WHY AFRICA SHOULD ADOPT THE AFRICAN MODEL LAW ON SAFETY IN BIOTECHNOLOGY

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Abstract

The article argues for the Africa-wide adoption of the African Model Law on Safety in Biotechnology. The adoption of this Law will provide a unique opportunity for governments in Africa to introduce national biosafety regulations that adhere to a broader and unified continental framework. The regulatory framework utilises the discretion given by the Cartagena Protocol on Biosafety for countries to adopt more protective measures than the agreed minimum set out in the Protocol. These provisions are therefore far more comprehensive than that required by the Biosafety Protocol and seek to give recognition to the importance of Africa as both a centre of origin and a centre of diversity with regard to food and other crops. The Model Law also embraces the precautionary principle and recognises the sovereign right of every country to require a rigorous risk assessment of any GMO for any use before any decision regarding the GMO is made. It captures extensively, the essential elements for a liability and redress regime, which should be incorporated into domestic biosafety legislation. Stricter controls regarding the introduction and use of genetically modified food as food aid can also be introduced through the adoption of the Model Law.

1 Introduction

Genetic Engineering has made a rapid entry into agriculture in the United States, Argentina, Canada, China, Brazil and South Africa, with these countries being responsible for 99 percent of the genetically modified (GM) crops grown globally.[2] These countries grow crops with transgenic resistance to certain herbicides, insects, or diseases ostensibly to overcome the productivity constraints of conventional breeding. These transgenic crops, and products such as kernels of maize and Soya beans, are known as genetically modified organisms (GMOs).[3]

Genetic engineering brings with it a wide range of biosafety concerns and broader socio-economic impacts. It requires the acceptance of intellectual property rights on living organisms, the privatisation of public research, and expensive research and development at the expense of farmer-based

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[2] International Service for the Acquisition of Agri-Biotech Applications Preview Global Status of Commercialized Transgenic Crops: 2003 No. 30 (2003). The global area of GM crops for 2003 was 67.7 million hectares.

[3] Future transgenic plants may offer a much wider array of products, including applications in rangelands, forests, landscaping, nutrition, pharmacology, biological control, production of industrial chemicals, and bioremediation.

innovation. Genetic engineering and GMOs impact on several fundamental human rights, including the right to nutritious, safe and culturally acceptable food, the right to informed choice, the right to democratic participation, the right to save and exchange seeds, and the right to a safe and healthy environment. It also raises far-reaching ethical concerns for those that adhere to value systems underpinned by African communal spirituality concerning life and food.

In response to these challenges, the former Organisation of African Unity (OAU) convened a group of biosafety experts in June 1999 to draft a comprehensive framework of biosafety regulations that would serve as a model law, designed to protect Africa's biodiversity, environment and the health of its people, from the risks posed by GMOs. This initiative resulted in the African Model Law on Safety in Biotechnology ('Model Law'), which was finalised in May 2001, in Addis Ababa, Ethiopia, by 89 participants representing 35 African countries.

At its 74th Ordinary Session convened in Lusaka, Zambia in July 2001, the OAU Council of Ministers endorsed the Model Law. The Council furthermore urged its member states to use the Model Law to draft their own national legal instruments in order to create a systematic and Africa-wide biosafety regime to regulate the movement, transport, and import into Africa of GMOs.[4]

The Model Law is not legally binding, does not have any legal relationship with any other biosafety laws in Africa or elsewhere, and does not require any formal process by individual Member States of the AU for its adoption. Instead, the Model Law is an attempt to facilitate the harmonising of existing legislation in the area of biosafety and to ensure the adoption of unified legislation in Africa. The Model Law has been strongly influenced by the Cartagena Protocol on Biosafety[5] (Biosafety

[4] Assembly of the Head of States and government Decision No. AHG/Dec. 164 *Council of Ministers Decision No. CM/Dec. 623* July 2001.

[5] *The Cartagena Protocol on Biosafety to the United Nation's Convention on the Conservation and Sustainable Use of Biological Diversity* was adopted by the Conference of the Parties to the Convention on 29 January 2000 http://www.biodiv.org/biosafety (accessed 10 May 2003)

[5] The Protocol uses the term 'living modified organism', (LMO) a term that has its roots in Articles 8(g) and 19(3) of the Convention on Biological Diversity. Article 3 of the Protocol defines a LMO as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. This definition clearly excludes a product of a LMO. This definition is one of the victories the genetic engineering industry won during the negotiations of both the CBD and the Protocol. In order to avoid confusing the reader, the term genetically modified organism (GMO) is used in this document because this is the more common term adopted in most literature. In this regard, GMO is used in the same way that

Protocol), negotiated under the auspices of the United Nation's Convention on the Conservation and Sustainable Utilization of Biological Diversity (CBD).

