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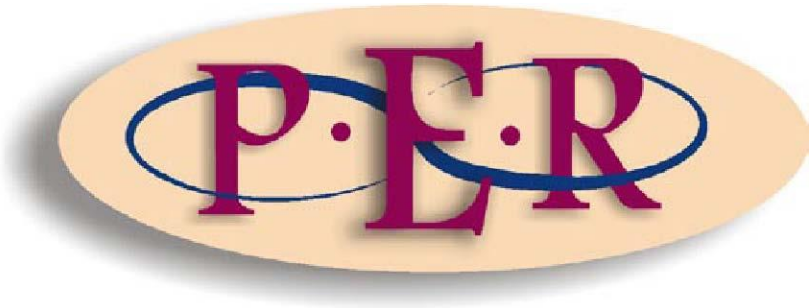

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TRANSBOUNDARY MOVEMENTS OF GENETICALLY MODIFIED ORGANISMS AND THE CARTAGENA PROTOCOL: KEY ISSUES AND CONCERNS

OJ Lim Tung*

1 Introduction

One of the first attempts[1] to legislate on international rules on biotechnology[2] goes back to the controversial[3] article 19 of the United Nations *Convention on Biological Diversity*[4] "(hereafter the CBD)" in 1992. The CBD did not provide for a biosafety mechanism *per se* due to there being disagreements over its content and scope.[5] Even though biotechnological applications were not regulated as such at the international level in the 1990s, the transboundary movements of genetically modified organisms (GMOs) had already started with bulk shipments of agricultural products[6] and biopharmaceuticals.[7] Only with the *Cartagena Protocol on Safety of*

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1 Apart from the then European Community's relevant directives. See EC Directive 90/220/EEC (23 April 1990) on the deliberate release into the environment of genetically modified organisms and EC Directive 90/219/EEC (23 April 1990) on the contained use of genetically modified micro-organisms. In 1976, before the publication of the European Community's directives, the United States (US) had established research guidelines elaborated upon by the National Institute of Health (NIH) for their grant recipients. These were adopted by other government agencies as well as private industry and a coordinated framework was published in 1986 by the Office of Science and Technology Policy. See Kirsch 2002 *Int'l & Comp Envtl L* 22.

2 Biotechnology is described by Agenda 21 as "a set of enabling techniques for bringing about specific man-made changes in deoxyribonucleic acid (DNA) or genetic material in plants, animals and microbial systems." See para 16.1 Agenda 21 *Report of the UN Conference on Environment and Development* UN Doc A/CONF.151/21 (1992); The insertion of a specified protein chain (gene) into the DNA of another organism creating a GMO. Kirsch 2002 *Int'l & Comp Envtl L* 21.

3 Views differed on the need to regulate genetically modified (GM) crops (Schnier 2001 *Fordham Envtl LJ* 385) and the need for internationally agreed rules on biosafety (Mackenzie *et al Explanatory Guide* 2).

4 United Nations Conference on Environment and Development *Convention on Biological Diversity* 5 June 1992 UN Doc UNEP/Bio.Div/N7-INC.S/4 reprinted in 31 ILM 818.

5 Street 2001 *Env L Rev* 250.

6 Mahieu *Le droit de la société de l'alimentation* 252; Lim Tung *L'encadrement juridique international des mouvements transfrontières des OGM* 35. While the World Trade Organisation (WTO) agreements regulate international trade, they were not concluded specifically to regulate GMOs. See part 4 of this paper.

7 For instance, plants may be genetically modified in such a way that they produce vaccines which can be administered by eating the crop. Nuffield Council on Bioethics *The Use of Genetically Modified Crops* 42-43; Le Gac *L'encadrement juridique communautaire* 63. In 2002 the market

Transboundary Movement of Living Modified Organisms[8] (LMOs) "(hereafter the Cartagena Protocol)" to the CBD in 2000 were the safe transfer, handling and use of LMOs (such as genetically engineered plants, animals, and microbes) across borders at last catered for, even though the protocol did not include the broader categories of GMOs. The protocol provides for an international biosafety framework for the transboundary movements of LMOs but there are still key issues in contention.[9] Negotiations on the regulation of biotechnology were fraught with compromise between ensuring the sustainable uses of biotechnology on the one hand, and environmental and health concerns on the other hand.[10] From the beginning there was a lack of consensus on the scope of the GMOs to be covered, the scope of the informed consent procedure prior to a transboundary movement, and identification and traceability issues. However, there has been some progress on liability and redress with regard to damage resulting from the transboundary movements of LMOs with the adoption of the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress*[11] "(hereafter the Nagoya SP)" to the Cartagena Protocol. There are also concerns on the harmonisation of national biosafety regulation, risk

for biopharmaceuticals was valued at US$400 billion, and its value has doubled ten years later. Ferraud-Ciandet N *Protection de la santé* 150.

8 *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (2000); Redick 2007 *Colo J Int'l Envtl L & Pol'y* 51. The Cartagena Protocol covers only LMOs (products of modern biotechnology which are capable of replication) instead of GMOs, due to a lack of consensus on the scope of the products to be covered by this protocol. An LMO means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (art 3(g) Cartagena Protocol) and is capable of transferring or replicating genetic material. LMOs can be considered as a sub-group of GMOs according to the Food and Agriculture Organisation (FAO) (see FAO 2004 www.fao.org/newsroom/fr/news/2004/43684/index.html).

9 Oliva 2002 *Int'l Legal Persp* 24.

10 Redick 2007 *Colo J Int'l Envtl L & Pol'y* 62.

11 See the Nagoya SP (adopted on 15 October 2010) available at http://bch.cbd.int/protocol/NKL_text.shtml; During the negotiation of the Cartagena Protocol, there was no consensus on the issue of liability and redress for damage resulting from the transboundary movements of LMOs, and only a 27 was included in this biosafety protocol. The Nagoya SP is a positive input to the international legal framework recognising that biodiversity may be threatened by damage resulting from transboundary movements of LMOs. It merely gives general guidelines to States parties on the elaboration of domestic regimes for liability and redress and is considered to be a set of administrative measures that States parties would have to implement. The Nagoya SP does not set up an international regime on liability and redress. Basic concepts that are relevant to the subject of liability and redress are left to States parties to address (such as the standard of liability, the concept of damage, the types of damage which can be compensated for, and evidence of the causal link between the damage and the particular GMO). By August 2013 this protocol had only 54 signatories, whereas it needs to be ratified by 50 States parties to enter into force. See Convention on Biological Diversity date unknown http://bch.cbd.int/protocol/parties/#tab=1.

assessment and risk management standards, the interpretation of socio-economic considerations, the monitoring of compliance with the provisions of the Cartagena Protocol and the settlement of GMO-related disputes. The Conference of Parties (COP) is called to regularly assess the effectiveness of the protocol[12] and to discuss opportunities to improve the regulation of the transboundary movements of GMOs, but consensus is needed among States parties on controversial issues before any change can be brought. This paper discusses the scope of the GMOs covered by the Cartagena Protocol, and identification and traceability issues, and highlights concerns about the harmonisation of national biosafety regulation, risk assessment and risk management aspects, the interpretation of socio-economic considerations, the implementation of the protocol's obligations and GMO-related dispute settlement.

2 The scope of GMOs covered by the Cartagena Protocol

To produce an agreement acceptable to all the major negotiating groups[13] and the multilateral trading system, a much weaker protocol was concluded. Only minimum standards of regulation for the transboundary movements of LMOs that may have an adverse effect on the conservation and sustainable use of biological diversity are

12 See a 35 Cartagena Protocol. The COP 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.

13 There were 5 different groups with similar positions negotiating for major issues among the 135 countries. The "Like-minded group" included all the developing countries (except Argentina, Chile and Uruguay) and was in favour of a strong biosafety protocol and the regulation of commodities with prior consent before shipments were allowed, as well as a well-documented identification of GMOs and liability and redress provisions. Zarrilli *International Trade in GMOs and GM Products* 58. The "Miami group" (the US, Canada, Argentina, Chile, Uruguay) consisted of the largest grain commodity and GM exporting countries (backed by the biotechnological industry) and wanted a biosafety protocol which would not affect the international trade of GMOs, an exclusion of commodities from the advance informed agreement (AIA) procedure and a saving clause so that the biosafety protocol would not undermine the application of trade agreements. The European Union (EU) was in favour of a biosafety mechanism which would include all categories of GMOs and the precautionary principle to protect human health. The "Compromise group" (such as Switzerland, Korea, Norway and New Zealand), which claimed to be acting as a facilitator, and the "Central and Eastern European Group" (which acted like the Like-minded group) were the smallest negotiating groups. Schnier 2001 *Fordham Envtl LJ* 403-405. In 2012 some of the developing countries of the Like-minded group are counted as the biggest GM crop exporters and are among the 10 top producers of GM crops (eg China, India, South Africa).

provided in this protocol,[14] while the scope of the advance informed agreement (AIA) procedure is limited.[15]

2.1 The limited scope of GMOs covered

Since an inflexible level of regulation covering all GMOs was considered as impeding innovative technology[16] during the negotiations on the Cartagena Protocol,[17] the term "LMOs" was agreed upon. Consequently, broader categories of GMOs are not covered by this protocol. Its scope is limited to LMOs that may have an adverse impact on biological diversity and therefore excludes LMOs those that have been processed and that are therefore not capable of transferring or replicating genetic material.[18] It should be noted, however, that domestic legislation[19] in different parts

14 Street 2001 *Env L Rev* 249.

15 The AIA is the main procedure for prior consent by the State of import before the first intentional transboundary movement of LMOs is undertaken (a 7 Cartagena Protocol).

