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WTO Law, Science and Risk Communication

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Preface

This first Special Edition of *EcoLomic Policy and Law* represents one of the outcomes of a Roundtable on 'WTO Law, Science and Risk Communication' organized by the Law Faculty of the University of Geneva on May 11, 2006.[1] It is not a Proceedings *sensu stricto* because the participants in this event and the authors are not the same in all cases, but the theme of the Roundtable is well reflected in these articles. It is a direct outcome of a research program financed by the Swiss National Science Foundation (SNSF) over a two year period 2004-2006 under the direction of Professors Anne Petitpierre and Laurence Boisson de Chazournes of the University of Geneva's Law Faculty. Chapter 1 which serves as the introduction consists in a detailed overview of this investigation. This research program is the second and concluding phase of an interrelated research agenda. It has been built on a previous three year SNSF program which covered the years of 2001-2004. A detailed overview of the first phase which was directed by the same two professors has been published in English as well as in a somewhat different French version in the same journal in 2004.[2]

The first phase of this research was centred on the relationship among the WTO, the Cartagena Protocol on Biosafety, and the Codex Alimentarius. It was focused to an important extent on science-based risk assessment and risk management in the domain of the multilateral regulation of trade in genetically modified organisms, with respect to threats to biodiversity and certain aspects of food safety. Concepts such as precautionary approaches, mutual supportiveness among WTO agreements and multilateral environmental agreements (MEAs) were important issues in this research.

This first phase concluded that the nature of import restrictions which are allowed under WTO agreements, and which are based on traditional science-based risk assessment procedures, is becoming more and more inadequate in light of an evolving societal debate over the relationship between the trade regime and scientific uncertainties. This debate includes the nature of recent scientific discoveries and processes as well as their wider societal ramifications. The researchers involved see a need for the international community to arrive at a reconciliation of principles, rules, standards and procedures which have been negotiated under disparate legal frameworks with often divergent objectives. The negotiations aiming at the goal of this reconciliation take place in the context of a wide consensus over the need to work toward the twin goals of mutual supportiveness, and of complementary regulatory frameworks that facilitate a constructive relationship with each other in their respective domain of authority such as biodiversity, trade, and food safety in the cases of the Biosafety Protocol, the WTO, and the Codex Alimentarius. The first

[1] The Program and Overview of the Roundtable is available at http://www.ecolomics-international.org/biosa_risk_comm_rt_program_overview_ge_law_fac_1105061.pdf

[2] *EcoLomic Policy and Law* issues 2004-7 and 2004-8 in French and English respectively : http://www.ecolomics-international.org/epal_2004_7_fns_unige_droit_ofefp_reg_int_biotech.pdf http://www.ecolomics-international.org/epal_2004_8_snsf_unige_lawfac_buwal_research_project_int_biotech_regulation.pdf

phase of research has concluded that this objective is not only legally coherent but also politically legitimate and realistic.

We have subsequently seen a need to return to some of the aspects of the first phase and to expand on them for essentially four reasons. First of all, the negotiations of some of the key agreements under consideration here have made important advances, especially at the third Meeting of the Parties of the Cartagena Protocol on Biosafety in Curitiba in 2006, where important hurdles regarding the required labeling of international shipments of genetically modified goods were overcome. Secondly, the WTO jurisprudence has also set an important new milestone related to the theme of this investigation, namely in the *EC-Biotech* case whose Panel ruling was released in September 2006. Thirdly, we have seen an important gap in the scientific literature on risk analysis. The Codex Alimentarius has established -- through formal multilateral negotiations -- a coherent set of the most widely recognized definitions applicable in the domain of food safety standards which are incorporated in the regulation of global food trade. This set of definitions includes risk analysis which is defined as "A process consisting of three components: risk assessment, risk management and risk communication."[3]

In spite of a considerable body of literature on risk assessment and risk management, including a discussion of the interrelated relationship between these two components of risk analysis, there is very little scientific analysis available with a focus on risk communication; we hope to make a contribution toward filling this gap. Fourth and last but not least, both phases of our SNSF research represent an attempt in providing a substantive contribution to the wider and increasingly important debate over WTO law and science. This debate refers to a key difference between the WTO agreements and the preceding GATT in the sense that the entry into force of the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) on January 1st, 1995, as part of the comprehensive WTO Agreement, has added a new dimension to the trading system (in parallel to other innovations which are not part of this research). Both agreements, especially the former one, specify under which condition an importing country may use scientific procedures and arguments in order to justify restrictive trade measures. Thus these two agreements have given a much increased importance to the WTO law and science debate; the research contained in this Special Edition is directly related to this ongoing scientific, political and legal analysis.

The introductory Chapter 1 is a detailed overview of the research conducted during these last two years, written by Professors Anne Petitpierre and Laurence Boisson de Chazournes and researchers Makane Moïse Mbengue and Urs P. Thomas, members of the Trade and Environment Research Group at the University of Geneva's Law Faculty. In this overview they discuss the legal ramifications of the global regulatory system which determines the WTO compatibility of trade-restrictive measures that a country of import may implement for environmental reasons under WTO law. This system is based on scientific evidence and on standards which are voluntary but which -- when respected -- convey an *a priori* assumption of WTO compatibility. 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 for such measures. SPS Article 5.7 furthermore spells out certain exceptions which may justify the restriction or the

[3] Codex Alimentarius Procedures Manual, 16th ed. 2006, 43. ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_16e.pdf

banning of certain goods for a certain time. The SPS and the TBT Agreements, as well as Article XX of the GATT Agreement, thus may be considered as a key benchmark or as a set of rules which are part of the comprehensive WTO Agreement,[4] and which determine in many cases under which condition an importing country may impose non-tariff barriers to trade for the protection of the environment and of public health. The discussion of related technical standards provides the underpinning of this chapter.

The relationship between technical standards and legal rules is very complex, Professor Laurence Boisson de Chazournes has described it through a framework which contains five levels of interactions: (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. This is done through standards.

One of the problems with standards consists in the fact that they tend to be intrinsically technical and difficult to understand for decision-makers whose background tends to be law, economics, or business administration, and who are often not well prepared to comprehend issues of a scientific and technical nature. The same applies for most other stakeholders, as well as for the public at large. At the same time, the issues at stake can be very serious, in fact life threatening in some cases. How can this conundrum be resolved? This is where risk communication procedures can fill a cognitive gap. Indeed, one of the key functions of the risk communication process consists in the transmission of scientific knowledge between the scientific community at its origin and official bodies which need this knowledge for the execution of their function, such as regulatory bodies, tribunals or judges.

An interesting example here consists in labels for genetically modified food which represent a new kind of regulation that has been described as an informational kind of regulation that succeeds earlier command-and-control and market-based instruments. The field of risk communication as such has emerged about thirty years ago as a distinct academic field of investigation in the wake of major environmental accidents such as spills of oil and chemicals. At the beginning information and education were provided only after an accident had occurred, but subsequently the regulators adopted a more vigorous and persuasive stance integrated into the marketing process of potentially hazardous goods. We are now observing a distrust of the public toward traditional top-down and opaque decision-making processes which may have a serious impact on public health and the environment. Regulatory authorities and industry are increasingly reacting to this distrust by offering possibilities for the public to participate in the decision-making process at an early stage before the principal choices have been made.

