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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 Biosafety 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 three 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.

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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_111020_05.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 Munich 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 Agreement⁷ 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 not enjoy previously. Contrary to the SPA Agreement, the TBT Agreements does not list the relevant 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_1110200_5.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

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 nearly 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 were 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 permeability²⁷ 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

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 Chazournes's call for internormativity³¹ 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 Truillé-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 Protocol³⁶ 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 München 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

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 than 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 were 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 referendum⁵⁶ 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 known 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

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 legislation⁶³ 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 Directive⁶⁴ 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.”

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 Parties⁶⁷ in Almaty, Kazakhstan, in 2005, in the adoption of an Amendment⁶⁸ 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

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, and⁷⁸
- 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 Understanding (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 open⁸⁴ 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 powers⁸⁷ 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 credibility⁹³ 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

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,

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 equivalent¹¹⁰ 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 these 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

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).

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

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 CCGP¹²⁸ 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

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 TERMS 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 marketing¹³² 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

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

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

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.

Annex No. 1

Research published by the members of the SNSF Research Group

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¹⁵⁰ World Health Organization, 20 Questions on genetically modified food (see especially question No. 20) http://www.who.int/foodsafety/publications/biotech/en/20questions_en.pdf

¹⁵¹ Bonny 2003 (National Institute of Agricultural Research, Paris), quoted by Tiberghien 2006, 23.

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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*".

WTO Law, Science and Risk Communication

- **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 : approches 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 Parties¹⁵² to the Cartagena Protocol on Biosafety¹⁵³ (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's¹⁵⁴ 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 2005¹⁵⁹. Furthermore, the first MOP was preceded and prepared by the three meetings of the

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

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

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 n° 11.092, on 12 January 2005, relative to the plantation and commercialization of genetically modified soy products of “*zafra*”, and the Law n° 11.105, on 24 March 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 Peru¹⁷³ - 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 America 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 place, 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

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 I¹⁸¹ 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 Paraguay¹⁸² 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

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

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 acceptance 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 °10. 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

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 Parties¹⁹⁵ 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.

This decision sets out documentation requirements that are clear, meaningful and practical for both exporters and importers of agricultural products, while being consistent with Eulaw. It provides for legal certainty for the international trade in agricultural commodities. As such, it is a landmark decision that bolsters the role of the Cartagena Protocol. I would like to express my deep appreciation to the Brazilian government that has been instrumental to achieve his outcome.¹⁹⁶

b) Some other particular aspects linked with Article 18.2(a).

The Parties that have not yet implemented internal legislation on the labeling of LMOs are particularly interested in the elaboration of minimal international measures on documentation. This way they can avoid becoming "*testing grounds*" of LMOs previously rejected by third states for not fulfilling the minimum conditions of security and guarantee through their internal legislation. This situation may be accompanied by another worrisome reality: the monopolization by a reduced number of multinational corporations in the market of LMOs.¹⁹⁷ In the last few years, a wave of mergers resulted in a situation where only a few conglomerates control much of the global agricultural and food market. In fact, these coalitions contribute to a trend which makes developing countries more and more dependent on the industrialized world. Therefore, the concentration of the commercialization of transgenic seeds places the farmer in a dependence relationship with these powerful quasi-monopolies.¹⁹⁸ This control can be appreciated particularly in the case of the so-called Terminator gene: these genetically modified seeds are sterile or produce sterile seeds, assuring the economic dependence of the farmers towards their suppliers.

In spite of this reality, it is certain that the lack of technical and financial conditions to implement a complete LMO identification system is progressively being overcome by resolutions that allow the Protocol's Executive Secretary to put into effect a program of technical assistance to increase the financing of biosafety systems in less developed countries. This is particularly relevant, since for the adoption of a decision relative to the proper use of LMOs, it is indispensable to have the necessary solid and responsible basis that for science-based risk management procedures. This can be only being made possible through detailed information accompanying LMO exports. Thus, the importing country will have the possibility to control its incoming shipments without third-party interferences, and the consumer will have the choice as to which products to consume based on their attached description. This has been the main motivation for most European and Asian

¹⁹⁶ IP/06/335 Date: 20/03/2006.

¹⁹⁷ The principal agro-chemical corporations are: Monsanto, Dow, Dupont, Bayer-Crop Science and Syngenta. In addition to those "giants of nutrition" we should also make reference especially to the following: Nestlé (Switzerland), Philip Morris (USA), Coca Cola Company (USA), PepsiCo Inc (USA), IBP Inc. (USA), Mars Inc. (USA), Danone Group (France) and Diageo (Great Britain). These transnational companies are those that possess the biggest economic power, and whose sales numbers are the highest in the market.

¹⁹⁸ The seed suppliers usually demand from the farmers the signing of an authorization agreement to forbid the exchange of seeds with another farmer, their re-utilization, and the reservation of the best seeds in each crop for later years.

countries to adopt strict regulations regarding genetically modified organisms. Some of these regulations go well beyond those specified by the Cartagena Protocol.¹⁹⁹

Notwithstanding the existence of specific internal legislations with regard to LMO identification, it is possible that in some, though rare, circumstances genetic contamination may occur. It is worthy to note at this point the case of the Bt-10 corn in order to better understand how difficult it is to achieve proper controls, and protection against potential risks, posed by LMOs within state or regional borders. The Bt-10 corn variety, despite not being approved for cultivation for human consumption, has been commercially distributed by Sygenta in large quantities between the years 2001 and 2004 in the United States. It has also been employed in 2001 for experimental purposes in Spain, Chile, Canada, Argentina and, increasingly, in France.²⁰⁰

¹⁹⁹ Many countries have national legislations to protect themselves from illegal LMO imports. Nevertheless, some of them seem to try to keep those same rights and levels of information from the less developed countries which lack national biosafety laws and means to enforce them. In this context, see the following European, US, and Mexican regulations:

Communitarian Regulations: Council Directive of 23 April 1990 on the contained use of Genetically modified organisms (90/219/EEC), Council Directive of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms (98/81/EC); Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC; Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC; Regulation (EC) n° 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms. For more information, see http://www.europa.eu.int/comm/environment/biotechnology/index_en.htm

- United States: In contrast to the EU, the US has not developed separate regulations for biotechnology, rather it regulates GMOs through existing legislation. While no mandatory risk assessment requirements for GMOs exist, the proposed Pre-market Notice Concerning Bioengineered Foods requires companies to submit information on safety considerations before marketing GM foods. Regarding labeling, the US Food and Drug Administration has issued voluntary draft guidelines for the labeling of GM foods. The non-approved varieties of LMOs are considered *regulated articles* under the North-American regulations on genetic engineering. To import a non-approved variety, first the exporter must obtain an importation license from the US Department of Agriculture for a regulated article. This import license must accompany the exportation. This must be addressed to closed warehouses and must arrive to a previously designed port. To use that shipment for human consumption, the exporter must make sure that the product is not impaired by pesticides under the regulations of the Environmental Protection Agency (EPA). NAPPO Biotechnology Panel. 2004. Discussion paper for development of module 4 of the NAPPO standard for importation of transgenic plants into NAPPO member countries. North American Plant Protection Organization; interviews with USDA regulators. For more information on the respective roles of USDA-APHIS, EPA, and FDA in federal regulation of genetically engineered plants, see the United States Agencies Unified Biotechnology website: <http://www.epa.gov/epahome/exitepa/htm>; <http://www.usda.gov/wps/portal/usdahome> and <http://www.cfsan.fda.gov/~lrd/biotechm.html#reg>: (US Food and Drug Administration).

- Mexico: the Mexican legal framework has the Law on Biosafety and Genetically Modified Organisms, published on 18 March 2005, in force since 17 April 2005. <http://sagarpa.gob.mx/>.

²⁰⁰ For this serious incident, see: Macilwain 2005, 423. In this article, the Director of the Pew Initiative on Food and Biotechnology, Michael Rodemeyer, comments: "The release reflects the absence of a thorough monitoring system for genetically modified products in the US food supply. This will raise questions in the minds of countries that import food from the United States about whether we have

Syngenta made much of the fact that the Bt-10 corn is identical to Bt-11, which is approved for human consumption in the US, the EU and Japan. As Herrera claims, they are similar but not identical. Bt-10 differs from Bt-11 in that it contains an inactive marker gene which originally conferred resistance to ampicillin, a commonly used antibiotic. This gene is a relic from the process used to select transgenic corn cells during strain construction. The release of such genes into the environment has been contested in the past because of the small chance that functional versions could transfer from crops to micro-organisms and spread problems of antibiotic resistance.²⁰¹

In the context of food aid, it is very unlikely that the presence of LMOs is controlled. This is why many studies brought up the presence of non-authorized genetically modified organisms in shipments of humanitarian aid, especially destined to some South American and sub-Saharan Africa countries, or countries immersed in serious armed conflicts such as Iraq or Afghanistan.²⁰² Moreover, it has been scientifically proved that a part of the emergency humanitarian aid distributed in different regions affected all around the planet contain LMOs.²⁰³ Because of this, some African countries, immersed in deep crisis, have come to the point of refusing the offer of certain corn shipments suspected of containing LMOs - principally from the United States²⁰⁴ - due to several causes: first of all, due to the risk of genetic contamination of their own traditional production; secondly, for the negative

adequate controls in place. It will provide ammunition for critics of genetically modified food - and it may provide incentives for countries to look at non-genetically modified varieties."

²⁰¹Herrera himself affirms: "We may never know exactly how or when the commingling occurred, to what extent the global food system was contaminated, or how Syngenta calculated its acreage proclamation. But, all agree that the fact that it did occur suggests that there was some sloppy handling of materials that should have been treated with the utmost of care at all times for any number of reasons - some scientific, others purely political". Herrera 2005, 514.

²⁰² Another report to be highlighted is the one presented by the Institute *Genetic ID*. Genetic identity testing helps agricultural and food industry clients to grow and sustain their markets and exports - guiding them through various countries' government regulations and procedures concerning restricted ingredients such as GMOs (<http://www.genetic-id.com>) that confirmed the presence of different varieties of genetically modified corn -- known as Starlink -- not for human consumption, with help from the World Food Programme (WFP <http://www.wfp.org/english>) and the United States Agency for International Development (USAID -- http://www.usaid.gov/about_usaid/) in Bolivia, Guatemala and Nicaragua.

Jeffrey L. Fox: "StarLink contains a Cry9Cgene, encoding a variant of the insecticidal protein derived from the soil bacterium *Bacillus thuringiensis* that EPA did not approve for human food use. Indeed when StarLink was registered, agency officials specified that it and other types of corn grown within 660 feet be used only in animal feed, industrial non-food uses such as ethanol production, and for seed increase," Fox 2001, 11.

²⁰³ The Commission considers fundamental that the authorities of developing countries have the lawful right to determine their own protection level and to meet the decisions they consider adequate to avoid the involuntary diffusion of genetically modified seeds. IP/03/681, 3.

²⁰⁴ The United States is not only the main producer and exporter of genetically modified products, but it also has concluded numerous Free Trade Agreements with countries in South and Central America which agreed to follow, in international trade, the North-American guidelines concerning genetically modified organisms. These Agreements are: Acuerdo de Libre Comercio Andino (Peru, Ecuador and Colombia) - EEUU (<http://www.tlc.gov.co/VBeContent/tlc/newsdetail.asp?id=4075&idcompany=37>); the CAFTA: Free Trade Agreement between the USA and 5 countries in Central America (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua) and Dominican Republic <http://www.minec.gob.sv/default.asp?id=84&mnu=70>; The Chile Free Trade Agreement (FTA), which was approved by Congress in 2003 (<http://www.ustr.gov>).

repercussion that this diffusion could have in the regional and international trade; thirdly, due to sanitary and environmental considerations; and last of all, due to questions concerning intellectual property rights. More specifically, among the African countries that prohibited the importation is Zambia, on the basis of a report made by scientists of East Africa. On the other hand, countries like Zimbabwe, Mozambique or Malawi ended up accepting the North-American corn under the condition that it was milled to avoid its diffusion.²⁰⁵

Clearly, it will be a long time until humanitarian aid is strictly focused on trying to efficiently respond to the existing humanitarian crises, and that the providing countries do not use these for the diffusion of genetically modified organisms, or to find commercial possibilities for the surpluses of their national production. This way only it will be possible to achieve one of the goals of the final Declaration of the World Food Summit referring to biotechnology: *"We are committed to study, share and facilitate the responsible use of biotechnology in addressing development needs."*²⁰⁶

c) Other Specific Aspects of Article 18

The COP-MOP 3 also engaged in long discussions on the documentation of LMOs destined for both contained use and for intentional introduction into the environment under para. 2(b) and (c) of Art. 18 respectively. Basically, the discussions were centered on determining the correct use of either commercial invoices or of other required documents which are used.

With the purpose of adopting a decision on this question, a note from the Executive Secretary was taken into consideration which compiled information and communications received by the different Parties, and which served, on one hand, as a guide to examine the determination of a unique document, and on the other hand, to evaluate the experience obtained in accordance with the application of the requirements of Art. 18.2(b) and (c).²⁰⁷

In this report, in accordance with the above-mentioned objective, the Executive Secretary prepared a synthesis of the obtained data based on the different communications presented, concluding that the majority of them were similar to those presented at COP-MOP 2. On this matter, Norway and the European Community supported the use of a unique document to complete the requirements of the Protocol under para. 2(b) and (c) of Art. 18.²⁰⁸ Despite Canada and the United States

²⁰⁵ Data from Doc. IP/03/681, done in Brussels, May 13, 2003.

²⁰⁶ WFS: 2002/3: *Draft Declaration of the World Food Summit: Five Years After* <http://www.fao.org/DOCREP/MEETING/004/Y6948E.HTM>. Together with the 1996 Declaration, it provides a framework to introduce important changes into the policies and programs necessary to eradicate nutritional deficiencies.

²⁰⁷ The Executive Secretary's note addresses the reports of the European Community and its member countries, Norway, Canada and the United States of America: UNEP/CBD/BS/COP-MOP/3/8/Add.1, 3 January 2006: *Handling, transport, packaging and identification of living modified organisms. Synthesis of information on experience gained with the use of documentation to fulfill the identification requirements of paragraphs 2 b) and 2 c) of Article 18. Note by the Executive Secretary*, 2.

²⁰⁸ Only Norway offered illustrative examples of a unique document to be used in the transborder movement of LMOs for restricted use and LMOs for intentional introduction in the environment. UNEP/CBD/BS/COP-MOP/3/8/Add.1, *op.cit.*, 4-5; UNEP/CBD/BS/COP-MOP/3/8/Add. 1, I Annex 1^a, *op. cit.*, 6-11.

considered that this question was out of the context of Art. 18.2(b), affirming that the documentation in the common commercial practices would be sufficient to guarantee a correct level of security.²⁰⁹

In the final decision adopted, COP MOP indicated the limited number of cases studies received on the experience in the use of the existing systems of documentation and recognized the necessity of an expanded practical experience.²¹⁰ Consequently, it required the Parties to submit more extensive information about the documentation assembled no later than 6 months before the MOP 4 to be able to consider the adoption of an individualized document in the proper context of the revision process of the application of the Protocol. Also, it recognized the right of the Parties to adopt internal measures, requesting from exporters of LMOs destined for contained use to implement standardized formats, independent documents and other systems of documentation. Furthermore, it mandated the Executive Secretary to make a report which analyzes the received information in order to study it at the moment of the revision of the Protocol, in accordance with article 35.²¹¹

With respect to Art. 18.3, if it is necessary when elaborating norms related to identification, handling, packaging and transport practices, COP-MOP engages in consultations to international organizations that are in some way related to the requirements of Art. 18.3 of the Protocol. In order to make this possible, the Executive Secretary invited some organizations to both provide their points of view about the rules or effective international practices regarding packaging and transport of LMOs, and about the convenience of elaborating norms and their different procedures.²¹²

The discussion on this matter, which took place in Working Group I, focused on the necessity of developing standards regarding the practices related to handling, transport, packaging and identification (HTPI) in the trans-boundary movements of LMOs.

