Biosafety Scoping Study

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The Centre for International Sustainable Development Law (CISDL) is based in the McGill University Faculty of Law. Its mission is to promote sustainable societies and the protection of ecosystems by advancing the understanding, development and implementation of international sustainable development law. CISDL works in cooperation with the McGill School of the Environment, the Université de Montreal Faculty of Law, and the Université de Québec à Montreal. It has guidance from the three Montreal-based multilateral environmental accords (the NAFTA Commission for Environmental Cooperation, the UNEP Biodiversity Convention, and the Montreal Protocol multilateral fund), and is currently involved in two international research projects related to sustainable biodiversity law. CISDL is developing materials and capacity building support for the development of regulatory frameworks for the regional and domestic implementation of the new Cartagena Protocol on Biosafety. CISDL is also developing a research project on the benefits of an international regime on access to genetic resources and benefit sharing for local communities, in collaboration with partners in developing countries.

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I Executive Summary

This scoping study examines the current context for biosafety and how this has been applied in the development of new national biosafety regulatory regimes. The field of biosafety arose from the development of modern biotechnology – practices such as cloning and recombinant DNA technology. Initially, both biotechnology and biosafety were largely the domain of developed countries but when negotiations on the Convention on Biological Diversity (CBD) began in the late 1980s, developing countries insisted that biotechnology be one of the key issues addressed. They were successful and Article 19 of the Convention contains provisions on biotechnology.

The Parties to the CBD subsequently agreed to negotiate a protocol to the Convention specifically addressing the issue of biosafety. The negotiations of the Protocol were rocky and nearly failed but agreement was finally reached on the Cartagena Protocol on Biosafety in 2000 and the Protocol entered into force in September 2003. Much work remains both to elaborate the provisions of the Protocol and to implement its requirements.

The Cartagena Protocol is not the final word on biosafety. Its scope is limited and other international agreements, particularly the WTO’s Agreement on the Application of Sanitary and Phytosanitary Measures, also include relevant rules. Whether these different agreements can be implemented in accordance with the rules of the others remains unclear. And ultimately, individuals are generally not interested in the content of the legal rules but have much more pragmatic questions and concerns about the health and safety of GM products and processes. These are the sorts of questions both the international and national biosafety regimes are trying to answer but more clear and consistent information is needed to meet this goal.

In conducting the scoping study, CISDL consulted with a range of different actors on biosafety research needs. The resulting series of questions falls into five categories: national and international biosafety governance; social and economic issues; biotechnology questions; technical questions of compliance; and sustainable development and the Biosafety Protocol.

The study concludes with three recommendations:
1. There is a need for developing countries to implement solid biosafety regulatory regimes now, in accordance with their specific concerns and priorities, and with regional and international support.
2. There is a need for significant support to focused, multidisciplinary biosafety research, capacity building and development in developing countries, paying equal attention to the regulatory and scientific aspects.
3. It is time for all actors in developing country governments, scientific communities, legal communities and civil society to start “acting” rather than “expecting”.

Attached to the scoping study are four appendices: a regulatory story on the drafting of Costa Rica’s National Biosafety Framework; descriptions of six current
biosafety capacity-building projects; the individuals and sources consulted on the biosafety research questions; and a biosafety bibliography.

II Context

According to the Secretariat to the Convention on Biological Diversity (CBD), biosafety “refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology.”¹ As this definition illustrates, biosafety is intricately bound to biotechnology. Biotechnology, in turn, is a broad term that can encompass a wide range of activities in a variety of different fields. As defined under the Canadian Environmental Protection Act, biotechnology means “the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms”.² This definition encompasses such age-old activities as the use of micro-organisms in brewing and bread-making and the domestication and selective breeding of crops. This definition of biotechnology also includes more modern practices like cloning, recombinant DNA technology, and cell fusion that permit humans to manipulate biology in ways that were not possible in traditional breeding practices. It is also to practices of “modern biotechnology” to which the Biosafety Protocol applies.³

The field of biosafety stems from the development of these modern techniques. In the early 1970s, American scientists Herbert Boyer and Stanley Cohen collaborated on a series of experiments that resulted in the creation of the first molecules of recombinant DNA and the first genetically engineered bacteria.⁴ The early transformations of bacteria and viruses in the laboratory raised concerns among scientists that resulted in two sets of guidelines for recombinant DNA research. The first set of guidelines emerged from the international Asilomar Conference on Recombinant DNA Molecules held in February 1975.⁵ It included recommended containment measures for different types of DNA experiments.⁶ The second set of guidelines was produced by the U.S. National Institutes of Health (NIH) and publicly released in June 1976.⁷ The NIH guidelines similarly created different levels of physical containment as well as biological containment for different types of recombinant DNA experiments according to their potential hazard. The NIH guidelines were stricter than those from the Asilomar Conference:

² S.C. 1999, c. 33 at s. 3.
³ Cartagena Protocol on Biosafety, Art. 3(i) definition of “modern biotechnology”.
⁵ This conference is frequently referred to as the second Asilomar Conference, the first having taken place a few years earlier in the same location but with primarily only American scientists in attendance. The first conference produced a book, Biobazards in Biological Research, but it did not have nearly the same impact as the second conference, Barnum, ibid. at 22.
⁶ Barnum, ibid. at 23.
⁷ Barnum, ibid. at 24.
Because of speculation that the closer the phylogenetic relationship between humans and the species used in recombinant experiments, the greater the risk to humans, experiments that required the use of DNA from mammals or viruses were terminated and DNA samples were destroyed.8

The NIH guidelines also had some legal weight as any institution receiving funding had to comply with them. Compliance by facilities in the private sector, on the other hand, was voluntary.9

The year after the NIH guidelines were published, they began to be reviewed. Further experience with recombinant DNA experiments had reduced some of the perceived risks. Revised guidelines were published in 1979 that reduced the stringency of the required containment measures for many types of experiments.10

At the same time, the field of biotechnology began to shift from experiments in the laboratory to industrial applications in the field. The first environmental releases of genetically modified bacteria began in the 1980s as did field trials for genetically modified plants.11 Concerns about the possible risks associated with recombinant DNA shifted as well and the risks became more complex.