16 Redick 2007 *Colo J Int'l Envtl L & Pol'y* 64.

17 Negotiators took almost one year to agree on the definition and the scope of GMOs to be covered by this protocol (Jacob 2001 *Transnat'l Law* 83; Glass 2001 *Nw J Int'l L & Bus* 493); Kohm 2009 *UCLA J Envtl L & Pol'y* 146-147.

18 LMOs which have been processed (for instance, GM tomato sauce) cannot reproduce themselves, unlike LMOs which have not been processed, such as GM tomatoes. However, the processed LMOs may have adverse effects on human health (Buechle 2001 *Ind J Global Legal Studies* 286). More than 90% of GM goods (especially commodities) are thus not covered by this protocol. Schnier 2001 *Fordham Envtl LJ* 414.

19 The following domestic legislation refers to GMOs and not LMOs. For instance, according to a 5(2) of the *Swiss Federal Law relating to Non-Human Gene Technology* "(hereafter the Swiss FLNHGT)" a GMO is any organism in which the genetic material has been altered in a way that does not occur under natural conditions by crossing or natural recombination (the *Swiss Federal Law relating to Non-Human Gene Technology Recueil Systématique* 814.91). The French definition of a GMO is an organism whose genetic material has been modified other than by reproduction or natural combination (a L 531-1-2° of the *French Code of Environmental Law*). S 10 of the *Australian Gene Technology Act* "(hereafter the AGTA)" 169 of 2000 defines a "GMO" as an organism that has been modified by gene technology or an organism that has inherited particular traits from an organism (the initial organism) being traits that occurred in the initial organism because of gene technology or anything declared by the regulations to be a GMO or that belongs to a class of things declared by the regulations to be GMOs. The South African definition of a GMO refers to an organism, the genes or genetic material of which have been modified in a way that does not occur naturally through mating or natural recombination or both, and "genetic modification" shall have a corresponding meaning (s 1 (xiii) of *the Genetically Modified Organisms Act* 15 of 1997). A 3 of the *Chinese regulations on Safety of Agricultural Genetically Modified Organisms* "(hereafter the Chinese regulations on biosafety)" refers to "agricultural GMOs" as animals, plants, micro-organisms and their products whose genomic structures have been modified by genetic engineering technologies for use in agricultural production or processing (*Chinese regulations on Safety of Agricultural Genetically Modified Organisms Decree* 304 of 2001). A 3 (V) of the Brazilian biosafety law refers to a GMO as "an organism whose genetic material, DNA/RNA has been altered by any genetic engineering technique" (*Brazil Biosafety Act* "(hereafter the BBA)" 11.105 of 2005). However, a 3 of the Malaysian biosafety law refers to an LMO (any living organism that possesses a novel

of the world and regional instruments[20] use the term "GMOs" and their biosafety frameworks cover not only LMOs but also broader categories of GMOs. Definitions of GMOs in domestic legislation in general do not specify or differentiate GMOs from LMOs to the extent that the organism to be genetically manipulated is described as an entity capable of replication or reproduction.

The Cartagena Protocol regulates LMOs differently, depending on whether they are to be released into the environment or meant for contained use[21] or for direct use as food, feed or to be processed (FFPs). One of the most contentious issues during the negotiations of this protocol was about the regulation of transboundary movements of LMOs intended for direct use as FFPs, which represent a large category of agricultural commodities.[22] These commodities include shipments of GM grains that are intended for use as feed for animals and for processing but can also be used as seeds.[23] There is, nevertheless, no compliance mechanism as to the final use of LMOs declared as FFPs, to the extent that some of them may not be used as declared for the purposes of export. The monitoring of the final use of these LMOs therefore still needs to be addressed.

It is also not clear in which categories some LMOs will be regulated under the Cartagena Protocol. Nutraceuticals[24] do not seem to be governed by this protocol to the extent that they cannot be considered solely as foodstuffs or pharmaceuticals (for instance, GM rice with added vitamin A). GM crops modified as "edible vaccines"

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combination of genetic material obtained through the use of modern biotechnology) and not a GMO (*Malaysian Biosafety Act* 678 of 2007). A 104 of the Canadian law on environmental protection (*Canadian Protection of the Environment Act* "(hereafter the Canadian EPA)" L.C. 1999, ch 33) refers to a "living organism" as a substance that is an animate product of biotechnology. At the regional level, the European definition of a GMO is an organism (any biological entity capable of reproduction or to transfer genetic material) of which the genetic material has been modified in a way which is not natural or by reproduction and/or natural recombination (a 2 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms).

20 EC Regulation 1946/2003 (15 July 2003) on transboundary movement is not limited to LMOs but also covers GMOs.

21 Any operation, undertaken within a facility, installation or other physical structure, which involves LMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment (a 3(b) Cartagena Protocol).

22 Saphen 2001 *Mich State Univ-Detroit College L J Int'l L* 65.

23 Zarrilli "International Trade in GMOs" 61.

24 Nutraceuticals are considered as foodstuffs with additional health value. Manga S-J *Le droit du commerce international des OGM* 9; Kohm 2009 *UCLA J Envtl L & Pol'y* 153.

or "biopharmaceuticals"[25] are also not catered for by the provisions of this protocol, since they are neither agricultural products as such, nor pharmaceuticals. Whether or not transgenic mosquitoes for disease control purposes[26] will be considered as pharmaceuticals is not clear. GM pigs are being used for organ transplant purposes[27] but the provisions of this protocol do not apply to this category of GMOs. The provisions applicable to LMOs in contained use may potentially apply to GM pigs for laboratory use[28] being transported from one country to another. However, these pigs will not be subjected to risk assessment requirements unless the party of transit decides to regulate the transport of such LMOs or the State party of import decides to subject such LMOs to risk assessment requirements.[29]

2.2 The AIA procedure

The Cartagena Protocol was drafted with the main purpose of addressing the safety of transboundary movements of GM crops, and consensus was not reached on the need for the application of the AIA procedure for all categories of LMOs covered by the protocol. The AIA procedure does not apply to LMOs in transit[30] and LMOs destined for contained use,[31] while a simplified procedure as per article 11 of the Cartagena Protocol is applicable for LMOs intended for direct use as FFPs instead of

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25 Buechle 2001 *Ind J Global Legal Studies* 319. Those who are in favour of the development of "edible vaccines" argue that injected vaccines are expensive and require trained staff for their administration as well as constant cooling during transport and storage. Nuffield Council on Bioethics *The Use of Genetically Modified Crops* 42-43.

26 For instance, mosquitoes containing a transgene for resistance to rodent malaria.

27 Jones 1988 *Food Drug Cosmet LJ* 352.

28 Lawrence 2007 *Ecology LQ* 263; Moye 2005 *NC L Rev* 1567.

29 Mackenzie *et al Explanatory Guide* 59.

30 The COP of the Cartagena Protocol merely encourages parties to continue to address issues related to the transit of LMOs through their territories using their domestic administrative and legal systems within existing regional and international requirements (see the *Fifth meeting of the COP serving as the meeting of the Parties to the Cartagena Protocol on Biosafety* "(hereafter COP-MOP5)" with regard to the rights and obligations of parties for the transit of LMOs). Each State may regulate the transit of LMOs as per domestic legislation. Eg, South Africa's (SA) transit policy was communicated to the BCH, according to which LMOs may transverse the territory of SA to another country only if that country confirms its acceptance of the consignment. See the Second regular national report on the implementation of the Cartagena Protocol on Biosafety for South Africa on the Biosafety Clearing-House Central Portal at Biosafety Clearing-House 2011 http://bch.cbd.int/database/record.shtml?documentid=102653.

