International Environmental
Law Research Centre

THE DEVELOPMENT OF BIOSAFETY REGULATION IN AFRICA IN THE CONTEXT OF THE CARTAGENA PROTOCOL

LEGAL AND ADMINISTRATIVE ISSUES

Patricia Kameri-Mbote

Published in: 11/1 *Review of European Community and International Environmental Law* (2002), p. 62.

This paper can be downloaded in PDF format from IELRC's website at
http://www.ielrc.org/content/a0203.pdf

RECIEL 11 (1) 2002. ISSN 0962 8797

The Development of Biosafety Regulation in Africa in the Context of the Cartagena Protocol: Legal and Administrative Issues

Patricia Kameri-Mbote

INTRODUCTION

The coming into force of the Biosafety Protocol (the Protocol) charts out a new direction in the growth and development of modern biotechnology. It is a timely and vital development given that in a very short timeframe, transgenic croplands have increased rapidly from zero in 1995 to 39.9 million hectares in 1999. Adoption rates to these transgenic crops have increased more than 23 times between 1996 and 1999.[1] Most of these have taken place in the industrial countries of the USA, Canada and Australia, and the developing countries of Argentina, China, Mexico and South Africa.[2] This decade will witness many African countries adopting and commercializing transgenic crops. However, efforts to invest have to be guided by sound mechanisms for assessing risks and benefits. This is crucial to enable African governments to make informed choices and decisions.

The Protocol, an internationally binding legal instrument concluded by parties to the Convention on Biological Diversity (CBD), was the result of the work of the Ad Hoc Working Group on Biosafety, which was set up in 1995. The Protocol aims at comprehensively addressing concerns raised about biotechnology. These concerns include safe handling, use and transfer of living modified organisms (LMOs).[3] All parties to the Protocol are obligated to comply with its terms. However, the obligations set out in the Protocol do not fully align with the national needs and priorities of many African countries. The numerous areas of non-consensus within the Biosafety Working Group support the validity of this assertion.[4] The Protocol contains not only elements of compromise, but also provisions forced upon some parties, particularly African States.[5] However, most African States intend to implement the Protocol.[6] To provide a suitable framework for the implementation of the biosafety measures, parties are required to put in place relevant national legislation.[7] For LMOs intended for direct use as feed, food or processing, only developed countries are obligated to put in place domestic regulatory frameworks, while developing countries, including those with economies in transition, need only make decisions based on risk assessments within a predictable timeframe.[8] The challenge for African States is to put in place effective legal and administrative structures to implement the Protocol.

In this article, the objective is to investigate the basic requirements of the Protocol and to identify and propose specific legal and administrative mechanisms that need to be instituted at the national and international levels to ensure that parties, especially African countries, comply with their obligations. The article seeks to articulate the principles on which these mechanisms should be founded. Emphasis will be placed on effective strategies for implementing the Protocol and the roles that civil society can play to monitor and ensure compliance. Lastly, recommendations are presented that may help realize national needs and priorities in biotechnology and biosafety in Africa.

[1] J. Clive, 'Global Status of Commercialized Transgenic Crops', 21 *ISAAA Briefs* (2000), 1, at 3.

[2] Ibid.

[3] These concerns are captured in the preambular paragraphs and Article 1 of the Protocol.

[4] For a detailed analysis of the positions of the various interest groups comprising the Biosafety Working Group, see T.B.G. Egziabher, 'An Analysis of the Sixth Negotiation Session of the Biosafety Working Group, Cartagena, 14–23 February 1999', *Report for the Like-Minded Group* (March 1999) (draft paper on file with the author).

[5] It is worth noting that the negotiation process was characterized by arm-twisting and threats and lacked effective participation and transparency as reflected in the documents produced after the Sixth Negotiation Session of the Biosafety Working Group in Cartagena (see, for instance, ibid.).

[6] This is evident from the resounding response seen when the Protocol was opened for signature in Nairobi on 24 May 2000. At least 65 signatures were recorded in that day according to the UN. See IUCN, *Environmental Law Programme Newsletter* (January–April 2000), at 5.

[7] Protocol, Article 2(1).

[8] Ibid., Article 11. See R. Mackenzie, 'Cartagena Protocol on Biosafety: Overview', *Environmental Law Programme Newsletter*, n. 6 above, at 1. This article is available at <http://www.iucn.org/themes/law/index.html>.

© Blackwell Publishers Ltd. 2002, 108 Cowley Road, Oxford OX4 1JF, UK and 350 Main Street, Malden, MA 02148, USA.

OVERVIEW OF THE BIOSAFETY PROTOCOL

The CBD was put in place in 1992 with three main objectives: conservation of biodiversity, sustainable use of genetic resources, and fair and equitable sharing of the benefits arising from the use of the resources. Under Articles 8 and 19 of the CBD, parties are required to maintain, among other things, the means to regulate, control and manage risks associated with the use and release of LMOs resulting from biotechnology.[9] Based on these provisions, the management of environmental impacts on the conservation and sustainable use of biological diversity, including risk to human health, is a major concern of biosafety and the reason for being of the Protocol.

Article 19 of the CBD is the basis upon which negotiations for the Biosafety Protocol were initiated. Contrary to suggestions that the negotiation process of the Protocol started in 1996, Veit Koester, the person hailed as 'the father of the Protocol'[10] contends that the process began way back in 1991, at the promulgation of the CBD.[11] The advance informed agreement (AIA) procedure (which is central to the Protocol) is envisaged by the CBD at Article 19(3), which provides:

> The parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, *in particular, advance informed agreement*, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have effect on the conservation and sustainable use of biological diversity.[12]

The AIA procedure enables countries importing LMOs to undertake risk assessments for all initial shipments of LMOs into their countries.[13] This principle, coupled with the precautionary approach, allows countries to refuse importation of LMOs whose safety is uncertain due to insufficient scientific evidence. The backbone of the decision-making process is the undertaking of risk assessments. To facilitate this procedure, a clearing house mechanism is established under Article 20 of the Protocol, and capacity building provisions in Article 23 of the Protocol are incorporated, representing important requirements for the Protocol's implementation.