The Protocol provides a legally binding framework of rules to be applied to the import, export, transit, handling and activities related to the use of GMOs in order to protect biodiversity, the environment and human health from the risks posed by GMOs.[6]

The Model Law seeks to introduce just such measures. It specifically recognises that Africa's biodiversity, environment and the health of its people can only be protected if countries in Africa adopt high standards of safety. Furthermore it seeks to subject the entire spectrum of GMOs, associated products and GMO related activities to rigorous safety assessments. The Model Law therefore considers the rules established by the Biosafety Protocol as a 'floor' rather than a 'ceiling' in determining the regulatory framework. In this regard, the Model Law fully utilises the discretion given by the Protocol to the Parties to adopt more protective measures than the agreed minimum set out in the Protocol.[7]

This approach is also in keeping with the need for special measures to be taken to conserve plant diversity and to retain the integrity of centres of origin of major crops. In this regard, the Biosafety Protocol expressly recognises the crucial importance to humankind of centres of origin and centres of diversity.[8] The Sub-Saharan savannah belt that stretches from Lake Chad to eastern Sudan is, for example, considered to be the centre of origin of sorghum and pearl millet. Sub-Saharan Africa is also the centre of diversity of cassava while Ethiopia, the Saharan oases and Sudan, are centres of genetic diversity of wheat.[9] These are all major sources of food for millions of people requiring the highest standards of safety and protection from genetic contamination.

LMO is referred to in the Protocol, both definitions denoting a genetically modified organism resulting from modern biotechnology.

[6] The Scope of the Protocol is set out in Article 4 and provides that the Protocol applies to the transboundary movement, transit, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.

[7] Article 2(4) of the Biosafety Protocol provides 'Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity that is called for by this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.'

[8] Recital 6 of the Preamble of the Protocol.

[9] Centres of Diversity: Global Heritage of Crop Varieties Threatened by Genetic Pollution, Greenpeace Report. September, 1999. http://www.greenpeace.org/~geneng, (accessed 10 May 2003) at 56.

Furthermore, the Model Law adopts the approach that proper application of the precautionary principle demands thorough regulation of the series of activities that may be undertaken in respect of a GMO. These activities include the import, transit, contained use, release or placing on the market of a GMO and the product of a GMO.[10] This approach is in keeping with the Article 8(g) of the Convention on Biological Diversity (CBD). Parties to the CBD are obliged to 'regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts, that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health.'[11] More importantly, however, is that such regulations can be introduced independently from any other recognised instrument in this field, including the Biosafety Protocol.

Finally, the Model Law strives to provide a holistic and comprehensive set of biosafety rules including those issues that are not dealt with by the Biosafety Protocol. These include mandatory labelling of GMOs and genetically modified food, and liability and redress for harm caused by GMOs to human health, the environment and for resultant economic loss. African countries have the sovereign right to take such measures, which the Biosafety Protocol in any event cannot and indeed, does not preclude. A fragmented biosafety system does not allow for the unique risks of GMOs to be fully taken into account and specifically and appropriately regulated. Holistic legislation is necessary to provide consistency and enable streamlined and more transparent decision-making.

2 Cartagena Protocol on Biosafety

The origin of the Biosafety Protocol is Article 19(3) of the CBD, which in turn, originates from a proposal made by the government of Malaysia during the negotiation of the CBD in November 1991.[12] The Malaysian proposal contained the core element of 'prior informed consent' or

[10] Preamble of the Model Law.

[11] Article 8(g) of the CBD refers to 'living modified organisms resulting from biotechnology' and therefore covers the broad range of organisms, whether plants, animals or microbes resulting from biotechnology, that are alive, including organisms whose genetic material has been modified through recombinant DNA technology. The intention of the obligation is for the Parties to approach the potential environmental and health risks of LMOs in a rational, precautionary manner based on the assessment and subsequent regulation, management or control of the risks.

[12] Wen Lian Ting. Leader of Malaysian delegation to negotiate the CBD. Personal communication.

'advanced informed consent' of importing countries that prevailed throughout the process of the Biosafety Protocol negotiation.[13]

Article 19(3) of the CBD obliges the Parties to the CBD to consider the need for and modalities of a Protocol setting out appropriate procedures. In particular this includes, 'advance informed agreement', in the field of safe handling and use of any living modified organism that may have adverse effects on the conservation and sustainable use of biodiversity. The Biosafety Protocol negotiations, however, only commenced in 1995 when the 'Jakarta Mandate' was adopted at the second Conference of the Parties of the CBD (COP2) in Jakarta, Indonesia. The Jakarta Mandate sanctioned the establishment of an Open-ended *Ad Hoc* Working Group on Biosafety, to elaborate a Protocol on Biosafety specifically focusing on the transboundary movement of living modified organisms (LMOs).

