bred International Inc. and Dow AgroSciences. These crops are engineered to produce a toxin, commonly called Bt, that is poisonous to certain insect pests that lodge inside cobs and stalks and eat the plant from the inside.

<sup>84</sup> For a thorough presentation of these criticisms, see "EU officials propose ban on genetically modified corn seeds", article appeared on the International Herald Tribune, on November 21, 2007. <http://www.ihf.com/articles/2007/11/21/business/GMO.php>

<sup>85</sup> The text of the draft decision is available at <http://www.gmo-safety.eu/en/news/600.docu.html>

<sup>86</sup> The EU Environment Commissioner Stavros Dimas seems to keep postponing a decision. The Commission asked EFSA to investigate certain safety aspects of the GM plants again.

<sup>87</sup> This regulatory committee, acting within the comitology procedure, regroups both national and Commission representatives and assist the Commission in the development of food safety measures at all stages of the food chain.

the Commission should take into account “the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration”. In any event, “[w]here the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences”<sup>88</sup>.

This pending decision, which symbolises the troubling relationship between law, science and politics within the existing regime, is producing the inevitable effect of upsetting the powerful biotechnology industry and exacerbated tensions with EU trading partners like the United States. Indeed, the European Federation of Biotechnology (EFB) addressed Commissioner Dimas an open letter in which it accused the Commission of renouncing a sound scientific basis with his proposals, thus discrediting the European Food Safety Authority (EFSA). This letter was only the latest part in a discussion on the EU approval process that was opened at the beginning of November 2008 by the German Minister of Agriculture, Horst Seehofer, who asked for a preliminary stop of any authorization until a thorough review of the decision process has taken place. He suggested that future decisions be made solely on the basis of scientific evidence. However, while his Dutch homologue supported this position, France and Austria proposed a temporary moratorium. Indeed, EU Member States continue to have different ideas about possible changes in the authorisation process for genetically modified plants in Europe. At their session in Luxemburg in October 2008, the EU environment ministers were unable to come to an agreement on joint proposals.

France, which has been holding the Presidency of the EU Council until the end of 2008, set up a working group to work on proposals for changes to the current authorisation process for GMOs. Some Member States want to introduce the possibility of prohibiting the cultivation of GM crops in certain ecologically sensitive or protected areas. Others want that such restrictions be applied only if there is a scientifically-based protective measure. Even France’s proposal that GMO authorisation be decided not only on scientific safety evaluations, but also on socio-economic factors, did not get wide-spread approval as yet.

In the meanwhile, European farmers suffer under high feed prices. These are derived from the fact that the import of soybeans and soymeal that contain traces of non authorised GMOs is illegal. Indeed, there is currently a zero tolerance policy in the EU for these plants. As a result, even minimal GMO traces on or below the limit of detection have led to whole shipments being rejected. Given the increasing shortage of animal feed in Europe, time seems to have come for the EU to set a threshold for unauthorised GM in feed. The Council has recently concluded its proceedings with respect to the soybean A2704-12 and cotton lines and, presumably, the Commission will follow EFSA’s scientific advice and authorise the products.

All of the above seems to clearly show how the EU’s regulatory framework for GM, as it is (not) functioning today, is not likely to be sustainable in its present form. As a result, the European Commission is increasingly put under intense pressure to reform its policy by virtually all its GM

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<sup>88</sup> See Article 7 of Regulation 1829/2003.

stakeholders: the industry<sup>89</sup>, the farmers, the environmental and consumer groups as well as trade partners.

The societal landscape in which the EU regime is supposed to work<sup>90</sup> combined with the increasing lack of support offered by Member States in the authorisation process together with their ever-increasing recourse to safeguard measures against the already authorised GM products are making the EU framework increasingly unsustainable, both outside and inside the EU. This cannot but provide a further incentive to the EU to seriously engage into Transatlantic regulatory cooperation as a possible way to solve part of its inherently unworkable regime.

### *The emerging economies entering the GM market*

Finally, with the rise of China, India and Brasil as new actors in the world economy, and as important growers of GM products, the future of biotechnology is more likely to depend on the regulatory responses provided by these countries rather than those coming from the US or the EU. The emergence of these countries and their rapidly-growing industries might provide one of the most persuasive drive for both the EU and US to work together in order to solve their disagreements over genetic engineering.

## **2. What kind of regulatory cooperation?**

Having proven the case for regulatory cooperation between the EU and the US on GM products, this paper would like to formulate some possible recommendations on how to engage and conduct such cooperation across the Atlantic.

