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Biosafety Regulation

A Review of International Approaches

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Abstract

Appropriately deployed, genetically engineered plants have the potential to contribute to sustainable gains in agricultural productivity in developing regions. However, uncertainty about the potential for adverse environmental and human health consequences arising from the introduction of genetically engineered plants in agriculture has led to the development of regulatory regimes that are applied specifically to assess the safety of these products. The experiences of countries with long-established biosafety systems do not provide a model for a single best approach to ensuring biosafety. However, they do point to a common set of issues facing governments and policymakers. These issues can be divided broadly into the design and objectives of a regulatory system; implementation mechanisms and regulatory structures; and a series of crosscutting considerations that include transparency, public involvement, integrating biosafety regulation in other national policy objectives, and regional or international harmonization. Drawing from selected country experiences, this report explores each of these issues in detail and provides policy direction on points of consensus.

Preface

The purpose of this volume is to provide the World Bank Agriculture and Rural Development Department (ARD) with a review of the key issues and policy options pertaining to the development and implementation of national biosafety systems. This information may be used by the department to inform its programs in biosafety capacity building.

The techniques of agricultural biotechnology are being applied to modify plants, animals, fish, veterinary biologics, and micro-organisms. However, the focus of this report is crop biotechnology, because it is genetically engineered plants that developing countries are immediately faced with evaluating for human, livestock, and environmental safety. To provide additional detail on the regulatory approaches that have been tested in countries in which genetically engineered plants have been approved for commercialization, country-specific examples of biosafety policies and practices related to crop biotechnology are presented in appendix 1.

This report synthesizes and builds on many of the issues and concepts introduced in a recent text, “A Framework for National Biosafety Implementation: Linking Policy, Capacity, and Regulation.”¹

¹ M. A. McLean, B. Frederick, P. L. Traynor, J. Cohen, and J. Komen, “A Framework for National Biosafety Implementation: Linking Policy, Capacity, and Regulation,” ISNAR Briefing Paper 47 (Mar. 2002)), The Hague.

Acronyms

ACRE	Advisory Committee on Releases to the Environment (UK)
AEBC	Agriculture and Environment Biotechnology Commission (UK)
AHAS	acetoxyacid synthase
AIA	Advance Informed Agreement
ALS	asacetolactate synthase
ANZFA	Australia New Zealand Food Authority
ANZFSC	Australia New Zealand Food Standards Council
APHIS	Animal and Plant Health Inspection Service (US)
AQIS	Australian Quarantine and Inspection Service
BIOCOG	Biotechnology Consultative Group (Australia)
BSE	bovine spongiform encephalopathy
<i>Bt</i>	<i>Bacillus thuringiensis</i>
CBAC	Canadian Biotechnology Advisory Committee
CBD	Convention on Biological Diversity
CBS	Canadian Biotechnology Strategy
CFIA	Canadian Food Inspection Agency
CFR	Code of the Federal Register (US)
CONABIA	Comision Nacional Asesora de Biotecnologia Agropecuaria (National Advisory Committee on Agricultural Biosafety) (Argentina)
DNA	deoxyribonucleic acid
EC	European Commission
EU	European Union
EEC	European Economic Commission
EPA	Environmental Protection Agency (US)
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration (US)
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FONSI	Finding of No Significant Impact
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GT	gene technology
ha	hectare(s)
HT	herbicide-tolerant
IAEA	International Atomic Energy Agency
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
IOGTR	Interim Office of the Gene Technology Regulator (Australia)
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ISNAR	International Service for National Agricultural Research
LMO	living modified organism
MARL	Ministry of Agriculture and Land Reclamation (Egypt)
MOSST	Ministry of State for Science and Technology (Canada)
NAS	National Academy of Sciences (US)
NBC	National Biosafety Committee (Egypt)
NBS	National Biotechnology Strategy (Canada)
NOHSC	National Occupational Health and Safety Commission (Australia)
NRA	National Registration Authority (Australia)
OECD	Organisation of Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator (Australia)

PPA	Federal Plant Protection Act (US)
PNTs	plants with novel traits
rBST	recombinant bovine somatotropin
rDNA	recombinant deoxyribonucleic acid
SAGENE	South African Genetic Experimentation Committee
SAGPyA	Secretary of Agriculture, Livestock, Fisheries and Food (Argentina)
SENASA	National Service of Health and Quality Agrifood (Argentina)
TGA	Therapeutic Goods Administration (Australia)
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Programme
UPOV	International Union for the Protection of New Varieties of Plants
USDA	Department of Agriculture (US)
WHO	World Health Organization

1. Introduction

1. Properly applied, agricultural applications of modern biotechnology have a significant potential to contribute to sustainable gains in agricultural productivity and to reduce poverty and enhance food security in developing regions.² Recent advances in molecular techniques have provided plant breeders with the unprecedented ability to introduce new traits into plants that could not have been accomplished through traditional cross-breeding.³ These new traits include enhanced resistance to diseases responsible for significant yield loss, tolerance to drought and soils contaminated with high concentrations of salt or heavy metals, and improved productivity potential. Modern biotechnology also is being used to create new food plants that exhibit improved nutritional traits, such as “golden rice” with increased vitamin A content or tomatoes with elevated levels of lycopene, and to create functional foods, such as edible vaccines.

2. The far-reaching possibilities of these new technologies and uncertainty about the potential for adverse environmental and human health consequences arising from the introduction of genetically engineered plants in agriculture has led to the development of regulatory regimes that are specifically applied to assess the safety of these products.⁴ The development of an effective national biosafety system is important to encourage the growth of domestic biotechnologies; ensure safe access to new products and technologies developed elsewhere; and provide for a level of public confidence that products placed on the market have been assessed as safe. The absence of a suitable framework hinders the ability of development agencies and the public and private sectors to invest in biotechnology within a particular country and to make the products of biotechnology available in that country. A biosafety framework typically includes

- ❑ A national policy specifically for biosafety that may stand alone or encompassed within a larger strategy for biotechnology
- ❑ A regulatory system that includes mechanisms for risk assessment and risk management
- ❑ Systems for monitoring and inspection

² Modern biotechnology has been variously defined. For this paper, the definition from the Cartagena Protocol on Biosafety is adopted:

“Modern biotechnology means the application of : *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.”

³ These include recombinant-deoxyribonucleic acid (rDNA) techniques and others, such as recombinant-RNA and cell fusion. The first recombinant-DNA molecule was created in 1972 by researchers at Stanford University. The group, led by Paul Berg, who received a Nobel Prize for the work, used enzymes found in bacteria—called restriction endonucleases—to cut DNA from two different sources (a bacterium and a virus) and used a different enzymatic reaction to splice these two foreign pieces of DNA together to create a functional, hybrid DNA molecule. In 1973 Stanley Cohen, also from Stanford, and Herbert Boyer, from the University of California at San Francisco, took this work to the next level by transferring an rDNA molecule into a bacterium in which it functioned alongside the bacterium’s own genes. In so doing, they created the first “genetically engineered” organism.

⁴ Common synonyms for “genetically engineered” include “genetically modified,” “transgenic,” “product of modern biotechnology,” and “product of rDNA technology.”

□ Procedures for ensuring transparency, public participation and accountability.

3. Internationally, the need to ensure biosafety through national systems of risk assessment was recognized as a priority within the Convention on Biological Diversity (CBD),⁵ and more explicitly within Chapter 16 of Agenda 21.⁶ The most prominent result has been the Cartagena Protocol on Biosafety, which addresses the safe transfer, handling, and use of living modified organisms (LMOs).⁷ The protocol, adopted in Montreal on January 29, 2000, has been signed by 100 countries and, as of June 30, 2002, ratified by 21. It requires ratification by 50 governments before it can come into force.

4. The objective of the Cartagena Protocol is to:

...contribute to ensuring an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.⁸

5. The protocol allows governments to signal whether or not they are willing to accept imports of agricultural commodities that include LMOs by communicating their decision to the world community via a Biosafety Clearing House, a mechanism set up to facilitate the exchange of information about LMOs and experience with them.⁹ In addition, commodities that may contain LMOs are to be clearly labeled as such when being exported. Stricter Advance Informed Agreement (AIA) procedures will apply to seeds, live fish, and other LMOs that are to be intentionally introduced into the environment. In these cases, the exporter must provide detailed information to each importing country in advance of the first shipment; the importer can then either authorize or refuse the shipment. The aim is to ensure that recipient countries have both the opportunity and the capacity to assess the risks associated with the products of modern biotechnology.

6. The CBD, Agenda 21, and the Cartagena Protocol all place significant emphasis on strengthening human resources and institutional capacity in biosafety within those countries that have yet to establish, or are in the process of establishing, biosafety frameworks.

⁵ Convention on Biological Diversity (CBD), 5 June 1992, Rio de Janeiro. <<http://www.biodiv.org/>>.

⁶ Chapter 16 of Agenda 21, entitled “Environmentally Sound Management of Biotechnology,” seeks to “to foster internationally agreed principles to be applied to ensure the environmentally sound management of biotechnology, to engender public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms, especially within developing countries, through the following activities:

- 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;
- Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology.”

United Nations Conference on Environment and Development (UNCED), Agenda 21, U.N. Doc. A/CONF.151/26, vols. I–IV, 1992.

⁷ “Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. From the Cartagena Protocol on Biosafety, Article 3 (g).

⁸ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, text and annexes, Secretariat of the Convention on Biological Diversity, Montreal, 2000 <<http://www.biodiv.org/biosafety/protocol.asp>>.

⁹ The pilot phase of the Biosafety Clearing House can be viewed at <<http://bch.biodiv.org/Pilot/Home.asp>>.

7. Although the experiences of countries with long established biosafety systems do not provide a model for a single best approach to ensuring biosafety, they do point to a common set of issues facing governments and policymakers. These issues can be divided broadly into issues related to the design and objectives of a regulatory system, implementation mechanisms and regulatory structures, and a series of crosscutting considerations that include transparency, public involvement, integrating biosafety regulation into other national policy objectives, and regional or international harmonization. Drawing from selected country experiences (appendix 1), this report explores each of these issues in detail and provides policy direction on points of consensus.

2. Biosafety

2.1. CONCEPTS OF BIOSAFETY RISK ASSESSMENT

8. As it will be treated in this report, the concept of biosafety involves assessing, monitoring, and managing the potential risks associated with living genetically engineered organisms on the health of ecosystems, plants, animals, and human beings. In this context, biosafety does not explicitly focus on issues pertaining to the safety of foods derived from genetically engineered plants or animals.

9. Concerns about potential adverse environmental and human health consequences arising from the introduction of genetically engineered plants in agriculture has led to the development of regulatory regimes that specifically assess the safety of these products. Central to these systems is a framework for biosafety risk assessment that evaluates the characteristics of the organism, the introduced trait, the environment into which the organism is introduced, the interaction between these, and the intended application.

10. Risk assessment is often defined as a science-driven *process of obtaining quantitative or qualitative measures of risk levels, including estimates of possible health effects and other consequences as well as the degree of uncertainties in those estimates,*¹⁰ free of the emotive factors that influence risk perception. The objective of risk assessment is to produce neutral and transparent risk information to inform the decisionmaking (risk management) function.

11. The focus of risk assessment must be on asking empirical questions about hypothetical risks, not speculative risks. That is, risk should be something that is testable by empirical means, rather than based on unsubstantiated logical possibilities. For example, the risk of altering a plant's potential for weediness as a consequence of genetic engineering is something that can be evaluated by assessing specific characteristics of the modified plant in relation to known weedy species (for example, seed dormancy, seed germination rates, seed dissemination, time to maturity, competitiveness). On the other hand, the risk of potential horizontal gene transfer from plants to other organisms is more speculative and is not amenable to direct testing case by case. Placing the emphasis on empirical questions and testable risks implies that disputes or uncertainties can be resolved through further study and analysis, something which is not possible for speculative risks based solely on potentialities.

12. Focusing on testable risks does not imply that "no evidence" means "no risk," nor that new analytical methods cannot be developed and applied. In the face of scientific uncertainty, or when risk assessment results are inconclusive, it is essential that improved analytical tools be developed and that provisional risk management decisions be taken on a precautionary basis.

13. When approached in this manner, the risk assessment process is reserved for experts only and is not open to considering normative questions, such as ethics or socioeconomic impacts. Risk assessments are not the appropriate vehicles for assuaging public fears (that is, perceptions of risk) or proving social benefit.

¹⁰ J. Fiksel and V. T. Covello, *Biotechnology Risk Assessment—Issues and Methods for Environmental Introductions* (Oxford, UK: Pergamon Press, 1986).

Familiarity

14. Assessing the environmental safety of a genetically engineered plant requires familiarity with the biology of the crop plant itself and the agricultural practices employed in its cultivation. This concept of familiarity is a key approach used in identifying and evaluating environmental risks and also in informing practices that may be needed to manage recognized risks. For example, knowledge about the biology of the plant can help identify species-specific characteristics that may be affected by the introduced trait, thus permitting the genetically engineered plant to become “weedy,” invasive of natural habitats, or otherwise harmful to the environment.

15. Likewise, the introduction of a new trait may result in changed agricultural practices that effect the environment. The widespread cultivation of herbicide-tolerant (HT) rapeseed (*Brassica napus*; canola) in the Canadian prairies has led farmers to switch to “no-till” cultivation.¹¹ Farmers are able to seed HT plants directly into the stubble of the previously harvested crop without any prior cultivation. This ability enables both soil conservation (topsoil is held in place by the residue of the previous crop) and water conservation (the stubble cover allows for better water retention and inhibits evaporation).

16. Transgenic plants expressing stress tolerance genes are much sought after, particularly for production in soils damaged by salinization or alkalization, or in environments in which water is the limiting factor for food production. Stress tolerance also may be used to extend the typical zones of production of a crop plant. For example, cold tolerance is considered a desirable trait, because it can be used to limit frost damage to crops and consequently extend production seasons. Cold tolerance also may permit the introduction of novel plants into areas in which they previously had not been grown. Introduction of novel plants approximates the introduction of an exotic species so necessitates the same close examination for potential ecosystem disruption.

17. Other ecological risks that must be assessed include the impact of introduced traits introgressing into related plant species through outcrossing, the potential build-up of resistance in insect populations to engineered insecticidal traits, unintended secondary effects on nontarget organisms, and potential effects on biodiversity. In this regard, it is important to distinguish between the biodiversity of natural populations and that of crops and other organisms within the agro-ecosystem. It is the latter context that is most relevant within the environmental risk assessment process for genetically engineered plants, which is designed to evaluate the incremental risks associated with replacing a conventional crop variety with a genetically engineered one.

Substantial Equivalence

18. In performing the environmental risk assessment of genetically engineered plants, the concept of familiarity is coupled with that of substantial equivalence. The latter is based on the principle that genetically engineered plants can be compared with their nontransformed counterparts that have an established history of safe use. The objective is to determine whether the genetically engineered plant presents any new or greater risks in comparison with its traditional counterpart, or whether it can be used interchangeably with its traditional counterpart without negatively affecting the environment in which it is grown. The goal is not to establish an absolute level of safety, but rather a relative level of safety, so that there is a reasonable certainty that no undue risk to the environment will result from the cultivation of the genetically engineered plant under anticipated conditions of production.

¹¹ In 2001 it was estimated that about 81% of the canola seeded was comprised of herbicide-tolerant varieties. The breakdown was 45% glyphosate-tolerant (transgenic), 16% glufosinate ammonium-tolerant (transgenic), 20% imidazolinone-tolerant (mutagenesis), and 19% conventional (Canola Council of Canada).