MAIN REQUIREMENTS OF THE PROTOCOL

The main requirements of the Protocol focus on risk assessment, risk management and risk communication, as set out in its Articles 7–9, 15 and 16. However, there are exemptions to these rules. The Protocol provides for the exemption of certain pharmaceuticals[14] from its scope, explicitly stating that this provision is 'without prejudice to the right of a party to subject all living modified organisms to risk assessment prior to the making of decisions on import'.[15] Along similar lines, Article 6 explicitly exempts LMOs in transit and those destined for contained use from the AIA procedure. Parties also are given leeway to regulate the transport of LMOs through their territory and to undertake risk assessments prior to making decisions on importing LMOs destined for contained use. This includes the right of the importing party to set standards for contained use within its jurisdiction[16] under which, for instance, Kenya and Zimbabwe (which are each experimenting with LMOs) have put in place standards for contained use.

Article 7 of the Protocol focuses on the application of the AIA procedure. Article 7(1) refers only to initial transboundary movements and not to subsequent movements of LMOs. This provision is also subject to the right of a party to require all LMO movements to undergo the AIA procedure.[17] However, Article 7 does provide exemptions for the importation of LMOs intended for use as food, feed or for processing without AIA procedures being followed.[18]

Under Article 8, the exporting party must notify (or require the exporter to notify) the importing party of the initial shipment of LMOs to be imported. The exporter is responsible for the accuracy of information in notification. To realize this goal, the exporting party is required to take necessary and appropriate legal measures to implement this obligation.[19]

Article 13 of the Protocol provides for a simplified procedure of notification of imports of LMOs. This

[9] CBD, Articles 8(g) and 19.
[10] See R. MacKenzie, n. 8 above, at 4.
[11] V. Koester, 'Excellence in the art of the possible', *Environmental Law Programme Newsletter*, n. 6 above, at 6.
[12] Emphasis added to highlight the relevance of the AIA principle on which the biosafety regime was to be founded.
[13] As discussed below, it is possible for a party to require that both first and subsequent imports of LMOs be subjected to the AIA procedure.
[14] The exemption covers the transboundary movement of LMOs, which are pharmaceuticals for humans and are regulated by other international regimes.
[15] Protocol, Article 5.
[16] Ibid., Article 6(2).
[17] Ibid., Article 7 read together with Articles 5 and 6.
[18] Special procedures of LMOs intended for use as food or feed, or for processing are made under Article 11 of the Cartagena Protocol. These simply require notification to parties through the biosafety clearing house. The end result is essentially to lay responsibility on importers to regulate and communicate that regulation to the party of export. For further details on this point see A. Cosbey and S. Burgiel, *The Cartagena Protocol on Biosafety: An Analysis of Results*, IISD Briefing Note (Winnipeg, 2000).
[19] Protocol, Articles 8(2) and 11(2).

© Blackwell Publishers Ltd. 2002.

simplified procedure allows States to export LMOs without a written permit, if the importing party consents. In effect, this system corrodes the AIA procedure as it alienates further opportunities to check accuracy of decisions. Article 10(3)(a) of the Protocol enjoins parties to inform exporters on how they intend to deal with subsequent imports. The time extension for decision making under the AIA procedure is fixed by the importing party.[20] Reasons for denial of import are required to be given by the would-have-been importing party.[21]

Article 12 of the Protocol allows exporters to request a review of decisions not to import LMOs. Importing parties must respond to this request within 90 days. Considering Africa's implementation in light of limitations in capacity, it will require great efficiency in the flow of information especially from a biosafety clearing house (BCH) to make informed decisions. The BCH is the mechanism set out by the Protocol to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs and, thus, to assist parties in implementing the Protocol. Article 19 of the Protocol on capacity building is designed to address some of these needs. National capacity building is one of the critical tools in implementing AIA procedures. Capacity building in the form of technical assistance and training, however, are not always forthcoming, despite the fact that such commitments are increasingly being included in international legal instruments. Articles 19 and 20 make provisions for technical assistance in the Protocol's implementation to developing countries. The Global Environment Facility has also put in place mechanisms to assist countries in meeting their obligations under the Protocol.

Article 15(3) of the Protocol provides that a party can require the exporter to carry out and bear the costs of a risk assessment. Given the fact that most African countries lack the capacity to undertake risk assessments, one can foresee situations whereby these countries are likely to rely on exporters' assessments. Three major issues arise from such scenarios. First, countries that rely on exporters to do the assessments will almost never develop their own capacities in that area. Second, the assessment may not be sound if the exporter (who has an interest in the assessment) not only selects but also pays the assessor. Third, handling liability and redress becomes problematic where the exporter's assessment is formed on the basis of the importing country.[22] Litigation could take place in the exporting country, inviting problems related to interpretation and undue pressure on weaker parties.

RECOMMENDATIONS ON THE LEGAL AND ADMINISTRATIVE MECHANISMS

Biosafety is about risk assessment and management. Consequently the framework and efficacy of biosafety laws and institutions will, to a great extent, depend on the capacity of countries to put in place mechanisms for risk assessment and management. Risk assessment can be defined as the identification of potential environmental adverse effects or hazards, and, when a hazard is identified, a determination of the probability of it occurring.[23] Article 16 of the Protocol stipulates that parties must establish appropriate domestic mechanisms to regulate, manage and control risks associated with LMOs. If a potential hazard or adverse effect is identified, measures must be taken to minimize or mitigate it. The ecological risks policy makers and regulators need to assess include the potential for the spread of traits such as herbicide resistance from genetically modified to unmodified plants (including weeds), the build up of resistance in insect populations, and the potential threat to biodiversity posed by widespread growth of monocultures of genetically modified crops.[24]

Risk management, on the other hand, refers to the methods applied to minimize potential hazards or adverse effects, which have been identified during a scientifically based risk assessment. Management actions should be based on, and be in proportion to, the results of the risk assessment. There are different ways of managing hazards or adverse effects identified in these assessments, including: confinement, restricted use, provision of guidance, technical support, and advice and record keeping.[25]

The basic requirements of the Protocol, as outlined above, include the AIA mechanism; the precautionary approach; risk assessment and management; and the clearing house mechanism. Although the Protocol only makes reference to the precautionary principle in its Preamble, textual analysis evinces incorporation of the principle throughout the Protocol.[26] The principle is

[20] Ibid., Article 10(3)(d).
[21] Ibid., Article 10(4).
[22] J. Mugabe, *From Cartagena to Nairobi: Towards an African Agenda on the Biosafety Protocol*, Background paper for panel discussion at the Fifth Conference of Parties to the Convention on Biological Diversity (Nairobi, 10 May 2000).
[23] Organization for Economic Cooperation and Development, *Safety Considerations for Biotechnology: Scale-up of Crop Plant*s (OECD, 1993).
[24] Ibid.
[25] Organization for Economic Cooperation and Development, *Recombinant DNA Safety Considerations: Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Technique* (OECD, 1986).
[26] See Protocol, Articles 12, 15 and 16.

