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TRADE, THE ENVIRONMENT, AND THE INTERNATIONAL REGULATION OF BIOTECHNOLOGY, PHASE 2

This synthetic overview of the research financed under the Swiss National Science Foundation project grant No. 101311 – 104072/1 covers the period of 1 June, 2004 to 31 May, 2006.

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Executive Summary

This report presents an overview of the second of two phases of research on related issues, a project which has been carried out by a group of researchers at the Faculty of Law of the University of Geneva. It has been financed under the Swiss National Science Foundation project grant No. 101311 – 104072/1 covering the period of 1 June, 2004 to 31 May, 2006, and it is to a certain extent relying on a previous research project carried out during the preceding three years, also financed by the SNSF (No. 1114-063942.00). The previous research analyzed the relationship between the Biosafety Protocol, the Codex Alimentarius and the relevant WTO agreements.[1] This second phase builds on this investigation and explores the related question of the role of scientific standards on environmental and public health issues in the context of trade restrictions. The global regulation of trade in genetically modified organisms (GMOs) through multilateral negotiations and organizations is at the center of both research programs, but the second phase has further emphasized the study of the relationship between WTO Law and science, and it covers new ground with regard to the communication of risk, an issue area that has been very much neglected in the literature.

WTO Law and Science

The relationship between WTO law and science has become more and more important since the April 1994 Marrakesh Agreement. It is partly due to the evolution in public awareness of the (potentially negative) effects of many products and processes which are becoming widely diffused.

The UN Environment Programme has been working for over a decade to enhance the capacity of countries, especially of developing countries and countries with economies in transition, to integrate environmental considerations into development planning and macroeconomic policies, including trade policies. It is therefore with that organization's Economics and Trade Branch that we organized a Colloquium on WTO Law and Science, on October 11, 2005.[2] Its purpose was to offer researchers and diplomats a forum where they were able to discuss the relationship between law and science in the development of trade and environmental policies and in the implementation of related legal agreements, primarily at the multilateral level. Presentations centered on the decisions of the Dispute Settlement Body of the WTO in relation with risk assessment, the precautionary approach, and international standards.

As a result of our previous work on trade and environment we identified the Codex Alimentarius as a particularly relevant example of the contribution of standards, based on a scientific approach, to the dispute resolution. Yet the painful experience

[1] Petitpierre et al. 2004a & b. http://www.ecolomics-international.org/ecolomic_policy_and_law.htm

[2] Colloquium on WTO Law and Science jointly organized by the Faculty of Law of the University of Geneva and UNEP Economics and Trade Branch in October 2005; the program and a short summary are available at http://www.ecolomics-international.org/biosa_report_colloquium_wto_law_science_law_faculty_geneva_unep_etb_11102005.pdf .

made by the EU with the application of the Codex Alimentarius in the 1998 *EC-Hormones* dispute before the WTO did not really help to clarify the role of internationally recognized standards, neither did it increase trust in science-based adjudication in Europe. On the other hand, it prompted academic reflection on the SPS's inability to take into consideration societal concerns which are based on a broad democratic support.

As described by Professor Laurence Boisson de Chazournes, the relationship between technical standards and legal rules is highly complex. The innovative framework of analysis of these interactions that she proposes consists of five levels:

(i) International standards may serve as bridges between legal systems that have very different objectives and constituencies.
(ii) International standards may in some cases correct a legal rule, for example when rules which were designed for stability turn out to be too rigid in their application.
(iii) When formal or traditional legal norms are not adequately developed, voluntary standards may serve as interim instruments which can bridge a legal gap.
(iv) A standard may give an "orientation" to the application of a customary rule of international law.
(v) In view of the fact that international norms have to be elaborated in a more and more technical context, they have to integrate the technological culture.

Risk Communication and its Relationship with Risk Assessment and Risk Management

The relationship between risk management and risk assessment is widely recognized as being interdependent and iterative. This interrelationship was an important part of our first research and has been now revisited in so far as risk communication is specifically considered as a distinct element of the risk analysis process (defined by the Codex Alimentarius as consisting of risk assessment, risk management and risk communication). In this context, we have been organizing a Roundtable on Risk Communication on May 11, 2006. Dr. Eric Schoonejans from INRA, Paris, discussed how one of the key risk communication questions relates to the transmission of scientific knowledge between the scientific community and official authorities such as courts, judges, or regulatory bodies. Prof. Peter H. Sand from the University of Münich analyzed how GM food product labels are part of the recent wave of *informational regulation,* sometimes described as a 'post-modern' third generation of environmental law (after command-and-control, and market-based instruments). Mr. Jeremy Wates, Secretary to the Aarhus Convention introduced this accord and pointed out that its 'participation pillar' emphasizes, in Art. 6.4, that public input must be possible *before* the essential environment-related decisions have been taken.

The need to communicate scientific knowledge to decision-makers is not only linked to the need to make sure that the decision-making process is based on sound scientific evidence, but also to a basic requirement of democracy. The regulation of risks is part of the basic functions and mission of a democratic system of rules and governance. Consequently, scientific experts cannot decide alone on important science-related policy issues. Besides, scientific controversies should also be brought to the attention of the public. We can easily find at the heart of this reflection the persistence of scientific uncertainty in hazardous situations where the extent of risk may range from a hardly conceivable potential to a statistically verified percentage. In addition, industrial risk assessment techniques are often, if not always, somewhat biased in favor of avoiding false positives, i.e. they tend to

downplay findings which would increase costs on technological developments. The public might therefore have a different “risk assessment” and “management”.

The scarcity of research into risk communication in comparison with the quite abundant literature on risk assessment and risk management raises the question as to what may have caused this unbalance in the amount of attention given to the three pillars of risk analysis. Relying on the three phases sketched out by two pioneers in this domain, Powell and Leiss, we can mention the following evolution of the question which also indicates to some extent the reasons for the above-mentioned scarcity:

(i) Risk communication as a distinct academic field of investigation was triggered about thirty years ago through major environmental accidents such as oil and chemical spills and concentrated at the beginning primarily on the provision of information and education after the event had occurred.
(ii) A more vigorous stance was later adopted by regulators which could be called the persuasion or marketing phase.
(iii) Based on negative experiences which underestimated the importance of building up the public’s trust, the top down and closed decision-making process inherent in the first two phases is being replaced by increased possibilities for the public to participate early in the decision-making process.

The issue of inadequate information disclosure in the face of uncertainty is located at the core of the relationship between law and science and related issues such as especially environmental governance. Withholding information, however, can have very serious consequences as shown by the European Environment Agency (EEA) in the case of the widespread use of asbestos products over many decades: “Information was not used, or ignored: or we were all taken by ‘surprise.’ “ The 1998 Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters is an attempt to sensitize the decision-makers in environmental matters about the importance of public participation and risk communication.

Some Recent developments: Attempts to include social aspects of risk analysis in the WTO process of dispute resolution, and the WTO’s Committee on Trade and Environment

The clash between the European Union on one hand and the US, Canada and Argentina on the other hand over the latter countries’ access to the European market for their GM crops and seeds is the main development for our subject, as far as trade relations are concerned. One of the main differences between the presently pending biotech disputes launched by the US, Canada and Argentina and the four SPS cases accumulated so far is that the dispute directly addresses the different public perceptions of GM food on the two sides of the Atlantic. This led to an exceptionally vigorous mobilization of formal NGOs, as well as more informal civil society organizations and resulted in the elaboration of three *amicus curiae* briefs to the WTO’s Dispute Settlement Body (DSB) during the first half of 2004, which we analyzed for the purpose of this project.

As far as trade and environment negotiations at the WTO are concerned, we considered the November 2001 Doha Development Agenda (DDA) resulting from the WTO’s fourth Ministerial Conference, which contains those issues which are scheduled for “negotiations,” (all remaining environmental provisions are to be “discussed” only, i.e. they have a lower level of priority). Three environmental objectives are to be negotiated "with a view to enhancing the mutual supportiveness

of trade and environment:" (i) the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs); (ii) procedures for regular information exchange between MEA Secretariats and the relevant WTO committees, and the criteria for the granting of observer status; (iii) the reduction or, as appropriate, elimination of tariff and non-tariff barriers to environmental goods and services. The first point is of major importance for our project, as the analysis of risks and their consequences can be different in MEAs and in the WTO practice. The four years after the Doha Conference saw some progress, especially in Environmental Goods and, to a lesser degree, in the clarification of the relationship between MEAs and the WTO agreements. In light of the deadlock of the negotiations in July 2006, however, the fate of the trade and environment aspects of the Doha Round remains uncertain.

Coherence and Mutual Supportiveness

The achievement or improvement of coherence among international regulatory frameworks in different sectors has always been one of the greatest challenges when implementing international law. It is hardly surprising as long as negotiations are carried out by representatives from ministries or other governmental bodies with quite different perceptions on specific issues than other concerned agencies. Trade, environment, and public health officials, for example, tend to view quite differently the long term impact of technological developments or policies. This is why we have such different approaches to risk analysis at the Biosafety Protocol, the Codex Alimentarius, and at the WTO's Committee on Trade and Environment and the SPS Agreement.

Regional differences in the fundamental approach to the creation of rules and standards are highly important as well. With regard to regulating GMOs the US has for many years used specific product-based methodologies. The European Union on the other hand emphasizes broader production (or processes)-related methodologies, a divergence which has resulted in a regulatory polarization. Yet the differences are not limited to differences in legal approach, they depend on "general issues" which have much to do with risk communication or political choices. The fact that arguments put forward by active opponents are often based on a form of opposition to extreme liberalism shows again the importance of risk analysis and risk communication to find the adequate response to those "general" but also quite vital questions.

1 WTO Law and Science

The relationship between WTO law and science has become more and more important since the WTO has emerged from the General Agreement on Tariffs and Trade (GATT) as a result of the April 1994 Marrakesh Agreement[3] and entered into force in January, 1995.[4] This is partly due to the evolution in public awareness, including its political and scientific ramifications, of the (potentially negative) effects of many products and processes which are becoming widely diffused. Products, as well as production processes, have become more sophisticated, which created a

[3] http://www.wto.org/english/docs_e/legal_e/04-wto.pdf
[4] The WTO Agreements are available at http://www.wto.org/English/docs_e/legal_e/legal_e.htm#tbt

need for more complex regulations, especially since this trend also created new opportunities for protectionist applications.[5] Economic globalization and the realization that threats to the ecosystem and public health don't respect national borders have greatly strengthened the importance, not to mention the legal clout, of international regulation and standards.

UNEP has been working for over a decade to enhance the capacity of countries, especially of developing countries and countries with economies in transition, to integrate environmental considerations into development planning and macroeconomic policies, including trade policies. It is therefore with that organization's Economics and Trade Branch that we organized a Colloquium on WTO Law and Science, on October 11, 2005.[6] Its purpose was to offer researchers and diplomats a forum where they were able to discuss the relationship between law and science in the development of trade and environmental policies and in the implementation of related legal agreements, primarily at the multilateral level. Presentations centered on the decisions of the Dispute Settlement Body of the WTO in relation with risk assessment, the precautionary approach, and international standards.

