



INTERNATIONAL FOOD
POLICY RESEARCH INSTITUTE

sustainable solutions for ending hunger and poverty

Supported by the CGIAR



PROGRAM FOR BIOSAFETY SYSTEMS

A partnership program for biosafety capacity development

Biotechnology, Biosafety and the Developing
World:

The Good, The Bad and The Ugly

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Director – Program for Biosafety Systems

Sustainable Agriculture Systems, Knowledge and Institutions

THE WORLD BANK

February 9, 2011

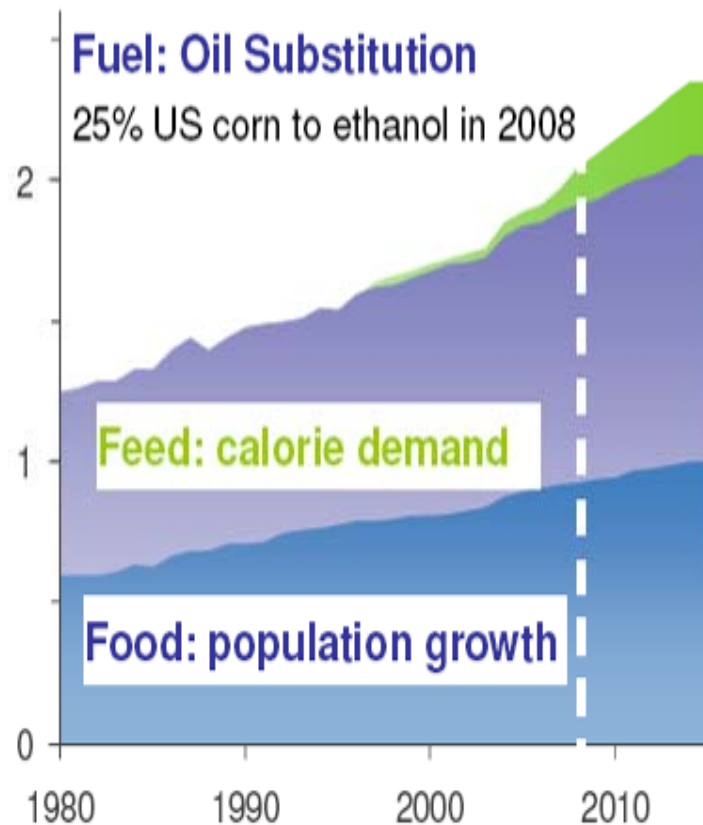


AIM OF THIS PRESENTATION

- **Overview of the Program for Biosafety Systems (PBS)**
- **Lessons learned from the “PBS Experience”**
- **The Good, Bad and Ugly of Biosafety Systems – process and architecture**
- **Where do we go from here?**