19. For example, the Cartagena Protocol includes the following a general principle for risk assessment of LMOs:

Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the nonmodified recipients or parental organisms in the likely receiving environment.¹²

20. Applying the concept of substantial equivalence requires that sufficient analytical data be available in the literature, or be generated through experimentation, to allow effective comparison between the genetically engineered plant and its traditional counterpart. A problem arises in that risk factors generally have not been established for traditionally bred plant varieties, so there is limited baseline information about the environmental risks associated with their introduction. This lack suggests a basic limitation of the substantial equivalence concept: dependence on a comparator, and on the information that is available or can be generated for the comparator, means safety assurance is relative to the components assessed for the particular comparator. The choice of comparator, therefore, is crucial to effective application of the concept of substantial equivalence.

21. Over the years, the use of substantial equivalence has been both endorsed as a useful risk assessment tool,¹³ and the subject of criticism,¹⁴ particularly that the approach is subjective, inconsistent, and “pseudo-scientific.”¹⁵ The terminology of “substantial equivalence” has been used and interpreted inconsistently among different regulatory and risk assessment experts. In addition to being used as a way of describing the approach to safety assessment, as discussed above, “substantially equivalent”¹⁶ has been used to connote a determination of safety¹⁷ following the assessment of a genetically engineered food or crop.¹⁸

¹² Conference of the Parties to the Convention on Biological Diversity. Cartagena Protocol on Biosafety, Appendix III. 29 January 2000

¹³ FAO/WHO, “Biotechnology and Food Safety,” FAO Food and Nutrition Paper 61 (1996) and “Safety Aspects of Genetically Modified Foods of Plant Origin” (2000). Reports of Joint Food and Agriculture Organization/World Health Organization Consultations., Rome.

OECD, “Report of the Task Force for the Safety of Novel Foods and Feeds,” C(2000)86/ADD, Organisation for Economic Co-operation and Development, Paris, 2000.

¹⁴ Royal Society of Canada, “Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada,” Ottawa, 2001. <http://www.rsc.ca/foodbiotechnology/indexEN.html>

¹⁵ E. P. Millstone, E. J. Brunner, and S. Mayer. “Beyond ‘Substantial Equivalence,’” *Nature* 401 (1999): 525–26.

¹⁶ When used to describe a genetically engineered food, “substantially equivalent” is not meant to convey that the new food is the same as the traditional food but rather that it can be used interchangeably in the diet with its traditional counterpart without affecting the health or nutritional status of consumers.

¹⁷ “Substantial equivalence embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety (that is, the food or food component can be concluded to be as safe as the conventional food or food component).” FAO/WHO, “Biotechnology and food safety.”

¹⁸ “GA21 and corn hybrids derived from it have been assessed and found to be substantially equivalent to traditional corn varieties. GA21 and its byproducts are considered to meet present ingredient definitions and are approved for use as livestock feed ingredients in Canada.” Decision Document 1999-33: Determination of the Safety of Monsanto Canada Inc.'s Roundup

22. Notwithstanding its limitations and critics, the concept of substantial equivalence remains a practical approach to framing the risk assessment, for which there currently are no better alternatives.¹⁹ Generally, this opinion has also been expressed in the most recent report of the Royal Society of London,²⁰ which stated that “some form of substantial equivalence, starting with a direct comparison of the novel foodstuffs with their unmodified counterparts, appears to be the only practical solution.”

Risk Management

23. Risk management is a decisionmaking process that is supported by risk assessment but also may be informed by other issues (as permitted in regulations). As we have presented it, risk assessment is a rigorous scientific tool that provides an objective measure on which to base a decision. In practice, it is rarely that clear cut. It is difficult to dissociate the perceptions of risk from risk assessment and impossible to ignore the uncertainty in science that limits objective quantification of risk. Furthermore, by itself, “sound science” cannot tell us the right choices to make. In the face of these realities, the realization is growing that risk management must consider more than just science and that, to gain stakeholder acceptance, it must address stakeholders’ key concerns.

24. In this sense, risk management is essentially a political process that takes into account societal values around acceptable levels of risk and scientific uncertainty to act in the public interest. Very often, it involves balancing individual rights (developers, industry, organizations) with the need to protect human health and the environment, including animal and plant health, from the adverse effects of unacceptable risks. Ideally, the political, social, economic, legal, ethical, and physical environments within which risk management decisions are made are properly defined and transparent.

25. Among the legitimate factors to be considered during decisionmaking are the potential benefits arising from the adoption of a new product. For example, although the introduction of herbicide-tolerant crops has given rise to concerns of even more widespread use of herbicides, the herbicides to which tolerant crops are being produced are those that are less persistent in the environment than some of the herbicides being replaced. Similarly, the introduction of insect-resistant crops, particularly Bt (*Bacillus thuringiensis*) cotton, has led to significant reductions in pesticide applications, with a resulting decrease in pesticide-related farm-worker illness.

26. Consideration also should be given to the risks associated with not using biotechnology to achieve desired goals. For example, the biodiversity of tropical rain forests can be maintained only if these natural ecosystems are not destroyed as a consequence of expanding the agricultural land base.

27. In actual fact, however, there are no biosafety regulatory systems that have formally included a benefits assessment within their regulatory structure. While benefits are not explicitly incorporated in decisionmaking, they may implicitly be awarded value during the risk assessment when the genetically engineered product is compared to its conventional counterpart.

Ready™ Corn (*Zea mays* L.) Line GA21, Canadian Food Inspection Agency
<<http://www.inspection.gc.ca/english/plaveg/pbo/dd/dd9933e.shtml>>.

¹⁹ FAO/WHO, “Safety Aspects of Genetically Modified Foods of Plant Origin,” FAO/WHO consultation 29 May–2 June 2000, World Health Organization, Geneva, 2000.

²⁰ The Royal Society of London, “Genetically Modified Plants for Food Use and Human Health—An Update,” Policy Document 4/02 (Feb. 2002).

2.2. BIOSAFETY CAPACITY BUILDING

28. The CBD, Agenda 21, and the Cartagena Protocol all place significant emphasis on strengthening human resources and institutional capacity in biosafety. The protocol makes clear that Parties to the protocol must develop or have access to “*the necessary capacities to act on and respond to their rights and obligations.*”²¹ These capacities include those related to legal and administrative matters, policy development and implementation, decisionmaking, and scientific analysis.

29. Successful implementation of the protocol is contingent on the development of national biosafety capacity in those countries that have yet to establish, or are in the process of establishing, biosafety frameworks. The protocol provides considerable flexibility with respect to how importing countries may meet their obligations with respect to risk management decisionmaking and the implementation of these decisions. As stated in Article 16, which deals with risk management, each Party has an obligation to “*establish and maintain appropriate mechanisms, measures and strategies to regulate manage and control risks identified in the risk assessment provisions.*” Parties have agreed to carry out these risk management functions under the protocol, but how a country fulfills this obligation is not clarified. The protocol also recognizes that developing country Parties and Parties with economies in transition will require assistance to achieve this,²² including financial support.²³

²¹ Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), “Indicative Framework for Capacity Building under the Cartagena Protocol on Biosafety,” Secretariat of the Convention on Biological Diversity, Montreal, 2000.

²² Cartagena Protocol, Article 22: Capacity Building

“The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, sub regional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity building in biosafety. Cooperation in capacity building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity building in biosafety.”

²³ Cartagena Protocol, Article 28: Financial Mechanism and Resources

“In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

Regarding the capacity building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity building requirements for the purposes of the implementation of this Protocol.

2.3. ISSUES IN BUILDING NATIONAL BIOSAFETY REGULATORY SYSTEMS

30. There are no examples of existing biosafety regulatory systems that were developed *de novo* from a comprehensive plan designed from the outset to anticipate every contingency and to be integrated and coherent, both internally and with other national and international policies. In the countries in which they exist, biosafety regulatory systems were developed piecemeal, usually beginning with voluntary guidelines and standards developed cooperatively by academia, industry, and government. Over time, these guidelines and standards were incorporated in statutory instruments, either under existing legislation covering food and agricultural products or under new legislation dealing specifically with gene technology. The evolution of biosafety policy and its implementation is ongoing, and to have a mix of voluntary and statutory mechanisms, even in those countries with long-established systems, is not unusual.

31. For countries seeking to develop a national biosafety regulatory system, it must be emphasized that there is no model for a single best approach. There are, however, a number of issues to be considered during conceptualization and implementation. These can be broadly divided into

- ❑ Design issues related to regulatory triggers
- ❑ Balancing inputs from the natural and social sciences
- ❑ Approaches to risk assessment
- ❑ Implementation issues relating to legislative approach (voluntary guidelines vs. statutory instruments)
- ❑ Structural elements necessary for risk assessment, inspection, monitoring, and enforcement
- ❑ Horizontal issues around integrating biosafety regulation in other national policy objectives
- ❑ Transparency and citizen engagement
- ❑ Regional or international cooperation and harmonization to leverage available expertise.

32. Drawing from selected country experiences (see appendix 1), the following three chapters explore each of these issues in detail and provide policy direction on points of consensus.

The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

The developed country Parties also may provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.”

3. Approaches to Designing Biosafety Regulations

3.1. PRODUCT VS. PROCESS APPROACH TO REGULATORY OVERSIGHT

33. Process-based regulation is the rule in almost all countries that have developed national biosafety regulatory systems. Even in countries employing a product-focused risk assessment process, the scope of regulatory oversight is defined by the process of genetic engineering. The case is the same for the Cartagena Protocol on Biosafety, which focuses specifically on living modified organisms, defined as

any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology” and modern biotechnology as “the application of: a. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or; b. fusion of cells beyond the taxonomic family.

34. Very clearly, the protocol is limited to addressing biosafety concerns that may be associated with the products of modern biotechnology, irrespective of the trait or traits that an LMO may express.

35. Canada is the only country in which regulatory oversight is triggered solely by the novelty of traits expressed by plants or the novel attributes of foods or food ingredients, irrespective of the means by which the novel traits were introduced. This “product-based” approach to regulation has been validated by numerous scientific bodies and expert consultations as being consistent with the scientific principle that the risks associated with genetically engineered plants and foods are not inherently different than the risks associated with products of more conventional breeding techniques.²⁴

36. The difference between product vs. process triggers can be illustrated using the example of herbicide-tolerant oilseed rape, varieties of which have been developed using both genetic engineering (for

²⁴ “No strict distinction exists between the health and environmental risks posed by plants genetically engineered through modern molecular techniques and those modified by conventional breeding practices.” U.S. National Research Council (U.S. NRC) press release, May 2000, following publication of the U.S. NRC report, *Genetically Modified Pest-Protected Plants: Science and Regulation* (The National Academies Press, Washington D.C., 2000).

“Risks associated with biotechnology -derived foods are not inherently different from the risks associated with conventional ones.” and “There is no scientifically valid reason to treat possible gene transfer events involving genetically engineered organisms differently from those involving naturally occurring organisms. In any case, it is the gene and the trait it confers, and whether or not it brings a reproduction or selection advantage to the recipient organism that are crucial concerns when possible impacts of potential gene transfer are being considered.” OECD (Organisation for Economic Cooperation and Development), “Report of the Task Force for the Safety of Novel Foods and Feeds,” Paris, 2000
<www.oecd.org/subject/biotech/report_taskforce.pdf>.

“Genetically engineered organisms should be evaluated and regulated according to their biological properties (phenotypes), rather than according to the genetic techniques used to produce them.” J. M. Tiedje, R. K. Colwell, Y. L. Grossman, R. E. Hodson, R. E. Lenski, R. N. Mack, and P. J. Regal, “The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations, *Ecology* 70 (1989): 298–315.

“Plant breeders use a variety of genetic techniques to enhance the ability of plants to protect themselves from plant pests. Regardless of the technique used, the committee considers these plants to be genetically modified.” National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* (Washington, D.C.: National Academy Press, 2000).

example, glyphosate tolerant)²⁵ and more established plant breeding tools, such as accelerated mutagenesis (for example, imidazolinone tolerant).^{26, 27} Each technology has the potential to introduce genetic changes resulting in unintended or unanticipated consequences, and the environmental impact of outcrossing from each of these herbicide-tolerant varieties is the same: recipient progeny could be herbicide tolerant. Building on this example, it is certainly feasible to create glyphosate-tolerant plants using the techniques of accelerated mutagenesis, or, similarly, to create imidazolinone-tolerant plants using genetic engineering methods. The technology of accelerated mutagenesis has been in use for about 70 years, while the genetic engineering of plants was introduced within the last 20 years.²⁸ Nevertheless, in every country except Canada, the only herbicide-tolerant varieties that are subject to environmental or food safety risk assessment or regulatory oversight are those produced through genetic engineering.

37. While Canada's approach is truest to the scientific principle that biotechnology is not inherently more risky than other technologies that have a long and accepted history of application in agriculture and food production, it is less prescriptive than process-based regulatory systems. Thus, it is more challenging for both developers and regulators to determine when a plant is a "plant with a novel trait" as defined in Canadian regulations than the simple test of whether it was produced using recombinant DNA or cell fusion technology.²⁹ In addition, ensuring compliance with regulations prohibiting the importation of unapproved "plants with novel traits" is technically and financially impracticable. Unlike products of genetic engineering in which the genetic basis of the novel trait (for example, the introduced DNA) is well characterized, plants with novel traits produced by accelerated mutagenesis or wide outcrossing, for example, may not have any readily identifiable markers suitable for diagnostic screening.

38. The development of biosafety regulations consistent with the philosophy of the Cartagena Protocol implies a trigger for regulatory oversight based on the process of genetic engineering rather than on the risks associated with the introduction of novel traits in plants and foods. Despite the scientific contradictions inherent in this approach, international consensus favors regulatory oversight limited by the narrow scope of genetic engineering. Generally, this consensus has been motivated by the observation that, in the absence of some system of *ex ante* evaluation to determine when a new plant variety does express a novel trait requiring more elaborate biosafety risk assessment, some form of "process-based" (for example, process of genetic engineering) regulatory trigger is the most practical approach.

²⁵ Glyphosate is an amino acid analogue that specifically binds to, and inactivates, the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS). The EPSPS enzyme, which is present in all plants and microorganisms but not in humans or animals, is involved in the biosynthesis of essential aromatic amino acids. Because these amino acids are needed for protein synthesis, which is required for plant growth and maintenance, the application of glyphosate quickly results in plant death.

²⁶ Imidazolinone herbicides are active against the enzyme acetohydroxyacid synthase (AHAS), also known as acetolactate synthase (ALS). This enzyme catalyzes the first step in the biosynthesis of the essential branched chain amino acids isoleucine, leucine, and valine.

²⁷ Using the former approach, the gene encoding a herbicide-tolerant form of a bacterial enzyme (analogous to the same enzyme present in plants) is introduced into the plant genome using recombinant-DNA technology, while with the latter method, mutations in the plant genome are induced by the application of mutagenic chemicals or ionizing radiation. In each case, plants displaying the trait of herbicide tolerance are selected (usually in tissue culture), and the new trait subsequently is transferred into commercially important varieties via traditional cross-breeding.

²⁸ By 2000, the Food and Agriculture Organization of the United Nations (FAO) estimated that more than 2200 cultivars worldwide had been produced either directly or indirectly by using this technique. M. Maluszynski and others, "Officially Released Mutant Varieties—The FAO/IAEA Database," in *Mutation Breeding Review* 12 (Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture and FAO/IAEA Agriculture and Biotechnology Laboratory, Vienna, 2000.)

²⁹ Agriculture and Agri-Food Canada (AAFC), JUS-96-004-01 (SOR/DORS): Amendments to the Seeds Regulations—Release of Seed (1996) <<http://www.inspection.gc.ca/english/plaveg/pbo/96004e.shtml>>.