In this regard, after intense discussions, the final decision recognized the necessity of making subsequent consultations in order to develop measures

²⁰⁹ UNEP/CBD/BS/COP-MOP/3/8/Add. 1, 3-4. To obtain a more complete vision of the submissions presented by the Parties and other Governments, see Doc. UNEP/CBD/BS/COP-MOP/3/INF/2, *Handling, Transport, Packaging and Identification (Article 18): Compilation of information submitted by Parties and other Governments and by organizations on experience gained with the use of documentation requirements under paragraphs 2 (b) and (c) of Article 18 of the Cartagena Protocol on Biosafety*, 3.

²¹⁰ See Decision BS-III/8: *Handling, transport, packaging and identification of living modified organisms: paragraphs 2 b) and 2 c) of Article 18*, UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 58.

²¹¹ Such as it was foreseen in the point 4 of the Decision BS-II/10: *Operations and activities of the Bio-safety Clearing-House*, Doc. UNEP/CBD/BS/COP-MOP/2/15, *op. cit.*, 33.

²¹² A reference is made of the following organizations: Economic Commission of the NNUU for Europe (UNECE), the International Organization of Normalization (ISO), the Universal Postal Union, the World Customs Organization and the International Air Transport Organization. The Secretary also invited the Commission of the Codex Alimentarius and the Centre of combined research, the Health and consumer's protection Institute or the European Commission. To observe how the different mentioned organizations try to cooperate and to upgrade the techniques for sampling and detection, UNEP/CBD/BS/COP-MOP/3/8/Add.2, 16 January 2006; *Consideration of the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices in the transboundary movement of living modified organisms* (Paragraph 3, article 18) and UNEP/CBD/BS/COP-MOP/3/INF/3, 31 January 2006: *Compilation of information submitted by Parties and other Governments and by organizations on the Article 18 paragraph 3 of the Cartagena Protocol on Biosafety*.

concerning HTPI practices, with the intention of avoiding duplication of efforts. It also invited the governments and organizations to submit to COP-MOP 4 visions and information on the adjustment of the existing rules and measures and the voids that can justify the development of new rules and measures for consideration. Moreover, it asked the relevant international bodies to modify or to expand their existing rules and measures. Finally, it required the Executive Secretary of the CBD to assemble information about the existing rules and measures, and to make it available in COP-MOP 4 and 5.²¹³

D) OVERVIEW OF THE OTHER ASPECTS ADDRESSED BY THE COP-MOP 3

Based on what was mentioned previously, the following matters debated during the COP MOP 3 are also of interest: capacity-building, risk assessment and risk management, the establishment of a process to evaluate and to revise the execution of the Protocol, the subsidiary bodies. Responsibility and compensation matters related to damages resulting from LMOs during international transport were also discussed, as well as cooperation with other organizations, conventions or programs. Parties also discussed public perception and participation in the implementation of the Protocol. All these different aspects are going to be analyzed in the following paragraphs.

a) Liability and Redress (Art. 27).

The Working Group was mandated with the task of elaborating options for elements of rules and procedures for liability and redress, which may include the definition of damage; valuation of damage to biodiversity and human health; threshold of damage; causation; analysis of damage scenarios of potential concern, and the application of international rules and procedures on liability and redress to such scenarios; channeling of liability; the role of parties of import and export; the standard of liability; mechanisms of financial security; and the right to bring claims.

After the consideration of the report of the special Work Group, the President worked jointly with the Secretary with the objective of achieving a decision draft that was discussed in the plenary session, and from which the Decision BS-III/12 arose.²¹⁴ At the same time, it was recognized that many developing countries and economies in transition are unable to elaborate international rules and procedures in conformity with Art. 27 due to a lack of financial resources.

b) Compliance: Report of the Compliance Committee (Art. 34).

The COP-MOP 3 proceeded to approach this question taking in consideration the

²¹³ Decision III/9: *Handling, transport, packaging and identification of living modified organisms: paragraph 3 of Article 18*, UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 59.

²¹⁴ The draft decision submitted by the President consisted of Doc. UNEP/CBD/BS/COP-MOP/3/L.2 - this document could not be consulted because it is not available for the public, but its data have been obtained from UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 26. On its side, the final Decision III-12: *Liability and redress under the Biosafety Protocol* can be consulted in Doc. UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 66.

report of the second meeting of the *Compliance Committee*,²¹⁵ and a note from the Executive Secretary on measures in cases of repeated non-compliance.

The Committee drafted a decision with a list of 12 recommendations for consideration in the COP-MOP 3. The second meeting of the *Compliance Committee* analyzed the questions relative to the application of the regulation of the Committee approved by the COP-MOP 2.²¹⁶ Regarding rule 14.1, it parted from the decision of the COP-MOP 2 in which it was recommended to the Committee to discuss and adopt a reasoned decision on the question of whether their meetings should be open or closed.²¹⁷ The Parties opted on a case by case basis to carry out electronic consultations in order to adopt a decision.²¹⁸ Also, the Committee debated the topic as to who should be present in the open sessions. It agreed to the general rule that only those Parties that express their desire to the Secretary could be present in these sessions of the *Compliance Committee*, although it left open the possibility to invite observers.²¹⁹ As for Art. 18, the idea of establishing a majority of 2/3 remained after COP-MOP 2 due to a lack of consent in this respect. After some deliberations, the Committee recommended to the COP-MOP 3 the study of a final decision in this regard.

If we proceed to analyze the question of the adoption of measures in the event of reiterated non-fulfillment, it should be pointed out that the *Compliance Committee* possesses the capacity to adopt measures with the objective of promoting the execution and to respond to cases of non-fulfillment. In this context, the Committee will consider the following factors: the capacity of the Party in question, the cause, the type, the grade and the frequency of the non-fulfillment. It was decided that it would

²¹⁵ The Compliance Committee was created by Decision BS-I/7 of COP-MOP 1, according to Art. 34 of the Cartagena Protocol. The Compliance Committee consists of 15 members elected by the COP-MOP itself on the basis of a geographical criterion: three members from each of the five United Nations regional groups. Decision BS-I/7: *Establishment of Procedures and Mechanisms on Compliance under the Cartagena Protocol on Biosafety* in 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, *op. cit.*, 98. Concerning the Compliance Committee, Ruth Mackenzie states: "With regard to how the procedure will function, the key issue to be resolved was how the procedure could be triggered. It was generally agreed that, in common with similar procedures established under other multilateral environmental agreements, any party could make a submission to the committee with respect to its own compliance with obligations under the Protocol. Eventually, it was also decided that a party could also trigger the compliance procedure in respect of another party, where it was affected or likely to be affected. This opens the possibility that a Party of import or Party of export could initiate the compliance procedure where, for example, it is of the view that another party has failed to abide by the Protocol's advance informed agreement procedure." Mackenzie 2004, 273.

The first meeting took place in Montreal – 14-16 March 2005 and was focused in developing the Regulations for their meetings and the preparation of a Working Plan.

²¹⁶ Decision BS-II/1: *Rules of procedure for meeting of the Compliance Committee*, UNEP/CBD/BS/COP-MOP/2/15, *op. cit.*, 29.

²¹⁷ This way, COP-MOP 2 modified what the Committee had agreed in its first meeting on this question. That is, holding all their meetings behind closed doors unless otherwise decided.

²¹⁸ In those cases in which the Committee would decide to meet in open session, the Secretary shall announce it on their Web Site.

²¹⁹ Several members of the Committee expressed their worries on the possible disadvantaged position that this rule could offer to Parties from developing countries, in case they were interested in taking part in the open sessions. This way, an equitable balance between developed and developing States would be impossible because of financial reasons.

be the COP-MOP 3 that would be in charge of integrating these questions in the revision process according to the Protocol's Art 35.²²⁰

The Working Group considered paragraphs 1,2,3,5 and 15 of the draft decision in the report of the *Compliance Committee*²²¹ and the elements of a draft decision on repeated cases of non-fulfillment contained in section III of the note by the Executive Secretary. The other paragraphs of the draft decision in the report of the Compliance Committee were considered under the relevant agenda items.

Finally, COP-MOP 3, based on the draft decision elaborated by the Working Group, adopted decision BS-III/1, which decides to review and to reconsider the effectiveness of the procedures and execution mechanisms as foreseen by the Section VII Decision BS-I/7,²²² including the adoption of measures relative to the cases of non-accomplishment as well as the question between quotation marks in the rule 18 of the rule of procedures in their fourth meeting.²²³ Also, it mandates the *Compliance Committee* to gather wider information about the experience of other environmental and multilateral agreements in connection with repeated cases of non-accomplishment for consideration at the COP-MOP 4. Furthermore, it requests the Parties that still don't have an appropriate legal and administrative framework, to elaborate it at the national level. Subsequently, it invites the Parties and other governments with well developed structures to cooperate and to share practical experiences with those parties that need it.²²⁴ In the end, the COP-MOP 3 chose five individuals to become members of the *Compliance Committee* for a four year period.²²⁵

²²⁰ UNEP/CBD/BS/COP-MOP/3/2/Add.1, 3 January 2006, *Compliance* (Article 34): Measures in cases of repeated non-compliance. For this purpose, Art. 35 states: "The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes."

²²¹ UNEP/CBD/BS/COP-MOP/3/2/annex, *op. cit.*, 12-13. Para. 1: Decides to remove the square brackets around Rule 18 on voting, in order to ensure efficiency, effectiveness, and independence in the work of the Committee and its members; para. 2: Calls upon Parties that still have no appropriate legal and administrative mechanisms in place at the national level to take the necessary measures and specifically to give appropriate attention to the development of national biosafety frameworks as enabling tools in their efforts to effectively implement their obligations under the Protocol, and urges those Parties that have duly completed the development of their national biosafety frameworks to take measures necessary to make these frameworks effective; para. 3: Calls upon Parties to allocate the resources necessary to make the frameworks operational; para. 5: Invites Parties and other Governments with a well developed and functional biosafety framework or system to cooperate and share their practical experiences with those Parties that have a demand in this regard; para. 15: Elects/re-elects...as members of the Compliance Committee to replace those who resigned and those whose term will end by 31 December 2006. See UNEP/CBD/BS/COP-MOP/3/2/Add.1, *op. cit.*.

²²² Section VII: *Review of the procedures and mechanisms*, Decision BS-I/7: *Establishment of the procedures and mechanisms on compliance under the Cartagena Protocol on Biosafety*: "The Conference of the Parties as the meeting of the Parties to the Protocol shall, at its third meeting and thereafter, in line with article 35 of the Protocol review the effectiveness of these procedures and mechanisms, address repeated cases of non-compliance and take appropriate action."

²²³ UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 14, 65.

²²⁴ Decision BS-III/, *Compliance*, in UNEP/CBB/COP-MOP/3/15, *op. cit.*, 33.

²²⁵ UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 14.

c) Other Issues

In the previous sections, some elements of the Protocol have been reviewed in a detailed manner. We shall proceed now with a more general analysis of some selected elements.

First, with regards to *capacity-building*, the delegates started from the principle that it is necessary for all Parties to the Protocol to have the capacity to execute their dispositions, to possess the capacity of understanding the potential effects of an LMO on their biological diversity and to take the appropriate decisions on the import.²²⁶

As a consequence, the COP-MOP pointed out the necessity to assure the existence of financial resources to guarantee an appropriate capacity to all Parties, including training and infrastructures. Furthermore, it stressed the necessity to increase the South-South and North-South cooperation, as well as to intensify the cooperation at national and regional levels. The Secretary presented a report relative to the progress observed in connection with the implementation of the *Plan of Action of Creation of Capacities*.²²⁷ The report stated that it was necessary to establish and execute national regulatory rules.

Regarding the position of developing countries concerning biotechnology, its defenders are of the opinion that it offers certain benefits for the economies of these countries, once they understand that it allows to increase the production in a sustainable way, an efficient use of the natural resources, increases in the productivity of crops, and contributing to eradicate hunger. The Food and Agriculture Organization of the United Nations (FAO), however, in its Reports on the evaluation of transgenic crops, is more cautious: in *The State of Food and Agriculture* of 2004 and in *The State of Food Insecurity in the World-2005*, it notes that there are few research programs of the public or the private sector dedicated to the problems of the developing countries, in spite of intensive research and large investments in biotechnology. Furthermore, there is not much research available on agricultural products whose characteristics would be of interest to poor countries.²²⁸

FAO Director Dr. Jacques Diouf requested new investments in research, education and technical assistance for the developing world: "*The developing*

²²⁶ At present, this is a complex task for most of the developing countries because biotechnology is a new and unknown field for them. In addition, their lack of infrastructure and technical capacity that prevents them from controlling LMOs importations (Glass 2001, 508).

²²⁷ UNEP/CBD/BS/COP-MOP/3/4, 28 February 2006: *Status of Capacity-Building Activities: Report on the progress in, and effectiveness of, the implementation of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety*, and Doc. UNEP/CBD/BS/COP-MOP/3/4/Add.1, 31 January 2006: *Status of Capacity-Building Activities (Addendum): Draft updated Action Plan for building capacities for the effective implementation of the Cartagena Protocol on Biosafety*. The Plan of Action consists of a key element at the moment of achieving a solution of the situations provoked by a lack of human, technical and financial resources in several States that an effective implementation of the protocol prevents them from carrying out (Falkner and Gupta 2004, 9-10).

²²⁸ *The State of Food Insecurity in the World 2005* <http://www.fao.org/docrep/008/a0200e00.htm> , *The State of Food and Agriculture 2000*, Rome, 2000, available at: <http://www.fao.org/docrep/x4400e/x4400e00.htm> . FAO helps countries to make progress toward the World Food Summit (WFS) goal of reducing the number of the hungry by half by 2015. It also works toward the *Millennium Development Goals*.

*countries need help, not only in laboratory techniques and knowledge, to carry out field tests of genetically modified crops, and other derived products.*²²⁹

We may conclude, as Simonetta Zarrilli points out, that the developing countries can benefit from biotechnology applied to agriculture, but only if certain minimum conditions are respected: first, the biotech products should not damage human health and the environment; second, these products should become available at reasonable prices; and third, biotechnology should be applied to eradicate nutrition problems and poverty. Nevertheless, at the present time, the private sector is patenting practically all its research, which may result, in the near future, in great damage to farmers in developing countries.²³⁰

The COP-MOP 3 decisions include the following points: adopting an updated version of the *Action Plan for Building Capacities*; requesting the Executive Secretary to prepare a synthesis report for COP-MOP 4 to undertake a comprehensive review of the Action Plan; inviting developing country Parties and Parties with economies in transition to coordinate and harmonize biosafety frameworks at the regional and sub-regional level; urging countries to integrate biosafety in sustainable development strategies.²³¹

Second, in the final decision, the COP-MOP requested the CBD Executive Secretary to expand the compilation of available guidance documents on *risk assessment and risk management* contained in the Biosafety Information Resource Centre of the Biosafety Clearing-House (BCH). Also, it invited governments and organizations to provide the BCH with additional links to relevant databases and information sources. The COP-MOP decided to consider the need for further guidance and the appropriate modalities for development of any such guidance at COP-MOP 4.²³²

Third, *the negotiations on the establishment of a process to evaluate and to revise the execution of the Protocol* were carried out in Working Group II based on a Note by the Executive Secretary in this sense.²³³ In this Note it was emphasized that a medium-term work program had been adopted by the Parties in Decision BS-I/12; the program envisaged the initiation of a process of review and assessment at the third meeting. The Executive Secretary was requested to prepare a report that compiles the submissions presented by the Parties relative to difficulties incurred when executing the provisions of the Protocol.²³⁴

²²⁹ Statement presented at the International Conference *Seed modified genetically, why not?*, organized by the Royal Swedish Academy of Agriculture and Forestry, Stockholm, May 14, 2001. FAO's official press statements 001/31. From the analysis of the available data and in spite the existence of claims to the contrary, we can conclude that LMOs are not being used, at present, to the benefit of humanity and the less favored, but they primarily benefit a small number of multinational companies. These are generating relationships of economic and social dependence for the farmers. This type of risks should be taken in consideration urgently in order to avoid a worsening of rural poverty which will be very difficult to reverse once GM crops have become widespread.

