

Biosafety Capacity Development: *Case study on PBS*

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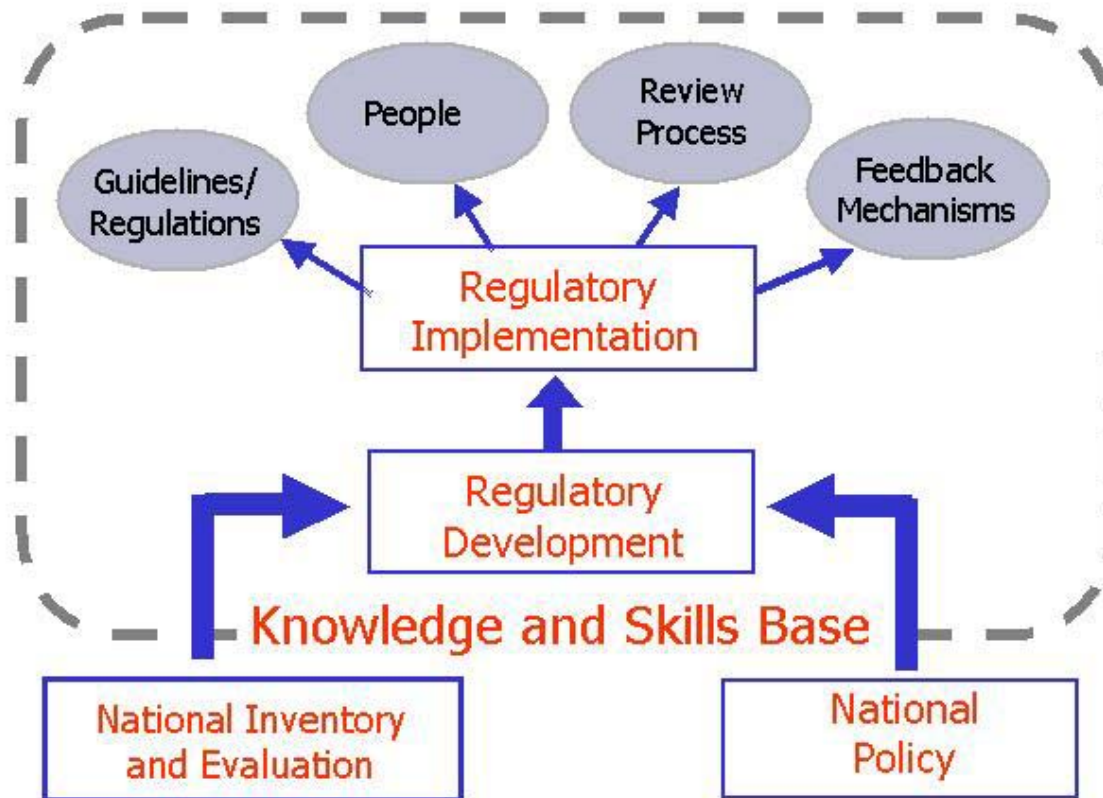


Program mission

- Mission: To empower partner countries for science-based biosafety decision-making while strengthening capacity to implement biosafety through innovative system design. (program proposal)
- ☑ Implemented by an international Consortium of US expert institutes, regional and national organizations in partner countries, and individual biosafety experts
- ☑ Lead agency: International Food Policy Research Institute (IFPRI)
- ☑ Donor organization: US Agency for International Development (USAID)
- ☑ Program started May 2003

