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AGRICULTURAL GENETIC ENGINEERING, INTERNATIONAL LAW AND DEVELOPMENT

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INTRODUCTION

The introduction of genetically modified seeds into the environment has been increasingly controversial, as illustrated by the ongoing debates concerning the commercialisation of Bt cotton in an increasing number of states in India over the past few years. In other countries too, in particular in the European region, the development of agricultural genetic engineering and the commercialisation of transgenic food products has been met with significant resistance. This is generally due to the fact that despite potential benefits, agricultural genetic engineering also has the potential to cause a number of negative impacts.

Debates around genetic engineering span a wide number of areas and concerns. These include trade facilitating measures, intellectual property rights, as well as impacts on the environment, human health, food security and livelihoods. In general, concerns are related to the contribution of agricultural genetic engineering to a broader process of sustainable and equitable development. It is this contribution to the broader process of development and not to the narrow notion of economic development which is considered here.

International law has been addressing the regulatory challenges posed by the development of agricultural engineering in largely asymmetrical ways. With regard to incentives for the development of genetic engineering, there have, for instance, been dramatic changes in the past couple of decades in patent law which has evolved from largely banning the patenting of life forms up to the 1980s to embracing it in the context of the TRIPS Agreement and other more recent bilateral or regional intellectual property related treaties. A number of trade facilitating agreements that apply to genetically modified organisms have also been adopted in the past two decades.

With regard to the question of safeguards, however, the international community has been much less forthcoming in developing responses that are sufficient to ensure, for instance, that the introduction of genetically modified organisms does not cause significant environmental harm, risks to human health or negative socio-economic outcomes. This is partly due to the fact that there remain significant disagreements among states concerning the necessary regulatory structure that needs to be put in place to ensure that incentives for the development of genetic engineering are balanced with sufficient safeguards to limit undesirable impacts arising as a result of the introduction of genetically modified organisms into the environment. International law currently reflects to a certain extent the fact that some of the most politically and commercially powerful states are backing up a regulatory system that would contain relatively few environmental safeguards.

To-date, one of the main responses given by states to the need for legal frameworks that address concerns arising from the development of genetic engineering has been the development of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol).[1] The protocol takes a broad view of biosafety which is not limited only to environmental considerations but also includes human health and socio-economic concerns. The Cartagena Protocol is therefore an apt starting point for examining links between development and genetic engineering.

This article starts by examining some of the issues that need to be addressed in any comprehensive biosafety regulatory framework. The second section then moves on to look at the basic structure of the Cartagena Protocol and to analyse its specific contribution and its shortcomings from the point of view of sustainability. Finally, the third section suggests some ways in which legal frameworks in the field of biosafety could be conceived to address sustainability concerns more effectively than what is currently achieved under the Biosafety Protocol.

I. ENVIRONMENT, HEALTH AND DEVELOPMENT CONCERNS

The introduction of genetically modified organisms into the environment raises a number of concerns which include environment, food security, gender, health, human rights and socio-economic aspects. These concerns need to be examined and integrated into any legal framework concerning genetic engineering. This section examines several of the main issues that are relevant in developing legal frameworks to ensure that genetic engineering contributes not only to economic and trade growth but also to sustainable and equitable development.

1 Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 January 2000, 39 *Int'l Leg. Mat.* 1027 (2000) [hereafter Cartagena Protocol].

A. Environment

Environmental impacts of genetic engineering have been given substantial attention over the past couple of decades. A number of issues have come up in this context. Potential environmental damage caused by genetically modified organisms include dangers linked to the instability of the genetic material and the possibility of further changes in genetically modified organisms, the transfer of genes to other organisms and the potential for transgenic varieties to outperform other varieties leading to the displacement or disappearance of wild species. As identified in the specific case of maize in Mexico, transgenes have already entered some landraces of maize.[2] It is acknowledged that once this happens, it is probably impossible to remove the transgenes.[3] There is therefore concern that environmental harm caused by genetically modified organisms, whether significant or not, is likely to be irreversible.

Some more specific pointers have been given by some of the field trials that have been conducted. UK field trials have, for instance, shed some more light on the potential for environmental harm of herbicide-tolerant genetically modified crops. In the case of beet and spring rape, the study found, for instance, a potential for these crops to disadvantage wildlife and indicated that the occurrence of fewer weeds may substantially reduce the availability of seeds important in the diets of some birds. Further, it indicated that these crops may exacerbate long-term declines of flowering weeds, including those that are important food resources for seed-eating birds.[4] This was largely confirmed by the last report concerning winter-sown oilseed rape.[5]

Certain environment-related concerns linked to the introduction of genetically modified organisms into the environment stem from the specific changes performed. Thus, environmental concerns would be heightened if gene transfers undertaken are not only from plants to plants but also from animals to plants, as seems technically feasible. Further, certain environmental concerns are more acute depending on the crop and country. Thus, the potential implications of introducing genetically modified maize in a country which is a centre of diversity for maize like Mexico are much more significant than for a country which has no wild relatives of maize.[6]

B. Human Health

The introduction of genetically modified organisms into the environment also has the potential to affect human and animal health. Health risks remain, like environmental impacts, a largely uncharted area. However, there are situations where they exist and this element needs to be taken into account in the development of legal frameworks regulating genetic engineering.