²³⁰ Zarrilli 2000, 545.

²³¹ Decision BS-III/3: *Capacity-Building*, in UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 36-38. See also: Annex to Decision BS-III/3: *Updated creation Plan for Building Capacities for the effective implementation of the Biosafety Protocol*, in UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 38-42.

²³² Decision BS-III/1: *Risk assessment and risk management*, UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, p. 63-65.

²³³ UNEP/CBD/BS/COP-MOP/3/13, 9 January 2006, *Assessment and Review (Article 35): Initiating a process of evaluation of the effectiveness of the Protocol*.

²³⁴ Decision BS-III/15: *Assessment and review*; UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 85.

Fourth, in relation to the *subsidiary bodies*, the discussions took place in Work Group I: the Secretary introduced a Note on subsidiary bodies and documents²³⁵, which was a compilation of views submitted by Parties and other governments on the need for subsidiary bodies to address scientific issues including risks assessment and risk management. Later on, the president of Working Group I, Mr. Ivars, introduced a decision draft on the matter. Some Parties were in favor of the establishment of a scientific subsidiary organ. Others considered the possibility of relying on the CBD Subsidiary Body on Scientific, Technical and Technological Advice, while still others considered it more important to concentrate efforts on capacity building.²³⁶

In the Decision, the COP-MOP pointed out that there are several mechanisms through which recommendations or scientific and technical advice can be provided to the COP-MOP. The COP-MOP also requested the Executive Secretary to prepare, for COP-MOP 4, a review of the results of the Ad Hoc Open-Ended Working Group on the Review of the Implementation of the Convention, and any decisions adopted by the CBD COP 8 relative to the revision of existing processes according the Convention. It was considered appropriate to review the estimated costs for a potential mechanisms for the provision of scientific and technical advice.²³⁷

Fifth and last, relative to the *Cooperation with other organizations*, the COP-MOP highlighted the importance of strengthening common objectives, and to increase efforts in the creation of capacities. Regarding this last point, it expressed concerns about the emergence of potential conflicts in the concurrent implementation of the WTO Agreements and the Biosafety Protocol. In light of the fact that - in spite of its requests - the CBD has still not been guaranteed an observer status in the SPS and TBT Committees of the WTO, it was decided to increase efforts to achieve such a status.²³⁸

²³⁵ Decision BS-III/13: *Subsidiary bodies (article 30)*, UNEP/CBD/BS/COP-MOP/3/11, 16 January 2006, *op. cit.*, 67.

²³⁶ The Conference of the Parties serving as the meeting of the Parties to the Protocol, in this medium-term programme of work adopted in Decision BS-I/12, had decided to consider subsidiary bodies at its third meeting. Furthermore, in its Decision BS-I/11 on other issues, it had decided to consider the need for designating or establishing a permanent subsidiary body that provided it with advice on scientific and technical issues arising in relation to the implementation of the Protocol.

²³⁷ UNEP/CBD/COP-MOP/3/15, *op. cit.*, BS-III/13: *Subsidiary bodies*, 67.

²³⁸ In this respect, on 29 May 2006, Pascal Lamy –WTO’s Director-General - met in Geneva with the Convention on Biological Diversity’s Executive Secretary, Mr. Ahmed Djoghlaflaf, to discuss how the two organizations may work together to fulfill their mandates, achieve sustainable development and be mutually supportive. This first-ever meeting of the WTO Director-General and CBD Executive Secretary opened up new avenues of collaboration. See Decision BS-III/6: *Cooperation*, UNEP/CBD/BS/COP-MOP/3/15, *op. cit.*, 47.

C) CONCLUSIONS

Looking at the brief history of the Biosafety Protocol we can conclude that the COP-MOP 3 represents a significant progress in the international regulation of biotechnology, although one of its key objectives, i.e. adopting a final decision on detailed requirements regarding how to identify and to document LMO-FFP exports, was met only partially for the time being.

The entry into force of the Protocol has by no means eliminated the potential emergence of future problems.²³⁹ Nevertheless, it can be said that the Cartagena Protocol, in its present state, already represents a remarkable success in the codification and progressive development of the international regulation of trade in genetically modified food because it improves the legal certainty of the trading nations.

Since the main aim of the Protocol is to avoid as much as possible the potential adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health, and focusing on the movements of these kinds of organisms, particular emphasis must be placed on the identification and labeling requirements. This way, the international community can be ascertained that trans-boundary movements are accompanied by the necessary documents based on the acquisition of the pertinent shipping details from the responsible individuals and institutions. This requirement is an important element when giving to the importing country some security at the moment of taking decisions regarding the permission to import a shipment, allowing it to be clearly and accurately informed about when it will receive it. On this question, the agreement achieved in COP-MOP 3 on Art. 18.2(a) represents a step forward that could in fact have been more important if the biotechnological industry and trade interests of some exporting countries had not blocked the achievement of a better protection of the developing countries that lack adequate internal regulations, and also of biological diversity as such.

With respect to this last point, the most interested Parties in elaborating minimal international specifications on documents are primarily the countries that have not yet implemented internal legislations on LMOs labeling. These countries are trying to make sure that the absence of such regulations does not turn them into *testing grounds* of LMOs previously rejected in other countries for not fulfilling the minimal conditions stipulated in their own laws.

For this reason, COP-MOP 3 made an appeal to the Parties who do not have yet an adequate internal legal and administrative framework to make an effort to create one and, in this way, to effectively comply with the obligations as they are foreseen in the Protocol. This means that in most cases the failure to comply with some of the security measures included in the Protocol by the Parties is not due to their lack of willingness and commitment, but to their lack of available means and resources. To correct this situation, COP-MOP 3 emphasized that the developed countries should give financial resources and share practical experiences with the economically less advanced ones with the aim to create the required capacities. It is

²³⁹ See for instance *Grain*, 2003, *Blinded by the gene*, Seedling, July 2003. www.grain.org/seedling/?id=239 and *Grain* 2004, *Confronting contamination. 5 reasons to reject co-existence*, Seedling, April, 2004. www.grain.org/seedling?id=280.

a necessary way for the “*machinery*” of the Protocol to work effectively in the near future.

As far as the decisions adopted by COP-MOP 3 are concerned, some of them deserve to be highlighted, since they have an important implication in the production, as well as in the trade and exportation of LMOs. To achieve these results, the Parties made important mutual concessions to obtain a consensus that, more or less, could satisfy all Parties and avoid finishing COP-MOP 3 “*empty-handed*”. In most instances, however, the decision was taken to defer certain points to later negotiations. The various Working Groups and Committees have been mandated with assembling information about practical experiences by the Parties for a consideration in COP-MOP 4.

The most difficult problem, perhaps, consists in the fact that the most important GMO exporting countries have not yet ratified or not even signed the Protocol (only Parties of the CBD can sign or ratify a protocol to the convention). This is an obstacle for the Parties in taking strong and binding decisions on implementation. The key to overcome this adverse situation lies in trying to find a balance between the desire of making a more strict and precise Protocol and the necessity of encouraging some of the most important LMO exporters to ratify the Protocol.

Basically, the main LMO exporting countries have an interest in taking part directly in the transformation and evolution of the Protocol, and in having a more effective participation with a view of defending their interests. In view of the blockages that have taken place in the COP-MOPs, it is a great challenge to try to entice these non-Parties towards ratification. This is crucial nevertheless to achieve firm, binding and implemented decisions on the requirements of identification, responsibility and compensation. The non-Parties will have to choose between adhering to the Protocol, despite not agreeing to some aspects of it, and so being able to influence directly its later evolution, or else to stay on the sidelines for an important period of time. In the meantime, they are limited to exerting an indirect influence through the lobbying and pressuring of certain like-minded Parties or Parties whom they manage to influence accordingly.

In addition to the environmental impact of LMOs, their economic, social and ethical effects needs to be taken into consideration by the international community. Given GM agriculture’s enormous economic potential in the international markets, it is not surprising that the questions of access to genetic resources and of sharing their economic benefits in most cases strongly polarizes the industrialized and the developing countries’ negotiation positions. This cleavage has been aggravated over the past few years by a quickly developing monopolization and control of the market through a small group of multinational corporations and interconnected distribution networks.²⁴⁰ This dynamics has undoubtedly increased prevailing inequities between developed and developing countries, since the latter have difficulties in gaining access to (increasingly patented!) new technologies and germplasm, and in introducing their products in Northern markets. For all these reasons, the key concern for many developing countries lies in the impact of these agricultural techniques on their often extreme levels of rural poverty. Last but not least, however, they are in many cases also very much concerned about damaging their export potential, especially on the European markets, which so far have been highly recalcitrant to accepting GM food on their supermarket shelves.

²⁴⁰ Matringe and Moretti 2006

The developing countries will only be able to benefit from these applications of biotechnology to farming if they manage to exert a sufficient measure of control over it. Under these circumstances, biotechnology may make a contribution in solving the problems of hunger and underdevelopment. Unfortunately, in spite of good intentions, the market-driven dynamics governing international trade yield the opposite result. Furthermore, economical and social dependency relations are being developed which are detrimental for the poor farmers. It should be noted in this context that a large number people in many countries unfortunately are still affected by alimentary food emergencies.²⁴¹

In order to feed a more and more numerous global population, it is evident that agriculture has to produce more food, but it is also true that this increase must be accompanied by better distribution patterns. This is why, in achieving this aim, biotechnology has “two faces”: on one side, it is presented, by its proponents, as a real guarantee of future benefits. On the other side, its critics point out, it can also become a destructive force regarding the world’s biodiversity, thus endangering global food security.

To conclude, the effectiveness and operationability of the Protocol will depend on the principles, regulations and guidelines in the Protocol itself, on the decisions of the COP-MOPs, and on how the related regulatory frameworks are applied domestically. The progress achieved at the COP-MOP 3 in the implementation of the Cartagena Protocol, as the primary mechanism to guide international cooperation to prevent and manage possible environmental risks from LMOs, has been widely recognized. Last but not least one should mention that related important work is also being carried out under the auspices of other intergovernmental organizations, such as especially the FAO/WHO Codex Alimentarius or the FAO’s International Plant Protection Convention.

²⁴¹ FAO *Hunger Map*. <http://www.fao.org/es/ess/faostat/foodsecurity/FSMap/map14.htm>; and *The State of Food Insecurity in the World 2006. Eradicating World Hunger -- Taking Stock Ten Years after the World Food Summit*: <http://www.fao.org/docrep/009/a0750e/a0750e00.htm>

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- www.cfsan.fda.gov (U.S. Food and Drug Administration)
- www.cibogem.gob.mx (Comisión Intersecretarial de Bioseguridad y Organismos Genéticamente Modificados de Méjico)
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**RISK COMMUNICATION, NOTIFICATION PROCEDURES,
AND INFORMING THE PUBLIC
IN MULTILATERAL ENVIRONMENTAL AGREEMENTS**

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Abstract

This article endeavors to shed some light on a specific aspect of the trade and environment domain, namely risk communication. Risk analysis in the context of international trade is defined authoritatively by the Codex Alimentarius as “a process consisting of three components: risk assessment, risk management and risk communication.” The Public International Law and the Trade Law literatures are rich with analyses of the treatment of several aspects of risk, such as the role of science, risk assessment, risk management, and on the closely related issue of the role of precaution under WTO law. The issue of risk communication, however, has not received the attention it merits. We are attempting here to provide a policy and law framework of risk communication which is relevant primarily in the context of the relationship between multilateral environmental agreements and WTO law. A certain emphasis is put on the Cartagena Protocol on Biosafety and the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters because both are at the forefront in the introduction of detailed innovative procedures for informing governments and other stakeholders about potential risks which may be caused through certain environment-related activities. With this objective, we are putting particular attention on exploring notification procedures and related anticipatory and preventive provisions because they are at the heart of the international community’s strenuous efforts in coming to terms with the exceedingly complex issue of risk analysis through international, regional or global and in most cases consensus-based negotiations. We conclude by observing a gradual opening of some intergovernmental dispute settlement mechanisms toward improved access to non-governmental input, which makes a good understanding of the dynamics of risk communication more important than ever.

1. Introduction

The literature on trade and environment issues has come a long way since Steve Charnovitz presented the first rigorous overview of the then fledgling issue area in 1992.²⁴² Inspired by Charnovitz's innovative research, we shall attempt here in a similar spirit to "examine the issues" related to a sub-domain of the trade and environment studies, namely risk communication. Risk analysis in the context of international trade is defined authoritatively by the intergovernmental institution which provides the most detailed multilaterally negotiated definitions regarding the interface of food safety and international trade as follows:

Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication.²⁴³

The notion of risk represents an exceedingly complex challenge to Public International Law and Trade Law.²⁴⁴ There is a considerable amount of literature on the treatment of several aspects of risk, such as the role of science,²⁴⁵ risk assessment,²⁴⁶ or risk management,²⁴⁷ as well as on the highly dynamic and iterative relationship between these two,²⁴⁸ and on the closely related issue of the role of precaution under WTO law.²⁴⁹ More recently, an in-depth investigation has been carried out into a new and important aspect of this problematic, namely the anticipation of risk.²⁵⁰ Last but not least, the 'Trade & Environment Group' at the Law

²⁴² Charnovitz, Steve. 1992. GATT and the Environment: Examining the Issues. *International Environmental Affairs* 4 (3) Summer: 203-234.

²⁴³ Codex Alimentarius Procedures Manual, 16th ed. 2006, 43.
ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_16e.pdf

²⁴⁴ See e.g. Christine Noiville. 2003. Du bon gouvernement des risques. Paris : Presses universitaires de France – Les voies du droit, 235 p.

²⁴⁵ See e.g. Christoforou, Theofanis. 2004. The Precautionary Principle, Risk Assessment, and the Comparative Role of Science in the Enary Principle, Risk Assessment, and the Comparative Role of Science in thC and the US Legal Systems. In *Green Giants, Environmental Policies of the US and the EU*, edited by Norman J. Vig and Michael G. Faure, 17-52. MIT Press, Cambridge, MA. Theofanis Christoforou. 2003. L'expertise scientifique au service du commerce international: analyses et perspectives. In *Droit de l'Organisation Mondiale du Commerce et protection de l'environnement*, sous la direction de Sandrine Maljean-Dubois, 461-485. Aix-en-Provence et Bruxelles: CERIC et Bruylant.