THE GLOBAL CHALLENGE

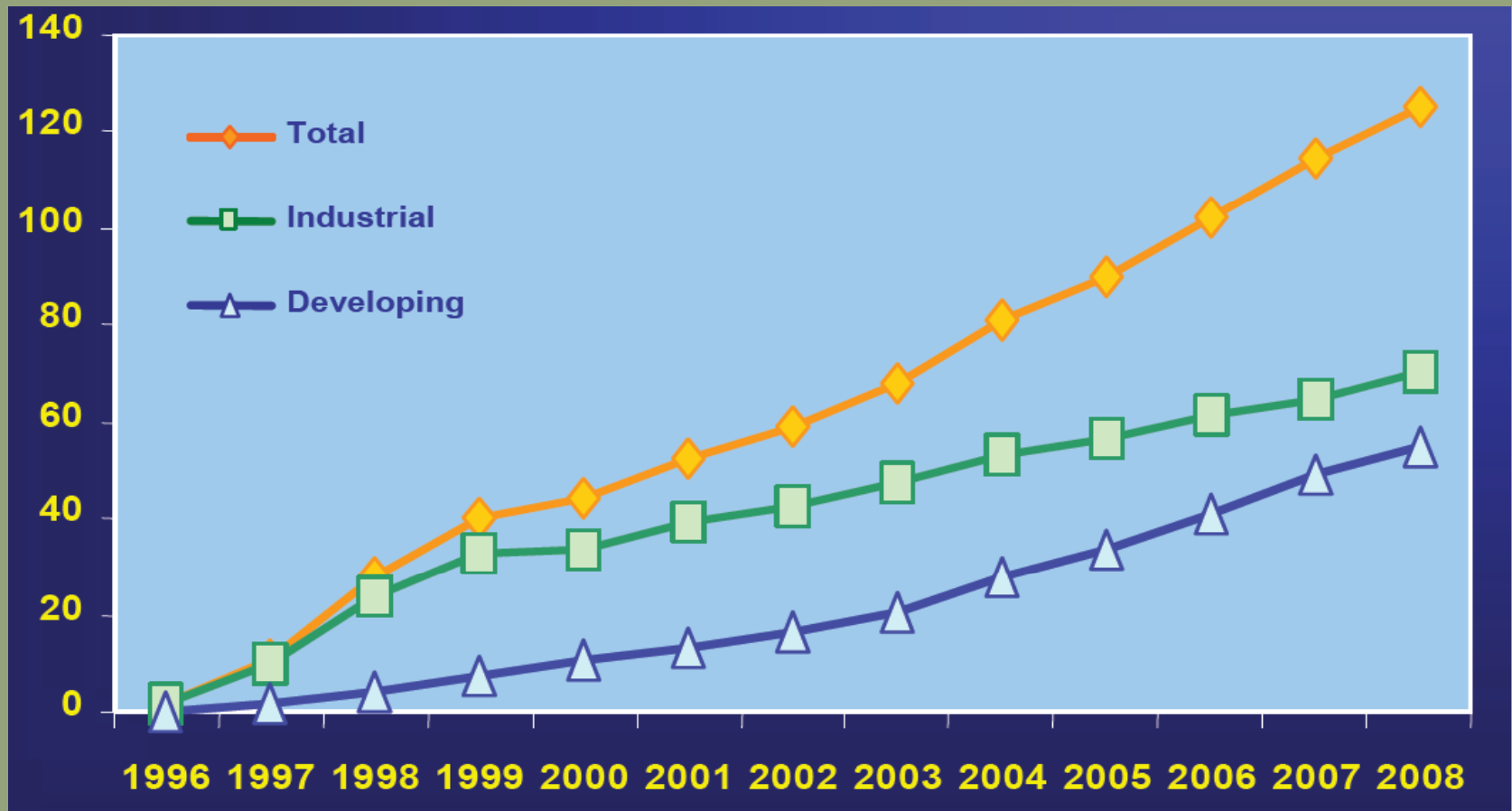
Increased demand for **F**ood, **F**eed, **F**iber and **F**uel



- World population will grow from current **6.5B** to **8B** by 2025 and **9.2B** by 2050
- Affluence in emerging economies will drive meat, cereals, edible oil consumption up
- Climate change will alter land, water availability and quality; introduce new pests
- Increase in biofuel consumption