Withholding information, incompetence, or the provision of wrong or otherwise inadequate data may lead to very serious public health and environmental

[4] These are the so-called WTO Legal Texts, they are available and searchable at http://www.wto.org/english/docs_e/legal_e/legal_e.htm

consequences. This happened for example in the case of asbestos products in many countries and over several decades, and it continues especially in many developing countries. The 1998 'Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters' emphasizes primarily the need to give a role to the public in decision-making and in the elaboration of procedures which make this role possible and effective before a decision has been taken. In the same vein, it sensitizes environmental decision-makers about the importance of communicating with the public in order to gain its support for the implementation of environmental measures and projects.

Access to environmental information can be a problem not only for the public but also for officials in Ministries whose mandate encompasses certain environmental responsibilities related to their core activities. This is arguably the case in trade Ministries who -- in an ideal world -- would always weigh environmental, public health and economic costs and benefits. In reality, however, Ministries tend to have a rather focused orientation, and in most countries their integration with related Ministries tends to be limited to more or less superficial linkages. This compartmentalization goes a long way in explaining the difficulties in reconciling trade-related and environment-related priorities and objectives. The often diverging goals of the member countries' Ministries in charge of negotiations at the WTO and of MEAs find reflection in the complexity and difficulty of the trade and environment negotiations under the Doha Development Agenda. Its Paragraph 31.(ii) relates to the negotiation of procedures on regular information exchanges between MEA Secretariats and relevant WTO Committees but it has not made significant progress so far. It is not surprising therefore that the achievement of coherence among international regulatory frameworks in different subject areas has always been one of the great challenges in the national implementation of international law.

In Chapter 2 Mireia Martinez Barrabez discusses the negotiations of the third so-called 'Conference of the Parties serving as the Meeting of the Parties' (COP-MOP) of the Cartagena Protocol on Biosafey in Curitiba, Brazil, in March 2006. This Protocol of the Convention on Biological Diversity regulates trade in raw unprocessed genetically modified crops. The emphasis in this article is put on one hand on presenting the stakes of one of the key unfinished negotiation issues, for which the Parties were not able to reach consensus during the final negotiations of the Protocol's text in Montreal in January 2000. Tensions among the Parties were heightened after the failure of the second MOP in Montreal in June 2005 to conclude, as prescribed in the text of the Protocol's Article 18.2(a), the modalities of handling, transport, packaging and identification -- i.e. essentially the labeling -- of GM crops which the Convention calls living modified organisms (LMOs). These tensions can be explained by the very large economic and political stakes involved in the international trade of agricultural LMOs. It should be mentioned that the ramifications of GM food crops, as well as others such as cotton, are much larger than GM seeds which are treated separately and more strictly in the Protocol. On the other hand the article is characterized by a very careful and detailed description of the procedures of the negotiating process itself, thus providing a rare illustration of the often slow advancement and modification of this kind of a multilateral search for consensus in crafting binding commitments. This analysis is therefore of particular interest for didactic purposes because the scientific literature tends not to go into much detail in the description of negotiation procedures. At the same time, this process can be considered to a wide extent as being characteristic for MEA negotiations in general.

This Article 18.2(a) has been intensely negotiated throughout the history of the Biosafety Protocol and in fact it nearly derailed the whole process. It stipulates essentially that LMOs which are not intended for planting or other release into nature (such as fish for example) are not subject to the same demanding notification requirements as those which are intended for such purposes. A compromise formula that was accepted by consensus as an interim solution stipulated that they may be labeled as *"may contain"* living modified organisms. The Curitiba negotiations did find a solution which is still not final but at least it turned out to be satisfactory for up to the year 2012 when this question is supposed to be settled. Most Parties favored a clear identification of GM products, together with detailed specifications of the contents. A minority group, however, with the support from non-Party GM crop export countries, however, insisted on modalities which are less strenuous for export countries. The compromise solution essentially requires an indication of the presence of GM products in the labeling of such shipments but it provides some loopholes for up to six years; the *"may contain"* formula may continue to be used during this time in those cases where there is some doubt about the identification of a crop.

The case of the Mexico caused some difficulties because it is the only one of the three NAFTA countries which is a Party, and its agricultural trade with the non-Parties US and Canada is very substantial. Therefore Mexico insisted on a clause which leaves a loophole for cross-border trade among Parties and non-Parties. The NAFTA countries have already ratified an agreement in 2003 which makes trade in LMOs less tightly regulated than the Biosafety Protocol, for example a crop is not considered as transgenic as long as the LMO content stays below the threshold of 5%, furthermore it does not take into consideration the "unintentional" presence of GM organisms.

The article also discusses progress on other issues which were less controversial, and which are also not resolved yet, such as especially liability and redress, and compliance. These issues are still a long distance from a conclusion; essentially the negotiations are still at the state of elaborating rules, procedures and definitions. As far as compliance is concerned, the Protocol has established a Compliance Committee which submitted a report of its second meeting that also is essentially not going beyond internal organizational questions.

In Chapter 3 Makane Moïse Mbengue and Urs P. Thomas focus on risk communication which, as mentioned above, constitutes together with risk assessment and risk management the concept of risk analysis. They have therefore explored features of risk communication in the cases of the Cartagena Protocol on Biosafety and of the Aarhus Convention on Access to Information and Public Participation in Decision-making in Environmental Matters. At the intergovernmental level, the procedures known as Prior Informed Consent or as Advance Informed Agreement, as they are found especially in the Rotterdam Convention which covers trade in certain hazardous chemicals and in the Biosafety Protocol respectively, can be considered as the most important innovations in risk communication procedures. The Aarhus Convention and the Cartagena Protocol on Biosafety go a step further and include provisions for non-governmental stakeholders. This opening up of Public International Law finds reflection in dispute settlement procedures which increasingly allow the use of *amicus curiae* briefs by non-governmental organizations as well as by private enterprises.

In order to fill a certain void in the risk analysis literature, the authors have developed a framework that consists of thee elements. There are two important kinds of procedures, first of all notification procedures which have a long history of

successful application, and secondly the provision of information to the public which has emerged more recently. These are supported by underpinning principles which assure their fair and transparent application, especially the principle of *ongoing monitoring* which has been incorporated into one of the most recent MEAs, the Cartagena Protocol on Biosafety, thanks to the requirement to review on a timely basis new scientific information. Such new information is required for justifying the maintenance of trade-restrictive measures, but also for the case of an importing country which has allowed the importation of LMOs at some point in time and subsequently decides to institute stricter regulations or an import moratorium.

In Chapter 4 finally, Maria Julia Oliva has looked at the September 2006 Panel report in the WTO's *EC-Biotech* case. She has taken up the challenge of distilling a particularly relevant legal outcome contained in the over 2000 pages long ruling and has focused on the ramifications for SPS Article 5.7 which spells out the measures an importing country may apply "in cases where relevant scientific evidence is insufficient." The importance of this Article 5.7 consists in the fact that it embodies to a significant degree the exceptions contained in WTO law with regard to obstacles to trade that are allowed for a limited period of time. These may be used to enable a country of import to implement protective measures for reasons of public health or safeguarding the environment from phytosanitary hazards. Article SPS 5.7 represents a crucial pillar of the trading system especially with reference to the role of science in WTO law, and with the related question of the application of precautionary measures. The Dispute Settlement Body has made some pronouncements on the concept of precaution, but so far it has not elaborated on the nature of SPS Article 5.7.

This is why the position taken in *EC-Biotech* the Panel has particularly important legal ramifications and potential implications for trade-related sustainable development policies. The Panel concluded that Article 5.7 should be characterized as an autonomous right -- and not only as an exception to the general obligations for WTO Members -- which determines the required modalities in applying sanitary and phytosanitary measures in light of insufficient relevant scientific evidence. Through the characterization of this Article as an autonomous right, the DSB may have facilitated the successful vindication of precautionary decision-making under WTO law. The author concludes, however, that although this ruling may have implications for placing the burden of proof on the complaining Parties, it is nevertheless not likely to revolutionize the acceptance of a precautionary argumentation in the WTO. Last but not least, even though the role of Article 5.7 is strengthened by giving it the nature of an autonomous right, it is not clear how this will affect future rulings.