© Blackwell Publishers Ltd. 2002.

operationalized through decision-making procedures which are based on sound science and rigorous risk assessment and management. The specific legal and administrative mechanisms that parties are required to institute are supposed to cover the related, but separate, fields of development, handling (including packaging and identification), transport, use, transfer and release of LMOs.[27]

It is anticipated that regulations on AIA, the precautionary principle, risk assessment and management, and capacity building will be incorporated into national legislation. The main objective of these legal and administrative mechanisms should be to ensure that the activities stated above are undertaken in such a safe manner that any adverse effects arising therefrom are reduced or prevented. The risks relate not only to biodiversity, but also to human health. All decisions should be based on risk assessments. The assessment of such risks should be done in accordance with sound science based on the available information.

To achieve the creation of the necessary institutional framework and mechanisms, both international and national actions are required. The following section sets out some of the legal and administrative regimes that need to be instituted at the international and national levels.

INTERNATIONAL LEVEL

The primary mechanism that must be created at the international level is the BCH. This is required under Article 20 of the Protocol. The establishment of this institution is the first major step towards compliance with the Protocol's obligations. The BCH is probably the most crucial component of the Protocol's machinery. It is critical to the effectiveness of other mechanisms because of its key role in information exchange. Measures need to be taken to operationalize the BCH, especially the component of its mandate on addressing the needs of developing countries. There is a need for effective institutions and people to make this mechanism work. This means mobilizing information and communication technologies to disseminate information.

The creation of the BCH may be used to enhance the emerging views on regional regulation through regional organizations. More specifically, the establishment of a regional BCH for Africa could promote international biosafety information-exchange mechanisms. The regional approach could be used to implement the Protocol's provisions on capacity building and co-operation through concrete measures on technology transfer, such as in the form of scientific and technical training. The strategy of a comprehensive and integral approach in Africa may be favourable because of its implications for the necessity to share and better use the limited capacities in the region. Such regional cooperation mechanisms in the field of biosafety have been effective mechanisms in a number of developing countries.[28]

The Secretariat of the Protocol also needs to be strengthened.[29] The modalities of operation for the Secretariat should be elaborated and the functioning of the BCH should be decided by the parties as a matter of priority. To make these regimes function effectively, it is equally important to establish modalities for enforcement mechanisms. The formulation of international rules and procedures on liability and redress is required under the Protocol to be completed by 2005.[30]

NATIONAL LEVELS

At the national levels, competent national authorities, national focal points and advisory groups (in the form of committees or commissions to serve as an oversight mechanism)[31] must be established to facilitate the implementation of the Protocol's obligations at national levels. There is a need to develop harmonized approaches to the risk assessment of products of modern biotechnology. National committees on biosafety need to publish expert reports on safety considerations, concepts and principles for risk assessment and information on field releases of transgenic crops and traditional crop-breeding practices. Safety considerations for genetically engineered organisms should include the issues relevant to human health, the environment and agriculture, which might be considered in a risk assessment.

The institutions that will need to be created will be essentially scientific bodies with the capacity to conduct risk assessments. They should be comprised of experts from government, private agencies and other institutions, which should work together in close association with competent national authorities in areas such as information dissemination. The problem of expenses could be solved partly through the levying of fees from applicants augmenting the resources available to the national institutions. In addition to undertaking

[27] Ibid., Article 2(2).

[28] O.R. Santos, 'Biosafety in Latin America and the Caribbean', *Environmental Law Programme Newsletter* (September–December 1999), at 17.

[29] The Secretariat also serves as the Secretariat to the Convention. See Protocol, Article 31.

[30] Ibid., Article 27.

[31] J. Richter *et al.* (eds), *Biotechnology for Crop Protection: Its Potential for Developing Countries* (German Foundation of International Development (DSE), 1998).

© Blackwell Publishers Ltd. 2002.

risk assessments and management, national bodies will need to provide systems by which countries provide AIA. They will administer requests for AIA, issue import and export permits, monitor compliance (through a compliance information system), and serve as points of contact and for liaison with the Secretariat. They will also perform other functions required by the Protocol, such as facilitating public awareness.

National legislation should authorize the established institutions to perform prescribed administrative functions required by the Protocol. A party may designate one institution to perform all the functions required,[32] which will provide the advantage of efficiently allocating the use of scarce resources with particular reference to financial constraints.[33] These institutions should be given legal authority and clear mandates in all aspects of biosafety, including authority for institutional collaboration.

National guidelines and/or regulations (including policies and strategies) should be put in place. These regulations ought to focus on building the capacities of the parties in risk assessment and management. Systems for environmental impact assessment and risk assessment should emphasize scientific, technical and infrastructure capacity. Such capacity would be enhanced through access to the latest technologies in those areas. For handling and transport, specific procedures could include rules on standards such as on labelling requirements and guidelines for contained use. This will be particularly important in respect of cases where the party of import is required to undertake proactive regulation. An example of such a case is Article 11 of the Protocol regarding the shipment of agricultural commodities. The legal measures should include intellectual property rights (IPR) policies. These ought to meet the standards preferred for foreign biotechnology transfers and investments. IPR policies should serve also to meet the confidentiality requirements of the Protocol.

On the whole, national legal and administrative regimes should be based on the precautionary principle, prior informed consent or advance informed agreement, public participation and consultation, access to information (without prejudice to the protection of confidential information), access to justice (through compliance, liability and compensation systems), and enforcement procedures and sanctions. The legal and administrative regimes may be built upon the existing mechanisms or based on new frameworks. The establishment of biosafety oversight capacity within existing regulatory structures would help strengthen those institutions. Information sharing, coordination and institutional synergy can achieve this oversight capacity. It is anticipated that most countries that lack any biosafety regulations will enact new legislation to create biosafety bodies within the administrative structures of government departments. These regimes must provide for effective enforcement mechanisms and provide means of action by any person to secure the enforcement of rights under the Protocol. This includes relaxing the requirements of *locus standi*, as well as recognizing interests such as community rights. The approach of the World Trade Organization (WTO) procedures[34] could also be used. The approach used by the WTO includes fair and equitable procedures not unnecessarily complicated or costly or entailing unreasonable timetables or unwarranted delays. Similar procedures could be adopted to apply to the implementation of the Protocol where necessary, such as under Article 25 on illegal transboundary movements. A case in point is the set of procedures and remedies that are made available both internally and at borders. These should include both provisional and final measures, and the availability of civil and criminal remedies (especially where there are wilful acts contravening biosafety obligations).

