International Liability and Redress for Genetically Modified Organisms and Challenge for China's Biosafety Regulation

Wen Xiang*

Abstract

The UN Cartagena Protocol on Biosafety (Biosafety Protocol) is an international instrument addressing the potential environment and health issues of Genetically Modified Organisms (GMOs). Its article 27 on Liability and Redress, which finally has been explored as a new treaty - "Nagoya-Kuala Lumpur Supplementary Protocol" (Supplementary Protocol) was recently adopted in October 2010. The new Protocol chose an administrative approach instead of an international civil liability regime, and left the implementation to the discretion of competent national authorities of the parties as rather a "national approach".

As a party to the Biosafety Protocol, China might take the Supplementary Protocol into account for its own biosafety regime. The interplay between the Biosafety Protocol (and the Supplementary Protocol) with China's national biosafety regime will be briefly examined in this paper. It argues that a comprehensive biosafety law will be needed to oversee the import and export of GMOs, as well as efficiently manage cultivation of GM crops within China. The paper concludes that the inclusion of a liability clause into the biosafety law seems necessary for China's obligation to the Biosafety protocol to deal with the uncertainties of GMOs, thereby ensuring the sustainable development of biotechnology.

Key words: Biosafety Protocol, Supplementary Protocol, Liability and Redress, China

* Wen Xiang, Ph.D Candidate, Center for Environmental and Energy Law, Ghent University, Belgium. E-mail: wen.xiang@ugent.be, May 2012.

Introduction

A genetically modified organism (GMO) is an organism in which the genetic material (DNA) has been altered by means of genetic engineering techniques.[1] It could be regarded as "a way that does not occur naturally by mating and /or natural recombination".[2] GMO include both living modified organism (LMO) which is capable of growing and organisms which are not able to be replicated any more.[3] The LMO is defined in the Biosafety Protocol as "living organism that possesses a novel combination of genetic material obtained through the use of biotechnology".[4]

Since the application of biotechnology appears in various areas such as agriculture, pharmaceuticals, mineral development and even environmental protection,[5] this paper mainly focuses on its main use in agricultural and food production, which provokes the "highly polarized reaction" among scientists, industry manufacturers, consumers and non-governmental organizations (NGOs), and regulators in developed countries and developing countries as well.[6] Like many other modern technologies, along with the benefits, biotechnology also brings corresponding environmental, health and social risks.[7]

---

[1] European Parliament and Council, Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, art. 2 (2)[hereinafter Directive 2001/18/EC]; Jane Rissler and Margaret Mellon, *The Ecological Risks of Engineered Crops*, (The MIT Press, Cambridge Massachusetts, 1996) 4.

[2] World Health Organization, Modern food biotechnology, human health and development: an evidence-based study, 2005, pp 2; 20 questions on genetically modified (GM) foods, World Health Organization, http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html, last accessed April, 2012; Directive 2001/18/EC.

[3] Vanessa Wilcox, 'Damage Caused by GMOs under International Environmental Law', in Bernhard A. Koch (ed), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment* (De Gruyter, 2010) 762, Wilcox discussed the different definition of GMOs and LMOs; http://en.wikipedia.org/wiki/Cartagena_Protocol_on_Biosafety, last accessed April, 2012.

[4] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, article 3 (g); Ruth Mackenzie, 'Environmental Damage and Genetically Modified Organisms' in Bowman and Boyle (ed), *Environmental Damage in International and Comparative Law: Problems of Definition and Valuation*, (Oxford University Press, Oxford, 2002) 65.

[5] Thomas O. McGarity, 'International Regulation of Deliberate Release Biotechnologies', in Francioni and Scovazzi (ed), *International Responsibility for Environmental Harm*, (Graham & Trotman 1991), pp. 321-324; Sean D. Murphy, 'Biotechnology and International Law', (2001) 42 Harvard Journal of International Law, 47-48.

[6] Robert Falkner, 'Introduction' in Falkner (ed.) *The International Politics of Genetically Modified Food,* (Palgrave Macmilan, 2006) 1; Marie Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology,* (Edward Elgar Publishing 2008), pp. 22-23.

[7] A. Bryan Endres, '"GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO damage in the United States and the European Union' (1999-2000) 22 Loy. L.A. Int'l & Comp. L. Rev. 453.

Status of GMOs cultivation in the world

The number of countries cultivating biotech crops reaches 29 and the accumulated hectarage planted during the 15 years since 1996 to 2010 exceeded 1 billion hectares, double of the number in 2005. USA contributes 66.8 million hectares at the top of the list, followed by Brazil, Argentina, India, Canada and China, etc.[8]

There are two main GM traits currently commercialized as herbicide tolerance (HT) and insect resistance (IR),[9] and the main biotech plants are maize, oilseed rape, soybeans and cotton, etc in the worldwide. As shown in a survey of Chinese plant biotechnologists, China is developing the largest capacity of plant biotechnology outside of North America.[10]

The most successful and large-commercialized GM plant promoted by Chinese scientists is IR Bt (*Bacillus thuringiensis*) Cotton which was introduced in 1999.[11] However, the recently approved Bt rice in China in 2009 has suddenly put the safety issue of GMOs at the top of public attention as a hotly debated issue, because of the central role of rice in the Chinese diet.[12]

Benefits of GMOs

The use of GMOs in agricultural areas are deemed to have several potential benefits, such as improving quality and quantity of certain crops which are important especially for those who are suffering from hunger and malnutrition in developing countries. It also helps by reducing the use of pesticides which is to some extent good for the preservation of natural habitats;[13] and improving "plant adaption to unfavorable environments" in the era of climate change.[14]

Risks of GMOs

Concerns about the potential risks associated with GMOs consist of direct and indirect impacts on environment and human beings.[15] Some of the effects include those on Non-target organisms and soil and water ecosystems; gene flow by pollination to wild