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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.

Participants:

Anne Petitpierre et Laurence Boisson de Chazournes, Professeures, Faculté de droit, Université de Genève; Makane Moïse Mbengue et Urs P. Thomas, Chercheurs, Faculté de droit, Université de Genève.

Participation in and Organization of Project-related Roundtables and Colloques
by Professor Laurence Boisson de Chazournes

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.[5] 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.[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.

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,

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

[6] 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 .

based on a scientific approach, to the dispute resolution. Yet the painful experience 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[7] and entered into force in January, 1995.[8] 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

[7] http://www.wto.org/english/docs_e/legal_e/04-wto.pdf
[8] 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.[9] 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.[10] 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),[11] and also of the Agreement on Technical Barriers to Trade (TBT).[12] 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."[13]

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.[14] The SPS

[9] Sampson 2000, 64.
[10] http://www.ecolomics-international.org/biosa_report_colloquium_wto_law_science_law_faculty_geneva_unep_etb_11102005.pdf
[11] http://www.wto.org/english/docs_e/legal_e/15-sps.pdf
[12] http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf
[13] Sampson 2000, 64.
[14] 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.[15] 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,"[16] 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."[17]

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.[18] 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.[19]

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.[20] Created in 1961 by FAO and WHO, it used to be considered as a technically oriented 'gentlemen's club.'[21] 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.

[15] SPS Art. 3.1 and 3.2.

[16] SPS Art. 3.3.

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

[18] 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.

[19] *Ib.* 65.

[20] 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 .

[21] 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.[22]

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.[23] 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"[24] 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.[25]"

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."[26] 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[27] 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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[22] 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.

[23] Echols 2001, Conclusions 148-156.

[24] Cottier 2001, 57.

[25] *Ib*.

[26] 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.

[27] *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.[28] 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.[29]

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:[30]

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[31] 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."[32]

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

[28] Brosset and Truilhé-Marengo, 2006, 18 see it as a very special feature which is an exception to classical international law.
[29] *Ib.* 19.
[30] Boisson de Chazournes 2006, 45-50.
[31] « Internormativité » p. 49.
[32] 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.[33]

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. [34]

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:

- the Codex Alimentarius,
- the multilateral regulation of trade in GMOs primarily through the Convention of Biological Diversity's Cartagena Protocol on Biosafety, and

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

[34] 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

- Multilateral Environmental Agreements (MEAs) which form the backbone of the WTO's negotiations and discussions at the Committee on Trade and Environment.[35]

This connection can be seen directly in the overlap between the Codex and the Biosafety Protocol[36] 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.[37]

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,[38] and the question of this interrelationship represents an important part of the first phase of the present research.[39] 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 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

[35] See Petitpierre et al. 2004 a & b *op. cit.*
[36] It was signed in January 2000 and entered into force in September 2003, http://www.biodiv.org/biosafety/protocol.shtml.
[37] 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.
[38] Noiville et de Sadeleer 2001.
[39] Petitpierre et al. 2004a & b.

scientific training in a non-partial and balanced fashion about the scientific argumentation of the parties.[40] 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.[41] 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."[42] 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".[43] 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 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

[40] Christoforou 2004a & b, 2003, 2002, 2000.
[41] http://www.ecolomics-international.org/biosa_risk_comm_rt_program_overview_ge_law_fac_110506.pdf
[42] Christoforou 2004b, 36.
[43] *Ib.*

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.[44]

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".[45] 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.[46] Ironically, the much promoted concept of 'sound science'[47] 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.[48]

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.[49] 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.[50]

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

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[44] Noiville et de Sadeleer 2001, 416.

[45] Christoforou 2002, 270.

[46] Christoforou 2004b, 34.

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

[48] 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

[49] Christoforou 2004, 35.

[50] 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.*

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,[51] 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.[52]

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.[53]

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.[54] As far as the evolution of this sub-discipline is concerned, Claudia Probart pays tribute to the three phases sketched out by two pioneers in this domain, Powell and Leiss:[55]

a) Risk communication as a distinct academic field of investigation was triggered about thirty years ago through major environmental accidents such as oil and

[51] *Ib.*
[52] Petipierre et al. 2004 a & b.
[53] 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.
[54] Probart 2002, 2.
[55] Powell and Leiss, 1997.

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 [56] 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-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:

[56] 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

> …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.).[57]

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."[58] 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."[59]

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.' "[60] 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.[61]

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[57] 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.

[58] Sand 2003, 487.

[59] *Ib.* 500.

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

[61] Fitze, 2006, 47.

2.3. Risk communication in international law

It is the purpose of the Aarhus Convention,[62] 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[63] 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[64] 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.[65]

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.[66] 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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[62] 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

[63] Lee and Abbot, 2003, 82.

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

[65] Lee and Abbot, 2003, 96.

[66] 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[67] in Almaty, Kazakhstan, in 2005, in the adoption of an Amendment[68] 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.[69]

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,[70] but

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

[68] 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

[69] 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/

[70] 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.[71]

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.[72] The three member Panel was duly composed only in March 2004.[73] 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*[74] 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"[75] 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.[76]

- the so-called 'Academics' Report,'[77]
- the CIEL-coordinated Report, and[78]
- the FIELD-coordinated Report.[79]

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

[71] 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."
[72] Boisson de Chazournes and Mbengue 2004, 289.
[73] Foster 2005, 438.
[74] European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS/291, 292, and 293).
[75] See for instance Boisson de Chazournes et Mbengue 2004, 289, or Bernauer 2003, 44.
[76] All three reports can be downloaded, see the following three footnotes and the List of References at the end for the URLs.
[77] Busch, Lawrence, Robin Grove-White, Sheila Jasanoff, David Winickoff and Brian Wynne 2004 ('Academics' Report').
[78] CIEL et al. 2004.
[79] 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." [80]

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).[81] 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.[82] 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.[83]

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.

[80] 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.

[81] 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

[82] Eckersley 2004, 10.

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

The DSU leaves this question open[84] and the AB has ruled for the first time in the case *US-Shrimps*[85] that indeed it does have this same right, an interpretation which has provoked numerous critiques and controversies at the WTO.[86] The question remains open whether the drafters of the DSU have intended to give the AB such powers[87] 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,"[88] it was certainly a bold step of the AB to admit *amicus curiae* briefs.[89] At the same time, it may be said that the DSB has used this self-attributed authority very sparingly.[90] 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)."[91]

3.2. *The 'Academics Report'*

The interdisciplinary 'Academics Report'[92] is the longest one of the three, its credibility[93] 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.[94] The strength of this brief lies in the rigorous and detailed treatment of

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[84] "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.

[85] 12 October 1998, WT/DS58/AB/R, para. 39.

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

[87] *Ib.* 416.

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

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

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

[91] Eckersley 2005, 20.

[92] 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.

[93] "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.

[94] "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.[95]

With regards to the nature of risk assessment, they note that risk assessment is by no means neutral, rather, it is socially constructed.[96] 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.[97] As far as the process of risk assessment is concerned, they point out that:

> …what looks like "delay"[98] 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.[99]

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.[100]

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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[95] "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.

[96] "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.

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

[98] 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.

[99] *Ib.* 37/38.

