Trade and Environment at the Crossroads: Evolution of the International Governance of Biosafety

Selcan Serdaroğlu
Assistant Professor
International Relations Department
Galatasaray University, Istanbul, Turkey
E-mail: sserdaroglu@gsu.edu.tr

Abstract

Since its entry into force in 2003, the Cartagena Protocol on Biosafety raises debate and controversy, even among signatory countries. The difficulties of risk assessment on biodiversity and human health, disparities in institutional capacity, uncertainty regarding the definition of liability and redress for the damage caused by the transboundary movement of living modified organisms (LMOs) are the most visible controversies. Two other related issues, but less explicit, are added to this chart: first, the relevance of an agreement combining environmental principles and trade provisions and second, the fact that the agreement may be used as a non-tariff barrier or any instrument of anticompetitive behaviour by the non-Parties, producers and exporters of LMOs. After the COP-MOP 5 held in Nagoya in October 2010, especially with the adoption of the Suppelementary Protocol on Liability and Redress, the international governance of biosafety still advance in the direction of a hybrid approach between environmental conservation and trade issues, with more emphasis on the role of the companies, the progressively generalized acceptance of biotechnological risks on biodiversity and the need for intervention measures.

Introduction

According to the ISAAA (International Service for the Acquisition of Agri-Biotech Applications)[1], a pro-biotechnology institution for the collection and dissemination of production patterns and data, the number of countries that grow GM crops rose in 2010 to 29. This represents a steady trend with the progressive integration of African countries (South Africa, Burkina Faso, Egypt) after those of North America (United States-the world leader, Canada), South America (Argentina and Brazil, respectively second and third largest producers), Asia (China and India), Europe (Germany, Spain, Czech Republic, Poland, Portugal, Romania, Slovakia) and Oceania (Australia). The total area of transgenic crops in the world is about 800 million hectares and is expected to reach 4 billion hectares in 2015 (deadline of the Millennium Development Goals). The agribusiness sector underlines the need to increase the biotechnological production in front of major development and environment concerns as the food security and fight against poverty or the climate change. In fact, strating with the Agenda 21, several international agreements, conventions, documents accepted the the potential contribution of "modern biotechnology" to sustainable development as a tool for the food security, health improvement and environmental protection.

However the promotion of these economic, environmental and social potentialities does not disguise the requirements of biosecurity, especially emanating from non-governmental environmentalists and consumers. Paradoxically, such demands are also adressed by companies in the need for stability in the global market and a "cover" in front of the challenges of the first group, which would be possible by the existence of solid mechanisms to assess and manage risks. The biosecurity includes the prevention of risks to biodiversity conservation and human health, but there is also some debate over whether the risks are actually associated with transgenesis. The level of toxicity and allergenecity of genetically modified crops for human is the subject of many studies attracting the attention of public opinion. On the other hand, studies concerning the dangers on non-target organisms (agricultural and natural/"wild" biodiversity not targeted by the genetic recombination) are rare or little known. Controversies are often marked by the prominence of scientific difficulties concerning the establishment of causal links between the transformation of native varieties and the planting of transgenic crops.

[1] Clive James, *Global Status of Commercialized Biotech/GM Crops: 2010*; ISAAA Brief 42, ISAAA, Ithaca, New York, Executive Summary, http://www.isaaa.org/resources/publications/briefs/42/executivesummary/pdf/Brief%2042%20-%20Executive%20Summary%20-%20English.pdf

In these circumstances, given the global dimension of the production and marketing of agricultural biotechnology, can the international governance be built, even gradually, in order to regulate the prevention of risks associated with the transboundary movements of living modified organisms (LMOs)? In the absence of consensus on the meaning of the knowledge about risks, are there any common objectives to be attained by states? Managing this uncertainty is the fundamental objective of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and its intrinsic problem in the same time. The aim of this paper is to present the trade issues of the Protocol, and to examine to what extent they take precedence over its environmental significance, according to the interests of real players in biotechnology, namely states and agribusiness companies. It will analyze the institutional weaknesses of implementation, including the origins of collective action problem and the difficulties in enforcing biosafety as an additional instrument for the conservation and sustainable use of biodiversity. The Supplementary Protocol on Liability and Redress opened for signature in March 2011 clarifies the responsibility sharing between states and business as "major actors" for the sustainable development, thus questioning the operationality of the Cartagena Protocol: Does the implementation depend on coordination of national legislation and/or the establishment of "networked governance" through the constituency[2] approach?