²⁴⁶ See e.g. Christoforou, Theofanis. 2003. The Precautioe European Community and the United States. In *Green Giants? Environmental Policies of the United States and the European Union*, edited by N. Vig and M. Faure. Cambridge, MA: MIT Press.

²⁴⁷ See e.g. Cottier, Thomas. 2001. Risk Management Experience in WTO Dispute Settlement. In *Globalization and the Environment – Risk Assessment and the WTO*, edited by David Robertson and Aynsley Kellow, 41-63. Cheltenham, UK and Northampton, Mass.: Edward Elgar Publ.

²⁴⁸ Christine Noiville et Nicolas de Sadeleer. 2001. La gestion des risques écologiques et sanitaires à l'épreuve des chiffres - le droit entre enjeux scientifiques et politiques. *Revue du Droit de l'Union Européen* 2: 389-450.

²⁴⁹ Gabrielle Marceau. 2005. Le principe de précaution dans la jurisprudence de l'OMC - Leçon inaugurale, Université de Genève, Faculté de droit. *EcoLomic Policy and Law* 2 (3): 1-20.

http://www.ecolomics-international.org/ecolomic_policy_and_law.htm

²⁵⁰ Makane Moïse Mbengue. 2007. "L'anticipation du risque environnemental et sanitaire : essai sur une théorie du risque en droit international". PhD thesis in Public International Law, defended at the Faculty of Law of the University of Geneva on June 6, 2007.

Faculty of the University of Geneva has reviewed the relationship between risk assessment, risk management and risk communication in the wider context of multilateral environmental agreements (MEAs) and the trading system in the opening chapter of the present *Special Edition*.²⁵¹

Coming back to the Codex Alimentarius' definition of risk communication, we note that the issue of risk communication has largely been overlooked in the Public International Law literature. This article aims at providing a policy and law framework of risk communication which is relevant primarily in the context of the relationship between MEAs, especially those which address important issues related to science or scientific evidence, the Codex Alimentarius, whose mandate of ensuring food safety in the international trade of food, beverage and feed products is inherently science-oriented, and WTO law. We shall focus here on the identification of those rules and other provisions of public international law which are applicable or which are likely to be applied in the process of risk communication. For this we are putting particular emphasis on the Cartagena Protocol on Biosafety to the Convention on Biological Diversity because it may be considered as a pioneering and particularly detailed model for those MEAs for which risk communication is an essential issue.²⁵² Provisions spelling out such rules constitute the foundation of the Biosafety Protocol. It contains a very detailed procedure called Advanced Informed Agreement (AIA).²⁵³

The AIA procedure spells out the modalities of risk communication that states have to apply if they wish to export or import living modified organisms (LMOs)²⁵⁴ that the importer intends to use for planting.²⁵⁵ AIA procedures are often called Prior Informed Consent (PIC) procedures and represent some of the most stringent provisions in intergovernmental information systems related to the analysis of risk through officially negotiated and established institutions, channels and procedures. The PIC procedures in fact have been used for naming a convention, namely the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.²⁵⁶ Another MEA of particular importance for risk communication in a more comprehensive sense is the so-called Aarhus Convention²⁵⁷ which was adopted in 1998 in Aarhus, Denmark. The PIC or AIA procedures as the strictest and most elaborate form of intergovernmental notification procedures are in the process of being fine-tuned through ongoing negotiations. Notification procedures as such are the most traditional and legally well established element of the more innovative concept of risk communication.

²⁵¹ Anne Petitpierre, Laurence Boisson de Chazournes, Makane Moïse Mbengue and Urs P. Thomas. 2006. Introduction to the Special Issue: WTO Law, Science and Risk Communication. SNSF Research Project 2nd Phase 2004-2006. *EcoLomic Policy and Law* 3 (1/2) 1-52. http://www.ecolomics-international.org/ecolomic_policy_and_law.htm

²⁵² For information on the Cartagena Protocol please consult the Website of its Secretariat at <http://www.cbd.int/biosafety/default.shtml>

²⁵³ Biosafety Protocol Art. 7: Application of the Advance informed Agreement Procedure.

²⁵⁴ Unprocessed, i.e. reproducible GM food products such as raw fruit or seeds are included in this term which also extends to non-food GM organisms like trees.

²⁵⁵ The Protocol uses the term « intentional introduction into the environment » Art. 7.

²⁵⁶ Explanations on the Convention are available at

<http://www.pic.int/home.php?type=t&id=5&sid=16>

The text of the Convention is available at <http://www.pic.int/en/ConventionText/ONU-GB.pdf>

²⁵⁷ Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, available at <http://www.unece.org/env/pp/documents/cep43e.pdf>.

As far as the Biosafety Protocol is concerned, it should be emphasized that those LMOs which are intended not for planting but directly for consumption by humans or animals - or for processing – are subject to a considerably less severe procedure.²⁵⁸ The trade volume in these GM food crops and other products, including for instance biofuels, is obviously immeasurably larger than that which is intended for planting, a fact which had an enormous impact on the negotiation and the conclusion of the Protocol.²⁵⁹ Not only in the AIA procedure, here too, risk communication represents an important component of the international regulations under the Cartagena Protocol. Thus, Parties to the Protocol are obliged to notify the Secretariat's Biosafety Clearing-House as well as other relevant international organizations and potentially affected states, if this appears appropriate, of any incident causing a risk that may require such communications. Specifically, such communications are required

...when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States.²⁶⁰

A key element of the strength of the Biosafety Protocol consists in the explicit importance given to information sharing through its Biosafety Clearing-House (BCH). This Internet-based body represents the heart of the communication aspects of the Protocol at the center of the trade and environment interface. Furthermore, the Protocol spells out the importance of the BCH and mandates it to:

1. 1. (...) (a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms (...)
2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.
3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information

²⁵⁸ Biosafety Protocol Art. 11: Procedure for LMOs intended for Direct Use as Food or Feed, or for Processing (this decision procedure is usually abbreviated as LMO-FFP).

²⁵⁹ For authoritative analyses of the Cartagena Protocol see Christoph Bail, Robert Falkner and Helen Marquard, eds. 2002. *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?* London: Earthscan/RIIA, 579 p.

Mackenzie Ruth et al. 2003. *An Explanatory Guide to the Cartagena Protocol on Biosafety*. IUCN Environmental Policy and Law Paper No. 46. Gland/Geneva: IUCN, Field, WRI. 294 p.
<http://www.iucn.org/themes/law/pdfdocuments/Biosafety-guide.pdf>

See also for an analysis of the Protocol's wider context: Badr Zerhdoud. 2005. Le Régime juridique international des biotechnologies: entre libre-échange et protection de l'environnement.

EcoLomic Policy and Law 2 (5/6), 64 p. http://www.ecolomics-international.org/ecolomic_policy_and_law.htm

A detailed analysis of the Cartagena Protocol's recent third Meeting of the Parties (COP-MOP 3), Curitiba, 2006) is provided by Mireia Martinez Barrabez in the present *Special Edition* at http://www.ecolomics-international.org/ecolomic_policy_and_law.htm

²⁶⁰ Biosafety Protocol Art. 17.1.: Unintentional Transboundary Movements and Emergency Measures.

required to be made available to the Biosafety Clearing-House under this Protocol (...).²⁶¹

To conclude, we should mention that the scope of application of risk communication is essentially limited in the Protocol to the 'horizontal' level, i.e. to communications among states, contrary to risk communications with any other stakeholders or the public at large which are not really taken into consideration except in a rather hortatory and vague sense through its encouragement and endorsement of public awareness and participation regarding LMOs,²⁶² as long as the confidentiality of the information in question is respected.²⁶³

After these introductory considerations we shall now attempt to establish a classification of the rules which exist under Public International Law with regard to risk communication. We have found that they can be divided into three categories, two of which precede the actual communication of risk, and one which provides a conceptual underpinning: (1) intergovernmental notification; (2) information of the public and risk communication; (3) the role of *ongoing monitoring* as an underpinning of risk communication.

2. The Three Components of the Risk Communication Framework

2.1. Notification Procedures and Risk Communication

Notification is the most common risk communication technique used at the intergovernmental level with a long tradition in Public International Law. One might call this the "information of the state" which is the counterpart to the "information of the public." If a risk assessment process indicates a cross-boundary risk of damage, then the state at the origin of this activity must give notification of the risk and of its evaluation to the state which could be affected. Furthermore, it must communicate the technical details and all other relevant content that is available and on which the evaluation is based upon.

Public International Law is based on the principle that the technical information deriving from a risk assessment includes not only what might be called the bare facts, i.e. technical measurements, statistics etc. but also their analysis as it is done and used by the country of origin for its own purposes with regard to transboundary risk assessment. Furthermore, the concept of 'available information' which is used in some international instruments must include also information which may become available at a later date, i.e. after the initially available analysis has been communicated to the states that might be affected by a certain risk. Generally speaking, international law requires that the state from which an activity originates is obliged to notify those states which may be affected by such an activity. These activities include both activities undertaken by the state and by private entities. The obligation to notify is a prerequisite for any system which aims to prevent cross-boundary damages or at least to reduce such risks to the minimum.

International instruments tend not to mention or emphasize the notion of "risk;" rather, risk is implied implicitly via projects which may be of a risky nature. Thus they often use terms such as "activities which may create a risk" or "planned measures."

²⁶¹ *Ib.* Art. 20

²⁶² Biosafety Protocol Art. 23: Public Awareness and Participation.

²⁶³ Biosafety Protocol Art. 21: Confidential Information

For instance the Revised Protocol on Shared Watercourses of the Southern African Development Community (SADC), adopted in Windhoek, Namibia, in 2000 goes to great length in explaining the meaning of the term and the ramifications of *Planned Measures*.²⁶⁴

This tendency, however, does not really affect the prior notification of risk. What matters is that a country does provide an advance warning, with adequate timing, to other countries which might be affected or concerned if it plans to undertake a dangerous activity or to authorize the use of dangerous substances. It must not violate the principle of customary law *sic utere tuo ut alienum non laedas*, i.e. it must not damage the environment of another country or areas beyond the limits of national jurisdiction through the use of its own resources.²⁶⁵

This obligation to inform or to notify other states of the risk of damages to which they are exposed has been recognized in the judgment of the International Court of Justice concerning the *Corfu Channel Case*.²⁶⁶ In this historically important case the ICJ has ruled that the obligation to notify, i.e. to communicate a risk which may or may not be known is based on elementary humanitarian considerations. Many years later, OECD provided a historically important impetus for the elaboration of environmental notification procedures in Public International Law in 1974 with its *Recommendation of the Council on Principles concerning Transfrontier Pollution*.²⁶⁷ It calls among other requirements for the application of the Polluter-Pays-Principle and for intergovernmental consultation before the commencement of construction projects which may represent a risk of cross-boundary pollution.^{268 269} A few years later, OECD again provided a significant contribution to the strengthening of notification procedures. The OECD Council, in its 1984 *Recommendation of the Council concerning Information Exchange related to Export of Banned or Severely Restricted Chemicals* prepared a set of guidelines for notifications with the aim of protecting 'man and the environment,'²⁷⁰ and in 1986 it added economic and commercial considerations to be taken into consideration.²⁷¹

²⁶⁴ Article 4 Specific Provisions. 1. Planned Measures, para. a) – h) with numerous sub-sections, see http://www.sadc.int/english/documents/legal/protocols/shared_watercourse_revised.php

²⁶⁵ Principle 2 of the 1992 Rio Declaration on Environment and Development stipulates : States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction. <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>

²⁶⁶ Quincy Wright, 1949. The Corfu Channel Case. *The American Journal of International Law*, Vol. 43, No. 3, pp. 491-494.

²⁶⁷ <http://www.fao.org/docrep/005/W9549E/w9549e06.htm>

²⁶⁸ E) The Principle of information and consultation

6. Prior to the initiation in a country of works or undertakings which might create a significant risk of transfrontier pollution, this country should provide early information to other countries which are or may be affected. It should provide these countries with relevant information and data, the transmission of which is not prohibited by legislative provisions or prescriptions or applicable international conventions, and should invite their comments.

<http://www.fao.org/docrep/005/W9549E/w9549e06.htm>

²⁶⁹ This provision has been incorporated much later by FAO in its 1998 volume on *Sources of International Water Law* (reprinted in 2001), available at <http://www.fao.org/docrep/005/W9549E/w9549e00.HTM>

²⁷⁰ [http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C\(84\)37](http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C(84)37)

²⁷¹ OCDE, *L'OCDE et l'environnement*, Paris, 1986, p. 89, par. 4 de l'annexe.

The principle of notification has been recognized also in other domains with transboundary effects. A particularly explicit and interesting example is contained in the 1991 Convention on Environmental Impact Assessment in a Transboundary Context (the UNECE Espoo EIA Convention, adopted in Helsinki on 25 February, 1991). Art. 3 on Notification stipulates in para. 2 the procedure to apply.²⁷² It then goes a step further and describes the steps to be followed in cases where a Party has not been notified but considers that there is a need for such a procedure:

When a Party considers that it would be affected by a significant adverse transboundary impact of a proposed activity listed in Appendix I, and when no notification has taken place in accordance with paragraph 1 of this Article, the concerned Parties shall, at the request of the affected Party, exchange sufficient information for the purposes of holding discussions on whether there is likely to be a significant adverse transboundary impact. If those Parties agree that there is likely to be a significant adverse transboundary impact, the provisions of this Convention shall apply accordingly. If those Parties cannot agree whether there is likely to be a significant adverse transboundary impact, any such Party may submit that question to an inquiry commission in accordance with the provisions of Appendix IV to advise on the likelihood of significant adverse transboundary impact, unless they agree on another method of settling this question.²⁷³

In a related context a short time later, the Convention on the Transboundary Effects of Industrial Accidents (Helsinki, 17 March, 1992)²⁷⁴ spells out the specifics of the procedures of the *Industrial Accidents Notification System*.²⁷⁵ The adoption of the innovative notification procedures contained in these two Conventions was followed immediately by another milestone of Public International Law. The 1992 UN Conference on Environment and Development in Rio de Janeiro supported and gave additional weight to these achievements by confirming the globally applicable right of

²⁷² “This notification shall contain, inter alia: (a) Information on the proposed activity, including any available information on its possible transboundary impact; (b) The nature of the possible decision; and (c) An indication of a reasonable time within which a response under paragraph 3 of this Article is required, taking into account the nature of the proposed activity; and may include the information set out in paragraph 5 of this Article.”

The text of the Espoo EIA Convention is available at

<http://www.unece.org/env/eia/documents/conventiontextenglish.pdf>

²⁷³ *Ibid.* Art. 3, para. 7.

²⁷⁴ The text of the Convention on the Transboundary Effects of Industrial Accidents is available at

<http://sedac.ciesin.org/entri/texts/industrial.accidents.1992.html>

²⁷⁵ Article 10

Industrial Accident Notification Systems

1. The Parties shall, with the aim of obtaining and transmitting industrial accident notifications containing

information needed to counteract transboundary effects, provide for the establishment and operation of compatible and efficient industrial accident notification systems at appropriate levels.

2. In the event of an industrial accident, or imminent threat thereof, which causes or is capable of causing transboundary effects, the Party of origin shall ensure that affected Parties are, without delay, notified at appropriate levels through the industrial accident notification systems. Such notification shall include the elements contained in Annex IX hereto.

