



PROGRAM FOR BIOSAFETY SYSTEMS

A partnership program for biosafety capacity development

esearch is bringing to the pipeline a wide range of agricultural applications of modern biotechnology, including nutritionally enhanced crops and genetic modification of plant varieties for greater resistance to insects, herbicides, and diseases, and for increased tolerance to drought and to soils contaminated with high concentrations of salt or heavy metals. Technologies alone cannot solve the complex problems of hunger and poverty, but some do have great potential to alleviate hunger and malnutrition in developing countries. It is therefore essential to assess the prospects of agricultural biotechnology and biosafety systems to regulate it.

The likelihood of transgenic plants causing harm to the environment or to human health has led to the development of regulatory regimes that are specifically applied to assessing the biosafety of these products. Development of an effective biosafety system is important to protect consumers and the environment as well as to ensure safe access to new products and technologies developed in-country or elsewhere. The Program for Biosafety Systems (PBS) addresses these challenges through an integrated program of research, capacity development, and outreach.



THE PBS APPROACH

To support the development and implementation of national biosafety systems, PBS works through a variety of partner—driven activities and initiatives including training workshops, a competitive grants program, biosafety policy analysis and policy development, and consultative guidance on biotechnology product development. These activities are designed and implemented in close collaboration with PBS regional coordinators and partners located in Asia and Africa. To help our partner countries meet their national goals for agricultural production and food security, public health, biodiversity conservation, and economic growth, PBS

- provides assistance as those countries develop and implement effective biosafety policies and procedures,
- helps strengthen their existing capacity for conducting scientifically sound risk assessments,
- fosters science-based decisionmaking at each stage of product development and use, and
- encourages regional collaboration and information exchange among stakeholders involved in biotechnology and biosafety and helps increase understanding of biotechnology applications and issues.

While PBS gears its strategic objectives on the needs and goals of its specific partner countries, it focuses on four overarching global components:

Policy Development and Implementation

Evaluating the implications of different country and regional regulatory approaches for genetically modified organisms (GMOs) by developing decision models to assist regulatory agencies. Working to generate new information, provide analysis of practical problems and cases, and make recommendations regarding national and regional regulatory systems and decisionmaking.

Capacity Building & Communication

Maintaining an active program of training, education, and capacity-building activities in biosafety to ensure that the people involved in biosafety decisionmaking are competent and confident enough to use the best available science to assess planned releases of GMOs and genetically modified (GM) food products.

Risk Assessment Research

Providing a mechanism for competitive grants on biosafety research in Asia and Africa through the Biotechnology-Biodiversity Interface (BBI) grants facility.

Regulatory Approval Strategies

Providing biosafety guidance for product development and helping institutions comply with regulatory requirements; working with regulatory agencies to assist them in developing review, approval and inspection processes, and in creating global resources for training and outreach.

CRITICAL ELEMENTS FOR EFFECTIVE BIOSAFETY SYSTEMS

The following five elements are recognized as being critical to the development and implementation of effective national biosafety systems:

- Research: Strategies and research agendas in biotechnology and biosafety
- Strategic Assessment: A national inventory and evaluation of legal, scientific, and technological capacity in risk assessment, risk management, compliance, and enforcement
- Biosafety Management: Development and implementation of regulations and strong national policies in biotechnology and biosafety decisionmaking, compliance and enforcement
- Risk Perception: A broad-based understanding of the benefits and risks of GM technology in agricultural innovation
- Risk Communication: The knowledge, skills, and capacity to communicate decisions on GM applications in an authoritative and transparent manner

EXPECTED OUTCOMES

PBS's goal is to effectively address biosafety within a sustainable development strategy anchored by agriculture-led economic growth, trade, and environment objectives, and to achieve the following strategic outcomes:

- An enabling regulatory environment that advances the safe use of new biotechnologies in agriculture will be in place in PBS partner countries in Africa and Asia.
- Partner countries with established regulatory systems will efficiently respond to emerging requirements from international standard-setting processes and agreements, or postcommercialization requirements.
- Models of robust risk assessment and regulatory approaches for biotechnology applications will have been developed based on scientific and policy research and stakeholder consultations—and incorporated into regulatory frameworks in partner countries.
- Regulatory authorities and scientific institutions in target countries will have conducted and implemented regulatory assessments and timely decisionmaking on a pipeline of promising agri-biotechnologies and traded commodities.

PARTNERS

PBS consortium members

- Donald Danforth Plant Science Center (DDPSC)
- International Food Policy Research Institute (IFPRI)
- Michigan State University (MSU)
- · Western Michigan University (WMU)

Collaborative national partners in Asia and Africa The Philippines

- Bureau of Plant Industry, Department of Agriculture
- National Committee on Biosafety, Department of Science and Technology
- National Institute of Molecular Biology and Biotechnology (BIOTECH), University of the Philippines at Los Baños

Indonesia

- · Agency for Agricultural Research and Development
- Center for Agricultural Biotechnology and Genetic Resources Research and Development

East Africa

- · Commission for Science and Technology, Tanzania
- Kenyan Agricultural Research Institute
- Kenya Plant Health Inspection Service
- National Agricultural Research Organization, Uganda
- National Council on Science and Technology, Kenya
- · National Council on Science and Technology, Uganda
- · Tropical Pesticides Research Institute, Tanzania

West Africa

- · Biotechnology and Nuclear Agriculture Research Institute, Ghana
- Institute for Rural Economy, Mali
- Ministry of Environment Permanent Technical Secretary, Mali
- · National Biotechnology Development Agency, Nigeria

Southern Africa

- AfricaBio, South Africa
- · National Institute for Agricultural Research, Mozambique
- · National Research Council, Malawi
- University of Malawi
- University of Pretoria, South Africa

Regional collaborative partners

- · African Biotechnology Stakeholders Forum (ABSF)
- AfriCenter, International Service for the Acquisition of Agri-biotech Applications (ISAAA)
- Association for Strengthening Agricultural Research in East and Central Africa (ASARECA)
- Centers of the Consultative Group on International Agricultural Research (CGIAR)
- East Africa Research Network on Biotechnology, Biosafety and Biotechnology Policy (BIO-EARN)
- Food, Agriculture and Natural Resources Policy Analysis Network (FANRPAN)

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