---

[8] ISAAA Brief 42-2010: Executive Summary, Global Status of Commercialized Biotech / GM Crops: 2010.
[9] Olivier Sancido, Jorg Romeis and Franz Bigler, *Ecological Impacts of Genetically Modified Crops: Ten Years of Field Research and Commercial Cultivation,* (Adv Biochem Engin/Biotechnol 2007) 107, 236.
[10] Jikun Huang, Scott Rozelle, Car Pray and Qinfang Wang, 'Plant Biotechnology in China' (2002) 295 Science 674.
[11] Wanhua yang, 'Regulation of Genetically Modified Organisms in China', (2003) 12(1) RECIEL 99.
[12] Jane Qiu, 'Is China Ready for GM Rice?' (2008) 455 Nature 851.
[13] L.L Wolfenbarger and P.R. Phifer, 'The Ecological Risks and Benefits of Genetically Engineered Plants', (2000) 290(12) Science 2090-2091; Jonathan H. Adler, 'The Cartagena Protocol and Biological Diversity: Biosafe or Bio-Sorry?' (2000) 12 Geo. Int'l Envtl. L. Rev. 772.
[14] Kristina Hug, 'Genetically Modified Organisms: Do the Benefits Outweigh the Risks?' (2008) 44(2) Medicina (Kaunas), 88-89; Murphy, *Supra* note 5, at 54.
[15] Philip J. Dale, Belinda Clarke, and Eliana M. G. Fontes, 'Potential for the Environmental Impact of Transgenic Crops', (2002) 20, Nature Biotechnology 568; Christopher P. Rodgers, 'Liability for the Release of GMOs into the Environment: Exploring the Boundaries of Nuisance', (2003) 62(2) Cambridge Law Journal. 371, 378.

relatives to create "Super weed" or "contamination" of conventional crops. Others are the declining of population of species which is detrimental for biodiversity; and allergenicity reaction of certain kinds of people if some known allergens containing in sources of genes for production of GM crops.[16]

Liability and Redress of GMOs

Different perceptions of uncertainties involved in GMOs have lead to the development of several initiatives to regulate them.[17] The divergence between the US and the EU could prove to be a good example.[18] While the EU sticks to justify the important role of Precautionary Principle in GMO use and trade, the US assumes the GM crops are not necessarily different from the conventional crops according to the principle of Substantial Equivalence.[19] In addition, the transatlantic divergence apparently influences the choices of developing countries when they start to face the challenge of biotechnology, since many of them are expecting to export food products to the European market. If they choose to follow the US way to produce GM foods, the chance for their products to be accepted by European counterparts shall not be optimistic.[20]

Even some well-funded national competent authorities like Department of Agriculture, Food and Drug Administration and Environmental Protection Agency of US are still increasing demand of budgets to cope with the new challenge associated with biotechnology.[21] Obviously, this appears not to be the case in developing states. If biotechnology offers particular benefits for the developing world to help confront the

---

[16] There are numerous publications analyzed the potential benefits and risks worldwide. *Id* note 12, *Supra* note 10; *Supra* note 9; David A. Cleveland and Daniela Soleri, 'Rethinking the Risk Management Process for Genetically Engineered Crop Varieties in Small-scale, Traditionally Based Agriculture', (2005) 10(1) Ecology and Society; Bruce E. Tabashnik, 'Communal Benefits of Transgenic Corn', (2010) 330(8) Science; Alan J. Gray, 'Ecology and Government Policies: the GM Crop Debate', (2004) 4 Journal of Applied Ecology; E. Ann Clark, Environmental Risks of Genetic Engineering, Euphytica (2006) 148.

[17] Maria Lee, Beyond Safety? The broadening Scope of Risk Regulation, Current Legal Problems, 2009, 62 (1), at 244, 246; Richard B. Stewart, 'GMO trade Regulation and Developing Countries' (2009) Public Law & Legal Theory Research Paper Series, Working Paper No. 09-70, 1.

[18] Alberto Alemanno, 'How to get out of the Transatlantic Regulatory Deadlock over GMOs? This is Time for Regulatory Cooperation', in J. Swinnen & D. Vogel, *Cooperation in Managing Biosafety and Biodiversity: California, The United States and the European Union*, (Edward Elgar, 2010).; Diahanna Lynch, David Vogel, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, (Council on Foreign Relations Press, April, 2001); Grace Skogstad and Elizabeth Moore, 'Regulating Genetic Engineering in the United States and the European Union: Policy Development and Policy Resilience', (2004) 23(4) Policy and Society'; Pollack and Shaffer (eds.) *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*, (Oxford University Press 2009).

[19] Robert Falkner and Asrti Gupta, 'The Limits of Regulatory Convergence: Globalization and GMO Politics in the South' (2009) 9 Int Environ Agreements 114, 117.

[20] Ernestine Meijer and Richard Stewart, 'The GM Cold War: How Developing Countries Can Go from Being Dominos to Being Players', (2004) 13(3) RECIEL 252.

[21] United Nations Development Programme, (UNDP, 2001) Human Development Report 2001: Making New Technologies Work for Human Development (UNDP, 2001), 4.

emerging issues such as increasing population and poverty[22], it might also pose "severe challenges",[23] because developing countries are normally in lack of enough capacity to adequately manage the GMOs and its potential risks.[24]

Furthermore, it was suggested that the consequences of accidents should be taken into account while developing a regulatory framework to ensure safe use of GMOs.[25] This is why developing countries proposed the Biosafety Protocol to ensure the environment and their citizens will not be put at risk during the transboundary movement of GMOs. It also explains their willingness to have an international binding civil liability to protect their own interests.

As a 'State- of- the-art' technology, there is still a little scientific data available concerning its risk and benefits, "particularly *long-term* risks and benefits."[26] Questions like how to take into account the uncertainties caused by the release of GMOs in the long run and whether and how the liability mechanisms could be developed to deal with those scientific concerns have left enough spaces for discussion.[27] Needless to say that the issue with regard to developing a liability mechanism for GMO release is not only hotly debated at the international level but also at the regional or national level.[28]

---

[22] Murphy, *supra* note 5, at 53

[23] *Supra* note 21, at 4.

[24] Meijer and Stewart, *supra* note 20, at 248.