The Biosafety Protocol negotiations have been described as 'one of the most difficult and complex negotiations between trade and environment'.[14] The negotiations spanned across a period of five years, and collapsed once[15] at the final round of negotiations in Cartagena, Colombia in February 1999 before it was finally adopted in Montreal, Canada in January 2002. The Biosafety Protocol came into effect on 11 September 2003, and to date, 107 countries have ratified the Biosafety Protocol, 22 of which are from Africa.[16]

The central regulatory element of the Biosafety Protocol is the Advanced Informed Agreement procedure, which applies to the first transboundary movement of GMOs for intentional introduction into the environment.[17]

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[13] V Koester 'The History Behind the Protocol on Biosafety and the History of the Cartagena Protocol Negotiation Process' at 6, Cartagena Protocol on Biosafety from Negotiation to Implementation: Historical and New Perspectives CBD News Special Edition United Nations Environment Programme

[14] J. Mayr 'Doing The Impossible: The Final Negotiations of the Cartagena Protocol' at 10 The History Behind the Protocol on Biosafety and the History of the Cartagena Protocol Negotiation Process, Cartagena Protocol on Biosafety From Negotiation to Implementation Historical and New Perspectives CBD News Special Edition United Nations Environment Programme.

[15] The negotiations collapsed in Cartagena because the Miami Group comprising of the major grain GMO producing countries, namely, the United States, Canada, Argentina, Uruguay and Chile opposed the inclusion of biosafety measures it perceived could hamper the free trade in GMOs. The Miami Group particularly opposed the inclusion of GM commodities such as maize and wheat that are traded internationally as food, feed and/or processing, from the scope of the Biosafety Protocol.

[16] Algeria, Rwanda, Togo, Gambia, Zambia, Egypt, Ethiopia, Senegal, South Africa, Burkina-Faso, Nigeria, Botswana, Cameroon, Djibouti, Ghana, Kenya, Lesotho, Liberia, Mali, Mozambique, Tunisia, and Tanzania currently constitute the 22 Parties to the Biosafety Protocol form the African continent.

[17] Articles 7-10 of the Biosafety Protocol.

The procedure seeks to ensure that importing countries have the opportunity to assess the environmental and human health risks associated with a GMO and take a decision based on the precautionary principle, before agreeing to its import. It obliges exporters to notify importers in advance of the first shipment and to supply certain prescribed information concerning the GMO. Receipt of this information needs to be acknowledged within 90 days. Within 270 days the importing Party must communicate its final decision with regard to the future status of the GMO. This decision is to be based on a risk assessment and may either approve or prohibit the import of the GMO, request further information, or extent the deadline by a defined period of time. In each case reasons for the decision need to be stated. Both the importing and exporting Parties may, at any time, initiate a review and change of the decision in the light of new scientific information.

3 Essential Provisions of the Model Law

3.1 Uniform provisions for all GMOs and activities

The Model Law applies to the import, export, transit, contained use, release and placing on the market of any GMO and a product of a GMO, whether it is intended for release into the environment, for use as a pharmaceutical, for food, feed or processing.[18] It establishes uniform provisions that apply to all these activities because it views the risks from all GMOs as being the same, whether they are used in agriculture, medicine or research, and regardless of whether they are classified as seed, or food. In so doing, it adopts the principles that inform the AIA procedure of the Biosafety Protocol. Whereas the Biosafety Protocol only requires that the AIA procedure applies outright to the first time a GMO is imported for direct introduction into the environment of the importing Party, the Model Law requires that its AIA procedure apply to all categories of GMOs, all its related uses and products of GMOs.

The Model Law requires the GMO exporter (notifier) to provide information to the relevant authority regarding the characteristics of the GMO under consideration as well as the information deriving from the risk assessment of that GMO.[19] These provisions are far more comprehensive than that required by the Biosafety Protocol. However, it

[18] Article 2 of the Model Law.
[19] Article 4 of the Model Law.

is not only prudent but critically important for a country to know which GMOs are entering the country and for which uses. There should also be a comprehensive assessment of the risks posed by the GMO prior to a decision being taken on its introduction in whatever form.

To this extent the Model Law is simply recognizing the sovereign right of every country to require a rigorous risk assessment regarding the use of *any* GMO *for any use* before it makes a decision. Countries also have the right to sufficient as opposed to minimum information being furnished about the GMO or its proposed use, prior to decision making, as required by the Protocol. Additionally, the Protocol does not preclude a Party of import from requiring that its prior informed consent first be obtained before any GMO is imported for any use. This includes, for example, GMOs that may be in transit through a country's territory, or GMOs that are imported for contained use purposes, both activities, which are excluded from the AIA procedure of the Protocol.[20] The Model Law has simply applied stricter regulations than that required by the minimum rules of the Protocol and in so doing, has fully utilised the room that the Biosafety Protocol allows for flexible domestic rule making.

The Model Law also deals with products of GMOs and GMOs that are pharmaceuticals in a similar manner. A product of a GMO is defined in the Model Law as 'any material derived by processing, or howsoever otherwise, from any genetically modified organism or from a product of a genetically modified organism.'[21] As noted elsewhere, a product of a GMO does not fall within the purview of the Protocol.[22] However, this does not mean the Protocol completely ignores a product of a GMO. In fact, the Protocol does introduce an indirect obligation on the exporter (notifier) to conduct a risk assessment in respect of product of the GMO irrespective of whether the GMO in question will be exported for direct introduction into the environment or as direct use as food, feed and processing.[23] The Model Law has in regard to products of GMOs, adopted a precautionary approach inasmuch as such products may have adverse effects on biodiversity, the environment and human health.[24]

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[20] Article 6 of the Biosafety Protocol specifically excludes the AIA procedure of the Protocol from applying to GMOs in transit and GMOs that are imported/exported for contained used purposes.