Genetics and Biosecurity: Principles, Issues and Actors

Between genetically modified organisms (GMO), living modified organisms (LMO) or transgenic organisms, the terms used to describe a genetic manipulation may sometimes be confusing and a source of controversy in international regulations. There are different methods of genetic manipulation. Genetic modification of an organism means the use of a technique of altering a gene or introducing one or more genes selected from the same organism or other organisms. The transgenesis does mean the introduction of a gene from another organism and is the main process used in biotechnological agriculture. Thus, in the case of transgenic soybeans, the most common genetically modified crop, a gene from a microorganism naturally resistant to glyphosate, the key component of Roundup herbicide produced by Monsanto, was introduced into the plant. The methods currently used have added to crops, beside the herbicide resistance, new characteristics such as resistance to insects (the introduction of the bacterium *Bacillus thuringiensis* giving rise to the variety of *Bt* corn and *Bt* cotton), resistance to viruses or enhancement of their vitamin content or nutritional value.

Biotechnology development is done through public research institutions and private partnerships between business and research communities in developed countries but also in so-called "SuperNARs"(National Agricultural Research Systems), "champions" in Agricultural Research (Brazil, China and India)[3]. The seed companies that share the international market (mainly Monsanto, Syngenta, DuPont and Bayer AG) hold patents on technologies for introducing specific gene (*trait*), such as "Roundup Ready", "Liberty Link" or "Bollgard". Soybean planted lands constitute 53% of the total area devoted to agricultural biotechnology in the world. That's why the soybean, as corn, is the focus of discussions on biosafety. The strategies of multinational enterprises to export their seeds to developing countries are often at stake, despite these countries' institutional and legal deficiencies concerning the introduction of such materials in their territory. Moreover, the social control that can be achieved by environmental and consumer protection NGOs are marginalized by the "developmentalist" discourse of public officials and private sector representatives, such as agribusiness multinational companies entering the market, for example in Brazil. Whatever the degree of development of countries, biotechnological agro-alimentary industry highlights the positive impacts of its production on the human and natural well-being: a contribution to food security with high productivity and low prices, increased nutritional quality of food, conservation of biodiversity by more environmentally friendly farming, climate change mitigation and, recently, more efficient production in terms of cost of biofuels.

[2] Within the Agenda 21, the participation of actors other than the states to the decision-making in sustainability issues is underlined by the use of "major groups" term, including women, children and youth, indigenous people, non-governmental organizations, local authorities, workers and their trade unions, business and industry, sicentific and technological community, farmers. http://www.un.org/esa/dsd/agenda21/res_agenda21_00.shtml
Defined in the Report of the panel of Eminent Persons, known also as Cardoso Report on UN-Civil Society Relations (2004), the constituency comprises "the three broad sectors, civil society, the private sector and the State, including parliaments and parliamentarians and local authorities". The UN and the governments should adopt a multi-constituency approach. The Cardoso Report on UN-Civil Society Relations: A Third World Network Analysis August 2004 http://www.un-ngls.org/orf/08twn.pdf and Marc Pallemaerts, Marlène Moreau, « Le rôle des parties prenantes dans la gouvernance internationale de l'environnement », *Idées pour le débat*, 07/2004, Iddri, novembre 2004, pp. 5-8

[3] Greg Traxler, *The Economic Impacts of Biotechnology-Based Technological Innovations*, ESA Working Paper No: 04-08, Agricultural and Development Economics Division, FAO, May 2004, p. 10

Various studies on the toxicity of foods containing GMOs and the risks of dispersion of GMOs into the environment beyond the organisms transformed by the activity of genetic recombination (*target organisms*) are trying to scientifically determine if damage can result of these processes and to measure them. The increase in production raises concerns indeed - for risks to human health and biodiversity - which result in the establishment of national regulations on biosafety, in addition to existing legislation regarding the protection of the environment and consumer rights. The precautionary approach is the founding principle of these legal instruments, even if all states do not have the institutional capacity to implement it, evenmore some do not have the political will of "sacrificing" the potential offered by biotechnology by adopting precautionary measures.

The effectiveness of regulation faces also a structural difficulty. It is indeed an area in which the relationship between business and government are both overlapping and contradictory in terms of economic anticipations and public choices. For the state, a new production with a global market has a positive impact on growth and trade balance. Meanwhile, the State is obliged to arbitrate between the allocation of benefits to various stakeholders and/or the promotion of their rights. On one hand, the protection of human health and environment, the right of the consumer to information, and the support for the subsistence of small farmers in the new distribution of cultivable land. On the other hand, the protection of intellectual property rights of big business against small producers now also able of transgenic but poorly traceable production due to uncontrolled seed multiplication, and encouraging investment by less restrictive regulations on risk assessment or the warning of consumers. Issues relating to the liability of operators for damage and financial guarantee/security (the prior constitution of a compensation fund) also complicate transactions between the state and business. In other words, the state benefits from the development of biotechnological agriculture, however what will be its degree of liability if companies create also negative externalities?