Up to this point, biotechnology and biosafety were primarily the domain of developed countries. Recombinant DNA experiments were conducted in the laboratories of industrialized countries and genetically modified organisms were being created to meet needs in developed countries. These same countries were also implementing some of the first regulatory regimes for GMOs such as Canada’s National Biotechnology Strategy, created in 1982, or the Coordinated Framework for the Regulation of Biotechnology published in the U.S. in 1986.12

It was in this context that negotiations on the Convention on Biological Diversity began in 1987. The emerging role and potential value of genetic resources in the world economy was becoming increasingly obvious. The U.S. was beginning to grant patents on genetically modified life forms13 and the debate over Plant Breeders’ Rights in UPOV versus Farmers’ Rights had already been raging at the UN Food and Agriculture Organization since 1980. From the very beginning of the discussions that led to the CBD, developing countries insisted that biotechnology be one of the key issues addressed in the Convention.14

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8 Barnum, ibid. at 25.
9 Ibid.
10 Ibid.
12 Barnum, ibid. at 192.
13 The U.S. Supreme Court decision in Diamond v. Chakrabarty, 206 U.S.P.Q 193 (U.S.S.C. 1980) granted a patent on a genetically modified microorganism and found that whether or not something is living is not relevant in determining whether or not it is patentable. In 1987, the U.S. Patent and Trademark Office issued a statement declaring that “nonnaturally occurring non-human multicellular living organisms” are patentable subject matter, U.S. PTO 1077 Official Gazette 24 (21 April 1987).
This insistence was successful and led to the inclusion in the Convention of Article 19 on the ‘handling of biotechnology and distribution of its benefits’. In general, the article provides that Parties to the CBD are to take measures to include countries that provide genetic resources in biotechnology research activities, to share access to the results and benefits of biotechnology, and to provide information about living modified organisms to Parties where they are to be introduced. Paragraph 3 of Article 19 obliges the Parties to the Convention to consider the need for a Protocol on living modified organisms resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biodiversity. This paragraph was somewhat controversial during the negotiations as some countries wanted to make the development of a protocol mandatory.  

At the same United Nations Conference on Environment and Development where the CBD was opened for signatures, over 140 governments agreed to Agenda 21. Section II of Agenda 21 is devoted to the ‘conservation and management of resources for development’ and it includes chapter 16 on the ‘environmentally sound management of biotechnology’. The chapter focuses on five areas within biotechnology: increasing the availability of food, feed and renewable raw materials; improving human health; enhancing protection of the environment; enhancing safety and developing international mechanisms for cooperation; and establishing enabling mechanisms for the development and environmentally sound application of biotechnology. The fourth of these areas is of particular relevance here and calls for:

   further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level. Only when adequate and transparent safety and border-control procedures are in place will the community at large be able to derive maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology.

The negotiation of the Biosafety Protocol is well-known and has been well-documented elsewhere. At the first Conference of the Parties (COP) to the CBD in 1994, the Parties authorized two meetings to discuss the need for a Protocol. The second of these meetings, by the Ad Hoc Open-Ended Group of Experts, included support by a large majority of the delegations present for the negotiation of a biosafety protocol. This report was considered by the Parties at COP-2 in 1995 and they agreed to establish the Ad Hoc Working Group on Biosafety to

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elaborate a protocol on biosafety.19 The Working Group was to endeavour to complete its work sometime in 1998.

In the end, it took until the year 2000 for the negotiating countries to reach agreement on the text for a protocol. The negotiations were rocky and reached the brink of failure when there was no agreement at a February 1999 meeting in Cartagena, Colombia. An extraordinary Conference of the Parties was called for January 2000 in Montreal and consensus was finally achieved. Three and a half years later, in September 2003, the Cartagena Protocol on Biosafety entered into force.

Without delving into too much detail, some of the most contentious issues during the negotiations included the scope of the Advance Informed Agreement procedure under the Protocol and the types of organisms it would cover; inclusion of the precautionary principle in the operational text of the Protocol; the allowance for socio-economic considerations in decision-making under the Protocol; and the relationship between the Protocol and other international agreements, particularly those of the WTO. Further research is still required in all of these areas, particularly in partnership with developing country researchers.

Just as the negotiations for the Protocol were commencing, UNEP released the “International Technical Guidelines for Safety in Biotechnology.”20 According to the Preface, the Guidelines are intended as a contribution to the implementation of Agenda 21. They were developed “on the basis of common elements and principles derived from relevant existing regional and international instruments and national regulations and guidelines, drawing upon experience already gained through their preparation and implementation.”21 The Guidelines “provide technical guidance on evaluating biosafety, identifying measures to manage foreseeable risks and to facilitate processes such as monitoring, research and information exchange.”22 In Decision II/5 from COP-2 in 1995, the Parties to the CBD agreed to launch negotiations for a biosafety protocol and recognized in this decision that instruments like the UNEP Guidelines could serve as interim mechanisms while the Protocol was being negotiated and could complement the Protocol once it was finalized.23

Much work remains to be done to develop the provisions of the Protocol. The first Meeting of the Parties to the Protocol was held in February 2004 when the Parties adopted a number of decisions ranging from capacity-building (BS-I/4 & 5) to liability and redress (BS-I/8). The Parties also adopted a medium-term program of work that sets out the subjects to be considered by the second through fifth Meetings of the Parties. These topics include notification procedures under the Protocol, risk assessment and risk management, handling, transport, packaging

19 UN CBD, COP-2, Dec. II/5, “Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms” (1995).
21 Ibid. at “Foreword”.
22 IUCN Guide, supra note 14 at para. 119.
23 Dec. II/5, supra note 18 at recital 13.
and identification, liability and redress, socio-economic considerations, public awareness and participation, subsidiary bodies, monitoring and reporting, assessment and review, and application of the advance informed agreement procedure (BS-I/12).

Much work also remains to be done in implementing the Protocol. Of the 188 Parties to the CBD, 116 have also become Parties to the Protocol.\(^\text{24}\) While the Protocol does provide default procedures for decision-making on LMOs, many countries will want to adapt their existing internal processes or create new mechanisms for decision-making in order to implement the agreement in their jurisdictions. To this end, numerous organizations have undertaken biosafety capacity-building project (see Appendix 2).

**The Cartagena Protocol versus Biosafety**

At times, discussions of biosafety at the international level tend to be dominated by the Biosafety Protocol. But the Protocol is, at best, only a partial answer to the issue. The scope of the Protocol is quite narrow – it does not cover processes of biotechnology that may pose biosafety risks, its procedures do not include the domestic use of modified organisms, and decision-making is always tied to the conservation and sustainable use of biodiversity. There is much more to the issue of biosafety than the Biosafety Protocol.

Countries that simply focus on creating domestic regimes that implement the Protocol will find themselves with partial systems. At the same time, there is a lack of clarity over what falls within the scope of the Protocol and can therefore be included as part of the implementation and what falls beyond the Protocol and therefore needs a different rationale if it is to be incorporated into a biosafety regulatory system. The issues raised by socio-economic considerations offer one example. The Biosafety Protocol permits the inclusion of socio-economic considerations in biosafety decision-making where these considerations arise “from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities”.\(^\text{25}\) How close must the connection be between the LMO and its impact on the conservation and sustainable use of biodiversity for this element to be permissible as a socio-economic consideration within the Protocol? Some connections are quite close, such as the link between a possible reduction in the use of chemical inputs in the production of GM crops and the conservation of biodiversity. Other connections are more distant, such as the adoption of GM crops undermining traditional worldviews leading to reduced conservation of biodiversity. Would both of these socio-economic considerations fit within the confines of Article 26 of the Biosafety Protocol?