[100] *Ib.* 6.

for a number of reasons, much higher degrees of both certainty and consensus.[101] 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.[102] [103]

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."[104] 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

[101] *Ib.* 7

[102] 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."

[103] 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).

[104] "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."[105] 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.[106] 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.[107]

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.[108] 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

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

[106] "…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.

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

[108] 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.[109]

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[110] 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.[111]

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.[112]

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

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

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

[112] *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.[113]

The second argument relates to the consistency of the measures taken by the EU with the SPS and TBT Agreements.[114] 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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[113] "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.

[114] 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."[115] 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.[116]

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."[117] 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."[118]

4 Evolution of the Most Recent Negotiations

4.1. WTO Committee on Trade and Environment

The November 2001 Doha Development Agenda (DDA)[119] 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:"

> (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

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

[116] "…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.

[117] 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)."

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

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

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."[120]

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.[121] 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"[122] 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.

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

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[120] DOHA WTO MINISTERIAL 2001**:** MINISTERIAL DECLARATION, WT/MIN(01)/DEC/1 20 November 2001 Ministerial declaration, Adopted on 14 November 2001, Paragraph 31. http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

[121] 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)."

[122] 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

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,[123] were particularly important for the evolution of the organization because of a detailed internal and external organizational review conducted in 2002,[124] 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.[125]

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 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

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

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

[125] 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

strengthen the case for the right of an importing country to apply precautionary measures where they are justified.[126]

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"[127] (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[128] 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.[129]

4.3. The Cartagena Protocol on Biosafety

At the second Meeting of the Parties (COP-MOP-2),[130] 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. 18.2.(a),[131] scheduled to be terminated two years after the date of entry into force of

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[126] 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.)

[127] Burns 2005, 1-9.

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

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

[130] 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.

[131] 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

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[132] 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.[133] 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.[134] 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.[135]

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.[136] 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,"[137] 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 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.[138]

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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.

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

[133] Ching and Lin 2005, 2.

[134] *Ib.* 5.

[135] 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.

[136] Aguilar et al., 2006.

[137] Sand 2006 forthcoming.

[138] Young 2006.

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")[139] 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.[140]

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,[141] especially to the much-cited contribution of Franz Perrez with regard to the exploration of the concept of 'mutually supportive'[142] as it is enshrined in the Biosafety Protocol's Preamble, together with the notion of a non-hierarchical relationship with other international

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

[140] 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.

[141] Petitpierre et al. 2004.

[142] Perrez 2004, 523-7.

agreements, i.e. especially the WTO.[143] 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."[144]

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.[145] 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]."[146] 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."[147]

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.[148] 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 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.[149] Other "general issues" such as the

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[143] 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.

[144] 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.

[145] Bernauer, 2003, 44-66.

[146] Tiberghien 2006, 5.

[147] *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).

[148] 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/

[149] See for instance Matringe and Musselli Moretti 2006.

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.[150]

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.[151]

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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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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THE BIOSAFETY PROTOCOL AND RISK COMMUNICATION: DEVELOPMENTS AT THE 3RD MEETING OF THE PARTIES (CURITIBA 2006)

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ABSTRACT

This article reviews the key results of the third Meeting Of the Conference of the Parties serving as the Meeting of the Parties[152] to the Cartagena Protocol on Biosafety[153] (COP-MOP 3). It is focusing to a large extent on one of the key elements of this meeting, i.e. Art. 18.2(a) addressing the question of handling, transport, packaging and identification of living modified organisms. This choice of a detailed analysis is justified due to the fundamental implications and links that the Protocol maintains with the WTO, and for which this specific Article is crucial because it specifies how international shipments of Genetically Modified (GM) commodities must be labeled. The sensitivity of the GM food issue in many parts of the world, combined with the huge economic stakes of this quickly growing sector of an increasingly globalized agriculture explains the complexities of a seemingly straightforward regulatory disagreement, but which in fact is based on diverging national interests.

The evolution of the labeling issue was therefore highly contested throughout the negotiations which in the end led to the adoption of the Biosafety Protocol in 2000. Subsequently, it had caused a serious and largely unexpected deadlock at the Protocol's second Meeting of the Parties in 2005, in Montréal. We shall also consider two other questions which are contentious and presently unresolved, namely liability & redress, and compliance. With the objective of presenting as much as possible an empirical rendering of these often thorny legal issues, and in order to do justice to this drawn-out, complex and often very tense negotiation process, we shall pay detailed attention to the procedural and documentary aspects of this particular MOP.

A) INTRODUCTION

The third meeting of the Cartagena Protocol's[154] COP-MOP took place in the Brazilian city of Curitiba (State of Parana),[155] between 13 and 17 March 2006. This meeting preceded the Conference of Parties of the Convention on Biological Diversity (CDB, COP-8), which also took place in the same city between 20 and 30 March 2006.[156] The MOP 3, as the previous conferences, witnessed a high level of

[152] This very cumbersome diplomatic terminology is commonly used to denominate the official meetings of the Parties of a Protocol that is attached to a Multilateral Environmental Agreement.

[153] For an in depth overview and discussion of the Cartagena Protocol see for instance Bail, Falkner and Marquard, ed. 2002; Boisson de Chazournes and Thomas, ed. 2000; or Zerhdoud 2005.

[154] The Cartagena Protocol on Biosafety has been ratified by presently 134 states, with Congo being the last one on 13 July 2006.

[155] Rio de Janeiro, Earth Summit, 1992: adoption of the Convention on Biological Diversity.

[156] The eighth Conference of the Parties of the Convention on Biological Diversity (CBD) attracted more participants than any of the previous COPs - over 4000, including 130 ministers and heads of delegation, 340 indigenous and local people's representatives, NGOs and many representatives of the private sector. 34 decisions were adopted that can be consulted in the Doc. UNEP/CBD/COP/8/31, 15 June 2006: *Report of the Eighth Meeting of the Parties to the Convention on Biological Diversity*. http://www.biodiv.org/doc/meetings/cop/cop-08/official/cop-08-31-en.pdf
These decisions have a great importance in achieving the objective of the Convention's 2010 Target

participation from Parties and non-Parties,[157] observing United Nations Members, Secretaries of international conventions, private agencies, and other related organizations (United Nations Agencies, international inter-governmental organizations, non-governmental organizations, academic institutions, industry organizations, indigenous organizations, and other observer organizations). Often, the positions taken during the week of negotiations were controversial, both among the Parties of the Protocol, and between those and the non-Parties, the resulting tensions and frictions rendering difficult the negotiation of a consensus for the relevant topics.

The opening of the meeting generated the hope of adopting certain important decisions with respect to key aspects that were not resolved in the two previous MOPs due to the deadlocks in the negotiations that were caused by pressures exerted by various states. Eighteen decisions were adopted with the main objective being to contribute to the implementation of the international law of Biosafety.[158] Among these decisions, as we shall see, it is especially worthy to note the agreement that was reached with regard to documentation requirements for exports of living modified organisms (LMOs) intended for human and animal nutrition or for further processing, as was required by the Art. 18.2(a) of the Protocol. In addition, other agreements included those concerning risk management and evaluation, the need to establish subsidiary bodies under the Protocol (Art. 30); handling, transport, packaging and identification of living modified organisms (Art. 18.3, 18.2(b) and (c)); risk assessment and risk management, liability and redress; matters relating to the financial mechanism and resources, capacity-building; operation and activities of the Biosafety Clearing House (BCH).