Financial and technical provisions, as well as procedures for information dissemination, often play a key role in facilitating compliance.[35] Information flows may be enhanced through imposition of such requirements as information exchanges by means of periodic reporting and joint management regimes and institutions. National biosafety authorities could be tasked with issuing policies, regulations and guidance that set out the regulatory parameters for information requirements. Included in the future regulations could also be procedural rights, such as access to information. Reporting requirements will obligate institutions to collect and transmit relevant information to the national focal point under strict and credible rules.

The calls for harmonization of biosafety regimes at the international level saw the formation of the African Regional Biosafety Focal Point in 1993 in Harare, Zimbabwe.[36] This focal point has had limited impact in developing regulations in the region, mainly because of financial constraints as well as the differing levels of economic development among African States.[37]

[32] Protocol, Article 19.1.
[33] See n. 22 above.

[34] See the enforcement measures under Part III of the TRIPs Agreement: Agreement on Trade-Related Aspects of Intellectual Property Rights, General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations (Marrakech, 15 April 1994), Annex 1C, reprinted in 33 *ILM* (1994), 1125.
[35] D. Hunter *et al.*, *International Environmental Law and Policy* (Foundation Press, 1998).
[36] African Regional Biosafety Meeting (Harare, Zimbabwe, July 1993).
[37] B.B. Keizire, *Agricultural Biotechnology and Food Security in Sub-Saharan Africa: Policy and Institutional Considerations*, Paper presented at Conference on Global and Dimensions of Food Security (University College, Cork, Ireland, 13–15 April 2000).

© Blackwell Publishers Ltd. 2002.

Establishing regional information centres and networks to promote awareness and to speed up information flows could alleviate this problem. Joint commissions could also be formed to formulate standards, plans and programmes to facilitate information flows. Indeed, the regional approach has already received an impetus from the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA), which is considering the need and modalities for a regional biosafety system.[38] It is hoped by ASARECA that such an approach would facilitate technology transfer, help attain market efficiencies and improve management of risks.

RECOMMENDATIONS ON THE ROLE OF CIVIL SOCIETY

Article 23 of the Protocol focuses on public awareness and participation. The Protocol calls upon parties to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs.[39] While a number of countries in Africa have put in place biosafety guidelines and frameworks, these do not articulate explicitly the issue of dissemination of information regarding biotechnology risks and benefits. For instance, Egypt has one of the most advanced biosafety systems on the continent, but it has yet to develop an official information strategy for informing the public about LMOs and biosafety.[40] Mechanisms of information gathering and information exchange, including access to databases and knowledge of global developments, are also scant.

The rapid pace of technological change and the wide-ranging nature of the perceived effects of biotechnology necessitate much greater public participation. The public controls the fate of biotechnology in its willingness or refusal to accept products produced through genetic engineering – thus it is essential to inform the public about all aspects of biotechnology. Unless efforts are put in place by parties to the Protocol to build public awareness, public opinion is likely to be misguided and misinformed from other sources.[41] Civic education and participatory bottom-up mechanisms should be developed to solicit views and input from the public at all levels before adoption or release of LMOs. A number of industrialized countries have launched programmes aimed at including the public in technology assessment and decisions involving the use and application of modern biotechnology. Besides disseminating scientific information, effective public participation also aims at minimizing scepticism and building trust between science and the end-users of products of science. Intermediary non-government organizations (NGOs) and institutions concerned with the social aspects of biotechnology can play a vital role in building such trust. However, efforts to disclose information may be limited by the proprietary and confidentiality nature of some information.[42]

Public knowledge and participation are vital to ensure that biotechnology and biosafety policies do not conflict with religious and cultural beliefs in society. The public can only make informed decisions if it is well equipped with information. Participation should be an important part of the risk/safety assessment process. Specific measures should be taken to inform the public when applications are received, what they are and their intended use. There should be the possibility for members of the public to comment at different stages in the process. In order to ensure transparency, countries should publish the outcome of the risk/safety assessments, together with documents describing regulatory decisions. For many years journals have been used to disseminate such information, but modern communication technologies, such as the Internet and email, have revolutionized the rate at which information is being exchanged and experiences shared. These media should be used. Another way of enhancing public access to information is to organize workshops, symposia, seminars and other forms of dialogue among the scientific and civic community on specific biosafety themes, making full use of the existing scientific and technological expertise in each country to facilitate it.

New or revised laws should make provision for public access to information with regard to the release and commercialization of LMOs. There is also a need to create advisory bodies for LMOs, which should include all stakeholders, representatives of science and technology institutions, national academies of sciences, industry, and representatives of public interest groups concerned with protection of public health and the environment. It is also important for scientists to strive to raise awareness among decision makers. Parties to the Protocol and stakeholders such as the African Biotechnology Stakeholders Forum (an organization based in Kenya that serves as a forum for discussions and information exchange on biotechnology

[38] J.I. Cohen, *Background Report Submitted to the Human Development Office for the 2001 Human Development Report. Channelling Technology for Human Development* (unpublished, 2000).
[39] Protocol, Article 23(1).
[40] M.A. Madkour *et al.*, *Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt*, ISNAR Country Report 62 (Agricultural Genetic Engineering Research Institute (AGERI) and International Service for National Agricultural Research (ISNAR), 2000).
[41] See n. 38 above.
[42] C. Juma and A. Gupta, *Biotechnology for Developing Country Agriculture: Problems and Opportunities* (International Food Policy Research Institute, October 1999).

© Blackwell Publishers Ltd. 2002.

and biosafety issues) should organize public awareness courses for civil servants and regional authorities to exchange information with the media and to disseminate professional information to government bodies and legislators. Commissions can also be established to design systems of public information concerning LMOs with the aim of managing public perception of risks associated with biotechnology.