Options

Product vs. process regulatory trigger

39. The use of a product-based approach to trigger regulatory oversight of products of modern biotechnology may be scientifically defensible. However, it is the process of genetic engineering that raises environmental and human food safety concerns with the public. Given that all but one country has chosen to adopt a process-based approach to regulatory oversight, it may be advisable for countries establishing biosafety systems to do the same.

3.2. BALANCING SCIENCE AND SOCIAL CONCERNS IN RISK MANAGEMENT

40. All countries face major dilemmas with respect to integrating the natural and social sciences in public decisionmaking. In Western societies, science has played a prominent role in public decisions, with scientific knowledge often being equated with “truth.” Developments in recent years have called into question this special status. Examples such as the bovine spongiform encephalopathy (BSE) crisis and dioxin-tainted Belgian beef all have contributed to the growing realization that scientific expertise used in decisionmaking is neither necessarily disinterested nor objective. Ideally, decisionmakers and scientists should have a close and continuing interaction based on mutual confidence, respect, and trust. However, cultural differences between the two groups, exacerbated by the undermining of the “science is truth” paradigm, have made such a positive relationship difficult to secure.

41. Within the context of a product of modern biotechnology, the need to consider possible socioeconomic risks was first brought to the fore, with the introduction of recombinant bovine somatotropin (rBST).³⁰ In implementing its original moratorium on rBST in 1990, the European Commission indicated, among other concerns, that the marketing of rBST might have a significant impact on milk productivity, and consequently on the European Community’s milk policy.³¹ Following years of intense debate, the European Commission issued an outright ban on marketing rBST within member states, effective 1 January 2000. Over the years, different reasons have been used to justify the moratorium and, ultimately, the ban on rBST. First, internal agricultural policy reasons were in vogue, then fears about a consumer backlash, next public health concerns, and, finally, animal health and welfare

³⁰ Bovine growth hormone (BGH; also referred to as bovine somatotropin, or BST) is a naturally occurring peptide growth hormone that regulates a cow’s milk production. In the late 1970s, Dale Bauman, Ph.D., an animal scientist at Cornell University, successfully transferred the gene responsible for BGH production in cows to a bacterium. The resulting product was called recombinant bovine growth hormone, or rBGH (or rBST). Simple multiplication of the bacterium meant that it could easily be produced in commercial quantities at a very reasonable cost. Four companies involved in rBST research applied for patents for their particular brands of rBST in the early 1980s, which resulted in many misstatements, exaggerations, and misunderstandings. The United States Congress held hearings in June 1986, and the basic findings were:

When injected in a cow, rBST could cause a 10%–25% increase in milk production;

There was also a 10%–15% increase in feed efficiency. This means that there was an effective decrease in feed costs per unit of milk produced, and therefore a lower average cost of production; rBST appeared to be safe both for human milk consumption and for cows.

The United States Food and Drug Administration approved rBST in November 1993, and the first commercial products were available in February 1994. However, the controversy surrounding rBST that has existed since the early 1980s continues. Specifically, questions have been raised about adverse health effects on animals treated with rBST, the appropriateness of the technology for an industry plagued with surpluses, the effects of increased milk production on milk prices, and the plight of the family farm.

³¹ Council Decision 90/218/EEC, OJ No. L 116 May 8, 1990.

concerns. Regarding the last justification, the European Union (EU) is following the same policy line as adopted by Canada on the issue. A different approach has prevailed in the United States, where the Executive Branch concluded a review of the literature on the social impacts of rBST with the statement: “At no time in the past has the Federal Government prevented a technology from being adopted on the basis of socioeconomic factors.”³²

42. The application of modern biotechnology to the genetic engineering of plants and in food production generally has given rise to widespread discussion on its social, ethical, and, at times, economic, acceptability. To date, no international consensus exists on how, or indeed whether, these concerns, which relate largely to justice, beneficence, and respect for cultural diversity, should be considered within a product approval system, or more generally within a national biosafety strategy. In Canada and the United States, science largely “determines” the regulatory decision, while in the European Union, science is but one consideration along with other factors that play a crucial role in the decisionmaking process. Notwithstanding these differences, a strong scientific capacity and knowledge base are essential to identifying hazards and assessing their impacts and likelihoods.

43. The Cartagena Protocol on Biosafety also does not reconcile the consideration of “safety” vs. “nonsafety” issues and provides little guidance on how these different types of concerns may be blended into the decisionmaking process. In carrying out risk assessments, the protocol acknowledges the primacy of the scientific method, the notion that scientific uncertainty should not be interpreted as a particular level of risk, and the importance of transparency in decisionmaking. Seemingly at odds with this approach, the protocol also provides for the consideration of nonsafety issues when it states that, in making decisions, the Parties “*may take into account, consistent with their international obligations, socioeconomic considerations arising 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*” (Article 26). This issue also is central to the uncertain relationship between the protocol and World Trade Organization (WTO) regulations, which state that the regulation of trade must be based on “sound scientific knowledge.” The WTO also does not accept socioeconomic concerns, such as the risk that exports of LMOs may replace traditional crops and undermine local cultures and traditions in importing countries, which are just the types of concerns that form part of the decisionmaking process under the Biosafety Protocol.

Options

Evidence-based scientific evaluation only vs. consideration of social factors as well

44. A decision to approve/disapprove a genetically engineered plant or food may be based exclusively on the results of the risk assessment or also may incorporate other political, social, economic, or ethical issues. The former is more common than the latter in those countries that have approved genetically engineered plants for commercialization. Critically, it is imperative that the factors that are used to inform decisions be transparent so that the public as well as product proponents understand how decisions are made. If socioeconomic factors are incorporated in risk management, their application should be defined within the regulations so that it is explicit that they are part of the regulatory decisionmaking process and are not considered within the risk assessment. Equally important is the creation of a regulatory structure that allows separation of the risk assessment and risk management processes. For example, a tiered approach, such as that in South Africa, provides a system in which the regulatory decision is “informed” by both the scientific risk assessment and other considerations. In this tiered approach, appropriate

³² U.S. Executive Office of the President, “Use of Bovine Somatotropin (BST) in the United States: Its Potential Effects.” A study conducted by the Executive Branch of the Federal Government, Washington, D.C., 1994, 35–36.

consideration also must be given to the potential impacts on other international agreements and to ensuring adequate openness and transparency to counter criticisms of “political interference” in regulatory decisions.

Consideration of risks only vs. risks and benefits

45. Currently, no biosafety regulatory systems employ a benefits assessment to explicitly inform the decisionmaking process. Instead, benefits may be assessed implicitly during the risk assessment when the environmental impact of the genetically engineered plant is compared to its conventional counterpart. If a benefits assessment is to be explicitly used to inform the decision to approve or disapprove a product, the criteria for such an assessment must be clearly described within the regulations so that there is no ambiguity about its form and function.

4. Implementing Biosafety Regulations

4.1. STATUTORY VS. NON-STATUTORY INSTRUMENTS

46. Experiences from different countries have shown that effective biosafety frameworks can be based on nonstatutory guidelines, statutory regulations entrenched in existing or new legislation, or some combination of these approaches.³³ Biosafety regulatory systems can be viewed as continually evolving, and, within industrialized nations, generally were initiated as voluntary systems of information guidelines, codes of practice, or risk assessment criteria. The competent authorities develop information guidelines, and technology developers abide by them.³⁴ As examples, Argentina, Australia, Canada, Japan, most European countries, and South Africa, all have used nonstatutory guidelines to manage the environmental safety of LMOs before promulgating new acts or regulations. There is no evidence that the nonstatutory management of LMOs under these regimes has compromised environmental safety.

47. The United States Food and Drug Administration (FDA) provides an example of a regulatory management system for genetically engineered food that, to date, has been voluntary. The cornerstone of FDA's 1992 policy for foods derived from new plant varieties is that foods produced through the application of genetic engineering techniques are not inherently more risky than foods produced through more conventional means.³⁵ Since publishing this policy, FDA has conducted its reviews of genetically engineered foods by consulting with companies about the safety and composition of the food. It has not required a food additive petition for any genetically engineered product, although it could make such a request in the future. Under the guidelines for this voluntary consultation process, developers of food products from genetically engineered plants are asked to provide summary information of their safety and nutritional assessment and to make a scientific presentation of their data to FDA scientists.³⁶ Without exception, all developers of genetically engineered foods have participated in this voluntary scheme, and, to date, FDA has completed 53 consultations.³⁷

48. The benefits of implementing voluntary guidelines include the speed with which the guidelines can be put in place and their flexibility, since revisions to incorporate new information requirements can be adopted without delay. However, in the absence of a statutory instrument, they afford limited capacity for independent, legally enforceable auditing and monitoring of compliance. Depending on the discretionary power of the competent authority, there may be no legal basis for the imposition of penalties or other

³³ Voluntary guidelines may include standards for facilities and practices designed to prevent the unintended release of, or inadvertent exposure to, genetically modified organisms (GMOs) or recombinant DNA; conditions to ensure reproductive isolation and site monitoring during the conduct of confined field trials; and risk assessment standards that define criteria for conducting environmental or food safety assessments.

³⁴ The competent authority is the body responsible for overseeing the development and implementation of, and compliance with, biosafety measures. It may be a government department or agency, or a statutory or nonstatutory committee.

³⁵ Food and Drug Administration (FDA), Statement of Policy: Foods Derived from New Plant Varieties, *Federal Register* 57 (1990): 22984-3001.

³⁶ FDA, Guidance on Consultation Procedures: Foods Derived from New Plant Varieties, Washington, D.C. <<http://www.cfsan.fda.gov/~lrd/consulpr.html>>.

³⁷ FDA, List of Completed Consultations on Bioengineered Foods 2001, <<http://www.cfsan.fda.gov/~lrd/biocon.html>>.

action in the event of noncompliance, nor opportunities for the public to seek redress through the courts should negligence be suspected. Importantly, the public may not have confidence that the government is adequately regulating these products, or that developers are abiding by voluntary guidelines. In part because of political and public pressures to do so, both Australia³⁸ and South Africa³⁹ have implemented new acts specifically to regulate gene technology and genetically modified organisms. In addition, the U.S. FDA has proposed a new rule requiring that all new foods derived from biotechnology be subject to mandatory review prior to marketing.

49. The foundation of any biosafety regulatory system is authority. Authority refers to the enabling legislation (acts, laws, decrees, and government orders) governing biosafety. At the national level, it is the authority to promulgate regulations, supersede subnational authorities, intercede in trade or domestic movement, and implement enforcement actions. The establishment of regulations (or executive orders) is necessary to enact prohibitions, restrictions, and requirements under the authority of national legislation. Authority also is used to create policy instruments such as permits, guidelines, and information requirements.

Options

50. When it comes to establishing legally binding regulations, a country that elects to develop a statutory biosafety system has two options:

Develop a new act and regulations to specifically address gene technology and/or genetically modified organisms vs. regulate the technology and/or its products under the auspices of existing legal instruments.

51. The advantage of the former is that an act can be developed that specifically addresses the product or process to be regulated; it can provide flexibility so that new technical advances also can be captured without significant regulatory amendments; and it can be perceived by the public as a positive response to addressing safety concerns. The disadvantages of developing a new act include (a) the extended time that can be needed to have it passed into law, particularly in the politically charged environment around biotechnology that exists in so many countries today; and (b) the fact that it may result in the regulation of genetically engineered organisms in perpetuity so that even if a history of safe use is established, these products could still be singled out for exceptional regulatory oversight.

52. Alternatively, amending an existing act or regulations under an act may provide a more immediate means of instituting a mandatory program of risk assessment for genetically engineered organisms. In most cases, amendments of regulations are at the prerogative of the responsible minister while amendments of an act itself still may have to move through the legislature. However, amending an existing act or regulations under an act also can limit the scope of the regulatory program for the following reasons. The act or statute under which genetically engineered organisms are regulated may restrict opportunities to request and disclose biosafety-related information, police compliance and take punitive action if desirable, or provide for public participation in the regulatory process.

³⁸ Office of the Gene Technology Regulator, Gene Technology Act, 2000 (2001) <<http://law.agps.gov.au/cgi-bin/download.pl?/scale/data/pasteact/3/3428>>.

³⁹ S. R. Moephuli, Registrar, GMO Act, South Africa. Personal communication (2002).

4.2. REGULATORY STRUCTURES, SECURING SCIENTIFIC ADVICE, INSPECTION, AND ENFORCEMENT

Locating the Biosafety Regulatory Authority

53. Government policies toward biosafety and genetically engineered crops and foods can be reflected in the decision on which ministry or department is the competent authority with respect to biosafety regulation. With their involvement in the CBD and the resulting Cartagena Protocol on Biosafety, environment ministries have positioned themselves to play a key role in the development of new biosafety regulatory regimes. This potential new role for environment ministries often is outside their relevant experience and expertise and risks being at odds with the traditional roles of agriculture ministries, which are normally involved in the evaluation of new crop varieties for introduction into agriculture and for regulating quality standards for seeds, including their import and export.

Options

Locate the biosafety regulatory authority within the agriculture ministry within the environment ministry

54. Countries wishing to create an enabling or permissive environment for the adoption of agricultural biotechnology products generally have placed the biosafety decisionmaking authority within agriculture ministries. As a rule, environment ministries have a much more cautious or preventive approach to introducing new technologies.⁴⁰ Thus, investing environment ministries with biosafety regulatory authority signals this approach as a significant government policy.

Concentrate the risk assessment and risk management functions within a single identifiable body vs. distributing this function among different government departments and ministries.

55. The responsibility to assess the biosafety of genetically engineered plants and their products can be situated within a single body, or may be distributed among a number of different government departments or government-appointed advisory committees. From a practical standpoint, the former may be simpler since the regulatory authority can act as a “single window” to coordinate the receipt and assessment of each regulatory package. The single body approach also provides a single point of contact for the public and other key stakeholders.

Securing Scientific Advice

56. Different structural approaches can and have been used to secure the necessary scientific advice for government decisionmaking. In considering the risk assessment of biotechnology products, some countries, such as the United Kingdom, have implemented a system of expert advisory committees, while others, such as the United States and Canada, have relied primarily on scientists and professionals working within government departments and agencies. Other countries, for example, Australia, have a combination of both.

57. Each approach has strengths and weaknesses. While independent advisory committees arguably may have in place much more transparent accountability frameworks than government departments, their effectiveness can be limited by the fact that their members are part time and cannot devote their full energies to risk assessments. Out of necessity, such committees may meet only bimonthly or several times per year, and the membership selection process, while transparent, may not result in the best combination of scientific expertise and regulatory experience. Nevertheless, members of advisory committees very

⁴⁰ R. L. Paarlberg, *The Politics of Precaution: Genetically Modified Crops in Developing Countries* (Baltimore: Johns Hopkins University Press for International Food Policy Research Institute, 2001).

often are scientists who continue to work in their fields of expertise so may be in a better position to maintain their scientific currency than their government counterparts.

58. For developing countries, a determining factor in locating the science evaluation function may be access to the required expertise, whether it exists within current government organizations, academia, or elsewhere. Where it is not extant within a country, opportunities to leverage available expertise on a regional or subregional level, or building capacity through training, need to be explored.

Options

Development of core competencies for risk assessment within government departments and agencies vs. reliance on expert advisory committees vs. a combination of both internal and external scientific expertise.

59. In many countries, the risk assessment expertise lies in academic and other public sector research institutions, not within the government bureaucracy. If the decision is made to locate the risk assessment function within the regulatory authority, the government must be committed to develop the appropriate expertise. Acquiring the requisite expertise generally is achieved through the hiring, secondment, or retraining of scientific staff. Alternately, and in an approach that has been used in countries such as Argentina, South Africa and many of the EU member states, the regulatory authority may appoint an expert advisory committee to undertake risk assessments. If advisory committees are used, appropriate conflict of interest provisions must be in place to ensure that the developers of genetically engineered plants do not end up in a position to assess their own products. These conflict of interest measures are particularly necessary in countries that have very limited scientific expertise outside of the R&D community. In either case, the regulatory agency/body must have some foresight mechanism in place to identify potential knowledge gaps and to promote and access training or the recruitment of new knowledge.