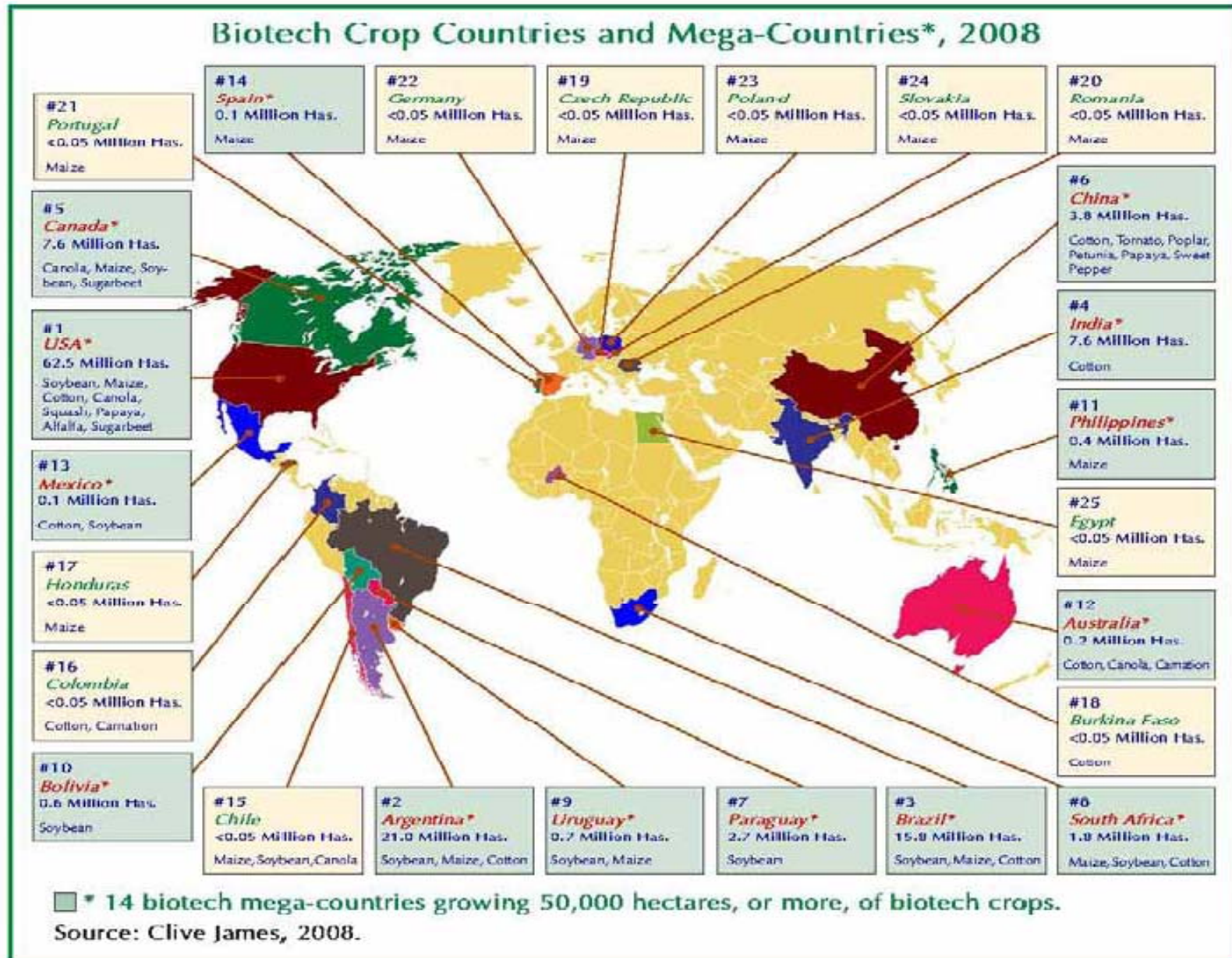
EXPERIENCE WITH GM CROPS IN THE DEVELOPING WORLD

Global Area of Biotech Crops, 1996 to 2008:
Industrial and Developing Countries (million ha)