[21] Article 1 of the Model Law.

[22] See footnote 5 above.

[23] Annex I (i) and Annex III (5) read together with Articles 8 (1), 11(1) 15 and Annex II of the Biosafety Protocol.

[24] See further *'Products Thereof' Should Be Covered By The Biosafety Protocol* Third World Network Briefing Paper October 1999, which sets out some of the adverse effects that products of GMOs may have on biodiversity, the environment and human health. Products of certain GMOs may contain recombinant DNA, which may persist and be transferred to the

Moreover, it has built on the indirect regulation of products of GMOs introduced by the Protocol and the mandate provided by Article 8(g) of the Convention on Biological Diversity.[25]

The Model Law's regulation of GMOs that are pharmaceuticals (which also include pharmaceuticals that are derived from GMOs) has come under severe criticism by Africabio, the lobby and advocacy group of the biotechnology industry.[26] However, Africabio has deliberately misinterpreted the Protocol by espousing the view that the Protocol excludes GMOs that are pharmaceuticals for humans, from the scope of the Protocol.[27] This is not correct as the Protocol merely excludes the AIA procedure and Article 12 dealing with review of decisions from applying to those genetically modified pharmaceuticals for humans that are addressed by relevant international agreements and organizations, such as the World Health Organisation (WHO).[28] Furthermore, it is unclear to what extent such relevant agreements and organizations need to 'address' GMOs that are pharmaceuticals in order for the AIA and Article 12 of the Protocol not to apply to such GMOs. The view has been expressed that information available so far shows that no pharmaceutical

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microflora in the intestinal tracts of humans and animals. The DNA contained in such products may be transferred by different pathways into the open environment, including soil and water systems. Products derived from GMOs containing antibiotic resistance marker genes and retaining DNA have the potential to transfer their antibiotic resistance genes to other organisms, for example the flora in the gut. This may exacerbate the frequency of antibiotic resistance in pathogens, which may result in outbreaks of new and re-emerging infectious diseases. http://www.twnside.org (accessed 10 May 2003)

[25] Article 8(g) of the Convention on Biological Diversity specifically addresses the 'use' of LMOs. Products of LMOs/GMOs make direct or indirect use of LMOs/GMOs. They may contain LMOs/GMOs in a processed form, such as flour derived from transgenic wheat or derivatives from LMOs/GMOs, such as enzymes. This demonstrates a specific use of LMOs/GMOs, which fall clearly within the ambit of 'use' in Article 8(g) of the Convention on Biological Diversity.

[26] Africabio Submission on the OAU Model Law on Biosafety http://www.africabio.com/policies/Submission%20OAU%20Model%20Law%20on%20Biosafety%20by%20AfricaBio.htm (accessed 6 September 2004)

[27] Africabio's erroneous submission reads as follows ' The OAU Model deviates significantly from the Protocol and extends well beyond its provisions. …Furthermore, the OAU Model includes human pharmaceutical products which had specifically been excluded from the Protocol. No valid reason was presented for extending the Model to pharmaceuticals.' Africabio Submission on the OAU Model Law on Biosafety http://www.africabio.com/policies/Submission%20OAU%20Model%20Law%20on%20Biosafety%20by%20AfricaBio.htm (accessed 6 September 2004)

[28] See further, IUCN and FIELD 'An Explanatory Guide to the Cartagena Protocol on Biosafety. Draft' April 2002.

for humans are covered by any other agreement or organization in their condition as a GMO and are therefore covered by the Protocol.[29]

In any event, genetically modified plants and animals used to produce pharmaceuticals are not exempt from the provisions of the AIA procedure of the Protocol. According to the rules of the WHO and its member states, it is highly unlikely that the actual genetically modified plant or animal will ever receive approval as a pharmaceutical as such. More so as further processing to achieve a standardized, reliable pharmaceutical will in any event be necessary. Furthermore, the exemption of the Protocol does not apply to genetically modified pharmaceuticals that are not dealt with by relevant international agreements or organizations nor where such agreements or organizations do not directly address the environmental and biodiversity impacts of a GMO. The exemption will also not apply to genetically modified pharmaceuticals that are intended for veterinary purposes. Additionally, an importing Party has the sovereign right to require a risk assessment prior to the import of any GMO for any use, as well as to require that its prior informed consent first be obtained.