60. The best approach may be to use elements of both: expert advisory committees who provide guidance for the development of new policies coupled with in-house experts who conduct the case-by-case assessment of products. Advisory committees can be used to address specific issues of scientific uncertainty. For example, new risks that may arise with advances in the genetic engineering of plants and foods can be proactively identified and product risk assessment and management practices changed if required. Such committees also can be used to address limitations in national scientific capacity by leveraging subregional or regional expertise with the additional advantage that the committee's output then may have a broader application. The use of in-house scientists to assess products on a case-by-case basis would permit the development of considerable expertise within the regulatory agency, would provide for a degree of consistency not afforded by the ever-changing membership of advisory committees, and could address the real or perceived conflict of interest that arises if product developers are also product assessors.

Monitoring and Enforcement

61. While the Biosafety Clearing House, which is being implemented under the Cartagena Protocol on Biosafety, is meant to facilitate a timely exchange of information about the trans-boundary movement and placing on the market of LMOs, there remain other practical, technical, and economic limitations to monitoring imports for LMOs.⁴¹ Furthermore, each country must have enforcement capabilities to

⁴¹ Monitoring refers to a systematic measurement of variables that seeks to identify new or additional information about a product, process, or activity over a period of time. As regards transboundary movement of LMOs, monitoring is required to

implement the required levels of inspection and audit, the imposition of administrative and monetary penalties, and trade sanctions.⁴² For any country with an active biotechnology research sector, additional resources may be required to undertake inspections of experimental field trials (for example, to ensure compliance with requirements for reproductive isolation and site monitoring), or to ensure adherence to institutional biosafety standards. As a rule, existing structures and human resources dedicated to carrying out inspection and enforcement actions for other agricultural and food commodities are used for biosafety-related activities.

62. Generally, within countries in which genetically engineered crops are grown on a commercial scale, the responsibility for post-market surveillance is covered by an ongoing duty of care by the developer. The developer is expected to monitor existing and emerging risks that may be associated with its product and notify the regulatory authorities whenever new information is uncovered.⁴³

63. Even though genetically engineered crops have been grown on a cumulative total of over 175 million hectares (ha) worldwide since 1996, knowledge of the potential long-term consequences to agricultural and natural ecosystems is limited.⁴⁴ Assertions of the lack of any adverse environmental effects are compromised by the lack of any systematic monitoring or surveillance to detect such effects.⁴⁵ The pre-market assessment of environmental risks of genetically engineered crops is based on data obtained from small-scale confined field trials, which generally are not suited to detecting small or low-probability effects that would become apparent only at larger spatial scales and over extended periods of time.⁴⁶ In its 2002 report on the “Environmental Effects of Transgenic Plants,” the United States National Academy of Sciences (NAS) recommended, first, that post-commercialization validation testing should be used to verify the effectiveness of pre-commercialization risk assessment.⁴⁷ Second, NAS recommended that post-commercialization validation testing be designed to test specific hypotheses regarding the major categories of risk, which include movement of transgenes, impacts of the whole plant through escape or impact on agricultural practices, nontarget effects, and resistance evolution.

ensure that national, regional, and international rules and regulations governing the movement of LMOs are respected; to test imports for the presence of unapproved events; and to establish that thresholds for adventitious presence have been met.

⁴² Enforcement results from the surveillance of mandatory activities to ensure that these are undertaken as required. Normally, enforcement is assumed by government agencies or agents and carries with it punitive measures should noncompliance be confirmed.

⁴³ A recent example of this idea in action is the new information relating to glyphosate-tolerant soybean (GTS 40-3-2) that was disclosed by Monsanto to regulatory authorities worldwide in May 2000. Monsanto had performed additional characterization experiments on GTS 40-3-2 as part of a seed quality control program and to facilitate the development of detection methodologies. During this work, Monsanto discovered that two additional partial nucleotide sequences corresponding to portions of the inserted 5-enolpyruvylshikimate-3-phosphate synthase gene also had been incorporated in the plant genome. In each case, regulatory authorities that previously had approved this line of glyphosate-tolerant soybean agreed that the additional nonfunctional sequences did not affect the overall safety of the product.

⁴⁴ C. James, “Global Review of Commercialized Transgenic Crops: 2001.” ISAAA Briefs 24: Preview, ISAAA, Ithaca, 2001.

⁴⁵ In this instance, monitoring refers to evaluating the cumulative long-term effects of genetically engineered crops and foods on the environment and human health.

⁴⁶ For example, in Canada, the current policy on confined field trials of plants with novel traits states that, for each crop species x trait combination, trials must be no larger than 1 ha, and no more than 10 trial sites comprising a cumulative total of 5 ha are allowed per province (for example, maximum of 10 x 0.5 ha trials per crop species x trait combination per province). Exemptions to these limits are permitted provided a sufficient scientific rationale is presented.

⁴⁷ National Academy of Sciences, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* (Washington, D. C.: National Academy of Sciences, National Academy Press, 2002).

64. With the exception of the risk of selecting for resistant populations of insects because of the introduction of [*Bt* crops, regulatory authorities have offered little if any guidance on monitoring parameters or sentinels for effective post-market surveillance. Within the EU, a new framework governing the environmental release of genetically engineered plants, under Directive 2001/18/EC, was agreed in April 2001.^{48, 49} Among other changes, the new directive requires that developers provide and implement a plan for monitoring the occurrence and impact of potential adverse effects of genetically engineered plants on the environment.⁵⁰ The period of post-market monitoring is established at the point of granting commercial approval, and subsequent renewal of commercial approval may be contingent on surveillance data.

Options

No post-market monitoring vs. short-term follow-up (under 5 years) vs. long-term follow-up (more than 5 years)

65. Although some governments may see a need for short- or long-term monitoring of cumulative effects, including benefits, of genetically engineered crops and foods, significant technical complexities in implementing such programs have yet to be addressed. For example, evaluating the long-term effects of genetically engineered foods necessarily requires the segregation of agricultural commodities and/or labeling of food products if monitoring is to be at all meaningful. In addition, the scope, procedures, and results of any post-market monitoring program must be communicated clearly to stakeholders and the public. Problematically, there are very few estimates of the costs associated with executing post-market monitoring programs.

66. If post-market monitoring is not to be required, it is advisable for the government to explicitly state within regulations or as a condition of authorization that an ongoing duty of care lies with the product developers to inform regulators of new information that may impact human health or environmental safety.

Time-limited vs. open-ended approvals

67. Bearing in mind the provisional nature of all scientific knowledge, biosafety regulatory systems require a systematized approach to evaluating new information and revisiting previous regulatory decisions and risk mitigation measures. New information, such as that derived from additional analyses of genetically engineered crops using improved methodologies or from monitoring and surveillance activities, could be used as the basis to modify approval decisions or revise risk mitigation measures (for example, insect resistance management plans).

68. While time-limited approvals, as proposed within the revised European Union Directive 2001/18/EC, offer a convenient mechanism, they are not without their drawbacks. Because of the rapid rate of technological advancement, the economic lifespan of a new genetically engineered crop may be fewer than 10 years, the time period proposed for renewal under Directive 2001/18/EC. In addition, it is

⁴⁸ Directive 2001/18/EC on the Deliberate Release in the Environment of Genetically Modified Organisms, Official Journal of the European Communities, L.106, 0001–38, 2001.

⁴⁹ Member states had until 17 Oct. 2002 to bring into force national measures to comply with the new directive's provisions, which focus primarily on harmonizing principles of environmental risk assessment; managing potential long-term cumulative effects on the environment and wildlife; post-market monitoring; and improving transparency, openness, and public consultation.

⁵⁰ 2001/18/EC includes an "obligation to implement a monitoring plan in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market."

uncertain what the implications would be of a developer's abandoning a product prior to, or at the time of, renewal. If time-limited approvals are to be a valid option, provisions must be in place to handle such eventualities, and they also must specify the nature and magnitude of the review to be conducted at the time of renewal.

5. Horizontal Issues

5.1. INTEGRATING BIOSAFETY REGULATION IN NATIONAL POLICIES AND STRATEGIES

69. Ideally, the evolution of a national biosafety system begins with a national policy that forms the basis for the development of specific legislation and/or regulations, leading finally to the design and implementation of the structural elements necessary for risk analysis, inspection, monitoring, and enforcement. Supporting and informing these processes would be detailed information developed by performing a national assessment of the existing regulatory, scientific, technical, economic, and social capacity. This ideal progression is rarely the case. In reality, portions of these activities often are completed simultaneously, usually in an attempt to meet short-term needs.

70. Whether elaborated within a national biotechnology strategy or as a free-standing national policy, the importance of a national biosafety strategy cannot be overstated, because it articulates a national approach to biosafety regulation and the goals and objectives of the regulatory framework. The strategy integrates political, social, ethical, health, economic, and environmental considerations in decisions regarding the safe and appropriate use of biotechnology methods and products. A national strategy also provides direction on many of the fundamental issues and public policy choices that must be considered during the development of regulations. Such issues include the extent to which social, ethical, and economic factors should be considered; the social acceptability of biotechnology and its products; and linkages with other national policies on food, agriculture, and economic development.

71. The experiences of other countries that have chosen to formulate national biotechnology strategies to integrate broad government objectives around biotechnology-related economic and regional development, and environmental protection are instructive for countries attempting to formulate their own national policy.⁵¹ In the early 1980s, such strategies placed a heavy focus on encouraging research and development, investment, and markets. Recently, however, there has been an increasing emphasis on

⁵¹ Examples from Australia, Canada, and South Africa are provided in appendix 1. These are not meant to be exclusive. Other national biotechnology strategies or related reports that may provide additional examples for a country developing such a policy include:

European Commission, "Life Sciences and Biotechnology – A Strategy for Europe," 2001
<http://europa.eu.int/comm/biotechnology/pdf/doc_en.pdf>;

Ministry of Agriculture and Forestry (Finland), Strategy for Biotechnology and Genetic Engineering in Agriculture, 2000
<http://www.mmm.fi/maatalous/bio_geenitekniikka/strategyengl.PDF>;

Ministry of Agriculture, Nature Management and Fisheries (Netherlands), Integral Policy Document on Biotechnology, 2000
http://www.minvrom.nl/minvrom/Docs/milieu/nota_biotechnologie_def.pdf;

Royal Commission on Genetic Modification (New Zealand), Report of the Royal Commission on Genetic Modification, 2001
<<http://www.gmcommission.govt.nz/RCGM/index.html>>;

Ministry of Education and Research (Sweden), Breakthroughs: A Swedish Biotechnology Policy, 2000
<http://utbildning.regeringen.se/propositionermm/sou/2000/sou2000_103sum.pdf>;

The Royal Society (United Kingdom), Genetically Modified Plants for Food Use and Human Health – An Update, 2002.
<<http://www.royalsoc.ac.uk/files/statfiles/document-165.pdf>>.

balancing the economic benefits of biotechnology with the need to protect the environment, human health, and safety. Newer and revised strategies have identified policy planks such as stewardship, citizen engagement, biosafety, and adequate regulation as important objectives. In addition, some national strategies provide for the creation of an advisory committee to serve as a focal point for initiating public dialogue and addressing cross-cutting issues related to the ethical, legal, and social implications of biotechnology. Such committees serve an important function as sources of “external” advice that can be used by government in the creation of new or revised policy.

5.2. TRANSPARENCY AND PUBLIC ENGAGEMENT

72. Within the context of government regulatory systems, transparency refers to the extent to which governments provide information on why and how certain products are regulated, how risk assessments are performed and decisions made, as well as the conclusions and decisions that have been reached. Transparency also can involve the perceived independence and objectivity of the regulatory decisionmakers. On the other hand, public engagement refers to the extent to which the public has input into either the formulation of regulatory policy or specific regulatory decisions. Although closely related, public information and participation can be mutually exclusive, because it certainly is possible to have an open and transparent process that does not involve public input.

73. Recent increased public pressure for greater transparency and public involvement in biotechnology regulation can be traced to the public’s heightened concern about governments’ ability to act fully in the public’s interest and to skepticism about science. Implicit in this concern is the perception that the interests of consumers are sacrificed to benefit big industry. With regard to biotechnology, there have been allegations that regulators have been too sensitive to the needs of the biotechnology industry and that the environment has become politicized to the point that regulators’ judgment has been clouded. In addition, the claims by some of significant, although as yet unsubstantiated, environmental and food safety risks associated with genetically engineered crops and foods have caused consumers to view both as potential health hazards. Finally, an issue central to the whole debate is the perception among consumers of a democratic deficit, that is, new technologies with unknown risks are being imposed on consumers without their consent, or perhaps even knowledge.

74. Practically, the extent to which transparency and public engagement are features of a developing biosafety system will depend on past practices of the government with respect to the development and implementation of legislation or regulations in other areas. Countries with a history of public engagement in policy development are likely to include the public in the process of developing a national biosafety system, while the converse also is true. Transparency and public participation are essential components to building trust in public institutions and in the risk assessment and risk management of new technologies. The dissemination of more and better information on agricultural biotechnology is a stabilizing force, not because the public generally reads scientific studies, risk assessments, or government decision documents, but because opinion leaders, members of special interest groups, or others who hope to shape public opinion do.

75. The Cartagena Protocol on Biosafety necessitates that national biosafety systems incorporate transparency as an element of both risk assessment and risk management. The protocol requires:

“a Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement

for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing House.”⁵²

76. At a minimum, the process and criteria for risk assessment and risk management should be widely published so that developers, stakeholders, and the public can be confident that the biosafety system is both credible and predictable. Some jurisdictions have surpassed this and, in addition, notify the public both when applications for the environmental safety assessment of a genetically modified organism are received by the competent authorities and when the regulatory decisions are made.

77. Public participation may be sought at a number of levels throughout the development and implementation of a biosafety system, including representation on, or membership of, advisory committees. Particularly relevant are the committees tasked with evaluating the social, ethical, and economic dimensions of biosafety; making input at public hearings during the development of policy or regulation; and commenting during the risk assessment process. As exemplified by recent proposed changes by the United States Food and Drug Administration and the European Commission, the trend is toward increasing openness and public involvement.

5.3. INTERNATIONAL AND REGIONAL HARMONIZATION

78. Except for countries that have an extensive or growing domestic biotechnology sector, and thus a significant domestic need for biosafety controls, the development of a comprehensive national capacity within every country is not likely to be feasible. The most achievable and cost-effective solutions are likely to involve combining national capabilities for risk assessment or risk management, or leveraging existing expertise in the private sector.

79. The Cartagena Protocol implicitly recognizes these issues in its assumption that subregional cooperation in harmonizing risk assessment criteria, information requirements, evaluation standards, and, to some extent, legal and regulatory systems is crucial to manage the transfer of LMOs across borders effectively. The protocol provides for the possibility that the risk assessment may be performed by the country of export, or a private sector exporter, with the understanding that the importing country maintains an independent national decisionmaking function. The viability of this option needs to be determined case by case, based on a business case for an exporter either to assist the country of import in capacity building or itself provide the necessary capacity.

80. *Harmonization can be considered to occur along three fronts: authority, administration, and analysis.* Harmonization of *authority* relates to the powers to promulgate regulations, supercede sub-national authorities, intercede in trade or domestic movement, and implement enforcement actions. Harmonization of authority rarely, if ever, occurs, because it involves the delegation of national prerogatives to a regional or subregional, body. Similarly, the development of model legislation or regulations seldom is applicable across different countries within a geographic region because of differences in legal systems.