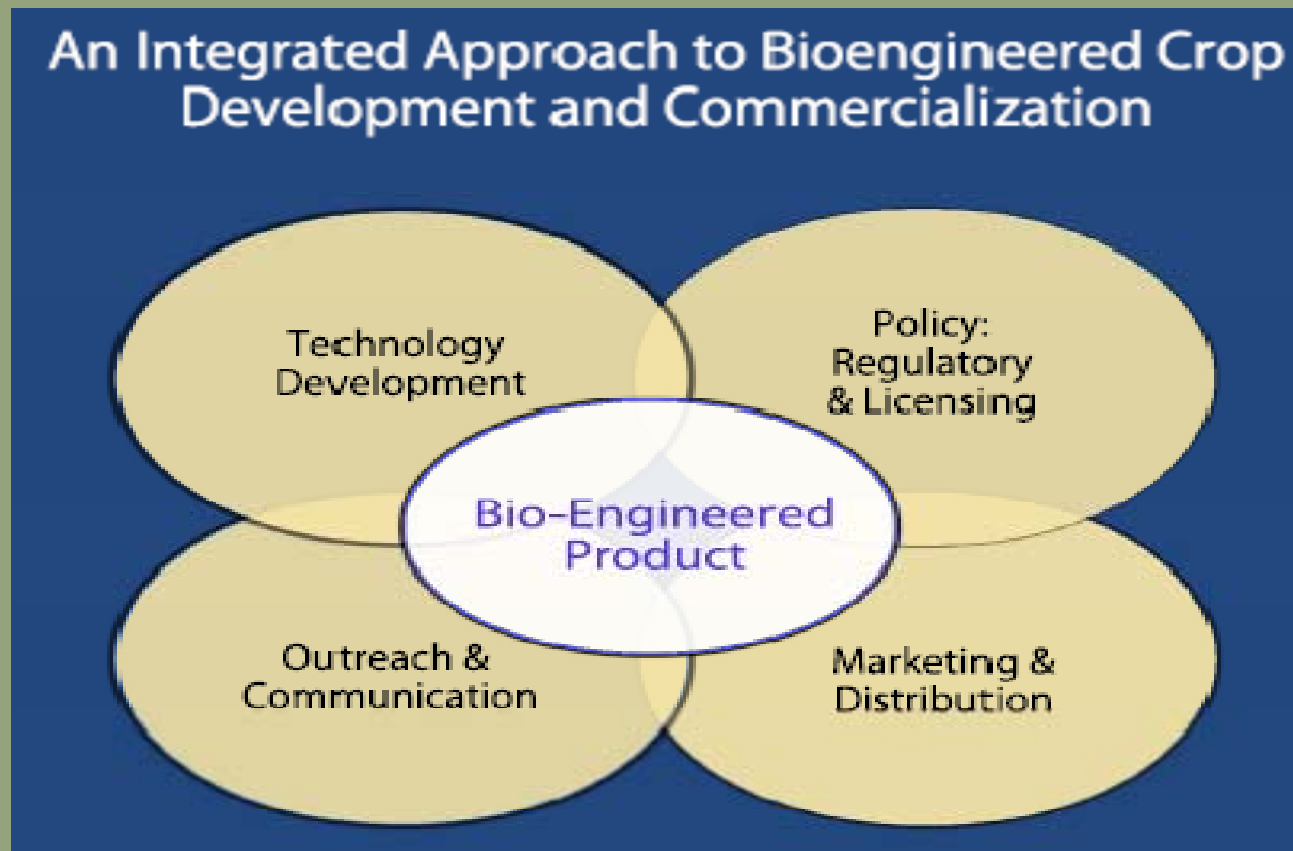


Source: James 2009

THE GLOBAL PICTURE



BIOSAFETY - A CRITICAL COMPONENT IN PRODUCT DEVELOPMENT



Source: ABSP-II, Cornell University



FOUNDATIONAL CONCEPTS



- Products of biotechnology becoming more widely accepted
- Benefit with minimal risk shown – nearly 2 decades
- Regulatory review and approval critical:
 1. product development
 2. consumer confidence
 3. end user adoption
- Absence/presence of functional regulatory systems are determining factors in availability of new crops, cropping systems/foods for poor farmers/consumers



PROGRAM FOR BIOSAFETY SYSTEMS (PBS)

MISSION : To empower partner countries to build and implement **FUNCTIONAL** and **EFFICIENT** regulatory systems by providing an **INTEGRATED** package of assistance

- **USAID-funded/IFPRI-managed**
- **2nd year of Phase II (2008-2013)**
- **National, regional, global activities**
- **Operational component supported by independent IFPRI policy research**
- **Comprehensive expertise:**
 - ❖ **Strategic Planning and Problem Solving**
 - ❖ **Legal**
 - ❖ **Technical**
 - ❖ **Communications and Coalition Building**



WHERE WE WORK

AFRICA

- **East Africa**: Kenya, Uganda, Ethiopia
- **West Africa**: Nigeria
- **Southern Africa**: Malawi, Mozambique
- **COMESA**: regional harmonization

SE ASIA

- **Philippines**
- **Indonesia**
- **Vietnam**
- **APEC**: regional work on LLP



WHAT WE DO

Integrated...Coordinated

Technical Frameworks

- legal instruments, implementing regs and guidelines

Practically-oriented Scientific & Product Advice

- facilitate progression of biotech products thru the reg. process; field trials, risk assessments

Capacity Building and Skills Development

- technical and communications training

Policy Analysis & Research

- on emerging national, regional, global issues (trade, socio-economics)

Strategic Planning and Communications

- problem solving, coalition building, stakeholder analysis, outreach and tactics