The broader scope of biosafety beyond the terms of the Protocol is also well-illustrated by developments in international trade law. Two recent cases and one ongoing dispute at the World Trade Organization (WTO) highlight the role of this organization and its agreements in the field of biosafety. The EC – Beef Hormones dispute involved complaints by Canada and the U.S. against a ban by the European Communities against the import of beef from cows that had been administered certain growth hormones. The dispute settlement panels and appellate body had to interpret various provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) relating to levels of sanitary or phytosanitary measures, risk assessment, and precaution. Ultimately, the European ban was found to be violating the provisions of the SPS Agreement. Europe has refused to lift the ban, however, and pays a penalty through tariffs on European goods imported in Canada and the U.S.

The Japan – Apples dispute similarly involved provisions of the SPS Agreement. The case concerned a complaint by the U.S. over certain Japanese requirements and prohibitions on the importation of American apples. The U.S. believed that the Japanese rules contravened articles 2.2 and 5.1 of the SPS Agreement in that they were maintained without sufficient scientific evidence and were not based on a risk assessment. Japan argued that its measures were provisional based on the insufficiency of the existing scientific evidence as allowed under article 5.7. Both the dispute settlement panel and the appellate body found that Japan's measures were in violation of articles 2.2 and 5.1 and were not saved by article 5.7.

Finally, there is the ongoing EC – Biotech dispute in the World Trade Organisation. This dispute involves claims by the U.S., Canada and Argentina that the European Communities' de facto moratorium on the approval of genetically modified products contravenes numerous provisions of different WTO agreements. The provisions include the above-mentioned articles 2.2 and 5.1 of the SPS Agreement as well as other SPS provisions on disguised restrictions on trade (art. 2.3), elements of a risk assessment (art. 5.2 and 5.5), and the requirement to seek additional information where provisional sanitary or phytosanitary measures are applied in cases of insufficient scientific evidence (art. 5.7), among others. The dispute also raises aspects of the GATT 1994 Agreement, the Agreement on Agriculture, and the Agreement on Technical Barriers to Trade. The Dispute Settlement Panel expects to issue its report by the end of June 2005.

Countries that are parties to the Biosafety Protocol as well as being members of the WTO need to create and implement biosafety regulatory regimes that respond to both international instruments. This is no easy feat and there are no definitive answers on how the two sets of obligations can be made to interact in a mutually supportive way. What is more, these are not the only two international fora in which biosafety discussions are ongoing. The Codex Alimentarius, the International Plant Protection Convention, and the World Organisation for Animal Health (OIE) are also involved as are regional organizations such as NAFTA. With each organization counting different countries as members, establishing who must do what becomes very complicated.
In developing countries, particularly in Francophone Africa, this morass of legal and regulatory obligations has caused considerable confusion. The lack of clarity has created difficulties for government officials from environment, health, agriculture, science and technology, industrial development, culture and other ministries, as well as for civil society groups and those working in the biotechnology industry, to decide on an adequate national biosafety framework, complete with effective regulatory regime, that fit their national policy objectives. These objectives are, of course, particular to each country.

And at the local level, most individuals are not concerned with the provisions of the Biosafety Protocol or WTO Agreements. Their questions are more straightforward. Are GM foods safe to eat? Are they easy to grow? Will they save me money or cost more? Will they harm the environment? These are, of course, the sorts of questions that biosafety regulatory regimes are ultimately trying to answer but at times, the discussions become bogged down in the minutiae of procedures, decision-making timelines, and notifications. More experience with the use of biosafety regulatory regimes should help to answer these questions by generating actual results – approvals, refusals, monitoring, etc. – that can be used as evidence to support answers to these questions. However, this depends on developing countries having the capacity to implement their biosafety systems and communicate the results to the public. Answering these sorts of questions would also benefit from clear and consistent information, which, on this subject, tends to be in short supply.

**III Development of the Field**

This section does not aim to expose the risks and benefits arising from the development and use of biotechnology. Many scientific studies have already examined these matters and IDRC is already aware of much of the debate through the work of its Task Force on New and Emerging Technologies. In CISDL’s experience, however, consideration of the legal aspects of biosafety leads inevitably to the scientific material when creating, developing and applying international legal norms in national legislation. This third part of the Biosafety Scoping Study will briefly survey the way international legal norms on biosafety are dealt with and applied by states at the national level.

CISDL’s analysis is based on the organization’s recent experience in many Latin American and Francophone African countries and in particular through the involvement of our multidisciplinary team with the UNEP-GEF Development Project (see Appendix 2). The objective of the project is to assist countries to develop the tools they need in order to apply the obligations in the Biosafety Protocol in their national laws.

One of the first concerns to arise during reviews of developing countries’ national biosafety frameworks involves the “scientific” parts of the Protocol. References to scientific terms, techniques or mechanisms that are included in the legislation or National Biosafety Framework are often not very clear. Definitions can be meaningless or taken out of context, techniques can be mixed up, risk assessment
or decision-making processes can be incomplete. This creates uncertainty in the national policy and/or law where precision and clarity are needed. Uncertainty threatens to hinder the implementation of a country’s biosafety law and policy, which could lead to negative impacts on the safety, development and well-being of the national population and environment as well as a significant waste of very scarce resources and political will.

The reason for these difficulties cannot be exclusively attributed to a lack of means or scientific capacity within a country. In fact, many countries have established highly competent scientific structures in very different fields (medical, agricultural, botanical, etc.) Even though these structures and institutions are limited in the techniques available for their use, and rely on the knowledge that is widely available, several countries have the basic structures and competent people to deal with biosafety issues, or could become part of sub-regional or regional cooperation frameworks that could complement one another.

Difficulties in fulfilling the obligations in the Biosafety Protocol, cannot, therefore, be solely attributed to a lack of capacity. Instead, a major obstacle has been a lack of cooperation or teamwork between national bodies and competent people working in the different areas addressed by the Protocol (i.e. both the legal and scientific domains.\textsuperscript{25}) Assistance with institutional and organizational collaboration (governance and regulatory reform) are important priorities, and are as significantly and simultaneously essential as assistance on the understanding, development and application of international norms. Bringing people together undoubtedly increases the efficacy of the work. Consulting scientific experts on their areas of competency during the drafting of a law in order to check the meaning and certainty of the facts or mechanisms described in the law would help to avoid confusion, contradictions and gaps.

Further specific weaknesses and concerns have been identified by developing country leaders, scientists and civil society representatives, in interviews and scientific consultations held during recent meetings, especially in Francophone Africa. Specific concerns relate mainly to the policy objectives set by a participatory process in the country in question.

In some countries, policies with regards to biosafety issues are very precautionary. This is especially true for small island developing countries such as Cape Verde, the Seychelles or Madagascar, for Muslim countries such as Algeria, and for countries with high dependence on tourism or agricultural trade with Europe, and fragile ecologies such as Ecuador. In some countries of Asia and Central Asia, there is also concern that the socio-economic changes wrought by biotechnology could, if not understood and properly managed, have similar costs and benefits as did the Green Revolution.