3. The Parties concerned shall ensure that, in the event of an industrial accident or imminent threat thereof, the contingency plans prepared in accordance with Article 8 are activated as soon as possible and to the extent appropriate to the circumstances.

states to be notified on activities which may cause significant adverse transboundary environmental effects in Principle 19 of its Rio Declaration:

States shall provide prior and timely notification and relevant information to potentially affected States on activities that may have a significant adverse transboundary environmental effect and shall consult with those States at an early stage and in good faith.²⁷⁶

Countries are free to decide how their neighbors are to be informed in order to fulfill these obligations. In general they communicate directly among themselves through diplomatic channels. In some cases it may happen that the country of origin of a given activity – in spite of its efforts and diligence – has not been able to anticipate the impact of an activity on other countries before commencing it. In such cases it has to catch up with its obligation to notify as soon as it becomes aware of such risks and has determined which other countries may be affected by this activity. A key purpose of risk communication in the framework of notification procedures consists in making it possible for an affected country to respond to the country of origin of the activity within a reasonable period of time. This time period may, for instance in the case of the Cartagena Protocol, amount to six to nine months depending on the specifics of the procedural steps. To take another example of notification deadlines, the above-mentioned SADC Revised Protocol on Shared Watercourses provides for a period of six months which may be extended by another six months in case this should not be adequate.²⁷⁷ Generally speaking, this delay should allow a country that might be affected by detrimental consequences to draw its own conclusions, and it is based on the assumption of good cooperation and good faith.

2.2. Informing the Public and the Question of Risk Communication

We can presently see the emergence of some new tendencies in Public International Law in general, and in international environmental law in particular. These tendencies tend to bring into the decision-making process those stakeholders whose life, health, property and environment are potentially affected by a certain risk. This is done by giving them the opportunity to express their point of view, and to be heard by the authorities who will make the final decision. It is particularly in the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters²⁷⁸ that we can see detailed provisions empowering the stakeholders facing environmental risks. The Aarhus Convention finds its roots in

²⁷⁶ <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>

²⁷⁷ Art. 4 Specific Provisions. (c) Period for reply to notification.

(i) Unless otherwise agreed, a State Party providing a notification under paragraph (b) shall allow the notified States a period of six months within which to study and evaluate the possible effects of the planned measures and to communicate the findings to it;

(ii) This period shall, at the request of a notified State for which the evaluation of the planned measures poses difficulty, be extended for a period of six months.

Available at

http://www.sadc.int/english/documents/legal/protocols/shared_watercourse_revised.php

²⁷⁸ The Aarhus Convention was adopted at Aarhus, Denmark, on 25 June 1998, the text is available at <http://www.unece.org/env/pp/documents/cep43e.pdf>

Principle 10 of the 1992 Rio Declaration on Environment and Development, of which it represents the realization in legal terms:

Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.²⁷⁹

Several MEAs contain provisions on the need to inform the public. For instance the Espoo Convention on Environmental Impact Assessment (EIA) in a Transboundary Context, adopted in Espoo, Finland in 1991,²⁸⁰ states in Art. 3 (8):

The concerned Parties shall ensure that the public of the affected Party in the areas likely to be affected be informed of, and be provided with possibilities for making comments or objections on, the proposed activity, and for the transmittal of these comments or objections to the competent authority of the Party of origin, either directly to this authority or, where appropriate, through the Party of origin.²⁸¹

In a similar vein, the UN Framework Convention on Climate Change dedicates its Art. 6 to “Education, Training and Public Awareness.”²⁸² Thus, Public International Law requires more and more that states, to the extent possible, provide information to their public and to the public of other states which may be affected on the risk of their activities, and on the damage which may result as a consequence. This process of risk communication has two fundamental components. First of all, states must inform the “public” of an activity it considers, of the risk that it engenders, and of the damage which might be caused. Furthermore, states must gather and take into consideration the opinion of the public.

It should be noted here that we are still at an early stage of negotiating agreements on risk communication which leaves important conceptual clarifications for a later date. For instance, what channels of communication are to be used for this process? Is it sufficient if the scientists of ministries and governmental institutions communicate with their counterparts in academia? Or, on the other end of the spectrum, does the risk communication process require a presentation of the issues at stake that makes them understandable to the public at large, for instance through talk shows and the mass media? Whoever or whatever is meant exactly by the rather vague term “public” often is not specified. The Aarhus Convention, however, represents an important exception to this observation, it specifies who is meant, in fact it differentiates between the public in general and the “concerned public” in order to make it very clear who has access to the rights which are enshrined in its three so-called pillars, i.e. access to information, public participation, and access to justice in environmental matters:

²⁷⁹ <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm> .

²⁸⁰ Information on the Convention is available at <http://www.unece.org/env/eia/eia.htm> .

²⁸¹ <http://www.unece.org/env/eia/documents/conventiontextenglish.pdf> .

²⁸² <http://unfccc.int/resource/docs/convkp/conveng.pdf>

4. "The public" means one or more natural or legal persons, and, in accordance with national legislation or practice, their associations, organizations or groups;
5. "The public concerned" means the public affected or likely to be affected by, or having an interest in, the environmental decision-making; for the purposes of this definition, non-governmental organizations promoting environmental protection and meeting any requirements under national law shall be deemed to have an interest.²⁸³

A distinction is made sometimes between two kinds of "publics." Public in a narrow sense refers to informed and involved individuals, or interest groups including NGOs and experts, whereas the public at large is constituted of non-organized individuals who are not affiliated to any group with regard to a risk in question. The participation of both kinds of publics can be encouraged through the organization of public meetings, conferences or hearings. Such events ought to be emphasized, as well as opportunities to consult the public. It is important to make sure that the public is indeed informed about policies, strategies and programs which are organized by the authorities. In some cases, however, the public's involvement in risk assessment may be hampered by confidentiality requirements related to corporate interests. Frequently, perhaps as a consequence of such sensitivities, the extent of the public's involvement in the elaboration of a policy, a legal framework or a research program is in reality quite limited. It should be noted here that the Aarhus Convention's distinctive mention of "the public concerned" makes it very clear and emphasizes that environmental NGOs play a particularly important role in this framework.²⁸⁴

In today's day and age risk communication is assuming a more and more important place in the public discourse due to the rapidly increasing pace of scientific, technical and generally societal innovation as the sociologist and futurologist Alwyn Toffler has correctly foreseen and analyzed already back in 1970 in his widely translated bestseller *Future Shock*.²⁸⁵ The fact that this phenomenon is not so recent anymore justifies a short historical digression which demonstrates the serious consequences of an incompetent and ill-fated risk communication process, namely the case of asbestos. Evidence of the linkage between the handling of asbestos and fatal lung diseases among British asbestos workers emerged already at the end of the 19th century.²⁸⁶ In Switzerland (home of the asbestos product *Eternit*), evidence of the disastrous health consequences of the inhalation of asbestos fibers was reported in 1927, and in 1939 the Swiss insurance for work-related health problems

²⁸³ Aarhus Convention Art. 2 Definitions, para. 4 and 5, available at <http://www.unece.org/env/pp/documents/cep43e.pdf>

²⁸⁴ Vera Rodenhoff. 2002. The Aarhus Convention and its Implications for the 'Institutions' of the European Community. *RECIEL* 11 (3): 343-357, (345). See also Elisa Morgera. 2005. An Update on the Aarhus Convention and its Continued Global Relevance. *RECIEL* 14 (29): 138-148, as well as Maria Lee and Carolyn Abbot. 2003. Legislation - The Usual Suspects? Public Participation Under the Aarhus Convention. *The Modern Law Review* 66 (1): 80-108.

²⁸⁵ Toffler, Alvin. 1970. *Future Shock*. Random House.

²⁸⁶ Gary Gardner. 2006. First Do No Harm. *World*Watch* January-February, 30-31, (31)

recognized the disease for the first time.²⁸⁷ Nevertheless, at the 1964 Swiss National Exhibition in Lausanne asbestos was touted as an exceedingly useful and valuable material for a large number of applications. The Swiss authorities prohibited asbestos as a construction material only in 1990.²⁸⁸

Industrialized countries have been maintaining detailed disease and fatality statistics on asbestos-related diseases for decades, and they have spent billions of dollars over the past few years to remove very widely used asbestos-containing construction materials from buildings. In light of countless human tragedies due to asbestos-related diseases across the world it is truly difficult to comprehend why governments have not acted decades earlier and why scientific and medical researchers have not made far greater efforts to communicate the risks that were known for a long time to be inherent in the handling of this material without very elaborate protective measures. Last but not least we should mention here that the WTO's Dispute Settlement Body has ruled that Member states may ban imports of asbestos and asbestos-containing products due to health reasons, and that they are not equivalent ("like") to substitute products which have been on the market for a long time.²⁸⁹

To return to our discussion of risk communication in the regulation of international trade, as we can see, risk communication is closely related to the risk assessment and the risk management processes conducted domestically and between states. The information which is to be made available to the public includes details on the activity in question as well as the nature and the potential seriousness of a risk that is related to the activity. For example, in the case of trade in GMO products, the importing country has to assume certain obligations regarding its domestic public which it must inform on the risks incurred. After having received the appropriate notification and technical details from the exporting country, it must, using appropriate means, inform those domestic stakeholders which could be affected by the GMOs before it answers the notification.

The data, the facts, and the contextualized knowledge which the public is entitled to receive as part of the "information of the public" process imply that the latter must be in a position to participate in the decision-making process which is related to risk assessment and risk management. In other words, simply communicating the risk by itself is not enough, the communication must necessarily be accompanied by an active and effective participation of the public at all levels of the risk analysis in an activity such as international trade in GMOs. This means that the assessment, the management and the communication of risk are interdependent, interactive and iterative as Christine Noiville and Nicolas de Sadeleer emphasize in a ground breaking article that analyses in great depth the highly complex nature of these interactions.²⁹⁰ We should recall in this context the ruling of the WTO's Appellate Body with regard to the dispute *EC-Hormones* which criticized the Panel for taking an approach that it considered wrongly as being focused entirely on quantitative analysis and opened the way for a much more comprehensive approach:

²⁸⁷ Urs Fitze. 2006. Impossible de démontrer l'innocuité du rayonnement. *Environnement 2* (Office fédéral de l'environnement). 47-49 (47).

²⁸⁸ Bernhard Raos. 2003. Lebensgefährliche Nachlässigkeit. *Beobachter* 28-31 (28).

²⁸⁹ European Communities - Measures Affecting Asbestos and Asbestos-Containing Products, WT/DS135/AB/R, 12 March 2001.

²⁹⁰ Noiville, Christine et Nicolas de Sadeleer. 2001. La gestion des risques écologiques et sanitaires à l'épreuve des chiffres - le droit entre enjeux scientifiques et politiques. *Revue du Droit de l'Union Européen* 2: 389-450.

... to the extent that the Panel purports to exclude from the scope of a risk assessment in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error. (...) 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.²⁹¹

As far as risk management is concerned, a government cannot take, fully informed, a risk-related measure or decision without having, in a preceding phase, communicated to the public the risks which are related to the activity in question, and without having given the public the opportunity to express its acceptance or otherwise of this activity. Some other instruments addressing international environmental issues in fact take into consideration this dialectic relationship between on one hand risk assessment and management, and on the other hand risk communication. An interesting example in this regard is offered by the UNECE's *Convention on the Protection and Use of Transboundary Watercourses and International Lakes*:

In order to promote decisions by the central, regional or local authorities which are fully informed, members should facilitate the participation of the public, which could suffer from accidental pollution, in hearings and preliminary inquiries, as well as in the presentation of the objectives of the decisions that are proposed. (...) The countries in which an incident has happened should take all appropriate measures in order to supply sufficient information in order to allow the exercise of those rights which domestic law accords with regard to the objectives of this code. This applies to legal entities as well as to individuals which are exposed to an important risk of exposure to accidental pollution of transboundary water bodies.²⁹²

There are numerous modalities which govern the participation in the decision-making process. Let us mention for instance the right to examine the general and specific information based on which decisions are taken and the right to either confirm or contest their exactitude; the analysis, the validation or the questioning of the ramifications of relevant policies; bringing opposing viewpoints before administrative tribunals or other jurisdictions, or to the attention of the media, relevant NGOs, or loose *ad hoc* grass-roots groupings all represent means of participation in the

²⁹¹ EC Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body, WT/DS26/AB/R, WT/DS48/AB/R, 16 January 1998.

²⁹² Code of Conduct on Accidental Pollution of Transboundary Inland Waters, Art. VII. Para. 1 & 2. Our translation of the original French version: «Pour promouvoir une prise de décisions en connaissance de cause par les autorités centrales, régionales ou locales dans les délibérations relatives à une pollution accidentelle des eaux intérieures transfrontières, les pays devraient faciliter la participation du public qui pourrait subir un préjudice aux auditions et enquêtes préliminaires et la présentation d'objections concernant les décisions proposées [...] Les pays dans lesquels se produit un incident devraient prendre toutes les mesures appropriées pour fournir aux personnes physiques et morales exposées à un risque important de pollution accidentelle des eaux intérieures transfrontières des renseignements suffisants pour leur permettre d'exercer les droits qui leur sont accordés en droit interne conformément aux objectifs du présent Code».

decision-taking process. These modes of participation in the decision-making process may indeed reduce or prevent transboundary damages to the environment.

The ways of implementing the legal obligation to “communicate the risk” is usually left to national authorities. It is up to them to choose the ways and means of disseminating relevant information according to the requirements of domestic policies and laws. This domestic context will determine if such information will be furnished to the media, NGOs, public national or local authorities etc. In cases where a certain activity such as e.g. trade in GMOs concerns the population of another country, it may be informed via its government if direct communications are difficult or impossible.

A more extensive implication in the environmental impact assessment or in the evaluation of a project or policy-related documents would be useful in order to achieve a better grasp of the preoccupations which the planned activities generate, as well as in the elaboration of alternative solutions and of respective consequences for the environment. We can observe indeed a trend towards enhanced opportunities for the public to participate in the national decision-making process regarding the elaboration and implementation of policies in the domains of the environment and public health. This way a government’s legitimacy is strengthened and regulations tend to be better respected. Last but not least, as Public International Law is evolving with regard to human rights, we may conclude that public participation in these issue areas is emerging as a right at the domestic level as well as internationally.²⁹³

2.3. Ongoing Monitoring, an Underpinning Principle of Risk Communication

Risk communication is not a linear process; rather, it is – very much like the overarching risk analysis which, as we have seen, also includes risk assessment and risk management - of an iterative and continuous nature. It implies an ongoing surveillance of risks that may have been identified or else which await identification, and which may not yield clear conclusions, or may even result in contradictory findings. Let us take for example the hypothesis of a country A which notifies its intention to export GMOs into country B. Country A’s notification concludes that there is no scientifically established or known risk for human health or for the environment for country B involved in such transactions. Country B, on the other hand, may notify country A that in light of the precautionary principle, it also has to take into consideration risks which so far have not been identified yet may indeed result from such transboundary movements. In other words, country B is contesting the claim of the absence of risks contained in A’s notification.

Faced with this kind of contradictory view points in the risk communication process, Public International Law provides for the initiation of consultations between the states involved. Either one of the parties may ask for such consultations with the purpose of arriving at a mutually acceptable solution concerning measures which will be applied in order to prevent cross-boundary damages or at least to reduce such risks to the minimum. The principle of *ongoing monitoring* (“suivi continu”²⁹⁴)²⁹⁵

²⁹³ See T. M. Franck, «Fairness in the International Legal and Institutional System: General Course on Public International Law», *Recueil des cours*, 1993-III, t. 240, p. 110.