1.1. Scientific evidence in WTO law

This trend in all industrialized countries has resulted in the adoption of the Uruguay Round's most scientifically oriented agreement, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS),[7] and also of the Agreement on Technical Barriers to Trade (TBT).[8] The former specifies the conditions which apply in order to make import restrictions based on scientific justification in the area of food safety and animal and plant health regulations WTO-compatible. The latter one on the other hand is focused on technical regulations and standards, as well as on conformity assessment procedures like testing or sampling which must not be more trade-restrictive than necessary in order to fulfill their legitimate objective. Both WTO agreements are relevant for the protection of the environment and of public health, and while both impose severe restrictions on an importing country that wants to ban or restrict certain imports they both "also recognize the sovereign right of governments to adopt whatever standards are appropriate to fulfill legitimate objectives, taking into account the risks that non-fulfillment would create."[9]

Perhaps in a proactive move anticipating such disputes, multilateral negotiations have given science based standards a legal relevance that they did non enjoy previously. Contrary to the SPA Agreement, the TBT Agreements does not list the relevants standards specifically, it states their relevance generically.[10] The SPS

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[5] Sampson 2000, 64.

[6] http://www.ecolomics-international.org/biosa_report_colloquium_wto_law_science_law_faculty_geneva_unep_etb_11102005.pdf

[7] http://www.wto.org/english/docs_e/legal_e/15-sps.pdf

[8] http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf

[9] Sampson 2000, 64.

[10] TBT Art. 2.4.: Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an

Agreement in its Art. 3 entitled "Harmonization" also emphasizes the general applicability of international standards where they exist, and it declares that import restriction based on international standards shall be deemed to be necessary and WTO compatible.[11] The SPS Agreement allows, however, that countries may impose import-restrictive measures which are more stringent than the relevant international standard, "if there is a scientific justification,"[12] or if they are in conformity with SPS Art. 5 on 'Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.' The SPS Agreement goes a step further than the TBT Agreement by mentioning by name three such frameworks as the authoritative standards, guidelines and recommendations within their respective scope and mandate, which are all held to be WTO-compatible, i.e. the Codex Alimentarius, the International Organization for Animal Health (still called by its acronym OIE based on its previous name of Office international des epizooties), and the International Plant Protection Convention, and it requires member countries to "play a full part, within their resources, in the relevant international organizations."[13]

As a result of both the requirement of WTO law and the previously mentioned evolution of society, the number of technical standards has multiplied by two or three over the past twenty years.[14] In the areas of the protection of the environment and of public health the concerns of scientists, politicians and the public at large have led to an increasing number of trade restrictions that are based on scientific arguments. Thus there is an increasing need to find the right balance between science and rule-based rights of an importing country under WTO law on one hand, and politically sensitive societal choices on the other hand. This represents a major challenge to governments. As far as the WTO is concerned these questions have underpinned more and more disputes before its Dispute Settlement Body, and this trend will arguably be reinforced in the coming years in view of the spread of biotechnology.[15]

1.2. The contribution of scientific knowledge and standards to the resolution of disputes

As a result of our previous work on trade and environment we identified the Codex Alimentarius as a particularly relevant example of the contribution of standards to the dispute resolution.[16] Created in 1961 by FAO and WHO, it used to be considered as a technically oriented 'gentlemen's club.'[17] This perception changed fundamentally

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ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

[11] SPS Art. 3.1 and 3.2.

[12] SPS Art. 3.3.

[13] SPS Art. 3.4., see also SPS Annex A, 3. International standards, guidelines and recommendations..

[14] In France, for example, there existed a little over 10'000 technical standards in 1982, whereas this number escalated to neatly three times that many by 2004: Brosset and Truilhé-Marengo, 2006, 13.

[15] *Ib.* 65.

[16] FAO and WHO have published two fundamental explanatory documents: For a brief overview see *Understanding the Codex Alimentarius*, 1999, http://www.fao.org/docrep/008/y7867e/y7867e00.htm and for a detailed explanation of its function *the Codex Alimentarius Procedures Manual*, 15th Edition 2005 ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf .

[17] Thomas, 2004, 11.

with the elevation of the Codex to a WTO-compatible standard as part of the conclusion of the Uruguay Round. From that moment on negotiators where always conscious of the fact that their decisions may have important consequences and ramifications for their country in case of a WTO dispute. As a result, the nature of the Codex negotiations became far more politicized and, one might add, often more acrimonious.[18]

The experience made with the application of the Codex Alimentarius in the 1998 *EC-Hormones* dispute before the WTO did not really help to clarify the role of internationally recognized standards, neither did it increase trust in science-based adjudication. On the other hand it prompted academic reflection on the SPS's inability to take into consideration societal concerns which are based on a broad democratic support.[19] Professor Thomas Cottier for instance speaks for many when he calls for the negotiation of a broader methodology which needs to correct "some deficiencies and weaknesses"[20] in the SPS Agreement: "A proper methodology referring to the social sciences should be developed in the context of risk management. In particular, this includes inquiries into the social and political acceptance of the existing risk (…). Examination of scientific evidence and social and political criteria should be undertaken in consecutive steps.[21]"

1.3. Technical standards and legal rules

When we talk about international standards we need to look at them in the context of two kinds of norms: technical standards on one hand, and legal rules – or - as Estelle Brosset and Ève Truilhé-Marengo title their analysis of these norms fittingly, "The things and the words."[22] Even if the boundary between standards and rules is "quite porous", in the words of these authors, we should keep in mind that standards are based on technical knowledge and experience. Legal rules on the other hand are part of a wider binding legal system which is why they are of a general, abstract nature. Technical standards like the Codex are voluntary for the members of the standardization organization, whereas legal rules like the SPS provisions are by no means voluntary for WTO members. The ambiguity and permeability[23] between the two kinds of norms arises from the fact that WTO members accept measures based on the Codex standards as corresponding to the definition of measures that are

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[18] Acrimony at the Codex arguably reached its peak in the wake of the 1998 *EC-Hormones* Dispute, in fact this dispute can be considered to exemplify most clearly so far the trade-related tensions related to different perceptions on scientific issues, especially on both sides of the Atlantic. What makes the Codex standards on beef hormones unique is that they have been imposed not only by a vote instead of the usual consensus, but to make matters worse, the proponents of the standards won by a very thin majority, in fact the number of abstainees was nearly twice the difference between the yes and the no votes: "at the request of the United States, a secret vote was held, and the standard was approved by 33 votes against 29 (with 7 abstentions). The standards were adopted in June 1995." Motaal 2004, 866.

[19] Echols 2001, Conclusions 148-156.

[20] Cottier 2001, 57.

[21] *Ib*.

[22] Brosset and Truilhé-Marengo, 2006, 13-42: They hasten to add, however, that the reality of the WTO-compatible standards is more complex than their appearance might suggest. In particular, the distinction between things and words is not really clear-cut, the boundary between these standards and rules is often not easy to determine.

[23] *Ib.* 26

justified for the protection of legitimate concerns. Codex standards therefore became WTO's accepted benchmark for national protective action.

The WTO system is characterized by a legal nature which is only half-way into the process of creating law for its members, who explicitly wanted to maintain control over the organization and refused to give it the power to act on its own by supporting the provisions of the trade agreements through decisions taken by the Secretariat.[24] Still, by selecting and validating standards the WTO, in spite of its member-driven or member-controlled nature, achieves a limited legislative power which is based on exogenous regulatory harmonization. Brosset and Truillé-Marengo therefore arrive at the interesting conclusion that one may consider the WTO as some sort of an international executive body which depends on other organizations that have been given the legislative powers, particularly in the areas of the environment and public health.[25]

As described by Professor Laurence Boisson de Chazournes, the relationship between technical standards and legal rules is highly complex. She is proposing an innovative framework of analysis of these interactions which consists of five levels:[26]

a) International standards may serve as bridges between legal systems that have very different objectives and constituencies, such as the international trading system and MEAs. The Biosafety Protocol can be considered as such a standard (although it has also broader functions such as promoting public awareness and participation). In its preamble the negotiators have refused a WTO savings clause and instead have explicitly made it clear that there is no hierarchy with other international agreements such as the WTO. Furthermore, the Protocol stipulates that trade and environment agreements should be "mutually supportive." Boisson de Chazourne's call for internormativity[27] may be seen as a key conciliatory feature which gives standards an important role to play in the path toward greater coherence in public international law. In the same vein, Boisson de Chazournes and Mbengue suggest elsewhere that "…the principles of coexistence and coherence are contained principally in the generic principle of mutual supportiveness. Biotechnology is an interesting area for the assessment of the applicability of such criteria of coexistence and coherence."[28]

b) International standards may in some cases correct a legal rule. Such situations may occur if a rule which was designed for stability turns out to be too rigid in its application. In such cases the application of a voluntary international standard may be preferable thanks to its flexibility and adaptability, especially when these characteristics are more important than legal security.

c) In cases where formal or traditional legal norms are not adequately developed yet, voluntary standards may serve as interim instruments which can bridge a legal gap. Examples of such applications can be seen in the regulation of

[24] Brosset and Truilhé-Marengo, 2006, 18 see it as a very special feature which is an exception to classical international law.
[25] *Ib.* 19.
[26] Boisson de Chazournes 2006, 45-50.
[27] « Internormativité » p. 49.
[28] Boisson de Chazournes et Mbengue Forthcoming.

sectoral, professional or scientific communities. The Codex Alimentarius or ISO can be seen as examples of this interaction between rules and standards. The key characteristic here consists in the unwillingness or inability of the concerned community to elaborate binding legal rules.

d) A standard may give an "orientation" to the application of a customary rule of international law. The relationship between the SPS's three above-mentioned standards represents a classical example of this. The compliance with these standards absolves an importing country from the obligation of demonstrating scientifically the justification of a measure. The fact that these standards prevent measures which are more trade-restrictive than necessary provides them with credibility and legitimacy vis-à-vis the WTO. *A contrario,* an importing country that does not comply with these standards will have the burden of proving, in case of a WTO complaint, that its measure is scientifically justified.

e) In view of the fact that international norms have to be elaborated in a more and more technical context, they cannot exist in isolation, rather they must integrate this technological culture. The International Organization for Standardization (ISO) represents an important example of this technicity, its standards are characterized by a very detailed approach to technical issues.[29]

1.4. The risk analysis process

At the conceptual level, the Codex made a substantial contribution in clarifying the definition of risk analysis terms as they are related to food safety. The most important ones for our purposes were formulated in 1997 as follows:

> *Hazard:* A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
>
> *Risk:* A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
>
> *Risk analysis:* A process consisting of three components: risk assessment, risk management and risk communication. [30]

The partition of the risk analysis process into the risk assessment, management and communication represents indeed the key insight which has been adopted beyond the confines of the numerous Codex negotiation fora, it therefore underpins the work of our group. We had previously addressed the connection that exists between:

[29] See for instance Krut and Gleckman, 1998.