Coordination – in country staff; issues management



RECENT PBS ACHIEVEMENTS

KENYA

- Stakeholder outreach for passage of Biosafety Bill in 2009
- draft implementing regulations and training lawyers and regulators

UGANDA

- CFTs (cotton, cassava, banana), regulatory policy, commercialization strategy and handbook

MALAWI

- submission of 1st field trial application pending

NIGERIA

- technical input to law
- public communication and stakeholder outreach
- support passage of biosafety bill through House of Representatives

PHILIPPINES

- extensive capacity building
- specific regulatory issues – IRM, stacked traits

VIETNAM

- facilitated first CFT



RECENT ACHIEVEMENTS GLOBAL AND POLICY

COMESA

- draft policy guidelines for harmonization
- biosafety roadmap
- regional regulatory status analysis

CARTAGENA PROTOCOL

- Technical resource at COP/MOP meetings
- Policy brief on liability and redress
- Trade implications/options re' handling, transport, packaging, identification Article 18.2.a
- Extensive body of work on socio-economic analyses

TRADE

- Labeling Policies of Genetically Modified Food: Lessons from an International Review of Existing Approaches
- Biosafety and Perceived Commercial Risks: The Role of GM-Free Private Standards
- Cost of regulations



WHY WE ARE SUCCESSFUL

- **INDEPENDENT** (*no SPECIFIC product affiliation; REGULATORY FRAMEWORKS FOR ALL-- public and private, internally and externally developed*)
- **STRATEGIC** - *a big picture approach*
- **CREDIBLE** (*IFPRI'S reputation independent research*)
- **PARTICIPATORY, HANDS-ON, PRACTICAL**
- **SUPPORTIVE POLICY RESEARCH ARM (IFPRI)**
- **COUNTRY PRESENCE** – *feet on the ground*
- **LONG TERM ENGAGEMENT AND DIVERSE EXPERIENCE** (*since 2003*)
- **REPRODUCIBLE TEMPLATES, MODELS**



