

Developing a Biosafety System

All countries with functioning biosafety regulatory systems have developed these systems gradually, usually beginning with voluntary guidelines and standards developed cooperatively by stakeholders in academia, industry, and government. Over time these were incorporated in laws, either under existing legislation covering food and agricultural products or new legislation dealing specifically with biotechnology. Even in countries with long-established systems, biosafety policy and its implementation continue to evolve and it is not unusual to have a mix of voluntary and mandatory measures.

For countries seeking to develop a national biosafety system, it must be emphasized that there is no model for a single best approach. The issues to be considered can be broadly divided into six elements, which are briefly discussed below.

NATIONAL INVENTORY AND EVALUATION

An inventory and evaluation of national priorities, agricultural policies, existing regulatory regimes, and national scientific and technical capacities, is an ideal prerequisite to the development and implementation of biosafety-related policies and regulations. This national appraisal provides a means to identify and characterize available resources and regulatory infrastructures, assess their adequacy for supporting a biosafety system, and identify gaps where capacities need to be strengthened.

NATIONAL POLICIES AND STRATEGIES

A national biosafety policy or strategy provides a set of principles to guide the development and implementation of a biosafety system and should describe the goals and objectives of the regulatory framework. Direction on many of the fundamental issues and public policy choices that must be considered during the development of regulations can be provided by such a strategy. Examples of these 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.

SCIENTIFIC KNOWLEDGE, SKILLS AND CAPACITY BASE

The human resource environment that both enables and limits biosafety implementation is shaped by the scope and quality of: competency in the biological sciences; expertise in information acquisition, communications, and management; and, experience in critical thinking, analysis, and decision-making. These capacities have an overriding influence on the development and implementation of a biosafety system. Addressing capacity needs is the top priority for many developing countries.

Building a strong base of scientific knowledge in support of the regulatory system, and development of core competencies in biotechnology product evaluation, are fundamental to any national biosafety system. These activities allow an improved scientific basis for assessments of potential risks and/or benefits, and they strengthen the scientific capabilities for risk management, inspection, and monitoring.

DEVELOPMENT OF REGULATIONS

Decisions on an appropriate regulatory framework should be informed by the national inventory and evaluation, and through extensive consultation with stakeholders, including the public. This is particularly true if a country chooses to incorporate non-safety issues into its decision-making process.

IMPLEMENTATION OF REGULATIONS

The central issues around the implementation of biosafety regulations involve the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication within existing financial, technical, and



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human resource constraints. Decisions made during the implementation phase directly affect the costs associated with assessing and managing risks and ensuring compliance with regulations.

CROSS CUTTING ISSUES

Cross cutting issues are those that are common to each of the five preceding elements and they are often the most challenging factors to address and resolve. They are, however, the issues that will ultimately dictate the scope of a national policy on biosafety, and the conversion of policy into practice. Cross cutting issues affect the implementation of the system designed to assess biosafety, and perhaps more importantly, those non-technical factors that are crucial to public acceptance and confidence in the decisions that are made by government on behalf of the people.

The twin issues of public information and participation have to do with the degree of transparency in a regulatory system, and the degree to which the public has input either into the formulation of regulatory policy or into specific regulatory decisions. 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, and as well, the conclusions and decisions that have been reached. Transparency can also involve the perceived independence and objectivity of the regulatory decision-makers.

Human, financial and infrastructure resources largely determine the scientific and administrative capacity of any country; they obviously influence any biosafety related policy or program. Funds must be available to develop and implement a national biosafety system; to support the infrastructure required, such as buildings, labs, equipment, and computers; to facilitate communication and public participation; to train scientific and regulatory personnel; and to foster the research required to assure that risk assessments are sound.

CONCLUSIONS

The development of an effective national biosafety system is important to encourage the growth of domestic biotechnologies; to ensure safe access to new products and technologies developed elsewhere; and to build public confidence that products in the marketplace are safe. The absence of a suitable framework affects the ability of the public and private sectors to invest in biotechnology and to make the products of biotechnology available so that the benefits they afford can be realized.