These uncertainties, coupled with the lack of collective action intended to result in an institutional framework for cooperation among the states, do not constitute a sufficiently precise basis to establish an international regime governing the prevention of biosecurity risks to human health and biodiversity. First, the production and trade of GMOs are rather the domain of firms, states often being "followers" in this process of redefinition of the use of land and crops, achieved through a top-down linear innovation[4] and according to the global demand dynamics. In addition, according to the institutional structure of states, the GMO industry can use the political support to reduce the potentially restrictive regulations, while ensuring that they remain sufficiently visible for marketing purposes (in the scope of greenwashing) and/or moral liability. Secondly, the risk associated with biotechnology has not the same connotation everywhere: depending on the assessment and management capacity based on an objective scientific structure, will the biosecurity be assured by logic of zero risk or acceptable risk? Thus, the European approach of precaution is clearly distinct from the American approach in which GMOs are considered through the principle of substantial equivalence, that is to say the risks associated with GMOs are not different from risks relating to conventional products with similar chemical characteristics. There is however an international protocol in this area, the Cartagena Protocol, which does not present a satisfactory answer to these difficulties and uncertainties.

An Almost Multilateral and Semi-Environmental Agreement?

The Cartagena Protocol on Biosafety is part of the Convention on Biological Diversity (CBD, 1992) and completes it in accordance with Articles 8 (g), 19.3 and 19.4 of the CBD. Adopted in Montreal January 29, 2000 by the Conference of Parties to the CBD, the Protocol came into force September 11, 2003. The negotiations leading to the adoption of a Protocol on Biosafety have been long and difficult. Section 8 (g) of the CBD emphasizes the responsibility of each Party to develop rules and mechanisms for managing and controlling risks associated with biotechnology, but the question of the creation of an international instrument is only partially reflected in Article 19.3 of the CBD: "*The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity*."

Although the goal of creating an international regime on biosafety is not clearly formulated, the Working Group on Biosafety established for this purpose began to gather in 1996 and culminated in 1999 with a text submitted for adoption to the Parties at the extraordinary meeting of the COP in Cartagena (Colombia).

[4] The top-down linear innovation is considered as the main feature of the modernisation of agriculture and refers to the externalization of plant selection outside the field, through public and private research. Christophe Bonneuil, Frédéric Thomas, *Gènes, pouvoirs et profits. Recherche publique et régimes de production des savoirs de Mendel aux OGM*, Éditions Quae, 2009, p. 546

The negotiations have been hampered by differences in positions between five groups of countries: the group of Central and Eastern Europe, the "group of compromise" (Japan, Mexico, Norway, South Korea, Switzerland, New Zealand and Singapore), the European Union (EU), the "Miami Group" (Argentina, Australia, Canada, Chile, USA, Uruguay) and the "like-minded" megadiverse countries including the G77 except Argentina, Chile and Uruguay. The main tricky points have opposed the EU, which required the adoption of the precautionary principle and the complete identification of all LMOs contented in agricultural goods and the Miami Group (or exporting countries of transgenic agricultural products) which required the subordination of any protocol on the protection of biodiversity to the World Trade Organization (WTO), since the transport of GMOs as raw material (commodity) falls under the jurisdiction of this organization.

Despite these objections, an agreement was reached between like-minded countries, the EU and the Compromise Group on articles whith a vague content, which led to the adoption of the "Protocol of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity" in January 2000. Its scope is defined by the Article 4: *"This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health"*; therefore pharmaceutical GMOs do not fall within the scope of the Protocol. The Miami Group countries have chosen to remain outside this framework, but they do participate in negotiations as observers within the groups of experts or working groups. The absence of the United States and Argentina, the two largest producers, has indeed created uncertainty about the effectiveness of this international regime. These came mainly from the issue of monitoring the likely adverse effects of biotechnological production of these countries. The latter could escape the imperatives of transparency and could not be held liable for damages incurred. Subsequently, the Article 27 on the preparation of international rules on liability and redress aroused discontent between the Parties, which might cause the adoption of contestatory positions during negotiations.

Despite these institutional weaknesses, the number of Parties to the Protocol is 160 in 2011 in countries, forming geographic groups: Africa (AFR), Asia Pacific (AP), Central and Eastern Europe (CEE), Latin America and the Caribbean (GRULAC), Western Europe and "other groups" (WEOG). In this configuration, the initial positions have evolved according to specific interests, for example Brazil, initially in the group of megadiverse countries, tends to approach the Miami Group countries. While gradually acquiring relatively clear content and implementation mechanisms, the Protocol appears to be the least known and even less appropriate to the outcomes of the Rio Conference on sustainable development. The imprecision of the causal link between, on one hand, the conservation and sustainable use of biodiversity, and on the other hand the transboundary movement of LMOs, and the primacy given to the regulation of international trade of these products may indeed lead to consider the Cartagena Protocol as both inconsistent in the context of the CBD and overlapping with the provisions of other international agreements, particularly those linked to the trade, Sanitary and Phytosanitary Measures Agreement (SPS), which governs the standards and conditions imposed on food trade and the Agreement on Technical Barriers (TBT) of the WTO, Codex Alimentarius (food code) of the FAO on the food "safety".[5]

In fact, there are several indications proving that the Cartagena Protocol has the characteristics of a trade agreement while being an environmental agreement. Three articles require further consultations: the Article 18 on the handling, transport, packaging and identification; the Article 20 on the operating procedures of the Clearing House (the coordination mechanism of the Protocol) and the Article 27 on liability and redress. In addition, there are concerns about a possible conflict with the obligations under the WTO and the uncertainties regarding the implementation of the precautionary principle.