There are several ways regulatory cooperation may occur and be improved between the two sides<sup>91</sup>.

*a) The focus of cooperation should be on mutual understanding, enabling the identification of divergence/convergence*

Although the harmonisation of substantive standards for the approval of GM products would be the most immediate way capable of solving the current deadlock over GMO across the Atlantic, this solution does not seem viable for the time being. Indeed, as shown above, the EU and US regulatory frameworks couldn't be more different and would therefore virtually impossible to find a common ground by identifying a set of common principles governing the use of GM

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<sup>89</sup> Pioneer, who introduced an application for an authorisation in 2007 sued the Commission at the European Court of First Instance in Luxembourg for delaying approval. See Case T-139/07, Pioneer Hi Bred International/Commission, pending. At the same time, the German chemicals giant BASF has warned of legal action against the Commission if it did not rule soon to allow cultivation in Europe of the company's high-starch biotech potato, the Amflora.

<sup>90</sup> New official European data clearly shows public opposition to GM food.

<sup>91</sup> For a recent list of recommendations on how to improve the transatlantic regulatory dialogue, see D. Vogel, Can it be done? Suggestions for better regulatory cooperation between the US and Europe, Transatlantic Thinkers n. 7, Bertelsmann Stiftung, p. 8.

products<sup>92</sup>. At the same time, mutual recognition, by presupposing the equivalence of respective rules and a real prospect of making them operate almost "automatically", cannot offer a realistic way out of the GM conundrum.

In light of the above, regulatory cooperation should focus, rather than on harmonisation and mutual recognition solutions, on the identification of alternative options which may bring close the regulatory approaches of both sides more gradually. In particular, being highly unlikely that the existing regulatory divergence be solved through the negotiation of common rules and standards, the competent authorities should first promote mutual understanding between their respective normative, institutional, economical and societal frameworks surrounding the GM sector in order to identify possible convergence and divergence. This is not a straightforward exercise as the relevant regulatory landscapes cannot mechanically be compared, but they first need to be fully understood within their respective contexts before being effectively compared.

Although this cooperation exercise won't lead to immediate results, it carries the potential to bring closer the two sides of the Atlantic, by paving the way for an effective dialogue between competent authorities and their respective staffs.

*b) Structured dialogue on each component of risk analysis, notably risk assessment*

In order to promote mutual understanding of their respective regimes and possibly identify points of divergence/convergence, the US and EU authorities should focus on a structured dialogue focusing on each component of risk analysis. However, being the risk assessment stage the most suitable for engaging into a comparative scrutiny, this should be the focus of the initial cooperation activity. Indeed, while risk management being dependent on local needs and desired level of protection tends to be local, risk assessment, by relying - at least in principle - only on science, has a vocation of universality. A further reason for prioritising cooperation on the scientific stage of the analysis is that, in both risk regulatory regimes, risk assessment is a central element, a sort of *Grundnorm* of the risk analysis paradigm.

*c) A Transatlantic Dialogue on risk assessment as the privileged institutional tool*

To engage into this recommended cooperation exercise aimed, primarily, at mutual understanding, and, secondly, at identifying possible common grounds, the US and the EU should rely on the recently launched Transatlantic Risk Assessment dialogue as their privileged institutional mechanism. This informal gathering of both scientific and non-scientific experts belonging to the relevant agencies and bodies represents an ideal framework for mutual understanding, collaboration and convergence on risk assessment methodologies. It is only by bringing together the responsible for the day-to-day risk assessment tasks on both sides of the Atlantic that a revealing of possible convergence may occur.

To enable these experts to engage into an effective dialogue, the priority should be on terminology. The identification of a common terminology represents a pre-condition for the functioning of this group. Indeed, the need for a more consistent use of terminology has been

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<sup>92</sup> On this point, it is worth mentioning that the set of shared recommendations agreed upon within the Biotechnology Consultative Forum, back in 2002, was the product of a collaboration exercise which did not involve representatives of the relevant authorities but rather merely private individuals.

identified as one of the causes of divergence of opinion between scientific bodies<sup>93</sup>. In particular, it might be necessary to cooperate on the way in which uncertainties are expressed. On this point, the dialogue might rely on the work already undertaken by some organisations, such as EFSA, IPPC and EEA, which have developed systematic approaches for evaluating and expressing uncertainties in risk assessment. Although the Transatlantic dialogue may recall the previous *EU-US Biotechnology Consultative Forum*, it differs greatly from that experience to the extent that it is not only composed of representatives of the relevant agencies rather than by independent experts, but it also focuses solely on risk assessment and not on risk management strategies.