The health risks associated with genetic engineering became a subject of intense scrutiny after the first major health-related scare concerning the genetically modified StarLink corn in the United States. Its introduction into the environment had been approved only under strict conditions because the Environmental Protection Agency had determined that StarLink corn was not fit for human consumption and only permitted its use for such other purposes as animal feed, ethanol production and seed increase.[7] The segregation from non-StarLink corn was not

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2 Commission for Environmental Cooperation of North America, Maize and Biodiversity – The Effects of Transgenic Maize in Mexico – Key Findings and Recommendations (Secretariat Article 13 Report, 2004).

3 *Id* at p. 12.

4 M. Burke, GM Crops – Effects on Farmland Wildlife (London: Farmscale Evaluations Research Team and the Scientific Steering Committee, 2003).

5 David A. Bohan et al., 'Effects on Weed and Invertebrate Abundance and Diversity of Herbicide Management in Genetically Modified Herbicide-Tolerant Winter-Sown Oilseed Rape', 272/1562 *Proc. R. Soc. B* 463 (2005). [11. Within the growing season, the lower abundance of dicots in the GMHT treatment might suggest that bees and butterflies, and other animals that depend upon dicots, would not fare well if GMHT WOSR were widely adopted. 11. In conclusion, this experiment has shown lrge and important differences in the treatment effects for dicot and monocot weeds, leading us to reject the null hypothesis for weed vegetation. We would expect to see greater numbers of monocots under GMHT WOSR herbicide regimes, as tested, and lower numbers of dicots. Such a decline in dicot abundance might adversely affect pollinator species and those taxa at higher trophic levels, such as some birds, dependent on dicots as a seed food resource]

6 *See, e.g.*, Yolanda Massieu & Michelle Chauvet, 'Contesting Biotechnology – Cross-continental Concerns about Genetically Modified Crops', *in* Niels Fold & Bill Pritchard eds, *Cross-continental Food Chains* 66 (Abingdon: Routledge, 2005). [71]

7 *Marvin Kramer v Aventis CropScience*, 11 July 2002, United States District Court, N.D. Illinois - Eastern Division, 212 F.Supp.2d 828.

successfully undertaken and this led to a massive recall whose legal and economic consequences have been significant and widespread.[8]

As illustrated by the StarLink case, potential health risks must be taken into account in assessing the suitability of specific genetically modified products for introduction into the environment or commercialisation. One of the problems faced by policy-makers at this stage is the fact that there are comparatively few studies of potential human risks. Existing studies, while not providing conclusive results, point to the need for more research in this area.[9]

C. Socio-Economic Aspects

Different types of socio-economic impacts can be identified. These include the potential for genetically modified organisms to negatively impact the income of farmers who do not grow genetically modified organisms and more specifically organic farmers. This can take place in any situation where genetically modified organisms cross over from the fields where they have been planted onto other plots through cross-pollination, dispersion or any other method.[10] In a situation where contaminated plots belong to farmers who are organic farmers, contamination by genetically modified organisms has immediate negative economic repercussions even in the case where there is no significant or immediate environmental harm. Impacts include the loss of earnings due to the fact that organic farmers must then sell their crops at the lower price fetched by conventional crops or the much more significant loss of organic certification which can take place under certain organic certification schemes.[11] This is due to the fact that an organic product is by definition free from genetically modified material.[12] The UK Biotechnology Commission has indicated that the loss of earnings due to a loss of certification could reach in the region of £500 per hectare in the case of organic maize in the UK.[13] The significance of the loss of organic certification led organic canola farmers in Saskatchewan (Canada) to sue Monsanto and Aventis, accusing them of having caused the contamination of their fields and thereby forcing them to abandon the production of organic canola.[14]

The loss of organic certification is the most visible form of socio-economic damage but is not the only form of damage likely to affect farmers. Another potential problem relates to the possibility for genetically modified organisms to compete with existing crops in the market place. Where genetically modified plant varieties are varieties which can grow in temperate climates while the original variety is a cash crop which normally grows only in developing countries, there is a potential for a loss of earnings for individual farmers in developing countries who may lose their export markets if their variety is substituted by the genetically modified one.[15]

D. Food Security

Food security refers to the question of availability of, access to and distribution of foodstuffs. It has been defined by the World Food Summit Plan of Action as physical and economic access to sufficient, safe and nutritious food by all people to meet their dietary needs and food preferences for an active and healthy life.[16] At present, overall availability

8 On liability issues related to the StarLink, *see, e.g.*, D. Uchtmann, 'Liability Issues: Lessons from StarLink', 10 *Rich. J.L. & Tech.* 23 (2004).

9 *See, e.g.*, Trudy Netherwood, 'Assessing the Survival of Transgenic Plant DNA in the Human Gastrointestinal Tract', 22/2 *Nature Biotechnology* 204 (2004).

10 For a discussion of the different transmission modes, *see, e.g.*, Commission du génie biomoléculaire, Impact sur l'environnement des cultures de colza génétiquement modifié tolérant à un herbicide (Paris: Ministère de l'écologie et du développement durable, 2003).

11 *See, e.g.*, Section 9.5.2, India, National Programme for Organic Production, Ministry of Commerce and Industry (2005).

12 *See, e.g.*, Department for Environment, Food and Rural Affairs, Compendium of UK Organic Standards (Version 3.5, 2003).

13 Agriculture and Environment Biotechnology Commission, GM Crops? – Coexistence and Liability (London: Biotechnology Commission, 2003).

