Biosafety Regulation and Bringing Biotechnology to Developing Countries

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Summary of Talk

- Background on CSPI and Biotechnology
- Status of GM crops worldwide, with Sub-Saharan Africa example
- International regulation and standards – Cartagena Biosafety Protocol
- National biosafety regulation – enabling or disenabling
- Development Assistance
- Conclusions
Center for Science in the Public Interest (CSPI)

- Food and nutrition consumer organization.
- No government or industry funding.
- Advocacy and education based on the best available scientific evidence
CSPI’s Biotechnology Project

- **Purpose**
  - Identifying benefits and risks
  - Establishing strong regulatory systems in US and abroad
  - Educating and informing the public

- **Positions**
  - Current crops in US appear safe to eat and environmental risks are manageable
  - Some benefits from current crops
  - Future products need to be assessed individually by regulatory systems in US and abroad

- **Involvement in Africa**
  - Worked in South Africa, Malawi, Kenya, Uganda, Tanzania, Ghana, Nigeria and West Africa.
Status of Development and Adoption of Biotech Crops

- Developed countries
- Developing countries
- Future pipeline
Current Status of Biotechnology in Sub-Saharan Africa

- Only one country with commercial products – South Africa (corn, cotton, soybeans)
- A handful of countries with field trials in past ten years – Kenya, Uganda, Burkina Faso,
- Laboratory research on products in some countries
- Biotechnology capacity is very limited
The Pipeline in Sub-Saharan Africa -- Private-Public Partnerships

- **Transferred products from developed countries**
  - Burkina Faso: Bt cotton
  - Kenya: Bt cotton and Bt corn
  - Malawi: Bt cotton

- **Locally developed products**
  - Nigeria: Bt cowpea
  - Kenya: Virus resistant cassava
  - Uganda: Disease resistant bananas; virus resistant cassava
  - South Africa: Bt potato; virus resistant corn
  - Transgenic sorghum
Background on Cartagena Protocol

- Key driving force in regulation of biosafety and establishment of biosafety regulations
- Agreement under Convention on Biological Diversity
- Negotiations completed in 2000
- Came into effect on September 11, 2003
- Many countries have not yet implemented requirements -- not self implementing
- Significant donor funds are being used across the continent to implement obligations
Status of Different Countries and the Protocol

- Major exporting countries – U.S., Canada, Argentina – are not parties
- EU and its member states are generally parties and have implemented it
- Few developing countries have implemented it
Purposes of the Protocol

- Common and coordinated approach among countries to address potential risks of LMOs
- Provide a degree of certainty in the field of biosafety regulation
- Balance needs of trade, the potential benefits of LMOs, and environmental protection
Biosafety Protocol -- Key concepts

- Applies to transboundary movement, transit, handling, and use
- Living modified organisms produced through modern biotechnology
- Addresses effects on conservation and sustainable use of biological diversity
- Also mentions taking into account risks to human health
- Discusses the precautionary approach
Issues Around Biosafety Protocol – Will it Achieve its Goals?

- Comprehensiveness -- Food Safety not covered by Protocol (Codex)
- Socio-economic considerations -- How much reliance on non scientific factors?
- Risk assessment procedures (including socio-economic assessments)
- Multi-agency topic – who is in charge?
Status of Biosafety Regulation in Sub-Saharan Africa

- One country with fully functional biosafety regulatory system – South Africa
- A handful of countries with partially operating systems (can handle and approve a field trial)
- Most countries have nothing more than a few draft documents on how their system will operate
- Limited regulatory capacity throughout the region
Biosafety Regulation – How Designed

- Transparency and public participation
- Stakeholders and consensus
- Lack of capacity requires reliance on others – particularly private sector and NGOs
- Models – advantages and disadvantages
  - Limitation of developed country models
  - Lack of experience in developing countries
  - Regulating without products
Biosafety Regulations – Role of Private Sector

- Need biosafety rules to invest and develop products
- Provide expertise on risk assessment and regulatory experience
- Don’t want perception of pushing controversial technology

- What is the proper balance and involvement?
Biosafety Regulation: Who Makes Decisions

- Decision by committees by consensus
  - Government committee – e.g. South Africa
  - Expert committee – include non governmental experts and stakeholders (developers?)
  - Issues of accountability and legitimacy

- High level government decisions
Biosafety Regulation: Enabling or Disenabling

- Law and regulations that enable GM crops – e.g. South Africa
- Lack of formal regulatory system can enable field trials (interim policies and procedures) – e.g. Uganda, Kenya
- Law and regulations that prevent GM crops – e.g. Zambia
- No formal law and regulations that prevent GM crops – e.g. Ghana, Mali
Development Assistance for Biosafety

- **GEF Funding to Implement Cartagena Protocol**
  - UNEP-GEF Biosafety Projects
  - World Bank
- **Other Donors**
  - World Bank
  - US AID (PBS Project at IFPRI)
  - European Donors
- **Capacity Building -- NGOs**
  - Universities and scientific groups
  - Environmental and consumer groups
Conclusions -- Roadblocks to Biotechnology Development

- Misinformation about biotechnology and biosafety
- No useful products produced by local scientific institutions
- International debate and the precautionary principle
- Perceived risks (trade and economic, not safety)
- Perfect being the enemy of good
Adopting Biotechnology in Developing Countries

- Political will to back biotechnology
- Benefits from a particular product (e.g. Bt cotton)
- Willingness to conduct field trials before biosafety policy and regulations are completed
- A perceived competitive advantage from adoption
- Private sector role
- Developing biosafety regulations along with biotechnology products
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