Finally, pursuing this initiative would represent a significant shift, in transatlantic regulatory cooperation, from political commitments stemming from High-level fora, such as the US-EU High-Level regulatory cooperation forum, to technical cooperation and dialogue where scientific experts may discuss and contrast their day-to-day risk assessment tasks.

*d) Sharing and exchange of information and best practices to improve mutual understanding*

To achieve consensus on aims and approaches to risk assessment, it might be advisable that the relevant authorities:

- develop and share best practices on key aspects of risk assessment approaches and methods;
- exchange information, documents and consultation on planned and on-going relevant activities.

Thus, for instance, the relevant authorities may attempt to cooperate in the conduct of the risk assessment of a new GM product, following the application for its evaluation under their respective frameworks.

It might be observed that following the conclusion of the 2007 EFSA/FDA agreement in the area of assessing food safety risk, a first step towards this direction has already been made. This agreement will indeed facilitate the sharing of confidential scientific and other information between the relevant transatlantic authorities. This represents indeed not only the first formal international cooperation agreement EFSA has signed but also the first formal step in cooperation with its US homologue<sup>94</sup>.

*e) Focusing on the interaction between risk assessors and risk managers by making explicit the so-called “risk policies”*

Besides the abovementioned procedural cooperation activities, the relevant authorities should also take action vis-à-vis one of the most controversial aspects of risk analysis: the interaction

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<sup>93</sup> Draft checklist of reasons of for diverging scientific evaluations of the « same » evidence, EEA workshop, Copenhagen, May 2008. See also DG SANCO study on risk terminology, available at [http://ec.europa.eu/health/ph\\_risk/studies\\_risk\\_en.htm](http://ec.europa.eu/health/ph_risk/studies_risk_en.htm)

<sup>94</sup> To know more on this agreement, see <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01664.html> and [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753816\\_1178621166798.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_1178621166798.htm)

between risk assessors and risk managers. There are indeed good reasons to believe that some, if not most, of the differences between the two regulatory frameworks fall within this difficult phase of risk analysis.

In particular, the US and the EU competent authorities should make explicit and, possibly, harmonise their respective “science policies”<sup>95</sup>. As is well known, these consist in decision rules about the way in which risk assessment scientists should proceed when they encounter specified types of uncertainties<sup>96</sup>. These methodologies, techniques and processes, by influencing all steps of risk analysis, tend to inevitably predetermine the scope and nature of scientific assessment leading to an inherent bias towards certain unwanted outcomes<sup>97</sup>. Thus, for example, one of the most common science policies is the presumption that a certain agent that can cause disease in laboratory animals can equally cause disease in humans<sup>98</sup>. The need for science policy arises notably because of the limited scientific knowledge allowing multiple versions that are scientifically plausible. In other words, when dealing with decisions involving technical and scientific aspects, scientific expertise and political decisions become so intertwined as to become impossible to separate. In fact, the elaboration of these policies and assumptions boil down to a risk management activity<sup>99</sup>. As a result, science is susceptible of being perceived not only as a neutral process but as a socially constructed one<sup>100</sup>. This is especially true when the underlying scientific knowledge is uncertain and calls for precautionary action. As “science policies” pervade risk analysis and are crucial to completing most risk assessments today, awareness of the exact role they play within risk assessment is imperative. Notably, it may be important to understand the origin, methods and principles upon which underlying assumptions and techniques of science policies are developed, especially in view of the elaboration of a harmonized approach to risk assessment. The need to inject some transparency into the scope of science policies is particularly important to the extent that their use by risk assessors is capable of determining the outcome of risk assessment, thus dramatically blurring the separation between risk assessment and risk management. In particular, this need is strengthened by the fact that the assumptions of science policies may contain different biases. Thus, some authors, mainly from the US, have argued that existing risk-assessment methods and protocols are inherently biased in favour of avoiding overly stringent regulatory measures, which they fear may impose undue costs

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<sup>95</sup> Because these policies usually specify which assumptions must be used to bridge gaps in scientific knowledge, they are also called “inference guidelines” or “default assumptions”. See NRC 1983, 28-37.

<sup>96</sup> This definition belongs to V. Walker, *The Myth of Science as a “Neutral Arbiter” for Triggering Precautions*, 26 *Boston College International and Comparative Law Review*, p. 214. On science policies, see also S. Breyer, *Breaking the Vicious Circle*, Harvard University Press ed., 1993, pp. 43-44

<sup>97</sup> D.A. Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, *Cornell International Law Journal*, Vol. 27, pp. 833-36; N. de Sadeleer, *The Precautionary Principle in EC Health and Environmental Law*, 12 *European Law Journal*, p. 185 and J. Bohanes, *Risk Regulation in WTO Law: A procedure-Based Approach*, 40 *Columbia Journal of Transnational Law*, pp. 354-359 (2002).