[30] These Definitions were adopted by the 22nd Session of the Commission (1997) on an interim basis: they are subject to modification in the light of developments in the science of risk analysis and as a result of efforts to harmonize similar definitions across various disciplines. http://www.fao.org/docrep/W5975E/w5975e07.htm#definitions%20of%20risk%20analysis%20terms%20related%20to%20food%20safety1

- the Codex Alimentarius,
- the multilateral regulation of trade in GMOs primarily through the Convention of Biological Diversity's Cartagena Protocol on Biosafety, and
- Multilateral Environmental Agreements (MEAs) which form the backbone of the WTO's negotiations and discussions at the Committee on Trade and Environment.[31]

This connection can be seen directly in the overlap between the Codex and the Biosafety Protocol[32] which both address trade in raw genetically modified food products (this is where their overlap ends, the Codex addresses all food, drink and feed products, whereas the Protocol includes all other GMOs such as genetically modified trees or non-edible plants). In an indirect fashion these negotiations are furthermore related because the Biosafety Protocol is an MEA, and as such it is included in the WTO's *generic negotiation* of MEAs-related questions. As far as the Codex is concerned we shall only be concerned here with environment-related food safety in the context of GM food products; it should be kept in mind that these represent only one of the Codex's numerous sectorial and intersectorial responsibilities. The Codex Alimentarius as a key instrument related to risk analysis is of interest for us even though its task consists in a double mandate which is essentially located outside the scope of our research, i.e. trade and environment.[33]

Discussions about risk assessment and risk management in the literature of WTO law based on science-related trade restrictions have been quite considerable. At the same time it is striking that in most cases hardly any mention is made of the importance and complexity of *risk communication* as a concept which is related to risk assessment and management and which may in many instance overlap with these two phases of risk analysis, while remaining distinct and with its very own dynamics.

2 Risk Communication and its Relationship with Risk Assessment and Risk Management

The relationship between risk management and risk assessment is widely recognized as being interdependent and iterative. Nevertheless the complexity of this relationship tends to be underestimated. It has been analyzed with particular insight and depth by Christine Noiville and Nicolas de Sadeleer,[34] and the question of this interrelationship represents an important part of the first phase of the present research.[35] This interrelationship is revisited in the second phase in so far as risk communication is specifically considered as a distinct element of the risk analysis process. A related difficulty consists in *communicating* the legal relevance and justification of scientific evidence on which a trade-restrictive measure is based to the

[31] See Petitpierre et al. 2004 a & b *op. cit.*

[32] It was signed in January 2000 and entered into force in September 2003, http://www.biodiv.org/biosafety/protocol.shtml.

[33] The double mandate of the Codex is described in one of its publications as "protecting the health of consumers and facilitating fair practices in the food trade:" *Understanding the Codex Alimentarius, op. cit.*, back cover.

[34] Noiville et de Sadeleer 2001.

[35] Petitpierre et al. 2004a & b.

attention of the lawyers and other members of a WTO Panel, or the Appellate Body (AB). This is a key concern of Theofanis Christoforou who has been dealing with the challenge of informing, educating and sensitizing a judiciary which may not have any scientific training in a non-partial and balanced fashion about the scientific argumentation of the parties.[36] As previously mentioned, WTO law has been putting its principal emphasis on "scientific evidence", which is often difficult for trade analysts to comprehend. So are also the stakes and relative merits of scientific arguments. Still, this process, which is very crucial for the effective and legitimate function of the Dispute Settlement Body (DSB), also requires an adequate contextualization of the scientific factors in terms that a non-scientist can grasp.

In this context, we have been organizing a Roundtable on Risk Communication on May 11, 2006.[37] Dr. Eric Schoonejans from INRA, Paris, discussed how one of the key risk communication questions relates to the transmission of scientific knowledge between the scientific community and official authorities such as courts, judges, or regulatory bodies. The challenge for the authorities is to make sure that the communication is fair and has taken into consideration adequately the ethical dimensions. Prof. Peter H. Sand from the University of Münich analyzed how GM food product labels are part of the recent wave of *informational regulation,* sometimes described as a 'post-modern' third generation of environmental law (after command-and-control, and market-based instruments). They also appear to have shifted the focus of regulatory attention, from an initial concern with novel risk communication towards a more fundamental debate over democratic governance: i.e., between the public's right-to-know, and a new 'soft paternalism' claiming to determine what citizens and consumers *need* to know. Mr. Jeremy Wates, Secretary to the Aarhus Convention (see below), introduced this accord and pointed out that its 'participation pillar' emphasizes in Art. 6.4. that public input must be possible *before* the essential environment-related decisions have been taken and some of the stakeholders are facing a *fait accompli.*

2.1. The communication of scientific knowledge

The need to communicate scientific knowledge to decision-makers is not only linked to the need to make sure that the decision-making process is based on sound scientific evidence, but also to a basic requirement of democracy. The importance of the regulation of risks can hardly be over-estimated. It "touches upon the basic functions and mission of a democratic system of governance."[38] Consequently, governments cannot abdicate their responsibility and let scientific or other kinds of sectoral experts, which are not accountable, make important science-related policy decisions, but, "in any democratic system of government the electorate must have an opportunity for the final say about which risks it will bear and which benefits it will seek to obtain".[39] For this purpose it is necessary that scientific knowledge, but also scientific controversy, should be brought to the attention of the public; they may thus serve as a basis for the public's perception of the facts which are scientifically relevant. This should ensure that the exchanges between risk managers and risk

[36] Christoforou 2004a & b, 2003, 2002, 2000.
[37] http://www.ecolomics-international.org/biosa_risk_comm_rt_program_overview_ge_law_fac_110506.pdf
[38] Christoforou 2004b, 36.
[39] *Ib.*

assessors should not be in a chicken and egg situation where the risks assessors may well influence the risk managers decisively but they in turn may have been selected, paid and given the key guidelines by the risk managers, so that it becomes exceedingly difficult to distinguish what is and what should be the role and the mandate of science and technology on one hand, and the role of political decisions on the other hand.[40]

One of the key issues at stake here is the question of the nature of science itself, insofar as the content of the communication is not clear for everybody. Should science be positivist, or should more emphasis be placed on context and proportionality? Christoforou criticizes the Appellate Body in the *EC-Hormones* dispute for having "adopted a narrow, positivist view of science and standard of proof in situations of scientific uncertainty".[41] At the same time he sees risk analysis techniques as strongly influenced by a "positivist view of science, considering it to be a powerful and neutral tool capable of predicting risk and causality," a view which as he points out has been demonstrated to be wrong many times.[42] Ironically, the much promoted concept of 'sound science'[43] which often represents a particularly confrontational and sometimes even aggressive form of the positivist view of science has a history which is not really flattering. It has been promoted for the first time in a clearly strategic and concerted manner in the early 1990s by tobacco industry spokespersons and leaders in a rearguard battle to trivialize the health effects of secondhand smoke.[44]

What are then the implications of this dynamics for the relationship between risk management, risk assessment and risk communication? We can easily find at the heart of this reflection the persistence of scientific uncertainty in countless hazardous situations where the extent of risk may range from a hardly conceivable potential to a statistically verified percentage. In addition, there are hardly any industrial risk assessment techniques which are not somewhat biased in favor of avoiding false positives, i.e. they tend to downplay findings which would increase costs on technological developments and on financial gain.[45] There is therefore a need to give the public an opportunity to make its own "risk assessment" and "management," the perception of risk among members of society at large being often different than that of experts.[46]

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[40] Noiville et de Sadeleer 2001, 416.

[41] Christoforou 2002, 270.

[42] Christoforou 2004b, 34.

[43] Mooney 2005, Ch. 6, 65-77: Junking "Sound Science."

[44] As the NGO 'Action on Smoking and Health' has documented, "It was at the 1994 hearings that industry leaders testified under oath that they did not consider nicotine to be addictive. Within days, documents leaked to Congress and the media from Brown & Williamson [RJ Reynolds Tobacco Company] appeared to contradict their testimony. http://www.no-smoking.org/jan98/01-30-98-6.html

[45] Christoforou 2004, 35.

[46] This perception "is wider than that of experts and reflects a number of legitimate concerns (e.g. familiarity with the risk, catastrophic potential, irreversibility of harm, threat to future generations, risk control possibilities, and voluntariness of exposure), which are frequently omitted from an expert risk assessment: *Ib.*

2.2. Communicating risks and risk management

There is a growing tendency, at least in the European Union, to take into consideration the public's perception of risk and their genuine and legitimate concerns rather then patronizing consumers and looking only at assumed commercial preferences. This more "adult" treatment of the public has important consequences for the communication of risk because it emphasizes consumer information, labeling,[47] and in a broader sense it implies a more participatory two-way relationship between the public or the clientele and the providers of goods and services, be they public or private. The role of science is much less taken for granted by this approach. It is easy to see that a more precautionary attitude will thus emerge in many instances. We shall not discuss precaution as such here, however, since it was extensively addressed in the first phase's report.[48]

The scarcity of research into risk communication in comparison with the quite abundant literature on risk assessment and risk management is quite striking and raises the question as to what may have caused this unbalance in the amount of attention given to the three pillars of risk analysis. One can only guess that the focus on democratic participation in the decision-making process which lies at the heart of risk communication is not particularly popular among those governmental and intergovernmental institutions which are in charge of safeguarding the ecosystems and public health at the local, national and international levels, and industry is probably not particularly keen either to promote this kind of a research focus. In addition, risk communication is more likely to be influenced by social and cultural context, so that the achievement of internationally recognized "standards" will be difficult to realize. Risk communication tends to address value-laden politically delicate questions whose discussion is made difficult by the fact that they require a certain familiarity ideally with all three domains of trade, environmental, and public health policy and law. There is therefore undoubtedly an important barrier of entry into this particular field of research which may also explain the dearth of research on risk communication. On the side of relevant jurisprudence, this barrier of entry is probably even higher, and in the case of the WTO it is arguably particularly demanding because of the high level of interconnectedness of its case law, and because of its sometimes very technical nature.[49]

Furthermore, where the public is insisting more and more on participatory decision-making, the issues at stake tend to be contentious or even polarized like in the nuclear energy issue, GMOs, or nanotechnologies. This may explain why risk communication is a relatively young discipline of applied research that emerged in the early 1970 as a distinct field of investigation, and why it focused originally on the regulation of environmental hazards and later expanded into public health and other economic and social risk issues.[50] As far as the evolution of this sub-discipline is

[47] *Ib.*

[48] Petipierre et al. 2004 a & b.

[49] On the other hand one may mention that the WTO's Web site is particularly informative and on the whole well structured, it represents in fact a very significant help for research both on WTO-related policy and jurisprudence.