The work that was achieved by COP-MOP 3 was built upon the negotiations, experiences, and results – but also the frustrations - of the previous meetings: COP-MOP 1, which took place in Kuala Lumpur (Malaysia) in February 2004, and COP-MOP 2, which took place in Montreal (Canada) in June 2005[159]. Furthermore, the first MOP was preceded and prepared by the three meetings of the

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and in putting into practice the CBD, as well, as for the attainment of the UN's Millennium Development Goals by the year 2015, especially the objective 7 on environmental sustainability, which supports the sustainable development principles. Among the most outstanding progresses made in the 8th COP it is worth underlining the advances in the discussion of key areas, including the adoption of a work program on island biodiversity; the continuation of the working group on protected areas to consider implementation and funding options; the identification of CBD's role on high seas; the endorsement of a framework of indicators to measure progress towards 2010; the renewed mandate given to the special group involving indigenous peoples and their knowledge; and the support given to the continuation of negotiations on an international regime on access and benefit-sharing (ABS) through a Working Group.

[157] 101 state Parties and 15 Non-party states assisted the meeting. Among the Non-party states, there are some of the main living modified organisms (LMOs) exporters: Argentina, Australia, Canada, the United States of America, Uruguay.

[158] UNEP/CBD/BS/COP-MOP/3/15, 8 May 2006, *Report of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety*, 32-88. http://www.biodiv.org/doc/meetings/bs/mop-03/official/mop-03-15-en.pdf

[159]See Report of the First Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Protocol on Biosafety: UNEP/CBD/BS/COP-MOP/1/15, 14 April 2004: *Report of the First Meeting of the Conference of the Parties Serving as the meeting of the Parties to the Cartagena Protocol on Biosafety*, and UNEP/CBD/BS/COP-MOP/2/15, 6 June 2005: *Report of the Second meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety.*

Intergovernmental Committee to the Cartagena Protocol on Biosafety (ICCP) that took place between 2000 and 2002.

B) SOME GENERAL POINTS ABOUT THE TWO PREVIOUS COP-MOPS

a) The main contributions brought about by COP-MOP 1.

The main objective of the 2004 COP-MOP 1 was the establishment of an operative set of guidelines that would accompany the implementation of the Protocol, with the aim of making important advances concerning the documentation requirements, complaints, responsibilities, restitutions and the Biosafety Clearing House (BCH).[160] Despite many difficulties associated with the negotiations in the pursuit of a consensus, thirteen decisions were adopted. In particular, it is important to note the creation of a Compliance Committee, the consideration of the potential risks of LMOs, and the establishment of an Open-Ended Technical Expert Group on identification requirements of living modified organisms.[161] In Kuala Lumpur a set of measures was adopted that have allowed the advancement and improvement of the application of the Protocol.[162]

b) The progress achieved at COP-MOP 2.

In general terms, it can be said that the main objective of COP-MOP 2 consisted in further facilitating the application of the Protocol, with particular consideration to developing countries, as well as the interests of LMO-importing and exporting states. In this sense, and undoubtedly, one of the priorities of the COP-MOP 2 was to advance and adopt a decision concerning the documentation requirements relative to the trafficking of LMOs for direct use as human or animal nutrition, or for further processing, as required by Art. 18.2 (a).[163] Additionally, although to a lesser extent, the following topics were considered relevant: the agreements relative to risk management and evaluation, building capacity and the BCH.

At the COP-MOP 2 the following issues were examined: the function and activities of the Biosafety Clearing-House, risk management and evaluation, manipulation, transport, packaging, identification, socio-economic considerations, technical and scientific questions necessary for the application of the Protocol, conditions of building capacity, employment of a list of experts on biosafety notification, public awareness and participation, and international proceedings for damage responsibility and restitution.[164]

COP-MOP 2 achieved significant advances concerning the effective application of the Protocol by adopting fourteen decisions that contributed to a better

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[160] For more information about the Biosafety Clearing-House see http://bch.biodiv.org/.

[161] The Decisions of all three COP-MOPs are searchable at http://www.biodiv.org/biosafety/cop-mop/search.aspx?menu=mop3 .

[162] For information about COP-MOP 1 see Mackenzie 2004.

[163] Art. 18.2(a) states: *"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."*

[164] Two Work Groups were set up: Group I was presided by Mrs. B. Ivars (Norway), and Group II was presided by Mr. O. Rey Santos (Cuba).

implementation at the national level, of which the following stand out: the adoption of firm measures on capacity-building,[165] public awareness and participation,[166] discussions concerning risk management and assessment,[167] including an agreement on the establishment of a Group of Technical Experts between the sessions.[168] Nevertheless, the meeting fell short of completing the main task mentioned in the Protocol text, i.e. the adoption of a decision on Living Modified Organisms for Food, Feed or Processing (LMO-FFP) documentation requirements within the two following years after the Protocol is in effect.

With respect to this last point, the chair of the Working Group 1 made a great effort to present a conciliatory text for consideration in the Plenary.[169] However, this project was subjected to several objections by New Zealand and Brazil, hence, it was not adopted.[170] In fact, no consensus was reached with respect to the following basic issues:

a) the creation of certain percentage thresholds governing the accidental or technically inevitable presence of LMOs;
b) the requirement of proper documentation of LMOs that have been approved in the importing State;
c) the necessary conditions to determine which LMOs may be transported when the purposely vague expression *"may contain"* genetically modified organisms (GMOs) is used.

In this manner, these two Parties of the Protocol finally blocked a draft agreement on Art. 18.2(a) which provided for identification of international shipments of LMOs

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[165] See Decision BS-II/3: *Status of capacity-building activities* and BS-II/4: *Capacity Building (Roster of Experts)*, in which a possible revision of the Action Plan for the creation of capacity for the effective application of the Protocol was discussed, to assure their adaptation to the current circumstances, and their capacity to respond to the necessities of the States. See Doc. UNEP/CBD/BS/2/15, *op. cit.*, Annex I, 37-45.

[166] Decision BS-II/13: *Public awareness and participation* addressed efforts to cooperate in the promotion of the education and the public understanding, with the purpose of increasing the knowledge and the understanding in relation to the safe manipulation, transfer and use. See Doc. UNEP/CBD/BS/2/15, *op. cit.*, Annex I, 54-55.

[167] Decision BS-II/9: *Risk assessment and risk management* contains an annex in which the attributions of the Group of Technical Experts are pointed out in Evaluation of the Risk. See Doc. UNEP/CBD/BS/2/15, *op. cit.*, Annex I, 49-50.

[168] With a view to facilitate an appropriate and opportune adoption of the decision set in para. 2 a) of Art. 18, the Group of Technical Experts met in the headquarters of the Organization of International Civil Aviation, in Montreal, from the 16 to 18 of March 2005. The report and the project of decision of the Group were submitted to the consideration of the COP MOP 2. For more information on this Group of Technical Experts, UNEP/CBD/BS/COP-MOP/2/10, 30 March 2005: *Report of the Open-Ended Technical Expert Group on Identification Requirements of living modified Organisms intended for food or feed or for processing.*

The meeting of the Group of Technical Experts was preceded by the creation of a working group on capacity and exchange of experiences relatives to the application of Art. 18.2 of the Protocol. The position defended by the States can be found in the same document. This workshop was organized according to the decision BS-1/6 of the COP-MOP 1, it took place in Bonn, from November 1 to 3 of 2004.

[169] UNEP/CBD/BS/COP-MOP/2/15, *op. cit.* Annex III: *Draft Decision on Handling, Transport, packaging and identification (art. 18.2(a)) submitted by the Chair of Working Group I,* 60-61.