The Scope of the Protocol: What Type of Governance?

The Protocol does not directly address the conditions of production of LMOs in the territory of the Parties but their transboundary movement: its main provisions describe the procedures of their exchange. In this context it is perceived at first as a trade agreement, although the need to combine trade and environment for sustainable development is mentioned in the preamble. The provisions reflect rather the regulation of the relationship between exporting and importing countries, and the mechanism for exchange of information aims to ensure transparency in the market release (commercial release) process of LMOs intended for direct use as food feed or processing (LMO-FFP). The information should include risk assessment and decisions of commercial release adopted by national authorities.

[5] Food safety concerns the qualitative aspects of nutrition (risks on human health); food security is rather related to the access to sufficient quantity of food.

The distinction between LMOs and GMOs is relatively clear with the stipulation that GMOs are intended for direct use as food or animal food, products containing GMOs (not alive) are not subject to regulations under the Protocol. However, this potential for consumption and processing of LMOs creates a confusion of the governance framework, particularly as the need to assess the likely adverse effects on human health is also in the scope of the Protocol. However, the risk management in this area is done according to the Codex Alimentarius and the SPS, which also regulates in its Article 5.2 measures based on the scientific assessment of risks to human animal and plant health.

The objective of the Protocol, defined in the Article 1 and taking into account the precautionary approach, is to "*... to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.*" The main instrument of protection is the procedure of Advanced Informed Agreement (AIA), a prior informed consent between the exporting and the importing Parties, which applies to the LMOs intended for introduction into the environment (mainly seeds). Thus, an exporter country or operator is required to send to importer - before the first transboundary movement - a written description of the LMO by identifying it in detail. The importer will then announce its decision of approval or rejection, or sending a request for additional information.

Following discussions at COP-MOPs, only the exporting country is required to provide the necessary information on identification before the transboundary movement of product, but this information should be addressed to the Biosafety Clearing-House and not directly to the importing country. A direct agreement between the exporting and importing countries is not mandatory. The importing country retains the right to conduct risk assessments on goods, invoking the precautionary principle and it may have a legislation of "zero tolerance" against the risk of dispersion resulting from intentional introduction of exported LMOs in its environment. Therefore the approval of the importing country and the nature of this approval are crucial.

However, the advanced informed agreement procedure does not apply to LMOs in transit (the transit falls under the regulations of each state), to LMOs intended for direct use as food or feed or to be processed and to LMOs to be used in a confined environment (i.e. when there is no contact with the environment). If the meeting of the Parties decides that an LMO has a minor negative impact on the conservation and sustainable use of biodiversity and human health, the prior agreement is not necessary either.[6] Notwithstanding these exceptions, nothing prevents the parties to require risk assessments for these different arrangements for the introduction of LMOs into their territory, on the basis of their national legislation. These multiple possibilities can still create a problem concerning the identification of damage and repair mechanisms that are not defined in the Protocol, but planned for a later discussion on the basis of the Article 27. If the damage occurs, it would be difficult to identify the types of "guilty" LMOs and to refer to the agreement.

The requirements concerning the identification of LMOs are completed by the necessity of providing accurate documentation (Article 18). However, there is no consensus regarding the use of the type of document: it is possible to use a specific document (stand-alone document), but also a commercial invoice with an additional section on the identity of the the LMO and any other information required by the Protocol. This "single document" should include common names, scientific and, if available, commercial names and the transformation code of LMOs. Currently, the Parties use the OECD guidelines[7] to determine the unique identifier codes for categories of LMOs. These identifiers should also be notified to the Clearing-House. Another debate, even heavier on the negotiations regarding documentation, focuses on the use of "contains and "may contain", whatever the type of accompanying document used. During the first COP-MOP, Brazil, Mexico (first, member of the Group of Compromise) and New Zealand have defended the use of the expression "may contain", which helps to keep legal uncertainty for a more flexible implementation.

[6] Articles 4, 5, 6 and 7 of the Cartagena Protocol, on the scope of the Protocol and the application of advanced informed agreement. According to the Article 5, the Protocol does not apply to LMOs which are pharmaceutical products for humans.