[50] Probart 2002, 2.

concerned, Claudia Probart pays tribute to the three phases sketched out by two pioneers in this domain, Powell and Leiss:[51]

a) Risk communication as a distinct academic field of investigation was triggered about thirty years ago through major environmental accidents such as oil and chemical spills and concentrated at the beginning primarily on the provision of information and education after the event had occurred. The proponents of this approach assumed that the public was overly concerned about these risks because it did not adequately understand the scientific issues and the probabilistic calculation in this context, otherwise they would have accepted these risks. The regulators who took this approach, however, failed in convincing the public of the wisdom of the acceptance of risks which constituted an integral part of their policies. In particular, they underestimated public opinion's concerns over the potential impact of these hazards on future generations.

b) Once it became clear that risk communication strategies based on information and education where not sufficient, regulators assumed a more vigorous stance which could be called the persuasion or marketing phase. It consisted in downplaying or trivializing risk on one hand, and emphasizing the trust-worthiness of the corporations and the sciences involved. This approach did yield some success but on the whole it did not manage to significantly reduce the gap between technical risk assessment and the public's trust. Trust in public institutions in fact can be considered as the foundation of consensus building, and the loss of confidence of significant portions of public opinion in the regulatory system has led to polarizing positions and a lack of convincing success in achieving a broad consensus for regulatory decisions. The success of Switzerland's November 2005 moratorium on GM agriculture adopted by referendum [52] could undoubtedly be listed as an example of this observation.

c) Based on negative experiences which consistently underestimated the importance of building up the public's trust, Powell and Leiss note that the top down communications and the closed decision-making process inherent in the first two phases are now more and more being replaced by increased possibilities for the public to participate early in the decision-making process. This new risk communication strategy emphasizes stakeholder involvement which includes the validation of public perception of risk. As Probart notes, however, it still remains to be seen whether greater public participation succeeds in reducing controversy and in building trust and consensus for example in the complex arena of food safety.

To summarize these three phases, it may be argued that risk communication is not really a process to make risk *acceptable,* that it is not a *marketing tool* and that it requires both *involvement* and *trust* from the public participants. Probart concludes that a risk communication process, in order to be effective, needs to work in a two-way pattern and should include an involvement of the stakeholders in the decision-

[51] Powell and Leiss, 1997.

[52] The referendum of 27 November 2005 passed with 57.5 % with a participation of 42%, a relatively high turnout for the Swiss direct democracy system which requires frequent votes: see http://www.parlament.ch/e/homepage/wa-va-volksabstimmungen/wa-va-volksabstimmungen-2005/wa-va-20051127.htm

making process before the critical issues have been decided. Too often risk communication is utilized only to try to convince consumers to accept proposed regulations which do not engender public trust and do not help in reducing decreasing controversy, especially with regards to potential food-related hazards, a relatively sensitive area. This observation is supported by professor Yves Tiberghien who notes:

> …the initial reaction triggered by civil society turns into a full-scale institutional legitimacy crisis and revealing a massive gap between government policy and public aspiration (a democratic deficit, a crisis of trust in administration or politicians, a protest against the global economic system etc.).[53]

The issue of inadequate information disclosure in the face of uncertainty is located at the core of the relationship between law and science and related issues such as especially environmental governance. How can these information deficits be explained? It is often not clear whether they are based, for good reasons, on sketchy or inadequate scientific evidence or knowledge, or on science which is not very advanced, i.e. on exogenous factors, or else on endogenous, "home made" factors: "The sad reality is that we are all too often kept in the dark – through neglect or by design, by public officials or private stakeholders."[54] As professor Peter Sand points out, prospects for more clarity are dim since in the wake of 9/11 and in the face of terrorist threats against targets such as pesticide manufacturers "a large part of industrial risk data in the United States is now in the process of being re-classified as "critical infrastructure information."[55]

This kind of a manufactured or artificial information deficit has led in some instances to huge negative consequences. In a much-cited document, the European Environment Agency (EEA) summarizes the fiasco of risk communication in the case of the widespread use of a large variety of asbestos products over many decades: "Information was not used, or ignored: or we were all taken by 'surprise.' "[56] This calamity which diminished countless lives and cost tens if not hundreds of billions of dollars in building repairs alone on both sides of the Atlantic (not to mention in the rest of the world where the asbestos is usually simply left in the buildings for financial reasons) is listed as an example by the EEA, in fact it may be the most important one. There is evidence (e.g. from life insurance) that the dangers of asbestos have been know since the beginning of the XXth century, but they have been literally covered up for decades in various industrialized countries by industrial interests and much of the scientific establishment. According to an account published by Switzerland's Federal Office of the Environment, there have been reports which revealed disastrous long term health effects due to the inhalation of asbestos fibers since 1927.[57]

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[53] Tiberghien 2006, 15 ; Probart emphasizes that the crises of trust or the « influence gap » should be avoided by providing adequate funding for civil society organizations at the local as well as at the international level, to ensure more public participation in both risk assessment and risk management: Probart 2002, 2.

[54] Sand 2003, 487.

[55] *Ib.* 500.

[56] European Environment Agency, 2002. *Late Lessons from Early Warnings: the Precautionary Principle 1896-2000*. Copenhagen.

[57] Fitze, 2006, 47.

2.3. Risk communication in international law

It is the purpose of the Aarhus Convention,[58] adopted in 1998, to sensitize the decision-makers in environmental matters about the importance of public participation and risk communication. The negotiations which led to its adoption started in 1996 and were concluded relatively speedily in just two years, partly due to intense NGO support. With 16 ratification (presently there are about 40 parties), it entered into force already in 2001. It contains, as is to be expected in a convention of this kind, many vague phrases like "meeting any requirements under national law," and it does not have a very efficient enforcement mechanism, yet its inclusion in EC legislation[59] gave it an additional bite. It addresses to some extent the challenge for decision-makers to give other voices than the experts' the opportunity to make a contribution. It has been noted in the case of the EC's Deliberate Release Directive[60] that

> if public concern is not framed in relatively narrow scientific or technical terms relating to the environment or public health (for example if it highlights our incomplete understanding of the technology, ethical issues, socio-economic impacts, for existing farming practices, or the commercial imperative driving the technology), its impact on the decision is at best uncertain.[61]

The incomplete understanding of key scientific questions such as the relationship between genes and proteins in the case of GMOs or the socio-economic impact of globalized monopolies on developing countries' agriculture and food security can often not be framed in these narrow disciplinary and conceptual frameworks and as a consequence often do not attract the attention they merit.[62] There seems to be good reason to suspect that these communication dynamics are just as relevant at the international level, i.e. for the Aarhus process, as they are in the European Union.

Some language on access to information and public participation on the other hand is quite specific, such as the following key provisions:

> Article 5.7 (c) Aarhus Convention (on Collection and Dissemination of Environmental Information): Each party shall "provide in an appropriate form information on the performance of public functions or the provision of public services relating to the environment by government at all levels."
>
> Article 6.4 Aarhus Convention (on Public Participation in Decisions on Specific Activities) : "Each Party shall provide for early public participation, when all options are open and effective public participation can take place."

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[58] Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters which was signed at Aarhus, Denmark, in June 1998: http://www.unece.org/env/pp/documents/cep43e.pdf

[59] Lee and Abbot, 2003, 82.

[60] Directive 2001/18/EC of the European Parliament and of the Council on the Deliberate Release into the Environment of GMOs.

[61] Lee and Abbot, 2003, 96.

[62] Saam, Bordogna and November, 2004.

> Article 6.11 Aarhus Convention: "Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment."

Article 6.11. of the Aarhus Convention is particularly contentious and resulted at the second Meeting of the Parties[63] in Almaty, Kazakhstan, in 2005, in the adoption of an Amendment[64] which represents a milestone in the history of this Convention. This Amendment, once it has entered into force, will replace above Art. 6.11, but it will be binding only for those parties who have ratified it. The UN Economic Commission for Europe has noted that a long squabble among its members has finally come to an end.[65]

Just as the Cartagena Protocol, with its provisions regarding risk assessment and informed consent of the parties, the Aarhus Convention is contributing to the effort of the international community to solve the problems connected with large scale risks. They are both providing a framework of risk analysis which includes the three aspects of dealing with social risks: assessment, management and communication. This last term is to be understood in the broad sense of providing decision-makers with scientific and social information, and giving the public at large both the information and the opportunity to have its reactions included in the process.

3 Attempts to include social aspects of risk analysis in the WTO process of dispute resolution: the *Amicus Curiae* Briefs and the *EC-Biotech* Dispute

A dispute over restrictions on trade in GM products has been expected for a long time, and there has been a widely shared opinion that all four SPS cases,[66] but

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[63] The full set of documents of the second MOP is available at: http://www.unece.org/env/pp/mop2/mop2.decisions.htm .

[64] ECONOMIC COMMISSION FOR EUROPE, Meeting of the Parties to the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters: ECE/MP.PP/2005/2/Add.2, 20 June 2005; REPORT OF THE SECOND MEETING OF THE PARTIES Addendum DECISION II/1 GENETICALLY MODIFIED ORGANISMS adopted at the second meeting of the Parties held in Almaty, Kazakhstan, on 25-27 May 2005: ECE/MP.PP/2005/2/Add.2, 20 June 2005, see http://www.unece.org/env/documents/2005/pp/ece/ece.mp.pp.2005.2.add.2.e.pdf

[65] United Nations Economic Commission for Europe, "Introducing the Aarhus Convention:" …The Meeting adopted an amendment to the Convention setting out more precise provisions on public participation in decision-making on deliberate release of genetically modified organisms, thereby bringing to a close a long-standing debate on the topic. The amendment will enter into force once ratified by at least three-quarters of the Parties. The Meeting reviewed the status of implementation of and compliance with the Convention on the basis of the national implementation reports and the report of the Compliance Committee and made recommendations to certain Parties found not be in compliance. The Meeting also adopted the Almaty Guidelines on Promoting the Application of the Principles of the Aarhus Convention in International Forums and a number of decisions addressing both substantive and procedural issues. Finally, it adopted the Almaty Declaration setting out the aspirations and priorities of the Parties and other stakeholders: http://www.unece.org/env/pp/

[66] For an overview of the precaution-related trade implications contained in these four rulings see Mbengue and Thomas, 2004.

especially *EC-Hormones,* have left many questions unresolved which will serve as a harbinger of forthcoming clashes over other applications of biotechnology.[67]

The clash between the European Union on one hand and the US, Canada and Argentina on the other hand over the latter countries' access to the European market for their GM crops and seeds started in May 2003 with the request for formal consultations and escalated in August 2003 to the next phase of the WTO dispute settlement process, i.e. when the US requested the establishment of a dispute-settlement panel in order to determine if the EU's so-called *de facto* moratorium on GMOs violated WTO law.[68] The three member Panel was duly composed only in March 2004.[69] This case has been expected for a long time and will clearly enter WTO history as one of the DSB's most important case, not to mention challenges. As a matter of fact, at the point of this writing, the *EC-Biotech*[70] Panel report has still not been released by the WTO, more than three years after the process was set in motion.