[25] The Cartagena Protocol on Biosafety: A Record on the Negotiations, Secretariat of the Convention on Biological Diversity, 2003, at 84.

[26] Brady L. Montalbano, 'It's Not Easy Being Green-Holding Manufacturers of Genetically Modified Bentgrass Liable under Strict Products Liability', (2005) 14 Penn. St. Envtl. L. Rev. 118.

[27] Christopher Rodgers, 'Implementing the Commnity Environmental Liability Directive: Genetically Modified Organisms and the Problem of Unknown Risk', in Bodiguel and Cardwell (ed), *The Regulation of Genetically Modified Organisms: Comparative Approaches.*(Oxford University Press 2010) pp.198-199; Jorge E. Vinuales, 'Legal Techniques for Dealing with Scientific Uncertainty in Environmental Law', (2010) 43 Vand. J. Transnat'l L 481-482. The article noted that most of the legal techniques that have been developed in the area of international environmental law are to deal with 'Risk' rather than 'Uncertainty'. The distinction between Risk and uncertainty can be seen in the quotation of this article from economist Frank Knight's seminal work, Frank H Knight, Risk, Uncertainty and Profit, 439.

[28] There are discussions with regard to the need for a separate liability regime both in international level or national (regional) level, some scholars are proponents of it while some others are against it. See Philippe Cullet, *Liability and Redress for Modern Biotechnology*, (15 Yearbook of International Environmental Law 2006); Holtby, Kerr and Hobbs (eds), 'International Environmental Liability and Barriers to Trade: Market Access and Biodiversity in the Biosafety Protocol' (Edward Elgar, 2007); Ryan Hansen, 'Developing International Uniform Liability Principles for Harms from genetically Modified Organisms', Bepress Legal Series, Working Paper 105; GMO Statutory Liability Regimes: An International Review, Canadian Institute for Environmental Law and Policy, December 2004; Kate Cook, 'Liability: 'No Liability, No Protocol'' in Bail, Falkner and Marquard (eds.), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?* (Royal Institute of International Affairs, 2003).

In general, legal liability regimes serve the functions such as prevention, correction, and reparation in terms of environmental issues.[29]

As noted by Jungcurt and Schabus:

The main function of liability and redress in international law is to provide for response measures and restitution in the case of certain activities causing damage to the environment. In addition, regimes for liability and redress contribute to preventing damage by exposing operators to financial liability, thus inducing them to adopt measures that minimize risks of damage.

Therefore liability and redress not only serves to enforce environmental rules that envisage implementation of the polluter pays principle, it can also be used as a mechanism to prevent damage from occurring which is particularly relevant since the Biosafety Protocol embodies the precautionary approach.[30]

The Biosafety Protocol and the Supplementary Protocol

History of the Biosafety Protocol

The Biosafety Protocol is the main international instrument addressing the potential environment and health issues of GMOs.[31] Its article 27 on Liability and Redress which has finally been explored as a new Supplementary Protocol,[32] was recently adopted in October 2010. Its full name "the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress" witnesses the contribution of two countries to the achievement that the Supplementary Protocol was adopted in Nagoya, Japan in 2010 and the mandate of the first negotiating group was adopted in Kuala Lumpur, Malaysia in 2004.[33]The Biosafety Protocol was actually adopted in Montreal on 29 January 2000 after several

---

[29] Loretta Feris, 'Who is to blame? Liability and Redress Related to GMOs' in Jeffery, Firstone and Bubna-Litic (ed), *Biodiversity Conservation, Law and livelihoods: Bridging the North-South Divide IUCN Academy of Environmental Law Research Studies*, (Oxford University Press, Oxford, 2008), 486; Rene Lefeber, *Transboundary Environmental Interference and the Origin of State Liability*, (Kluwer Law International, 1996), at 1. Lefeber concluded that three functions of liability as corrective function, preventive function and reparative function; Elizabeth Duall, 'A Liability and Redress Regime for Genetically Modified Organisms under the Cartagena Protocol', (2004) 36 Geo. Wash. Int'l L. Rev 192-193; Alfonso Ascencio, The Transboundary Movement of Living Modified Organisms: Issues Relating to Liability and Compensation', (1997) 6(3) RECIEL, 294-295.

[30] Stefan Jungcurt and Nicole Schabus, 'Liability and Redress in the Context of the Cartagena Protocol on Biosafety', (2010) 19(2) RECIEL 19 (2) 198; Cook, *Supra* note 27, at 373-374; Philippe Sands, *Principles of International Environmental Law*, (Cambridge University Press 2nd edition, 2003), at 268, 522.

[31]. Jungcurt and Schabus *Id*, at 197; Wilde, *supra* Note 4, at 288-289.

[32] BS-V/11, International rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, Fifth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 5).

[33] Lim Li Lin, 'The Rift at Nagoya on GMO Safety and Socioeconomic Impacts' (2010), Third World Resurgence No. 242/243, <http://www.twnside.org.sg/title2/resurgence/2010/242-243/cover06.htm> , accessed April, 2012.

years of negotiations, and it entered into force on 11 September 2003, after ratification by fifty states parties to the Cartagena Protocol. As of July 2010, there were 159 parties to the Cartagena Protocol.[34]

Its main scope is about "transboundary movement, transit, handling and use of all living modified organisms that may have the adverse effect on the conservation and sustainable use of biological diversity", and also the "risks to human health".[35] As stated in its article 27, the issue with regard to liability and redress was required to develop within four years of its ratification.[36]

In accordance with the Decision BS-I/8 concluded in the first COP/MOP conference in 2004, an Open-ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress (hereinafter referred to as an Ad Hoc Group on Liability and Redress) was established with a mandate to summarize general issues related to the "potential or actual damage scenarios of concern". It is mandated to consider the international rules and procedures on liability and redress that might be applied to those concerns, and to elaborate on options for elements of rules and procedures.[37]

Negotiation Process of the Supplementary Protocol

The Ad Hoc Group on Liability and Redress had five working group meetings between 2005 and 2008. Although some agreements were reached on some elements of an international regime, delegates did not reach "common ground" on some key issues such as whether the regime should be legally binding and what kind of legal approach was necessary to address the liability and redress issue.[38] While most of the developing countries argued for an international binding civil liability regime, the majority of developed countries including the EU would prefer to implement a "domestic administrative approach" with introduction of the concept of international rules mainly because they normally have already had the domestic civil liability in place.[39]

Due to the fundamental disagreements in the last working group meetings, the final meeting of the Ad Hoc Group on Liability and Redress held in March 2008 in Cartagena was unable to resolve these issues and the Friend of Co-Chair was mandated consequently to take over the responsibility.[40] The Group of Friends of Co-Chairs

---

[34]Patricia Kameri-Mbote, 'Towards a Liability and Redress System under the Cartagena Protocol on Biosafety: A Review of the Kenya National Legal System', (2004) 1 East African Law Journal (2004) 119.