[7] The unique identifier is an « alphanumeric » code with three parts identifying the producer (name of the firm), the transformation (*event*) code and the verification number (the sum of numbers and numerical values of letters used to define to producer and the transformation code). For example MON-Ø1445-2 means that the producer is Monsanto, 01445 is the transformation code and 2 is the sum of numbers and letters used. OECD, Series on Harmonization of Regulatory Oversight in Biotechnology No: 23, Revised 2006: OECD *Guidance for the Designation of a Unique Identifier for Transgenic Plants*, ENV/JM/MONO(2002)7/REV1, 07-Nov-2006, pp. 11-12

Thus, they limited the adoption of restrictive measures by importing countries like strict traceability requirements or product recalls.[8] Subsequently, at the instigation of Brazil, a more flexible use of these terms has been accepted. This is a two step approach: if the identity of the LMO is known through methods such as identity preservation systems, "contains" should be the appropriate term. If the identity is unknown, "may contain" is more appropriate to inform the importing Party. This proposal has not been finalized and further discussions were required for the 5th Meeting of the Parties (2010), with "the aim of considering" a decision at the 6th meeting (2012) on the use of "contains". Indeed, besides the technical difficulties of a sound traceability, the use of a specific document cover is problematic because of the additional transaction costs required and the disadvantage for the exporting countries that signed the Protocol vis-à-vis others who have not signed, mainly the United States and Argentina. A risk assessment based on scientific evidence must be made and notified to the importing countries and the cost of this process is assumed by the notifying Party if the importer requires it. This reinforces the commercial dimension given to the Protocol, which provides non-tariff barriers outside the WTO structure and cause unfair competition which can damage the Parties with respect to non-Parties.

Risk Assessment and Management as Regards Biodiversity

The fundamental concern of the Parties to the Protocol on the conservation of biodiversity relates to the "adverse effects" of organisms resistant to insects or herbicides on other "non-target" organisms or on the receiving environment. The approach is precautionary; any environmental release decision, commercial approval and transport of LMOs must be preceded by a risk and environmental impact assessment and on the biodiversity and human health. However, the definition of risk is problematic under the Cartagena Protocol, as well as the degree of scientific uncertainty, yet preventive measures should be adopted by the Parties. In fact, preventive measures will fluctuate between the precautionary principle and the reluctance to adopt an irreversible legal framework that will not be converged with the interests - difficult to reconcile - of all economic and social actors. Also the implementation of the Protocol is tainted with ambiguity. First is raised the question of the nature of risk on biodiversity (agricultural/"cultivated" and natural/"wild" biodiversity). The definition of risk associated with biotechnology do not contain normative constitutive elements[9], it is difficult to understand the causal link between the release of a modified organism into the environment and the alteration of the biodiversity, if this is not observable in the immediate future. Furthermore, assessment of the likely or unlikely damage also depends on the scientific interpretation and the particularities of the ecosystems affected. Thus, risks can be identified locally, but can not be defined in universal terms.

Determining the level of risk is another controversy: the absence of risk or existence of an acceptable risk? Parties have adopted a flexible framework "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk." (Annex III, General Principles 4)[10]. Therefore, there is no threshold for recognition of a risk or a common approach to prevention: the risk is identified and managed locally. Nevertheless, the Protocol includes a specific methodology for risk assessment under Annex III. Once the characteristics of an LMO (including biological characteristics of the recipient organism) are known, its potential risk "that may have adverse effects on biological diversity in the likely potential receiving environment" should also be identified. This is the conventional methodology of risk assessment. Its detailed implementation requires the adoption of the "tiered approach"; more precisely the risk is assessed based on different correlations of risk and exposure.

The risk assessment should be also made for non-recipients and related species that may have an ecological interdependence with the LMOs. Furthermore, the analysis must be made on a case by case basis. In other words, there can be no assessment reports on general or universal terms on an identified LMO; an assessment study on the consequences of a release of LMOs to the environment in a country can not be used in another as a solid scientific proof for the same organism. The comparative analysis of the impact of non-GM crops and LMOs on the environment can also be an assessment tool, but this can not be accepted as sufficient by public agencies for environment release decision or commercial approval. However, the tendency to use use the same single risk assessment has been observed in several countries, including Brazil, where the LMOs have become a subject of legal liability, which resulted in a change in the legal framework and encouraged the public opinion to consider this issue more carefully.

[8] According to national laws, if the conformity/identity preservation controls of imported LMO-FFPs reveal the presence of higher percentages of LMO in shipments than the specified threshold, the operators may be subject to investigations or litigation cases. The use of "may contain" allows evoking an adventitious presence.

[9] Ulrich Beck, *La société du risque: Sur la voie d'une autre modernité*, Paris, Editions Flammarion, 2008, p. 49

[10] http://www.cbd.int/biosafety/issues/risk.shtml

Risk management by the Parties is also poorly defined. Under the Article 16, Parties must adopt the necessary measures for prevention and management when risks are assessed, to prevent unintentional transboundary movements of LMOs and cooperate to identify *traits* that may cause adverse effects. In the same vein, the COP-MOPs agreed on the necessity of capacity building and created the *Ad Hoc Technical Expert Group on Risk Assessment* that works on existing approaches in this field to identify the differences (gaps) between the Parties and capacity building needs.[11] Besides the shortcomings of the scientific capacity to implement a relevant methodology of the Protocol, the main difficulty is the establishment of a prior assessment of biodiversity. Even though different indicators have been developed they do not provide references to evaluate the possibility of dispersion and interaction of LMOs with non-targeted environment. Moreover, the use of Payment for Ecosystem Services (PES) for risk and damage assessment is not yet relevant in current discussions between the Parties. Even if the operational instruments of an objective assessment are not available, the progressive realization of legal liability and compensation processes can at least ensure intersubjective application of the precautionary principle.