14 *L. Hoffman & D. Beaudoin v Monsanto & Bayer Cropscience*, Judgment, G.A. Smith J., Queen's Bench for Saskatchewan, 11 May 2005, 2005 SKQB 225.

15 *See, e.g.*, Nuffield Council on Bioethics, Genetically Modified Crops: the Ethical and Social Issues 54 (London: Nuffield Council on Bioethics, 1999).

16 World Food Summit, Plan of Action, Rome, 17 November 1996. [http://www.fao.org/docrep/003/w3613e/w3613e00.htm]

at a global level is not a major concern since the world produces enough food for its present population.[17] Availability is a concern in the case of countries suffering from armed conflicts, in situations where sufficient arable land is not available or in the case of persistent drought. Food availability will also be an increasing concern in the future if food production does not keep pace with population growth. Today, however, the problem of under-nourishment is more often linked to the problem of lack of access to food and maldistribution of foodstuffs than to unavailability per se.[18] Food security at an individual level implies that people must either have sufficient income to purchase food or the capacity to feed themselves directly by growing their own food. There is therefore a direct link between poverty and food security.[19] More specifically, food security is influenced by individuals' capacity to work, individual and household access to land and their control over the land and other productive assets, including seeds.[20]

The realisation of food security at the individual level is directly linked to agricultural biodiversity. Diversity constitutes from an environmental point of view one of the ways in which resilience of agricultural systems can be ensured while from a socio-economic point of view, agro-biodiversity constitutes to a large extent one of the basic productive assets of poor farmers. This is important in view of the fact that the introduction of genetically modified seeds has the potential to directly or indirectly displace existing plant varieties. The loss of diversity is generally deemed to be negative from the point of view of agro-biodiversity conservation which is recognised as a basic requirement for meeting food needs of future generations.

II. THE CARTAGENA PROTOCOL AND DEVELOPMENT

The Cartagena Protocol is the main international law framework concerning biosafety. Its adoption and coming into force constitutes an important development in view of the widely different views that negotiating states held concerning the safety of genetically modified organisms.[21] The negotiated text is significant because it places the question of the safety of genetically modified organisms clearly within the field of environmental law.

The Cartagena Protocol is an important environmental law treaty by virtue of being a protocol to the Biodiversity Convention whose basic principles concerning biodiversity conservation and sustainable use also apply. International regulation of activities related to genetically modified organisms is first of all justified by the fact that all biodiversity is a common concern of humankind and international cooperation is necessary to address a diversity of issues, especially where there is scope for transboundary impacts, as in the case of gene transfers.

The protocol takes up this challenge by generally proposing to regulate most activities related to genetically modified organisms from their international transfer, to handling and use.[22] One of the main contributions of the protocol to the development of environmental law is the central place given to the precautionary principle in the regulation of genetically modified organisms. It is not only the main background principle for the regulation of genetically modified organisms under the protocol but is also given content in the context of specific procedures adopted to regulate their transboundary movements.[23]

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17 *See, e.g.*, Carl F. Jordan, 'Genetic Engineering, the Farm Crisis and World Hunger', 52 *Bioscience* 523-529, 526 (June 2002).

18 As illustrated in the case of India where the absolute number of undernourished people increased in the 1990s while huge food surpluses built up. *See, e.g.*, FAO, *The State of Food Insecurity in the World 2005* (Rome: FAO, 2005)[30] and Ramesh Chand, 'Whither India's Food Policy? – From Food Security to Food Deprivation', 40 *Econ. & Pol. Wkly* 1055 (12 March 2005).

19 *See, e.g.*, Mahbub ul Haq Human Development Centre, *Human Development in South Asia 2002 – Agriculture and Rural Development* 96 (Karachi: Oxford University Press, 2003). [96. Food availability different from food sec. former doesn't guarantee latter. For them widespread food insecurity due mostly to lack of purchasing power of poor.]

20 Concerning the link between food security and land tenure, *see, e.g.*, Bina Agarwal, *A Field of one's Own – Gender and Land Rights in South Asia* (Cambridge: Cambridge University Press, 1994). [Land remains one of the primary economic assets in many developing countries and is in most cases very unequally distributed. Land reform is thus of primary importance even in countries like Egypt where it appears that, despite an apparent shortage of land, landlessness could be virtually eliminated through land reform. *See* Timothy Mitchell, 'The Use of an Image - America's Egypt and the Development Industry', 26 *Ecologist* 19 (1996).]

21 *See, e.g.*, Robert Falkner, 'Negotiating the Biosafety Protocol: The International Process', *in* Christoph Bail, Robert Falkner and Helen Marquard eds, *The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment and Development?* 3 (London: Earthscan, 2002).

22 Article 1, Cartagena Protocol, note 1 above.

23 *See, e.g.*, Owen McIntyre & Thomas Mosedale, 'The Precautionary Principle as a Norm of Customary International Law', 9 *J. Envtl. L.* 221 (1997).

The main operative part of the protocol provides a system for the regulation of transboundary movements of genetically modified organisms by specifying the conditions under which trade can be undertaken. This comes in the form of a procedure for advanced informed agreement (AIA). In essence, the AIA procedure gives the importing state the right to refuse entry to genetically modified organisms covered by the procedure on the basis of a risk assessment carried out according to the provisions of the Protocol.[24] In other words, importing states have the right to restrict imports in order to minimise possible adverse effects on the conservation and sustainable use of biodiversity of genetically modified organisms.