[35] Cartagena Protocol, *supra* note 4, art. 4.

[36] *Id,* art. 27; Katharine E. Kohm, 'Shortcomings of the Cartagena Protocol: Resolving the Liability Loophole at an International Level', (2009) 27 Journal of Environmental Law, 161.

[37] Establishment of an Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Protocol (CBD COP/MOP Decision BS-I/8, 27 February 2004); CBD Handbook (the 3rd Edition), at 1410.

[38] Jungcurt and Schabus, *supra* note 30, at 198.

[39] *Id*, at 198. Anne Daniel, 'Civil Liability Regimes as a Complement to Multilateral Environmental Agreements: Sound International Policy or False Comfort?' (2003) 12(3) RECIEL, 234.

[40] Gurdial Singh Nijar, Sarah Lawson-Stopps and Gan Pei Fern, *Liability and Redress under the Cartagena Protocol on Biosafety: A Record of the Negotiations for Developing International Rules*, Volume 1, KL: CEBLAW, at 24; Dire Tladi, 'Civil Liability in the Context of the Cartagena Protocol: to be or not be (binding)?' (2010) Vol 10 (1) International Environmental Agreements: Politics, Law and Economics, 18.

comprises six representatives each from the African Group, the Latin America and Caribbean Group (GRULAC), and Asia-Pacific Group; two representatives from European Union and Central and Eastern Europe; and one representative each from New Zealand, Norway, Switzerland and Japan.[41]

Four informal meetings were held by the Friend of Co-Chair between 2008 and 2010. The fourth one was scheduled three days prior to the COP/MOP-5 meeting in Nagoya to finalize the final draft of liability and redress.

The discussion on legal approach of the international liability proved to be the most contentious issue. There were three options discussed: a binding instrument on civil liability, completely non-binding instrument and the dual approach, i.e., a binding instrument on administrative approach and a non-binding civil liability instrument.[42]

During the negotiations, three main positions were adopted respectively by three groups of parties. One of the groups consists of Malaysia, Ethiopia, Colombia, Liberia, Burkina Faso, India, Namibia, Norway and South Africa, and was in favor of a binding international civil liability instrument. While Japan, Brazil and Paraguay sitting on the other side argued for non-binding instrument, the EU, New Zealand and Switzerland chose a "middle" way by proposing for the binding instrument on administrative approach with a non-binding civil liability instrument.[43] This will be discussed later in the course of this paper.

It is important to note that two outstanding issues were left to the final Friends of Co-Chairs meeting in Nagoya, the one is definition of LMOs and "product of LMOs",[44] and another is a provision on "financial security".[45]

a. Financial Security

After a series of bilateral meetings between parties and the Friend of Co-Chair, Co-Chair Lefeber reported the disagreements of Brazil, Mexico, Paraguay and South Africa on the financial security issue, because they could not accept it in an operative part of the text rather than inclusion of a preambular reference and a technical study. Malaysia rejected this proposal and insisted on the need for the inclusion of this provision in the operative text.[46]

Finally after informal consultations, Malaysia reported that parties have agreed on a compromising language, which is "Parties retain the right to provide, in their domestic law, for financial security" and they should exercise this right "in a manner consistent

---

[41] Lim Li Ching, New Treaty on Liability for GMO Damage is Born: Report of the 4th Meeting of the Group of the Friends of the Co-Chairs, Third World Network, 2010, at 1.
[42] Tladi*, Supra* note 40*,* at 20*;* Jungcurt and Schabus, *supra* note 30, at 201.
[43] Tladi, *Id*, at 20.
[44] Draft Decision BS-V/--, International Rules and Procedures in the Field of Liabiloty and Redress for Damage Resulting from Tranboundary Movements of Living Modified Organisms, art. 3.2.
[45] *Id*, art. 10, Financial Security mechanism normally refers to special fund, insurance, etc to ensure the redress will be available.
[46] Summary of the Fifth Meeting of the Parties to the Cartagena Protocol on Biosafety: 11-15 October 2010, Earth Negotiation Bulletin, Vol. 9, No. 533, at 9.

with their rights and obligations under international law, taking into account the final three preambular paragraphs of the Protocol".[47] They also agreed that after the entry into force of the Supplementary Protocol, the first COP/MOP meeting shall request the Secretariat to undertake a comprehensive study which will consist of "the modalities of financial security mechanism" and "an assessment of the environmental, economic and social impacts of such mechanism" particularly on developing countries, as well as "an identification of the appropriate entities to provide financial security".[48]

b. Product Thereof

As for the definition of LMOs and "product thereof", it seems surprisingly even more difficult to reach an agreement among some Parties which are Friends of Co-Chair. The discussion was based on the outcome of last Friends of Co-Chair meeting, which was to replace "product thereof" with "including products containing LMOs".[49] The key issue was whether that "product thereof" would only refer to living materials, or the dead materials shall also be included.[50] Japan opposed the latter one, and argued that this would make the scope of the Supplementary Protocol go beyond the scope of Biosafety Protocol. This opinion was supported by South Africa, Philippine, Brazil, Paraguay and China.[51]

Mexico noted that the discussion of "product thereof" is unnecessary since the Biosafety Protocol only refers to LMOs.[52] On the contrary, Bolivia, Namibia, the African Group with the exception of South Africa, Malaysia, Ukraine and South Korea were in favor of the inclusion of "product thereof".