<sup>98</sup> For an illustration of the most common risk assessment policies used by the Codex bodies in charge of conducting most of the risk assessment leading to the adoption of the Codex standards (JECFA and JMPR), see Joint FAO/WHO Consultation Risk Management and Food Safety, (FAO Food and Nutrition Paper 65, Rome 1997), p. 7-9.

<sup>99</sup> Walker, *supra* note 96, p. 263.

<sup>100</sup> Sociologists of science, but not exclusively, have produced a great deal of works problematizing a monolithically, but still common, understanding of science. See, e.g., P.L. Berger and T. Luckman, *The Social Construction of Reality – A Treatise in the Sociology of Knowledge* (New York: Doubleday, 1966) and S. Jasanoff, *Science at the Bar* (Cambridge: Harvard University Press, 1995).

on innovation and technological progress and ultimately on society (progressive risk estimations)<sup>101</sup>. On the other hand, others assert that such assumptions and policies tend to be chosen in order to arrive at the most conservative risk estimations<sup>102</sup>. The latter refer to the *Hormones* case, where the scientific experts advising the panel made repeated references to the way in which ADI (acceptable daily intake) figures were established using very sensitive end points from human primates, with the vulnerability of sensitive members of the population taken into account when establishing safety factors<sup>103</sup>.

By showing awareness of the important role of these policies in risk analysis, the Codex Alimentarius Commission has agreed, during one of its last meetings in Rome in July 2007, that its members work together to render science policies explicit<sup>104</sup>.

Since many of the potential differences existing between the US and EU regulatory approaches over GM may hide behind the veil of science policies, which tend to be, under both regime, rather opaque and difficult to identify, it is recommended that both sides work together to identify them.

#### *d) The identification of a basic set of common transatlantic risk analysis principles*

Once engaged into an effective dialogue between risk assessors, and having identified the main sources of divergence and made explicit all science policies, it might be highly desirable that the US and EU authorities work closely in pursuit of a common risk assessment methodology for GM products. In doing so, the relevant authorities may take advantage of the inputs brought by other regulatory regimes around the world. The existing Global Risk Assessment dialogue, run in parallel to the transatlantic dialogue, might ensure a regular exchange of information among authorities, thus promoting the knowledge of alternative assessment methods and approaches.

### **Some Conclusions**

All recommendations formulated at the end of this paper stem from an innovative approach to regulatory cooperation which prioritises a short-term objective over a more ambitious agenda. As illustrated above, if the ongoing transatlantic deadlock over GM still has a chance to be surmounted, this will require an informal and pragmatic dialogue between the relevant authorities, who are embedded in their respective regulatory, economical and societal risk analysis frameworks, rather than a high-level forum made of non-experts. The immediate goal pursued by this dialogue should not be harmonisation of standards, but mutual understanding of the respective frameworks. Achieving this less ambitious objective of mutual understanding might reveal a Herculean task, but – if successful – this regulatory cooperation exercise may identify the real points of regulatory convergence/divergence, thus leading to the setting up some

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<sup>101</sup> Breyer, supra note 96, and C.F. Cranor, *Regulating Toxic Substances – A Philosophy of Science and the Law*, 1993. For a similar viewpoint, but from the EU, see G. Majone, *What Price Safety? The precautionary principle and its policy implications*, *Journal of Common Market Studies*, Vol. 40, No. 1, pp. 89-109, 2002.

<sup>102</sup> Button, *The Power to Protect*, Hart, 2006, p. 98.

<sup>103</sup> Button, supra note 102, p. 98, refers to the *Hormones* Panel Report, Annex: Transcript of the joint meeting with Experts, para 65. See also, Breyer, supra note 96, p. 46; Walker, supra note 96, p. 166.

<sup>104</sup> The 30th Session of the Codex Alimentarius Commission (CAC) was held in Rome, Italy on July 2-7, 2007.

common transatlantic risk assessment principles. In so doing, the relevant authorities should not feel compelled to look exclusively at GM products, but they should be free to cooperate on newly emerging risks, such as nanotechnology applications. Nothing indeed excludes that a possible convergence upon the regulatory approach to be taken towards a new technological hazard, implying a less confrontational context, might pave the way for a successful cooperation in the highly contentious GM sector.