Civil society plays a crucial role in monitoring and ensuring compliance with legal obligations. International, regional and national NGOs, as well as the private sector, were instrumental not only in the conception of the ideas of a biosafety protocol,[43] but also in the negotiation process. Recently, the presence of these groups in the implementation process has been and continues to be noticeably more enthusiastic than before. The relevant legal and administrative regimes (national policies and legislation) should provide for effective participation of NGOs. The most appropriate forum would be achieved by linking all the concerned interest groups in inclusive consultative processes.

As indicated above, capacity building (especially in developing countries) is one of the most important issues in the implementation of the Protocol. In this respect, it is undoubtedly clear that governments cannot afford to proceed alone. The complementary efforts of civil society are indispensable. The Protocol provides for transparency in application of the decision-making procedures.[44] Civil society can play a great role here by keeping checks and balances on the relevant authorities. Transparency also implies participation. Their perspective should be seen to be supportive of the precautionary principle and its corollary scientific basis of decision making.

In line with their roles in the negotiation process, NGOs will be relied upon by decision makers for them to gain access to a wide range of legal and scientific expertise. Equally, the strength of NGOs can be seen in the creation of opportunities for public awareness. Due to the diversity of interests that NGOs represent, governments should tap that potential by working closely with civil society to ensure meaningful participation by NGOs. African States should not adopt restrictive approaches, as done in a country like China, where the biosafety policies are shielded against local and international political challenges. Civil society will have to continue guarding against technocratic abuse by increasing awareness, raising State concern through pressure, information generation, monitoring, compliance, and fostering technology transfer.

NATIONAL ATTEMPTS AT LEGAL AND INSTITUTIONAL ARRANGEMENTS FOR BIOSAFETY

Many countries in Africa have either put in place or are in the process of putting in place biosafety policies and laws to comply with the requirements of the Protocol. For instance, under their science and technology institutions, countries like Kenya and Uganda have managed to develop biosafety guidelines and policies. What is pending is the putting into force of legislation concerning existing policies. Enforcement of guidelines and policies is impossible without appropriate laws. With the exceptions of Zimbabwe[45] and South Africa,[46] none of the African countries has managed to put in place a biosafety law. Outside of Zimbabwe and South Africa, framework legislation on biosafety is lacking and most countries depend on science and technology laws and policies for overall guidance.

The implementation and coordination of biotechnology and biosafety activities is also being conducted under national science and technology institutions. However, it is only Zimbabwe that has managed to establish an autonomous body – the Biosafety Board.[47] Apart from formulating detailed biosafety guidelines and standards, the Board also gives technical advise on the release and management of LMOs. In other countries, laws that can be used to regulate LMOs are scattered across numerous pieces of legislation relating to environmental protection, natural resources management, food and drugs, industrial development and agriculture. In order to address biosafety concerns adequately, such laws should be revised and harmonized.

What is also lacking is the capacity to handle various aspects of biosafety such as risk assessment and management. For example, in Uganda, there is a shortage of trained manpower in biosafety.[48] A critical mass of molecular biology and risk assessment scientists is

[43] This was mainly achieved through civil society's work on conservation of biodiversity, sustainable use of genetic resources, and fair and equitable benefit sharing in the 1980s.
[44] Protocol, Article 10.

[45] Government of Zimbabwe, Research (Biosafety) Regulations (Statutory Instrument No. 20/2000).
[46] Republic of South Africa, Genetically Modified Organisms Act, *Government Gazette* (1997).
[47] I. Sithole-Niang and J. Mugwagwa, *Agricultural Biotechnology Assessment in Sub-Saharan Africa: Country Specific Study – Zimbabwe*, draft Study commissioned by the African Centre for Technology Studies (2001) (on file with the author).
[48] B.B. Keizire *et al.*, *Agricultural Biotechnology Assessment in Sub-Saharan Africa, Country Specific Study – Uganda*, draft Study commissioned by the African Centre for Technology Studies (2001).

© Blackwell Publishers Ltd. 2002.

lacking throughout Africa. To alleviate this problem, efforts to put in place biosafety laws should be accompanied by corresponding capacity-building initiatives to enforce national regulations. Capacity for implementation should be considered in the wider context of availability of human capital, financial resources, and existing institutional and infrastructure capabilities. In many of the African countries at infancy stages of biotechnology development, such capacities and resources are either completely missing or inadequate. Resources such as more facilities and equipment to carry out proper monitoring and risk assessments are crucial if capacity building is to be enhanced. African countries that are signatories to the CBD should be assisted by the wider international community and counterparts in the developed world in order to formulate and implement national biosafety frameworks. African countries should also be assisted in establishing mechanisms and procedures for safe contained uses and releases into the environment of genetically modified organisms (GMOs). This requires both financial and technical support.

Most African countries lack advanced scientific expertise regarding biotechnology, although the situation is improving steadily. The larger problem is the harnessing of this expertise and the strengthening of institutional structures so that they are suitable for the implementation of a comprehensive policy regime. Indeed the consideration of biotechnology apart from biosafety has limited African attempts at building biosafety capacity.

Article 7 of the Protocol exempts from the AIA procedure any LMOs that are commodities. Generally these commodities are LMOs intended for use as food, feed or for processing. The critical question is whether national laws can deviate from this exemption. The main argument by the countries opposed to the coverage of commodities by the AIA provisions was that it would be impossible to apply the AIA procedures to large quantities of traded commodities.[49] Indeed, most developing countries may not have the capacity to subject such massive volumes of commodities to AIA procedures. Yet, in the spirit of the Protocol, that capacity limitation should not subordinate safety interests to trade pursuits. The other ground of opposition was the argument by the Miami Group (Chile, Argentina, Canada, the USA and Uruguay) that the agricultural commodities are not intended for introduction into the environment and thus pose no threat to biodiversity.[50] African countries have opposed this position all along and have maintained that it is very difficult to prevent the escape of such commodities into the natural environment.[51] Some countries have adopted biosafety policies that are not supportive of the broader considerations of issues such as public health and environmental consequences. The precautionary principle has been applied to a large extent to ban LMOs without due consideration of the benefits that would necessarily be foregone.[52] For a number of years Kenya's policies were designed to prevent dealings in all GMOs. The 1998 biosafety guidelines introduced a permissive approach, although precautionary overtones can be found in most of the provisions, as is evident from the discussion below.[53]

COUNTRY-SPECIFIC EXAMPLES IN AFRICA

Most countries in Africa legislating for safety in biotechnology have sought to institute mechanisms for risk assessment and management from the point of entry through laboratory and field trials. This section highlights the approaches that a number of countries in different parts of Africa have adopted.