²⁹⁴ The Government of the Province of Québec, Direction adjointe de l’évaluation, de la recherché et des affaires extérieures, Unité d’éthique (Ministère Santé et services sociaux) has elaborated a « Note de clarification relative au concept de *suivi continu* et de l’éthique des projets », available at <http://ethique.msss.gouv.qc.ca/site/download.php?b00dbb6b088e4f0bcb915176d8a75b04>.

should be applied here. It means that consultations should preferably take place before the authorization and the beginning of an activity. In this context, *ongoing monitoring* appears to be intrinsically linked with the general principle of *good faith*.

In order for the efforts of working toward a mutually acceptable solution to be successful and for the risk to be eliminated or at least minimized, the measures envisaged must be applied jointly in cooperation by the parties involved in a risk communication process. This notion of cooperation is grounded in the principle of *due diligence* which, like the principle of *good faith*, must underpin all phases and all activities in such an undertaking. This can only be achieved if the solution results in an equitable balance of interests.

In the *Lake Lanoux* case,²⁹⁶ the arbitral Tribunal noted that, in certain situations, it is possible that the potentially affected country refuses to engage into serious negotiations, thus violating the principle of *good faith*. In anticipation of such situations, certain international legal instruments contain provisions which allow the country at the origin of a certain activity to go ahead with its plans because otherwise a possibly affected country would be in reality in a position to exercise a right of veto. Nevertheless, the country which decides to go ahead with its plans is obligated in doing so to take into consideration the interests of countries which could be affected. This is a case where consultative risk communications are important because that is how the real preoccupations of each country involved can be taken into consideration in the implementation of a given activity.

Under the much more recent Cartagena Protocol's Advance Informed Agreement procedure a potential importing country is obliged to communicate its decision to the exporting country concerning a potential importation into its territory within 270 days. Nevertheless, even though the non-communication of a decision by the importing country "shall not imply its consent to an intentional transboundary movement,"²⁹⁷ this does not mean that it is entitled to rest silent regarding a request to carry out a GMO shipment *ad vitam ad eternam*. The Cartagena Protocol has also incorporated the principle of *ongoing monitoring*: a Party of import may at any time, "in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity"²⁹⁸ reconsider its decision. In this case its obligation consists in informing "any notifier that has previously notified"²⁹⁹ GMO shipments, as well as the Secretariat of the Protocol's Biosafety Clearinghouse, of its decisions and of the reasons for it. It should be noted that this Principle of *ongoing monitoring* cuts both ways, i.e. a Party of export or a notifier is entitled to ask a Party of import to review its decision if "a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the (negative) decision was based."³⁰⁰

²⁹⁵ In spite of the fact that many international instruments simply refer to the notion of 'monitoring' we prefer to use the concept of 'ongoing monitoring' which better reflects the French term 'suivi continu' or 'surveillance continue.' The two notions are synonymous.

²⁹⁶ *Lake Lanoux* arbitration (*France v. Spain*). *Arbitral Tribunal* November 16, 1957.

<http://www.lfip.org/laws666/lakelanoux.htm>

²⁹⁷ *Ibid.* Art. 10. 5.

²⁹⁸ *Ibid.* Art. 12 Review of Decisions, Para. 1.

²⁹⁹ *Ibid.*

³⁰⁰ *Ibid.* Art. 12.2

3. Conclusions

Risk communication processes are not only intrinsically linked to risk assessment and risk management carried out by governmental agencies, they also provide a key role for NGOs and grassroots groupings. They illustrate a new kind of relationship in the international legal order between states on one hand and individuals and/or NGOs on the other hand. We can observe that the traditional vertical approach in which scientific information and evidence has been communicated exclusively by governmental sources to non-governmental recipients is now increasingly yielding to a more horizontal approach with interactive risk communication channels. In this much more dynamic framework non-governmental actors are able to express their opinion on issues like risk assessment and risk management both at the domestic and international levels.

These developments represent a real paradigm shift which has been accompanied by the creation of concrete rights to access to environmental information and an entitlement to risk communication *de lege lata* at the international level. The above-mentioned Aarhus Convention can be seen as the latest manifestation of this movement. Non-governmental actors demand more and more to be able to be heard and to participate actively in dispute settlement proceedings, especially with regard to environmental and health issues. Requests to submit *amicus curiae* briefings to certain dispute settlement mechanisms, for instance under NAFTA's Chapter 11 or the WTO's Dispute Settlement Understanding are a clear illustration of this trend.

For instance in the case *Methanex Corporation v. United States*, which was submitted under NAFTA's Chapter 11, and which was centered on such environmental and health questions,³⁰¹ the arbitral tribunal was approached not only with a request for the presentation of an *amicus curiae* brief, but in addition to that certain NGOs requested also complete access to the procedure, which implied four different demands: (1) the possibility to submit written communications; (2) the possibility to attend the hearings; (3) the possibility to make oral appeals; and (4) the possibility to have access to all documents exchanged among the parties. Such demands are unprecedented in an arbitral case involving a state and a private investor. The NGOs were prepared with numerous arguments and insisted in particular on the wide ramifications of this case for the public interest. Access rights to this extent are not given presently by the various dispute settlement mechanisms, but as the public's entitlement to risk communication is gradually crystallizing, we can see increasing openness in a first stage with regard to the submission of *amicus curiae* briefs.

To conclude, we can certainly state that this gradual opening of intergovernmental dispute settlement mechanisms toward non-governmental input of information can only be beneficial for efforts to deal with the complex manifestations of risk through anticipatory and preventive approaches and frameworks. The study of risk communication undoubtedly will require a great deal more research. Many Multilateral Environmental Agreements would be of great interest to investigate in future research projects focusing on risk communication; this applies generally to

³⁰¹ Regarding *Methanex* see P. DUMBERRY, « The Admissibility of *Amicus Curiae* Briefs by NGOs in Investors-States Arbitration : The Precedent set by the *Methanex* Case in the context of NAFTA Chapter 11 Proceedings », *Non-State Actors and International Law*, vol. 1, n°3, 2001, pp. 201-214 . B. STERN, « L'entrée de la société civile dans l'arbitrage entre Etat et investisseur », *Revue de l'Arbitrage*, 2002, n°2, pp. 329-345.

those MEAs which are characterized by major trade concerns and at the same time by the need to convey to all state Parties as well as to local stakeholders scientifically demanding information which is crucial for ensuring the protection of both the environment and of public health. More specifically, the interconnected risk-related concerns of notification, communication, public participation, as well as technology cooperation and transfer, are all of great relevance but not much investigated in a number of Conventions regulating transboundary movements of hazardous waste, pesticides and other chemicals.

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PRECAUTION AS AN AUTONOMOUS RIGHT IN THE SPS AGREEMENT: IMPLICATIONS OF THE *EC-BIOTECH* FINDINGS REGARDING THE NATURE OF ARTICLE 5.7

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Abstract

Although the concept of precaution has been dealt with by WTO cases, it was only in the *EC-Biotech* Panel Report that the nature of Article 5.7 of the SPS Agreement, one of the main provisions contemplating precautionary measures, was specifically addressed. The Panel found that Article 5.7 should be characterized as an autonomous right – not an exception to the general obligation for WTO Members to base their sanitary and phytosanitary measures on scientific principles and, specifically, on a risk assessment. The clarification of the relationship between Article 5.7 and other SPS Agreement provisions has a potentially significant impact on the interface of WTO rules and sustainable development. Initial considerations of the *EC-Biotech* Panel Report noted that, by characterizing Article 5.7 as an autonomous right, this decision may facilitate the successful vindication of precautionary decision-making in the WTO. The present article examines the possible theoretical and practical consequences of the *EC-Biotech* analysis and findings on the nature of Article 5.7, including the exclusion of other provisions from applicability to precautionary measures, the placing of the burden of proof on the complaining parties, and the broader interpretation of its terms. It concludes that, while the Panel in the *EC-Biotech* case recognized and supported the critical role of precaution in the SPS Agreement, its characterization of Article 5.7 as an autonomous right is unlikely to revolutionize the consideration of precaution in the WTO.

1. Introduction

Precaution is not an exception but an integral part of science-based decision-making. It is well recognized that scientific and policy judgments should and do interact in the analysis of risks leading to regulatory decisions.³⁰² In addition, even as debate continues over the nature, terminology, and scope of precaution, its application is now generally considered a legitimate and distinctive approach in the face of scientific uncertainty and risks to health or the environment.³⁰³

The boundaries of precaution in the context of sanitary and phytosanitary measures have been addressed by a number of World Trade Organization (WTO) cases. Article 5.7 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), as one of the main provisions contemplating precautionary measures, has been at the core of a number of disputes.³⁰⁴ Various Panels and the Appellate Body have thus considered, for example, the characteristics of the four requirements that must be met in order for WTO Members to adopt and maintain measures under Article 5.7.³⁰⁵ The Appellate Body also looked at Article 5.7 as part of the context of Article 2.2, which refers to it explicitly, noting that “Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence.”³⁰⁶

It was only in the *EC-Biotech* case, however, that a WTO Panel specifically addressed the nature of Article 5.7 within the SPS Agreement.³⁰⁷ In particular, the Panel found that Article 5.7 should be characterized as an autonomous right – not an exception to the general obligation for WTO Members to base their sanitary and phytosanitary measures on scientific principles and, specifically, on a risk assessment.³⁰⁸ Indeed, the relationship between Article 5.7 and other SPS Agreement provisions is one of several issues considered by the *EC-Biotech* Panel

³⁰² There is some distinction in regulatory approaches, however, as to the moment in which policy considerations enter the analysis of risks. The traditional approach considers risk assessments, for example, as objective and value-free, public values and concerns are only deemed relevant in the phase of risk management. Increasingly, however, it is acknowledged that even risk assessments are necessarily impacted by political and cultural factors. For an in depth analysis of the very dynamic and complex relationship between the assessment and the management of risk see: Christine Noiville and Nicolas de Sadeleer. 2001. La gestion des risques écologiques et sanitaires à l'épreuve des chiffres - le droit entre enjeux scientifiques et politiques. *Revue du Droit de l'Union Européen* 2: 389-450.

³⁰³ In 2002, for example, Dr. John D. Graham, of the Executive Office of the President of the United States, speaking on the American view on the role of precaution in risk assessment and management, noted that the US government supports precautionary approaches to risk management, while not recognizing a precautionary principle.

³⁰⁴ The Appellate Body in *EC-Hormones* found that “the precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement.” Report of the Appellate Body, European Communities – Measures Concerning Meat and Meat Products (EC-Hormones), WT/DS26/AB/R, WT/DS48/AB/R, adopted on 13 February 1998, paragraph 124.

³⁰⁵ See, e.g., Report of the Appellate Body, Japan – Measures Affecting Agricultural Products (Japan-Varietals), WT/DS76/AB/R, adopted on 19 March 1999, paragraphs 86-94, and Report of the Appellate Body, Japan – Measures Affecting the Importation of Apples (Japan-Apples), WT/DS245/AB/R26, adopted on 10 December 2003, paragraphs 169-188.

³⁰⁶ Japan-Apples, *supra* note 4, paragraph 80.

³⁰⁷ Panel Report, European Communities – Measures Affecting the Approval and Marketing of Biotech Products (EC-Biotech), WT/DS291/R, WT/DS292/R, WT/DS293/R, 29 September 2006.

³⁰⁸ *Id.*, paragraph 7.2997.

Report with a potentially significant impact on the interface of WTO rules and sustainable development.³⁰⁹ The Panel's analysis of the right-exception distinction, though, has been described as "tangled," and the implications of depicting Article 5.7 as an autonomous right remains uncertain.³¹⁰

The present article aims to provide a brief overview of the *EC-Biotech* analysis and conclusions in regard to the nature of Article 5.7, and some initial thoughts on the implications of these findings for the future consideration of precautionary measures in the SPS Agreement. After this Introduction, Section II will examine the relevant fragments of the *EC-Biotech* Panel Report. Section III will then turn to the legal repercussions of the Panel's findings for the applicability, the burden of proof, and the interpretation of Article 5.7. Finally, Section IV will provide some closing remarks on the impact of *EC-Biotech* for precautionary measures in the context of the SPS Agreement.

2. *EC-Biotech* Arguments, Analysis, and Findings on the Nature of Article 5.7

The nature of Article 5.7 of the SPS Agreement arose in *EC-Biotech* as an issue of applicable law. Having found that the SPS Agreement was indeed applicable to the various national measures challenged in the *EC-Biotech* case (herewith referred to as "safeguard measures"), the Panel had to determine the specific provisions under which to consider these measures.³¹¹ Complaining parties claimed the safeguard measures fell under, and were inconsistent with, Article 5.1 of the SPS Agreement, which requires that SPS measures be based on a risk assessment. The European Communities (EC), on the other hand, argued that the safeguard measures – as provisional measures – fell to be assessed under Article 5.7 of the SPS Agreement. Moreover, the EC submitted that, since the relationship between Article 5.1 and Article 5.7 is one of exclusion, even if there was an inconsistency with Article 5.7, Article 5.1 would not become the relevant applicable provision.³¹²

Although it found that the provisional character of the safeguard measures did not in itself determine the applicability of Article 5.7, as argued by the EC, the Panel still considered the relationship between Articles 5.1 and 5.7 as a threshold question in establishing the applicable provisions of the SPS Agreement.³¹³ In addressing this question, the Panel focused on the distinction between rights and exceptions in the SPS Agreement, following the EC argument that, if Article 5.7 is a right and not an exception, it would become the applicable rule to the exclusion of all others. It should be noted, however, that in WTO jurisprudence, the distinction between right and exception has been primarily considered as relevant for the purpose of the allocation

³⁰⁹ Other aspects of the *EC-Biotech* case are analyzed, for example, in María Julia Oliva and Simonetta Zarrilli, "WTO Panel Report on the 'EC-Biotech' case: Considerations for Trade and Development," UNCTAD Trade and Development Board, TD/B/COM.1/CPR.4, 26 February 2007.

³¹⁰ Tomer Broude, "Genetically Modified Rules: The Awkard Rule-Exception-Right Distinction in *EC-Biotech*," International Law Forum of the Hebrew University of Jerusalem Law Faculty, Research Paper No. 14-06, December 2006.

³¹¹ See *EC-Biotech*, supra note 6, paragraph 7.2923.

³¹² The European Communities, nevertheless, noted that none of the Complaining Parties has presented a claim of violation under Article 5.7. As a result, it considered consistency with Article 5.7 to be irrelevant in the case because the complaining parties had invoked the wrong provision.

³¹³ See *EC-Biotech*, supra note 6, paragraph 7.2947-48.

of the burden of proof.³¹⁴ As a result, much of the Panel's analysis, as well as the parties' arguments, referred to claims and previous cases relating to the issue of burden of proof, and thus combined both procedural and substantive legal considerations.

The EC put forth two points to support its argument that Articles 5.1 and 5.7 presented a relationship of exclusion, thus making Article 5.7 an autonomous right and the only relevant provision for the safeguard measures. First, it made reference to textual similarities with other provisions that prior WTO cases had found to provide exclusions to rights and obligations in the SPS Agreement. It noted that Article 2.2, which must be constantly read with Article 5.1, contains wording "substantially identical" to that of Article 3.1. In *EC-Hormones*, the Appellate Body had looked at Article 3.1 in regard to Article 3.3, and found to manifest a relationship of exclusion, making Article 3.3 an autonomous right in the SPS Agreement.³¹⁵ This similarity, argued the EC, suggested that the relationship between Articles 2.2 and 5.1 and Article 5.7 is also one of exclusion. Secondly, the EC noted that the text of Article 5.7 is incorporated by reference into the text of Article 2.2.³¹⁶ Article 5.7 would therefore form part of Article 2 and thus set out basic rights and obligations of equal status to the others in that article.