31 Parties can regulate LMOs destined for contained use in their territories and undertake risk assessments before authorising imports (a 6(2) Cartagena Protocol).

the more stringent AIA procedure. LMOs that are pharmaceuticals for people[32] and are addressed by other relevant international agreements or international organisations, do not need to undergo an assessment of risks prior to their import, as is required under the AIA procedure. The exclusion of these LMOs from the AIA procedure only was a compromise to the extent that the "Miami Group" wanted to exclude pharmaceuticals completely from the scope of the Cartagena Protocol. A State party has the right to subject all LMOs to a risk assessment prior to the approval of an import, but States parties rarely use this right.[33] It is argued that the AIA procedure should also cover pharmaceuticals for the use of people. While there are relevant international agreements under the aegis of the World Health Organisation (WHO) that are applicable to pharmaceuticals for people, it should be pointed out that many of these agreements deal with human health concerns and do not address the environmental and biodiversity impacts of LMOs.[34]

The exporter of the LMOs is responsible for seeking consent before proceeding to an intentional transboundary movement of LMOs for the first time, but not prior to subsequent movements of the same categories of LMOs.[35] The Cartagena Protocol does not specify if other exporters can rely on this authorisation to export the same category of LMOs for the same purposes. It is also important that the validity of the authorisation for the first intentional transboundary movement of LMOs be limited to

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32 Eg micro-organisms that are genetically modified to transmit the hepatitis B vaccine. Mackenzie *et al Explanatory Guide* 55; Saphen 2001 *Mich State Univ-Detroit College L J Int'l L* 68.

33 See a 5 Cartagena Protocol.

34 Mackenzie *et al Explanatory Guide* 56. See the existing agreements or programmes under the aegis of the WHO 2014 www.who.int/countries/fr/index.html. The movement of pharmaceuticals intended for people is subject to the "Certification Scheme on Pharmaceutical Products Moving in International Commerce" applicable to finished dosage forms of pharmaceutical products intended for administration to human beings or to food-producing animals. The competent authority of the exporting country of the pharmaceutical will need to notify to its counterpart in the country of import that this pharmaceutical has been authorised to be placed on the market within its jurisdiction (WHO 2014 www.who.int/countries/fr/index.html). During the negotiations of the protocol, many countries initially opposed to exempting pharmaceuticals for people were reassured by the incorporation of a risk assessment in this certification mechanism. See WHO date unknown www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/. See the 1970 *Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products* "(hereafter the Pharmaceutical Inspections Convention)". Biopharming (the genetic engineering of plants to grow pharmaceuticals, antibodies and industrial enzymes) poses more serious risks to human health and the environment than crops intended for consumption. Richmond 2006 *Pac Rim L & Pol'y J* 585.

35 Kameri-Mbote 2002 *RECIEL* 63.

a period of five years, for instance, subject to the level of scientific knowledge on the adverse impacts of GMOs. It could also be required that the exporter of these LMOs completes another authorisation procedure before proceeding to an intentional transboundary movement if new scientific information on these particular LMOs is available before this period. The need for an AIA implies that the exporter needs to conduct a risk assessment with regard to the LMOs to be exported, whereas other simplified procedures[36] do not require a risk assessment. If an AIA is not applicable to a category of LMOs, the country of import has nevertheless the discretion to request a risk assessment prior to approving the import of this category of LMOs. However one could say that not all countries of import (especially developing countries) have the necessary technical and financial capacity to undertake risk assessments, and countries of export should provide a risk assessment before authorisation.

Simplified procedures apply to LMOs that are considered less dangerous for the environment to the extent that they cannot transfer or replicate their genetic material, and no risk assessment is required for the approval of these procedures. These procedures are not as stringent as the AIA procedure and can be considered as a compromise to the scope of the application of the AIA. Article 11 of the protocol provides for a simplified procedure which is completed through written notification to parties through the Biosafety Clearing House (BCH). If the State of import decides that the import of a specific category of LMOs for direct use as FFPs will be allowed, only a notice needs to be communicated within 15 days to the BCH as per annexure II of the Cartagena Protocol. For LMOs intended for direct use as FFPs, only developed countries have obligations to put in place domestic regulatory frameworks. Developing countries including those with economies in transition need to take decisions based on risk assessments only within a predicted framework.[37] Although an AIA procedure is not required by the Cartagena Protocol regarding

36 See aa 11 and 13 Cartagena Protocol. The COP of the Cartagena Protocol is also competent to consider particular categories of LMOs as safe LMOs and consequently to exempt them from the AIA procedure.

37 Kameri-Mbote 2002 *RECIEL* 62.

imported agricultural commodities, some countries may require field trials[38] before approving the import of GM agricultural commodities. Article 13 of the protocol provides for a simplified procedure allowing States to export LMOs without a written permit if the importing party consents,[39] provided all adequate measures have been taken. The country of import may inform the BCH about cases in which an intentional transboundary movement may take place at the same time as the transboundary movement is notified to the Party of import. The country of import may also inform the BCH about LMOs considered as not hazardous, which are to be exempted from the AIA procedure.

3 Identification and traceability issues

The traceability of GM products is the backbone of biosafety regulation and it is in line with basic sanitary requirements and the requirement of transparency of methods of production.[40] Tracing back GM products through the application of a general labelling system[41] was heavily discussed during the negotiations of the Cartagena Protocol. On the one hand, the "Miami Group" and the United States (US) wanted to avoid the segregation of LMOs and labelling requirements. On the other hand, the European Union (EU) wanted GM plants, bacteria, animals or agricultural or food products to be labelled on the basis of health and environmental grounds as well as to allow for better consumer choice. Vocal debates on the labelling of LMOs resulted in compromises as to whether they should be labelled and which ones should actually be labelled. This part discusses the need for an international identification system for GM products and the harmonisation of thresholds of GM content for non-GM products at the international level.

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38 For instance, the Republic of Korea approved ten biotech events for food and feed use only, but required field trials for these commodities. Redick 2007 *Colo J Int'l Envtl L & Pol'y* 97-98.

39 Kameri-Mbote 2002 *RECIEL* 64.

40 Granjou *La gestion des risques* 311. The Codex Alimentarius Commission (a food standards - setting commission under the aegis of the FAO and the WHO) defines "traceability" as "the ability to follow the movement of a food through specified stage(s) of production, processing and distribution." See FAO date unknown www.fao.org/ag/againfo/themes/en/meat/quality_trace.html. Traceability in general is the ability to follow the movement of a product from its first stage of production to the consumer.

41 Maljean-Dubois "La Régulation du Commerce International" 36-37; Tracy 1999 *Buff Envtl LJ* 137.

3.1 An international identification system for GM products

An international identification system[42] is needed so that a product can be identified from its first stage of production to the stage where it reaches the consumer. However, it may not be an easy task to achieve over the whole of the production process without rigorous management. Being able to trace back GM products in a food chain facilitates precise labelling, identification, detection and monitoring of their effects on the environment and human health. An efficient traceability mechanism needs to be harmonised[43] at all stages of the production of GMOs, with appropriate risk management measures in order to facilitate the withdrawal of hazardous products[44] from the market. During the negotiations of the Cartagena Protocol, the EU wanted to extend the traceability debate on food standards while the US was of the opinion that it is the Committee of the Codex Alimentarius that is competent for such an issue.[45] However, at the international level the Codex Alimentarius Commission[46] does not consider traceability as a priority but merely as one of the tools to be used for the inspection and accreditation/certification of foodstuffs.[47] This commission did consider labelling issues pertaining to GM food that would allow consumers an informed choice, but has not taken a stand between the

42 Mansour and Key 2004 *Int'l Law* 55.

43 There is a diversity of labelling standards in different countries. For instance, no mandatory labelling is required for GM products in the US and in Canada (Strauss 2006 *International Lawyer* 98). Mandatory labelling is required for products containing 1% GM content in Australia and New Zealand (see Food Standards Australia New Zealand GM Food Labelling, Compton 2003 *Pace Int'l L Rev* 385), for Saudi Arabia and for China (Appleton 1999-2000 *New York UELJ* 568). The labelling threshold for GM products is 0.9% for the European Union (see Europa Summary of EU Legislation http://europa.eu/legislation_summaries/environment/nature_and_biodiversity/l21170_en.htm and Regulation 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC Official Journal L 268/24 18.10.2003), 3% for Korea (Compton 2003 *Pace Int'l L Rev* 387) and 5% for Japan (Coffield 2000 *Canada-US LJ* 27) and for South Africa (see the South African Labelling Regulations (GN R293 in GG 34180 of 1 April 2011) in terms of s 120(1) of the *Consumer Protection Act*).