The difference between the presently pending biotech disputes launched by the US, Canada and Argentina and the four SPS cases accumulated so far is of course that the present economic stakes are much larger and that the dispute directly addresses very different public perceptions of GM food on the two sides of the Atlantic. These differences have led not only to "completely opposite legal strategies"[71] but also to an exceptionally vigorous mobilization of formal NGOs as well as more informal civil society organizations especially in the industrialized countries, but also in the developing world. This mobilization has resulted in the elaboration of three *amicus curiae* briefs to the DSB during the first half of 2004, i.e.[72]

- the so-called 'Academics' Report,'[73]
- the CIEL-coordinated Report, and[74]
- the FIELD-coordinated Report.[75]

Each of these was elaborated by the cooperation of several NGOs or academic authors. They are not contradicting each other, to a certain extent they address the same or similar subject areas, but they vary considerably by the different emphasis they put on these questions - as a matter of fact their approaches and their focus of analysis can be considered to be complementary. We may note here - as a

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[67] See for instance Cottier 2001, 58: "… given the potential for serious trade disputes in the field of biotechnology and its underlying social and cultural problems, the first experiences under the SPS Agreement should not be forgotten. The next step should be towards a better structured SPS Agreement and towards clarification and improvement of its inextricable components."

[68] Boisson de Chazournes and Mbengue 2004, 289.

[69] Foster 2005, 438.

[70] European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS/291, 292, and 293).

[71] See for instance Boisson de Chazournes et Mbengue 2004, 289, or Bernauer 2003, 44.

[72] All three reports can be downloaded, see the following three footnotes and the List of References at the end for the URLs.

[73] Busch, Lawrence, Robin Grove-White, Sheila Jasanoff, David Winickoff and Brian Wynne 2004 ('Academics' Report').

[74] CIEL et al. 2004.

[75] FIELD et al. 2004.

confirmation of our earlier comment on the scarcity of literature and analysis addressing specifically the concept of risk communication, that none of the three reports uses this term at all, but the ideas underlying risk communication may be present indirectly, for example in the 'Academics' Report' which refers to a citation of the US National Research Council concluding that "the first and probably most important step in effective risk assessment and risk management is to establish public participation that involves all the stakeholders." [76]

3.1. The legal status of *amicus curiae* briefs

The legal status of *amicus curiae briefs* at the WTO is based on the right of a dispute settlement Panel at the WTO to accept or to seek information and technical expertise from external sources as specified in Annex 2 to the Marrakesh Agreements Establishing the WTO, the Dispute Settlement Understandig (DSU).[77] This seemingly clear disposition on the acceptance of information and technical advice is nevertheless contentious and, like contentious issues at the WTO in general, politicized. Support for *amicus curiae* submissions at the WTO is limited essentially to the two largest economic actors, the US and the EC, whereas developing countries especially in Asia tend to oppose the acceptance of such reports.[78] As professor Laurence Boisson de Chazournes and Makane Moïse Mbengue point out, however, the term *amicus curiae* brief which is traditionally used in such cases does not appear in the DSU, in fact *amicus curiae* briefs need to be placed conceptually on the confluence of several terms of which each has a somewhat peculiar connotation, namely information, brief, expertise, or consultation.[79]

Furthermore, an important question is left open by the DSU, namely whether the Appellate Body (AB) has the same right of seeking information and external advice.

[76] Busch et al. 2004 *op. cit.,* p. 18, footnote 65: "National Research Council, Building Consensus Through Risk Assessment and Management of the Department of Energy's Environmental Remediation Program 26.

[77] This portion of the WTO Legal Texts may be considered as the charter of its Dispute Settlement Body. DSU Article 13 deals with the " Right to Seek Information": "1. Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate. However, before a panel seeks such information or advice from any individual or body within the jurisdiction of a Member it shall inform the authorities of that Member. A Member should respond promptly and fully to any request by a panel for such information as the panel considers necessary and appropriate. Confidential information which is provided shall not be revealed without formal authorization from the individual, body, or authorities of the Member providing the information."
Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a panel may request an advisory report in writing from an expert review group. Rules for the establishment of such a group and its procedures are set forth in the DSU's Appendix 4.
http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm

[78] Eckersley 2004, 10.

[79] Boisson de Chazournes and Mbengue 2003b, 403. In the French original : renseignement, avis, or expertise, consultation.

The DSU leaves this question open[80] and the AB has ruled for the first time in the case *US-Shrimps*[81] that indeed it does have this same right, an interpretation which has provoked numerous critiques and controversies at the WTO.[82] The question remains open whether the drafters of the DSU have intended to give the AB such powers[83] or whether the question was left open on purpose, perhaps because it was not possible to find a consensus. In light of Art. 3.2 of the WTO rules on dispute settlement which represents one of its cornerstones: "Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements,"[84] it was certainly a bold step of the AB to admit *amicus curiae* briefs.[85] At the same time, it may be said that the DSB has used this self-attributed authority very sparingly.[86] This positive view on the potential of *amicus curiae* briefs is supported by professor Robyn Eckersley who considers that "…the *amicus* briefs in *EC-Biotech* have generated a green public sphere within the judicial arm of the WTO while also influencing broader public spheres beyond (regionally and domestically)."[87]

3.2. *The 'Academics' Report'*

The interdisciplinary 'Academics Report'[88] is the longest one of the three, its credibility[89] arises from the fact that the authors have achieved recognition in academic research programs as well as in governmental and intergovernmental bodies that are focused on the interactions between law, science policy, ethics and risk analysis.[90] The strength of this brief lies in the rigorous and detailed treatment of

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[80] "Working procedures shall be drawn up by the Appellate Body in consultation with the Chairman of the DSB and the Director-General, and communicated to the Members for their information." DSU, *op. cit.* Art. 17.9.

[81] 12 October 1998, WT/DS58/AB/R, para. 39.

[82] Boisson de Chazournes and Mbengue 2003b, 415.

[83] *Ib.* 416.

[84] DSB Art. 3.2, see also DSB Art. 19.2.

[85] As pointed out by Boisson de Chazournes and Mbengue (2003b, 418) the AB « a fait preuve d'audace ».

[86] Boisson de Chazournes and Mbengue 2003b, 418.

[87] Eckersley 2005, 20.

[88] Busch et al. 2004 *op. cit.* The same five academics have also published a scientific article based on this investigation, see Winickoff et al, 2005, albeit with a changed sequence of names. The report provides a summary of the professional achievements of each of the co-authors (p. 2). We can see the interdisciplinary approach of these distinguished researchers from this article: David Winickoff is Assistant Professor of Bioethics and Society at the University of California, Berkeley. Sheila Jasanoff is Pforzheimer Professor of Science and Technology Studies at Harvard University's John F. Kennedy School of Government. Robin Grove-White is Professor of Environment and Society at Lancaster University. Lawrence Busch is University Distinguished Professor of Sociology and Director of the Institute for Food and Agricultural Standards at Michigan State University. Brian Wynne is Professor of Science Studies at Lancaster University.

[89] "The five persons submitting the brief are highly qualified in precisely those fields of sociological research within which the most problematic aspects of the *Biotech* dispute are situated." Foster 2005, 440.

[90] "They have made extensive contributions to the literature on risk and on the regulation of genetically modified organisms and they have extensive practical experience as advisers to national governments, international organizations and national science academies, and as officers of societies and non-governmental bodies engaged in work relating to genetically modified organisms." Foster 2005, 441.

risk assessment and other science-related issues, especially risk management, scientific evidence, justification and expertise from an interdisciplinary social science perspective.[91]

With regards to the nature of risk assessment, they note that risk assessment is by no means neutral, rather, it is socially constructed.[92] Furthermore they emphasize the scientific and political value of participation, especially in the GMO case where scientific knowledge is neither uniform nor complete, and because it is partly related to food, which has a special cultural status in human society.[93] As far as the process of risk assessment is concerned, they point out that:

> …what looks like "delay"[94] in one regulatory culture may be "*bona fide* prudence" in another… An overly rigid conception of proper risk assessment and regulation in this area could therefore lead to inadequate future risk assessments, put human populations or ecologies at undue risk, and undermine the legitimacy of the SPS agreement and the WTO more generally.[95]

In the same line of thought, they oppose the US view that this procedure can be reduced to a specific scientific methodology, and their insight into the risk determinants *certainty* and *consensus* is particularly interesting:

> For this purpose, it is essential to recognize that risk assessment is neither a single methodology, nor a 'science'. Rather, contrary to the view advanced in the U.S. submission, we must reconceptualize 'risk' situations as lying within a matrix defined by two variables: *certainty* and *consensus*. At one extreme are cases characterized by *high certainty* with respect to the knowledge base to be relied upon, and *high consensus* with respect to the parameters of the scientific issues to be addressed, the analytic methods to be applied, and the values to be protected. At the other extreme are *low certainty* and *low consensus* on such matters.[96]

The authors place the GM technology in the *low certainty* and *low consensus* range, contrary to the previous SPS cases as well as to *EC-Asbestos* to which they attribute,

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[91] "The major contribution of the five-person *amicus curiae* brief submitted in the *Biotech* case is the force with which it conveys the need for the *Biotech* panel to take into account contemporary multidisciplinary scholarship on risk and risk assessment in undertaking the interpretation and application of WTO law." [see summary of the report p. 4-6] Foster 2005, 442.

[92] "The integration of risk assessment into the regulatory architecture of states is a value-laden, political, and culturally influenced process ... The validity of risk assessment is measured, ultimately, only by the confidence and trust it inspires—not only among experts but also in the wider public." *Ib.* 21.

[93] *Ib.* 18. See also Echols 2001, Chapter 3 – Food Production, the Culture of Food and Food Safety in Historical Perspective, 29-41.

[94] This refers to the provision of art. 5.7 SPS which makes it a duty of the States which have taken provisional restrictive measures for failure of sufficient scientific evidence to act "without delay" in removing the uncertainty that justified action.

[95] *Ib.* 37/38.