The Evolution of the Protocol: More Environmental Regulations or More Business?

In the current state of negotiations, following the COP-MOP 5 in 2010 in Nagoya (Japan), the progress of international governance on biosafety focuses on liability and redress in the context of the objective stated in the Article 27 of the CBD. Thus, the framework of activities/products involving LMOs, the definition of damage and identification methods for the conservation of components of biodiversity are acquiring content and gaining clarity. Discussions on the definition of injury and limits of liability have often reflected the concerns of the Parties as regards their legal and financial commitment compared to non-Parties, the questioning of their credibility and potential use of these instruments as commercial "shields". In the vision of the Parties to the Protocol, also exporters of LMOs, a strict reading of the Article 27 may be a non-tariff barrier, though unregulated within the WTO. Furthermore, how the loss of biodiversity and risks to human health will be assessed and in what terms, in order to establish compensation schemes?

Issues relating to liability and compensation were discussed before the entry into force of the Protocol in the workshops supported by the European Union. Subsequently, the Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress was established[12], also including representatives of non-Parties (Argentina, Australia, Canada, China, Gabon, Guinea, Ivory Coast, Morocco, Philippines, Thailand and the USA). The group held five meetings since 2005, supported by the Group of Friends Co-Chairs on Liability and Redress established by the COP-MOP 4 in 2008. In this institutional context at several levels, five intricate issues have been negotiated:

- Is a new concept of damage necessary or the conventional meaning can be used? In other words, will the potential damage that can be caused by the transboundary movement of LMOs be considered as "environmental damage"?
- How to measure the damage? What is the scientific proof of harm, and, moreover, is there an objective need of proof because the protocol is based on the precautionary approach?
- How to establish the causal link between the transfer of LMOs and the damage?
- What will be the type of responsibility? State liability or civil liability?
- What is the mode of compensation and reparation, especially if the exporting Party refuses to pay or has no ability to pay? Will there be a special fund for financial security?

Parties' positions have emerged around these concerns and uncertainties, with an active position of the private operators and the NGOs, like a proposal to establish a fund by business without invoking the state liability, which has been criticized and rejected by the Greenpeace. At the second meeting of the Group of Friends Co-Chairs in February 2010, a compromise was reached on the definition of terms and the finalization of the text at the third group meeting (June 2010) in Kuala-Lumpur, before the text be submitted to the adoption of the Parties at the COP-MOP 5.[13]

[11] Decision BS-II/9 on the risk assessment and management, adopted at the COP-MOP 2 (2005), http://www.cbd.int/decision/mop/?id=10787

[12] Decison BS-I/8 on the establishment of an Open-Ended Ad Hoc Working Group of legal and technical experts on liability and redress adopted at the COP-MOP 1 (2003), http://www.cbd.int/decision/mop/?id=8290

[13] IISD Reporting Services, *Deuxieme réunion du Groupe des amis des co-présidents sur la responsabilité et la réparation dans le cadre du Protocole de Cartagena sur la prévention des risques biotechnologiques*. Bulletin des négociations de la Terre, Vol. 9 No : 459, 15/02/2010, p.4 and UNEP, *Rapport du Groupe des amis des coprésidents sur la responsabilité et la réparation dans le contexte du Protocole de Cartagena sur la prévention des risques*

After delays and further discussions, although the draft Protocol was negotiated in more depth and a consolidated text on the lines guidelines to assist Parties to develop mechanisms for civil liability was adopted, finally the "Nagoya-Kuala Lumpur Suppelementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety", its official name, have been adopted by the Parties and opened to their signature in March 2011. The Supplementary Protocol aims at implementing early intervention measures in damage to conservation and sustainable use of biodiversity arising from transboundary movements of LMOs. There are six important elements made more efficient: the definition of injury, intervention measures, the responsible operator; civil liability; compensation arrangements associated with them, and the scope of this new regime.

In this new text, the link between biosafety and the conservation of biodiversity is relatively established, damage is defined as an adverse effect "measurable or otherwise observable" by the means of "scientifically established baselines recognized by a competent authority" (Article 2.b.i) and a causal link between the transfer of an LMO and the damage should be established in accordance with the national legislation (Article 4). Although, initially, the draft text also included the terms of "imminent threat" of an "incident" and "preventive measures", they are eliminated in the Supplementary Protocol. However, a "significant" adverse effect is underlined by reference to specific factors (Article 2.3) and response measures to "prevent, minimize, contain or mitigate the damage" and to "restore biodiversity" are adopted (Article 2.2.d.i.ii).The reference to domestic law as the framework of the causal link between a transboundary movement of LMOs, including derivatives, and a deterioration of biodiversity and/or human health shows that the Protocol determines modestly principles but does not provide rules of coordination between the Parties.