More specifically, in the case of a first transboundary movement for intentional introduction into the environment, the exporting state first has to notify in writing the importing state before the movement of a genetically modified organism takes place.[25] Information requirements for this notification are included in Annex I. The state of import must then acknowledge receipt of the notification and indicate whether the procedure is to follow the importing state's regulations – which must comply with the Protocol – or the procedure outlined in the Protocol.[26] Importantly, failure to acknowledge receipt of a notification does not signify that the state of import agrees to the LMO movement. The final decision indicating whether the movement will be allowed or denied must be based on a risk assessment carried out in a scientifically sound manner according to the methodology outlined in Annex III. The party of import has nine months to take a decision whether to allow the movement or refuse it. Importantly, if the state of import fails to notify the exporting state its decision within the agreed time frame, this cannot be construed as an acceptance of the shipment.

With regard to the risk assessment, the protocol recognises that there may be cases where scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the importing state may be insufficient to provide the basis for precise conclusions. In such cases, in accordance with the precautionary approach the importing state is authorised to take a negative decision with regard to the proposed transboundary movement with a view to avoid or minimise potential adverse effects.[27]

In the case of genetically modified organisms intended for direct use as food or feed, or for processing, the AIA procedure does not apply and they are covered by separate provisions under Article 11. In effect, state parties to the Protocol only undertake to provide each other with information concerning the regulatory framework that they adopt in this field. With regard to import decisions, importing states must take decisions in pursuance of their legal framework which must be consistent with the overall objectives of the Protocol. The Protocol takes account of the fact that developing countries or countries with an economy in transition may not have regulatory frameworks in place in this field. In this case, Article 11(6) outlines criteria on which these countries must base their import decision. The Protocol indicates that the risk assessment must again be undertaken in accordance with Annex III. In all cases, import states can rely as in the case of the AIA procedure on the precautionary principle to take a negative decision even in the face of uncertainty with regard to the adverse effects on the environment or human health.

Apart from Article 11 exceptions, the AIA procedure only applies to genetically modified organisms that have not been excluded from its scope. Exclusions include, for instance, pharmaceuticals for humans that are regulated by other treaties.[28] In practice, this implies that the AIA procedure will apply mainly to seeds and micro-organisms which constitute only a small percentage of all genetically modified organisms that are traded. Further, it applies only to the first intentional transboundary movement and neither applies in case of transit nor in cases where genetically modified organisms are destined for contained use.[29]

This brief review of some of the main elements of the protocol clearly indicates that its adoption has made an important contribution to the development of environmental law. Nevertheless, further comments in the context of the protocol's contribution to development are required.

Firstly, while the protocol has the potential to be a comprehensive instrument for the regulation of genetic engineering given the objectives it sets for itself, existing operational measures largely focus on trade-related issues. In other

24 Articles 10 & 16, Cartagena Protocol, note 1 above.
25 Article 8, Cartagena Protocol, note 1 above.
26 Article 9, Cartagena Protocol, note 1 above.
27 Article 10(6), Cartagena Protocol, note 1 above.
28 Article 5, Cartagena Protocol, note 1 above.
29 Article 6, Cartagena Protocol, note 1 above.

words, the broad framework set out in Article 1 of the protocol is not comprehensively operationalised at present and further measures need to be adopted to move beyond existing trade-specific measures. In other words, while it is conceptually reasonable to include trade measures in the context of an international treaty regulating the movement of genetically modified organisms, there is no reason to limit the focus to trade measures when both the protocol's own objective clause and the underlying Biodiversity Convention provide much broader mandates.

Secondly, the protocol is noteworthy because it goes beyond environmental measures and recognises links with other areas. Thus, risks to human health are specifically included in the broad objective clause. Further, the protocol acknowledges that environmental and health impacts of genetically modified organisms cannot be looked at in isolation from broader socio-economic issues. Article 26 focuses on the situation of developing countries as it singles out socio-economic impacts on indigenous and local communities for specific attention. However, the protocol restricts itself to noting the existence of a link between the introduction of genetically modified organisms into the environment and socio-economic consequences as negotiating states could not agree on anything more specific or practical.[30]

Thirdly, with regard to the trade-environment debate, the protocol makes two distinct contributions. The protocol acknowledges that there are certain situations where trade and environmental treaties may be in conflict.[31] Even though the preamble does not provide a legally binding solution, this recognition is already a step forward compared to the absence of any recognised links in trade treaties. Further, the protocol makes more specific contributions to the trade-environment interface by providing what are in effect more specific trade-related measures than what the Agreement on the Application of Sanitary and Phytosanitary Measures offers in a WTO context, such as with regard to risk assessment and management.

Overall, the protocol provides a sound starting point for the regulation of genetically modified organisms at the international level. Nevertheless, at this stage, it does not yet provide an appropriate basis for comprehensively addressing all development-related concerns of genetic engineering. This is due to the fact that the scope of the protocol is currently limited by a number of exceptions which make the existing AIA effective only in a relatively limited number of cases. This is also due to the fact that a number of elements need to be elaborated in much more detail than what is the case at present. This includes the need for more detailed clauses on socio-economic aspects as well as the need for a binding and more specific clause concerning the relationship between the protocol and trade treaties.

