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# Building and strengthening functional biosafety regulatory frameworks

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## **Biotechnology and Biosafety Program Goals**

- Increase agricultural productivity and farmer incomes
- Enhance environmental sustainability of agriculture
- Increase access to and availability of nutritious foods
- Create enabling policy environment for agriculture
- Build technical capacity for research and regulation



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## Why biosafety capacity building?

- Fully functional biosafety systems are necessary to evaluate new applications of biotechnology
  - Ensure that only safe products of biotechnology are deployed
  - Includes providing tools and information to assess safety and make decisions on introduction of new products
- Non-functional or absent biosafety systems prevent the introduction of any bioengineered crop, beneficial or otherwise.



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## **Fully functional biosafety framework**

- Is science-based
- Is effective, efficient, predictable
- Addresses research, field trials, commercialization, cultivation, commodity imports
- Has clear regulatory authority, without overlapping mandate or gaps in mandate



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# USAID biosafety programs and activities

- **Program for Biosafety Systems**
  - Country programs in Africa and Southeast Asia
  - Regional frameworks and harmonization
- **South Asia Biosafety Program**
  - India, Bangladesh, Pakistan
- **Support to public-sector product development projects**
  - ABSPII: banana, eggplant, potato
  - AATF: rice, cowpea
  - Danforth: cassava
- **Participation in USG interagency outreach and events**
- **Oversight and environmental compliance**



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# Program for Biosafety Systems Led by IFPRI

- **Geographic scope**
  - Comprehensive country-led biosafety programs in countries where bioengineered crop development is underway
  - Regional programs in East and West Africa and Asia
  - Global policy research activities
- **Works with in-country partners**
  - Government ministries, NARS, Universities, NGOs
- **Different programs for individual country needs**
  - Technical support to development of legislation
  - Regulation and guideline development
  - Institutional strengthening and procedural support
  - Training in risk assessment, CFT management, inspection and monitoring
  - Risk communication training



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**SOUTH ASIA**  
BIOSAFETY PROGRAM

# South Asia Biosafety Program

Led by Center for Environmental Risk Assessment and IFPRI

## Strengthening institutional governance of biotechnology in Bangladesh, India and Pakistan

- Capacity building for research institutions and regulatory agencies
- Builds relationships with national regulators
- Brings regulations/guidelines in line with international standards
- Increase transparency and science-based regulation
- Reliable, predictable systems foster investment



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## **Biosafety capacity building – entry points**

- Design of biosafety system
  - Legislation, when necessary
  - Designation of institutions(s) with regulatory mandate
  - Implementing regulations and guidelines
- Training of regulators, inspectors, product developers
- Operationalization and implementation of biosafety system
- Public sensitization on regulatory framework



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## **Biosafety capacity building activities**

- **Generic training**  
Wider reach, cost-effective, insufficient depth, leaves questions
- **Training for specific outcomes**  
Resource, time intensive, builds specific skills, confidence
- **Legislation and regulation development**  
Long-term support for document drafting, review, approval
- **Operational and organizational support**  
Help implement systems, formalize processes, timelines
- **Support to product developers**  
Ensure high-quality data, safe products, research partnerships



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# Best practices and lessons learned

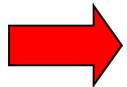




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## Tailor interventions to each country's needs

- Avoid umbrella or blanket approach
- Build on existing authorities and mandates
- Consult with country experts and build on previous biosafety work

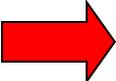


Bangladesh vs. India



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## Ensure long term approach in project design

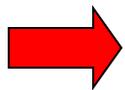
- Biosafety frameworks can take many years to design and implement (Kenya, Uganda, Bangladesh)
  - Build several years of support into project design – don't stop at draft documents
  - Avoid one-off activities, time interventions appropriately
-  Program for Biosafety Systems is in its second 5-year phase



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## Invest in individuals

- Successful projects need a committed in-country partner
- Invest in capacity building and long-term mentoring for individuals
- In-country leaders are best drivers for lasting policy change

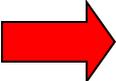


Each USAID biosafety program has country leader



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## **Strengthen biosafety research capacity**