After several informal consultations, Malaysia presented a compromising reference consisting of an amendment to the Bolivian proposal, as amended by Mexico, stating that "product thereof" include materials that "are capable of replicating in the environment". While Japan, Brazil, the EU, Norway, Switzerland, Ukraine and the African Group in principle accepted this proposal, the Philippines however suggested an amendment to this reference as "are capable of naturally reproducing in the environment".[53] Paraguay, South Africa, India and China requested for more time to consider the proposal, and China noted that this might still change the scope of the Biosafety Protocol.[54]

The three days' meeting failed to resolve the last issue. Informal consultations continued on Saturday, 9th October 2010. Malaysia supported by Ukraine suggested deleting the

---

[47] UNEP/CBD/BS/COP-MOP/5/L.2, art. 10.2.
[48] *Id, art.*10.3.
[49] Ching, *supra* note 41, at 3.
[50] See discussion before in the 'Introduction of GMO' of this paper, the difference between GMOs and LMOs.
[51] *Supra* note 41, at 3.
[52] *Supra* note 46, at 8.
[53] *Id.*
[54] Interview with Chinese Delegate of Friends of Co-Chairs (anonymous), (October 2010) the official believed that the "Product thereof " should not include the 'dead transgenic' materials which are not able to be replicated in the environment, because it is not compatible with the scope of LMOs as defined in the Biosafety Protocol.

"product thereof" and to replace by "LMOs in the context of the Protocol", India, China, Paraguay and the Philippines then proposed "as defined in the Proposal" for consideration.[55]

It was not until late Sunday, 10th October 2010, that the Friends of Co-Chairs reached a final agreement to delete the reference to "product thereof" and to include a statement of different understanding (*See below)* of parties on the application of Article 27 of Liability and Redress of Biosafety Protocol in the COP/MOP 5 report.[56] The draft of the Supplementary Protocol text was then adopted in the early morning of Monday, 11th October 2010.

It stated:

It emerged during the negotiation of the Supplementary Protocol that Parties to the Protocol hold different understandings of the application of Article 27 of the Protocol to processed materials that are of living modified organism-origin. One such understanding is that Parties may apply the supplementary Protocol to damage caused by such processed materials, provided that a causal link is established between the damage and the living modified organism in question.[57]

Also worthy of note is an initiative of voluntary-based liability and redress mechanism "Compact" of biotechnology.[58] Suffice it to say that one of the main reasons why countries do not ratify existing international regimes on liability and redress is because of its lack of financial security or insurance policy. As a result of the uncertainty of damage caused by GMOs, "a cap could be introduced on the amount that operators can be liable for, in combination with a fund to compensate damage beyond the cap and /or rules on residual State liability." The cap would "make the risk insurable from the perspective of financial institutions," according to the "Compact" of biotechnology. [59]

---

[55] *Supra* note 41, at 4.
[56] *Supra* note 46, at 8.
[57] UNEP/CBD/BS/COP-MOP/5/17, at 21.
[58] The "Compact" is the first private sector liability and redress mechanism that provides defined process for countries to file and claims related to damage to biological diversity caused by LMOs produced by the members of "Compact". It was initiated in 2006 and accompanying the negotiation of Supplementary Protocol, it comprises of six leading plant biotechnology companies: BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto and Syngenta. It is said that this private sector initiative complements the Supplementary Protocol with a defined process for the binding arbitration of a State's claim. It intends to provide both for resolution of claims of damage and for assurance of financial security to respond to such claims. However, the "Compact" only applies to the misuses of LMOs of the members' release into environment, and only loss of biological diversity is compensable rather than traditional damage as to human health, so only State will be entitled to bring a claim under the "Compact". The "Compact" Q & A, and The Compact: A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a Living Modified Organism, First amended text, 19 Nov. 2010; Amandine J. Bled, Privatizing Anticipatory Governance? The Biotechnology Industry "Global Compact" Initiative for Liability and Redress under the Cartagena Protocol on Biosafety, Panel: New Approached to International Risk Governance: from Reactive to Anticipatory Policy-making, ISA 2009, New York.
[59] Jungcurt and Schabus*, supra* note 30, at 205.

The "Compact" set up by six leading biotechnology companies is such a voluntary scheme.[60] The contribution of the "Compact" to the liability and redress regime for damage caused by GMOs will be seen in the future,[61] how it works and "complements" the Supplementary Protocol still remains unknown.

Summary of the Supplementary Protocol

Ten years after the adoption of the Biosafety Protocol, the Supplementary Protocol, as earlier stated, was adopted in the COP-MOP 5 conference as a new treaty on 15th October, 2010.[62] It is an important step towards the implementation of Article 27 of Biosafety Protocol on liability and redress of biodiversity damage associated with the transboundary movement of GMOs.

Due to the unwillingness of some parties to agree to binding norms on civil liability,[63] the Supplementary Protocol finally comprises of a set of administrative approach to provide that Parties have rights to deal with response measure in the event of damage caused by LMOs according to their domestic regulations.