Egypt Egypt's biosafety regulations and guidelines were published in draft form in January 1994.[54] One of the key features under this system is its procedure for field tests. These procedures require an advance import permit for importation of genetically engineered material. The permit is obtained from the Supreme Committee for Food Safety established under the Ministry of Health. This permit is then presented to the National Biosafety Committee (NBC). The request for such a permit is supposed to be made at least 8 weeks before the proposed initiation of importation. Several assessments are made before a decision on whether to issue or deny the requested permit is taken.

The Egyptian regulations and guidelines have no explicit provisions for access to information and public participation. There is, however, recognition in the introductory part of the Guidelines of the need for public acceptance. Section 1.2 of the Guidelines, which lists the membership to the NBC, makes provision for inclusion of non-technical members to represent the interests of the surrounding community with respect to health and protection of the environment. The main

[49] See n. 22 above.
[50] See R. MacKenzie, n. 8 above.
[51] See n. 22 above and n. 4 above.

[52] I.M. Goklany, *Applying the Precautionary Principle to Genetically Modified Crops* (Policy Study No. 157, Center for the Study of American Business, 2000).
[53] Republic of Kenya, *Regulations and Guidelines for Biosafety in Biotechnology for Kenya* (National Council for Science and Technology (NCST), 1998).
[54] Government of Egypt, Ministry of Agriculture and Land Reclamation, Ministerial Decree No. 85/1995, established the National Biosafety Committee, while Ministerial Decree No. 136/1995 adopted the Biosafety Regulations and Guidelines.

© Blackwell Publishers Ltd. 2002.

problems in Egypt regarding biosafety include low consumer awareness and lack of information. The regulations are also very general in nature and there is a recognized need for details on principles, goals and objectives, basis for review and decision making, and post-trial follow-up activities.[55]

Kenya The National Council for Science and Technology (NCST) of Kenya was designated by the Government to lead the implementation of biosafety measures in the country. In 1998, *Regulations and Guidelines for Biosafety in Biotechnology for Kenya* were published by the NCST.[56] These guidelines require that the release of LMOs be preceded by approval by the National Biosafety Committee (NBC). The authorities are supposed to undertake risk assessments before making the decision to approve or deny approval of the import. In order to do so, they should be provided with enabling information, such as a description of the LMOs and their intended uses in Kenya.[57] The guidelines provide that it is an offence to import LMOs without prior approval of the NBC. Penalties for offences under the biosafety regulations were left to be made by the Minister. To do this the Minister requires the powers to be conferred upon him by an Act of Parliament. To date, this has not been done, although there are some prescribed penalties in draft form under the proposed National Biosafety Bill.[58]

The Proposed Kenya Legal Framework for Safety in Biotechnology forms the basis of the National Biosafety Act.[59] Under the proposed framework, an exporter of LMOs or related products is required to provide to the NCST a written AIA of the competent authority of the importing country.[60] The exporter is also required to comply with other regulations on foreign trade in LMOs. Before approving the export, the importing country is empowered to consider other relevant concerns it may have. Significantly, the provisions of the proposed regime preclude the export of LMOs or their products that have been banned under the laws of the country of export. In practice, the NBC in Kenya applies relatively high standards in screening GMOs and is slow in approving imports of GMOs and related products.[61]

The biosafety framework law makes no provision for access to information and public participation. Given that Kenya does not have access to information legislation, the country's basis for implementation of the Protocol's provision on public awareness and participation is weak. Further, the failure to promulgate the framework into a binding legal instrument relegates it to a non-binding status. It is difficult to say with certainty when the regulations will be passed. However, it is encouraging to note that the NBC has been considering applications for LMO work on the basis of the draft framework. One of the greatest constraints to an effective biotechnology framework in Kenya is the dearth of human resource capacities to expeditiously handle applications coming before the NBC, especially in view of the fact that the applicants are in many instances members of the NBC.

Cameroon Cameroon requires the importation of LMOs to be preceded by an AIA. Under the draft Bill for Regulating Safety in Modern Biotechnology in Cameroon, the user, namely:

> any person(s), institution(s) or organization(s) (including companies) responsible for the production, testing, marketing and distribution of organisms with novel traits,

should notify the National Biosafety Authority (NABA) in writing of the intention to import, and is responsible for the accuracy of the information provided.[62] Article 44 of the draft Bill states that:

> [i]mportation or exportation of all genetically modified organisms must receive the prior informed consent or the advanced informed agreement of the NABA, in collaboration with the competent administration(s).

This draft law does not distinguish between LMOs that are commodities from other LMOs. The Protocol envisages that domestic legislation distinguishes between these commodities. This bold step taken by the Cameroon Government can be seen as an attempt to respond to the loopholes in the Protocol that may be used for the importation of LMOs without the AIA.

The biosafety measures in Cameroon incorporate the Protocol's requirement that the country of import indicate how it intends to deal with subsequent imports. Article 45 of the draft Bill requires the NABA

[55] See n. 40 above, at 27–28.

[56] Republic of Kenya, *Regulations and Guidelines for Biosafety in Biotechnology for Kenya* (National Council for Science and Technology (NCST), 1998).

[57] See, for instance, ibid., at Annex F.

[58] It seems that the proposed penalties may not achieve the desired goals as they are relatively lenient. For example, a person who imports LMOs without the AIA of the country of import may only be liable to a fine not exceeding 50,000 Kenyan shillings, approximately US$650 (see NCST, *Pilot Biosafety Enabling Activity Project: Kenya Biosafety Framework* (United Nations Environment Programme/Global Environmental Facility, 1999), at clause 15). In such circumstances, one may find it more convenient to commit the offence and pay the fine.

[59] The legislation is yet to be passed by Parliament into law.

[60] See n. 58 above, at clause 13.

[61] R.L. Paarlberg, *Governing the GM Crop Revolution: Policy Choices for Developing Countries*, Food, Agriculture and the Environment Discussion Paper No. 33 (International Food Policy Research Institute, December 2000).