III. ELEMENTS FOR THE DEVELOPMENT OF BROADER BIOSAFETY LEGAL REGIMES

As noted above, the Cartagena Protocol provides a basic regulatory framework that addresses a number of relevant issues. At the same time, it does not provide a comprehensive regulatory framework and raises a number of further questions with regard to the regulation of genetically modified organisms at the international level.[32] This section examines some of the issues that need to be further analysed and addressed with a view to provide a comprehensive international regulatory framework that is as detailed in its consideration of incentives for the development of genetic engineering as in its consideration of concerns related to the environment, health, food security and other socio-economic aspects.

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30 Debates concerning socio-economic aspects are ongoing but member states are yet to adopt a decision that would give more specific content to Article 26. *See, e.g.*, Decision BS-II/12, Socio-economic Considerations, *in* Report of the Second Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, UN Doc. UNEP/CBD/BS/COP-MOP/2/15 (2005).

31 Preamble, Cartagena Protocol, note 1 above.

32 *Cf.* Lian Chawii, 'Biosafety in India – Rethinking GMO Regulation', 40 *EPW* 4284 (24 September 2005). [4288. Concluding Remarks. It appears that biotechnology is developing at a pace in which technological strides in the field can seldom be regulated through credible biosafety norms. These anxieties have, perhaps, contributed to the growing scientific and popular reaction against GMOs, whose potential risk continues to be a matter of intense debate worldwide. Notwithstanding these claims about the protocol possessing several salutary features, biosafety regulations still remain inadequate.]

A. Environment

Addressing environmental consequences of the introduction of genetically modified organisms is the primary objective of the protocol. This is consequently an area which receives significant attention. However, even though the protocol is built on sound environmental principles, much more needs to be done to ensure that the regulatory regime is environmentally-friendly in all its aspects at the international level and framed in such a way that even smaller and weaker countries can take advantage of all its provisions.

At the international level, while a number of environment-related aspects are covered in the protocol, there are some important gaps which need to be filled. One of them is the question of liability which is mentioned but not comprehensively addressed at Article 27 of the protocol. A liability regime is required in case of damage occurring as a result of the introduction of genetically modified organisms into the environment. Since it is impossible to preclude the occurrence of damage in the near or long-term, it is necessary to introduce rules which clearly establish the consequences for all interested parties. A process is now under way to develop rules for liability in the context of the protocol.[33] Its successful conclusion is a prerequisite for ensuring the effectiveness of environmental measures adopted, for instance, with regard to risk assessment and management. In other words, the effective implementation of the legal regime for biosafety adopted under the protocol requires the adoption of liability rules.

The importance of the type of international legal measures which are adopted go beyond the international law level. Indeed, in the case of the Biosafety Protocol, one of its main impacts is to provide small and economically less developed importing countries some tools on the basis of which a positive or negative decision can be taken with regard to imports of specific genetically modified organisms. However many exceptions the protocol may include, it has the immense advantage of providing a set of binding measures on which an importing state can base its decision to reject a particular genetically modified organism. The importance of a strong regulatory framework at the international level in the context of a technology which is strongly promoted by some of the most economically powerful nations is illustrated in the case of Malawi. Malawi faced a major food crisis in 2001-2002.[34] As part of food aid being sent to alleviate the food emergency, some shipments of genetically modified maize were sent to Malawi. This created a major controversy in Malawi, as well as Zambia and Zimbabwe because donors determined that they were not ready to pay for the milling of the maize before entry into Malawi, thereby raising the possibility that genetically modified maize might enter the food chain. At the end of the day, the crisis was resolved in such a way that Malawi accepted the shipments but determined that all maize should be milled upon entry. In the middle of this crisis, Malawi adopted a biosafety law as a way to give a legal basis to any decisions being taken in the future. This law introduces a regulatory framework which is fairly similar to what other sub-Saharan African countries have done. However, it specifically provides that the biosafety measures introduced under the Act can be circumvented by the minister in times of food security crises.[35] This provision could be read as a food security response to possible future food emergencies but is in fact a more direct political response to the pressure that was applied on Zambia, Zimbabwe and Malawi to accept as food aid genetically modified maize.[36] One of the lessons arising from the Malawian law is that there is no necessary conflict between the application of the precautionary principle and food security. In this specific case, the only requirement of the precautionary principle would have been to get the grain milled, a solution which was technically easily available and financially bearable for developed countries keen on gifting maize. The Malawian law is therefore an unsatisfactory response to existing challenges, not because it seemingly puts food security ahead of environmental concerns but because it fails to acknowledge the various links that may exist between the two in the short or long term and because it confuses legal principles with political expediency.[37] This constitutes an inappropriate long-term response to the challenges posed that is illustrated by the fact that the original rejection of genetically modified food aid was motivated by various

33 *See, e.g.*, Report of the Open-Ended ad hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety on the Work of its Second Meeting, UN Doc. UNEP/CBD/BS/COP-MOP/3/10 (2006).

34 On the food crisis in general, *see, e.g.*, Stephen Devereux, State of Disaster – Causes, Consequences & Policy Lessons from Malawi (ActionAidMalawi, 2002).

35 Section 18, Malawi, Biosafety Act, 2002, Act No. 13 of 2002.

36 *Cf.* Communiqué of Regional Workshop on 'GE/GM Food Aid' Held at Malawi Institute of Management, Lilongwe, 11 to 14 December 2002.