UGANDA



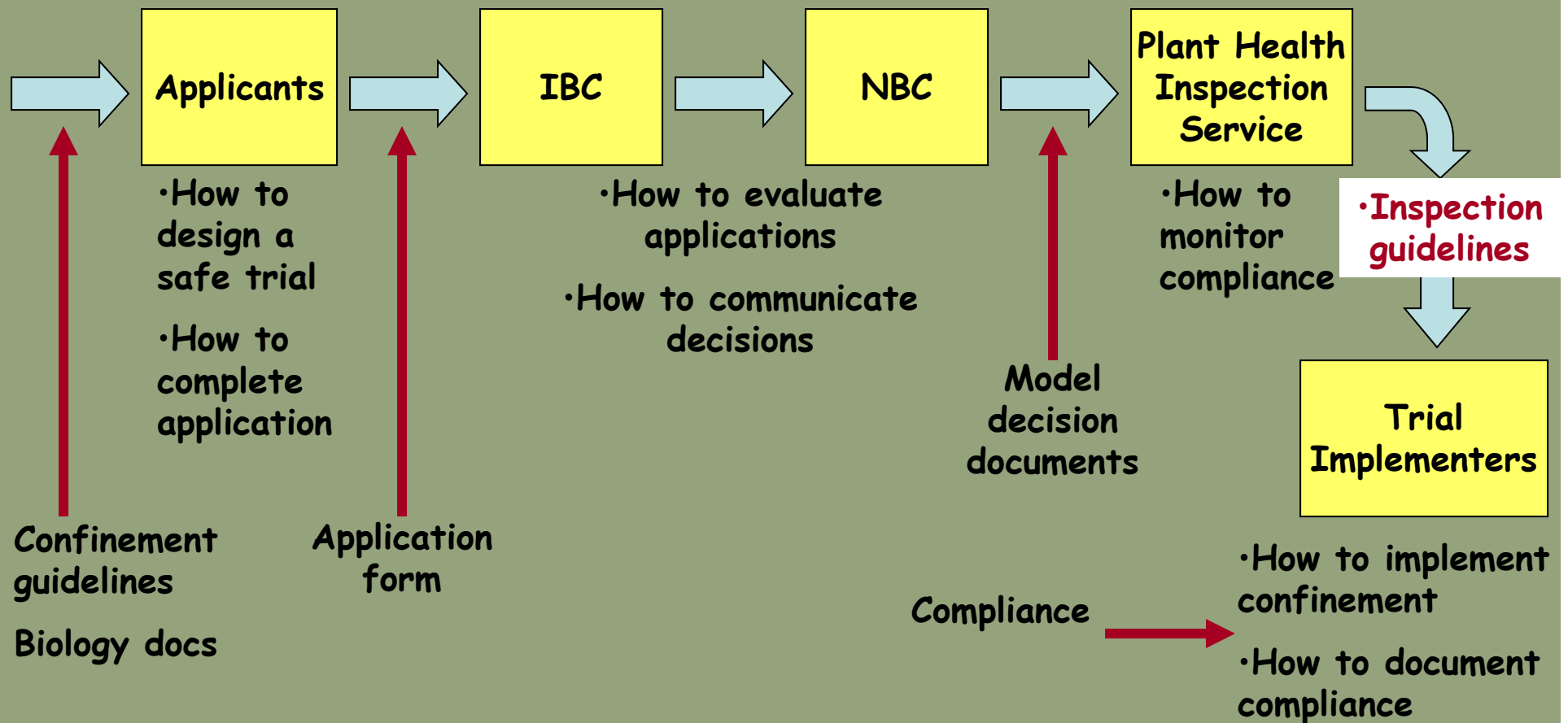
UGANDA

Building Policy and Field Trial Capacity

- Advisory services for drafting and review of legislation
 - National policy adopted (April 2008)
 - Specs for containment greenhouse
 - Facilitation of Confined Field Trials (CFTs)
 - Comprehensive training program – 4 MSc, IBCs, inspectors
 - Communication strategy implemented
- ✓ **CFT APPROVED AND IMPLEMENTED FOR BANANA, COTTON AND CASSAVA**

ANATOMY OF A CONFINED FIELD TRIAL

Field trial regulations





REGULATORY CAPACITY TO CONDUCT CONFINED FIELD TRIALS (CFTs)



- Training of NBC, IBC, inspectors in field trial design and management
- Assistance in preparation of application for field trial of GM bananas
- Analysis, report on options for NARO containment facility
- To date, field trials approved/conducted for banana, cotton, cassava



REGULATORY CAPACITY TO CONDUCT CONFINED FIELD TRIALS (CFTs)

*Task Force developed guidelines
for CFT review and conduct
including:*

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



Kasese cotton confined field trial site



FUTURE PRIORITIES IN UGANDA

Supporting legislation and commercialization

- **Open Forum on Biotechnology**
- **Stakeholder Mapping and Message Development**
- **Strategic communications plan and coordination**
- **Strategic and technical support as bill moves through legislative process**
- **General Release Manual for biotech crop commercialization procedures**

IT'S NOT JUST ABOUT THE SCIENCE!!!

Markets/Policy-Political/Socio-cultural

- Product development considerations
- Links to markets – local, regional and global
- Trade competition and retaliation
- Enabling policy/regulatory climate
- Complex and diverse institutional players
- Technological gaps & science literacy
- Concerns about food system control, risk, consumer rights



Net - Map

toolbox

Influence Mapping of Social Networks[®]



**Program for
Biosafety Systems**



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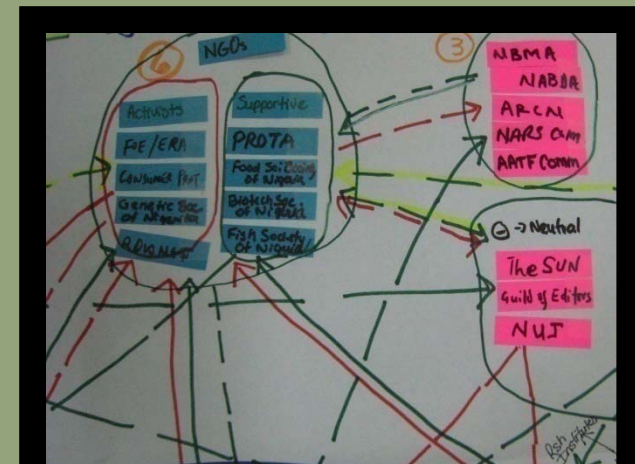
**CGIAR Challenge Program on
WATER & FOOD**