PBS approach

Basic Elements of Biosafety Implementation



Main components

- Asia

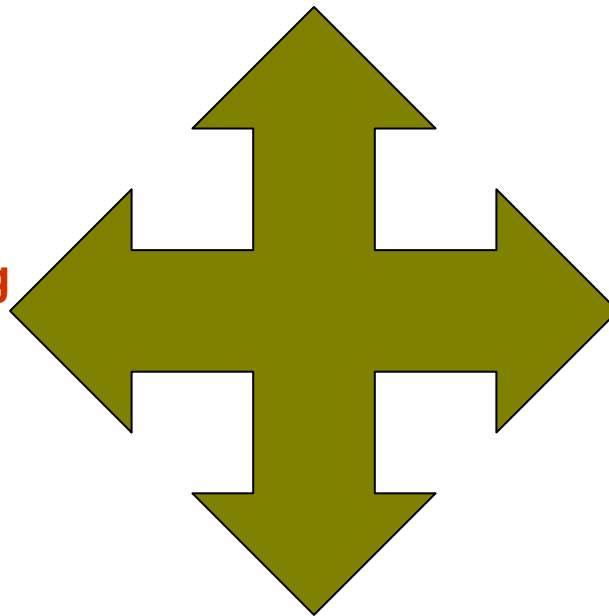
- * Indonesia
- * Philippines

**I. Policy Development
and Implementation**

- Africa

- * West Africa
(Ghana, Mali, Nigeria)
- * East Africa
(Kenya, Uganda)
- * Southern Africa

**IV. Capacity Building
Communications**



**II. Risk Assessment Research
Competitive Grants (BBI)**

**III. Biosafety Guidance for
Product Development**

Summary of strategic outcomes

1. Establishment and Operation of Country/Regional Advisory Groups
2. Contributions to Policy Development
3. Establishment of Interim Processes
4. Enabling Environment for the Conduct of Experimental Field Trials
5. Sub-regional Approaches to Biosafety Risk Assessment, Risk Management, and Communication
6. Regional Communications Strategies for Biotechnology-Biosafety-Food Safety
7. Improved Knowledge and Increased Scientific and Technical Capacity to Support Product Commercialization, and Risk Assessment/Risk Management Activities

Achievements

Action plan element:

Risk assessment and scientific /
technical expertise

Achievement (1): BBI Program

Strengthen the science base for biosafety assessments through environmental risk assessment and risk management research

- **To assist regulatory bodies in making science-based decisions about the effects on biodiversity of introducing genetically engineered organisms into the environment.**
- **To begin generating scientific data on potential risks associated with applications of biotechnology on biodiversity in developing countries.**
- **Develop strategies for managing potential risks in the context of agro-ecosystems found in developing countries.**
- **Build collaboration between agricultural research and environmental conservation communities in the U.S. and developing countries.**
- **Build capacity in risk assessment and risk management research.**

Results of consultations in partner countries

- **Identify information needs based on**
 - National/regional issues
 - Types of regulatory packages currently under consideration by NBCs or likely to be pending
- **Identify areas where research is needed to enable decision making by regulatory authorities**
- **Modify application process; establish small grants facility**
- **Vital role of PBS regional coordinators and advisory groups**

2005

Can Bt-Cowpea be Deployed in Africa without Incidence on Wild Cowpea Biodiversity and Demography?

R.S. Pasquet, ICIPE Kenya; **J.T. Ouedraogo**, INERA, Burkina Faso; **S. Demissew**, Addis Ababa University, Ethiopia; **P. Gepts**, University of California, Davis USA

Gene Flow from Cultivated Rice (*Oryza sativa*) to its AA Genome Wild Relatives in the East African Region: Key Research for Transgene Risk Assessment

S. Kiboi, University of Nairobi, Kenya; **M. Nkya**, National Plant Genetic Resources Centre, Tanzania; **T. Haileselassie**, Addis Ababa University, Ethiopia; **A. Snow**, Ohio State University, USA; **D. Kiambi**, McGill University, Canada

Post Commercialization Monitoring of Asian Corn Borer *Ostrinia furnacalis* Resistance to Bt Corn in the Philippines and the Impact of Pollen Dispersal on Non-target Lepidoptera

B.F. Cayabyab, **A.C. Sumalde**, UP Los Banos; **W.R. Cuaterno**, Bureau of Plant Industry, Manila; **E.P. Alcantara**, Nat. Inst. of Mol. Bio. and Biotech., University of the Philippines; **B.D. Siegfried**, University of Nebraska, USA

Ecosystems Approach in the Assessment of the Environmental Impacts of Herbicide-tolerant (Ht) Corn on Wild Biodiversity in Corn Production Systems in Luzon, Philippines

C.I. Villamor, **V.O. Sinohin**, **S.A. Pasicolan**, **H.O. San Valentin**, **E.F. Rimando**, and **J.B. Ehora**, Ecosystem Research and Development Center (ERDB), College, Laguna, Philippines