44 Granjou *La Gestion des Risques* 339; Wal 1997 *Rev Fr Allergol* 332; A 1 of EC Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

45 See FAO-WHO 2002 www.who.int/foodsafety/codex/en/codex_eval_report_en.pdf. See Codex Alimentarius date unknown www.codexalimentarius.org/committees-and-task-forces/en/.

46 The Codex Alimentarius is also one of the WTO's reference bodies on food/feed safety including traceability systems. Redick 2007 *Colo J Int'l Envtl L & Pol'y* 61; Dufour, Barsalou and Mackay 2006 *Cahiers de Droit* 485-486.

47 Codex Alimentarius Commission *Principles for Traceability* 1-3.

adoption of product-based labelling or a process of production-based labelling.[48] The tolerance of the adventitious presence of GM content in imported products was also lengthily discussed, as well as the standards and guidelines for the assessment of GM food. However, no stand has been taken[49] on these issues due to a lack of consensus.

The Cartagena Protocol was finalised with compromises on the labelling of LMOs subject to transboundary movements. It states merely that States parties should take measures to require identification documentation to accompany shipments with LMOs to be used directly as FFPs. The shipments must be clearly identified as goods that "may contain GMOs" and it must be stated that they will not be introduced into the environment. More specific and detailed requirements pertaining to the identification of these LMOs[50] were meant to be decided by the COP convened two years after the entry into force of the Cartagena Protocol, in consultation with other relevant international organisations. In 2006, States parties to the Cartagena Protocol in Curitiba (Brazil) discussed the designation to be used on the products or on commercial invoices during shipping and the "may contain LMOs" designation succeeded after intense negotiations.[51] States parties were encouraged[52] to implement laws that mandate the disclosure of biotech crop inputs where the identity of the traits[53] is "known through means such as identity preservation systems".[54] Where the identity of the traits is known (for instance, Roundup Ready

48 For years, the Committee of the Codex Alimentarius on the Labelling of foodstuffs presided by Canada tried to negotiate for a solution to the labelling of GM foods to no avail. Buechle 2001 *Ind J Global Legal Studies* 311-312.

49 Two meetings in March 2000 and 2001 failed to reach consensus on traceability issues due to conflicts between the EU and the US. Maljean-Dubois "La Régulation du Commerce International" 51-52; Lim Tung *L'encadrement juridique international des mouvements transfrontières des OGM* 15.

50 See a 18(2)(a) Cartagena Protocol.

51 See the Curitiba Consensus in March 2006 (International Institute for Sustainable Development *et al* 2006 www.iisd.ca/biodiv/bs-copmop3).

52 Secretariat of the CBD *Decisions of COP-MOP3* 2007.

53 Each trait in a biotech crop (eg resistance to a particular herbicide or virus) has been given unique identifiers for the genetic transformation event they are known to contain by means of the identifying information elaborated by the OECD. It has a unique identification system known as the OECD Unique Identifier for Transgenic Plants which the BCH approves and lists as suitable for planting or import and suitable for food or feed. OECD date unknown bch.biodiv.org/organisms/uids.shtml.

54 This term requires interpretation as to its meaning in the context of existing agricultural management practices, but for certified seed production it means procedures to preserve the

Soybeans), there would be shipment disclosure. But where the identity of the traits is not known, parties are not requested to enact legislation mandating lists of all possible traits[55] that a shipment "may contain" upon arrival in port. The importing party has the discretion to decide what will be requested in the list[56] and the appropriate procedure to be completed. Paragraphs 2 (b) and (c) of article 18 of the Cartagena Protocol also place obligations on parties to take measures to require more precision on the documentation accompanying LMOs destined for contained use and LMOs for intentional introduction into the environment and any other LMO within the scope of the protocol. Accompanying documents need to clearly identify them as LMOs, to specify any requirements for their safe handling, storage, transport and use, and to provide other specific information. There is no consensus yet on the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices pertaining to these LMOs.[57] The sixth meeting of the COP to the CBD serving as the *Meeting of the Parties to the Cartagena Protocol on Biosafety* "(hereafter COP-MOP6)" mainly requested parties to continue to use a commercial invoice or other documents required or utilised by existing documentation systems.[58]

An international identification system is necessary, with labelling requirements for GM products, to be able to segregate GM products from non-GM ones and avoid

purity level of a seed product.

55 In practice, grain exporters find it costly to mandate a list of all possible traits since this would involve testing, trade disruption, and efforts to preserve products from adventitious presence of GM content. Redick 2007 *Colo J Int'l Envtl L & Pol'y* 74.

56 Only a few countries such as Mexico and Japan have listed their approvals of traits at the BCH in accordance with a 11, but there might be inadvertent commingling at the time of import (Redick 2007 *Colo J Int'l Envtl L & Pol'y* 75).

57 The Secretariat of the CBD had the task to explore possibilities to strengthen inter-organisational cooperation (through inter-agency administrative agreements) regarding the creation, under the umbrella of the World Customs Organisation, of a new tariff position for LMOs and their different uses (for direct use as FFPs or contained use or for intentional introduction into the environment). Another possibility was to share the International Portal on Food Safety, Animal and Plant Health with the FAO with a view to storing all available information on one website. The Secretariat of the CBD also had to advise the UN Committee of Experts on the Transport of Dangerous Goods about LMO risks, and eventually, propose some adaptations to the UN Model Regulations. See Secretariat of the CBD *Analysis of information on standards relevant to the handling, transport, packaging and identification of LMOs* COP-MOP6.

58 Parties can also use the documentation required by domestic regulatory and/or administrative frameworks. See Secretariat of the CBD 2012 www.iisd.ca/biodiv/bs-copmop6/.

mistakes[59] in handling shipments during transboundary movement. Without an international identification system and segregation procedures for GM and non-GM products, there is no effective traceability of GM products. It is also important for an international traceability system to ensure that there is transmission and conservation of information on GM products, as well as a unique identification code[60] to be used at each stage of production until the products are placed on the market. All required documents, labels, standardised delivery notes recorded in official registers and identification codes would need to be transmitted in writing by the different operators involved at each stage of production.[61] Due to a lack of consensus, the Cartagena Protocol does not indicate any requirement for the segregation of LMOs for the purposes of transboundary movement. Mandatory GM food labelling at the international level may still be opposed presently by the biotechnology industry or its advocates in the food industry for fear of stigmatising GM foods.[62]

3.2 Harmonisation of labelling thresholds for GM products

Due to a lack of consensus on the need for labelling GM products, an international labelling threshold could not be determined.[63] States have different approaches on

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59 In the US, corn intended to be used as animal feed got mixed up with food for human consumption. Consequently the corn producer had to withdraw all the products; Buechle 2001 *Ind J Global Legal Studies* 159; Beebe 2004 *WMELPR* 511; Bratspies 2003 *WMELPR* 593; Hutchinson 2008 *San Diego Int'l LJ* 236; Hamilton 2005 *Wash U JL & Pol'y* 46; Nelson 2002 *Drake JAL* 242; Woodsmith 2003 *San Joaquin ALR* 210; Isham 2006 *Journal of Food Law & Policy* 100; Winn 1999 *Food & Drug LJ* 670. However, where bulk processing systems are used for shipping of grains, the identification of each biotech trait in a shipment that contains various biotech traits will pose challenges, if ever there are international segregation rules on shipments. UNEP 2006 www.biodiv.org/doc/meetings/bs/mop-03/official/mop-03-15-en.pdf.

60 The term "unique identifier" means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO. See a 3(4) EC Regulation 1830/2003. The OECD has not yet developed a unique identifier for other types of GMOs such as micro-organisms or animals. See Secretariat of the CBD *Analysis of information on standards relevant to the handling, transport, packaging and identification of LMOs* COP-MOP6.

61 EC Regulation 1830/2003 provides for a traceability mechanism for two categories of products, namely products that consist in GMOs or which contain GMOs, and feed intended for human consumption and GM animal feed. Operators using or handling GM products need to transmit and retain during 5 years relevant information (that the product contains or consists of a GMO) at each stage of its introduction on the market. See a 4(1) of this regulation.