\textsuperscript{25} This problem is not unique to biosafety and the need for collaboration among people from different disciplines is also evident in access and benefit-sharing, see Kathryn Garforth & Jorge Cabrera, \textit{Sustainable Biodiversity Law: Global Access, Local Benefits: A Scoping Study on Future Research Priorities for Access to Genetic Resources and Benefit-Sharing} (Montreal: CISDL, August 2004), online: CISDL \url{http://www.cisdl.org/pdf/CISDL_ABS_Scoping_Study.pdf} at 14.
In other countries, policies with regards to biosafety issues are intermediately protective – simultaneously biosafety and development oriented. This is especially true for countries with ‘porous’ boundaries such as Togo, Niger and Mali, where public or governmental concerns are high, and there is a strong dependence on subsistence agriculture or food trade, but there is also a need to learn to address products which enter the country regardless of controls.

And in still other countries, policies have sought primarily to encourage development of biotechnology, while ensuring an adequate level of biosafety. This is particularly true of those countries with a close relationship to the U.S. such as Burkina Faso, Mozambique, Chile or Argentina. Such countries might also serve as ‘gateways’ for crops or aquaculture LMOs to the rest of their continents.

However, for all countries (including those who are WTO members and those seeking to eventually join, and those who receive significant levels of food aid), overlaps and potential conflicts between different international accords are of serious concern. Other important questions for future biosafety research related to legal and policy regimes include issues such as the need to balance legal and scientific aspects of obligations and requirements under national and international law, the need to ensure solid and informed participation of civil society in decision-making, and the need to develop or learn the best possible risk assessment laws and techniques for effectiveness in different local contexts. It is to such questions that we turn next.

**IV Research Questions**

In the process of conducting this scoping study, CISDL consulted with a range of different actors in the biosafety field (see Appendix 3). There is widespread agreement that many unanswered questions remain and much more work is needed on biosafety research that focuses on the concerns of developing countries. Here are some of these questions and concerns that would need to be developed in order to reach a better level of understanding and application of biosafety norms and issues. The questions are grouped into categories for ease of reference.

**National and International Biosafety Governance**

What obstacles do countries face in ratifying the Biosafety Protocol? Why are some countries not ratifying the Protocol? (A comparative analysis of why different countries have not ratified the Protocol would be useful in helping others understand specific reasons why countries have not ratified.)

What obstacles do countries face in creating and implementing a regulatory framework on biosafety either to comply with the Biosafety Protocol or to go beyond its provisions? How best to pass beyond these obstacles, and overcome barriers – what are the best practices among regulatory options that other countries with similar policy objectives have used?
Can analysis, based on comprehensive case studies, be developed to demonstrate how, in reality, a country’s obligations under different international instruments related to biosafety (e.g. the Biosafety Protocol, the IPPC, Codex, etc.) can affect the national biosafety process?

How useful is the information on the Biosafety Clearing-House (BCH)? Would the inclusion or availability of other information be more useful? Would more types of information or other types of information increase use of the BCH (e.g. through reciprocity – “we find it useful so we will contribute”)?

Would the inclusion of more information on decision-making in the BCH be useful? For example, rather than having only a summary of the risk assessment for a particular organism, would it be possible to also include information on why the decision to block or allow import was made?

How could countries take more advantage of/better use the BCH mechanism? What strategy could be used to induce countries to better take account of the BCH in their national biosafety frameworks and legislation? Would regional cooperation assist?

How can developing countries design and use regional biosafety mechanisms for the purposes of scientific and regulatory risk assessment, particularly when faced with porous borders or similar requests from exporters? What is the potential for cooperation between laboratories or scientific institutions, and between regulatory bodies, and how could this be encouraged? Can joint systems be set in place to support monitoring, certification, etc.?

The notion of ‘Risk Management’ (Biosafety Protocol Art. 16) does not exist explicitly in the WTO Agreements, at best one may consider that Article 5.3 of the SPS Agreement represents an opening in that direction. Risk management, and the Protocol’s Art. 16, might be de facto contested through the Doha Declaration’s introduction of the term of “Specific Trade Obligation” (para. 31(i)) by being considered neither specific nor obligatory enough. What does this say about issues like compatibility, coherence, WTO-UN relations, or the environmental mandate, potential or aspirations of the Doha Development Agenda?

Does the Biosafety Protocol’s Meeting of the Parties represent an ‘international standardizing body’ in the sense of TBT Art. 1.1 (Assuming that it is about to create rules such as the ones on liability, redress etc.)? Is the Protocol itself a Standard in the sense of TBT Annex 1, paragraph 2 and SPS Annex A, paragraph 3(d)? What are the legal stakes?

How can developing countries best participate in and follow-up the Meeting of the Parties to the Biosafety Protocol in an informed manner? Which representation is most effective, and how can information be shared between one meeting and the next?
How can developing countries achieve coherent and coordinated participation in other fora besides the CBD that also deal with related issues on trade, tracking and labelling, liability and redress, basic information for risk management and assessment, and food safety?

What are alternative governance options for addressing GMO regulatory issues and mechanisms for harmonizing or resolving differences in existing approaches and methods?

What are the different views, interests, and roles played by different non-governmental institutions (including business firms) regarding GMO risks and regulations, and their implications for governance? How to ensure full ‘participation’ in a biosafety decision-making process, while staying within the meager resources of most countries (and civil society actors), and not allowing one sector to ‘dominate’ a process?

How to ensure transparency and participation when there does not appear to be an adequate level of basic knowledge about biosafety issues, and biotechnology, among a country’s population, and how best to inform the population without ‘propagandizing’?

**Social and Economic Biosafety Issues for Developing Countries**

What are the social, cultural, and economic dimensions of GMO risks and regulation as well as the scientific dimensions of environmental health and safety effects? What procedures or methodologies can be used for the assessment of socio-economic considerations in biosafety decision-making?

Does the decision of a state to ratify one international biosafety-related instrument, but not another, affect farmers’ and consumers’ choice? How is it possible to avoid predetermination in their understanding of biosafety and in their behaviours? How is it possible to avoid exclusion of a part of a country’s people in socio-economic decision-making relating to biotechnology?

What is the impact of a widespread switch to raising genetically modified organisms for export on domestic food consumption and nutrition? How can countries with high levels of public apprehension due, for example, to religious or cultural factors, address the dichotomy between international and domestic cultural standards?

What is ‘sound science’? How does the requirement for scientific risk assessments under the Protocol (see, in particular, Article 15) correspond to similar requirements in the WTO’s SPS Agreement (see, in particular, Art 2.2, Art. 3.3, Art. 5.1 & 5.2)? Can decision-making include social science considerations as provided in Article 26 of the Protocol?

Imported GM crops which have been grown efficiently with huge machinery on very large farms in industrialized countries, perhaps subsidized directly or
indirectly by the country of export, could be relatively cheap in the country of import and interesting to urban markets. At the same time these low-price (dumped?) imports may be devastating for the domestic farmers (often the majority of the population) who tend to be suffering most from poverty already, find themselves now unable to sell their production, and cannot afford to buy the patented seed/fertilizer/pesticide package. This may even drive rural populations into urban slums and cycles of social exclusion. How can a developing country protect itself against such occurrences or trends, under the Protocol’s Article 26 on socio-economic considerations?