[170] UNEP/CBD/BS/COP-MOP/2/15, *op. cit.*, para. 163.

intended for feed, food and processing. New Zealand and Brazil were the only two of 119 countries present to object to labeling provisions, insisting on the use of the expression *"may contain GMOs"* and rejecting the expression *"does contain."* With respect to the position of these States, one should note the following controversies: on one hand, New Zealand is neither an importer nor an exporter of LMOs, and as such its ideological stance on free trade left many perplexed, as it did not take into consideration any matters of environmental or health relevance. On the other hand, Brazil had been, until the arrival to power of President Lula da Silva, a member of the group of developing countries that, along with the majority of Latin American and South African States, was able to vocalize its will to approve the Protocol. This position was taken in order to fight for environmental protection, health and other interests of developing states, under the intense pressure exerted by the LMO industry and the principal exporting countries.[171]

[171] Besides, the existence of internal rules on biosafety in both States makes still more incomprehensible the position they adopted at the COP-MOP 2. In Brazil, all LMOs-FFP that are imported should have a previous formal approval of the CTNBio - the regulatory office of transgenics - after an analysis case by case. It is furthermore necessary to highlight their legal framework: Law nº 11.092, on 12 January 2005, relative to the plantation and commercialization of genetically modified soy products of *"zafra"*, and the Law nº 11.105, on 24March 2005. It should be noted furthermore that in Brazil, under their current president Luiz Inácio Lula da Silva, a Temporary Measure was introduced in 2003 that authorizes the sale of genetically modified soy of *"zafra"*, which implied a fundamental change of Brazil with regards to the regulation of GMOs. At the same time, it opened their access into Paraguay and Bolivia, since their markets are closely linked to the Brazilian one. The present year represents the fourth year in a row, in which the sale of transgenic soy is allowed by Ordinance - approved later by the Congress - to avoid that farmers in the South of Brazil, who use genetically modified seeds in spite of the existing prohibition in this sense, lose sales opportunities. http://www.mma.gov.br (Ministry for the Environment Brazil).
Regarding New Zealand, at the moment one can say the import of any LMOs-FFP is not allowed, so there is no commercial planting of genetically modified cultures, due, in part, to the strong rejection manifested by its population. New Zealand has already a rigorous system of controls in place, under the Hazardous Substances and New Organism Act 1996 (HSNO) and the Biosafety Act 1993, covering the import and domestic use of GMOs. The Imports and Exports (Living Modified Organisms) Prohibition Order 2005 was passed to enable New Zealand to comply with this obligation. The Prohibition Order came into effect on 25 May 2005. Since then, anyone who exports an LMO without getting the necessary approval would be breaking the law. Therefore, exporters need to get an authorization to export - available by contacting either ERMA or the Ministry for the Environment. http://www.mfe.govt.nz (Ministry for the Environment New Zealand).

C) THE MAIN CONTROVERSIAL ISSUES ON HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS (LMOS) DEBATED AT THE COP-MOP 3

Art. 18.2(a) assumes a vital role in the analysis of the problems associated with the safety of modern biotechnological uses. Just as in the previous conferences, the most controversial topic throughout the discussions of MOP 3 was trying to adopt a set of rules under Art. 18.2(a) with respect to documentation requirements that accompany LMOs exportation intended for use as food or feed or for processing. Nevertheless, in this paragraph we are also going to pay attention to other specific aspects on Art. 18.

a) Article 18.2(a) at the heart of the COP-MOP 3.

The debate was again focused on the use of *"contains"* versus *"may contain"* GMOs. As such, two completely opposed positions emerged, reflecting the existing disagreement between LMO exporting and importing States.

On one hand, the majority of the Parties of the Protocol were favourable to the establishment of a clear identification of exports containing LMOs with *"does contain"* together with an explanation of the contents. At the same time, they specified that LMOs are not to be exported from a Party if it does not allow the importation of the LMO in question. It follows logically that it is the duty developed countries - which are the primary exporters of LMOs - to evaluate the latter before exportation, since developing countries - which are usually importers of LMOs - do not have the necessary legal and scientific capacities or resources for such a task. [172]

On the other hand, a small group of Parties - in particular, Mexico, Paraguay and Peru[173] - insisted on a convenient way of identifying exports, thus supporting the

[172] In addition to the Parties, a large number of groups belonging to civil society took an active role. They opposed the employment of the expression *"may contain"* as a documentation option, criticizing the opposition to stricter documentary requirements by certain countries and by the biotech industry due to their commercial interests. During the MOP 3 of the Protocol and of the COP 8 of the CBD in Curitiba a *Global Civil Society Forum* was organized with the purpose of providing a space and a forum for Brazilian and other civil society organizations to exchange experiences, as well as to discuss and to affirm common positions in relation to the current issues related with biodiversity. It is interesting to underline that most of them presented cases which drew special attention to the situation in Latin Amercia in relation with genetic contamination: in the first place, the testimony of Mrs. Sofia Gatica, representative of the group of Mothers of Ituzaingó – a district surrounded by transgenic soy in the city of Cordoba (Argentina), - who presented, along with other people, the disastrous effects that the indiscriminate fumigation of fields of soy produced on the population´s health. In the second p lace, we should mention the Paraguayan case of Mrs. Petrona Villasboa who declared that all her family was contaminated by the fumigations with glyphosate in the fields of transgenic soy that surrounded her house in the year 2003. As a consequence of these facts, her 11 years-old son died.

[173] These states received support from non-Parties (mainly, the big exporters of LMOs: United States, Canada and Argentina – i.e. members of the so-called Miami Group -, as well as from the biotech industry, who jointly carried out an intense lobbying effort throughout the duration of the negotiations. It should be mentioned that the United States has not signed the Protocol; Canada has only signed it but not ratified – on 19 April 2001; and Argentina also has not ratified it, but it signed it on 24 May, 2000. It must be remembered that, in International Law, giving binding consent is of capital

use of the expression *"may contain LMOs,"* all the while being fully aware that this will make it more difficult for Parties to comply with Protocol obligations, or to efficiently control LMO imports through the adoption of sovereign decisions regarding admission and proper management of LMOs in each state's territory.[174]

Despite this general context of incompatible positions, and particularly after the failure to adopt a concrete decision in MOP 2, as well as the past due date of 11 September 2005 for the implementation of above-mentioned decision,[175] the Parties were conscious that a new deadlock in MOP 3 would not encourage the prospect of a future application of the Protocol. As a result of this situation, countries continued to operate based on an interim decision adopted at MOP 1: Decision BS-I/6. They also used as working documents a note from the Executive Secretary,[176] a text of the Open-Ended Technical Expert Group on identification requirements of living modified organisms and a text of the presidency of COP MOP 2, which made an important contribution at the moment of adopting a decision.[177]

The negotiations around this topic took place within *Contact Group, the Group of the Friends of the President, and Working Group I,* and they were centered on a draft presented by Brazil and entitled *Proposal of Initial Compromise.*[178] This draft underlined the necessity of proper labeling with the expression *"does contain LMOs"* of transnational exports destined for food, feed or processing, and that such labeling was to happen only in the event of a complete identification and separation of transgenic products. Equally, the draft admitted the use of the expression *"may contain"* in those cases where the GMOs were not originally identified. In reality, the use of the latter expression gives rise to a legal incertitude for it does not precisely state whether a shipment contains LMOs or not. Its use therefore goes along with the

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importance because without it, the state is not legally liable by the international agreement. Consequently, the aforementioned states are not legally bound by the provisions of the Protocol because they did not ratify it, exercising their sovereign right not to give consent. Díez de Velasco 2005, 158-159.