62 Schoenbaum 2000 *ICLQ* 37.

63 All GM food labelling should use predetermined thresholds, as it is not possible to ensure zero GM in a product once GMOs are present in the production system. Bullock 2002 *Food Policy* 81-

traceability standards which need to be harmonised with sound detection methods and a harmonised minimum threshold of the tolerance of GM content.[64] In practice, the threshold of tolerance of GM content is often equivalent to the labelling requirements of GMOs or the adventitious presence of GM content.[65]

A lack of harmonised thresholds undoubtedly has an impact on the organic products' industry. Organic food producers in countries with no tolerance threshold for GM content or a higher level of threshold tolerance (for example 5%) may not get access to the organic market in countries having a low tolerance threshold (for example 1%). However, providing information on the identification of traits at a zero tolerance threshold may have technical and practical limitations.[66] The reliability or accuracy of the lists of traits might be another issue. Seeds tested as negative for such a biotech trait may be considered as negative in one country and positive in another country. Consequently, an action filed in different countries to seek compensation for the contamination of non-GM crops will have different outcomes.

4 Main concerns about the regulation of biosafety at the international level

In addition to the key issues that have been analysed in this paper, there are concerns about the harmonisation of biosafety regulation, the interpretation of socio-economic considerations, the harmonisation of risk assessment and risk management standards, and the monitoring of compliance. This part ends with concerns about the likelihood of GMO-related disputes being settled under other recourse mechanisms than the CBD dispute settlement mechanism.

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64 A few examples of different labelling thresholds for GM products are as follows. A 0.9% threshold is applicable in the EU and Switzerland; a 1% threshold in Australia, New Zealand and Brazil; and a 5% threshold in Japan, SA and Taiwan; while there is no labelling threshold in the US.

65 EC Regulation 49/2000 allows a *de minimis* labelling threshold of 1% (for each ingredient individually considered) for the accidental content of GM material in non-GM products; Zarrilli "International Trade in GMOs" 50. Japan has a 5% tolerance for approved biotech crops in non-GM bulk shipments for imported soybeans from the US for non-GM food products. Redick 2007 *Colo J Int'l Envtl L & Pol'y* 105-106.

66 Redick 2007 *Colo J Int'l Envtl L & Pol'y* 94.

4.1 Harmonisation of biosafety regulation

Since the adoption of the Cartagena Protocol, there has been a noticeable increase of countries having biosafety frameworks not necessarily with the same standards. In 2002, the Fund for Global Environment adopted an initial strategy with some measures to be taken. This strategy was followed in June 2001 by a United Nations project of the Environment Programme (UNEP)-Global Environment Facility (GEF)[67] with US$ 39 million to help 100 developing countries to set up national biosafety frameworks (NBFs).[68] By 2007 more than 130 countries had developed or were in the process of developing their NBFs with the support of the GEF. By May 2012, 121 countries had completed most parts of their NBFs[69] and biosafety frameworks can be said to be partially or fully in place in most States parties to the protocol. The harmonisation of these biosafety frameworks is needed to ensure the safe handling of GMOs during transboundary movement in different regions of the world.[70] In 2013 most of the regional groups[71] did not have an overarching regional biosafety framework as such, although several States within these regional groups may have NBFs or draft frameworks.

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67 This project included a contribution of US$ 6 million for the setting up of NBFs, based on the experience and lessons to be learnt from a previous set of pilot projects undertaken in 18 countries between 1997 and 1999.

68 The main components of an NBF are a regulatory system set in place to address safety in the field of modern biotechnology, an administrative system to handle requests for permits for certain activities, a decision-making system that includes risk assessment and management for the release of LMOs, and mechanisms for public participation and information. UNEP/GEF *Building Capacity for the Implementation of the Cartagena Protocol on Biosafety* 2002 15.

69 See UN Environment Programme date unknown www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx. The Cartagena Protocol has a total number of 166 States parties.

70 See national reporting figures. 143 countries out of 163 submitted their second national report before 30 September 2011 (CBD 2013 http://bch.cbd.int/protocol/cpb_natreports.shtml). Only half of the parties have implemented the core provisions of the protocol with an AIA procedure. International Institute for Sustainable Development *et al* 2012 www.iisd.ca/vol09/enb09585e.html.

71 The categories of the UN regional groups are the African group (54 members, 28% of UN members, 39 NBFs), the Asian Group (53 members, 27% of UN members, 36 NBFs), the Central and Eastern Europe Group (23 members, 12% of UN members, 18 NBFs), the Latin America and Caribbean Group (GRULAC) (33 members, 17% of UN members, 29 NBFs) and the WEOG (Western Europe and other groups) with 15% of UN members) UN Environment Programme date unknown www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx.

The African region has a Draft African Union Model Law on Safety in Biotechnology[72] which sets higher standards than those of the Cartagena Protocol. This region can be said to have been confronted with GMO issues in a special way through GM food aid,[73] and several countries took a negative stand even in the midst of serious national food needs.[74] Harmonisation projects[75] are also being undertaken by various institutions having vested interests in the biotechnological industry, such as the US-funded Aid Programme for Biosafety Systems in East and West African countries.

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72 The obligations set out in the Cartagena Protocol did not fully align with national needs and priorities of many African countries and even contain some provisions which are considered to be forced upon African countries. See Kameri-Mbote 2002 *RECIEL* 62. The Draft Revised African Union model law on Safety in Biotechnology is meant to set standards for the African continent subjecting the entire spectrum of GMOs to safety assessments. However these standards serve mainly as guidelines to African countries, since this model law on biosafety has not yet been finalised. See Draft Revised African Union Model Law on Safety in Biotechnology 2011 http://hrst.au.int/en/sites/default/files/2011-FinalDraftAMLS-en.pdf.

73 In 2002, Zambia refused maize offered by the US for health reasons and risks of contamination of local varieties of maize, since part of the stock contained GM maize. The government of Zimbabwe authorised the entry of GM food aid in July 2002 but requested that the GM maize be milled as soon as it arrived to avoid risks of contamination of local varieties. Uganda announced that GM agricultural products could be imported but only for consumption and not for agricultural purposes. Sudan requested that food aid from the US be certified "non-GM" whilst Angola accepted GM food aid only if all the GM cereals were milled before their entry into its territory. Zarrilli *Le commerce international des OGM* 11-12; Hamilton 2005 *Wash U JL & Pol'y* 41.

74 In 2006 44 countries in Africa are said to have received food aid from the World Food Programme (WFP) and the USAID including GM food or with traces of GM content, mostly in the US donations. The WFP has adopted a policy that allows recipient countries to specify whether they are prepared to receive food aid contaminated with GMOs. Moola and Munnik *GMOs in Africa* 5.

75 The West African Regional Biosafety Project was funded by USAID in this region while the Economic Community of West African States (ECOWAS) and the Common Market for Eastern and Southern Africa (COMESA) are being used as a forum to regulate biosafety with seemingly weaker biosafety policies. The African Union's Biosafety Strategy envisions that Regional Economic Communities or bodies will facilitate regional trade and implement the African Biosafety Strategy. Cooperation is being sought in a few countries within a region willing to set up legislation favourable to the development of GM crops, which would then be used as a springboard to reach that particular region in terms of model policies. Although a 23 of the Cartagena Protocol encourages public awareness and participation, the target seems to be mainly to establish a one-stop regional market for GM seeds without going through a democratic debate. The COMESA policy on GM technology has been drafted after the conclusion of a process taking nine years, and has been submitted for national consultation. According to this policy, once the COMESA has approved the development of a GM crop in one of the Member States, this approval will be applicable in these 19 countries. A biosafety map is also being discussed under the COMESA for the development of national regulations on GMOs as well as communication schemes for the dissemination of information on GMOs. See International Service for the Acquisition of Agri-biotech Applications (ISAAA) 2010 www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=6828.

The Asian region is poised to play a crucial role in determining how widely GM crops will be accepted on an international scale.[76] It has many developing countries struggling to feed their populations, but also includes some of the biggest exporters of GM products such as China[77] and India, as well as a good agricultural import market.[78] There seems to be no regional Asian biosafety mechanism yet, but general guidelines are available on the release of agriculture-related GMOs under the aegis of the Association of South East Asian Nations (ASEAN) Economic Community.[79] Harmonisation strategies are being carried out by private institutions such as the International Food Policy Research Institute (IFPRI) for Asian countries.[80]

The Latin America and Caribbean Group (GRULAG) has some of the biggest initial exporters of GM crops such as Argentina[81] and Brazil,[82] but no regional biosafety mechanism *per se.* Mexico serves as a centre of origin for maize and key corn innovators and does regulate some food safety aspects in relation to GMOs.[83]

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76 Richmond 2006 *Pac Rim L & Pol'y J* 570-571.