[62] Republic of Cameroon, draft Bill for Regulating Safety in Modern Biotechnology in Cameroon 1999, at Articles 40 and 41.

© Blackwell Publishers Ltd. 2002.

to respond within 90 days of receipt of notification showing, *inter alia*, how its decision affects subsequent imports or exports of the same LMOs. It may request additional information or extend the notification by 60 days in order to arrive at a more informed decision. Failure to grant an AIA within that timeframe will constitute a refusal. There are no explicit provisions on access to information or public participation in the draft bill.

Zimbabwe Zimbabwe passed its Research (Biosafety) Regulations 2000, under section 32 of its Research Act.[63] Section 4 of the Regulations empowers the Research Council of Zimbabwe to establish a 'Biosafety Board'. The Board has since been established and is functional.[64] The biodiversity focal point is the Ministry of Mines, Environment and Tourism. There are also considerations for setting up a biosafety clearing house within this Ministry.[65] Functions of the Board include approving safety aspects of imports of LMOs and advising customs authorities on imports.[66] The Board and the Research Council, acting in consultation, are charged with the obligation of issuing biosafety guidelines or standards in respect of such matters as the requirements and procedures for the import and export of LMOs.[67] Such guidelines, regulations and procedures are already in place and offer an adequate legal framework. The main problem seems to be lack of capacity for enforcing the regulations.[68] It is also noteworthy that the regulations make no provision for access to information or public participation.

Uganda The search for an appropriate legal framework for the regulation of biosafety matters is still underway in Uganda. Currently there is a draft Uganda Biosafety Framework that is being discussed by the Uganda National Council for Science and Technology. This proposed biosafety framework is geared towards defining the scope within which institutions engaged in biotechnology may operate, and to enhance coherence in the institutional, administrative, policy and regulatory regimes. The framework envisages the creation of institutional biosafety committees at all centres involved in biotechnology research and development activities.[69]

Uganda vests the administrative and implementation responsibilities for biotechnology in several institutions. The three key bodies with varying mandates for biotechnology are the Uganda National Council for Science and Technology, the National Biosafety Committee and the National Agricultural Research Organization. The Uganda National Council for Science and Technology Statute 1990 vests the Council with powers for formulating science and technology policy including biotechnology.[70] Pursuant to this mandate, the Council has developed the draft National Biosafety Regulations.[71] These draft regulations state that the Government is to establish a competent authority that will, *inter alia*, make decisions on the importation of LMOs.[72] Under Article 4, no importation of GMOs shall be made without prior approval of the competent authority. An importer is required to apply in writing to the authority giving the information required under the regulation's procedures. This information includes risk assessment reports. There are no explicit provisions on access to information or public participation. The implementation of the regulations is dependent on human resource capacity, which has been noted to be inadequate.[73]

South Africa South Africa enacted the Genetically Modified Organisms Act in 1997.[74] The Act provides for measures to ensure that all activities involving the importation or use of GMOs are carried out in a manner that limits adverse impacts to the environment.[75] It requires any importation of GMOs to be preceded by an application for a permit.[76] The Registrar of the Council of GMOs issues the permit.[77] There is an Advisory Committee that advises on such matters as the import and export of GMOs.[78] The GMO regulations[79] provide that an applicant shall notify the public of any proposed release of GMOs prior to the application for a permit for such release. Public notifications shall be in the form of a standard notice published in the printed media informing the public of the intended release.[80]

Mauritius With the assistance of United Nations Environment Programme, Mauritius has finalized its National Biosafety Framework Guidelines for consideration by the legislative authority.[81] It is worth noting

[63] See n. 45 above.
[64] See n. 47 above, at 19.
[65] Ibid.
[66] See n. 45 above, at section 5(3)(l)–(n).
[67] Ibid., section 9(2)(k).
[68] See n. 47 above, at 20.
[69] Z.M. Nyiira, *et al.*, *Uganda Biosafety Framework* (Uganda National Council for Science and Technology (UNCST), 2000).
[70] Government of Uganda, 1990, Uganda National Council for Science and Technology Statute (Statute No. 1).
[71] See n. 69 above.
[72] Ibid., Article 3.
[73] See n. 48 above, at 20.
[74] See n. 46 above.
[75] Ibid., Preamble.
[76] Ibid., Article 5.
[77] Ibid., Article 9.
[78] See, for instance, ibid., Article 11(1)(a)(iv).
[79] Government of South Africa, GMO Regulations No. 1420 of 26 November 1999, section 6(1). These regulations were made under section 20 of the Genetically Modified Organisms Act (see n. 46 above).
[80] GMO Regulations No. 1420, ibid., section 6(2).
[81] Government of Mauritius, *Pilot Biosafety Enabling Activity Project: National Biosafety Guidelines for the Safe Development and Introduction of Genetically Modified Organisms in Mauritius* (United Nations Environment Programme/Global Environmental Facility, 1999).

© Blackwell Publishers Ltd. 2002.

that this framework was prepared prior to the completion of the negotiations on the Protocol. Consequently, a number of important issues need to be incorporated into the framework to bring it in line with the Protocol.

The guidelines were set up by the National Committee for Biosafety Regulation (NCBR). The NCBR is responsible for issuing permits for working with LMOs. With regard to AIAs, the guidelines require an applicant to allow for adequate time for risk assessment of the application by the NCBR. However, no guidance on time is given as envisaged by the Protocol.[82] All imports are to be preceded by an import permit. In this regard, Mauritius adopts the normal process favoured by most countries (as opposed to the simplified procedure in Article 13 of the Protocol). The exporter of LMOs is made responsible for notifying the importing party.

Adequate provision is made for confidentiality, including requirements for the elimination of conflicts of interest[83] and the establishment of confidentiality agreements. The signing of confidentiality agreements is important. However, the guidelines impose no duty on the applicant to justify confidentiality (which requirement is optional under the Protocol, but is mandatory in most national frameworks in Africa). Given the central role of information in achieving the goals of the Protocol, measures should be put in place to prevent the abuse of this exception by applicants or other related practices that unreasonably hinder information flows.

The guidelines require the importer to bear the costs of review. Although this is in line with the Protocol, it may be necessary to explore ways of promoting the role of small-scale and emergent local industries in biotechnology, for instance through fee waivers. Another noteworthy measure in Mauritius regards the need for creating public awareness. The guidelines make it an obligation for the applicant to publish press releases in local papers on any applications made. This innovative approach can be enhanced by making the press releases user friendly, and by publishing them in languages understood in the area where the desired activity is due to take place.