Intervention measures refer to both prevention and reparation, but more to the latter. Certainly, the approach to conservation and sustainable use of biodiversity becomes more explicit as the "nearest equivalent" in the restoration of biodiversity elements and the replacement by other elements, if required "at an alternative location" are accepted as necessarily possible options depending on conditions. In applying these measures, the division of tasks between the authority and the operator or operators is specified. The definition of the operator is sufficiently broad and responsibilises stakeholders at all stages of the value chain, from the innovation to the transport of LMOs. Thus, the operator is any person who has direct or indirect control of the activity (Article 2.2.c) when the damage was a result of a transboundary movement of LMOs, a definition that has been relatively well-received by Brazil, China, India, South Africa and the African Group. This person may also be located upstream of the transport of LMOs, as the "developer, producer, notifier", or downstream, as the "exporter, importer, carrier or supplier".

Regarding the scope (Article 3), Parties remind the conservation and sustainable use of biodiversity and risks to human health caused by the transboundary movement of LMOs and derived products, without excluding any kind of use purpose.[14] However, the Cartagena Protocol has a more general scope and accepts, as noted above, exceptions concerning the necessity of pior informed agreements: the Article 6 of the Protocol excludes LMOs in transit and those intended for contained use from the regulatory framework. Thus, the new regime on liability and redress may remedy a deficiency or inaccuracy of the initial compromise. Finally, the most important provision is that the responsibility also applies to the damage resulting from transboundary movements of LMOs carried out by non-Parties (Article 3.7) through the "domestic laws" for the implementation of the Supplementary Protocol. The identification of products from non-signatory countries can at least be applied in the territory of signatory countries.

The state is not excluded from the process of liability because the competent authorities should identify the operator, assess damage and determine intervention measures. Based on relevant information, including scientific information available to the BCH for Biosafety, the intervention measures must be taken if damage is evident. The implementation of these measures rests with the operator and/or, where appropriate, the competent authority has the right to request payment of fees and expenses resulting from the damage that has been evaluated (Article5). The establishment of the link, even flexible, with the implementation of civil liability (Article 12) comforts probably exporting parties who feared an additional obligation and increased transaction costs due to a security/financial security required as part of the liability. First, national laws and/or rules and procedures, or a combination thereof, shall be applied with reference to civil liability.

---

biotechnologiques sur les travaux de sa deuxieme réunion, Kuala Lumpur 15-19 juin 2010, Unep/Cbd/Bs/Gf-L&R/3/4, le 19 Juin 2010,
http://www.cbd.int/doc/meetings/bs/bsgflr-03/official/bsgflr-03-04-en.pdf

[14] Direct use as food or feed or processing, contained use and intentional introduction into the environment ... The scope also covers non-intentional and illegal transboundary movements.

The Parties have to determine "objective" or "fault-based" characteristic of this liability, more precisely the need for proof of the fault causing damage. Secondly, the Parties may require the operator a financial guarantee and encourage financial market mechanisms for this purpose, (Article 10). It can be said that the Supplementary Protocol somehow balances the importance attached by the Parties to the commercial characteristics (non-tariff barrier) of the Cartagena Protocol, particularly during the COP-MOPs or in national debates, and highlights the conservation and sustainable use of biodiversity in a more pronounced manner. The accountability of non-Parties can significantly increase the effectiveness of the governance in biosecurity, making it expensive for them to not comply with the rules decided by their overall competitors. In fact, the major operators of the transport activity of LMOs are often the same multinational companies located in countries Party or not-Party to the Protocol and the new regime seems at least clarifying the relationship between states and firms. States have no obligation to reach agreements on issues where there is no real compromise. Business can operate within aligned and known regulatory frameworks, in other words, the looseness and lack of regulation at national level will no longer be an investment asset. Finally even if the domestic legislation is seen as a basic instrument for the purpose of liability and redress, it is now done on the basis of an intersubjective framework agreed by the Parties.

Conclusion

As for the international governance of biosafety, the baseline is established by national laws that will coexist in line at first on principles and standards of the Cartagena Protocol, and then those of the Supplementary Protocol. Risk management assessment and liability and redress mechanisms are also those defined by the competent national authorities. The international coordination of these instruments is achieved through the BCH and at the level of information exchange. In this framework, what is the usefulness of an international agreement based on national legislations? Does it clarify the cognitive uncertainties and interactions of states between companies?