77 China has been using native Chinese genetic resources to improve commercial rice productivity with biotech rice, and imports mainly soybeans to feed its population (Redick 2007 *Colo J Int'l Envtl L & Pol'y* 100). According to information submitted to the CBD secretariat on 17 July 2000, China has completed the UNEP/GEF project for formulating the national biosafety framework and has strengthened legislative and administrative measures for biosafety management, and capacity-building in this field. China has regulations on the safety of agricultural GMOs, safeguarding human health and the safety of animals, plants and micro-organisms, protecting the environment and promoting research on agricultural GMOs (Chinese regulations on biosafety).

78 Malaysia is the 26th largest agricultural export market for the US with respect to GMO soybean and corn shipments (valued at US$36 million in 2005) and is considered as an influential voice among developing countries and in the Islamic world, with its leadership on "halal issues". The year 2005 marked the new National Biotechnology Policy to give impetus to develop the biotechnology sector. See USDA *Malaysia Biotechnology Annual 2006* 3.

79 See ASEAN 2009 www.asean.org/communities/asean-economic-community/item/asean-cooperation-in-food-agriculture-and-forestry-major-achievements.

80 Gruere, Bouët and Mevel *Genetically Modified Food and International Trade.*

81 Richmond 2006 *Pac Rim L & Pol'y J* 578. Argentina's biosafety regulatory system comprises of farming and sanitary rules and administrative laws emanating from the national authority (the Secretariat of Agriculture, Livestock, Fisheries and Food) with a detailed system on the procedures applicable for the use, release and placing on the market of GMOs of both animal and plant origin. Secretariat of Agriculture, Livestock, Fisheries and Food *Revision of Argentina's National Biosafety Framework* 1-2.

82 Brazil's biosafety framework provides for safety standards for GMO-related activities as well as biosafety institutions.

83 See Redick 2007 *Colo J Int'l Envtl L & Pol'y* 106-107. Mexico is also a State Party to the Cartagena Protocol and has made an agreement on the application of a 18(2)(a) with its partners of the North American Free Trade Agreement (NAFTA), the trilateral trade bloc agreement applicable to North American countries (the US and Canada) as from 1 January

The Central and Eastern Europe (CEE) Group does not have a regional biosafety framework, but the UNEP took initiatives for the setting up of appropriate biosafety systems with funds from the GEF. The European Federation of Biotechnology and the UN Industrial Development Organisation's Biosafety Information Network and Advisory Service (BINAS) have been involved in helping the CEE countries to develop regulatory frameworks on biotechnology. In September 1994 a task force for regulatory oversight for CEE countries was established with limited success in the development of regulatory frameworks within this region.

The Western Europe and other groups (WEOG) is another UN regional group which is composed of countries with individual NBFs, but also has one of the most stringent regional biosafety framework for members of the EU. This region also includes exporters of GM products such as Canada and Australia,[84] while the US is mainly an observer.[85]

States parties to the Cartagena Protocol can conclude bilateral, regional or multilateral agreements or arrangements with States which are not parties to this protocol concerning transboundary movements of LMOs.[86] Such agreements which

1994. See NAFTA date unknown www.nafta-sec-alena.org/Default.aspx?tabid=87&language=en-US. The NAFTA provisions on sanitary and phytosanitary measures recognise NAFTA governments' right to have more stringent measures than the international standard. See article 713(3) NAFTA. Scientific evidence must be demonstrated and these measures can be maintained only on scientific grounds with risk assessments. Risk analysis under NAFTA allows shipments designated non-GMO to have up to 5% of approved GM material. The regulations also refer to the standards of the WTO reference bodies. Coffield 2000 *Can-US LJ* 241.

84 The AGTA consolidates the regulation of GMOs and GM products and provides for an agency overseeing all GMO-related issues, namely the Office of the Gene Technology Regulator (OGTR). Other committees like the scientific committee, the community committee and an ethics committee provide advice to the OGTR and Ministerial Council. Richmond 2006 *Pac Rim L & Pol'y J* 587.

85 The US is not a member of any regional group but attends meetings of the WEOG as an observer and is considered to be a member of that group only for electoral purposes. See UN 2014 http://www.un.org/Depts/DGACM/RegionalGroups.shtml. There are several administrative agencies ensuring that GM agricultural products are safe: the United States Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS) protecting agriculture from pests and diseases, the Food and Drug Administration (FDA) governing the safety and labelling of drugs, food and feed. The Environment Protection Agency (EPA) ensures the safe use of pesticides and herbicides in the environment and the safe use of industrial microbes in the environment, while the NIH has guidelines for the laboratory use of GMOs. Coffield 2000 *Can-US LJ* 239. As members of the NAFTA, the US and Canada are subject to the provisions of this regional agreement in respect of sanitary and phytosanitary measures.

86 See a 24 Cartagena Protocol.

came into being prior to the protocol or after its coming into force[87] should not provide a lesser degree of protection, but in practice there does not seem to be any compliance mechanism in this matter. Bilateral or multilateral trade agreements are said to be used by some industrialised countries as an indirect means to weaken the provisions of this protocol.[88]

4.2 The interpretation of socio-economic considerations

The Cartagena Protocol includes socio-economic considerations[89] which States parties can take into account when reaching a decision on an import of LMOs. However, the understanding and scope of socio-economic considerations need to be clarified in this protocol. Adequate research and studies are required to fill knowledge gaps and to identify specific socio-economic issues related to LMOs. Appropriate methods of assessment of socio-economic considerations, particularly regarding social and other impacts on indigenous and local communities, are sorely needed.[90] Consensus should be sought on general guiding principles to be used for the consideration of the socio-economic impacts of GMOs, taking into account the specific circumstances applicable to States parties. In practice, measures that are likely to be considered on the basis of socio-economic grounds would probably run the risk of being considered as barriers to trade. The African Centre for Biosafety (ACB) initiated discussions with regard to two South-African assessment studies submitted to the Secretariat of the Cartagena Protocol, but no light has been shed yet on the interpretation of socio-economic considerations.[91] However, COP-MOP6

87 See a 14 Cartagena Protocol.

88 Grain 2007 www.infogm.org/spip.php?article3114 84; GRAIN is a non-governmental organisation promoting sustainable practices in agriculture. See Grain 2014 www.grain.org.

89 Considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity for the indigenous and local communities. See a 26(1) Cartagena Protocol.

90 See Centre for International Sustainable Development Law *Biosafety Scoping Study* 9-11; Oliva 2002 *Int'l Legal Persp* 25-26; See Secretariat of the CBD *Workshop on socio-economic impacts of LMOs* 2011.

91 These two studies highlighted the South African experience regarding the rejection of GM Spunta G2 potato for commercial release, GM yeast and grapes for wine production. The failure of the governmental massive "Food Production Programme" in the Eastern Cape was also underscored in these studies. This Food Production Programme promotes the use of GM maize for small-scale farmers. See the study on the "Potential Economic Benefits of a Genetically Modified Tubermoth-resistant Potato Variety in South Africa: an Ex-Ante Socio-economic Evaluation for Commercial Producers" (African Centre for Biosafety 2011 www.acbio.org.za/index.php/gmo-regulatory-

made a groundbreaking decision by establishing an *Ad Hoc* Technical Expert Group (AHTEG) to develop conceptual clarity on socio-economic considerations with a view to developing future guidelines.[92]

4.3 Risk assessment and risk management standards

There is no standard-setting body or a common structured approach to the assessment of risks with regard to LMOs which will be subject to transboundary movements. Assessment and the management of risks[93] need to be carried out in a scientifically sound and transparent manner and can take into account expert advice as well as guidelines developed by relevant international organisations, but there may be conflicts on the standards to be applied.[94]

A State party may require the exporter to carry out and bear the costs of a risk assessment,[95] but not all developing countries have the technical and financial capacity to carry out risk assessments. Developing countries will tend to rely on the

issues/110-south-africa/349-submission-on-socio-economic-considerations) and the study on the "Smallholder potato production activities in South Africa: a Socio-economic and Technical Assessment of 5 cases in 3 provinces" (African Centre for Biosafety 2011 www.acbio.org.za/index.php/gmo-regulatory-issues/110-south-africa/349-submission-on-socio-economic-considerations).