[96] *Ib.* 6.

for a number of reasons, much higher degrees of both certainty and consensus.[97] This risk profile of the *EC-Biotech* can be summarized as follows:

- There is not enough information available on the biological properties as well as on the impact at both the environmental and the social level of the still relatively new technologies that are used. The public values with regard to the impact on both public health and the environment have not been properly assessed.
- The scientific basis of risk assessment is not mature yet, it is fluid even at the national level and much more so in an international context. The behavior of both farmers and consumers in industrialized and developing countries shows enormous differences while at the same time the social and behavioral dimensions of these potential hazards are not well known.
- There needs to be more research both in the natural and the social sciences on the precise meaning of terms such as 'risk,' 'risk assessment,' 'rational and objective,' and it is by no means clear what is meant by the notion of 'sufficient scientific evidence.'
- The role of the DSB in this case ought to be limited to "reviewing the adequacy of executive decision-making processes – not that of an adjudicatory body reviewing the substantive merits of the parties' risk assessments.[98] [99]

The SPS Agreement does not define the word 'risk' although it uses it a number of times. In their emphasis on the social construction of risk the authors document that in other much publicized situations of risk analysis, e.g. in the cases of the Columbia space shuttle accident and in the Chernobyl disaster the investigation emphasized organizational and behavior factors that led to the calamities. In the first case NASA's history, culture and socio-economic realities were found to have played a major role. In the second case it was clear that political and organizational structures and determinants in which nuclear power generation in general and the specific tasks of the operators more specifically must be placed played a key role in the breakdown of safety mechanisms and features. The authors then link these observations to the Appellate Body's ruling on *EC-Hormones* which emphasizes "risk in human societies as they actually exist."[100] The Academics' interpretation is that "Member States are encouraged to consider how risk arises within patterns of human behavior and practice in societies. This point needs to be factored into evaluations of the adequacy

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[97] *Ib.* 7

[98] In Winickoff et al. 2005: 85, the same authors stress that "WTO judges charged with interpreting the SPS Agreement should use anti-protectionism as their guiding norm, rather than fall back upon a singular conception of scientific sufficiency. This orientation would not only foster coherent science-based policymaking but would also be consistent with the spirit of the SPS Agreement—and the entire postwar history of the trading regime."

[99] It is clear indeed that in the area of biotechnology "…the WTO has moved onto centre stage in regulatory areas that would not normally be considered part of traditional trade policy." (Sampson 2005, 145, Chapter 7 'Biotechnology, Sustainable Development and the WTO).

[100] "It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but *also risk in human societies as they actually exist*, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die (italics added)." EC-Measures concerning Meat and Meat Products (WT/DS26/AB/R, WT/DS48/AB/R), 16 January 1998.

of risk assessments."[101] One may indeed consider this language of the ruling as an opening towards the kind of social construction of risk that these authors call for, but in the end the AB stuck to a much more narrow interpretation of WTO law. It seems indeed that at this time we are still a long way from the approach to the handling of risk in trade law that this report advocates.

3.3. *The CIEL-Coordinated Report*

Contrary to the two other *amici curiae,* the CIEL Report contains a 'Motion to submit an Amicus Curiae Brief' which contains a separate and concise statement of purpose.[102] In addition, it insists on the uncertainty still arising from the use of GM crops. As pointed out, the SPS Agreement allows certain trade-restricting measures on an interim basis in case of 'insufficient scientific evidence' through Art. 5.7. Uncertainty is not a sufficient factor but in the evaluation of the adequacy of scientific evidence it represents a key element. The NGOs of the CIEL group argue that in the case of GM crops there resides a very substantial level of uncertainty which justifies taking interim trade-restrictive measures as the EC has done.[103]

The strength of this report which essentially focuses on the GM situation in the US lies in the detailed documentation of the inadequate surveillance and regulation of GMOs by the United States's responsible governmental agencies and in the advocacy of precautionary approaches. In light of the still relatively recent scientific and technological developments which made the introduction of GM food possible, the report emphasizes the need to use a "case-by-case" assessment approach; it realizes that this principle is widely respected but at the same time notes critically that there are also a number of blanket assertions on the safety of classes of products or on certain technologies which it considers *ipso facto* as unscientific. It notes that the US Department of Agriculture has been chided by an expert committee of the US National Academy of Science for applying the statement that there was "no evidence of harm" equally and without any distinction to products that had undergone no or little testing, as well as to others which were tested extensively.[104] Particularly worrisome is the finding that

> …claims concerning the lack of effects from the tens of millions of hectares of transgenic crops that have been planted in the United States during the past three years are nonscientific. There has been no environmental monitoring of these transgenic crops, so any effects that might have occurred could not

[101] Busch et al. 2004 *op. cit*, 26.

[102] "…The *amicus* brief offers significant additional technical, scientific and legal information critical to the Panel's deliberations. It describes how current scientific information still entails substantial uncertainty regarding the impacts of genetically modified organism on human, animal and plant health. The *amicus* brief also provides analysis and expertise to assist the Panel in the interpretation of the role of uncertainty in establishing the scope of precaution in the SPS Agreement. Particularly, it examines uncertainty in light of the object and purpose of the SPS Agreement, as well in the light of relevant rules of international law. Thus, the *amicus* brief considers the broader implications of the dispute for development, health, and the environment. This analysis is offered by a coalition of non-profit, public- interest organizations with expertise in international environmental and trade law…" CIEL et al. 2004. Motion to Submit an Amicus Curiae Brief.

[103] CIEL et al. 2004,para. 38-40.

[104] CIEL et al. 2004, para. 9, 10.

> have been detected. The absence of evidence of an effect is not evidence of absence of an effect.[105]

In the same vein, there is a general lack of post-marketing surveillance in the US in spite of the fact that numerous expert review panels and scientists consider these as just as necessary as in the case of the introduction of drugs. This lack of post-marketing surveillance means that the very often proclaimed assertion that GM food never caused any negative health impact is without substance. Furthermore, when there might be some evidence it tends to be unavailable for independent assessment because of alleged intellectual property concerns. There have even been cases where governmental regulatory agencies of states trading with the US were unable to obtain information necessary for their decision-making process. The US Food and Drug Administration "surveillance" consists simply in summary information supplied by corporations on a voluntary basis, based on which it issues a declaration stating that a certain product is substantially equivalent[106] to its conventional counterpart. At the conceptual level, the fundamental difference between traditional breeding techniques and transgenic genetic modifications which, as their name indicates, break across the barrier between species, is often trivialized or even denied which is obviously everything but scientific.[107]

The report emphasizes the uncertainty which still lies with the sequencing of genes, however important this scientific advance may be, as well as the many questions which are still unanswered. For instance certain kinds of DNA which do not code for protein, so-called 'junk DNA,' may be far less useless than assumed until recently, scientists are discovering important other functions of theses genes. This is one reason why European scientists are advocating a more cautious approach which can take into consideration unintended effects of genetic modifications. The CIEL report gives special attention to genetically modified proteins, and to the widely used GM crops which generate novel versions of insecticides derived from the soil bacterium *Bacillus thuringiensis (Bt)*.This is a concern especially for GM corn and cotton-based products such as cottonseed cooking oil. While these insecticides require additional testing with regards to allergies, insect resistance is a concern with respect to *Bt* crops as well as with respect to the insecticide glyphosate marketed as 'Roundup'. It is a considerable worry for farmers which depend on GM soybeans and canola/rapeseed, especially as organic farmers use related natural *Bt* insecticidal sprays which could be rendered ineffective. This, in turn would add to the problems that conventional as well as organic farmers have in any case in "co-existing" with neighboring farmers using GM seeds.[108]

3.4. *The FIELD-Coordinated Report*

The coalition of participants which put together the FIELD-coordinated *amicus curiae* report is the largest group of the three, with fifteen NGOs located in Europe, North

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[105] *Ib.,* source : National Research Council, Environmental Effects of Transgenic Plants (2002), p. 79

[106] The term "substantial equivalence," or at least its substantial use in the biotechnology discussions, originates in OECD 1993, see Tibeghien 2006, 9.

[107] CIEL *op. cit.* para. 11-16.

[108] *Ib.* para. 18-29. For and in-depth discussion of Co-existence see Boisson de Chazournes and Mbengue 2005.

and South America, and India, including large organizations such as Greenpeace International. The strength of the report lies in the discussion of trade-restricting measures which fall under the SPS and TBT Agreements. With regard to trade law, heart of this Coalition's brief consists in the argument that the EC's actions are not to be considered 'measures' in the sense of WTO law, and that even if they were to be considered as such they are fully compatible with WTO law. The first argument is based on the nature of the measure taken:

> The 'general' *de facto* moratorium, as recorded in the minutes of a meeting of the Council of the European Union and in statements of Member State officials, is an expression of political intent. It is not legislation of a general nature and it is not mandatory in its effect… A sovereign entity's expression of political intent is not subject to WTO scrutiny (see section 3.1.1). In our submission, we do not address the question of whether the relevant WTO Agreements apply to the EC's specific *de facto* moratoria or the EC Member States' safeguard actions.[109]

The second argument relates to the consistency of the measures taken by the EU with the SPS and TBT Agreements.[110] The coalition argues specifically that the EC's suspension of GM approvals, i.e. the general as well as the specific de facto moratoria, and certain EC Member States' 'safeguard' actions on approved GM products under the Deliberate Release Directive and the Novel Foods Regulation comply fully with the WTO's provisions on precaution, necessity, risk assessment, provisional measures, discrimination, transparency, and fairness, and it briefly summarizes the reasons why in the view of the proponents of the brief each the EC actions fulfils, in each of these provisions, its obligations under WTO law. In view of the fact that this case is characterized by features which go beyond specific legal provisions due to their vast socio-economic and political impact and ramifications, it would seem appropriate to single out, among these defensive arguments, the most important one from a trade policy standpoint, i.e. discrimination:

> GM crops and products are not 'like' their conventional counterparts for the purposes of TBT Article 2.1 and GATT Article III. Moreover, the challenged 'measures' do not arbitrarily or unjustifiably discriminate between Members or constitute a disguised restriction on international trade for the purposes of SPS Article 2.3 and GATT Article XX. In particular, a comparison of the challenged measures and the EC's regulation of GM processing aids, or novel non-GM crops or food derived from novel non-GM crops, does not show an arbitrary or unjustifiable distinction in levels of protection in different situations which amount to discrimination or a disguised restriction on trade (SPS Article 5.5) (see section 3.2.3).

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[109] "The US, Canada and Argentina (the 'complainants') have challenged the European Communities (the 'EC') over three categories of 'measures': (1) the 'suspension' of GM approvals (EC's general *de facto* moratorium), (2) the failure to consider applications for GM approvals (EC's specific *de facto* moratoria), and (3) EC Member States' 'safeguard' actions on approved GM products under the Deliberate Release Directive and the Novel Foods Regulation." FIELD et al. 2004, para. 4.

[110] If the Panel finds that the three categories of 'measures'are subject to the SPS Agreement, the TBT Agreement and/or the GATT, the Amicus Coalition respectfully submits that the three categories of measures are consistent with the EC' obligations under those Agreements: FIELD et al. 2004, para. 5.