81. Harmonization around *administrative functions* concerns procedures to implement norms, rules, and standards. It includes record-keeping, communication, information exchange, and notification systems. Within the context of the protocol, one example of this type of harmonization is the Biosafety Clearing House, the mechanism via which scientific, technical, environmental, and legal information relating to the risk assessment and transboundary movement of LMOs will be shared among the parties.

⁵² Secretariat of the Convention on Biological Diversity, Cartagena Protocol on Biosafety to the Convention on Biological Diversity (text and appendixes), 2002 <<http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>>.

82. For countries with a small national science community, the ability to capitalize on external expertise and information through harmonization of risk assessment principles, information requirements, and standards of assessment can be crucial to their abilities to implement effective biosafety systems. Harmonization of *risk assessment* can occur at two levels. The first is *conceptual*, that is, agreement on general principles of risk assessment. Examples include the consensus documents on food safety and environmental risk assessment prepared by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), as well as the Organisation for Economic Co-operation and Development (OECD). Such documents have formed the basis for international agreement on the fundamental approach to risk assessment. The second level is *technical* and involves agreement on methodologies, information requirements, or criteria for determining unacceptable risks. One example of this latter approach is illustrated by the Canada–U.S. bilateral agreement (appendix 1).

83. Key determining factors for successful harmonization can be summarized as the adoption of common values and objectives; shared interests and concerns; economic and other benefits; the need to overcome differences and avoid disputes; the need to cooperate against other interests; and the need to simplify procedures. In the absence of some or all of these factors, the chances of achieving effective harmonization are small.

6. Concluding Comments

84. Within the scientific community, consensus is growing that, properly applied, biotechnology has an important role to play in increasing agricultural productivity, reducing poverty and enhancing food security in developing regions, and conserving the environment. Within the context of rural development, biotechnology solutions must address the production constraints and commodities relevant to poor producers and consumers, and the associated risks and benefits must be assessed locally.

85. The development of an effective national biosafety system is important both to encourage the growth of domestic biotechnologies and to ensure safe access to new products and technologies developed elsewhere. The absence of a suitable regulatory framework hinders the ability of development agencies and public and private sectors to invest in biotechnology within a particular country and to make the products of biotechnology available in that country.

86. In reviewing relevant experiences from countries with established biosafety systems, this publication has attempted to underscore many of the issues and options that governments and policymakers will face in developing new frameworks. It is worth re-emphasizing that while there is no consensus on the single best approach to developing a national biosafety system, there are a common set of issues that must be addressed in a way that is consistent with other national policies and priorities. Furthermore, biosafety measures should not be viewed in isolation but as part of an agricultural regulatory framework that includes plant and animal quarantine, the approval of new plant varieties, the regulation of pesticides, the production of vaccines and veterinary drugs, and the use of biocontrol agents. Specifically, approaches to the implementation of biosafety measures—legislative options, incorporating science advice, decisionmaking processes, and mechanisms for public involvement—should be consistent with other practices within food and agriculture regulation.

Appendix 1 Regulation of Genetically Engineered Plants and Foods: Country-Specific Examples

87. The following case studies are provided as examples of biosafety policies and practices that have been challenged with the assessment and approval of one or more genetically engineered plants. These studies exemplify the key issues that should be considered during conceptualization and implementation of a national biosafety regulatory system.

A1.1 IMPLEMENTING BIOSAFETY REGULATIONS

Statutory vs. Nonstatutory Instruments

88. Case by case, the flexibility afforded by implementing voluntary guidelines must be weighed against potential limitations in monitoring and enforcement powers, including the impact of public perception. Despite their limitations, voluntary guidelines have proven very useful as countries develop biosafety systems. The case studies below illustrate two examples in which nonstatutory measures have been used to ensure biosafety.

Argentina

89. Argentina is the second largest producer of transgenic crops, with 11.8 million ha (22 percent of the global area of transgenic crops) under cultivation in 2001, mainly transgenic herbicide-tolerant soybean and herbicide-tolerant and insect-resistant maize.⁵³ Approvals for the environmental release of genetically modified organisms (GMOs) and their use in human food or livestock feeds are conducted under regulations administered by the Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) and SENASA (National Service of Health and Quality Agrifood). In 1991 SAGPyA created the Comisión Nacional Asesora de Biotecnología Agropecuaria (The National Advisory Committee on Agricultural Biosafety, or CONABIA) as a mechanism to provide advice on the technical and biosafety requirements for environmental releases, human food, and livestock feed uses of genetically engineered plant and animal materials.⁵⁴ CONABIA's membership is composed of both public and private sector representatives with a wide range of expertise in agricultural biotechnology. Members are selected according to a transparent process (SAGyPA Disposition No 004/00) and are approved by SAGPyA. Argentine regulations concerning the environmental release of GMOs were developed by CONABIA and are enforced by SAGPyA.

90. The regulatory framework for biosafety encompasses the contained use, deliberate release (that is, confined field trials), and commercialization of GMOs. The regulatory requirements for GMOs are based in guidelines in the form of non-legislative resolutions that are integrated in the overall regulatory system that governs the release of products in the agricultural sector. Under this framework, specific guidelines were developed to establish conditions under which environmental releases of transgenic materials may be conducted and the resulting data reviewed by CONABIA (Resolutions SAGyPA No 656/92, No

⁵³ James, "Global Review of Commercialized Transgenic Crops."

⁵⁴ Comisión Nacional Asesora de Biotecnología Agropecuaria (CONABIA) (National Advisory Committee on Agricultural Biotechnology), 2000, <siiap.sagyp.mecon.ar/programas/conabia_ingles/FRAMEING.htm>.

837/93, and No 289/97). Although the system is not considered voluntary, there is no specific law that makes the resolutions legally binding.

Other regulations

91. In addition to the environmental release of GMOs, SENASA administers the safety evaluation of foods and food ingredients containing or composed of GMOs (SAGPyA No 511/98). Feed and food evaluation standards are defined by SENASA, and the Secretary is responsible for their enforcement. In addition to the scientific assessment of risk performed by CONABIA and SENASA, all products are subject to an economic analysis by the National Office of Agrifood Markets within SAGPyA, which studies the potential impact of the approval on domestic and international markets.

92. Products of biotechnology must comply with existing regulations related to plant protection (Decree–Law of Agricultural Production Health Defense No 6704/66 and its amendments), seeds registration (Seed and Phytogenetic Creations Law No 20.247/73), and animal health (Law of Veterinarian Products Supervision of Their Elaboration and Creation No 13.636/49).

Egypt

93. The mandate for biosafety regulation in Egypt is shared among several government ministries and agencies: Ministry of Agriculture and Land Reclamation (MARL); Ministry of Health; Ministry of Trade and Supply; the Egyptian Organization for Standardization and Quality Control; and the Ministry of the Environment.

94. *Ministry of Agriculture and Land Reclamation.* Egypt's biosafety regulatory system was initiated in 1993 with the drafting of biosafety guidelines for the use, handling, transfer, and testing of GMOs in laboratories, greenhouses, and field experiments, which were published in draft form in 1994. To formalize the biosafety system, the Ministry of Agriculture and Land Reclamation (MARL) issued two decrees in 1995: the first to establish a National Biosafety Committee (NBC) and the second to adopt biosafety guidelines for Egypt.⁵⁵ The biosafety guidelines are not legally binding.

Other Regulations

95. Law No. 53 of 1966 provides MARL with the statutory responsibility for seed activities in Egypt. MARL Decree No. 82/1998 established policy and provided guidance on the procedures and protocols for the release of crop varieties developed by the Agricultural Research Centre. Conventional and transgenic varieties are handled in the same way: variety identification is standardized and conforms to international standards issued by the International Union for the Protection of New Varieties of Plants (UPOV). Performance testes are also conducted.

96. Decree No. 242/1997 by the Ministry of Health prohibits the import of genetically engineered foods unless their safety has been established. The decree also requires that imported seeds carry a certificate confirming that the seeds were not derived from untested genetically engineered plants. Genetically engineered plants and seeds can be imported if they have been assessed for safety and approved in the country of origin.

97. Article 151 of the Egyptian Constitution states that any international convention that Egypt ratifies will become Egyptian law.

⁵⁵ M. A. Madkour, A. S. El Nawawy, and P. L. Traynor, "Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt," ISNAR Country Report 62, International Service for National Agricultural Research, The Hague, 2000.

Statutory Options

98. The following case studies are examples of different approaches that have been taken in developing biosafety regulations. These studies also exemplify how these approaches blend with other regulations for foods, the import and export of commodities, and the movement of conventional plants across borders. Australia and South Africa are examples in which new legislation was developed specifically to deal with gene technology and genetically modified organisms, whereas in the United States and Canada, biosafety was addressed through modifying existing laws.

Australia

99. Until 2001, the regulation of biotechnology and its products in Australia was coordinated under five different systems⁵⁶: the Australia New Zealand Food Authority (ANZFA), the Therapeutic Goods Administration (TGA), the National Registration Authority (NRA), the National Occupational Health and Safety Commission (NOHSC), and the Australian Quarantine and Inspection Service (AQIS).

100. From 1987 through June 21, 2001, the Genetic Manipulation Advisory Committee (GMAC), which was housed within the Interim Office of the Gene Technology Regulator (IOGTR) of the TGA, was the nonstatutory body responsible for overseeing the research, development, and use of novel genetic manipulation techniques in Australia, and the environmental release of GMOs. GMAC was concerned with any operation that resulted in or used organisms of novel genotype produced by genetic manipulation that fell under its scope of review. GMAC had defined its scope as:

any experiment involving the construction and or propagation of viroids, viruses, cells or organisms of novel genotype produced by genetic manipulation which are either unlikely to occur in nature, or likely to pose a hazard to public health or to the environment.

101. While compliance with GMAC's voluntary scheme was high, limitations were identified, including:

- ❑ The voluntary system of compliance with GMAC guidelines was not designed to provide for product regulatory approvals, because its original focus was the oversight of research.
- ❑ It had no legal provisions to ensure compliance by auditing or monitoring practices, nor to ensure that punitive actions were taken in the event of noncompliance.
- ❑ The existing product regulatory system was not designed with GMOs in mind; as a result, there were gaps and deficiencies within the framework.
- ❑ There were no established standards or rules for risk assessment or management.
- ❑ The voluntary system was not sufficiently transparent nor did it include adequate public consultation, which lacks compromised public confidence in its effectiveness.

102. In response to these inadequacies, the States, Territories, and the Commonwealth of Australia collaborated to develop a nationally consistent regulatory system for GMOs. This system was developed through extensive consultations with relevant government agencies, academic and private sector developers, consumer and environmental groups, primary producers, industry, and the public. The end

⁵⁶ Interim Office of the Gene Technology Regulator (IOGTR), Information Sheet (IOGTR), Fact Sheet 3: "About the GMAC," Office of the Gene Technology Regulator, Commonwealth Department of Health and Aged Care, Canberra, 1999.

product is the Gene Technology (GT) Act,⁵⁷ which received Royal Assent on December 21, 2000 and came into force in June 2001. The act does the following:

- ❑ Establishes a statutory officer, the Gene Technology Regulator, to administer the legislation and make decisions under the legislation
- ❑ Establishes three key committees (the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee, and the Gene Technology Community Consultative Group) to provide scientific, ethical, and policy advice
- ❑ Regulates all “dealings,” that is, research, manufacture, production, commercial release, and import, with live, viable organisms that have been modified by techniques of gene technology, including the progeny of such GMOs that also share a genetically modified trait
- ❑ Establishes a scheme to assess the risks to human health and the environment associated with various dealings with GMOs, including opportunities for extensive public input
- ❑ Provides for monitoring and enforcement of the legislation
- ❑ Creates a centralized, publicly available database of all GMOs and genetically engineered products approved in Australia (the Record of GMO and genetically engineered product dealings).

103. The provisions of the Gene Technology Act are “in addition to, and not in substitution for, the requirements of any other law of the Commonwealth (whether passed or made before or after the commencement of the Act).”

Other Regulations

104. Under the Australian Constitution, the responsibility for regulating the safety of food produced for consumption within Australia is vested in the States and Territories. As a result, Australia has a complex and varied food regulatory system, encompassing several agencies and types of legislation across three levels of government. A 1998 review of food regulation found approximately 150 acts and associated regulations related to food or agrifood businesses in Australia that were administered by several Commonwealth agencies, over 40 State and Territory agencies, and over 700 local governments.

105. National food standards are developed by ANZFA and are adopted by the States and Territories by reference and without amendment after being agreed by a majority of members of the Australia New Zealand Food Standards Council (ANZFSC). The council is comprised of Commonwealth, State, Territory and New Zealand health ministers. In July 1998, ANZFA established *Standard A18-Food Produced Using Gene Technology*,⁵⁸ which came into force on May 13, 1999. Under this standard, the sale of food produced using gene technology is prohibited unless the food is included in the table to clause 2 of the standard. The standard requires that a pre-market safety assessment be conducted on all foods produced using gene technology. However, the standard provides an exemption for foods currently on the market provided that an application was accepted by ANZFA on or before April 30, 1999; that the food is lawfully permitted in a country other than Australia or New Zealand; and that ANZFSC has not become aware of evidence that the food poses a significant risk to public health and safety.

⁵⁷ Office of the Gene Technology Regulator (OGTR), Gene Technology Act, 2000, Canberra, 2001. <<http://law.agps.gov.au/cgi-bin/download.pl?scale/data/pasteact/3/3428>>.

⁵⁸ Australia New Zealand Food Authority (ANZFA), Standard A18: Food Produced Using Gene Technology, 1999, Canberra <http://www.anzfa.gov.au/documents/gen37_99.asp>.

South Africa

106. In 1978 the South African Genetic Experimentation Committee (SAGENE) was formed to encourage recombinant DNA research, provide guidelines for responsible management of recombinant microorganisms, approve and classify research centers and projects, and arrange advanced training for scientists.⁵⁹ The terms of reference for SAGENE were changed in 1989 to make the committee South Africa's national advisory body for the environmental release of GMOs. As a nonstatutory committee, SAGENE promulgated the following guidelines beginning with the laboratory guidelines in the early 1980s, and then comprehensively in 1996:

- ❑ Guidelines and Notification Procedures for Laboratory Containment of Genetically Modified Organisms, which describe essential and recommended practices for genetic manipulation in the laboratory.
- ❑ Guidelines for the Categorization of Genetic Manipulation Experiments, which apply to cloning in prokaryotic and lower eukaryotic organisms, and to the genetic manipulation of plant cells. They provide guidance on assessing the risk to human health and safety and to environmental safety, when working with experimental GMOs, and were designed to conform to South Africa's Occupational Health and Safety Act, 1993 (Act. No. 85 of 1993).
- ❑ Guidelines and Notification Procedures for the Large-scale Use of Genetically Manipulated Organisms, which describe the factors to be considered in the risk assessment of the large-scale use of GMOs and the notification protocol for informing SAGENE of large-scale work. Large-scale use refers to "the use or growth of GMOs in a pilot plant or commercial manufacturing facility on a scale of 10 liters or more."
- ❑ Guidelines for the Trial Release of Genetically Modified Plants in the Republic of South Africa, which provide recommendations for the risk assessment and monitoring of genetically modified plants cultivated in experimental field trials. The guidelines require applicants to adhere to the Environmental Conservation Act, 73 of 1989 and the principles and requirements of the Integrated Environmental Management Procedure of the Department of Environmental Affairs and Tourism.