2004

Investigation of Secondary Ecological Effects of Bt Corn in the Philippines

E. Alcantara, B. Lavina-Caoili, P.A. Javier, University of the Philippines; **M. Dulce J. Mostoles**, Camarines Sur State Agricultural College, The Philippines

Baseline Susceptibility and Genetic Diversity among Eggplant Shoot and Fruit Borer (ESFB) Populations

S. Parimi and U.B. Zehr, MAHYCO Ltd, India; **B.D. Siegfried**, University of Nebraska, USA

Risk Assessment and Management Options for Stacked-Gene Transgenic Crucifers in India and Indonesia

A.M. Shelton, Cornell University, USA; **R.T. Roush**, UC Davis, USA; **D.A. Russell**, LaTrobe University, Australia; **G.T. Gujar**, Indian Agricultural Research Institute, India; **A. Rauf**, Bogor Agricultural University Bogor, Indonesia

Environmental Risk Assessment of Genetically Engineered Sorghums in Mali and Kenya

F. Sagnard and E. Weltzien-Rattunde, ICRISAT-Mali; **A. Toure and M. Kareembe**, Institut d'Economie Rurale du Mali, Mali; **O. Koita**, Universite de Bamako, Mali; **R. Folkertsma**, ICRISAT-University of Hohenheim and ICRISAT-Nairobi, Kenya; **B. Kanyenji**, Kenyan Agricultural Research Institute (KARI), Kenya

Achievements

Action plan element:
Institutional capacity
building

Achievement (2): Policy development

- Legal analysis of regulatory systems – East Africa
- Regional policy roundtables: Collaboration, information exchange → harmonization (?)
- Review meeting by East Africa legal experts

- ECAPAPA-COMESA-ACTS study: “Towards a regional approach to biotechnology and biosafety policy in East and Southern Africa”
- Partner-country policy development; e.g., Uganda, Malawi

Analysis of regulatory systems

- Adequate Legal Authority
- Comprehensive
- Clear Safety Standards
- Proportionate Risk-Based Reviews
- Transparent and Understandable
- Participatory
- Post Approval Oversight
- Flexible and Adaptable
- Efficient, Workable, and Fair
- Opportunities for Regional Harmonization: Common regulatory pathways

East Africa regional policy roundtable – Follow on

- Development and adoption of East Africa strategic plan
- Setting schedule and agendas for periodic meetings of the NBCs, plant protection and quarantine offices
- Regional review of common documents needed for the regulatory process
- Define entry point for regional collaboration, e.g., EAC, ASARECA
- Specialized workshops on confined field testing, to understand what they are, and are not, and the type of approvals needed.

Malawi: In-country collaboration

➤ 2005/06 priorities:

- Overall guiding policy on biotechnology
 - National biotechnology policy task force
 - National and international consultants
 - Background papers; consultations
 - Drafting & review of policy documents
- Training of Biosafety Inspectors
 - Development of course contents and syllabus
 - Endorsement by Genetic Resource Board
 - 1-week intensive course & follow-up
- Outreach (policy makers) and public awareness