For the complaining parties, Article 5.7 could not be an autonomous right as "it does not provide basis for a claim of an alleged breach of a WTO obligation, but acts as a defence to shield measures that would otherwise violate Articles 2.2 and 5.1."³¹⁷ In addition, Canada argued that equating the relationship between Articles 2.2 and 5.1, and Article 5.7, with the relationship between Articles 3.1 and 3.3 was inappropriate because of the different purposes and characteristics of these articles.³¹⁸ Article 3.1 of the SPS Agreement contains an obligation for WTO Members to base their sanitary and phytosanitary measures on international standards. Article 3.3 gives WTO Members, in the view of Canada, a "separate but equal" right to adopt measures to achieve levels of protection higher than those provided by those standards.³¹⁹ Canada submitted that Article 5.7 does not exist as such an option that can be freely chosen by the Member concerned. Rather, it is a temporary solution that must eventually give way to the obligations in Articles 2.2 and 5.1, and an exception that is only required if a measure is found to be inconsistent with these articles.

In addressing these arguments, the Panel began by examining the relationship between Article 2.2 and Article 5.7. In order to do this, it resorted to what it considered the "general test" to determine the relationship between two provisions for the purpose of allocating burden of proof,³²⁰ articulated by the Appellate Body in *EC-Tariff Preferences*³²¹ on the basis of previous cases, including *EC-Hormones*:

³¹⁴ The WTO jurisprudence on burden of proof as it relates to the EC-Biotech Panel Report is further analyzed in Section III of the present paper.

³¹⁵ See *EC-Hormones*, supra note 3, paragraph 104.

³¹⁶ See *EC-Biotech*, supra note 6, paragraph 7.2952.

³¹⁷ *Id.*, paragraph 7.2955.

³¹⁸ *Id.*, paragraph 7.2957.

³¹⁹ *Id.*

³²⁰ *Id.*, paragraph 7.2967.

³²¹ Appellate Body Report, *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries (EC-Tariff Preferences)*, WT/DS246/AB/R, adopted on 20 April 2004.

...In cases where one provision permits, in certain circumstances, behaviour that would otherwise be inconsistent with an obligation in another provision, and one of the two provisions refers to the other provision ... the complaining party bears the burden of establishing that a challenged measure is inconsistent with the provision permitting particular behaviour *only* where one of the provisions suggests that the obligation is not applicable to the said measure.³²²

Evaluating the relationship between Article 2.2 and Article 5.7, the Panel in *EC-Biotech* came to the conclusion that Article 5.7 should be characterized as a right and not an exception from a general obligation under Article 2.2.:

Thus, we find the general test provided by the Appellate Body in *EC - Tariff Preferences* to be applicable, and application of that test leads us to the conclusion that Article 5.7 should be characterized as a right and not an exception from a general obligation under Article 2.2. In other words, we consider that in the same way that "Article 3.1 of the SPS Agreement [...] excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement", Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7. As we will explain further below, characterizing Article 5.7 as a right rather than as an exception has implications for the allocation of the burden of proof.³²³

Using the *EC-Tariff Preferences* test, it considered that

The relationship in question is one where 'one provision [namely, Article 5.7] permits, in certain circumstances, behavior [namely, the provisional adoption of SPS measures in cases where scientific evidence is insufficient on the basis of available pertinent information] that would otherwise be inconsistent with an obligation in another provision [namely, the obligation in Article 2.2 not to maintain SPS measure without sufficient scientific evidence], [where] one of the two provisions [namely, Article 2.2] refers to the other provision, [and] where one of the provisions [namely, Article 2.2, and in particular the clause 'except as provided for in paragraph 7 of Article 5'] suggests that the obligation [in Article 2.2 not to maintain SPS measure without sufficient scientific evidence] is not applicable' to measures falling within the scope of Article 5.7.³²⁴

The Panel recognized the existence of substantive differences between articles with similar texts and relationships, including Articles 3.1 and 3.3, as noted by Canada, but did not consider that these differences supported characterizing Article 5.7 as an exception.³²⁵ Moreover, it also found its view consistent, for example, with the characterization of Article 5.7 as a "qualified exemption" in *Japan-Agricultural Products II*.³²⁶

As to the implications of its finding, the Panel noted that they were twofold. First, in terms of applicable law, "characterizing Article 5.7 as a qualified right rather than an exception means that if a challenged SPS measure was adopted and is

³²² *Id.*, paragraph 88 (footnotes omitted), cited in *EC-Biotech*, supra note 6, paragraph 7.2962.

³²³ See *EC-Biotech*, supra note 6, paragraph 7.2969.

³²⁴ *Id.*, paragraph 7.2968.

³²⁵ *Id.*, paragraph 7.2979.

³²⁶ *Id.*, paragraph 7.2972. Appellate Body Report, Japan – Measures Affecting Agricultural Products (Japan-Agricultural Products II), WT/DS/76/AB/R, adopted 19 March 1999.

maintained consistently with the four cumulative requirements of Article 5.7 ... the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence is not applicable to the challenged measure. Conversely, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7 ... the relevant obligation in Article 2.2 is applicable to the challenged measure...”³²⁷ The Panel thus did not accept the EC’s arguments regarding the complete exclusion of Article 5.1 if a challenged measure fell under Article 5.7. Second, in terms of burden of proof, characterizing Article 5.7 as an autonomous right entails that, “in cases where a complaining party alleges that an SPS measure is inconsistent with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence, it is incumbent on the complaining party, and not the responding party, to demonstrate that the challenged SPS measure is inconsistent with at least one of the four requirements set forth in Article 5.7.”³²⁸

The Panel then turned to examine the relationship between Article 5.1 and Article 5.7, also using the *EC-Tariff Preferences* test as a basis to determining whether Article 5.7 is a right in relation to Article 5.1. It thus considered three issues. First, the Panel looked at whether Article 5.7 permits, in certain circumstances, what would otherwise be inconsistent with Article 5.1. It found that under Article 5.7, SPS measures may be provisionally adopted and maintained even if they are not based on the type of risk assessment required by Article 5.1, so this is indeed the case.³²⁹ Second, the Panel addressed whether either Article 5.1 or Article 5.7 refers to the other provision. In this regard, the Panel found a number of implicit references, including the expression “a more objective risk assessment” in Article 5.7, which it construed as an implicit reference to the type of risk assessment required in Article 5.1.³³⁰ Lastly, the Panel examined whether there is any suggestion that the obligation in Article 5.1 is not applicable to measures falling within the scope of Article 5.7. It concluded that Article 5.1 is indeed not applicable to these measures, as suggested by the phrase “[i]n cases where relevant scientific evidence is insufficient” in Article 5.7, and by the clause “except as provided for in paragraph 7 of Article 5” in Article 2.2, which necessarily implies that Article 5.1 – a specific application of Article 2.2 – cannot be applicable in situations covered by Article 5.7.³³¹

As a result, the Panel found that Article 5.7 should be characterized as a right also in relation to Article 5.1.³³²

The implications, regarding both allocating the burden of proof and determining applicable of law, were considered to be similar to those deriving from the nature of Article 5.7 as a right vis-à-vis Article 2.2. In relation to burden of proof, it would be thus be up to the complaining parties to prove inconsistency with both Article 5.7 and Article 5.1.³³³ In relation to applicable law, Article 5.1 would only be

³²⁷ See *EC-Biotech*, supra note 6, paragraph 7.2973.

³²⁸ *Id.*, paragraph 7.2975.

³²⁹ *Id.*, paragraph 7.2992.

³³⁰ *Id.*, paragraph 7.2993.

³³¹ *Id.*, paragraph 7.2994-5.

³³² *Id.*, paragraph 7.2996.

³³³ The Panel did recognize that previous panels have found inconsistencies with Article 5.1 without specifically examining whether the complaining party had adequately proved inconsistency with both Articles 5.1 and 5.7. However, in its view, this only reflects the fact that in those cases the responding party had not invoked the provisions of Article 5.7 in response to a claim of violation under Article 5.1.

applicable to a challenged measure if the measure was found to be inconsistent with at least one of the four requirements of Article 5.7.

In the specific *EC-Biotech* circumstances, however, the Panel chose to move away from the above-mentioned inferences. Even if, according to these inferences, it should have begun its analysis with Article 5.7, which the EC had invoked as applicable, the Panel considered that the “critical legal issue” was whether the relevant safeguard measures met the requirements set out in the text of Article 5.1.³³⁴ Therefore, it chose to follow the order of analysis established by previous WTO jurisprudence, and began its analysis of the consistency of the safeguard measures with the SPS Agreement by considering whether they met the Article 5.1 requirements:

Under this approach, should we find that a relevant safeguard measure meets the requirements set out in the text of Article 5.1, there would be no need to examine the Complaining Parties' claims under Article 5.1 further... Should we find, however, that the safeguard measure does not meet the requirements set out in the text of Article 5.1, we would need to go on to examine whether this measure is consistent with the requirements of Article 5.7. If the safeguard measure were consistent with the requirements of Article 5.7, Article 5.1 would not be applicable and we would consequently need to conclude that the European Communities has not acted inconsistently with its obligations under Article 5.1. Conversely, if the safeguard measure were inconsistent with the requirements of Article 5.7, Article 5.1 would be applicable and, in view of the assumed fact that the safeguard measure does not meet the requirements set out in the text of Article 5.1, we would need to conclude that the European Communities has acted inconsistently with its obligations under Article 5.1.³³⁵

3. Implications of Characterizing Article 5.7 as an Autonomous Right in the SPS Agreement

Article 5.7 of the SPS Agreement has long been considered central to achieving the objective of sustainable development in the WTO. In reflecting the precautionary principle, Article 5.7 incorporates an essential basis for policy making in cases in which sanitary and phytosanitary action is needed to prevent and mitigate risks to human health and the environment before there is comprehensive and clear scientific evidence.³³⁶ In addition, WTO Members have the right under the SPS Agreement to determine their appropriate level of protection, and it is Article 5.7 that ensures that insufficient scientific evidence does not impede them from taking measures to attain and maintain that level of protection. As a result, commentators have argued that Article 5.7 cannot be considered an exception within the SPS Agreement.³³⁷ Rather, it has been maintained that Article 5.7 should be regarded as a central element in the science-based approach of the SPS Agreement, which aims to limit arbitrary or

³³⁴ See *EC-Biotech*, supra note 6, paragraph 7.3005.

³³⁵ *Id.*, paragraph 7.3006.

³³⁶ The precautionary principle has been incorporated, in various forms, in international environmental agreements and declarations, including the Rio Declaration. There is no single formulation of the precautionary principle, but a common element is the recognition that lack of certainty regarding the threat of environmental harm should not be used as an excuse for not taking action to avert that threat.

³³⁷ See, e.g., Center for International Environmental Law et al, “Amicus Curiae Brief to the *EC-Biotech* Case,” 1 June 2004.

unjustifiable trade restrictions while ensuring that no WTO Member is prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health.³³⁸

Article 5.7 was finally recognized as a right, not an exception, in the *EC-Biotech* Panel Report. Nevertheless, this determination was made by no means on the basis of the role or relevance of precautionary measures in the SPS Agreement. The Panel analyzed the nature of Article 5.7 from a strictly textual perspective, considering the language similarities with other provisions of the SPS Agreement. Moreover, although the issue had been raised as one of substantive law, the Panel examined the nature of Article 5.7 primarily for its procedural implications, linking it with the allocation of burden of proof. Commentators worry about this “hodgepodge of substantive and procedural arguments” and note that “at no point does the panel step back to try and form a coherent, holistic understanding and orientation of the Article 2.2-5.1/5.7 relationship.”³³⁹

Such a holistic approach may not be appropriate in WTO jurisprudence. In *EC-Tariff Preferences*, the case that provided the “general test” used by the Panel to evaluate the nature of Article 5.7 in *EC-Biotech*, the Appellate Body did go further in its substantive consideration of the provisions at issue, looking not only at their text but also at their object and purpose. Nevertheless, in the end it did not consider these arguments as determining factors. Indeed, the Appellate Body noted that “the status and relative importance of a given provision does not depend on whether it is characterized, for the purpose of allocating the burden of proof, as a claim to be proven by the complaining party, or as a defense to be established by the responding party.”³⁴⁰

If characterizing a provision as an autonomous right within a WTO agreement does not reflect or affect its status or relevance, then, what are the real consequences of the *EC-Biotech* findings regarding the nature of Article 5.7? The Panel discusses theoretical implications in two areas – applicability of law and allocation of burden of proof. As will be described below, however, there are a number of ambiguities and inaccuracies in the Panel’s analysis and conclusions that may limit the actual impact of its findings. In addition, potential implications of *EC-Biotech*’s recognition of Article 5.7 as a right beyond those identified by the Panel will also be considered.

3.1. APPLICABLE LAW

Although the determination of the applicable law was the context in which the nature of Article 5.7 was raised and decided, the contours of the *EC-Biotech* Panel Report in this area are far from clear. Such lack of clarity partly derives from the intermingling of substantive and procedural elements in the Panel’s analysis. In particular, there is a blur between the concept of “applicability of the law,” to which the EC seems to refer in its arguments, and the concept of “application of the law,” on which the Panel focuses when determining the consequences of Article 5.7 as an autonomous right.

WTO Panels are charged with determining the applicable law in a dispute. That is, each Panel must ascertain the provisions that govern the factual situation at

³³⁸ Id.

³³⁹ Broude, *supra* note 10, page 6.

³⁴⁰ *EC-Tariff Preferences*, *supra* note 20, paragraph 98.

issue. This is a substantive determination, based on the contemplation of the scope of the various WTO agreements and, within those agreements, specific provisions. The determination of the applicable law consists of several sub-functions, including, in cases where two legal rules overlap, establishing whether both were meant to apply or whether one takes precedence.³⁴¹

After the determination of the applicable law, WTO Panels must then actually apply the law to the facts at issue. This is a procedural process through which the challenged measure is successively submitted to a test of compatibility with the applicable provisions. After that, a Panel makes a final determination in which the measure is found to be consistent or inconsistent with the provision that applies in the particular case.³⁴²

In the *EC-Biotech* case, the EC introduced the debate on the nature of Article 5.7 as a matter of applicable law. In its view, the nature of Article 5.7 as an autonomous right determined that, to the extent the safeguard measures fell within the scope of the SPS Agreement, they needed to be assessed under Article 5.7 and *only* Article 5.7. The EC based its argument on the two different categories developed by WTO jurisprudence for rules exempting Members from compliance with more general rules: provisions that establish an exception to other provisions, and provisions that exclude the application of other provisions.³⁴³ The EC submitted that Article 5.7 was in the latter category and, as a result, any measure that fell in its scope should not be considered in relation to Article 5.1.

The Panel agreed with the EC in that Article 5.7 is a right, not an exception. However, it defined the consequences of such a nature in relation not to the applicability but to the application of the law. Contrary to the EC position, the Panel found that the applicability of Article 5.7 did *not* exclude that of Articles 2.2 and 5.1. The Panel stated that if a measure is adopted and maintained consistently with Article 5.7, then Articles 2.2 and 5.1 are not applicable. If, in contrast, a measure is found to be inconsistent with Article 5.7, the Panel considered that Articles 2.2 and 5.1 would then become applicable.