107. Initially, South Africa's National Department of Agriculture managed the experimental use and subsequent commercial release of GMOs using interim guidelines under amendment of the Agricultural Pest Act, 1983 (Act No. 36 of 1983). SAGENE reviewed all applications for experimental trials and environmental release of GMOs and made recommendations to the government in this regard.⁶⁰ The interim system issued permits for GMO activities under the Plant Pest Act, but was compulsory only for imported genetically engineered seeds and plant material. Application for permits to conduct greenhouse and field trials with genetically engineered plant material was voluntary (M. Koch, personal communication). For this reason, in combination with the fact that regulation of GMOs was becoming a more controversial issue, South Africa elected to produce a new legal instrument specifically to regulate GMOs. In 1997 the Genetically Modified Organism Act was passed. The act was developed to

- ❑ Provide for measures to promote the responsible development, production, use, and application of genetically modified organisms

⁵⁹ Z. M. Ofir, "Biotechnology in the New South Africa," *Biotechnology and Development Monitor* 20 (1994): 14–15.

⁶⁰ M. Koch, "Public Awareness Information on Genetically Modified Food," *Africabio* <<http://www.africabio.com/news/old/article22.html>>.

- ❑ Ensure that all activities involving the use of genetically modified organisms (including importation, production, release, and distribution) shall be carried out in such a way to limit possible harmful consequences to the environment
- ❑ Give attention to the prevention of accidents and the effective management of waste
- ❑ Establish common measures to evaluate and reduce the potential risks arising from activities involving the use of genetically modified organisms
- ❑ Lay down the necessary requirements and criteria for risk assessments
- ❑ Establish a council for genetically modified organisms
- ❑ Ensure that genetically modified organisms are appropriate and do not present a hazard to the environment
- ❑ Establish appropriate notification procedures for specific activities involving the use of genetically modified organisms and provide for matters connected therewith.

108. The act, which came into force in 1999 with the publication of regulations, created:

- ❑ *An Executive Council (EC)*. This independent decisionmaking body will make decisions on all applications for work with GMOs. The Council is made up of representatives from six government departments and, when making its decisions, will take into account issues such as socioeconomics, trade, labor and safety to humans and the environment.
- ❑ *A Scientific Advisory Committee*. This body of scientists will review the human and environmental safety of GMOs and advise the Council of its findings.
- ❑ *Registrar and Inspectorate*. The Registrar will administer the GMO Act on behalf of the Minister of Agriculture, will issue permits at the request of the EC, and will use the Inspectorate to monitor and inspect local work with GMOs.

Other Regulations

109. All imports and exports of agricultural materials require a permit issued under the Agricultural Pest Act, 1983. In addition, if the item to be imported is a GMO, a permit for import or export is required under the GMO Act.

110. The safety of all foods, including foods derived from biotechnology, is regulated under the Foodstuffs, Cosmetic and Disinfectants Act, 1972 (Act No. 54).

United States

111. Three United States departments share responsibility for regulating agricultural biotechnology: Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA).

112. *USDA-APHIS*. The USDA's Animal and Plant Health Inspection Service (APHIS) is the lead agency for the regulation of genetically engineered plants, including the experimental evaluation of these products in confined field trials. In 1993 USDA finalized a regulation under the Federal Plant Protection Act (PPA) (formerly the Federal Plant Pest Act) that described a petition process for determining whether

particular plants would no longer be regulated and, therefore, could be commercially planted.^{61, 62} A regulated article is defined as any organism that has been altered or produced through genetic engineering if the donor organism, recipient organism, or vector or vector agent belong to any genera or taxa designated as, or believed to be, a plant pest.⁶³ APHIS also can designate any product of genetic engineering a regulated article if the article is deemed to be a plant pest. For a crop to achieve nonregulated status, USDA prepares “environmental assessment” and “determination of nonregulated status” documents that address a number of safety concerns, including impacts on agriculturally beneficial organisms and the potential to become a plant pest.

113. APHIS’ authority to regulate genetically engineered plants stems from the fact that, to date, these plants have been products of *Agrobacterium tumefaciens* (a bacterial pest causing crown gall disease in plants), mediated transformation, and/or contain regulatory sequences derived from a plant pest (cauliflower mosaic virus 35S promoter). Although APHIS’ regulations for genetically engineered plants apply only to plant pests, the agency’s broad discretionary authority provides it with sufficient latitude that any transgenic plant could be considered a plant pest and so fall within its mandate.

114. EPA. The Environmental Protection Agency is responsible for regulating pesticides in the United States, including pesticidal substances produced through biotechnology. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the EPA ensures that pesticides meet federal safety standards. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that the EPA determine safe levels of pesticide residues in food. In 1994 the EPA published proposed regulations describing policies for pesticidal substances expressed in transgenic plants under FIFRA and FFDCA. In 2001 this rule was finalized along with two others that clarify which plant-incorporated protectants are exempt.^{64, 65, 66} A plant-incorporated protectant is a pesticidal substance that is produced and used by the living plant, typically to protect the plant from pests, such as insects, viruses, and fungi.

Other Regulations

115. The FDA is responsible for assuring that foods derived through genetic engineering are as safe as their traditional counterparts. Under the FFDCA, the FDA has the authority to require pre-market review and approval in cases in which protection of public health is required, such as when a substance is added

⁶¹ United States Department of Agriculture (USDA), “Introduction of Organisms and Products Altered or Produced through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” 7 CFR 340, 1993 <<http://www.aphis.usda.gov/bbep/bp/7cfr340.html>>.

⁶² United States Department of Agriculture (USDA), “Genetically Engineered Organisms and Products: Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status,” *Federal Register* 58: 17044-59. <<http://www.aphis.usda.gov/bbep/bp/393rule.txt>>.

⁶³ A plant pest is defined as any living stage of invertebrate animals, bacteria, fungi, parasitic plants, or viruses; or any organisms, agents, or substances that can directly or indirectly damage or cause injury to plants or parts thereof.

⁶⁴ Environmental Protection Agency (EPA), Regulations under the Federal Insecticide, Fungicide and Rodenticide Act for Plant-Incorporated Protectants (formerly Plant Pesticides), 40 CFR Parts 152 and 174, *Federal Register* 66 (2001): 37772–817.

⁶⁵ EPA, “Exemption for the Requirement of a Tolerance under the Federal Food, Drug and Cosmetic Act for Residues of Nucleic Acids that Are Part of Plant-Incorporated Protectants (formerly Plant Pesticides), 40 CFR Part 174, *Federal Register* 66 (2001): 37817–30.

⁶⁶ EPA, “Exemption for the Requirement of a Tolerance under the Federal Food, Drug and Cosmetic Act for Residues Derived through Conventional Breeding from Sexually Compatible Plants of Plant-Incorporated Protectants (formerly Plant Pesticides), 40 CFR Part 174, *Federal Register* 66 (2001): 37830–54.

intentionally to a food and there are questions about its safety. FDA also has post-market authority to remove a food product from commerce and sanction those marketing the food if it poses a risk to public health. In the United States, the complex array of criminal and civil sanctions, including tort and contractual remedies, available to governments and private parties provides food producers and manufacturers with every incentive to bring safe, wholesome foods to market.

116. In 1992 the FDA published in the *Federal Register* a Statement of Policy on its approach to the regulation of foods derived from genetically engineered plants.⁶⁷ The purpose of this policy was to provide a risk-based “decision tree” to guide plant breeders and food manufacturers through issues critical to ensuring the safety, nutritional value, and wholesomeness of new foods. Under this “standard of care,” which applies equally to new foods produced through traditional breeding as well as biotechnology, FDA also provided guidance on regulatory issues such as cases in which an introduced substance is not generally recognized as safe and would require pre-market approval as a food additive, and for which special labeling would be required under FFDCA. Food producers are not required to seek FDA pre-market approval or apply a special label for a new variety of food if it is substantially equivalent to existing varieties already on the market.

117. In January 2001, the FDA published a proposed rule for mandatory pre-market notification for genetically engineered foods. Under this rule, the FDA will require the submission of data and information about genetically engineered foods destined for human or livestock consumption 120 days prior to the commercial distribution of such foods. This means that when the proposed rule is finalized, the FDA will move from its current voluntary system to a mandatory system for the regulatory oversight of genetically engineered foods and livestock feeds.

118. Before commercialization, genetically engineered plants/organisms also must conform to standards set by state and federal marketing statutes such as state seed certification laws, the Toxic Substances Control Act, and the Federal Plant Protection Act. There are no national requirements for variety registration of new crops.

Canada

119. In Canada, the regulation of agricultural biotechnology products is coordinated between the Canadian Food Inspection Agency (CFIA), Health Canada, and Environment Canada. In all cases, these agencies have used existing acts to incorporate new or amend existing regulations.

120. *CFIA*. The CFIA is responsible for regulating the importation (Plant Protection Act), environmental release (Seeds Act), variety registration (Seeds Act), and use in livestock feeds (Feeds Act) of plants with novel traits (PNTs), including transgenic plants. PNTs are plant varieties/genotypes that are not considered substantially equivalent, in terms of their specific use and safety both for environment and for human health, to plants of the same species, with regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms, and impact on biodiversity. PNTs may be produced by conventional breeding, mutagenesis or, more commonly, by recombinant DNA techniques.⁶⁸

121. The first confined field trial of a PNT in Canada was authorized in 1988 in accordance with voluntary guidelines that were published in 1995 as Regulatory Directive 95-01: Field Testing Plants with

⁶⁷ May 29, 1992, 57 FR 22984.

⁶⁸ Canadian Food Inspection Agency (CFIA), Regulations Amending the Seeds Regulations, *Canada Gazette* 134 (2000): 3294-99.

Novel Traits in Canada. These guidelines have been amended three times since, most recently in 2000.⁶⁹ Information guidelines for the environmental risk assessment of PNTs were published in 1994 as Regulatory Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits. In 1996 the Canadian government amended the Seeds Act and Regulations⁷⁰ with the promulgation of Part V, Release of Seed, which was further amended in 2000. These regulations allow for the testing of PNTs in field trials under confined conditions, and prescribe the requirements for mandatory environmental and human health safety assessment prior to authorization for unconfined environmental release.

Other Regulations

122. The importation into Canada of PNTs, including transgenic plants, and any products derived from them requires a permit issued under the Plant Protection Act. Typically, permits are issued with specific conditions to limit the movement or use of the PNTs after entering Canada.

123. Health Canada is responsible for the assessing the safety of all food products, including novel food products under the Novel Food Regulations of the Food and Drugs Act, which were promulgated in October 1999.⁷¹ Under these regulations, a manufacturer or importer of a novel food must notify Health Canada 45 days prior to the sale or advertising for sale of these products. The department undertakes to respond within 45 days should additional safety information of a scientific nature be required, and will notify the manufacturer within 90 days of receipt of such information as to whether it is sufficient. Until the Novel Food Regulations came into force in 1999, the safety assessment of novel foods was based on voluntary compliance with the “Guidelines for the Safety Assessment of Novel Foods.”⁷²

124. Under the Canadian Environmental Protection Act (CEPA), Environment Canada is responsible for administering the New Substances Notification Regulations and for performing environmental risk assessments of CEPA-defined toxic substances, including organisms and microorganisms that may have been derived through biotechnology.

A1.2 POSITIONING SOCIOECONOMIC CONSIDERATIONS WITHIN BIOSAFETY REGULATION

125. The examples that follow are meant to illustrate some different approaches that have been used to address the issue of incorporating (or not) socioeconomic concerns in regulatory decisionmaking.

Argentina

126. In 1991 the Argentine Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) created the Comision Nacional Asesora de Biotecnologia Agropecuaria (The National Advisory Committee on Agricultural Biosafety, or CONABIA) as a mechanism to provide advice on the technical and biosafety

⁶⁹ CFIA, Directive 2000-07: Guidelines for the Environmental Release of Plants with Novel Traits within Confined Field Trials in Canada.

⁷⁰ Agriculture and Agri-Food Canada (AAFC), JUS-96-004-01 (SOR/DORS): Amendments to the Seeds Regulations—Release of Seed. <<http://www.inspection.gc.ca/english/plaveg/pbo/96004e.shtml>>.

⁷¹ Health Canada, Schedule No. 948: Novel Foods Regulations, 1999 <http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/sch948e.pdf>.

⁷² Health Canada, Guidelines for the Safety Assessment of Novel Foods, 1994 <http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/novele.pdf>.

requirements to be met in environmental releases, human food, and livestock feed uses of genetically engineered plant and animal materials. Additional regulations, administered by the National Service for Agrifood Safety and Quality (SENASA), apply to safety evaluations of foods and food ingredients containing or composed of genetically modified organisms (see section 0 for a complete description of the Argentine system).

127. In addition to the scientific assessment of risk performed by CONABIA and SENASA, all products are subject to an economic analysis by the National Directorate of Agrifood Markets within SAGPyA, which studies the potential impact of the approval on domestic and international markets. This consideration of economic consequences is one example of addressing a particular type of socioeconomic concern within a product approval system.

South Africa

128. South Africa's Genetically Modified Organism Act, which was implemented in 1999, controls the production, importation, distribution, and environmental release of genetically modified organisms (GMOs), including LMOs.⁷³ Prior to the coming into force of this legislation, these activities were subject to a series of voluntary guidelines published by the South African Committee for Genetic Experimentation (see section above on implementing biosafety regulations in South Africa).

129. The new act creates two new structures that serve to separate the risk management decisionmaking and scientific risk assessment processes. The Executive Council, which is comprised of up to eight persons, including one representative from each of six government departments, is responsible for advising on authorizations. In so doing, the Council also will take into account socioeconomic issues relating to labor and trade impacts. A separate scientific body, the Scientific Advisory Committee, is responsible for performing risk assessment reviews of potential environmental risks associated with the release of GMOs into the environment. Their findings and advice are provided as input to the Executive Council for formulation of a final recommendation to the Minister.

130. In this example, separating the activities of risk assessment from risk management has provided a mechanism for including non-science issues in the decisionmaking process without prejudicing the science-based evaluation process.

Canada

131. The authority for reviewing the environmental and livestock feed safety of plants with novel traits, including genetically engineered plants and their products, and for authorizing their release or use in commerce, resides with Canadian Food Inspection Agency under the Seeds Act and Regulations, and the Feeds Act and Regulations. Canadian regulators employ an evidence-based approach to risk assessment that considers only the additional scientifically defensible risks associated with a particular product, without consideration of possible benefits. In Canada, the scientific risk assessment largely "determines" the regulatory decision, and there are no opportunities to consider broader socioeconomic issues.

132. Within the context of the Canadian Biotechnology Strategy, the federal government established the Canadian Biotechnology Advisory Committee (CBAC) as an independent expert advisory body with a mandate to provide advice to government on broad policy issues associated with the ethical, social,

⁷³ South African Genetically Modified Organism Act, No. 15, *Government Gazette* 383 (18029) (23 May 1997).

regulatory, economic, scientific, environmental, and health aspects of biotechnology.⁷⁴ CBAC's 1998 interim report on improving the regulation of genetically modified foods in Canada examined the question of related social and ethical concerns but did not make specific recommendations other than ones aimed at strengthening environmental stewardship.⁷⁵ These included introducing a stronger ecosystem perspective in environmental risk assessments and funding a research program to examine long-term impacts. Future advice in this area, particularly with respect to the development of a public "acceptability framework," may shape the direction of national policy and the federal framework for regulating biotechnology products.

United Kingdom

133. Since 1990, under Directive 90/220/EEC, the United Kingdom and other European Union member states have had a harmonized approach to considering applications for the environmental release of GMOs. This directive, which applied to the release and marketing of all GMOs except the marketing of products derived from them (for example, novel foods, or human or veterinary medicines), was replaced by a new framework under Directive 2001/18/EC, which took effect on April 17, 2001. Member states had until October 17, 2002 to bring into force national measures to comply with the new Directive's provisions. These provisions focus primarily on harmonizing principles of environmental risk assessment; managing potential long-term cumulative effects on the environment and wildlife; post-market monitoring; and improving transparency, openness and public consultation. With respect to ethical and socioeconomic issues, the new directive does not include these as specific factors to be taken into account. However, it does provide for consulting ethical committees on matters of a general nature and for periodic reporting on the socioeconomic implications of environmental releases of GMOs.