What impact could the adventitious presence of GMOs in exports from developing countries have on these countries’ access to markets?

Article 2.2 of the WTO’s TBT Agreement on the preparation, adoption and application of technical regulations allows certain objectives and elements to be taken into account when evaluating the legitimacy of a trade measure. How can an importing country invoke, in this legal context, legitimate and relevant objectives and elements of consideration which are based on approaches other than biological risk assessment, e.g. socio-economic risk assessment or other societal concerns and issues?

Within a process of democratic participation, decision-making should necessarily involve and take into account the points of view, needs, and concerns of experts, people involved in each process, people potentially affected by the short and long-term consequences of policies, policy-makers. How could this be built into the requirements for scientific decision-making under the Protocol? What role do consumers play in decisions about access to public information and the use and labeling of genetically modified products?

Emerging Questions in Biotechnology for Developing Countries

What strategies are being used by the biotechnology industry to break into markets where people are poor? Does the arrival of biotechnology in these markets help people or make them poorer?

What obstacles do developing countries face as they try to commercialize the products of local and domestic biotechnology research and development? What can be done to overcome these obstacles?

What is the ‘right to choose’ in relation to biotechnology? What are its bases in individual autonomy and the competitiveness of the marketplace? In what areas of the economy might choice be limited as a consequence of the prevailing business model of the biotechnology industry? How might farmers’ choices be affected by biotechnology? How might consumers’ choices be affected by biotechnology?

What are other options besides biotechnology for solving the challenges faced by poor farmers? For example, what role could small-scale irrigation play in
increasing agricultural productivity in comparison to the development of higher-yielding varieties through biotechnology?

How much information does the biotechnology industry provide on the effects of biotechnology on land, water, food, the health and well-being of workers handling it, potential market effects on regional products and by-products, potential biodiversity loss, cost-benefit analyses that do not include negative externalities, industry liability for long-term effects of their products, and the burden of proof on industry? What should governments do to make sure people are aware of the implications of biotechnology in the above-listed areas? What measures should be taken to provide people with full information on these aspects where industry is not willing to provide it willingly? Should this be done at the international level? Who should do the monitoring?

**Developing Country Technical Compliance with the Cartagena Protocol**

What are the major scientific and regulatory capacity needs and limitations that are hindering developing countries from effectively implementing the Biosafety Protocol? What efforts have been made to address these needs and limitations, have these succeeded, and what are the major remaining gaps?

What are the legal and institutional difficulties faced by developing countries in implementing a biosafety regulatory regime (e.g., understanding of the implications of a labeling/tracking system, the details of such a system such as the allowable limit for the incidental presence of GMOs, liability, coexistence, regulations of commodities, technical feasibility of tracking the presence of GMOs in imports/internal market, institutional design to handle GMOs, export requirements, intellectual property rights, etc.)?

How can developing countries conduct regulatory assessments or use other new tools to identify the areas of their biosafety systems that need to be strengthened (e.g. scientific capacity, regulatory capacity, innovation)? How can they prioritize these different areas once they are identified?

What other fields of regulation, apart from the specifics of biosafety, are also key for the effective functioning of a biosafety system? (e.g. intellectual property, liability rules, consumer protection, other safety systems, access to information, access to justice, competition, etc.)

What are the scientific and technical challenges faced by developing countries in implementing a biosafety regulatory regime (e.g., understanding of and capacity to implement risk assessment and risk management, assess socio-economic considerations, conduct decision-making based on sound science, etc.)?

How would it be possible to deal with scientific compliance issues in national biosafety frameworks and laws in a more comprehensive manner? How to address, for example, technical scientific definitions of terms; determination, limitation of rights and obligations regarding certain scientific techniques and mechanisms;
including/excluding certain scientific techniques from a legal mechanism and other issues in a way that is relevant to each country’s specific circumstances, but also consistent?

What types of tools have been used to build biosafety capacity to date (e.g. training workshops, manuals, etc.)? How effective have these tools been and what are some areas for improvement? How can developing countries optimize the use of their existing capacities and adapt them to cover the field of biosafety? How can existing legal and administrative frameworks in related areas (e.g. phytosanitary measures) be affected by and contribute to the national biosafety framework?

Article 18 of the Biosafety Protocol on “handling, transport, packaging and identification” is one of the most controversial areas of the Protocol. What are the real underlying issues and concerns of the different stakeholders in regards to this provision?

The Biosafety Protocol does not yet contain any Liability and Redress provisions (Article 27) at this point in time. Can a country justify an import ban on GM products on this ground? How can developing countries begin to prepare for negotiations on this issue in the Meeting of the Parties to the Protocol, what would be their interests and agendas, and how can they cooperate to achieve maximum success?

Can standard risk assessment procedures be developed that will be accepted by the international community both in the context of the Biosafety Protocol and beyond?

How can the confidentiality of information be better understood and protected? If confidentiality is well defined in a country’s national biosafety framework, how is it possible to improve its application and implementation in law?

How can countries create public participation structures that do not overwhelm their other obligations under the Protocol? How can countries strike the right balance between the confidentiality of information and public participation? How can countries include public participation in their biosafety mechanisms?

**Sustainable Development and the Biosafety Protocol**

What is or can be the role of the Biosafety Protocol in fostering sustainable development? Why is ensuring the safe use of biotechnology products critical for sustainable development?

How do States, and in particular developing countries, see the link between the Biosafety Protocol and sustainable development? Do they consider sustainable development issues when complying with their obligations deriving from the Biosafety Protocol in national frameworks or legislation?
What are the key analytic and normative principles, such as the precautionary principle and environmental impact assessment, and what is their relevance for governance?

V_ Recommendations

Based on the discussions and research that CISDL has conducted for this scoping study, we have three recommendations for IDRC for its work on biosafety.

1. There is a need for developing countries to implement solid biosafety regulatory regimes now, in accordance with their specific concerns and priorities, and with regional and international support.
2. There is a need for significant support for focused, multidisciplinary biosafety research, capacity building and development in developing countries, paying equal attention to the regulatory and scientific aspects.
3. It is time for all the actors in developing country governments, scientific communities, legal communities and civil society to start “acting” rather than “expecting”.

Each of these is discussed in more detail below.

1. **There is a need for developing countries to implement solid biosafety regulatory regimes now, in accordance with their specific concerns and priorities, and with regional and international support.**

Extensive work is being undertaken towards the implementation of the Biosafety Protocol (see Appendix 2), particularly in developing countries. If appropriate measures are not put in place now, it will be very difficult to amend the systems in the near future. This will be due to both a lack of political motivation at the national level and lack of support at the international level as current capacity-building projects draw to a close.