As a result, this paper would argue that the implications of the *EC-Biotech* characterization of Article 5.7 as a right do not in fact refer to the applicability of law. The SPS provisions applicable to measures adopted in cases of insufficient scientific evidence have not effectively changed. Articles 2.2, 5.1, and 5.7 all remain applicable provisions. As the EC stated in one of its submissions, the applicability of a WTO agreement “does not and cannot depend on whether or not it is consistent with one or other substantive provisions of that Agreement.”³⁴⁴ The situation is no different as regards Article 5.7 of the SPS Agreement or other specific provisions.

Though both Article 5.1 and 5.7 remain applicable, as a matter of application, only one provision will apply in each particular case. It is solely in this application process that the Panel situates the consequences of the nature of Article 5.7. These consequences are, in this regard, limited to altering the order of examination of the different applicable provisions. In the case of an exception, a WTO Panel should, as a first step, examine the consistency of a challenged measure with the general rule. If the measure is considered at this stage to be inconsistent, the Panel should then examine, as a second step, whether the measure is nevertheless justified by the

³⁴¹ Joel P. Trachtman, “The Domain of WTO Dispute Resolution,” 40 Harv. Int'l L.J. 333 (1999).

³⁴² EC-Tariff Preferences, *supra* note 20, paragraph 102.

³⁴³ Michelle T. Grando, “Allocating the Burden of Proof in WTO Disputes: A Critical Analysis,” *Journal of International Economic Law* Vol. 9 No. 33, Oxford University Press 2006.

³⁴⁴ Second Written Submission of the European Communities, *EC-Biotech*, July 2004, paragraph 83.

exception. It is only at this latter stage that a final determination of consistency with the general rule can be made.³⁴⁵ In the case of an autonomous right, as described by the Panel in *EC-Biotech*, it is with this provision that a Panel would need to begin its examination. Nevertheless, as was noted in Section II, the *EC-Biotech* Panel in fact rejected to follow through on these findings, choosing, in the end, to follow the same order of examination as if Article 5.7 had been an exception, commencing by considering Article 5.1 and only then moving on to Article 5.7.

3.2. BURDEN OF PROOF

Characterizing Article 5.7 as an autonomous right, the *EC-Biotech* Panel found, would also have implications for the allocation of burden of proof. Indeed, this is the area in which the theoretical consequences of the nature of Article 5.7 seem most clear. The practical effects for future cases involving Article 5.7, however, are not evident.

In the WTO, as in most civil and common law systems and international tribunals, “the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defense.”³⁴⁶ The rule seems simple enough, but WTO jurisprudence has struggled with distinguishing the provisions that establish affirmative defenses and thus place the burden of proof on the defending party. Nevertheless, it is widely accepted that certain provisions, even while exempting WTO Members from compliance with more general rules, are not such defenses or exceptions but “positive rules that establish obligations in themselves” or “autonomous rights.”³⁴⁷ In such cases, the burden of proof does not fall on the defending party. Rather, it is the complaining party that has the burden of proving, in addition to the claimed inconsistency with regards to the general rule, that the defending party does not fall under or meet the requirements of these provisions. As a result, after the *EC-Biotech* finding that Article 5.7 establishes an autonomous right, in cases where a complaining party alleges that an SPS measure is inconsistent with Articles 2.2 and 5.1, it would be this complaining party that bears the burden, rather than the responding party, to demonstrate that the challenged measure is inconsistent with at least one of the four requirements set forth in Article 5.7.

The implications of this allocation of burden of proof for future cases involving Articles 5.1 and 5.7 are still uncertain. The burden of proof in international proceedings is “the obligation of each of the parties to a dispute... to prove its claims to the satisfaction of, and in accordance with the rules acceptable to, the tribunal.”³⁴⁸ Each tribunal, as a result, regulates the process of presenting or evaluating evidence

³⁴⁵ EC-Tariff Preferences, *supra* note 20, paragraph 101.

³⁴⁶ Appellate Body Report, United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India (US-Wool Shirts and Blouses), WT/DS33/AB/R and Corr.1, adopted 23 May 1997, page 14.

³⁴⁷ The US-Wool Shirts and Blouses spoke of Articles XX and XI:(2)(c)(i) of the GATT as exceptions as opposed to “positive rules,” and the expression was taken up in several posterior cases looking at burden of proof issues. The “autonomous right” language was used in *EC-Hormones*.

³⁴⁸ Mojtaba Kazazi, *BURDEN OF PROOF AND RELATED ISSUES (A STUDY ON EVIDENCE BEFORE INTERNATIONAL TRIBUNALS)*, The Hague, Kluwer Law, 1996, page 10. As such, it is comparable with the notion of burden of proof utilized in civil law, and to the meaning of burden of proof as “burden of persuasion” in common law systems.

necessary to decide whether or not the burden of proof has been discharged.³⁴⁹ It is worth considering the rules established in WTO jurisprudence, which delineate the responsibilities that must now be taken on by a complaining party in relation to Article 5.7 of the SPS Agreement.

It should be noted, for example, that in WTO cases the duty to present evidence on a particular claim does not rest solely on the party bearing the burden of proof. The duty of parties to cooperate in the presentation of evidence at the international level derives from the idea of the peaceful settlement of disputes, and seeks to provide tribunals as much information on the case as possible.³⁵⁰ In the WTO, the Dispute Settlement Understanding (DSU) provides that “the use of the dispute settlement procedures should not be intended or considered as contentious acts and that, if a dispute arises, all Members will engage in these procedures in good faith in an effort to resolve the dispute.”³⁵¹ The principle of cooperation was confirmed in *Argentina-Textiles*, in which the Panel noted the requirement for collaboration of the parties in the presentation of the facts and evidence, and particularly the role of the respondent in providing the tribunal with relevant documents that are in its sole possession.³⁵²

As a result, not bearing the burden of proof does not absolve a WTO Member of all responsibilities in the course of a dispute. This is particularly true in light of the standard of proof used by Panels and the Appellate Body. With the standard of proof of a *prima facie* case, as will be described below, a party not bearing the burden of proof will nevertheless need to rebut the presumption created by the initial presentation of facts supporting a claim or defense.

The standard of proof is the level of evidence required in a particular legal action to discharge the burden of proof, i.e. to convince the court that a given proposition is true. Tribunals have the authority to determine the standard of proof that needs to be satisfied by a proponent of a claim or affirmative defense in order to discharge the burden of proof.³⁵³ In municipal law, standards of proof vary, ranging, for example, from preponderance of evidence to beyond a reasonable doubt.

In the WTO, beginning with *US-Wool Shirts and Blouses*, the standard of proof required has been a *prima facie* case. Under this standard of proof, in order for the proponent of a claim or defense to establish its position – and thus discharge its burden of proof – it will be sufficient to submit evidence of a *prima facie* case.³⁵⁴ In other words, it is not necessary to present conclusive evidence, but merely evidence that, unless rebutted, would be sufficient to prove the claim or defense. It is then be up to the opposing party to rebut that *prima facie* case. As stated by the Appellate Body in *US-Wool Shirts and Blouses*, if the party with the burden of proof “adduces

³⁴⁹ Joost Pauwelyn, “Evidence, Proof, and Persuasion in WTO Dispute Settlement: Who Bears the Burden?” *Journal of International Economic Law* 1 (1998), page 233.

³⁵⁰ Kazazi, *supra* note 47, page 375.

³⁵¹ WTO Dispute Settlement Understanding, Article 3.10.

³⁵² Panel Report, *Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items (Argentina-Textiles)*, WT/DS56/R, 1997, paragraph 6.40. The Panel noted, however, that this obligation does not arise until the claimant has done its best to secure evidence and has produced a *prima facie* case.

³⁵³ Hendrik Lambert Botha, “Burden of Proof in WTO Law: A Study of the Manner in which the Concept of Burden of Proof has been Interpreted and Applied by the WTO Dispute Settlement Body,” World Trade Institute, University of Berne, 2002.

³⁵⁴ Pauwelyn, *supra* note 48, page 246.

evidence sufficient to raise a presumption that what is claimed is true” then it is up to the other party to adduce sufficient evidence to rebut the presumption.³⁵⁵

In this context, the allocation of burden of proof has minimal consequences for the outcome of cases. Moreover, it has been noted that, in light of Article 13 of the DSU, which gives Panels the right to seek information, opinions, and technical advice from any relevant source, WTO cases are decided on the basis of a “basket of evidence,” consisting of the evidence and legal argument of both parties to the dispute as well as arguments and evidence submitted by independent experts.³⁵⁶ Indeed, as Pauwelyn observes: “An explicit determination of who bears the burden of proof (and further evaluation of whether or not this burden has been discharged) should only be made in the event the trier of fact is in doubt because the evidence is incomplete or in equipoise. When, in the eyes of the adjudicator, the evidence is complete and clear (in one or the other way), the issue of burden of proof becomes of academic interest only.”³⁵⁷ Cases involving Article 5.7 are not likely to differ in this regard.

3.3. INTERPRETATION

In calls for Article 5.7 to be considered as an autonomous right in the SPS Agreement, commentators noted that the interpretation of the requirements of Article 5.7 directly affected the ability of countries to respond effectively to health and environmental needs.³⁵⁸ Given the importance of an interpretation ample enough to allow WTO Members to take all necessary measures to address these needs, this line of argument seems to have aimed at avoiding the possible narrow interpretation of the requirements of Article 5.7 if this provision was considered an exception. Indeed, in municipal and international law, the principle of restrictive interpretation is often applied to exceptions, on the basis that such a narrow interpretation ensures the protection of the rights and obligations contained in the general rules of the laws or treaties.³⁵⁹ Consequently, the characterization of Article 5.7 as an autonomous right could create potential implications in the interpretation of this provision.

In the WTO, the relevance of the right-exception distinction in interpretation seems to be less significant, however. Article 3.2 of the DSU establishes that the dispute settlement procedure serves to clarify the provisions of WTO agreements “in accordance with customary rules of interpretation of public international law.” From

³⁵⁵ US-Wool Shirts and Blouses, *supra* note 45, page 14. It should be noted that the Appellate Body in this and other cases, as well as numerous Panels, speak of the shift of the burden of proof once a *prima facie* case has been established. However, commentators agree that the *prima facie* case is a standard of proof, not burden of proof issue. Indeed, the burden of proof in international proceedings does not shift and remains with the party that bears it throughout these proceedings.

³⁵⁶ Lambert Botha, *supra* note 52, page 32.

³⁵⁷ Pauwelyn, *supra* note 48, page 258. The concept of burden of proof implies that, in the event in which the evidence is insufficient for a determination, or is considered to be in equipoise (equally balanced), the tribunal will find against the party that bears the burden of proof. See, e.g., Panel Report, United States – Section 301-310 of the Trade Act of 1974 (US-Trade Act), WT/DS152/R, 1999, paragraph 7.14, and Panel Report, United States – Import Prohibition of Certain Shrimp and Shrimp Products – Recourse to Article 21.5 of the DSU by Malaysia (US-Shrimp), WT/DS58/RW, 2001, paragraph 5.19.

³⁵⁸ See, e.g., CIEL et al, *supra* note 36.

³⁵⁹ Myress McDougal et al, *THE INTERPRETATION OF INTERNATIONAL AGREEMENTS AND WORLD PUBLIC ORDER: PRINCIPLES OF CONTENT AND PROCEDURE*, Yale University Press, 1994, page 183.

early on, the reference to customary rules was determined to allude to Articles 31 and 32 of the Vienna Convention on the Law of Treaties (Vienna Convention).³⁶⁰ Within the criteria announced in these provisions, the Appellate Body has attached the greatest weight to the need to consider “the ordinary meaning of the terms of the treaty,”³⁶¹ clearly preferring a method of literal interpretation.³⁶²

In WTO jurisprudence, therefore, although the principle of strict interpretation of exceptions has not been excluded, it does have a much smaller reach. In *EC-Hormones*, the Appellate Body said that “merely characterizing a treaty provision as an ‘exception’ does not by itself justify a ‘stricter’ or ‘narrower’ interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in the light of the treaty’s object and purpose, or, in other words, by applying the normal rules of treaty interpretation.”³⁶³ There is an evident reference to Articles 31 and 32 of the Vienna Convention, which do not give grounds for preferring one portion of the text over another, construing the latter more narrowly than the former.³⁶⁴ As a result, in spite of the principle of restrictive interpretation, in the WTO context it is not the nature of Article 5.7 but its wording that is likely to impact the breadth of its construction.

4. Conclusion

The defense of precautionary measures taken under the SPS Agreement has not proved straightforward. WTO jurisprudence has acknowledged the relevance of the precautionary principle in the SPS Agreement and provided an arguably low threshold for some of the requirements needed to act in cases of insufficient scientific evidence.³⁶⁵ However, to date, no sanitary or phytosanitary measure assessed under Article 5.7 has ever been found consistent with WTO rules.

Initial considerations of the *EC-Biotech* Panel Report noted that, by characterizing Article 5.7 as an autonomous right, and thus allocating the burden of proof of inconsistency on the complaining parties, it may facilitate the successful vindication of precautionary decision-making in the WTO.³⁶⁶ Indeed, theoretical implications of recognizing Article 5.7 as a right in the SPS Agreement involve excluding other provisions from applicability to precautionary measures, placing the burden of proof on the complaining parties, and allowing a broader interpretation of its terms.

A closer look, however, reveals that the *EC-Biotech* finding on the nature of Article 5.7 is unlikely to revolutionize the consideration of precaution in the WTO. First, the analysis on the relationship between rights and exceptions issue in the *EC-*

³⁶⁰ See, e.g., Appellate Body Report, United States – Standards for Reformulated and Conventional Gasoline (US-Gasoline), WT/DS2/AB/R, adopted 20 May 1996.

³⁶¹ Vienna Convention on the Law of Treaties, Article 31.1.

³⁶² Claus-Dieter Ehlermann, « Six Years on the Bench of the ‘World Trade Court’ » in THE WTO DISPUTE SETTLEMENT SYSTEM 1995-2003, edited by Federico Ortino and Erns-Ulrich Petersmann, Kluwer Law International, 2004, page 509.

³⁶³ *EC-Hormones*, supra note 3, paragraph 104.

³⁶⁴ David Palmeter and Petros C. Mavroidis, DISPUTE SETTLEMENT IN THE WOLD TRADE ORGANIZATION: PRACTICE AND PROCEDURE, Cambridge University Press, 2004, page 151.

³⁶⁵ Review within a “reasonable period of time,” for example.

³⁶⁶ Heike Baumüller and María Julia Oliva, “EC-Biotech Report: Overview of Key Issues and Implications” Environmental Policy and Law, Volume 37, Number 1 / 2007.

Biotech Panel Report is regarded as tangled and unclear – it does not depart from past rulings, but does raise questions on the consistency and appropriateness of current WTO jurisprudence on the issue.³⁶⁷ Second, certain implications are expressly negated by the Panel. For example, the Panel recognized Article 5.7 as an autonomous right, but considered that it did not completely exclude Articles 2.2 and 5.1 as applicable provisions. Finally, some of the potential impacts are limited due to the contours of WTO jurisprudence. Allocating the burden of proof on the complaining parties may be an important legal issue, but the practical consequences of such a burden may be minimal given the approach towards evaluating evidence in WTO disputes. Similarly, in light of the well-established practice on interpretation in the WTO dispute settlement system, it is doubtful that the status of Article 5.7 will modify the consideration of its terms.

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³⁶⁷ See, e.g., Simon Lester in his review of the EC-Biotech case for the American Journal of International Law, Vol. 101 No. 2, April 2007.