37 *Note* that while genetically modified maize received in the form of food aid was 'officially' milled before entry into Malawi, senior officials in the government suggest that this was in fact not done.

considerations such as risks to human health, impacts on domestic agricultural biodiversity and impacts on agricultural exports to European countries at least.[38]

The two distinct examples chosen here, liability and national level regulation in least developed countries both indicate that there is a need to adopt more specific international standards concerning biosafety which provide not only a specific legal regime for the first intentional transboundary movement of genetically modified organisms for intentional introduction into the environment but also for all other activities related to the safety of genetic engineering. This is something which can in principle be successfully undertaken by each country separately as illustrated by the adoption of the Swiss gene technology act.[39] In practice, international cooperation is required to ensure that smaller and less economically developed countries can adopt precaution-based regulatory frameworks and to ensure that the international community contributes to the costs associated with risk assessment and management in developing and least developed countries.

B. Food Security

In most developing countries, given the extent of malnutrition, one of the main incentives for introducing genetically modified organisms are prospects for enhancing food security. As noted above, the main concerns with regard to individual food security are access to and distribution of food rather than overall availability. As a result, genetic engineering is mostly relevant in the context of concerns over future declining per capita availability of food supplies due to population growth and degradation of arable land, the increasing use of productive land for cash crops which do not contribute to meeting the food needs of the local population and the growing dependence of countries on international trade for meeting their food needs. These points need to be examined separately in the broader context of Article 26 of the protocol.

A number of problems have emerged over the past several decades in many countries concerning the degradation of arable land. This has been ascribed to a number of factors which include the introduction of hybrid and high-yielding varieties in green revolution areas. Initially, green revolution seeds contributed to significant yield increases.[40] However, the initial yield gains tapered off after a couple of decades and the new agricultural techniques associated with these seeds, which include the application of large doses of chemical pesticides and fertilisers as well as substantial use of irrigation water causing waterlogging, have been blamed for declining yields.[41] The challenge that arises today for policy makers in developing countries is to ensure that the shortcomings of the green revolution provide lessons for future developments in avoiding similar failures. Genetically modified seeds developed to-date have generally been seeds that add on one further trait to existing high-yielding seeds. From a food security point of view, it seems inappropriate to propose more of the same type of seeds to developing countries. A major effort thus needs to be made to provide new types of seeds. From a food security point of view, the real issue is the need for research that targets food crops and in particular so-called orphan food crops that do not attract enough attention because of they are not sufficiently attractive economically. This can take the form of incentives for the private sector to take up orphan crops as has been done in some countries for orphan drugs.[42] This could also take the form of additional resources to ensure that public sector agricultural research centres or

38 *See, e.g.*, Noah Zerbe, 'Feeding the Famine? American Food Aid and the GMO Debate in Southern Africa', 29/6 *Food Pol'y* 593-608 (2004). [599. The concerns articulated by recipients of GM food aid in Southern Africa centered on three key areas: (1) the potential health impact of GM food on recipients; (2) the impact of GM food on domestic agricultural biodiversity; and (3) the impact of GM food on their ability to export agricultural commodities in the future. 605. In rejecting US food aid containing GMOs, African governments were operating in the best interest of their countries in the context of the current international political economy. They were attempting to ensure the long-term viability of their economies, centered on agricultural production, in an international economic environment where the deck is stacked against them. Unable to compete with the huge subsidies afforded farmers in the United States and the European Union, African governments were attempting to develop specialized production in non-GM and certified organic agriculture]

39 Switzerland, Federal Law Relating to Non-human Gene Technology, 2003, *Recueil systématique* 814.91.

40 *See, e.g.*, Gordon R. Conway & Edward B. Barbier, *After the Green Revolution – Sustainable Agriculture for Development* (London: Earthscan, 1990).

41 *See, e.g.*, Bina Agarwal, Gender, Environment and Poverty Interlinks in Rural India 7 (Geneva: UNRISD, 1995) and G.S. Dhaliwal & V.K. Dilawari, 'Impact of Green Revolution on Environment', *in* B.S. Hansra and A.N. Shukla eds., *Social, Economic and Political Implications of Green Revolution in India* (New Delhi: Classical Publishing, 1991).

42 For the United States, *see* 21 *USC* 360bb.

International Agricultural Research Centres have the wherewithal to undertake the development products that are not necessarily commercially viable but important from a food security point of view.[43]

Another issue related to food security concerns the balance between food crops and cash crops. This is a question which needs to be addressed in view of the overall limited availability of land and the need to balance food sovereignty with the need to earn hard currency from the export of agricultural commodities. This issue arises because most agricultural markets include subsidies and price distortions.[44] As a result, it is insufficient to simply determine that farmers should be left to grow the crops that bring them the highest earnings. Each government provides different types of incentives to encourage farmers to grow certain crops.[45] In a context where government intervention exists and will not disappear, it is essential that governments focus first of all on ensuring sufficient food availability at the national level before providing incentives for cash crops. The dangers presented by a heavy reliance on cash crops to buy food stuffs on the international market are well illustrated by the catastrophic collapse of the food distribution system in Malawi in the early part of this decade.[46]

C. Sovereignty and Equity

Most international environmental issues have strong links with the principle of state sovereignty. Genetic engineering is no exception. As noted above, there are strong links between biological diversity conservation and policies adopted in the field of genetic engineering. Biodiversity clearly falls under the sovereignty of states and all states are therefore concerned by potential transboundary environmental contamination which may ensue from the introduction of genetically modified organisms in one country.