3.2 The Model Law and the World Trade Organisation

The provisions of the Model Law, which are trade-related, are compatible with the relevant agreements under the World Trade Organisation (WTO) because these are justified by a rational policy purpose such as, for example, the protection of human life or health. Trade-related measures that are relevant to biosafety fall within the purview of three agreements of the WTO, namely, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Agreement on Technical Barriers to Trade (TBT) and the General Agreement on Tariffs and Trade (GATT) 1994. These agreements allow biosafety measures to be taken, including import bans, use restrictions such as risk assessments and risk management measures, and traceability, identification and labelling requirements.

The SPS agreement regulates sanitary and phytosanitary measures that will affect trade provided it is with respect to protecting plant, animal and human health. Biosafety measures aimed at the regulation of imported GMOs to protect plant, animal and human health would be covered under the SPS agreement. The SPS agreement allows countries to set their own standards, as long as these are based on science, are applied only to the

[29] Institute for Sustainable Development and Third World Network. 'The Convention on Biological Diversity With Some Explanatory Notes From A Third World Perspective' May 2000.

extent necessary to protect human, animal or plant health, and do not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail. Countries are allowed to set higher standards based on appropriate risk assessment, as long as the approach is not arbitrary.

The TBT agreement regulates measures affecting trade which are technical and industrial standards (including packaging, marking and labelling requirements), and that do not fall under the SPS agreement. Labelling requirements for GMOs that are imported and which are aimed at informing the consumer would typically be regulated by the TBT agreement. The TBT agreement allows for national regulations, which should not be more trade restrictive than necessary, to fulfil legitimate objectives. Legitimate objectives include *inter alia*: national security requirements, the prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment.

If a measure does not fall specifically under the TBT agreement, it would still have to comply with GATT 1994. Article XX of GATT 1994 allows governments to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism. Thus, a key trade principle is that of non-discrimination. Members are not allowed to apply a measure that would constitute a means of arbitrary or unjustifiable discrimination between countries. There is nothing in the Model Law that is aimed at distinguishing GMOs from different countries or discriminates between GMOs that may be developed locally and GMOs imported from other countries.

The relationship between the Biosafety Protocol and the WTO agreements is not addressed by the substantive provisions of the Protocol. The Preamble of the Biosafety Protocol emphasises on the one hand that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party existing under existing international agreements, and on the other, it states that this is not intended to subordinate the Protocol to other international agreements. The Preamble also states that trade and multilateral environmental agreements should be mutually supportive. Thus, how the implementation of the provisions of the Biosafety Protocol relates to the WTO agreements is an open question. If a conflict were to arise between the WTO agreements and the Biosafety Protocol, there would be ambiguity about which agreement would prevail.

4 Stringent Regulation of GMOs: Decision-making Based on the Precautionary Principle

The Precautionary Principle has evolved in international and national environmental law and jurisprudence since the 1970s to specifically address situations where there is lack of scientific uncertainty or consensus. In short, the precautionary principle provides that uncertainty regarding serious potential harm (i.e. the harm does not have to be proven) is not a valid ground for refraining from preventative measures.[30] In practise, the Precautionary Principle is built on common sense ideas such as 'prevention is better than cure' and there must be scrutiny of all available *alternatives* and an examination of *justifications* and *benefits* as well as risks and costs.[31]

The Model Law adopts a strict interpretation of the precautionary principle when decisions are to be made concerning GMOs and GMO uses. It does not allow approvals to be given unless there is firm and sufficient evidence that GMOs or products of GMOs pose no risk or no significant risk to human health, biodiversity and the environment.[32] This provision is buttressed by the provision that where a country finds that risks cannot be avoided, approval must be refused.[33] By adopting this interpretation of the precautionary principle, the Model Law sets the standard for African countries to strive towards. In any event, this interpretation is particularly pertinent when dealing with decisions to release GMOs into the environment for field trials and commercial cultivation. GMOs reproduce, spread and interact with all other life forms in ecosystems and once released they cannot be recalled, resulting in far-reaching and irreversible consequences. Genetic contamination is not a problem that can be contained.

Article 5.7 of the SPS agreement of the WTO allows members to provisionally apply the Precautionary Principle, where an appreciable threat has been identified within a risk assessment.[34] The SPS agreement

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[30] An Explanatory Guide to the Cartagena Protocol on Biosafety 'IUCN Environmental Policy and Law Paper No. 46' at 12.

[31] See further A. Stirling 'Science and precaution in the management of technological risk' 1999 *Report for the European Commission - JRC Institute of Prospective Technological Studies* Seville. http://www.jrc.es/pub/EURdoc/eur19056len.pdf

[32] Article 6(7) of the Model Law.

[33] Article 8(5) of the Model Law.

[34] Article 5.7 of the SPS agreement provides 'In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or Phytosanitary measures on the basis of the available pertinent information, including that from the relevant international organisation as well as form sanitary or Phytosanitary measures applied by other Members. In

does not prescribe a specific safety standard, as every Member is free to set its own level of safety as long as this is based on a scientific risk assessment. Where there is uncertainty, an importing country may take a decision to ban or restrict a GMO. However, an importing country will be required to provide scientific evidence to justify the ban and restriction.[35] Thus, African countries, when adopting the Model Law should ensure that the burden of proof is shifted onto importers to demonstrate the absence or low levels of harm, and require the insuring of liability for any existing adverse impacts.