92 International Institute for Sustainable Development *et al* 2012 www.iisd.ca/vol09/enb09585e.html.

93 A risk assessment under this protocol is meant to identify or evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity in the potential receiving environment also taking into account risks to human health. The methodology described in annex III of the protocol follows the conventional risk assessment paradigm, beginning with the identification of a potential hazard, such as the characteristics of an LMO which may have an adverse effect on biodiversity. Risks are then characterised based on a combined evaluation of the likelihood of adverse effects and the consequences should those effects be realised. Risk management pertains to decisions that are made after a risk assessment has been made (a 16 of this protocol). A "risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems." The nature and magnitude of all identified risks are taken into consideration to elaborate procedures that can eliminate or decrease these risks. A balancing of risks on the basis of scientific evidence needs to be effected with the support of the different actors involved in the GM-related activity/transboundary movement of LMOs.

94 See annexure III (3) Cartagena Protocol. Studies carried out on the effects of GM maize on rats by French scientist Séralini were highly criticised by the conclusions of separate and independent assessments carried out by the European Food Safety Authority (EFSA) following publication of the paper in the journal Food and Chemical Toxicology on 19 September 2012. EFSA Press Release; See Séralini G-E *et al* 2012 *Food and Chemical Toxicology* 4221-4231. This paper was retracted by this journal on the basis of its inconclusiveness in November 2013. See the retraction notice to the Séralini study at ScienceDirect 2013 www.sciencedirect.com/science/article/pii/S0278691513008090.

95 See a 15(3) Cartagena Protocol.

exporter's assessments to a large extent and will have to bring scientific evidence of the additional risks they have evaluated. Scientific evidence with regard to risks might also be an issue regarding liability procedures. If litigation takes place in the exporting country there may be pressure on weaker parties to give up their rights or claims.[96] A roster of experts[97] on biosafety was established in 2000 to provide advice to developing countries and countries with economies in transition that are parties to the Cartagena Protocol. These biosafety experts also provide support to conduct a risk assessment associated with the transboundary movements of LMOs. Technical documents have been produced by the AHTEG on Risk Assessment and Risk Management after discussions on the risk assessment and risk management of GMOs, as well as guidelines on mosquitoes, abiotic stress tolerant plants, and stacked genes.[98] Although some progress has been made in the assessment and management of risks in these areas, there is still room for improvement. There should be a balance of legal and socio-economic experts as well as technical experts on the roster. The AHTEG recommendations are called to be more specific with regard to geographical requirements and long-term assessments should also be done. Best practices on biosafety-related expertise, experiences gained and challenges met in nominating independent experts need to be shared. A harmonised risk assessment and risk management system is sorely needed at the international level. Unfortunately a wait-and-see approach[99] has affected discussions on risk assessment and risk management so far. This has been the case in particular for the revised guidance on the risk assessment of LMOs for nationally adapted risk assessment approaches.

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96 Kameri-Mbote 2002 *RECIEL* 64.

97 See Decision EM-I/3 on the adoption of the Cartagena Protocol and interim arrangements (CBD date unknown https://www.cbd.int/decision/cop/?id=7174). The BCH provides an open-ended online expert forum on risk assessment and risk management. A training manual and electronic training on the risk assessment of LMOs are available at the BCH Central Portal. See BCH date unknown http://bch.cbd.int/.

98 The Meeting of the Parties (MOP) to the Cartagena Protocol established this expert group to develop the support necessary for the assessment of GM fish, trees, insects, algae and micro-organisms. See COP-MOP 5 in October 2010 in Nagoya.

99 This approach consists either of gathering more information and reviewing the issue at a later stage, or of waiting until there is a problem to trigger a review. See Secretariat of the CBD 2012 www.iisd.ca/biodiv/bs-copmop6/.

4.4 Monitoring of compliance

The Intergovernmental Committee for the Cartagena Protocol (ICCP) developed compliance procedures and mechanisms and a Compliance Committee was established during the first meeting of the COP in 2004.[100] However, general compliance with regard to the implementation of the obligations under the Cartagena Protocol[101] needs to be better monitored, while the BCH as a repository pertaining to information on LMOs[102] has to be updated regularly by States parties.[103] The timely reporting of information especially for risk assessment of LMOs and the AIA procedure as well as the standardization of information are sorely needed. After the Compliance Committee reported on how to improve its supportive role where States parties are facing compliance difficulties, COP-MOP5 approved that where a State party has revealed compliance difficulties the Compliance Committee may make recommendations to the COP-MOP regarding measures of assistance.[104] If the information within the national reports submitted by countries shows such difficulties, the Compliance Committee may also consider taking measures of assistance. A more active role of the Compliance Committee is most welcome to ensure effective national reporting on the implementation of obligations. One of the reasons for the persistent low rate of implementation is said to be related to the fast-changing landscape of biotechnology and countries' shifting interests. The number of States exporting GMOs tends to increase with an inevitable influence on their decisions regarding transboundary movements of GMOs.[105]

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100 A compliance mechanism under an international environmental treaty is normally devised to help States parties to fulfil their obligations and deals with non-compliance; Secretariat of the CBD *Report of the Compliance Committee Under the Cartagena Protocol on Biosafety* COP-MOP5 2010.

101 See a 33, which requires parties to monitor the implementation of their obligations under the protocol and to report to the COP on the related measures taken.

102 The BCH was set up also to facilitate the exchange of information on LMOs and assist parties to better comply with their obligations under the protocol. Global access to a variety of scientific, technical, environmental, legal and capacity building information is provided in all 6 of the UN languages. See CBD date unknown http://bch.cbd.int/protocol/cpb_art20.shtml; Smits and Zaboroski 2001 *Asper Rev Int'l Bus & Trade L* 99.

103 The number of clearing house postings appears to lag far behind actual approval practices. Redick 2007 *Colo J Int'l Envtl L & Pol'y* 66.

104 International Institute for Sustainable Development *et al* 2010 www.iisd.ca/vol09/enb09533e.html.

105 See Secretariat of the CBD 2012 www.iisd.ca/biodiv/bs-copmop6/.

4.5 GMO-related disputes settled mainly under the trade settlement dispute mechanism

The CBD dispute settlement mechanism, the WTO dispute settlement mechanism or a voluntary private sector compensation mechanism known as the "Compact"[106] are available to affected parties when there are GMO-related claims at the international level. Article 27(5) of the CBD states that its provisions on dispute settlement apply also to issues relating to one of its protocols, with possible recourse to the International Court of Justice or arbitration. When there is a damage resulting from a transboundary movement of LMOs that started after the entry into force of the Nagoya SP, the State party in whose jurisdiction the transboundary movement was made may apply domestic liability and redress procedures. It should be pointed out that pending the entry into force of the Nagoya SP, affected parties in GMO-related disputes may still use existing domestic liability procedures if adequate liability and redress rules are provided. If the damage has affected several States, the affected parties need to agree on which domestic liability procedures will apply. Only claims in relation to damage resulting from the transboundary movements of LMOs may be referred to the CBD's dispute settlement mechanism and not those of the broader categories of GMOs. In practice, although the CBD provides for a dispute settlement mechanism, disputes pertaining to the trade of GMOs have been referred to the WTO dispute settlement mechanism.[107] The WTO dispute settlement system was chosen by the affected parties in the dispute on the GM commodities' exports which involved States that are not parties to the Cartagena Protocol.[108] As for the dispute

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106 A redress mechanism initiated by six of the biggest biotechnological firms, namely BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto and Syngenta, which became operational in 2010. See the Compact's website at The Compact date unknown www.biodiversitycompact.org/. See the acknowledgement of the Conference of parties to the Cartagena Protocol with regard to the existence of the Compact. Decision BS-V/11 COP-MOP 5 CBD 2010 www.cbd.int/mop5/documents/.

107 See the biotechnological products' dispute between the EU and the US, Canada and Argentina (WTO - European Communities – Measures Affecting the Approval and Marketing of Biotech Products) and the canned tuna dispute between Egypt and Thailand (WTO Egypt - Import Prohibition on Canned Tuna with Soybean Oil). The WTO dispute settlement bodies have more than 30 cases to deal with per year and had had more than 400 cases by November 2009 (Carreau and Juillard *Droit International Économique* 105) compared to the CBD dispute settlement system which has never dealt with any case yet (Ferraud-Ciandet *Protection de la Santé* 147).