This is not to say that countries should expect that they can create a biosafety regulatory regime and be done with the issue within their country. Biosafety systems require revision as experience with biotechnology grows, and as both the science and the industry change. The biosafety regulatory regimes that countries create today will need reviewing and updating in the future. But given the current momentum behind biosafety, it is imperative that the regulatory systems that developing countries are drafting at present are the best they can be based on current realities.

A second component to this recommendation is that the biosafety regulatory regimes being created by developing countries should include all areas that countries wish to regulate and otherwise address, in a way that is appropriate to the special circumstances of that country. For example, they do not simply need to be regimes on living modified organisms within the scope of the Protocol, but must have appropriate scope. They should address the specific policy objectives (whether firmly precautionary, intermediate, or development oriented) of the
country and its people. They can also address the specific pressing questions of highest importance to the developing country within its own context, including food aid issues, religious or cultural questions, adequate risk assessment and decision-making procedures, and levels of public participation and information; as well as challenges related to porous borders, uneven rule of law, and insufficient levels of scientific or technical knowledge and regulatory cooperation.

As discussed in Part II, there is more to biosafety than the Biosafety Protocol. Countries need to decide which areas of biosafety and biotechnology they wish to regulate and proceed from there in creating their systems rather than relying on the terms of international agreements like the Biosafety Protocol to determine the scope of their regulatory systems for them.

2. There is a need for significant support to focused, multidisciplinary biosafety research, capacity building and development in developing countries, paying equal attention to the regulatory and scientific aspects.

Biosafety is a multidisciplinary field and should not be approached in an isolated fashion. Integration and cooperation is needed at a number of levels: the research level, the legal level, and the drafting and implementation level.

As is well illustrated by the research questions in Part IV of this study, biosafety research draws on a number of different fields including science, law, philosophy, and economics. In funding research on biosafety, IDRC should keep these different disciplines in mind and consider projects that approach the issue from a variety of different fields of inquiry.

The multidisciplinary aspect of biosafety also comes to the fore as countries draft and implement biosafety laws and policies. This occurs in two manners. First, the people responsible for developing the biosafety system can, and often do, work in multidisciplinary teams to ensure that they have input from relevant specialists in the field, particularly concerning the scientific aspects of biosafety. Secondly, those responsible for developing the biosafety system can be given greater support to become aware of the different international obligations that their country may have already incurred and how these could impact the system to be implemented. These various obligations may be in fields as diverse as plant, animal and human health rules, trade law, and human rights. The exact extent or meaning of some of these commitments and how they interact may not be entirely clear but if a multidisciplinary team includes individuals who are familiar with these different areas, they should be able to bring these international commitments to the attention of the rest of the team and work through how best to ensure that the biosafety system respects these obligations.

It is also important for neighbouring countries to cooperate and share information relating to the development of their biosafety systems. Countries can learn a lot from how their neighbours have approached biosafety regulation and cooperation in this area can help to create regulatory systems that complement one another and operate more efficiently. In addition, many developing countries, particularly
in Francophone Africa, share porous borders, weak scientific or technical capacity for risk assessment and other procedures, and similar requests from exporters. Increased attention to the formation of cooperative networks of scientists and laboratories, regulators and law enforcement agencies, decision-makers, civil society groups and other actors could offer one of the best alternatives for effective implementation of the objectives of all countries.

A country must also determine, however, the degree to which it and its neighbours have similar goals for their biosafety regulatory systems. To this end, countries should avoid copying the biosafety regulatory regimes of their neighbours and should instead design regimes that are adapted to their particular situation. Countries in a region can work together on the foundations, sharing general information and understanding, but work alone on national application with a multidisciplinary team.

3. *It is time for all actors in developing country governments, scientific communities, legal communities and civil society to start “acting” rather than “expecting”.*

As described in Part II, above, discussions of potential biosafety rules has been going on for quite some time. Most recently, these discussions have resulted in agreement on the Cartagena Protocol on Biosafety. While the Protocol still leaves some areas for further negotiation and discussion by the Parties, countries need to be implementing the existing rules now. For better or for worse, biotechnology has arrived and genetically modified organisms are now a component of much agricultural trade. Countries need to move from expecting or anticipating the arrival of biotechnology and biosafety rules, to acting to implement the rules they want regulating biotechnology in their country.

In order to ease the transition from expectation to action, it will be crucial to stress the progress and achievements that are made. These achievements can be anything from agreement on biosafety rules, to the hiring and/or training of personnel, to the successful resolution of the first biosafety application. At the same time, moving to action on biosafety will also support the need for more experience with biosafety and biosafety rules. This will not only build experience with biosafety within a country but will also begin to generate the information that a country’s citizens want on the health and safety of the products and processes of biotechnology.
Appendix 1

The Drafting of a National Biosafety Framework in Costa Rica: The Story of an Emerging Regulatory Regime

Costa Rica has had a lot of experience dealing with the field testing and experimentation of GMOs. Since 1992, the country has approved the field testing of several agricultural GMOs (see Table 1) through interpretation of the scope and provisions of the Plant Health Law No. 6248 of 1978. In 1997, the new Plant Protection Act No. 7664 of 1997 and its regulations No. 26921 of 1998 replaced the Plant Health Law. The Plant Protection Act includes a chapter (arts. 40 to 44) dedicated to the regulation of GMOs in agriculture.

In 2002, a UNEP-GEF Project for the development of a National Biosafety Regulatory Framework (NBF) was initiated. The project had as one of its main outcomes the drafting of a new legal framework for biosafety to be in compliance with the Cartagena Protocol. A National Executive Agency and a National Advisory Group were established.

The main lessons, difficulties and divergences arising from the process of drafting the NBF were as follows:

- For the first time, a participatory process was launched for the drafting of a regulation on GMOs, including the extensive participation of the Health and Environment Agencies, universities and researchers. NGOs and the private sector had some more limited involvement in the process. NGOs strongly opposed any Regulatory Framework. Instead, these groups were looking for a “moratorium”. Food trade organizations also opposed the drafting on the grounds that a new system was not necessary given the existing legal framework and administrative practices for GMOs.

- Biosafety and biotechnology are two changing fields. There was tension between two approaches to the NBF: drafting highly detailed and precise laws (making them difficult to change in the future due to the Parliamentary approval process), or drafting only the general aspects, leaving the details for the regulations (to be drafted by the Executive Branch). Some of the regulators and scientists involved in the process were in favor of the first approach while other participants looked for a balance between these two options. A compromise solution was reached but most of the substantive technical regulation is still left for drafting by each of the competent authorities. A lot of work to implement the NBF remains to be done, after its approval, for the drafting of the detailed technical regulations. The Health and Environment Agencies have indicated their needs for capacity building in this area as Competent Authorities under Article 19.1 of the Protocol.
The most substantive controversial issues were related to:

- The involvement of the different national agencies, the Ministries of Environment and Health in the approval process. Especially in the case of the Ministry of Environment, an agency with a minor role under the current legal framework, there were demands to strengthen and clarify its role (as an agency with the mandate to protect and conserve biodiversity). Finally, both of those Ministries as well as the Ministry of Agriculture were designated competent authorities under Article 19.1 of the Protocol.