NETMAP: *Benefits, Process, Goal*

Tool developed by IFPRI

Used successfully previously to:

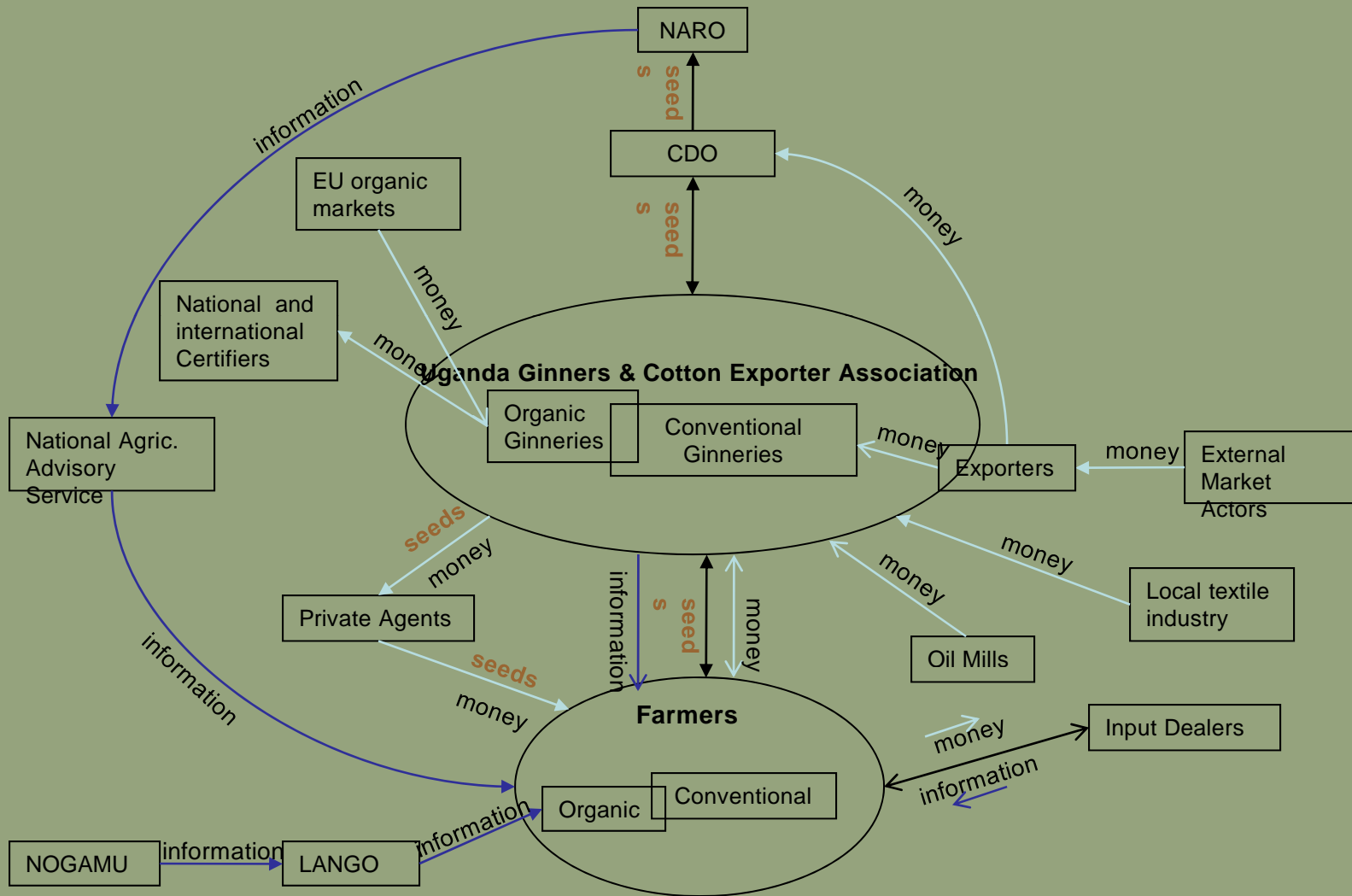
- Moved a multi-county water project forward
- Nigeria – biosafety bill passed the House
- Ethiopia – strategy for a successful biotechnology economy
- Uganda – what is needed to kick start bill



NETMAPPING IN ACTION



RESULTS!