The proposed framework for Mauritius, unlike most other regulations in the region, introduces detailed guidance in many areas of biosafety, including risk assessment and risk management. However, the guidelines do not provide for consideration of such factors as the risks that would arise from refusal to grant a permit (such as implications on acquisition and adaptation of technology). Specific details are also given on the handling of GMOs.

EXPERIENCES IN AFRICA GENERALLY

The manner in which national laws respond to the need to close the loopholes in the Protocol varies. Most biosafety regulations in Africa require rigorous procedures for all LMOs without distinguishing case-by-case characteristics. This approach to regulate more strictly, and even to extend regulations to cover exempted activities, requires further research to determine the most appropriate policy stances to be adopted by developing countries.

In virtually all the countries reviewed here, the existing pieces of legislation on biosafety were enacted prior to the promulgation of the Protocol. They were intended to bring into effect the requirements of the CBD. Thus, although many national regulations address most of the requirements of biosafety, there are gaps that reduce the effectiveness of those regimes. The science and technology policies developed so far are seldom in accordance with the changing context of technological developments. A notable weakness of the current legal frameworks is the inadequate legal mandate given to institutions to effectively deal with biosafety issues in an integrated approach. Most of the laws are still in draft form and lack details on the execution of the regulations. Also lacking is the promotion of private sector capabilities as anticipated in Article 22(1) of the Protocol.

There is a need to harmonize national regulations in order to realize the goals of international data collection and information exchange.[84] This will aid in facilitating uniform interpretation as well as easing the burden of compliance across borders. The procedures for registration and approval of applications should provide for distinctions between containment and release, and research and production, among others. Research and contained use would then require less rigorous procedures.[85] Now that the Protocol is in place, it behoves the parties to revisit the current regulations with a view to aligning the national laws with the requirements of the Protocol as outlined above. Regulatory agencies will also have to reduce regulatory costs especially for emerging and small-scale groups, for instance by making flexible data requirements, fee waivers and legal assistance to comply with regulatory systems.[86]

[82] See Protocol, Article 10, which gives decision-making timelines of 90 days, 270 days and the possibility of extensions to be specifically defined.

[83] Given the limited number of experts in Mauritius and most other African countries, one can foresee a situation where applications are reviewed by persons with some form of remote interest in the application. A case in point is where a country has its experts in the academic institutions actively engaged in private industry ventures.

[84] See n. 31 above.

[85] Ibid.

[86] See n. 38 above.

© Blackwell Publishers Ltd. 2002.

CONCLUSIONS AND RECOMMENDATIONS

The central operative mechanism of the Protocol is the AIA procedure. By virtue of this tool, parties have a right of access to information from the exporter of LMOs. Whether Africa benefits from implementation of the biosafety measures largely depends on national institutional capabilities. As African countries continue the search for national regulatory mechanisms appropriate to their needs, it has become clear that neither the Protocol nor the national frameworks alone will facilitate the achievement of the goals of safe development of biotechnology.[87]

Capacity in African countries to implement biosafety regulations must be built. This will include putting in place procedures and institutions for management of compliance problems as well as means to enable States to comply with obligations. Studies indicate that non-compliance in the environmental arena is primarily due to lack of institutional capacity, and only secondarily due to bad faith.[88] It is instructive to note that while the Protocol was being negotiated, negotiators from many developed countries made promises to facilitate capacity building in order to break the deadlock in the negotiation process. The main problem encountered by developing countries, especially those from Africa, was that capacity building would not be a panacea for the deficiencies of the Protocol. Indeed it was pointed out that the developed world is not committed to capacity building, as evidenced by the lack of materialization of the promises made at Rio de Janeiro in 1992.[89] African countries can cooperate by, among other things, compelling developed country parties to implement the promises recognized in the Protocol on special and differential treatment, particularly on technical and financial assistance and capacity building. However, in pursuing these obligations, Africa must guard against unreasonable financial and political duress from the North.

Capacity-building initiatives will need to be focused on four principal areas: allocation of financial and human resources; access to information; technical assistance and training; and incentives and inducements.[90] It should involve technology transfer, development of relevant facilities, and training in the use of scientific techniques of risk assessment and management.[91] AIA procedures can only be meaningful if an effective system of information flows is put in place. Institutional structures, such as national biosafety committees and biosafety clearing houses, should be constituted from the scientific community, as most of the implementation of biosafety regulations is to be based on sound scientific principles. There is also a need for expertise in these structures to facilitate consistent and expeditious implementation of regulatory instruments. Risk assessment and management should be strengthened in national legislation, regulation and institutions.

African States must ensure that their national laws have high standards. However, this does not mean that countries should establish rigid regimes to implement the Protocol. Such measures could be anti-biotechnology in nature and tantamount to voluntary exclusion from the mainstream of biotechnological development. The pathway of reasonable flexibility appears to be the best approach to national regimes regarding the issue of AIA.[92] Under such an approach to LMOs, the sort of caution adopted would operate within a fairly permissive policy framework. Independent national or regional scientific capacity systems in LMO-related matters will go a long way in shaping the potential of the GMO revolution used to address local needs and the requirements for sustainable development. The bottom line must remain the protection of the environment and human health, and the promotion of biotechnology research and development.

Dr Patricia Kameri-Mbote is a law researcher and teacher based in Nairobi. She studied law in Nairobi, Warwick, Zimbabwe and Stanford, and currently teaches intellectual property rights law at the University of Nairobi. She is research director at the African Centre for Technology Studies in Nairobi. She has also taught international environmental law at the University of Kansas.

[87] I. Virgin and R.J. Frederick (eds), *Biosafety Capacity Building: Evaluation Criteria Development* (Stockholm Environment Institute, 1996).
[88] See n. 35 above.
[89] See n. 4 above.
[90] T. Yongo, 'Towards implementation of the Biosafety Protocol', *Environmental Law Programme Newsletter*, n. 6 above, at 12.
[91] L.M. Oda *et al., Global Biotechnology Risk Assessment Regimes: Biotechnology Research and Development in Latin America*, United Nations Environment Programme draft study (United Nations Environment Programme, 2000).
[92] See n. 22 above.

© Blackwell Publishers Ltd. 2002.