Sovereignty-related concerns have in fact been voiced by states negotiating the Biosafety Protocol. This has been in the context of the protocol's focus on international trade in genetically modified organisms. In fact, the main implication of an instrument like the Biosafety Protocol is that it restricts states' capacity to ban genetically modified organisms, should they wish to do so. This was perceived and resented by some of the states participating in the negotiations. Indeed, the draft preamble put forward by the African group in 1997 included a paragraph '*[a]cknowledging* that any State has the sovereign right to ban the entry or release of living modified organisms into its territory'.[47] Further, several member states specifically argued that states had the sovereign right to reject genetically modified organisms that do not have clear advantages and have negative socio-cultural effects.[48]

These proposals reflect the desire of a number of states to keep their options open with regard to the introduction of genetically modified organisms. This was due to a perception that benefits of introduction did not necessarily outweigh concerns. The African group thus proposed that

> [n]othing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent with the objective and provisions of this Protocol and are in accordance with the rules of international law, in order to better protect human and animal health, biological diversity, the environment and the socio-economic welfare of societies.[49]

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43 Efforts to remedy this problem include, for instance, the setting up of the Global Crop Diversity Trust. *See, e.g.*, Constitution of the Global Crop Diversity Trust, 4 October 2003.

44 This is, for instance, reflected in current agriculture-related negotiations in the WTO. *See, e.g.*, World Trade Organization, Doha Work Programme – Ministerial Declaration, Ministerial Conference, Sixth Session, 18 December 2005, WTO Doc. WT/MIN(05)/DEC.

45 For instance, price support schemes run by the Government of India. *See, e.g.*, Department of Agriculture and Cooperation at http://agricoop.nic.in/prices.htm.

46 *See, e.g.*, Kwesi Owusu and Francis Ng'ambi, Structural damage – The Causes and Consequences of Malawi's Food Crisis (London: World Development Movement, 2002).

47 *Id* at p. 3.

48 Report of the First Meeting of the Open-Ended ad hoc Working Group on Biosafety, Aarhus, 22-26 July 1996, UN Doc. UNEP/CBD/BSWG/1/4 (1996). [90. Several representatives stressed the sovereign right of States to reject LMOs which did not have clear advantages and which had a negative socio cultural effect; that provision was not embodied in WTO and should be part of the present protocol.]

49 Open-Ended ad hoc Working Group on Biosafety, Compilation of the Views of Governments on the Contents of the Future Protocol, Second meeting, Montreal, 12-16 May 1997, UN Doc. UNEP/CBD/BSWG/2/2 (1997) at p. 50.

A decade after the launch of the negotiations for the Cartagena Protocol, the concerns voiced then remain valid in view of the continued uncertainty concerning negative impacts and the very limited progress towards the development of genetically modified plant varieties meeting the specific food security needs of African countries, for instance.

States' stance on sovereign control can, for instance, also be linked to trade policies. For the majority of developing countries that had not introduced genetically modified organisms before the adoption of the Protocol and are mostly potential importers, trade has been an important consideration given the central role that exports of agricultural commodities play for them. The benefits of imports need to be weighed against the potential loss of export markets for agricultural commodities, an issue of great importance for countries exporting to regions of the world where some or all imports need to be certified as being free from genetically modified organism contamination.[50] This led the African group to propose as part of socio-economic measures that

> [a] Party that intends to produce, using a living modified organism, a hitherto imported commodity, shall notify the other Party or Parties whose export is to be affected long enough, and in no case less than seven years in advance so as to enable them to diversify their production and to implement measures concerning the biodiversity that would be reduced following the disruption of production of the commodity in question. The Party substituting its import in such unnatural way shall, when the affected Party is a developing country, provide financial and technical assistance to the affected Party.[51]

Sovereignty issues highlighted above largely reflect concerns of smaller and weaker states. In fact, one of the main achievements of the Biosafety Protocol is to provide importing states that may not be legally, institutionally or politically equipped to reject requests for imports an important tool to take independent decisions that have a strong basis in international law. This confirms that the Biosafety Protocol is a treaty which takes into account, at least indirectly, the special situation of developing and particularly least developed countries. This is in keeping with the principle of differential treatment which provides a basis for recognising that some states are differently able to comply with certain obligations and benefit from legal rules in place.[52] In fact, at present small developing and least developed countries cannot expect to gain much from the introduction of genetically modified seeds, in part because there are a number of other tools which can be used to address existing food security concerns. The Cartagena Protocol takes the situation of these countries into account to the extent that it provides ways in which an importing state can refuse a consignment of genetically modified organisms.[53]

However, equity considerations in the protocol cannot be qualified as effectively introducing differential treatment in favour of developing countries. Ratification of the Protocol has a number of implications which reduce the range of options that countries can exercise. Firstly, the AIA procedure is not a procedure which allows a country to generally ban the import of genetically modified organisms. Secondly, the African proposals seeking to make the Protocol an instrument providing a range of options from complete acceptance of genetically modified organisms to a ban were not carried forward in the final version of the Protocol. As a result, the overall impact of the protocol is to have driven a wedge into the regulatory framework of most developing countries that have adopted, as a result of their ratification of the protocol, legal frameworks that only regulate the conditions under which trade in genetically modified organisms can take place. A majority of these countries may or may not have needed to introduce genetic engineering at this juncture but the protocol, through the adoption of a trade-based environmental law instrument, has largely contributed to most countries accepting at least the principle that genetically modified organisms can be introduced.