NET MAP BENEFITS

- **CLEARLY IDENTIFIES CONSTRAINTS AND OBSTACLES**
- **HELPS DEFINE THE “MIDDLE GROUND”**
- **IDENTIFIES A STRATEGY AND IMPLEMENTATION PATHWAY FORWARD**
- **DEVELOPS STRATEGIES TO LEVERAGE NETWORKS VS. BEING OVERWHELMED BY THEM**
- **OPEN DISCUSSION OF CHALLENGES AND PARTICIPATORY PROCESS BUILDS A “NATURAL” COALITION FOR ACTION**
- **BLUEPRINT FOR MESSAGE CUSTOMIZATION AND TARGETING**
- **EFFICIENT AND RATIONALE USE OF RESOURCES (HUMAN, FINANCIAL)**

BIOSAFETY POLICY – PBS LESSONS LEARNED

- **Balance**
- **Science is NOT static**
- **Transparent, predictable, science-based, flexible**
- **Product Evolution**
 - Regulations should reflect product development stage*
- **Investment**
 - Regulatory system should promote internal and external investment, trade*
- **Local Test**
 - Can local organizations/ private companies comply with and afford the system?*
- **Other Laws**
 - Reconciliation with other applicable laws – seed laws, plant variety protection, food safety laws*
- **Resources**
 - Implementation and capacity building*
- **Strategic Communication & Outreach**
necessary to create and implement good policy – PLAN AHEAD!

BIOSAFETY POLICY – PBS LESSONS LEARNED

continued

- **Patience is a virtue**
there are no shortcuts
- **Hard line positions**
counter productive
- **Listening**
a critical skill
- **Relationships**
are everything

BIOSAFETY POLICY – The Good!

- **Many countries are gaining experience with the technology via CFTs**
- **Recognition of the important role that communications and outreach have to insure function**
- **Many service providers to build capacity**
- **Scientists in the developing world are making their voices heard and having impact on the regulatory system architecture**
- **Developing country farmers realizing benefits – helping to drive policy in other/neighboring/peer countries**
- **Need for harmonized regional policies recognized...acted upon**
- **Political leadership is becoming more evident (Vietnam, Nigeria, Indonesia)**

BIOSAFETY POLICY – The Bad!

- **Non-science elements in regulatory policy – i.e. socio-economic**
- **Requirement for risk assessment inappropriately applied**
- **Many service providers involved – confused advice**
- **Regulatory process between ministries/departments not well defined**
- **Regulatory power usually concentrated in MOE's or in obscure ministries (i.e. Finance)**
- **Harmonization efforts uneven and laborious**
- **Countries stuck on the “CFT” treadmill ; minimal commercialization**

BIOSAFETY POLICY – The Ugly

- **Turf wars between ministries – impacts progress**
- **Opposing view points of donors and donor-funded projects**
- **Severe lack of capacity – knowledge vacuum creates opportunity for loud voices and influencers**
- **Policy heavily focused on risk; creates disincentives and is out of sync with evidence based global experience**
- **Expensive “infrastructure” for confined field trials**
- **Strict liability clauses – a troubling trend**
- **Gender/gender impact – missing from biosafety policy discussions**
- **Regulations are typically locally unaffordable and unenforceable**
- **Process – time consuming, laborious and human capital intensive!**

WHERE DO WE GO FROM HERE?

A FEW THOUGHTS:

On the ground coordination among service providers

Strategic and coordinated approach to outreach and communication

Training AND funding not just for product development but for regulatory capacity (by national programs and donors)

Cultivate the middle ground

Comprehensive gender impact study

Demand driven research that focuses on constraints impacting regulatory decision making

Reposition the Biosafety Protocol for what it was intended to be – not the “de facto” regulatory framework it has become

Thank You!

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Acknowledgements

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colleagues,**

PBS website

<http://programs.ifpri.org/pbs/pbs.asp>