The coalition subsequently engages in a detailed discussion of risk assessment, provisional measures and precaution (which it considers is "an international standard and is relevant to the Panel's analysis of those provisions in the WTO Agreements) concerning risk, including SPS Articles 2 and 5, TBT Articles 2.1 and 2.2 and GATT Articles III and XX."[111] It bases this argument on pronouncements of the AB in *EC-Hormones,* such as its statement that governments commonly act on the basis of prudence and precaution in appropriate circumstances.[112]

It is interesting from the point of view of risk communication to mention the argument of the coalition according to which Europeans have a strong reticence with regard to GM food. This could be confirmed by statistical information, such as a 2001 Eurobarometer survey conducted by the European Commission showing that 71 % of the persons polled declared: "I do not want this type of food."[113] Finally, "a majority of EC Member States considered it necessary to review and revise the EC systems intended to protect human, plant and animals health, as well as meeting consumers' demands for more information and choice over the form of labeling and the protection of non-GM food supplies."[114]

4 Evolution of the Most Recent Negotiations

4.1. WTO Committee on Trade and Environment

The November 2001 Doha Development Agenda (DDA)[115] resulting from the WTO's fourth Ministerial Conference contains a number of specific objectives with regard to trade and environment. Three relatively narrowly defined targets of para. 31 contain those issues which are scheduled for "negotiations," whereas all remaining environmental provisions included in the DDA are to be "discussed" only, i.e. they have a lower level of priority. The following three environmental objectives are to be negotiated "with a view to enhancing the mutual supportiveness of trade and environment:"

[111] *Ib.,* para. 98.

[112] "…a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned." *EC-Hormones* (WT/DS26/AB/R, WT/DS48/AB/R), 16 January 1998: FIELD et al. 2004, para. 41.

[113] This argument is confirmed by Tiberghien 2006, 22/23; he documents that the Eurobarometer survey shows how European public opinion turned from a positive attitude toward GM food in the mid 1990s to "widespread public hostility in 1999." Furthermore, "The general 2001 Eurobarometer on Science and Technology concluded (…) unlike most other scientific domains, opposition to GMOs increases with knowledge about them (p. 16)."

[114] FIELD et al. 2004, para. 60.

[115] http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

> 31.
>
> (i) the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). The negotiations shall be limited in scope to the applicability of such existing WTO rules as among parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question;
>
> (ii) procedures for regular information exchange between MEA Secretariats and the relevant WTO committees, and the criteria for the granting of observer status;
>
> (iii) the reduction or, as appropriate, elimination of tariff and non-tariff barriers to environmental goods and services.

In addition, it is noted "that fisheries subsidies form part of the negotiations provided for in paragraph 28."[116]

The four years after the Doha Conference saw some progress, especially in Environmental Goods and to a lesser degree in the clarification of the relationship between MEAs and the WTO agreements. This progress was confirmed in the Hong Kong Ministerial Declaration.[117] In light of the deadlock of the negotiations in July 2006, however, the fate of the trade and environment aspects of the Doha Round – as are the other issues under negotiation - is uncertain at the time of this writing. As long as significant results are not achieved in the "triangle of issues"[118] which consists in the key negotiation obstacles of the agriculture modalities in market access and domestic support, and in non-agricultural market access (NAMA), it would seem unlikely that any advancement can be expected on the trade and environment front.

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[116] DOHA WTO MINISTERIAL 2001**:** MINISTERIAL DECLARATION, WT/MIN(01)/DEC/1 20 November 2001 Ministerial declaration, Adopted on 14 November 2001 http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

[117] WT/MIN(05)/DEC, 22 December 2005, DOHA WORK PROGRAMME, Ministerial Declaration. http://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm#envir

30. "We reaffirm the mandate in paragraph 31 of the Doha Ministerial Declaration aimed at enhancing the mutual supportiveness of trade and environment and welcome the significant work undertaken in the Committee on Trade and Environment (CTE) in Special Session. We instruct Members to intensify the negotiations, without prejudging their outcome, on all parts of paragraph 31 to fulfil the mandate.
31. We recognize the progress in the work under paragraph 31(i) based on Members' submissions on the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). We further recognize the work undertaken under paragraph 31(ii) towards developing effective procedures for regular information exchange between MEA Secretariats and the relevant WTO committees, and criteria for the granting of observer status.
32. We recognize that recently more work has been carried out under paragraph 31(iii) through numerous submissions by Members and discussions in the CTE in Special Session, including technical discussions, which were also held in informal information exchange sessions without prejudice to Members' positions. We instruct Members to complete the work expeditiously under paragraph 31(iii)."

[118] Informal TNC meeting at the level of Head of Delegation, Chairman's Introductory Remark, Monday, 24 July 2006, http://www.wto.org/english/news_e/news06_e/tnc_dg_stat_24july06_e.htm

4.2. Codex Alimentarius

The scope of the Codex Alimentarius includes trade in all food, drink and feed products. In our research, however, we are limiting our interest to environment-related food safety. This focus means that we are essentially looking at the Codex regulations of GM products including those crosscutting Codex issues which are relevant for this particular product category, such as for example the Codex's approach to risk analysis or to food labeling or its general functioning and the elaboration of its procedures. The Codex Alimentarius is characterized by a highly procedural and well-structured way of functioning. This is unavoidable for a science-based authority in charge of food safety and applies equally for its national counterparts dealing with food safety. We have noted that the years 2002 and 2003, which were covered in the first phase of this research project,[119] were particularly important for the evolution of the organization because of a detailed internal and external organizational review conducted in 2002,[120] and because of the adoption of three standards on GM foods that were negotiated, not without great difficulties, by the Japan-based Codex Taskforce for Food Derived from Biotechnology over the previous four years.[121]

Over the past two years there has been less visible action in this particular domain of the Codex Alimentarius. Nevertheless, an important evolution is taking place at the level of conceptual and procedural clarifications where the Codex arguably is at the forefront among intergovernmental organizations. The Codex has recently started to debate a question which is not new but which goes to the heart of its scientific nature and identity, namely whether it makes a difference if standards are based on risk rather than on science. In 2005 the Codex Committee on General Principles (CCGP), which is hosted by France (the Codex's decentralized Committees are all hosted by a member country), desired to go beyond the approach of the SPS Committee, which seems in this case somewhat one-dimensional in using the two concepts interchangeably. The CCGP discussed for a couple of hours the merits of distinguishing between the two concepts. The discussion was shaped to some extent by two facts: first of all, in some cases, standards were established based on epidemiological evidence without a proper risk assessment, and secondly some discussions on this question have already taken place in the Codex Committee on Meat Hygiene hosted by New Zealand. Not coincidentally, the latter tends to take a rather narrow interpretation of scientific issues in such debates, unlike other Codex members, especially the EU countries, who tend to prefer a more flexible approach, providing leeway for the accommodation of what the Codex calls 'factors other than science.' The French government, for instance, like all host governments of Codex

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[119] Petitpierre et al. 2004a and b.

[120] http://www.codexalimentarius.net/web/evaluation_en.jsp, (note the links in the right border).

[121] PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY *CAC/GL 44-2003*. ftp://ftp.fao.org/es/esn/food/princ_gmfoods_en.pdf

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS. *CAC/GL 45-2003* ftp://ftp.fao.org/es/esn/food/guide_plants_en.pdf

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS PRODUCED USING RECOMBINANT-DNA MICROORGANISMS *CAC/GL 46-2003* http://www.fao.org/es/ESN/food/risk_biotech_taskforce_en.stm

Committees, has been trying to advance its own perspective on certain issues when opening the negotiations with a brief introduction. The EU member countries tend to take a more comprehensive and open-ended view on food safety policies and to strengthen the case for the right of an importing country to apply precautionary measures where they are justified.[122]

The WTO, the Codex Alimentarius, and to a lesser degree the Biosafety Protocol, more or less share a risk analysis philosophy which can be described as being grounded in the assumption that scientists understand the kinds of risks which are involved in any given process and production method. Uncertainties tend to be admitted primarily in the magnitude of potential hazards only. We have seen, however, over the past thirty years, "a number of unanticipated long-term damages associated with many substances that were heretofore presumed safe, including DDT, PCBs and chlorofluorocarbons"[123] (one could add lead in paints and gasoline, asbestos, or bone meal, among others). Such experiences and misjudgments tend to be overlooked or underestimated by the scientific establishment, but cases with a history of several decades may well be pertinent for GM food which has been on the market in significant quantities for less than ten years.

At the 2005 CCGP[124] New Zealand offered to prepare a discussion paper which at the CCGC's 2006 session gave raise to a vigorous debate without a conclusion. One may summarize that those Codex members who defend a relatively important place for precaution in their regulatory approach are open for risk-based standards, whereas those who promote a narrow reliance on risk assessment methods insist on science-based standards. In the end, it was decided that New Zealand would review its discussion paper, and that a more focused debate would continue in an ongoing working group, and that a workshop for the same purpose would be organized in order to prepare the continuation of this debate at the next session.[125]

4.3. The Cartagena Protocol on Biosafety

At the second Meeting of the Parties (COP-MOP-2),[126] which took place in Montréal in 2005, the negotiation on GM labeling pretty much dominated the meeting. An interim solution had originally been found in January 2000 for the conclusion of Art.

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[122] Thus Mr Guillaume Cerutti, the Director-General of Competition Policy in the Consumer Affairs Division at the Ministère de l'Economie, des finances et de l'industrie , who welcomed the participants on behalf of the French government, in his opening presentation made his government's broader perspective on the role of science in the regulation-building process crystal clear: "Il a encouragé les délégués à tenter de définir des principes directeurs d'action qui articuleraient science, précaution et autres facteurs légitimes." (ALINORM 05/28/33A 2005, *op. cit.*, para. 2.)

[123] Burns 2005, 1-9.

[124] http://www.codexalimentarius.net/web/archives.jsp?year=05 (para. 24)

[125] PROPOSED NEW DEFINITIONS OF RISK ANALYSIS TEMS RELATED TO FOOD SAFETY Para. 149-162.
http://www.codexalimentarius.net/web/archives.jsp?year=06

[126] In view of the fact that the Protocol is part of the Convention, and its Meeting of the Parties is usually held back-to-back with the Conference of the Parties of the Convention, the somewhat cumbersome term 'The Conference of the Parties serving as the Meeting of the Parties to this Protocol,' or COP-MOP is commonly used, as in the text of the Protocol itself.

18.2.(a),[127] scheduled to be terminated two years after the date of entry into force of the Protocol (September 11, 2003). This solution allowed to overcome an obstacle that the drafters of the Protocol were unable to surmount in the final round of the Protocol's negotiations, the exporters of GM products (or, in the case of non-members like the US and Canada, their allies who had ratified the Protocol) having insisted on the lowest possible visibility of GM labeling essentially for marketing[128] reasons. Issues like traceability and segregation of GM and conventional crops also played an important role in crafting this compromise. The key term of the interim solution, which generated sufficient consensus back in 2000, was that packaging or containers containing GM commodities not destined to serve as seeds could be marked as "may contain" living modified organisms (LMOs) until a more permanent solution would be found. This issue in fact was so contentious during the negotiations that it turned out to be the last issue to be decided prior to the adoption of the Protocol.