Achievements

Action plan element:
Risk management

Achievement (3): Biosafety guidance for public R&D

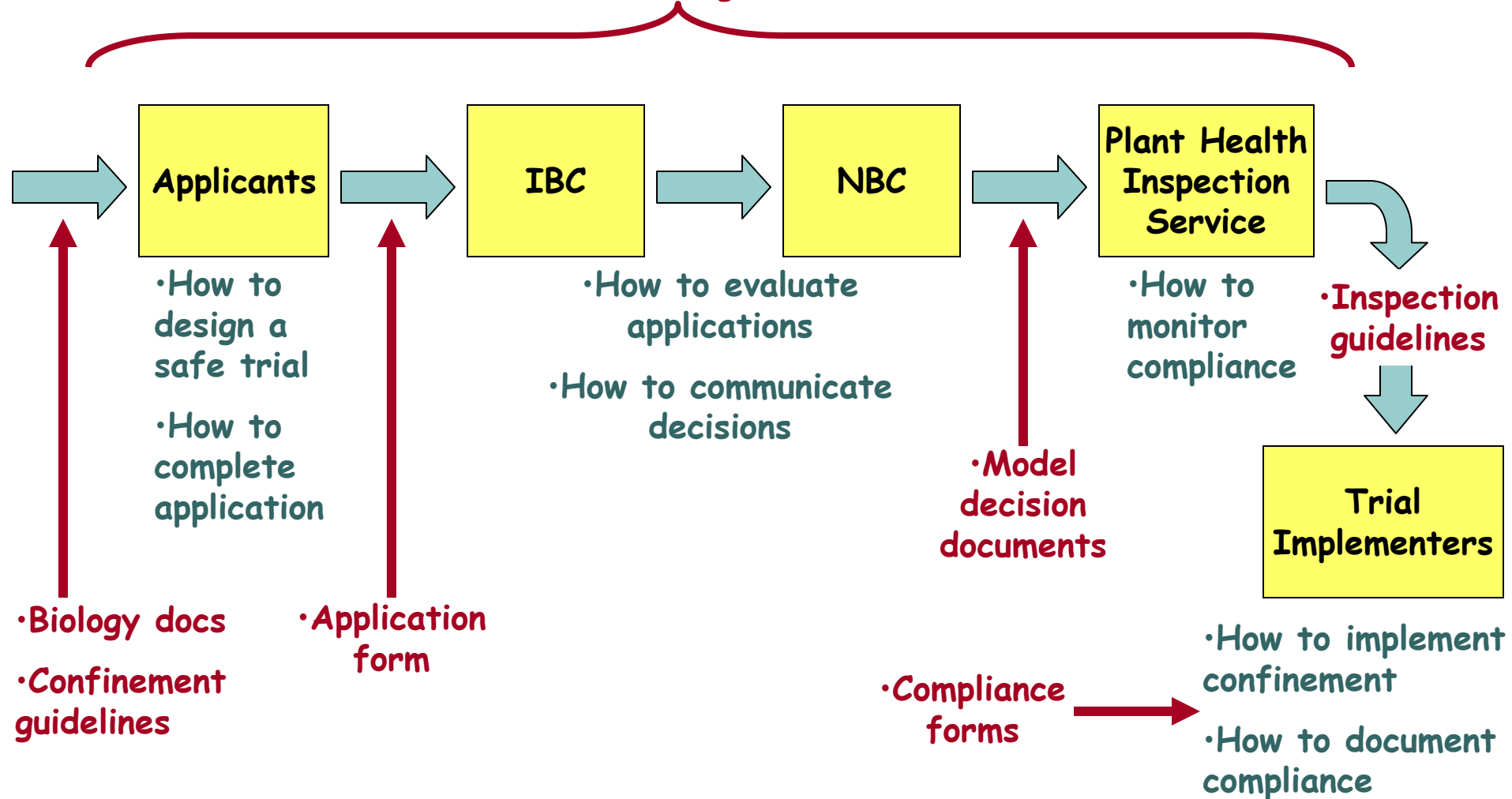
- Assist public-sector R&D institutes to incorporate biosafety consideration into product development efforts
- Examples:
 - Virus-resistant papaya (Philippines)
 - Virus-resistant sweet potato (Kenya)
 - Fungal-resistant banana (Uganda)
- Assistance to applicants and regulatory agencies, with focus on field trials

Why are field trials important?

- **Essential for product development and adaptation to local conditions**
- **Essential for subsequent environmental and food safety assessment**
- **Allow farmers and decision-makers see and decide for themselves**

Facilitating Safe Confined Field Trials

Field trial regulations



Integrated Confinement System: Uganda

- **Training of IBC in field trial design and management (Machakos and Jinja)**
- **Uganda Task Force and PBS collaborate on development of:**
 - **Guideline for CFT review and conduct**
 - **Internal Operating Procedures**
 - Agricultural Sector Advisory Panel
 - Documents: development, review, adoption
 - **Standard Operating Procedures for CFTs**
 - Shipping and storage
 - Confinement requirements for CFTs
 - Termination of trial
 - Post-harvest management
 - Reports
 - Incidents
 - **Guidance Documents**
 - Fee Schedule
 - Preparation of a field map
 - Specific crop requirements
 - Biology documents: Banana, cassava, etc
 - **Manual and Checklist for Inspections**
- **Assistance in preparation of application for field trial of GM bananas**