The Biosafety Protocol deals with the need for precautionary action in the face of scientific uncertainty, and allows Parties to ban or severely restrict the import of a GMO.[36] States that are party to both the Biosafety Protocol and SPS agreements could feasibly meet the requirements of both agreements without conflict, where regulation is in accordance with scientific findings as opposed to political or trade interests.

4.1 Stringent regulation for GMOs imported for use as food, feed and processing and the problems of genetically modified food aid for Africa

As discussed earlier, the AIA procedure of the Biosafety Protocol does not apply outright to GMOs that are imported for use as food, feed and processing. This includes for example, genetically modified agricultural commodities, including for example, genetically modified Soya or maize for food or feed use, or genetically modified tomatoes. In terms of the Protocol, genetically modified **food aid** provided by countries, as emergency relief will also fall under this category of GMOs because it will be classified as GMOs intended for direct use as food, feed or processing.

For this category of GMOs, the Protocol establishes a multilateral information exchange procedure through the Biosafety Clearing House

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such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or Phytosanitary measure accordingly within a reasonable period of time.'

[35] Article 2.2, 3.3 and 5 of the SPS agreement.

[36] Articles 10(6) and 11(8) of the Biosafety Protocol contain identical provisions and provides 'lack of scientific certainty due to insufficient relevant 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 Party of import, taking also into account the risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food, feed, or processing, in order to avoid or minimize such potential adverse effects.'

(BCH), a website administered by the Secretariat of the Biosafety Protocol. A Party to the Protocol is obliged to communicate to the BCH when it approves a GMO in its country for domestic use.[37] The onus is therefore on the Party of import to track and locate particular approvals of GMOs for food, feed and processing via the BCH in order to come to a decision on how to deal with shipments from specific countries. This is an ominous task for African countries that have little by way of the requisite capacity and resources to fulfil this task.

The Model Law recognises that strict controls are necessary in Africa, where genetically modified food is donated to African countries as food aid. The World Food Programme has admitted that it has since 1996 been delivering food aid that included genetically modified food products, without warning the recipient countries.[38] This food aid had been donated by the United States, the world's single largest donor of food aid. During the recent food crisis in Southern Africa, the US provided 60 per cent of the total emergency aid to the affected countries in the region. However, much of this 'in kind' aid comprised of genetically modified food, which the US insisted the affected countries must accept. Zambia, as has been well documented,[39] banned GMOs from entering its territory and other countries like Mozambique, Malawi and Zimbabwe requested that the genetically modified food be milled prior to it being distributed.

The Model Law, as was noted above, requires its AIA procedure including notification provisions to apply to this category of GMOs. It requires the prior informed consent of the importing country before the import is authorised, a risk assessment to be conducted, and the strict interpretation and application of the precautionary principle. However, this is not to say that the Model Law advocates that food aid as a whole is acceptable, even if the food donated is subject to safety regulations. The Model Law is alive to the complexities of the issues regarding the politics of food aid. These range from dependency on imports and concomitantly, the perpetuation of debt cycles, dislocation of local markets and its impact on local markets by undercutting local producers or produce, market reforms in the agricultural sector of recipient countries, the failure of good governance and so forth.

Hence, African countries currently receiving genetically modified food aid are doubly at risk. First from the risk posed by GMOs to human health, biodiversity and the environment and second, from the negative

[37] The Procedure dealing with the category of GMOs imported for direct use as food, feed and processing is set out in Article 11 of the Protocol.

[38] F Pearce 'UN is slipping modified food into aid' 19 September 2002 *New Scientist*.

[39] Zambia Bars Altered Corn from U.S. Associated Press Lusaka, Zambia, Aug. 17 2002.

socio-economic impacts that may derive from receiving the food aid itself. The Model Law will, however, go some way to addressing some of these risks. Over and above the strict application of the precautionary principle, approvals of genetically modified food aid (or any GMO for any other use for that matter) are not allowed in terms of the Model Law unless the recipient country makes a carefully considered decision that genetically modified food will:

(a) Benefit the country without causing any risk/significant risk to human health, biological diversity and the environment;
(b) Contribute to sustainable development;
(c) Not have adverse socio-economic impacts; and
(d) Accord with the ethical values and concerns of communities and not undermine community knowledge and technologies.[40]

In a separate Article, the Biosafety Protocol also gives special attention to socio-economic considerations. A Party under the Protocol, or under its domestic measures implementing the Protocol, is entitled to take into account socio-economic considerations arising from the impact of GMOs on the conservation of biological diversity, especially with regard to the value of biodiversity to indigenous and local communities.[41] However, since the Protocol does not yet provide any guidance regarding how socio-economic considerations should be approached in practise, the provisions of the Model Law fill this gap.

