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# The Second Decade of Biotech Products: Domestic and International Regulatory Challenges

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# Summary of Talk

- Background on CSPI and Biotechnology
  - Biotech Crops and their regulation so far
  - Future biotech products and regulatory challenges in the US
  - The Status of biotech products in Sub-Saharan Africa
  - The Biosafety Protocol
  - Regulatory challenges in developing countries
  - Conclusions
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# Center for Science in the Public Interest (CSPI)

- Food and nutrition consumer organization.
  - Nutrition Action Healthletter – 900,000 subscribers in US and Canada.
  - No government or industry funding.
  - Advocacy and education based on the best available scientific evidence
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# 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
- Regulatory systems in US and abroad need strengthening to address next generation of products

- Involvement in Africa

- Worked in South Africa, Malawi, Kenya, Uganda, Tanzania, Ghana, Nigeria and West Africa.
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# Biotech Crops -- The First Decade

- Numerous products
    - Corn, cotton, canola, and soybeans
    - Bt pesticides and herbicide resistance
  - In a few markets
    - US, Canada, China, Argentina, Brazil, and a few others
  - Significant benefits and little actual harm
  - Much controversy
  - Evolving regulations
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# US Regulatory System – the First Decade

- No major food safety or environmental problems
  - Lots of economic problems
  - Lack of enforcement and independence oversight
  - FDA role is minimal
  - USDA and EPA – mixed results to date
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## The Second Decade -- What applications to expect

- More of the same – built in Bt pesticides, herbicide resistance, stacked genes
  - Transgenic animals
  - Plants producing pharmaceuticals and industrial products
  - Nutritionally enhanced products?
  - Transgenic rice and wheat?
  - Developing country products?
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# Overarching Challenges

- Consumer acceptance
  - Beneficial products
  - Marketing issues
    - Segregation
    - Coexistence
    - Labeling and traceability
    - Asynchronous approvals
  - Highly controversial applications
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# US Regulatory Challenges -- USDA

- Revision of regulations
    - Learning process from ten years of regulation
  - Appropriate proportionate reviews
  - Address recent court cases
  - Involvement of states
  - Need to be more transparent and participatory
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# US Regulatory Challenges -- FDA

- Food safety is critical issues for consumers
  - Current policy is a “voluntary consultation”
  - Reviews are not comprehensive and response is inadequate
  - Not consistent with how other countries ensure food safety nor how environmental issues are addressed
  - Needs to be updated to a mandatory pre-market approval process.
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# US Regulatory Challenges – Pharmaceutical Crops

- Currently treated very similar to other GE crops
  - Should be science-based regulation based on risk – using food crops is riskier than using non food crops
  - Need more transparency and participation for these controversial applications
  - Need for stricter confinement and more government oversight
  - Mandatory FDA food safety review
  - Add regulatory burden to discourage use of food crops without extra confinement obligations
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# US Regulatory Challenges – Transgenic Animals

- Coordinated framework? Roadmap to commercialization
  - FDA – New Animal Drug approval process
    - Lack of transparency and public participation
    - Ability to address environmental issues?
  - USDA BRS – transgenic animal group but what regulatory authority?
  - How to involve other agencies (federal and state)?
  - Range of applications
  - Ethical, religious, socio-economic issues
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# US Regulatory Challenges – Other Issues

- Adventitious presence
  - Imports from other countries
    - Food products from China
    - Imported fish
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## 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
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# The Pipeline in Sub-Saharan Africa

- 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
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# 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
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## 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
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# 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
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# 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
  - Sets forth risk assessment and approval process for the movement of LMOs
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## Issues Around Biosafety Protocol – Will it Achieve its Goals?

- Comprehensiveness -- Food Safety is not covered by Protocol (Codex)
  - Safety Standards – not specified
  - Socio-economic considerations -- How much reliance on non scientific factors?
  - Risk assessment procedures (including socio-economic assessments)
  - Liability, redress, and other unresolved issues
  - Multi-agency topic – who is in charge?
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# The Protocol and Setting Up Appropriate Regulatory Systems

- Need to address not only imported products but also domestically produced products
  - Proportionate risk based reviews
    - Match risks and regulatory process
    - Efficient use of resources
    - Allows for regulatory system to focus on riskier applications
    - One of the more difficult concepts to put into law and/or regulations
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# Product Development and Biosafety Regulation

- Where there is a potential product, biosafety regulatory development advances
  - Designing biosafety regulation in the absence of a potential products can lead to unworkable and overly cautious systems
  - Any biosafety regulatory system needs to be flexible to learn from practical experience regulating products
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# Roadblocks to Biotechnology

## Development in Africa

- 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
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# Situations Conducive to Adopting Biotechnology in Africa

- 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
  - Lessening of the international debate (make the mountain into a hill)
  - Developing biosafety regulations along with biotechnology products
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# Conclusions

- Second decade will have both promise and controversy
  - US regulatory system is evolving but has some tough issues to address
  - Biosafety Protocol will continue to play a major role in national regulations
  - There are a number of hurdles to greater adoption worldwide, including regulatory issues.
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