Biotechnology, Commercial vs. Noncommercial Registration Strategies

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Difference Between Commercial & Noncommercial Biotech

- **Commercial: i.e. Genetically engineered crops.**
  - **Multinational company with profit incentive to pay for development and regulatory process**
- Noncommercial for the public good/ benefit:
  - **Government agencies, research organizations with little money to pay for regulatory process. Need for lower cost and streamlined regulatory process**

Commercial Biotech Product Regulatory Strategy

- i.e. B.t. maize resistant to the African Armyworm, *Spodoptera exempta,* Mediterranean corn borer, *Sesamia nonagrioides*, stem borers, *Chilo partellos, C. orichalcociliellus* & European corn borer, *Ostrinia nubilalis*
- 1. Preliminary market study. Corporation determines there is a potential profit for armyworm and borer resistant maize seed sales in several African countries

Commercial Biotech Product Regulatory Strategy

- Issue: How to register and gain public acceptance of armyworm and borer resistant Bt maize in several African countries?
- 2. Project budget to launch seed sales: $10-20 million over 5-10 years
- Steps:
- 3. Product development including laboratory, greenhouse, & small-scale field testing. African adapted maize variety. Would be done in USA & African research centers

Commercial Biotech Product Regulatory Strategy

- 4. Register project in United States to obtain EPA "Gold Seal Certificate Letter" certificate, which is a form of guarantee of EPA registration and risk assessment process
- This certificate should help registration process, but more information/data may be needed in each African county.

Commercial Biotech Product Regulatory Strategy

- 5. EPA Registration: (work done by company):
  - Preregistration meetings (Details of registration requirements shown later)

Commercial Biotech Product Regulatory Strategy

- 6. USDA Animal & Plant Health Inspection Service (APHIS) Permit and Deregulation Requirements:
  - Permits may require Environmental Assessment (EA) under National Environmental Policy Act (NEPA)
  - Deregulation may require an EA or EIS (Environmental Impact Statement)

Commercial Biotech Product, Regulatory Strategy for African Countries

- 7. What agencies regulate Bt maize?
  - Have preregulatory planning meetings with regulators to begin interaction and assess regulatory needs.
  - Translations of safety data & other documentation

Commercial Biotech Product, Regulatory Strategy for Several African Countries

- 8. Conduct in-country field performance and demonstration trials
- Application includes "Gold Seal" certificate
- Registration & other fees may apply

Commercial Biotech Product, Public Acceptance Strategy

- 9. Advertise in public media
  - Concentrate on cost benefits and reduced pesticide use to farmers to gain public acceptance.
  - Emphasize minimal hazard & reduced risk
  - Develop a public strategy to deal with European trade issue, as needed (i.e. label maize as genetically protected against insect feces and aflotoxins)

Commercial Biotech Product Public Acceptance Strategy

- 10. Market Penetration to local pesticide and/or seed distributors and dealers.
  - Dealer training, demonstration trials, farmer meetings
  - Local advertisement (posters, calendars)
  - Promotionals (i.e. tea shirts, caps, tea/coffee mugs,)
  - Introductory price specials

Noncommercial Biotech Product Regulatory Strategy

- Noncommercial, for public good/benefit
- Need for lower cost and streamlined regulatory process
- Probably need commercial or other incentives for sustainability
- i.e. GE *Metarhizium anisopliae* var. *acridum* expressing scorpion toxin or other modification for improved control of *Schistocera gregaria, Locusta migratoria, Locustana pardalina, Nomadacris septemfasciata, Dociostaurus maroccanus*

Biotech Product Regulatory Strategy

- Potential for more effective biocontrol of migratory locusts than:
- Green Muscle®, nonengineered *M. anisopliae* developed by LUBILOSA (LUtte BIologique contre les LOcustes et les SAuteriaux); IITA & Centre for Agriculture and Biosciences International (CABI), UK.
- http://www.lubilosa.org/Userhb.pdf

Biotech Product Regulatory Strategy

- **Green Muscle®**
- Effective against: *Zonocerus variegatus, Hieroglyphus daganensis, Kraussella amabile, K. angulifera, Oedaleus senagalensis*
- First production: Cotonou, Benin at IITA station
- Commercial interests:
- BCP (Biological Control Product Co.), S. Africa
- NPP (Calliope) in France (Senegal?)

Biotech Product Regulatory Strategy

- **Green Muscle®**
- Registered by BCP in S. Africa. Also reg. in Burkina Faso, Cape Verde, Chad, Gambia, Guinea Bissau, Mali, Mauritania, Niger, Senegal
- Large-scale use done, Recommended by FAO

Biotech Product Regulatory Strategy

- **Green Muscle®**
- 2001, FAO Expert Consultation and Risk Assessment on the Importation and Large-Scale Use of Mycopesticides Against Locusts
- http://ispi-lit.cirad.fr/text/biopesta.htm

Biotech Product Regulatory Strategy

- *M. Anisopliae* registered in USA by EPA
- 2001, *M. anisopliae*, strain ESF1, termites, by EcoScience, NJ, USA (discontinued?)
- 2003, *M. anisolpliae*, strain 52, ticks, beetles, flies, thrips by Earth BioSciences, CT, USA acqu. by Novozymes, Denmark
- 1999, GE *M. anisopliae* FR Notice of small-scale field testing, Univ. MD, USA
- 1999, *M. anisopliae*, strain ESF1, EUP for deer ticks, Univ. Rhode Island

Biotech Product Regulatory Strategy

- GE *M. anisopliae*
- Green Guard™ used in Australia
- Use of an established risk assessment & registration process
  - official certificate/letter validates registrations, risk assessments, the "Gold Seal Certificate letter"

Biotech Product Regulatory Strategy

- Alternatives:
- OECD, EPA & Canadian pesticide risk assessment test guidelines are now mostly harmonized (same)
- Register in any OECD member country
- Guidance for Reg. of Microbial Pesticides
- http://www.oecd.org/dataoecd/4/23/28888446.pdf
- Register in USA, EPA
- US A.I.D. may require EPA registration to fund

Regulatory Strategy (EPA)

- Requires approx. $500,000 and 3 years for registration process for a GE *M. anisopliae*.
  - Funding by philanthropic foundation?
  - by industry with proprietary rights?
  - by AID Agency?
  - by international organization?
  - by grant?

Regulatory Strategy (EPA)

- Registrant may be a University, may be foreign entity
  - Preregistration meeting(s)
  - Product Chemistry (biology) and composition, 4 data requirements
  - Analysis & Certified limits, 2 data req.
  - Physical & Chem. Characteristics, 10 req.

Regulatory Strategy (EPA)

- Residue data requirements (food use) 9 data studies req.
- Petition for tolerance or exemption from requirement of a tolerance
- Acute tox data 10 study req.
- Nontarget organisms. 7 study req.
- T & E Species
- Registration Fees (may be exempt if public institution)

Regulatory Strategy for African Countries

- Identify appropriate agencies?
- Is registration required?
- Have preregulatory planning meetings with regulators to begin interaction and assess the needs
- Translations of safety data & other documentation, as required

Biotech Product Public Acceptance Issues

- **Green Muscle®** already widely accepted in Africa for locust and grasshopper control
- Demonstration trials to show benefits and safety
- Radio,TV, & press coverage
- Must address GE risk as perceived by public
- Benefits of safety & pesticide reduction
- Use/adapt to existing locust/grasshopper control programs