134. In June 2000, the UK government established the Agriculture and Environment Biotechnology Commission (AEBC) to provide independent strategic advice on biotechnology developments and related implications for agriculture and the environment. This committee is similar in structure and mandate to Canada's CBAC, except that the remit of the latter includes the entire spectrum of biotechnology applications and issues, not solely those specific to agriculture. Among its other roles, the AEBC will advise the UK Government on the ethical and social implications arising from agricultural biotechnology developments and their public acceptability.

A1.3 REGULATORY STRUCTURES, SECURING SCIENTIFIC ADVICE, INSPECTION, AND ENFORCEMENT

Locating the Risk Assessment Function

135. The following case studies are examples of countries that have chosen to locate the risk assessment function with expert advisory committees (UK) or with scientists and professionals working within government departments and agencies (Canada, U.S.).

⁷⁴ Industry Canada, "The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process," Ottawa <<http://strategis.ic.gc.ca/cbs>>.

⁷⁵ Canadian Biotechnology Advisory Committee, "Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada: Interim Report to the Government of Canada Biotechnology Ministerial Coordinating Committee," Ottawa, 1998 <<http://www.cbac-cccb.ca>>.

United Kingdom

136. Within the UK, the Advisory Committee on Releases to the Environment (ACRE) is an independent statutory advisory committee, appointed by the Secretary of State for the Environment, which reviews applications for field trials or general (commercial) releases of GMOs under parts B and C of Directive 90/220/EEC (now Directive 2001/18/EC). Originally convened as an advisory body in 1990, ACRE was re-appointed as a statutory committee under the Environmental Protection Act 1990, which requires Ministers to seek advice from ACRE on all applications for the environmental release of GMOs. The committee represents a broad-based source of scientific expertise in agronomy, ecology, entomology, microbiology, molecular biology, plant breeding, rural development, virology, and weed ecology. It has no specific representation from the social sciences or from stakeholder groups such as industry or environmental pressure groups.⁷⁶

Canada and the United States

137. In contrast, the biosafety risk assessment of transgenic plants in the United States involves only government evaluators within the Biotechnology Permits Branch of USDA–APHIS. A similar arrangement exists within the Plant Biosafety Office of the Canadian Food Inspection Agency (CFIA). In these countries, the incorporation of external scientific expertise, in the form of expert panels or committees, is not a general requirement but nonetheless has been accommodated *ad hoc*. Two examples include the CFIA consultations with the Bt Corn Coalition (1998) to establish mandatory insect resistance management plans, and a USDA–APHIS expert panel consultation (1997) on the risks associated with incorporating plant viral genes into transgenic plants.^{77, 78} Other examples of standing committees include the US EPA Scientific Advisory Panel and Health Canada’s Scientific Advisory Panel. In these countries, *ad hoc* committees and advisory panels provide advice on the formulation of government policy and/or regulations, or advice on specific issues, such as the allergenic potential of Cry9C protein.⁷⁹ Unlike committees such as ACRE, these bodies do not participate in the evaluation of specific applications or petitions.

A1.4 HORIZONTAL ISSUES

Integrating Biosafety Regulation in National Policies and Strategies

138. The following are examples of national strategies that include guiding principles and coordinating structures for implementing national biosafety systems. In addition, each provides for the creation of an advisory committee to serve as a focal point to initiate public dialogue and address cross-cutting issues related to the ethical, legal, and social implications of biotechnology.

⁷⁶ Advisory Committee on Releases to the Environment, Department of the Environment, Transport and the Regions, Annual Report 7, (2000) <<http://www.defra.gov.uk/environment/acre/pubs.htm>>.

⁷⁷ Canadian Food Inspection Agency, Plant Health and Production Division, Plant Biosafety Office, Insect Resistance Management of Bt Corn in Canada, 1998 <<http://www.inspection.gc.ca/english/plaveg/pbo/bt/btcormai1e.shtml>>.

⁷⁸ USDA-APHIS, Summary of Public Meeting on Virus-Resistant Transgenic Plants, 5 Aug. 1997 <<http://www.aphis.usda.gov/biotech/virus/virussum.html>>.

⁷⁹ U.S. EPA, “Assessment of the Scientific Information Concerning StarLink Corn,” SAP Report 2000-06, FIFRA Scientific Advisory Panel (SAP) Meeting, Washington, D.C., 28 Nov. 2000.

Australia

139. The development of Australia's National Biotechnology Strategy was begun in 1999 with the establishment of the Commonwealth Biotechnology Ministerial Council to coordinate government biotechnology activity. At the same time, government established the Biotechnology Consultative Group (BIOCOG), a panel of experts from industry and the scientific and research community, to provide it with independent advice. Overall, the goals of the strategy are to capitalize on existing advantages in biotechnology, achieve sustainable industrial growth, strengthen coordination of government activities at the Commonwealth and State levels, develop a catalytic role for government, and provide a basis for ongoing consultation and strategy development.

140. As a result of a series of consultations and assessments, Australia's strategy identified six key themes, two of which—biotechnology in the community and ensuring effective regulation—are relevant to biosafety. The remaining themes focused on the economic and trade aspects of biotechnology. A key thrust of the theme on biotechnology and the community was to establish a dialogue with Australians that would serve to increase awareness of biotechnology, its applications, and the regulations in place to safeguard the environment and health; to address ethical and socioeconomic concerns; to examine community health benefits arising from biotechnology; and to examine the role of biotechnology in sustainability and natural resource management issues.

141. The strategy also forms a broad policy platform that describes the Australian approach to biotechnology regulation. It establishes the role of the Office of the Gene Technology Regulator as the principal body responsible for biosafety and articulates as an overarching goal the need to ensure that potential risks from the introduction of GMOs are accurately assessed and effectively managed. Furthermore, the strategy defines the principles on which environment risk assessment should be based and identifies specific objectives. These include the establishment of a *framework and scientific methodology for risk assessment*, the identification of priorities for an environmental risk assessment program, improvement of the scientific knowledge base, monitoring for unforeseen consequences, and monitoring regulatory effectiveness.

Canada

142. Biotechnology has been the object of special attention within the Canadian federal government for at least 20 years. In 1979 Ministry of State for Science and Technology (MOSST) published the report, "Biotechnology in Canada," and the joint industry–university task force report, "Biotechnology: A Development Plan for Canada," was presented to the MOSST Minister in February 1981. These early reports ultimately led to the creation of a National Biotechnology Strategy (NBS) in 1983 to encourage research and development, investment, and market acceptance, of this new technology.

143. In 1990 a review of the NBS recommended an increased focus on the regulatory issues affecting biotechnology and the development of those technologies that would bring new products to market more rapidly. After a significant public consultation, the federal government announced its coordinated regulatory framework for products of biotechnology on January 11, 1993. The objectives of this framework were to maintain Canada's high standards for the protection of human health and the environment; use existing legislation and regulatory institutions; develop clear guidelines for evaluating products that are in harmony with national and international standards; provide a sound scientific basis for risk assessment and product evaluation; ensure that both the development and enforcement of regulations are open and include consultation; and contribute to the prosperity and well-being of Canadians.

144. Partly in response to changing budgetary imperatives, a review of the objectives of the NBS was conducted during 1996/97, leading to a renewed Canadian Biotechnology Strategy (CBS) in 1998.⁸⁰ The new CBS was based on the principles of promoting sustainable development, competitiveness, public health, innovation, transparency, and scientific excellence. Among the 10 key themes identified by the strategy are 3 that relate directly to biosafety: building public confidence, expanding the science base to support regulations, and regulating to protect human health and the environment. With respect to the regulatory framework, the strategy emphasizes efficiency and effectiveness, international harmonization, transparency, and human technical and scientific capacity.

South Africa

145. South Africa's National Biotechnology Strategy is emerging, a first draft having been prepared in June 2001. The South African experience illustrates that the formulation of national policy need not occur prior to the development of biosafety regulation, as was the case for Canada, but can occur at any time. Biosafety regulation is achieved under the Genetically Modified Organism Act 1997, which was implemented in 1999, and prior to that was governed by voluntary guidelines published by the South African Committee for Genetic Experimentation. The government recognized the need to develop a coordinating policy to stimulate innovation and human resource development and encourage research and development investment in South Africa, while preserving the environment. These motivations are similar to those expressed by other countries that have developed similar strategic policies. Of relevance to this discussion, the South African strategy aims to increase public understanding of biotechnology by improving communication of risks and benefits, communicating as a single voice across government departments, and including biotechnology issues (ethical, social, environmental) within school curricula.

Transparency and Public Engagement

Australia

146. In many respects, the Australian approach to regulating GMOs and products derived from them, such as novel foods, is a model of transparency and public involvement. The Office of the Gene Technology Regulator (OGTR), which administers Australia's new Gene Technology Act 2000, is responsible for reviewing and approving the deliberate environmental release of GMOs, either in experimental field trials or as commercial plantings. Commercial plantings are distinguished from field trials in that they do not have provisions for reproductive isolation; however, OGTR reserves the right to place conditions or restrictions on their conduct. Irrespective of whether the release is an experiment trial or a commercial planting, OGTR engages in two rounds of public notification and request for comment. These practices are the same as those previously followed under the voluntary system of guidelines administered by the Genetic Manipulation Advisory Committee.⁸¹ Upon receipt of applications for intentional release, OGTR publishes notices in the Commonwealth of Australia Government Notices Gazette, as well as national and regional newspapers, and its own website (<http://www.ogtr.gov.au>). These notifications also serve as a request for public comment. Similar notifications, including the publication of risk assessment reports and opportunities for public input, are provided for proposed decisions on the environmental release of GMOs.

⁸⁰ Industry Canada, "The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process," Ottawa <<http://strategis.ic.gc.ca/cbs>>.

⁸¹ Genetic Manipulation Advisory Committee, Public Information Sheets on deliberate release proposals, including field trials and general releases, that have been assessed by GMAC <<http://www.health.gov.au/ogtr/volsys/infosheets.htm>>.

147. The Australia New Zealand Food Authority (ANZFA), which is responsible for the regulation of novel foods under *Standard A18–Food Produced Using Gene Technology* in the Australian Food Standards Code, engages in similar public consultation processes. In soliciting public comment, ANZFA publishes a draft risk analysis report that provides a background to the application; highlights the issues addressed during the risk assessment; summarizes public comment submitted in response to the notification of application; and deals with legitimate issues raised in public comments.⁸²

United States

148. Under the Coordinated Framework, three agencies share responsibility for regulating biotechnology.⁸³ The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is the lead agency with respect to the environmental review and deregulation of transgenic plants, while the U.S. Environmental Protection Agency (EPA) is responsible for the registration of plant-incorporated protectants (for example, plant-expressed toxins derived from *Bacillus thuringiensis*). Since 1992, the U.S. Food and Drug Administration (FDA) has been operating under a policy for regulating bioengineered foods that took the position that these foods should not be subject to additional regulation solely because they were produced using modern biotechnology. In that context, FDA has worked with developers through a system of voluntary consultation and review prior to the commercial introduction of these products.⁸⁴

149. U.S. law requires that all petitions for a determination of nonregulated status, or applications for registration of a plant-incorporated protectant, be published in the *Federal Register* prior to any regulatory decision. In the case of APHIS petitions, this notification includes a synopsis of the petition (that is, general characteristics of the transgenic plant) and explains the role of other regulatory bodies (EPA and FDA), and the process for submitting comments and obtaining more information, including a copy of the petition, less any confidential business information. Following its assessment, and if it determines that the plant poses no significant risk to other plants in the environment and is as safe to use as more traditional varieties, APHIS publishes a “determination of non-regulated status” in the *Federal Register*. This notice advises the public of the availability of all written comments received, APHIS’ environmental assessment, and the Finding of No Significant Impact (FONSI) for the article. This statutory requirement for public notification and request for comment does not apply in the case of confined experimental field trials of transgenic plants; however, APHIS does periodically publish a notice in the *Federal Register* indicating the availability of a listing of current field trials.

150. Public notification and opportunities for public input have not been a part of FDA’s voluntary consultation process with industry prior to the introduction of new foods. This situation is poised to change with the proposal by FDA of a new rule requiring that all new foods derived from biotechnology be subject to mandatory review prior to marketing.⁸⁵ The new rule proposes to increase transparency by providing for pre-market publication of a notification prepared by the developer that would describe the new food and the related safety data. While addressing the criticism that the existing system lacks openness, the proposed rule does not go so far as to allow opportunities for public comment during the

⁸² Australia New Zealand Food Authority, Recent Standards Development: Applications <<http://www.anzfa.gov.au/foodstandards/recentstandardsdevelopment/index.cfm>>.

⁸³ The Coordinated Framework for Regulation of Biotechnology Products, *Federal Register* 51: 23303 (26 June 1986).

⁸⁴ FDA, Center for Food Safety and Applied Nutrition (CFSAN), “Guidance on Consultation Procedures: Foods Derived from New Plant Varieties” <<http://vm.cfsan.fda.gov/~lrd/consulpr.html>>.

⁸⁵ FDA, CFSAN, “Pre-market Notice Concerning Bioengineered Foods, *Federal Register* 66 (12): 4706–38, Docket No. 00N-1396 (18 Jan. 2001).

consultation period. In March 2001, the FDA published the results of the 51 voluntary industry consultations regarding bioengineered foods that have occurred since 1994.⁸⁶ The publication of this information, which previously was available only by request under the Freedom of Information Act (FOIA), provides further evidence that FDA is seeking to improve regulatory transparency.

European Union

151. The revision to Directive 90/220/EEC governing the environmental release of GMOs, which took effect on April 17, 2001 (Directive 2001/18/EC), makes new provisions for increased transparency and public involvement. These changes establish a mandatory requirement for public notification and some form of consultation with the public or special interest groups prior to the conduct of experimental or farm-scale trials (for example, environmental releases under Part B). The new directive does not specify the exact form or scope of consultation other than to require that it include a “reasonable time period.” The new directive also contains requirements for seeking public input on applications for Part C releases (for example, marketing consents), and any proposed changes of policy with respect to categories of Part B releases or the information requirements for Part C applications. While respecting the principle of protecting confidential business information, the new directive specifically excludes from such protection information pertaining to a general description of the GMO; name and address of the notifier; purpose of the release; location of the release; methods and plans for monitoring of the GMO; and the environmental risk assessment.

152. To make the decisionmaking process more predictable and transparent, the new Directive also establishes, for the first time, clear deadlines for each stage of the regulatory process. The directive also sets a maximum term for new Part C marketing consents of 10 years and requires that all existing consent holders reapply for an extension by October 2006.

International and Regional Harmonization

Canada–U.S. Bilateral on Agriculture Biotechnology

153. In recent years, Canada and the United States have engaged in bilateral discussions on harmonizing their approach to the risk assessment of transgenic plants. These efforts have aimed at establishing a shared set of criteria in the areas of molecular characterization and environmental risk assessments that each country will use to review submissions for regulatory approval.

154. In 1998 officials from the Biotechnology Permits Branch (USDA–APHIS), the Plant Biotechnology Office (CFIA), and the Office of Food Biotechnology (Health Canada) met to compare and harmonize, when possible, the information requirements and standards for submissions dealing with the molecular genetic characterization of transgenic plants.⁸⁷ The two countries reached substantial agreement in detailing the essential elements of molecular characterization data required to be submitted by a petitioner and to be used by the agencies for decisionmaking. They also reached agreement on quality standards for submitted information in the form of checklists for reviewers. It was anticipated that these efforts will facilitate cooperation and information-sharing between the agencies as well as expedite the review process.