5 Public Participation and Access to Information

The Model Law provides for public participation and access to information as important and indispensable components of environmental governance. In doing so, it expressly takes into account Article 23 of the Protocol, which obliges Parties to consult the public in decision-making. Article 23 is based on Principle 10 of the Rio Declaration from the 1992 United Nations Conference on Development. Principle 10 articulates three pillars of public participation, namely: (1) the right to information of citizens, (2) their right to participate in environmental decisions which

[40] Article 6(8) of the Model Law.
[41] Article 26 of the Protocol.

affect them, and (3) their access to mechanisms to redress and justice when their rights are violated.[42]

The Model Law requires that the public be engaged in the decision-making process by way of a notice and comment procedure[43] and public consultations, at the discretion of the competent authority.[44] The Model Law gives the competent authority sufficient latitude to decide when the public should be invited to make comments; the only mandatory requirement is that the public be given sufficient notice in order to invoke meaningful public reaction.[45] The competent authority is also given enough room for manoeuvre to decide when and how public consultation should be affected. These provisions do not require that there be public consultation for every application concerning a GMO or its products. It is therefore not true, as alleged by Africabio, that the provisions governing public consultation of the Model Law are impractical to implement because public consultation is required for individual applications.[46]

The Model Law requires that the information the applicant furnishes when making application for approval, be made available to the public.[47] It must be noted that the Protocol does not specify what information Parties must make available to the public as this is left to the individual Parties to regulate. However, the Protocol does emphasise that public awareness and education should encompass access to information on GMOs that are **imported,** at the very least.[48] The Model Law does,

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[42] Principle 10 of the Rio Declaration provides that environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.

[43] Article 5(2) of the Model Law.

[44] Article 5(3) of the Model Law.

[45] Article 5(2) of the Model Law.

[46] Africabio's erroneous submission reads as follows 'Engaging public opinion on individual applications/transactions is impractical' Africabio Submission on the OAU Model Law on Biosafety. http://www.africabio.com/policies/Submission%20OAU%20Model%20Law%20on%20Biosafety%20by%20AfricaBio.htm (accessed 6 September 2004)

[47] Article 5(1) of the Model Law. The information the application is required to furnish is set out in Annex I of the Model Law as well as Article 4(3). This information is considered to be adequate as opposed to minimum information that any competent authority will require in order to make an informed decision as to whether an application should be allowed or rejected.

[48] Article 23(1)(b) of the Protocol.

however, limit the information that the public may have access to, where such information is deemed to be confidential.

Again, it is not true, as stated by Africabio, that the Model Law requires all information to be made available to the public.[49] The Model Law, clearly in accordance with the Protocol,[50] invites the applicant to consult with the competent authority in order for the applicant and the competent authority to reach mutual agreement as to which information should be excluded from the public domain, where such information is considered to be of a confidential nature.[51] However, as a necessary safeguard, the Model Law does give the competent authority discretionary powers to override considerations of confidentiality in favour of the public interest.[52] Additionally, the Model Law also excludes, as does the Protocol,[53] certain categories of information, which cannot be considered confidential.[54] It must also be noted, that confidential business and proprietary information are in any event protected by other international agreements and national legislation.

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[49] Africabio's erroneous submission reads as follows 'Requiring all information to be made available to the public (Art. 5) will stall all import/export transactions while awaiting public consultation.' Africabio Submission on the OAU Model Law on Biosafety http://www.africabio.com/policies/Submission%20OAU%20Model%20Law%20on%20Biosafety%20by%20AfricaBio.htm (accessed 22 September 2004)

[50] Article 21 of the Protocol requires the Party of import to permit the notifier to identify information submitted under the procedure of the Protocol or as required as part of the AIA procedure that it be treated as confidential, provided that justification shall be given for such requirement/protection.

[51] Article 12 of the Model Law implements several provisions of the Protocol dealing with confidential information: it sets out a procedure for the protection of confidential information; sets out a general obligation to protect confidential information where there is mutual agreement as to what constitutes confidential information as specifically set out in Article 21(1) of the Protocol and specifies categories of information that cannot be deemed to be confidential information.

[52] Article 12(3) of the Model Law.

[53] Article 21(6) of the Biosafety Protocol does not allow the following information to be considered confidential: (a) the name and address of the notifier; (b) a general description of the GMO; (c) a summary of the risk assessment of the effects on the conservation and sustainable use of biodiversity, taking also into account the risks to human health; and (d) any methods and plans for emergency response.

[54] Article 12(2) does not allow the following information to be confidential information: (a) description of the GMO or products, names and addresses of the applicant, purpose and location of the import, transit, contained use, release or placing on the market of the GMO or product; (b) methods or plans for monitoring the GMO or product and for emergency response; and (c) the evaluation of possible effects, in particular any pathogenic and/or ecologically disruptive effects. Additionally, Article 5(5) expressly requires that the public be given access to information on any GMO or product that has been granted or denied approval for any of the uses covered by the Model Law. This information is not considered to be confidential information as it is information that the notifier is in any event required to furnish when intending to export GMOs intended for direct introduction into the environment. See in this regard, Article 8(1) read with Annex I (m) of the Protocol.