- The institutional framework and administrative system was changed several times. The role of the National Biosafety Council (to advise on policy and regulatory issues or technical aspects, or to actually make the final decision on a GMO), composition and affiliation (to which Ministry or as an independent body) of a National Council on Biosafety, were discussed and different views were expressed. The creation of a new Technical Office (with the mandate of handling the solicitors requests and conveying them to the competent authority) was also considered and subsequently rejected.

- The scope of the NBF also generated a huge controversy, including over issues such as: how to deal with commodities (GMOs for food, feed and processing), processed food containing genetically modified ingredients, microorganism and potential transgenic fish; and the definition of GMO (or modern biotechnology). The last version of the Draft followed the Cartagena Protocol.

- The objectives of the new NBF were also hotly debated. Some suggested the support and encouragement of biotechnology should be one of the key objectives of the new law. Others strongly opposed this view. According to them, the purpose of the NBF is to minimize and avoid the negative impacts of the introduction of a GMO on biodiversity and human health, not to favor the development of GMOs. Instead, the support and encouragement of this technology should be part of a science and technology law or policy.

- The issues of labeling and traceability issues were also raised. Two lessons can be learnt from this debate. First, there is a lack of easily understandable information and expertise on labeling and traceability, especially concerning the technical implications (including trade issues) of such measures in reality. Second, most of the participants were reluctant to include any provisions in the NBF on these issues, leaving them for a specific technical regulation to be drafted at a later stage. However, very general guidelines about the principles and objectives of any labeling requirements were incorporated in the Draft.

- There was a general agreement about the need to balance the confidentiality and the rights of private firms for the non-disclosure of information, and the needs and rights of the public to be informed and to submit any comments they have. A public notice will be published
(following the current system) inviting comments and oppositions. Also, the competent authorities are entitled to initiate public consultations. Confidential information must be respected.

- Finally, issues regarding coexistence, liability and redress were not considered.

**Table 1 Number of transgenic events allowed in Costa Rica per year and by crop**

<table>
<thead>
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<th>Year</th>
<th>Maize</th>
<th>Soya</th>
<th>Cotton</th>
<th>Banana</th>
<th>Rice</th>
<th>Tiquisque</th>
<th>Petunia</th>
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<td>96</td>
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Appendix 2  Biosafety Capacity-Building Projects

Decision BS-I/5 from the first Meeting of the Parties (MOP) to the Biosafety Protocol addresses the issue of capacity-building. It includes an “Action Plan for Building Capacities for Effective Implementation of the Cartagena Protocol on Biosafety”, an implementation toolkit, the creation of a Coordination Mechanism for the implementation of the Action Plan, and a set of indicators for monitoring the implementation of the Action Plan. In preparation for MOP-2, the Secretariat has prepared a document on the “Status of Capacity-Building Activities” that provides an update on the activities undertaken as part of this decision.28

The Biosafety Clearing-House lists over 100 biosafety capacity-building projects that are either ongoing or have been completed.29 CISDL has selected 6 to review below.

1. UNEP-GEF Biosafety Projects
(Information drawn from the projects’ website, www.unep.ch/biosafety)

Following the adoption of the Biosafety Protocol in January 2000, the Council of the Global Environment Facility (GEF) adopted a strategy on biosafety, which is aimed at assisting countries to be prepared for the entry into force of the Protocol. The United Nations Environment Program (UNEP) designed three related projects that work towards fulfilling the GEF strategy. These are the Global Project on Development of National Biosafety Frameworks, the Project on Implementation of National Biosafety Frameworks, and the Biosafety Clearing-House Project.

(a) UNEP-GEF Development Project

This project ran from June 2001 to December 2004 although work continues in some countries. It is designed to assist countries in developing their National Biosafety Frameworks so that they can comply with the Cartagena Protocol on Biosafety. The project will also promote regional and sub-regional cooperation on biosafety. There are currently 123 participating countries.

The project has three components:
- development of frameworks, including information gathering, analysis, consultation, training, and preparation of a draft national biosafety framework (draft legal instruments, administrative systems, risk assessment procedures, systems for public participation and information).
- regional workshops, to increase understanding of the Biosafety Protocol and assess implications for risk assessment and decision-making at national levels.

- sub-regional workshops, for capacity-building, to identify opportunities for collaboration and mechanisms for sharing of risk assessment and management experiences, and for networking to share lessons and experiences.

The project includes a series of toolkits to assist countries in the development of their national biosafety frameworks. These cover four phases:
• Phase 0: starting the project;
• Phase 1: taking stock;
• Phase 2: consultation and analysis; and
• Phase 3: developing the regulatory regime.
Countries are also required to submit documentation on their progress towards a National Biosafety Framework including an initial status report at the start of the project, a national progress report submitted during the third series of sub-regional workshops (discussed below); and a final draft National Biosafety Framework at the end of the project.

There have been three series of workshops. The first was regional workshops on ‘Understanding the development of National Biosafety Frameworks’. These were held in the first half of 2002. The second was sub-regional workshops on ‘Risk Assessment and Management & Public Awareness and Participation’. These were held from November 2002 to May 2003. The final round was another series of sub-regional workshops on ‘Development of Regulatory Regime and Administrative Systems for National Biosafety Frameworks’. These were held from October 2003 to May 2004. Documentation related to the toolkits and workshops can be found at [http://www.unep.ch/biosafety/devdocuments.htm](http://www.unep.ch/biosafety/devdocuments.htm).

(b) UNEP-GEF Implementation Project

The Implementation Project also began in June 2001. It involves 12 demonstration projects to support countries with the implementation of their national biosafety frameworks and each of the 12 projects is expected to last about three years. The participating countries are: Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda, India and Colombia (projects managed by the World Bank), and Malaysia and Mexico (projects managed by UNDP).

The Implementation Project included a study tour and meeting of national coordinators in January 2004. National coordinators of their respective Implementation Projects met together and toured several European countries to learn from their experiences with national regulation of biosafety. The Project has also compiled the results of a survey of examples of national policies on biosafety, as requested by national coordinators. Canada is included amongst the countries having responded to the survey.

Finally, the Implementation Project is in the process of preparing a guide for the implementation of national biosafety frameworks. The guide identifies five common components of national biosafety frameworks. These are:
• A government policy on biosafety;
• A regulatory regime for biosafety;
• A system to handle notifications or requests for authorisations;
• Systems for monitoring and enforcement; and
• Approaches for public information and public participation.

The regulatory regime is divided, in turn, into three types of provisions:
• General provisions such as objective, scope and definitions;
• Operational provisions such as contained use, release, placing on the market; and
• Other provisions on topics like confidentiality, public participation, and compliance.

(c) Biosafety Clearing-House Project

The Biosafety Clearing-House (BCH) Project began at the end of 2003. Its objective is to develop human resources and establish an appropriate national BCH infrastructure to enable countries to fully participate in and benefit from the BCH established under the Biosafety Protocol.