Response measures are required of the "operator"[64] or the competent authority if the operator is unable to take any response measures. The Parties shall require the operators to keep the competent authority informed immediately once damage occurs, and to evaluate the damage and take appropriate measures to deal with damages. The competent authority shall identify the operator which has caused the damage, and evaluate the damage and determine the appropriate measures which can be used by operators to deal with LMOs damage. This might be suitable for the purpose of such a Protocol to protect biodiversity, which is different from traditional damage such as property loss or human injuries, operator or competent authority may be in most appropriate position to consider what measures shall be taken to deal with damages [65]

The Supplementary Protocol provides "flexibilities to accommodate different priorities, legal systems" of the parties and "practices of operators" involved. However, the success of this approach will largely depend on the "competence" of such competent authorities

---

[60] Telesetsky, *supra* note 58, at 5.
[61] *Id.*
[62] Mariam Mayet, Biosafety Protocol: Ten Years in and Lagging far Behind, African Centre for Biosafety, October 2010, http://www.biosafety-info.net/article.php?aid=738, last accessed April 2011.
[63] Noah Sachs, 'Beyond the Liability Wall: Strengthening Tort Remedies in International Environmental Law', (2008) 55 UCLA Law Review 837, at 841-842; Maia Lee, 'Tort, Regulation and Environmental Liability', (2002) 22(1) Legal Studies, 34; Stuart J. Smyth, Drew L. Kershen, 'Agricultural Biotechnology: Legal Liability Regimes from Comparative and International Perspectives', (2006) Global Jurist Advances, 6 (2), 59-60.
[64] *Supra* note 47, art. 2.2 (c), "Operator" means any person in direct or indirect control of the living modified organism which could, as appropriate and as determined by domestic law, include, *inter alia*, the permit holder, the person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier;
[65] Tladi, *supra* note 40, at 20, this is mainly argued by the EU who is in favor of the comprise approach; Smyth, Endres, Redick and Kershen (ed), *Innovation and Liability in Biotechnology: Transnational and Comparative Perspectives* (Edward and Elgar, 2010) at 73-75.

of the parties.[66] If the competent authority is endowed with enough expertise to determine adequate response measures in a timely manner, it works somehow efficiently to dealing with prevention and reparation of damage.

However, in case of developing countries lacking the necessary resources or competent authorities, they might find them difficult to monitor the transboundary movement of GMOs and respond to the possible damage.[67] It is expected that the imbalance between developed countries and developing countries to implement the Supplementary Protocol will inevitably exist. The only way to address this gap will be by increasing "capacity building" for developing countries and emphasizing the collaboration between developing countries and developed countries.[68]

Fifty states and the EU have signed the Supplementary Protocol by March 2012 and will enter into force until 40 ratifications. Czech Republic and Latvia are the first group to ratify it by February, 2012.[69]

The Regulation of GMOs in China

Status of Biotechnology Research and Development (R&D) in China

Unlike most developed countries, where agricultural biotechnology is dominated by a few multinational companies, many developing countries are in favor of public research for their own domestic needs, and to improve the research capacity.[70] China is a perfect example. As mentioned earlier, China is one of the countries with tremendous interests in developing biotechnology.

It is estimated that China's population will reach 1.45 billion by 2020, and an increase of 25% of grain productivity will be needed to cope with the overload population and shortage of food, caused by "increasing urbanization, industrialization" and "farmland reduction" accompanying the shift of farmer labor to the cities.[71] Chinese government is "putting its weight" behind GMOs as the country's staple food resources.[72]

Since the first transgenic plant-Bt tobacco has been commercialized in 1990s in China, the Chinese government is increasingly investing on the R&D of new GMO plant varieties.[73] Bt Cotton is the most successful GM crop in China, 13Bt cotton varieties were

---

[66] Jungcurt and Schabus, *supra* note 30, at 202.
[67] *Id.*
[68] *Id.;* Daniel, *supra* note 39, at 238-239.
[69] http://bch.cbd.int/protocol/parties/#tab=1, Last accessed April, 2012.
[70] Joel I Cohen, 'Poorer Nations Turn to Publicly Developed GM Crops' (2005) 23, Nature Biotechnology 27; Falkner, *supra* note 6, Chapter 10, Internationalising Biotechnology Policy in China, at 176.
[71] Qiu, *supra* note 12, at 850.
[72] *Id.*
[73] Jikun Huang and Qinfang Wang, Agricultural Biotechnology Development and Policy in China, 5 AgBioforum 4 (2002), at 125-126; Qifa Zhang, 'China: Agricultural Biotechnology Opportunities to Meet the Challenges of Food Production', in G. J. Persley and M. M. Lantir (eds) *Agricultural Biotechnology and the Poor* ,(Washington, D. C., Consultive Group on International Agricultural Research, 1999), 46.

planted in 12 provinces, it is reported that control of cotton bollworm was satisfactory with introduction of Bt Cotton. It is to be noted that the percentage of terminal and square damage in Bt cotton was less than 1 % when compared to an average damage of 40-90% of non-Bt cotton.[74]

In 2008, the State Council of China approved an investment of $3.5 billion on R&D initiative of genetically modified plants for the next 12 years.[75] Two insect-resistant GM rice have recently been issued the biosafety certificates by the Ministry of Agriculture in 2009,[76] which has triggered a nation-wide debate, because rice plants occupy an important role in Chinese daily meal. Moreover, some illegal release of Bt rice has been found in the farmlands and supermarkets of the south and central area of China in 2005 without any official approval.[77] The question also has been raised as a significant international consequence of possible "contamination" of Chinese rice supply, as China is the largest rice producer and consumers in the world.[78]

China and the Biosafety Protocol

International laws or treaties should necessarily reflect the interests of States, moreover, implementation of these international laws at national level seems to be of necessity to make them effective.[79] China signed the Biosafety Protocol in 2002, and ratified it in 2005. As a party to the Biosafety Protocol, China is considering the implementation of it in its national legislations.[80] Therefore, China is inevitably confronting a dilemma to balance the innovative application of biotechnology and increasing awareness of biosafety.

There appears to be three options available to governments to deal with innovation and uncertainties. First option, is to make only revisions on the basis of existing regulations in order to remove the existing gaps in the regulations; second option is to develop an entirely new regulatory framework because there is no regulation available, which could be very costly; and third option is to leave the authority to the industries to develop the

---

[74] Shirong Jia and Yufa Peng, GMO Biosafety Research in China, Environ. Biosafety Res. 1 (2002), at 6.

[75] Richard Stone, 'China Plans $ 3.5 Billion GM Crop Initiative, Science' (2008), 321 Science; In 2008, Premier Wen JIabao told *Science* that he is "strongly advocate making great efforts to pursue transgenic engineering", See: (2008) 322 Science, 362.