6 Labeling and Traceability

A biosafety law is not complete without a comprehensive labelling and identification/traceability system.

Labelling is one tool in a comprehensive traceability system and has a dual function as it provides access to information and functions as a mechanism to manage risks. As an information tool, labelling upholds the consumer's right to know what he or she is purchasing or using. As a risk management tool, the information that labels can provide to end-users can refer to a GMO or GMO product's toxicity or environmental safety. Consequently, with this information, the end user can take appropriate steps to minimise or avoid the risks specified, for example, by following instructions on a label.

Traceability is the ability to track a GMO. The concept behind traceability is to create a system to ensure that information is available on the origin of a GMO as it moves from its point of manufacture or production to the end user. A traceability system will enable African governments to trace a GMO back to those responsible for the import and export, as well as those responsible for the GMO's original development. This is particularly important in the cases where an illegal import or release is suspected and where damage occurs from intentional and unintentional releases.

The Model Law sets out provisions on labelling and traceability, which African countries should use and build on.[55] However, experience in developing countries has shown that the process of establishing labelling and identification/traceability systems are often delayed or hamstrung for various reasons. These include vociferous opposition by the biotechnology companies and double standards on the part of food producers who label their products in Europe but refuse to do the same in developing countries.

7 Liability and Redress

Parties to the Biosafety Protocol are obliged in terms of Article 2(2) of the Protocol to ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a

[55] Article 11 of the Model Law.

manner that prevents or reduces the risks to biological diversity, taking also into account the risks to human health. Breach of these obligations will give rise to State liability. The general principle of international law is that States are under an obligation to protect within their own territory, the rights of other States to territorial integrity and inviobility.[56] Furthermore, States have a responsibility to ensure that private individuals do not cause harm to the environment, by exercising due diligence to prevent private individuals from causing harm, for e.g. taking measure to prevent harm from occurring.

During the negotiations of the Biosafety Protocol, developing countries argued strongly in favour of the establishment of an international liability and redress regime[57] for the resultant harm from GMOs to determine who should be responsible for such harm and how redress and compensation should be addressed. However, agreement could not be reached, and instead, a compromise was struck to include an enabling provision only. Article 27 provides requires the 'Conference of the Parties serving as the meeting of the Parties to this Protocol, shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for the damage resulting from the transboundary movement of living modified organisms, analysing and taking into account of ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.'

At the first meeting of the Conference of the Parties to the Biosafety Protocol (MOP1) in February 2004 in Kuala Lumpur, Malaysia, a working group of experts was established to begin negotiations for an international liability and redress regime. The working group will meet five times and propose international rules and procedures on liability and redress in a final report in 2007. In the interim, however, Parties to the Protocol may develop domestic liability and redress regimes or use existing civil law remedies. The Model Law captures extensively, the essential elements for a liability and redress regime, which should be incorporated into domestic biosafety legislation.[58] Additionally, the Model Law contains a critically important provision to ensure that those

[56] *Trail Smelter Arbitration* United Nations Reports of International Arbitral Awards vol.III, 1909-1982. This principle is also recognised and reiterated by the International Court of Justice (ICJ) in the *Corfu Channel* Case 1949 ICJ Rep.4.

[57] Following the precedent already set by the Oil Pollution Liability and Compensation Convention on Civil Liability for Oil Pollution Damage, 1969; the Basel Protocol on Liability and Compensation Resulting from the Transboundary Movement of Hazardous Wastes and their Disposal; the Convention on Civil Liability for Nuclear Damage etc.

[58] Article 14 of the Model Law.

responsible for environmental and other harm, will be required to provide adequate resources for redress. It requires that where approval is granted, the applicant must furnish evidence of insurance cover or some other adequate arrangements to meet its obligations under the law.[59]

8 Conclusion

African countries are urged to adopt the Model Law and subscribe to the common environmental standards and protective measures established by it. In doing so, African countries will demonstrate to its own citizens and the international community that it is committed to protecting Africa's people, environment and biodiversity. The Model Law has after all, been drafted by a group drawn from various countries in Africa. This grouping itself has comprised of scientists, regulators, lawyers, development specialists, researchers and policy makers who have been involved in biosafety issues pertaining to Africa, for a long period of time, including the negotiation of the Biosafety Protocol. The Model Law is therefore a piece of legislation drafted by Africans, for Africa, taking into account the unique circumstances of the continent. Its endorsement by the AU, lends substantial weight to its acceptance as a model for countries on the African continent to adapt and implement. Africa's biodiversity can only be protected from the risks posed by GMOs if Africa as whole, subscribes to common and uniform safety standards, based on the precautionary principle. Such unified legislation will also greatly assist Africa from being used by the powerful biotechnology industry as experimental and dumping grounds for its products.

[59] Article 6(7) of the Model Law.