D. Links with Intellectual Property Rights

Biosafety cannot be analysed separately from intellectual property rights that provide incentives for the development of transgenic products. Indeed, while the latter provide incentives for the development of commercially viable

50 Concerning import requirements in the European Union, *see, e.g.*, Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268/1, 18.10.2003 and Regulation (EC) No 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, OJ L 268/24, 18.10.2003.

51 UN Doc. UNEP/CBD/BSWG/2/2, note 49 above at p. 72.

52 *See generally* Philippe Cullet, *Differential Treatment in International Environmental Law* (Aldershot: Ashgate, 2003).

53 Article 10, Cartagena Protocol, note 1 above.

transgenic products, the former provides a framework to determine which new products should be introduced into the environment. Direct links between biosafety and intellectual property rights emerge from the fact that most commercialised genetically modified organisms are protected by patents or other intellectual property rights.

Existing links between biosafety and intellectual property rights are not acknowledged in current legal frameworks insofar as there are only limited ways in which biosafety concerns can influence the grant of a patent since patent laws do not make compliance with biosafety regulations a condition of the grant of patents. Today, intellectual property rights provide incentives for the development of products that are expensive to develop. Once the products are developed, there is a strong pressure for the product to be granted the necessary clearances for commercialisation.

A formal acknowledgment of existing links is crucial to ensure that biosafety frameworks are not largely emptied of their substance in practice. At present, the lack of direct links between the two implies that biosafety regulations are usually only triggered after the grant of intellectual property rights. One of the ways to make the regulatory framework more effective would be make the observance of biosafety regulations a condition of patentability. This could be either conceived as an additional procedural or substantive requirement for patentability.[54]

The need to provide a formal link between biosafety and intellectual property rights is well illustrated by the Canadian case *Monsanto v Schmeiser*.[55] This case concerned a genetically modified variety of canola commercialised by Monsanto which is resistant to the application of Roundup Ready, an herbicide that kills most plants. Mr Schmeiser was found to be in possession of genetically modified canola even though he had never purchased any Monsanto seeds. This led Monsanto to bring an action against Mr Schmeiser for infringement of their patent on Roundup Ready Canola. After several years of litigation, the Supreme Court found that the patent had been violated but that Mr Schmeiser did not owe anything to Monsanto.[56]

This judgment raises a number of important questions from the point of view of patent law which are not addressed here.[57] Here, the main relevance of *Monsanto v Schmeiser* is the part of the judgment which was never written. Indeed, all the different judges that looked at the case up to the Supreme Court decided that the dispute concerned the question of the infringement of Monsanto's patent. The judgement therefore did not discuss biosafety-related issues since it never looked at the question of the company's own potential responsibility in spreading transgenic constructs into the environment. Had biosafety been clearly linked to the patent system in Canada, the judges would have been forced to examine not only whether Mr Schmeiser had violated Monsanto's patent but also whether Monsanto could be deemed responsible for introducing into the environment a genetically modified construct which has the potential to self-replicate.

CONCLUDING REMARKS

The existing international biosafety regime provides the lineaments of a comprehensive regulatory regime based on environmental principles. The Cartagena Protocol's reliance on the precautionary principle as the basic regulatory principle for genetically modified organisms is a sound choice. The regulation of some aspects of international trade in genetically modified organisms is also a welcome step, especially for importing countries.

The existing legal regime for biosafety nevertheless needs to be significantly strengthened so as to provide a more comprehensive regulatory regime which offers an effective response not only to the trade-related environment and health challenges but also to the socio-economic and food security-related challenges linked to the introduction of genetically modified seeds. In other words, it is necessary to ensure that the Biosafety Protocol and related national level frameworks not only contribute to effective environmental safeguards but also contribute to ensuring that the commercialisation and introduction of genetically modified organisms into the environment contribute to other dimensions of development, in particular to food security.

54 *Cf.* Article 80, Costa Rica, Biodiversity Law 1998 providing that intellectual property rights on inventions using biological resources can only be granted if a certificate of origin is provided to the organs instituted under the Biodiversity Act.

55 *Monsanto Canada Inc. v Schmeiser*, Supreme Court of Canada, Judgement of 21 May 2004, 2004 SCC 34.

56 *Id* at §§ 97 and 105.

57 For further details, *see* Philippe Cullet, 'Monsanto v Schmeiser: A Landmark Decision concerning Farmer Liability and transgenic Contamination', 17 *J. Envtl. L.* 83 (2005).

A broader biosafety regulatory regime would build on the basic principles of the Biosafety Protocol and go further than the existing regulatory regime. In view of the controversial nature of the technology and the important economic stakes involved for certain countries, it is first important to ensure that countries' sovereign rights to determine whether to introduce genetic engineering or not should be preserved. It is also necessary to ensure that the special situation of countries whose economies are heavily dependent on exports of agricultural commodities be taken into account. This requires the introduction of differential treatment measures with a view to strengthen in particular the position of least developed countries. Besides these elements seeking to provide as equitable a regulatory framework as possible, a broader biosafety regulatory framework would ensure that the multitude of issues which need to be considered, from environmental concerns to health risks, socio-economic aspects and food security concerns are all an integral part of the measures proposed.

The adoption of a broader biosafety regime does not necessarily imply restrictions on trade but puts trade in the broader context in which it should be seen. In other words, while agricultural trade is an important concern for many countries, in the case of the dozens of countries where a large part of the population fails to have access to sufficient food, trade concerns should not be allowed to trump food security and food sovereignty concerns.