Achievements

Action plan element:

Human resource
development and training

Achievement (4): Training / communication activities

- **Enabling the authorization and safe conduct of experimental field trials**
 - Compliance management
 - Training of inspection staff
- **Regulatory strategies for scientists and regulators**
 - Focus on requirements for the evaluation of field trials, with subsequent training addressing the more extensive requirements for commercial releases
- **Food safety and environmental risk assessment**
 - Introductory, awareness raising
 - In-depth technical training

Training / comm. activities

- **Policy development seminars**
 - Review findings from program components
 - Consider options for regulatory efficiencies
 - Regional collaboration and harmonization
- **Communication and outreach**
 - Communication skills for key spokespersons
 - Supporting ongoing communication programs

FY 2005 Education, Training & Outreach activities

-- Africa --

493 beneficiaries (116 female / 377 male)

Observed scattering of efforts

PBS Annual General Meeting, Sep.2004 / RIBIOS-CBD, Oct.2004:

- What is added value of PBS in training if other groups are also doing this?

PBS External Advisory Board, Sep.2004:

- What's the overall strategy?
- What are the needs and priorities?
- Mechanisms for evaluation and monitoring impact needed

USAID, March 2005:

- What's our strategy "beyond workshops"?

Common Principles & stronger central facilitation

- **Why ?** -- Rationale: Outlines for training / education events will clearly indicate its contribution to PBS strategic outcomes
- **Who ?** -- Getting the right people
- **What ?** -- Training plan: training objectives, methodology and expected results, preliminary program
- **How ?**
 - Local collaboration (and co-sponsoring), and involvement of local/regional resource people: Continuity, sustainability
 - Substantial number (at least half of the presentations or faculty) of resource people from the target country or sub-region: Database of resource people

Common Principles (cont'd.)

- How ?
 - Development of training / education materials: Peer review of training materials, ensure a strong “PBS brand”, develop a web-based repository
 - “Hands on”: regulatory issues associated with (public) GM events of relevance to the country or sub-region. Results and recommendations from BBI-supported projects.
 - “Pre-course assessment” of participants’ views and expectations regarding the topics for training – re-visit at end of event
 - Evaluation reports. Participant database. Methodology for follow-up surveys to better determine the actual impact

Implications for training activities

- Stronger justification of proposed training, in relation to strategic objectives, as part of longer term plans
- Emphasis on small-group, individual training around a well defined goal / output tailored to country need
- Follow up support; build network of local / regional experts; support local curriculum dev't.
- Less emphasis on generic training approaches – acknowledging that the need for this continues

Topics for coordination group guidance

- 1. Implementing a partner-driven approach**
 - Regional, national coordinators and advisory groups
 - Program development increasingly based on country / regional strategies
 - Takes long lead times in some cases
- 2. Moving policies from draft to adoption & getting decisions**
- 3. Determining program impact**

Topics for coordination group guidance

- 1. Implementing a partner-driven approach**
- 2. Moving policies from draft to adoption & getting decisions**
 - **Good progress at drafting stages**
 - **Process of adoption and enactment is unpredictable**
 - **Delays in decision making, program implementation**
- 3. Determining program impact**

Topics for coordination group guidance

- 1. Implementing a partner-driven approach**
- 2. Moving policies from draft to adoption & getting decisions**
- 3. Determining program impact**
 - **Results impact on policies, procedures, people**
 - **Measurable indicators, levels of impact still to be determined**
 - **Area for common action**

Cooperation / Coordination

- CBD Secretariat / COP-MOP 2 (BBI side event)
- ASARECA, CORAF, SADC
- UNEP-GEF (PBS EAB member)
- ABSP-II, BIO-EARN, BECA, etc.
- CGIAR, HarvestPlus challenge program
- Public Research and Regulation Initiative

Coordination ⇒ Synergies

- Common goal: CBD articles 16, 19
- But different philosophies, interpretations & donor interests
- Synergies are possible around well defined country action plans and priorities – division of labor
- “Light” formal coordination – centralized (info) services and support