The aspiration to create a relatively flexible framework, taking care not to harm the biotechnology in the name of the conservation of biodiversity components and goods and services provided by them, is probably linked to the approach taken in Agenda 21. This point of view is repeatedly emphasized by various UN bodies: Biotechnology holds great potential for human well-being if its development and use are accompanied by adequate safety measures for the environment and human health.[15] However, even if the Cartagena Protocol has no real institutional depth, the negotiation process on the accompanying documentation for the LMOs, risk assessment and management mechanisms and the responsibility, may render biotech agricultural activities and transboundary movements more visible and therefore likely to be monitored. The importance of establishing the correlation between changes of components of biodiversity, goods and services provided by it, and the damage being stressed, it can also be argued that the Protocol is gaining more content through the Supplementary Protocol.

Concerning different actors, states and firms, which are the real operators of activities involving LMOs, the lines of action are relatively specified and individual interests become clearer. Through the Supplementary Protocol, business will also become part of the governance within the context of civil liability and private financial compensation mechanisms. Therefore the "Trade and Industry" are integrated in the governance as stakeholders.

On the subject of the role of states in the governance, the establishment of groups appears to be the implementation particularity of the Protocol. The participation of Parties to the COP-MOPs and working groups on the basis of regional divisions seems to facilitate the harmonization of their positions. The emerging countries play both a contestatory role when protesting against restrictive demands and a cooperative one when negotiating for less expensive compromises. Consequently, they develop intermediate policies respecting the international commitments in accordance with the precautionary principle and their domestic regulations and priorities of the biotechnology industry. The question whether this attitude is significantly different from that of developed countries remains unresolved. Hence, again, one of the aspects of sustainable development becomes operational by the involvement of companies, which will be favorable in terms of reputation/stabilization of their business strategy and for the states in terms of credibility in their choice of ensure biosafety.

[15] Secrétariat de la CBD, *La prévention des risques biotechnologiques et l'environnement. Introduction au Protocole de Cartagena relatif à la Convention sur la diversité biologique*, http://www.cbd.int/doc/publications/bs-brochure-04-fr.pdf

References

Beck U. (2008), *La société du risque: Sur la voie d'une autre modernité*, Editions Flammarion, Paris, 521 p.

Bonneuil C., Thomas F. (2009), *Gènes, pouvoirs et profits. Recherche publique et régimes de production des savoirs de Mendel aux OGM*, Éditions Quae, 619 p.

CBD, *MOP 1 Decision BS-I/8: Establishment of an Open-Ended Ad Hoc Working Group of legal and technical experts on liability and redress in the context of the Protocol*, http://www.cbd.int/decision/mop/?id=8290

CBD, *MOP 2 Decision BS-II/9: Risk assessment and risk management*, http://www.cbd.int/decision/mop/?id=10787

IISD Reporting Services (2010), *Deuxième réunion du Groupe des amis des co-présidents sur la responsabilité et la réparation dans le cadre du Protocole de Cartagena sur la prévention des risques biotechnologiques*. Bulletin des Négociations de la Terre, Vol. 9 No : 495, le 22 février 2010, http://www.iisd.ca/biodiv/bs-gflr2

James C. (2010), *Global Status of Commercialized Biotech/GM Crops: 2010*; ISAAA Brief 42, ISAAA, Ithaca, New York, Executive Summary, http://www.isaaa.org/resources/publications/briefs/42/executivesummary/pdf/Brief%2042%20-%20Executive%20Summary%20-%20English.pdf

OECD Environment Directorate (2006), *Revised 2006: OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants*, Series on Harmonization of Regulatory Oversight in Biotechnology, No: 23, ENV/JM/MONO(2002)7/REV1, 07-Nov-2006, Paris, http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2002)7/rev1&doclanguage=en

Pallemaerts M., Moreau M. (2004), « Le rôle des parties prenantes dans la gouvernance internationale de l'environnement », *Idées pour le débat* 07/2004, Iddri, novembre 2004, 45 p.

Secretariat of the Convention on Biological Diversity (2000), *Cartagena Protocol On Biosafety To The Convention On Biological Diversity Text And Annexes***,** Montréal, 30 p.

Secretariat of the Convention on Biological Diversity (2010), *Nagoya-Kuala-Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety*, Montréal, 12 p.

Secrétariat de la CBD, *La prévention des risques biotechnologiques et l'environnement. Introduction au Protocole de Cartagena relatif à la Convention sur la diversité biologique*, http://www.cbd.int/doc/publications/bs-brochure-04-fr.pdf

Traxler G. (2004), *The Economic Impacts of Biotechnology-Based Technological Innovations*, ESA Working Paper No: 04-08, Agricultural and Development Economics Division, FAO, May 2004, p. 10

UNEP (2010), *Rapport du Groupe des amis des coprésidents sur la responsabilité et la réparation dans le contexte du Protocole de Cartagena sur la prévention des risques biotechnologiques sur les travaux de sa deuxieme réunion*, Kuala Lumpur 15-19 juin 2010, UNEP/CBD/BS/GF-L&R/3/4, le 19 juin 2010, http://www.cbd.int/doc/meetings/bs/bsgflr-03/official/bsgflr-03-04-en.pdf