108 In this dispute, only the EU is a party to both the CBD and the Cartagena Protocol while

on the prohibition of the import of canned tuna with allegedly GM soybean oil between Egypt and Thailand, both countries are States parties to the CBD and the Cartagena Protocol, yet the complaint was referred to the WTO dispute settlement body.[109] Egypt took into account some of Thailand's claims and Thailand decided not to continue the dispute settlement proceedings any further. The WTO Committee on Trade and Environment (CTE) stated that while WTO members have the right to choose to bring a dispute to the WTO dispute settlement mechanism, WTO members which are also parties to the Cartagena Protocol should not undermine the obligations they accepted under this MEA.[110] Consequently, if a dispute arises between WTO members which are also parties to the Cartagena Protocol over the use of trade measures they are applying pursuant to this protocol, they should consider trying to resolve it under the CBD settlement mechanism.[111] However, future disputes on the transboundary movements of GMOs involving trade aspects are also not likely to be settled under the CBD dispute settlement mechanism.

Since 2010 States may choose to settle claims regarding transboundary damage by LMOs under the "Compact" if the damage is caused by one of the GM products of the six major plant biotechnology companies. The "Compact" was elaborated by these GM companies with regard to damage caused to biological diversity by one of their biotech-derived products. If a claim against a Compact member cannot be settled, the matter can be resolved by way of arbitration under the aegis of the Permanent Court of Arbitration.[112] This mechanism provides for contractual liability between importers and exporters. However, transboundary damage may affect parties who are not in a contractual relationship, especially in cases of the unintentional or illegal release of LMOs or in areas beyond national jurisdiction.

Argentina and Canada are parties to the CBD but not to the Cartagena Protocol. The US is not a member of either the CBD or the Cartagena Protocol. See CBD date unknown www.cbd.int/convention/parties/list/#tab=1.

109 See the list of parties to the CBD and the Cartagena Protocol at CBD date unknown www.cbd.int/convention/parties/list/#tab=1.

110 WTO *Report of the CTE* 1996 par 178.

111 WTO *Report of the CTE* 1996 par 178.

112 Either recourse under the Compact or a remedy under an otherwise applicable law but no double or multiple recoveries is allowed. See The Compact date unknown www.biodiversitycompact.org/about/principles.

5 Conclusion

The biosafety framework under the Cartagena Protocol represents the first attempt by governments to agree upon a binding global regime with a baseline of legal controls on the import and export of LMOs (and not all categories of GMOs). This protocol is also said to address risks associated with biotechnology in a manner conducive to its productive development and use.[113] This global regime needs to be translated into national legal regimes and is a floor rather than a ceiling of biosafety regulation.[114]

In spite of all the conflicts on the setting up of a stringent biosafety international framework due to its impact on the international trade of GMOs, this framework pertains not only to trade aspects but also to transboundary movements of GMOs for non-trade purposes. Transboundary movements of GMOs for trade purposes and for non-trade purposes must be clearly distinguished during discussions at the international level.

This paper makes recommendations in relation to the key issues and concerns identified in the international biosafety framework:

It is unclear whether some categories of LMOs such as nutraceuticals and biopharmaceuticals are covered by the Cartagena protocol. The need for a consensus on an international identification system for GM products with a harmonised threshold of GM content is highlighted. The implementation of the protocol must be better monitored to ensure that States parties comply with their obligations. A better monitoring of illegal movement of GMOs considered as hazardous (pathogenic GM micro-organisms) for public health or security (bioterrorism) is sorely needed.[115] Since different national standards result in a less efficient international biosafety system, the harmonisation of national biosafety regulation is important. Harmonisation strategies need to be ensured by competent

113 Hagen 2000 *Geo Int'l Envtl L Rev* 699.
114 Hagen 2000 *Geo Int'l Envtl L Rev* 698.
115 Bioterrorism is a threat to food security and targets principally the cultivation of agricultural products, animals, food products at all stages of the food chain. Ferraud-Ciandet *Protection de la Santé* 76.

international bodies based on international agreements instead of private actors with vested interests. The harmonisation of identification and traceability standards, risk assessment and risk management standards, and the communication of information on biotechnological risks must be reached with inter-State cooperation. NBFs in general seek to balance importer and exporter interests more than to comply with the Cartagena Protocol's requirements. Consensus is sorely needed on the scope and interpretation of socio-economic considerations.

The key issues and concerns identified relate generally to the compromises made by the negotiators of the Cartagena Protocol with a view to building consensus. Remedies to these shortcomings and the full compliance of States parties with this protocol's requirements will depend largely on the fast-changing landscape of biotechnology, different countries' interests, and different degrees of scientific knowledge on the effects of GMOs on the environment, human health and animal health.

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LIST OF ABBREVIATIONS

AATF	African Agricultural Technology Foundation
ACB	African Centre for Biosafety
AHTEG	Ad Hoc Technical Expert Group on Risk Assessment and Risk Management
AIA	Advance Informed Agreement
APHIS	Animal and Plant Health Inspection Service
ASEAN	Association of South East Asian Nations
Asper Rev Int'l Bus & Trade L	Asper Review of International Business and Trade Law
BCH	Biosafety Clearing House
BELJ	Buffalo Environmental Law Journal
BINAS	Biosafety Information Network and Advisory Service
Canada-US LJ	Canada-United States Law Journal
Canadian EPA	Canadian Protection of the Environment Act
CBD	United Nations Convention on Biological Diversity
CEE Group	Central and Eastern Europe Group
Colorado JELP	Colorado Journal of Environmental Law and Policy
Columbia JEL	Columbia Journal of European Law
COMESA	Common Market for Eastern and Southern Africa
COP	Conference of Parties

COP-MOP1	First meeting of the Conference of Parties serving as the meeting of the Parties to the Cartagena Protocol
COP-MOP3	Third Meeting of the Conference of Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety
COP-MOP5	Fifth meeting of the Conference of Parties serving as the meeting of the Parties to the Cartagena Protocol
COP-MOP6	Sixth Meeting of the Conference of Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety
CTE	Committee on Trade and Environment
DNA	Deoxyribonucleic acid
Drake JAL	Drake Journal of Agricultural Law
ECOWAS	Economic Community of West African States
EFSA	European Food Safety Authority
ELPJ	Environmental Law and Policy Journal
ELR	Environmental Law Review
EPA	Environment Protection Agency
EU	European Union
FDA	Food and Drug Administration
Food & Drug LJ	Food and Drug Law Journal
FFPs	Food, feed or to be processed

Geo Int'l Envtl L Rev	Georgetown International Environmental Law Review
GM	Genetically modified
GMOs	Genetically modified organisms
GRULAG	Latin America and Caribbean Group
ICCP	Intergovernmental Committee for the Cartagena Protocol
Int'l & Comp Envtl L	International and Comparative Environmental Law
ICLQ	International and Comparative Law Quarterly
IFPRI	International Food Policy Research Institute
IISD	International Institute for Sustainable Development
Ind J Global Legal Studies	Indiana Journal of Global Legal Studies
IPPC	International Plant Protection Convention
LMOs	Living Modified Organisms
MEAs	Multilateral Environmental Agreements
Michigan State University-Detroit College of Law's JIL	Michigan State University-Detroit College of Law's Journal of International Law
MOP	Meeting of the Parties
NAFTA	North American Free Trade Agreement
Nagoya SP	Nagoya – Kuala- Lumpur Supplementary Protocol
NBFs	National biosafety frameworks

New York UELJ	New York University Environmental Law Journal
NIH	National Institute for Health
Nw J Int'l L & Bus	Northwestern Journal of International Law & Business
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
OIE	World Organisation for Animal Health
ORIL	Oregon Review of International Law
OSHA	Occupational Safety and Health Administration
Pacific Rim LPJ	Pacific Rim Law and Policy Journal
Pace Int'l L Rev	Pace International Law Review
RECIEL	Review of European Community and International Environmental law
Rev Fr Allergol	Revue Française d'allergologie et d'immunologie Clinique
SA	South Africa
San Diego Int'l LJ	San Diego International Law Journal
SJALR	San Joaquin Agricultural Law Review
Tulane JTIP	Tulane Journal of Technology and Intellectual Property
UCLA J Envtl L & Pol'y	University of California Los Angeles Journal of Environmental Law and Policy

UNCED	United Nations Conference on Environment and Development
UNCTAD	United Nations on Trade and Development
UNEP-GEF	United Nations for the Environment Programme - Global Environment Facility
US	United States
USAID	United States of America
USDA	United States Department of Agriculture
Wash U JL & Pol'y	Washington University Journal of Law & Policy
WEMA	Water Efficient Maize for Africa project
WEOG	Western Europe and other groups
WFP	World Food Programme
WHO	World Health Organisation
WMELPR	William and Mary Environmental Law and Policy Review
WTO	World Trade Organisation