[76] Mao Chen, Anthony and Gong-yin Ye, Insect-Resistant Genetically Modified Rice in China: From Research to Commercialization, Annual Review of Entomology, Vol.56, 2011, at 81.

[77] Report of Greenpeace, China, Scandal: Greenpeace discovers illegal GE rice in China, April 2005, http://www.greenpeace.org/eastasia/news/scandal-greenpeace-ex, Last accessed April, 2012.

[78] The Status of GM rice R & D in China, Nature Biotechnology, Vol.25, no.7, July 2007, at 718; Final Report of a Mission Carried out in China From 27 November to 03 December 2008 in order to Evaluate Official Control Systems for Commission Decision 2008/289/EC on Emergency Measures Regarding the Unauthorised GMO "BT 63" in Rice Products, DG (SANCO)/2008-7834-MR-FINAL, European Commission.

[79] Murphy, *supra* note 5, at 48.

[80] Falkner, *supra* note 6, Chapter 10, Internationalising Biotechnology Policy in China, at 174, "The change of China's environmental policy, especially in the case of GMO regulation is influenced by international environmental force"; Ying Song, 'Chinese Environmental Lawmaking Framework', (2002) 1 Chinese Journal of International Law, 232.

standard for their products unless the "market failure or public opinion dictates the need for government involvement".[81]

In the case of GMO regulation, China opted for the second option because few rules were available for regulation of GMOs before 2002. But from 2002 on, China mainly choose the first option because of its fairly comprehensive agricultural regulations on GMO is already in place. The next step might be more on the consideration of biosafety issue, especially the concern of the environment and health associated with GMOs, since the initiative about commercialization of GM rice has been put on the agenda of Chinese government in recent years. The public in China is increasingly concerned about the safety issue of GMOs, simply because rice contributes as the main stable food for Chinese dietary.

Regulations of GMOs and Competent Authorities in China

There are five major government agencies that are responsible for the regulation of GMOs. They are the Ministry of Science and Technology (MOST), the Ministry of Agriculture (MOA), the Ministry of Environmental Protection (MEP, formerly State Environmental Protection Agency (SEPA)), the Ministry of Health (MOH) and the General Administration for Quality Supervision and Inspection and Quarantine (AQSIQ).

The MOST is responsible for the national research and development of genetic engineering as designated by the Regulation on Genetic Engineering Management.[82]

The MOA is mainly responsible for the regulation of agricultural GMOs. The Regulations on Safety of Agricultural Genetically Modified Organisms was adopted by the State Council in 2001, which designated the MOA as the competent authority to oversee the regulation of agricultural GMOs.

According to the State Council Regulations, the MOA issued three implementation regulations in 2002 which are the Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms; the Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms; and the Implementation Regulations on Labeling of Agricultural Genetically Modified Organisms.[83] The MOA

[81] Stuart James Smyth, 'A Decade of Regulating Agricultural Biotechnology Liability in Canada: A Case Study From 1994-2004', (PhD thesis of University of Saskatchewan, 2005), 15.

[82] *Supra* note 11, at 99; Decree No. 17 (1993) of the State Commission of Science and Technology, the Ministry of Science and Technology is the formerly State Commission of Science and technology.

[83] *Id*, at 100; Regulations on Safety of Agricultural Genetically Modified Organisms, Decree No. 304 (2001) of the State Council (SOC Decree 304/2001); Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms (Decree No. 8 (2002) of MOA); Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms (Decree No. 9 (2002) of MOA); Implementation Regulations on Labeling of Agricultural Genetically Modified Organisms (Decree No. 10 (2002) of MOA), both these regulations and implementation regulations were notified to the Committee on Sanitary and Phytosanitary Measures (SPS Committee) of World Trade Organization (WTO) in 2002.

adopted a fourth regulation in 2006 as the Measures for Biological Processing Review and Approval for Agricultural Biotechnology.[84]

The MEP is the focal point for implementation of the CBD and the Biosafety Protocol. Its main responsibility is to ensure the biosafety administration, i.e. the conservation of biodiversity and protection of environment.[85] A National Biosafety Framework was formulated by the MEP with coordination of other relevant competent authorities in 1998 and 1999.[86] It provided for overall objectives and principles for national biosafety management, and aimed at establishing a sound biosafety administration system.[87]

The MOH is mainly in charge of the management of GMO food. The MOH adopted the Administrative Measures on Hygiene of GMO Foodstuffs in 2002; it defined the GMO food and required that all food products containing GMOs be subject to a safety assessment and shall be labeled on the market.[88] However, in 2007 MOH adopted the Administrative Measure on Novel Food with the intention to repeal the Administrative Measures on Hygiene of GMO Foodstuffs.[89] Its article 2 (4) states that the Measure applies to the food ingredients of which the elements changed due to the use of new techniques. It is reasonable to include biotechnology as one of the new techniques.[90]In the recently adopted Food Safety Law of China, the Article 101provided that the Law applies to GM foods,[91] however it also provided that if there is other specified law or regulations concerning GM food, then these special rules shall apply. Therefore, it is clear that the Administrative Measure on Novel Food is the main regulation for administration of GM food in China.

The AQSIQ is mainly in charge of the import and export of GMOs, and it adopted the Administrative Measure on Inspection and Quarantine of Entry and Exit of GM Products in 2004, including the GMO inspection methods.[92]

---

[84] John D Conner, Michael Boucher and Jeffrey Li, China's Regulation of Agricultural Biotechnology, The Metropolitan Cooperate Counsel, 2006, at 67.

[85] *Supra* note 11, at 101.

[86] UNEP-GEF Project on the Support for the Implementation of the National Biosafety Framework of China, at 4, http://www.unep.ch/biosafety/old_site/Implementation/Countries/China-State-of-developments.pdf, last accessed April, 2012.

[87] National Biosafety Framework of China, China Environmental Science Press, 2001; A Biosafety Information Exchanging Center (BIEC)is established under MEP with financial support from United Nations Environment Programme (UNEP), its main task is "collecting, processing analyzing and storing domestic information on biosafety, sharing information and expertise internationally, and promoting scientific cooperation", *supra* note 11, at 100.