155. Although slight differences remain between the two countries’ requirements, for the most part, petitioners are able to submit very similar data packages on their molecular characterization to both

⁸⁶ FDA, CFSAN, “List of Completed Consultations on Bioengineered Foods” <<http://www.cfsan.fda.gov/~lrd/biocon.html>>.

⁸⁷ CFIA, “Canada and United States Bilateral on Agricultural Biotechnology,” Ottawa. <<http://www.inspection.gc.ca/english/plaveg/pbo/usda/usda01e.shtml>>.

regulatory agencies. The clarification of data requirements and standards provided petitioners with a better understanding of the agencies' needs, enabling petitioners to adjust their research programs to meet these standards.

156. During 2001, Canada and the United States finalized their discussions on harmonizing the evaluative criteria for environment risk assessments. These harmonized criteria, published in 2002, more clearly explain the detailed information requirements related to assessing potential risks of outcrossing, weediness, and impacts on non-target organisms.⁸⁸

157. Both countries also are engaged in separate bilateral discussions with the European Union on similar risk assessment harmonization issues related to the molecular characterization of transgenic plants.

⁸⁸CFIA, "Environmental Characterization Data for Transgenic Plants Intended for Unconfined Release," Ottawa. <<http://www.inspection.gc.ca/english/plaveg/pbo/appenannex2e.shtml>>.

Table A1. Summary of characteristics of regulatory frameworks

<i>Characteristic of regulatory framework</i>	<i>Argentina</i>	<i>Australia</i>	<i>Canada</i>	<i>Egypt</i>	<i>Japan</i>	<i>S. Africa</i>	<i>UK (EU)</i>	<i>USA</i>
Conceptual approach	“X” indicates conformity with the first alternative in each dichotomous comparison							
Regulatory oversight triggered by the process of genetic engineering (recombinant-DNA technology) vs. product attribute	X	X		X	X	X	X	X ^a
Regulatory decisionmaking requires political involvement vs. occurs solely within competent authority	X	X		X		X	X	
Implementing biosafety regulation								
Statutory instruments are employed vs. voluntary guidelines		X	X		X	X	X	X ^b
New laws were passed to specifically address gene technology vs. existing statutes used		X			X	X	X	
Decisionmaking process includes consideration of economic and/or social factors vs. are based primarily on science assessment	X ^c					X ^d		
Scientific risk assessment by an expert committee vs. by evaluators within the public service	X	X ^e		X		X	X	
Mandatory requirement for post-market validation testing or monitoring vs. no, or limited, monitoring							X ^f	
Horizontal issues								
Biosafety regulation under the umbrella of an overarching national biotechnology policy vs. no national strategy		X	X			X		
Mandatory requirement for public notification of decisions vs. no legal requirement for notification		X					X ^g	X
Mandatory requirement for public comment prior to decisions vs. no legal requirement		X					X	X

Notes:

- a. Applies to USDA-APHIS and U.S. EPA. To date, U.S. FDA policy has been that bioengineered foods are not inherently more risky than other foods so has engaged in voluntary consultation only.
- b. Exception is U.S. FDA voluntary consultation process with developers.
- c. In addition to the scientific assessment of risk performed by CONABIA and SENASA, all products are subject to an economic analysis by the National Directorate of Agrifood Markets within SAGPyA, which studies the potential impact of the approval on domestic and international markets.
- d. The Executive Council, which advises the minister on approvals, also will take into account socioeconomic issues relating to labor and trade impacts.
- e. Mixed approach in which food safety assessments are conducted by evaluators within the ANFZA but environmental considerations are considered by an expert committee.
- f. The recent revision to Directive 90/220/EEC (Directive 2001/18/EC) proposes a statutory period of mandatory post-market monitoring. The period will be agreed at the point of giving commercial approval; at the end of the review period, a decision to renew the commercialization approval will be made based on any monitoring evidence.
- g. Recent revision to Directive 90/220/EEC (Directive 2001/18/EC) governing the environmental release of GMOs, which took effect in Oct. 2002, makes new provisions for increased transparency and public involvement.

Appendix 2 UNEP/GEF Global National Project

158. In 2000 the Global Environment Facility published its “Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety.”⁸⁹ The main objectives of this strategy are to:

- Assist countries to establish national biosafety frameworks
- Promote information-sharing and collaboration, especially at the regional and subregional levels
- Promote collaboration with other organizations to assist capacity building for the protocol.

159. To implement the GEF Initial Strategy, two sets of activities are underway:

- The UNEP/GEF Global Project for the development of national biosafety frameworks in up to 100 countries (with contributions of up to USD 200,000 dollars per country), and;
- Demonstration projects to support the implementation of national biosafety frameworks (with contributions of up to USD 1,000,000 dollars per country). These projects will soon be initiated by the implementing agencies: UNEP (8 projects); UNDP (2 projects); and the World Bank (2 projects).⁹⁰

160. The Global Project, which was started in June 2001 and will be implemented over 42 months, has three phases⁹¹:

Phase I. Preparatory activities and the gathering of the necessary information to produce:

- Inventories of the current use of modern biotechnology as defined in the Cartagena Protocol on Biosafety; existing legislation or legal instruments related to biotechnology/biosafety; and, active or planned National Projects for capacity building related to the safe use of biotechnology.
- A report on existing subregional biosafety frameworks and mechanisms for harmonization of risk assessment/management.
- Rosters of relevant experts within the country, identifying their experience and expertise so that adequate coverage in all areas of expertise is obtained and potential gaps can be identified.

Phase II. Analysis for the preparation of a National Biosafety Framework, which includes:

- Access to relevant information for all stakeholders in accordance with the requirements of the Cartagena Protocol on Biosafety
- Mechanisms for adequate involvement of all stakeholders, including public and private sectors, on issues related to biosafety

⁸⁹ <http://www.unep.ch/biosafety/GEF_strategy.pdf>.

⁹⁰ P. van der Meer, personal communication, 2002.

⁹¹ United Nations Environment Programme, UNEP-GEF Biosafety Unit, UNEP-GEF Global Project on Development of 100 National Biosafety Frameworks, Geneva, 2001 <<http://www.unep.ch/biosafety/documents.htm>>.

- Identification of the components of the national Biosafety Framework, in consultation with all relevant stakeholders.

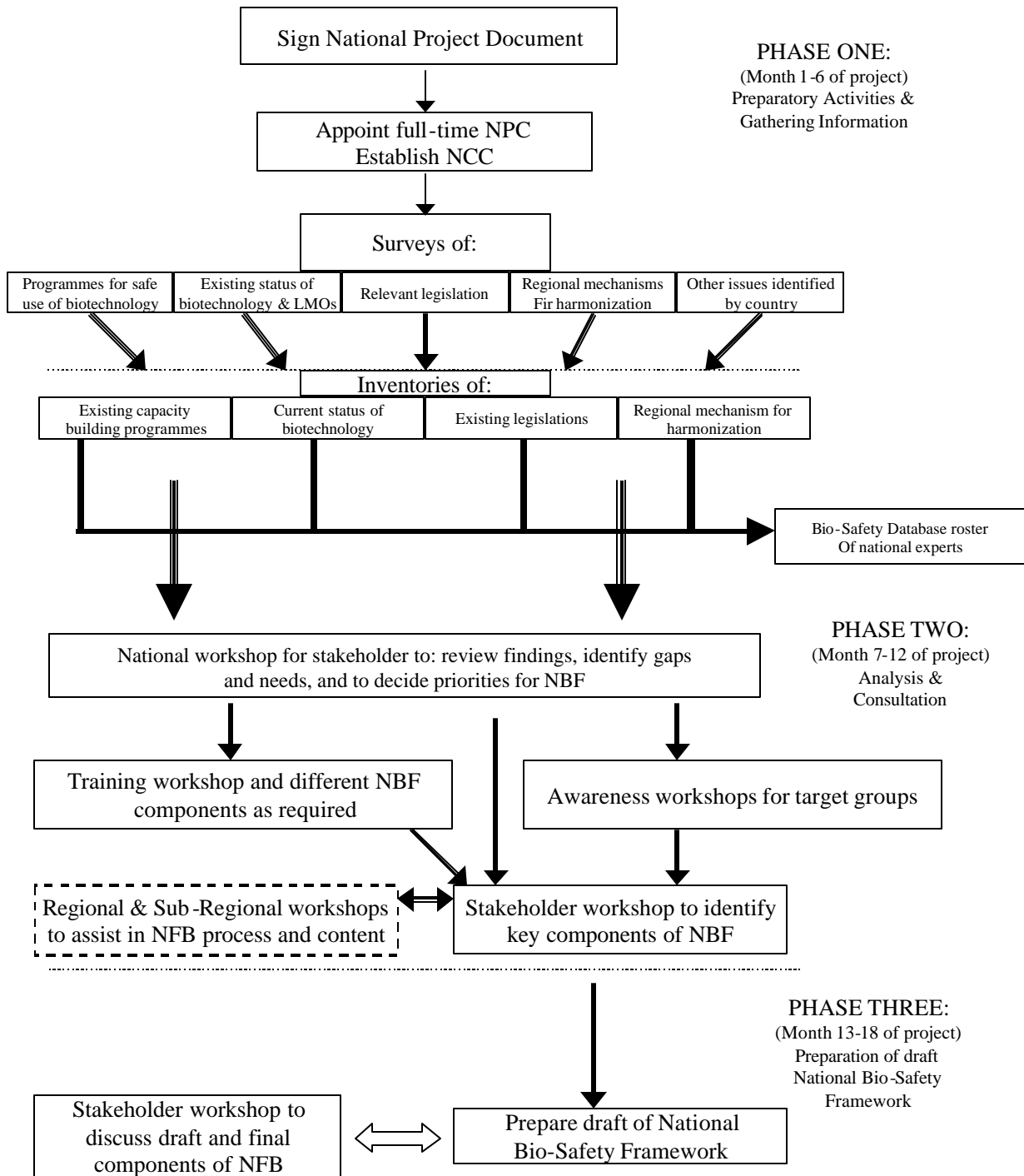
161. *Phase III.* Preparation of a draft National Biosafety Framework, which includes:

- Draft of legal instruments, including guidelines, as appropriate
- Systems for risk assessment and management, including audit, which take into account national and subregional/regional needs.
- Administrative system for compliance with the Cartagena Protocol on Biosafety
- Mechanisms for public consultation in decisionmaking processes regarding LMOs
- Mechanisms for sharing scientific assessments at subregional levels, while allowing for decisionmaking at the national level
- Identification of country needs and mechanisms for participation in the Biosafety Clearing House
- Publication of inventories, reports of national meetings, draft and/or final National Biosafety Framework, relevant regulations, and guidelines.

162. The United Nations Environment Programme (UNEP) has published a flow chart for the National Project participants that suggests a strategy to meeting the project requirements of Phases I-III (figure A2)⁹².

⁹² UNEP, National Project Document, Geneva, 7 < <http://www.unep.ch/biosafety/NPD100402.pdf>>.

Figure A2. Suggested flow chart for national project to develop national biosafety framework



Source: UNEP, National Project Document, 7.

Appendix 3 Preliminary List of Key Required Capacities for Implementation of the Cartagena Protocol

163. As part of the “Report of the Open-ended Expert Meeting on Capacity Building for the Cartagena Protocol on Biosafety,” a list of key capacity requirements for complying with the protocol was developed. The list is reproduced below.⁹³

Table A3. Key capacity requirements to comply with the Cartagena Protocol on Biosafety		
<i>Institution-building</i>	<i>Risk assessment</i>	<i>Risk management</i>
<p>Needs assessment and biosafety framework planning</p> <p>(a) Inventory of existing and anticipated biotechnology programs and practices</p> <p>(b) Capacity to develop present and future import/export data</p> <p>(c) Accurate understanding of industry biotechnology practices in relevant sectors</p> <p>(d) Capacity to compile and analyze existing legal and administrative biosafety regimes</p> <p>(e) Multidisciplinary strategic planning capacity</p> <p>(f) Capacity to relate biosafety regime to other international obligations</p>	<p>General risk assessment capacities</p> <p>(a) Ability to coordinate multidisciplinary analyses</p> <p>(b) Enhancement of technological and institutional capacities for risk assessment</p> <p>(c) Capacity to identify and access appropriate outside expertise</p> <p>(d) Understanding of relevant bio-technology processes and applications</p> <p>(e) Science and socioeconomic capacities</p> <p>(f) Analyze risks to conservation and sustainable use of biodiversity⁹⁴</p>	<p>General risk management capacities</p> <p>(a) Understanding of application of risk management tools to different biotechnology sectors</p> <p>Decisionmaking capacities</p> <p>(a) Identification and quantification of risks, including through sound application of the precautionary approach</p> <p>(b) Capacity to assess relative effectiveness of management options for import, handling, and use, when appropriate</p> <p>(c) Capacity to assess relative trade impacts of management options, when appropriate</p> <p>(d) Impartial review of proposed management regime</p>

⁹³ Intergovernmental Committee for the Cartagena Protocol on Biosafety, “Indicative Framework for Capacity Building under the Cartagena Protocol on Biosafety,” Secretariat of the Convention on Biological Diversity, Montpellier, 2000 <<http://www.biodiv.org/doc/meeting.asp?wg=ICCP-01>>.

⁹⁴ Specific types of scientific expertise required will vary from case to case but, broadly, involve two areas: ability to evaluate genetic modifications and ability to evaluate interactions with the receiving environment.

Table A3. Key capacity requirements to comply with the Cartagena Protocol on Biosafety		
<i>Institution-building</i>	<i>Risk assessment</i>	<i>Risk management</i>
Biosafety regime development	(g) Undertake life-cycle analysis	prior to decision making
(a) Develop/strengthen legal and regulatory structures	(h) Analyze risks to human health of effects on biodiversity	Implementation of decisions
(b) Develop/strengthen administrative processes to manage risk assessment and risk management	(i) Analyze ecosystem effects of living modified organism introduction	(a) Identification and handling of living modified organisms at point of import
(c) Develop domestic/regional risk assessment capacity	(j) Assess food security issues arising from risks to biodiversity	(b) Monitoring of environmental impacts against expected impacts
(d) Capacity to administer notification, acknowledgement, and decision response process	(k) Value and roles of biodiversity to local and indigenous communities	(c) Capacity to monitor, enforce, and report on compliance
(e) Capacity to make and report decision on LMO import in required time frames	(a) Other socioeconomic considerations related to biodiversity	
(f) Emergency notification and planning and response capacity	(b) Enhancement of related scientific, technical capacities	
(g) Enforcement capacity at borders		
Long-term regime building/maintenance		
(d) Capacity to monitor, review, and report on the effectiveness of risk management program, including legal, regulatory, and administrative mechanisms		
(e) Capacity to monitor longer-term environmental impacts, if any (based on current baselines)		
(f) Establishment of environmental reporting systems		
Cross-cutting capacities		
Data management and information-sharing		

Table A3. Key capacity requirements to comply with the Cartagena Protocol on Biosafety		
<i>Institution-building</i>	<i>Risk assessment</i>	<i>Risk management</i>
(a) Exchange of scientific, technical, environmental and legal information (b) Collection, storage and analysis of scientific, regulatory and administrative data (c) Communication to the Biosafety Clearing-House		
Human resources strengthening and development (a) All aspects of regime development, evaluation and maintenance for risk assessment and risk management (b) Raising awareness of modern biotechnology and biosafety among scientists, government officials (c) Training and longer-term education (d) Procedures for safe handling, use and transfer of living modified organisms		