[174] The tensions produced during the COP-MOP 3, due to the existence of opposed interests, are similar to those that took place in the complex negotiations of the Cartagena Protocol on Biosafety. For an in depth discussion of these negotiations see for instance Bail, Falkner and Marquard 2002; Zarilli 2000; Franconi 2001, 55 ff.; Pommerance 2000, 614-621; Mayr 2002.

[175] Art. 18.2.(a): "… no later than two years after the date of entry into force of this Protocol."

[176] UNEP/CBD/BS/COP-MOP/3/8, 22 November 2005: Note of the Executive Secretary: *Taking a Decision on the Detailed Identification/Documentation Requirements of Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing – Article 18, paragraph 2 (a)).* This document suggested elements of action that COP-MOP 1 estimated to be adequate to find a solution to this question.

[177] UNEP/CBD/BS/COP-MOP/3/8, *op. cit.,* 3-11.

[178] In fact, on the basis of the negotiations of COP-MOP 3, we may conclude that Brazil maintained a position that was completely opposed to the one it had in Montreal, because in Curitiba it defended the use of the explicit expression *"contains LMOs"*. In this sense, speculation occurred about the different roles that Brazil played at these two Meetings, and that, basically, it was due to the conjunction of a series of factors: the internal consultation process that preceded the negotiations, a stronger paper of its Ministry of the Environment, and – maybe the decisive reason - a political interest in achieving successful negotiations in its own country. Other critical voices suggested that Brazil could be having a commercial advantage in advance - in particular, in comparison with other countries of Latin America – as a consequence of having the capacity to implement a system that would allow Brazilian exporters to easily separate the biotechnological products from the conventional ones. In any case, these aspects will be analyzed more specifically later.

precautionary principle mentioned in the same Protocol for safety purposes.[179] Eventually, Brazil's proposition was relegated to a transition period of four years before taking full effect.

Based on Brazil's proposition, the Contact Group was focused on discussions about the objectives of LMO-FFP documentation. Also, it provided a forum for exchange of ideas about the justification of the expression *"may contain"*, fields of implementation, intentional movements of LMO-FFP, and its relation to the threshold of accidental presence of LMOs in a particular product. Upon this base, the co-presidents drafted a text for the consideration of the Working Group I.[180]

The discussions in the Working Group I[181] were based on the text, in which a series of disagreements emerged with regard to several issues, such as the requirements to identify which LMOs a shipment may contain and thresholds for adventitious or technically unavoidable presence of LMOs, including whether or not they trigger the documentation requirements, among others. As a result of these deliberations, the President recommended that in MOP 5 a decision should be finally made regarding the issue of compliance with LMO regulations of importing countries, and that in MOP 6 a decision should be made regarding the *"may contain"/"does contain"* controversy.

However, Mexico and Paraguay[182] were opposed to this approach. They considered that in the case of certain States requiring further detailed information, it would be possible for them to consult the BCH.[183] Besides, it should also be

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[179] The Preamble of the Protocol states: *"Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development…"* On the other hand, Art. 1 of the Protocol, relative to the objective, says: *"In accordance with the precautionary approach contained in Principle 15 of the Declaration of Rio on Environment and Development, the objective of this Protocol is to contribute to ensure an adequate level of protection… "*

[180] The Contact Group was presided by Mr. François Pythoud, Switzerland, and L.A. Figueiredo Machado, Brazil. This Group held interesting discussions regarding unsolved issues and produced a draft decision without brackets for the consideration of the Working Group.
UNEP/CBD/BS/COP-MOP/3/15, *op. cit.,* 23, para. 142.

[181] The meeting established two working groups. Working Group I, under the chairmanship of Ms. Ivars, to consider Operation and activities of the Biosafety Clearing-House, Handling, transport, packaging and identification, Risk assessment and risk management, Subsidiary bodies and Other scientific and technical issues that may be necessary for the effective implementation of the Protocol UNEP/CBD/BS/COP-MOP/3/15, *op. cit.,* 11.
The Working Group I adopted its report: UNEP/CBD/BS/COP-MOP/3/L.1/Add.1, but it is a restricted document, therefore it has been incorporated into the present report in the discussion of the appropriate agenda items.

[182] Mexico and Paraguay possess 0.1 and 1.8 million hectares respectively. Peru does not currently produce commercially genetically modified crops but it is in the process of drafting new regulations to promote biotechnology. Garton, Falkner and Tarasofsk, 4; Clive 2005.

[183] On this matter, see Rule 40 of procedures for meetings of the Conference of the Parties to the Convention on Biological Diversity. It is important to note – in order to understand the role played by Mexico and by Paraguay at the COP-MOP 3 - an explanation provided by Prof. Díez de Velasco: the consensus method frequently used consists in the adoption of a decision inside the bodies of the organizations without using to the formality of voting. This way, the president of the organism in question or the spokesperson of a group of the member countries of it negotiates a text project with the different delegations or groups of countries, until he or she verifies that this project doesn't raise any important objection on the part of any of them, and then declares that the decision can be adopted by consent. Thus, it constitutes a method based on dialogue and commitment among groups of states (in this case, basically, between exporting countries of LMOs and developing countries), which favors the search of acceptable formulas by all parts of the negotiation. The price to pay is that this approach

mentioned that Mexico suggested a considerable number of changes and amendments, of which the following are the most notable: use of the expression *"urge"* instead of *"require"* by Parties and considering that the expression *"may contain"* need not be accompanied with an exhaustive list of exported LMO species.[184]

Based on Mexico's insistence, the final decision included a clause that would prevent the application of the general rules approved by the COP-MOP with respect to cross-border transport between Parties and non-Parties.[185] In accordance with this idea and with the general rules of the Protocol, Article 24 already considered the possibility of bilateral agreements among Parties and non-Parties regarding cross border movements, but in a compatible way with the objective of the current Protocol of Cartagena.[186] In fact, this clause allows Mexico to maintain a series of commercial agreements with the United States and Canada since it had already ratified a regional agreement on 29 October 2003,[187] which spares it from observing the established requirements of the Cartagena Protocol, in accordance with Chapter Nine of the *North American Free Trade Agreement* (NAFTA). This trilateral agreement includes key aspects that defy the rules of the Protocol and potential future decisions. It states that exportation *"is not transgenic"* if it contains less than 5% transgenic material, that the *"unintentional"* presence of transgenic material in a shipment does not constitute a reason for obligatory labeling with the expression *"does contain"*, and that abiding by NAFTA rules is considered adequate with regard to the rules of the Protocol.[188] It is therefore obvious that Canada and the United States, being two main exporting States, would favor a very high threshold of LMO tolerance that would thereby avoid the demands imposed in the context of the WTO. Thus there won't be a direct conflict with norms of a Multilateral Environmental Agreements (MEA).[189]

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tends to lead to texts with ambiguous compromise contents that allow different interpretations. Not voting allows the text to be approved without the states having to explicitly show a consensus. Sometimes, this mechanism precedes other decision adoption procedures, so that when it is not possible to reach a consensus, they use a system of majorities. Díez de Velasco, 2006, 109-112; Combacau and Sur, 2004, 732-734.

[184] Amendments proposed by the delegation of Mexico to the fourth preamble para. and to operative para. 4 and by the delegation of Paraguay to operative para. 4 (i) and (ii). UNEP/CDB/BS/COP-MOP/3/15, *op. cit.*, 24.

[185] This provision could reduce the universalization of the Protocol, preventing it from achieving the acceptation and implementation of its rules internationally.

[186] Indeed, this provision is supported by Art. 14.1 as well as by Art. 24 of the Cartagena. Protocol.