At the COP-MOP-2 meeting the previous acrimony returned with a vengeance. Up to 11 versions of texts were on the table.[129] On the last day Switzerland introduced a "non-paper" in order to bridge the divide which was eventually forwarded by the chair of the working group to the plenary despite reservations from Brazil and New Zealand.[130] During the final plenary these two countries, in a very rare display of intransigence in light of an overwhelming consensus blocked a decision and prevented the implementation of the negotiated time frame.[131]

At the following COP-MOP-3 in Curitiba, Brazil, in 2006 the situation had changed considerably. Brazil and Australia were cooperative with the majority opinion whereas a new front of resistance arose at the beginning consisting of Paraguay, Peru and Mexico.[132] In the end, however, a consensus was achieved which requires the label "contains LMOS" for GM products that have been clearly identified and separated as such. On the other hand the "may contain" label continues to be acceptable for six more years in those cases "in which the presence of transgenics has not been documented and identified from the origin,"[133] by which time a new solution is scheduled to be negotiated. The consequences and implications of this compromise are somewhat uncertain. Labeling will generate some cost for industry and it may discourage consumers from buying these products, but it may also present

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[127] Article 18 Handling, Transport, Packaging and Identification:
2. Each Party shall take measures to require that documentation accompanying:
(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.

[128] It can be noticed that in this case the argument is based on risk *communication* rather than scientific analysis or risk assessment.

[129] Ching and Lin 2005, 2.

[130] *Ib.* 5.

[131] It has been suggested that those countries were acting in favor of non-members, who are big exporters of GM products, i.e. the U.S. in the case of Brazil, and Australia, in the case of New-Zealand.

[132] Aguilar et al., 2006.

[133] Sand 2006 forthcoming.

advantages for industry: "product labeling often has the effect of acclimatizing local governments and consumers to the presence and consumption of LMOs -- conditioning the market for such products.[134]

5 Coherence and Mutual Supportiveness: Ramifications and Recent Developments

The achievement or improvement of coherence among international regulatory frameworks in different sectors has always been one of the greatest challenges to internal law. This state of affairs is hardly surprising considering that these negotiations are usually carried out by representatives from the most relevant ministry or other governmental body, who very often have quite different perceptions on specific issues than other concerned agencies. Trade, environment, and public health officials for example tend to view quite differently the long term impact of any given technological development or policy. This is why we have such different approaches to risk analysis - especially to risk management - at the Biosafety Protocol, the Codex Alimentarius, and at the WTO's Committee on Trade and Environment and the SPS Agreement. Clearly, legal coherence and consistency appears as a still distant and quite vague goal in international law, but it has been recognized as guiding principle for governmental action ("impératif de cohérence comme guide à l'action administrative")[135] in the European Commission's classic policy paper on the precautionary principle; the need for coherence in legislation and implementation of public policies has been emphasized by the European Commission as a general goal:

> Measures should be consistent with the measures already adopted in similar circumstances or using similar approaches. Risk evaluations include a series of factors to be taken into account to ensure that they are as thorough as possible. The goal here is to identify and characterize the hazards, notably by establishing a relationship between the dose and the effect and assessing the exposure of the target population or the environment. If the absence of certain scientific data makes it impossible to characterize the risk, taking into account the uncertainties inherent to the evaluation, the measures taken under the precautionary principle should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.[136]

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[134] Young 2006.

[135] Noiville et de Sadeleer 2001, La cohérence des mesures de gestion, 428-431.

[136] Commission of the European Communities, Brussels, 02.02.2000, COM(2000) 1, Communication from the Commission on the precautionary principle, para. 6.3.3. http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_fr.pdf . Note that the English version of this policy paper of the European Commission uses the term 'consistency' where the French version uses 'cohérence' and 'cohérent.' This may well be a correct translation, but the term "coherence" has been so widely used in English in this context that it can be considered as equivalent for the purpose of this discussion.

As far as the relationship between the Biosafety Protocol and the WTO agreements is concerned, we may refer to the report of our first phase,[137] especially to the much-cited contribution of Franz Perrez with regard to the exploration of the concept of 'mutually supportive'[138] as it is enshrined in the Biosafety Protocol's Preamble, together with the notion of a non-hierarchical relationship with other international agreements, i.e. especially the WTO.[139] At the same time it is worth to remember, as many commentators have pointed out, and as professor Gary Sampson, a former WTO divisional director puts it: "The Protocol resulted from intensive and protracted negotiation in which particular emphasis was placed on avoiding any inconsistency with WTO rules."[140]

Regional differences in the fundamental approach to the creation of rules and standards are highly important also. With regard to regulating GMOs the US has for many years used specific product-based methodologies. The European Union on the other hand emphasizes broader production (or processes)-related methodologies, a divergence which has resulted in a regulatory polarization.[141] Different attempts have been made to draw general conclusions from what might appear as a technical difference. For example, professor Yves Tiberghien wondered: "What underlies the diversity of national responses (regulatory polarization) in a new technology with attractive potential for all? [round brackets in the original]."[142] and he sees the roots underlying these very different approaches in fundamentally divergent world views on certain aspects of globalization, considering in fact the EU-US clash over GMO policies "a proxy for larger issues."[143]

The answer to Prof. Tinberghien's questions implies analysis of different approaches to "new technologies" which go beyond a narrow scientific focus which often determines the regulation of trade in GM products.[144] It has often been emphasized that socio-economic problems are important for understanding the opposition to GMOs. The strong and increasing concentration of suppliers of GM seeds and related products such as pesticides and fertilizers, as well as their coalitions with

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[137] Petitpierre et al. 2004.

[138] Perrez 2004, 523-7.

[139] Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,
Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,
Understanding that the above recital is not intended to subordinate this Protocol to other international agreements.

[140] It is a short step from this observation to the conclusion that this is an example of regulatory chilling as described by Thomas 2002, 200-202. For an explanation of the concept of regulatory chilling see Stilwell and Tuerk 1999.

[141] Bernauer, 2003, 44-66.

[142] Tiberghien 2006, 5.

[143] *Ib. :* a view for which he argues consistently in his study, and for which he finds support in the 2003 Eurobarometer*;* in his opinion this is due to the importance in the European debate of « generalists », who have interest in a wider range of public affairs : thus, « public opinion on biotechnology is likely to derive in part from views about the credibility of wider political and scientific institutions, as well as those solely related to biotechnology" (*ib.* 23, citing Eurobarometer 2003 55.2: 29, p. 3).

[144] Prof. Tinberghien has been doing intensive research on GM policies in various part of the world, such as Japan, Korea and China: see the site he is running: http://www.gmopolitics.com/

processors and worldwide distributors of agricultural products leads us toward a new world of agriculture that is largely dominated by a small number of monopolistic transnational corporations. Although the resulting dependence of farmers on these networks, which in many cases have more financial resources than governments, is not limited to the specific case of GM products, it has become a key issue in the debate, and it is getting increasing attention.[145] Other "general issues" such as the impact of negative experiences in "technological" or "food related" technologies should also be taken into account, as well as, maybe, a greater emphasis in some countries of GMO-related medical research, rather than food production. All those factors would need a deeper analysis in relation with each country situation. It is not exaggerated in fact to consider that both phases of our research strive to prepare a solid legal ground for further research which goes beyond specific issues of biodiversity and public health and includes issues of agribiodiversity and food security in a comprehensive way.[146]

Another general aspect is connected with the relevance of GM trade to the concept of "globalization", as GM products are very seldom the result of local production or the answer to local needs:

> For some people, especially many activists, biotechnology also symbolizes the negative aspects of globalization and economic liberalism: destruction of local cultures and economies, growing trend of commodifying everything, including genetic resources, and aggravated competition often perceived as disloyal due to the rivalry created between economies with different levels of development (…). So, certain surveys reveal that economic motives have become an important cause of opposition to GMOs (…) Arguments put forward by active opponents show that they often perceive this struggle as a form of opposition to extreme liberalism.[147]

This trend has been, and still is, strongly influenced by the protection of intellectual property rights on seeds, especially genetically modified ones. And the debate about intellectual property rights is, further, influenced (at least in Europe) by the fear that parts of the human body could become the object of patenting. This shows again the importance of risk analysis and risk communication to find the adequate response to those "general" but also quite vital questions.

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[145] See for instance Matringe and Musselli Moretti 2006.
[146] World Health Organization, 20 Questions on genetically modified food (see especially question No. 20) http://www.who.int/foodsafety/publications/biotech/en/20questions_en.pdf
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Annex No. 3
Organization of and Participation in Project-related Roundtables and Colloquiums by Professor Laurence Boisson de Chazournes

- **19 mai 2004**, Maison internationale de l'environnement, Genève. Table-ronde sur *"Biotechnology, trade and the environment"*. Présentation d'un rapport sur *"Codex and its relevance for the debate on trade and biotechnology"*.

- **11-12 octobre 2004**, Max-Planck-Institut für ausländisches öffentliches Recht und Völkerrecht, Heidelberg, Allemagne. Colloque sur le thème "*Ensuring Compliance with Multilateral Environmental Agreements"*. Présentation d'un rapport sur les MEAs.

- **12-13 novembre 2004**, New York University, New York, USA. Commentateur dans le colloque sur *GMO Regulatory Conflicts Meeting*.

- **20 avril 2005**, Geneva Environment Network, Genève. Table-ronde sur *"Promoting Compliance with Environmental treaties"*. Intervention sur *"Compliance and technical and financial assistance: the interplay"*.

- **26-28 mai 2005**, IUHEI, Genève. *ESIL Research Forum on International Law : Contemporary issues*. Présidence d'une session sur *"Law and policy in the international protection of the environment / la protection internationale de l'environnement : aspects juridiques et politiques"*.

- **24 juin 2005**, CERIC, Université d'Aix-Marseille III, France. Atelier sur "*Environnement et santé : les enjeux de la normalisation internationale"*. Rapport sur *"Normes, standards et règles en droit international"*.

- **2 & 3 septembre 2005**, World Trade Institute, Berne. The World Trade Forum 2005 : *Genetic engineering : Challenges posed by a new technology to the world trading system*. Présentation d'un rapport sur *"Trade, environment and biotechnology."*

- **11 octobre 2005,** HEI, Genève, Colloque organisé en collaboration avec la prof. Anne Petitpierre et M. Hussein Abaza, chef du ETB-PNUE sur *"Commerce et développement durable : le rôle du droit et de la science."*

- **14-15 novembre 2005**, Montpellier, France. Second International Conference on Co-existence between GM and non-GM based agricultural supply chains, organisée avec l'Institut National de recherche agronomique (INRA) (France) et la Commission européenne (Joint Research Centre). Présentation d'un rapport sur : *"International legal aspects of the co-existence between GM and non-GM products : apporaches under international environment law and international trade law"*.

- **29 mars-1er avril 2006,** American Section of International Law, Présidence d'un panel sur *"Le droit international de l'environnement"*.

- **11 mai 2006,** Université de Genève, Table ronde organisée par les professeures Laurence Boisson de Chazournes et Anne Petitpierre sur « *Le droit de l'OMC, la science et la communication du risque.* »

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