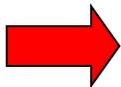
- Regulators need access to high quality data of relevance to specific crop applications
  - Build capacity of in-country scientists to build knowledge base for crops that will go through their regulatory systems
  - Link biosafety research to specific applications
-  Biotechnology and Biodiversity Interface; new grants program under SABP/Pakistan



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## Flexibility and South-South collaboration

- There is no one-size-fits-all biosafety framework
- Facilitate South-South collaboration, information exchange and mentoring
- Systems that work in the US may not work in Malawi...
  - Identify similarities in political institutions or resource constraints
  - Joint work across common crops and environmental issues



Technology and knowledge transfer between  
India, Bangladesh and Philippines



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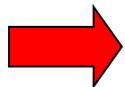




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## Parallel investments in biosafety and bioengineered crop development

- Biosafety systems and bioengineered crop development need to move forward together
- Need political support for controversial decisions
- Need functional biosafety system to support investment in new technologies



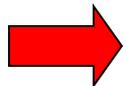
Example: Bangladesh, Bt eggplant; Uganda, virus resistant cassava



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## Test new biosafety systems with real cases

- Applications act as test cases
- Build skills in risk assessment
- See where system needs improvement
- Training coincides with need – high turnover in regulatory authorities



Banana, cassava, cowpea, rice in Africa



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## **New food safety guidelines adopted in India**

- SABP led a needs assessment: comprehensive food safety assessment process and guidelines needed
- Long term roadmap, ICMR lead with BCIL and SABP support
  - International conference and stakeholder input
  - Drafting team for food safety guidelines
  - Expert and stakeholder input into guidelines
  - Committee addresses input and reviews guidelines
  - Guidelines officially adopted into India regulatory system
- Technical training workshops to implement guidelines
- India now better positioned to review pipeline of crops
  - Eggplant, rice, potato, okra, maize, wheat



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# Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants



Indian Council of Medical Research,  
New Delhi

2008



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## Confined field trial guidelines





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## **Kenya adopts comprehensive biosafety legislation after 7 years of consultation, review and debate**

- PBS partners with coalition led by National Council of Science and Technology and other key Kenyan stakeholders
  - Drafters of legislation had access to technical expertise
  - Bill in line with international biosafety standards
  - Helped parliamentarians gain access to biotechnology and biosafety information
  - Developed briefing materials and facilitated field visits
- Next step: implementing guidelines and continued training of regulators



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## Uganda conducts confined field trials

- System must be able to accept, review and issue decisions
- PBS helped build capacity of Govt of Uganda to review applications and conduct field trials (UNCST)
  - Uganda Biotechnology and Biosafety Policy
  - Guidelines and SOPs for evaluation, implementation and monitoring of confined field trials
  - NARO (product developer) has enhanced capacity for conduct of field trials and oversight of biotech crop development
- Dual approach with regulators and product developers
  - Crops undergoing testing: banana, cotton, maize, cassava, rice
- Need to complete establishment of regulatory system
  - Commercial approvals
- NARO emerging as center of expertise on biotechnology



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# Banana and cassava field trials in Uganda

**GM Cassava Plants**

For Research Purposes Only  
Not Approved for Food or Feed

**AUTHORISED PERSONNEL ONLY**

**NBC AUTHORIZATION NUMBER: 3/2010**

**TITLE: Confined Field Trial of Transgenic Cassava  
for Resistance to Cassava brown streak  
virus Imparted through Gene Silencing  
Induced by the Virus Coat Protein. PLANTED 11-2010**





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## Emerging biosafety challenges

- Data needed for new crops and traits relevant in developing countries
  - Crop biology documents
  - Expert panels for risk assessment of new traits
- Gene flow issues
  - Understand *consequences* of gene flow more important than just measuring incidence of gene flow (Bt cowpea)
- New regulatory approaches for novel crops (cassava, banana)
  - Construct-based rather than event-based approval
- Bioengineered animals for disease control (mosquitoes) or food



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# Thank you

Thanks also to PBS and SABP colleagues and all our biosafety and biotechnology partners around the world!



**FEED <sup>THE</sup> FUTURE**

The U.S. Government's Global Hunger and Food Security Initiative