[88] Administrative Measures on Hygiene of GMO Foodstuffs, Decree No. 28 (2002) of the Ministry of Health, it was notified to the SPS Committee of WTO in 2002.

[89] Administrative Measure on Novel Food of MOH, 2007.

[90] *Id.*, Article 2 (4).

[91] Food Safety Law of China, adopted in 2009, Article 101.

[92] Administrative Measure on Inspection and Quarantine of Entry and Exit of GM Products of the AQSIQ 2004.

Links between the Biosafety Protocol and China's Biosafety Framework

a. Precautionary Principle

As stated in Article 1, the precautionary approach is the key element of the Biosafety Protocol.[93] China applied this approach in its biosafety regulation, such as the Regulations on Safety of Agricultural Genetically Modified Organisms provided that agricultural GMOs shall be evaluated as different catalogues based on their potential risks,[94] and risk assessment shall be established to oversee the activities including research, experiment, production, process, operation, import and export of GMOs.[95] Only upon the issue of a safety certificate can GMOs be released into the environment or approved for import, and all the products containing GMOs shall be labeled before placed on the market.[96]

b. Advanced Informed Agreement (AIA)

Article 7 of the Biosafety Protocol provides that the AIA shall apply prior to the first intentional transboundary movement of LMOs for international introduction into the environment of the party of import, and article 8 provides that the party of export shall notify, or require the exporter to ensure notification in writing to the competent authority of the Party of import prior to the intentional transboundary movement of LMOs.[97]

It is important to note that the application of the AIA is limited in scope, as it only applied to the GMOs that are intended for introduction into the environment of the party of importing,[98] but as for those intended for food, feed or processing (FFP), the party of exporting only need to inform the parties of importing through the Biosafety Clearing-House about their final decisions on domestic use of GMOs for FFP.[99]

The Regulations on Safety of Agricultural Genetically Modified Organisms and Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms[100] incorporate these requirements but with broader scope of the GMOs including those for research and experiment, environmental release as well as food or feed processing for exporting and importing. The national regulations provided that both

---

[93] *Supra* note 4, Article 1.
[94] *Supra* note 83, Regulations on Safety of Agricultural Genetically Modified Organisms.
[95] *Supra* note 83, Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms.
[96] *Supra* note 83, Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms; Implementation Regulations on Labeling of Agricultural Genetically Modified Organisms.
[97] *Supra* note 4, Article 7 and 8; Dayuan Xue and Clem Tisdell, 'Global Trade in GM Food and the Cartagena Protocol on Biosafety: Consequences for China', (2001) 15 Journal of Agricultural and Environmental Ethics, 338.
[98] *Id*, Article 7.1.
[99] Xueman Wang, 'Challenges and Dilemmas in Developing China's National Biosafety Framework', (2004) 38(5) Journal of World Trade 912; *Supra* note 4, Article 11.
[100] *Supra* note 83, Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms, Chapter 3 and 4.

of them shall follow the AIA procedure, and the decision shall be made by MOA and AQSIQ within 270 days upon the application from the exporters.[101]

c. Liability Regime

As stated before, the international liability and redress issue resulted as the Supplementary Protocol last year, but China has already included some provisions regarding liability issues into its national regulations, though most attention has been paid to the non-compliance to the procedural requirements of the administrative regulations rather than the biosafety issue.[102]

The Regulations on Safety of Agricultural Genetically Modified Organisms provides that the MOA shall issue a suspension in case of illegal production and application of agricultural GMOs without due consent, and a fine of no less than RMB 20,000 (3000 US Dollars) will be imposed with a cap of RMB100,000 (15,000 US Dollars).[103] Illegal importing of agricultural GMOs shall also be punished with a fine,[104] and the operators who are not in line with labeling requirements of GMOs shall bear the responsibility according to the Implementation Regulations on Labeling of Agricultural Genetically Modified Organisms.[105]

The current national regulations have not yet referred to any liability with regard to the biodiversity loss, health injuries or any social-economic concern associated with GMOs.

Conclusion

According to its priority and capacity, Chinese government mainly focuses on the agricultural GM crops and GM food. It is suggested that a more cohesive framework is needed to confront the biosafety issue associated with GMOs throughout their full lifecycle, and to avoid the unnecessary conflicts between competent authorities such as MOA and MEP while dealing with biosafety issues.[106]

As the precautionary principle has been applied to all stages of the research and commercialization of GMOs in China, there are concerns about the post-market monitoring system and liability regime which shall be included into the biosafety framework as many other countries have already carried it out. No matter how effective regulations are to deal with the uncertainty of GMOs, unexpected risks and liability will

[101] Song, *supra* note 80, at 39.
[102] *Id*, at 40.
[103] *Id*, at 34; *Supra* note 83, Regulations on Safety of Agricultural Genetically Modified Organisms, Article 45.
[104] *Supra* note 83, Regulations on Safety of Agricultural Genetically Modified Organisms, Article 50.
[105] *Id*., Article 52.
[106] Due to the core role of the MOA in regulation of GMOs, especially agricultural GMOs in China, the MEP has been sidelined to some extent, this is why that the MEP is coordinately working with the MOST on a new National Biosafety Law which will be superior to the regulation of the State Council and the administrative regulations. The new law is expected to take more consideration of biosafety issue associated with GMOs during the full lifecycle, and with a more involvement of the MEP.

still come out due to misappropriate use of GMOs or ineffective enforcement of pre-market legislations.

China is drafting a National Biosafety Law since 2005, the MEP and MOST are leading the process with coordination of other related Ministries such as MOA and MOH. China's next step might be to consider the incorporation of the new Supplementary Protocol into its own biosafety regime to oversee the import and export of GM crops, as well as efficiently manage cultivation of GM crop within China.

It is expected that China will take into account the liability and redress of GMOs either as a provision in the proposed National Biosafety Law, or a specific liability decree, and inclusion of a liability clause seems to be necessary for China's obligation to the Biosafety Protocol to deal with the uncertainty of GMOs, and to ensure the sustainable development of biotechnology.