This objective is divided into three components:
- **Strengthening capacity** in countries through training of key stakeholders. The training will cover (i) data entry and management; (ii) identification and access to information required for decision-making under the Protocol; and (iii) access to and registration of information in the BCH.
- **Creating an enabling environment** for Parties to meet their obligations under the Protocol by providing the necessary computer hardware and software.
- **Developing and disseminating a training package** which will be developed close collaboration with the CBD Secretariat to ensure consistency between national inputs and the BCH central portal.

The BCH Project will compile a roster of experts and conduct training workshops on the BCH both with the experts at the regional/sub-regional level and in each participating country.

The participating countries will be required to:
• Establish a BCH Task Force to assist in the implementation of the project at the national level;
• Provide an analysis of the country’s staffing and equipment requirements;
• Provide detailed cost information on the purchase of equipment and other project expenses;
• Nominate three people who will attend the regional/sub-regional workshops and then be able to deliver training at home at a national-level workshop; and
• Provide a long-term strategy for sustaining the national BCH and fulfilling the country’s obligations under the Biosafety Protocol.

2. ISNAR Biotechnology Service
(Project website: [http://www.isnar.cgiar.org/ibs.htm](http://www.isnar.cgiar.org/ibs.htm))

The project of the International Service for National Agricultural Research is divided into three phases. The first phase ran from 1993-1997, the second phase
from 1998-2002, and the follow-up phase from 2003-2007. Under the project, ISNAR serves as an independent advisor “to national agricultural research programmes in developing countries on matters of biotechnology policy and research programme management, including biosafety.” The program of work covers two broad areas: research and outreach. The specific topics addressed in the two categories are broader than biosafety and include setting priorities for agricultural biotechnology, intellectual property rights, and managing human resources for biotechnology.

The project has resulted in a wide array of publications including briefing papers, country reports on the biosafety regulatory systems of Argentina and Egypt, and research papers. The project has also undertaken a biotechnology management training program, primarily in Asia and Africa, and resulted in the creation of a web-based decision support toolbox for biosafety. The project is funded by the Netherlands Ministry of Foreign Affairs, the Swiss Agency for Development and Cooperation, the UK Department for International Development, and Japan Official Development Assistance.

3. East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN)
(Project website: http://www.bio-earn.org/)

BIO-EARN began in 1999 and operates in four East African countries – Ethiopia, Kenya, Tanzania and Uganda. The goal of the project is to build national capacity and competence in biotechnology, biosafety and biotechnology policy in these four countries.

The project has undertaken the development of national biosafety frameworks, human resources development, public awareness, education and participation, and risk assessment. Specific activities include short training courses on biotechnology policy, regional workshops, training in biosafety assessment and field evaluation of transgenic crops, and research on risk assessment.

The project is supported by funds from the Department for Research Co-operation of the Swedish International Development Cooperation Agency and is scheduled to continue until 2008.

4. Rockefeller Foundation Support for Capacity-Building in Agricultural Biotechnology and Biosafety
(Website: http://www.rockfound.org)

The Rockefeller Foundation has been supporting capacity-building in this area since 1991 and their work is ongoing. Their goal is to provide “funding support to promote plant biotechnologies needed by resource-poor farmers and develop capacities for the safe use of biotechnology, including capacity to develop and
implement biosafety regulations.” They work primarily in Africa, Asia and the Pacific, and Latin America and the Caribbean.

The Foundation has supported the development of national biosafety frameworks and their coordination and harmonization at the regional level, human resources development, institutional strengthening, and public awareness, education and participation. Specific activities include:

• The assessment of international initiatives for capacity-building in the field of biosafety and biotechnology in Southeast Asia and sub-Saharan Africa, by the United Nations University;
• Enhancing the capacity of Tanzania’s Tropical Pesticides Research Institute to implement biosafety regulations and assess and manage potential risks associated with genetically modified staple crops, through the training of one of its scientists at Agriculture and Biotechnology Strategies (Canada);
• Project by the Center for Science in the Public Interest to inform the international debate around scientific and regulatory issues related to biotechnology and to put forward middle ground on the biotechnology debate.
• The establishment of the Asia-Pacific Consortium on Agricultural Biotechnology to harness the benefits of agricultural biotechnology for human and animal welfare while safeguarding the environment and sustainable agricultural development in the Asia-Pacific region by the Asia-Pacific Association of Agricultural Research Institutions.

5. Third World Network Biosafety Capacity Building Programme for Developing Countries
(Project website: http://www.twlside.org.sg/bio.htm)

The Third World Network operates in three main capacity-building areas: information exchange and data management, human resources development and training, and public awareness, education and participation. Their goal is to “monitor scientific and policy developments in biosafety and genetic engineering”. They engage in the publication of documents, reports, articles, and briefing papers analyzing the science of biosafety as well as national and international developments in the field. They hold briefing sessions and panel discussions during biosafety meetings, and also undertake public education and awareness building to strengthen public participation in biosafety decision-making.

6. U.S. Initiatives for Capacity-Building: Department of State

The U.S. Department of State is engaged in on-going capacity-building efforts in the areas of human resources, public awareness, education and participation, information exchange and data management, and technology transfer. Its goal is to “build capacity, through collaborative projects, to develop and use biotechnology to address economic development and food security in developing countries.” The Department of State focuses specifically on supporting science-based biosafety regulation. It has also provided funds to the CBD Secretariat to assist with the establishment of the Biosafety Clearing-House and regional educational and
information-gathering workshops.

(Please note that the activities of the Department of State is not the only capacity-building work undertaken by the U.S. government. Other departments involved in this area include the U.S. Department of Agriculture, National Science Foundation, National Institutes of Health, and USAID.)
Appendix 3  A Selection of Individuals & Sources Consulted on Biosafety Research Questions

Dr. Christopher Briggs, Global Programme Manager, UNEP-GEF Biosafety Unit, International Environment House, 15, Chemin des Anémones 1219, Châtelaine, Geneva, Switzerland


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Mr. Charles Gbedemah, UNEP-GEF Development Project Regional Coordinator Africa, United Nations Environment Programme, Nairobi, Kenya

Mr. Koffi Dansey, UNEP-GEF Development Project Assistant Regional Coordinator for Francophone Africa, United Nations Environment Programme, Nairobi, Kenya

Dr. Urs Thomas, Faculty of Law, Université de Genève

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Mr. Erie Tamale, Environmental Affairs Officer, Capacity-building and Outreach, Biosafety, Secretariat of the Convention on Biological Diversity

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Appendix 4  Biosafety Bibliography

There is a near-infinite number of references on biosafety as illustrated by a search of the bibliographic information on the Biosafety Clearing-House, http://bch.biodiv.org/resources/references.aspx. These references relate to all facets of biosafety including the science, law, politics and ethics of the issue. CISDL has included resources it has found useful as part of its biosafety research in this bibliography.

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**Miscellaneous**