[187] It is a trilateral agreement adopted under the title: *Requirements for the documentation of Living Modified Organisms Intended for Direct Use as Food or Feed or for Processing.*

[188] At present, Mexico tries to promote a similar agreement with other Latin American Countries (as Argentina, Brazil or Uruguay). The threshold established by the European Union is notably higher: 0.9 %.

[189] Information assembled in: http://cronica.diputados.gob.mx/PDF/59/2004/feb/040218.pdf -Diario de los Debates, Estados Unidos Mexicanos. Órgano Oficial de la Cámara de Diputados del Congreso de los Estados Unidos Mexicanos. Poder Legislativo Federal, LIX Legislatura Comisión Permanente, 18 de febrero 2004, sesión N º10. The text of the trilateral agreement is available at http://www.cibiogem.gob.mx/normatividad/Documento%20Trilateral/Trilat-arrgmt%20Esp.htm (Requirements of Documentations for Living Modified Organisms for Food, Feed or Processing OLM /AFP). The NAFTA text is available at: http://www.nafta-sec-alena.org/DefaultSite/index_e.aspx?ArticleID=309 (NAFTA Secretariat).

Finally, the Parties maintained a favorable position with respect to the text proposed by the President and a bracket-free *"compromise text"* was submitted for adoption by the Plenary as proposed by the Working Group.[190] In the final decision on the Art. 18.2(a), the COP-MOP urged Parties and non-Parties to adopt measures that would ensure the use of a commercial invoice or other documents that accompany the LMOs-FFP. In addition to this, it also required the submission of information about the actual application of article 18.2(a) six months before the due date of MOP 5, with the objective of a reconciliation of different documentation requirements.

Especially important were the following six requirements regarding LMOs-FFP in addition to abiding by the internal regulations of importing countries:

1) In those cases where the identity of LMOs is known through means such as identity preservation systems, the expression *"contains"* should be used.
2) In those cases where the identity of LMOs is not known through means such as identity preservation systems, the expression *"may contain"* should be used.
3) LMOs may not be intentionally introduced into the environment.
4) Common, scientific, and commercial (when possible) names should be used.
5) A unique identification code, or *"event code,"* should be used.
6) The communication of the web address to the Biosafety Clearing-House. LMO information should be available in the BCH.

Moreover, the COP-MOP also required of the CBD Executive Secretary to provide funds for the implementation of Art. 18.2(a). Additionally, COP-MOP encouraged Parties and non-Parties to cooperate in their use and development of detection technologies, and to submit related information to the CBD Executive Secretary for consideration at MOP 4.[191]

At the same time, it can be observed that the interim period was extended from four years (Brazil's suggestion) to six; further, there would be a revision and evaluation of this decision in COP MOP 5, in 2010, with the aim of reaching a decision after having experienced the labeling system in order to eventually reach a final decision in COP MOP 6, in 2012, with regard to the use of the expression *"does contain LMOs."*[192]

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[190] Draft decision UNEP/CBD/BS/COP-MOP/3/L.19 (restricted circulation), as orally amended, it was adopted as decision BS-III/10: *Handling, transport, packaging and identification of living modified organisms: paragraph 2 (a) of article 18*, in Doc. UNEP/CBD/BS/3/15, *op. cit.*, 60-62.

[191] In connection with all the obtained results - but making a special reference to the Art. 18.2(a) - Ms. Marina Silva, Minister of the Environment of Brazil, expressed that important decisions had been taken for the future of the Protocol, in the areas of capacity-building, risk analysis, the Biosafety Clearing-House and the financial mechanism of the Protocol. The negotiations on the main item on the agenda, concerning the requirements for documentation and identification of living modified organisms for use in food, feed or for processing in paragraph 2(a) of Art. 18, had been an outstanding example of mutual understanding and represented a step forward with respect to previous debates on the subject. She was pleased to note that the final decision explicitly authorized the Executive Secretary to mobilize funds to help Parties implement the conditions of Art. 18.2(a). UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 30.

[192] The COP-MOP meetings are now held every two years. This rhythm is foreseen in the Rule 4 of the Rules of Procedure. Based on the Art. 29.6 of the Cartagena Protocol, the decision BS-III/18 *(Date and venue of the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol)* decided to hold its fourth meeting in conjunction with the ninth meeting of the

The participating delegations made concessions in order to satisfy all interests. Besides, it can be said that Mexico's position has influenced the results obtained at the COP-MOP 3, allowing for little progress with respect to the previous COP-MOPs, and leaving open the door to possible future conflicts, such as possible demands by the WTO's Appellate Body against those states that refuse to import non Protocol-documented LMOs. This would give rise to commercial discrimination that would defy the main GATT principles of elimination of commercial barriers.[193]

In any case, before closing the analysis of the results obtained with regard to Art. 18.2(a), it is important to mention the role that Brazil played throughout the conference, not only in terms of host government, but also in its intense efforts to eliminate barriers towards a final consensual decision, presenting a well-elaborated proposition that served as a reference point to many discussion and debates. In fact, Brazil, as previously indicated, maintained a position entirely opposed to that which it had defended in Montreal, at MOP 3 it was in favor of the use of the expression *"does contain LMOs."*[194]

The positive attitude of Brazil was recognized by several MOP 3 Parties[195] as well as by the European Commission, which itself spoke of COP MOP 3 and declared:

> It adopted a landmark decision of detailed documentation requirements for genetically modified organisms in the international trade of agricultural commodities. In the final hours of negotiations, trade implications of documentation requirements were the main focus of major players such as Mexico and Brazil. The final compromise would not have been possible without the political commitment of the Brazilian government to make MOP 3 a success.

The Environment Commissioner states:

Conference of the Parties to the Convention. Date and place for COP-MOP 4 are still in the process of being determined. UNEP/CBD/BS/COP-MOP/3/1/Add.1/Rev.1, 9 December 2006: *Organization of the Meeting: Revised annotations to the provisional agenda (reported for technical reasons),* 12 or Decision III/18: *Date and venue of the fourth meeting of the Conference of the Parties serving as the meeting of the Parties of Protocol,* in Doc. UNEP/CBD/COP-MOP/3/15, *op. cit.,* 107.

[193] See GATT Art. I (General Most-Favoured-Nation Treatment), Art.V (Freedom of Transit), Art. XI (General Elimination of Quantitative Restrictions), Art. XIII (Non-discriminatory administration of Quantitative Restrictions), Art. XIV (Exceptions to the Rule of Non-discrimination) and the Art. XX disposition (General Exceptions). See the following examples of WTO disputes concerning these questions: United States (WT/DS291), Canada (WT/DS292), Argentina (WT/DS 293), Thailand (WT/DS 205). Wiers 2002, 227-304; see also the WTO´s Web site on dispute settlement: http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm#disputes

[194] Only Brazil, among the world's leading agricultural exporters - the largest increase in any country in 2005 was in Brazil, provisionally estimated at 4.4 million hectares - has adhered to the Cartagena Protocol. This causes the additional costs of identifying and separating transgenic products which will drive up prices, thus putting it in a disadvantageous position in the competition with other exporting countries that have not ratified the Protocol. Clive 2005, Executive Summary.

[195] The representatives of Ethiopia (on behalf of the African Group), Austria (on behalf of the European Union, Bulgaria and Romania) and Kiribati (on behalf of the Asia-Pacific group) expressed their thanks to all those who had made the meeting a success. UNEP/CBD/BS/COP-MOP/3/15, *op. cit.,* BS-III/17: *Tribute to the Government and people of the Federative Republic of Brazil*, 87 and UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 30.