

GMO Regulatory Experience in the Philippines:

Lessons for Developing a Regulatory
Framework for GE Pests

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Outline



- Philippine Policy Statement on Modern Biotech
- Evolution of the Biosafety Regulatory Structure
- Bt corn & Bt Eggplant Experience
- The Regulatory Process: GM Crops
- Previous assessments of the regulations
- Lessons for Building a Regulatory Framework for GE Pests

Policy Statement on Modern Biotechnology



- “We shall promote the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment, and industry development”
 - Issued on July 16, 2001 by then President of the Philippines (Gloria Macapagal-Arroyo)

Evolution of the Regulatory Structure



- **E.O. 430 (1990):** Establishment of NCBP and Philippine Biosafety Guidelines
 - Established due to advocacy efforts of scientists from UPLB & IRRI
 - UPLB & IRRI formed committee to develop biosafety guidelines (14 members)
 - Drafted initial biosafety guidelines & recommended establishment of NCBP & national implementation
 - Draft submitted to NAST and NAST led the process
 - Public consultations (**primarily science community**)
 - E.O. 430 established (after further public consultations with other stakeholders)

Evolution of the Regulatory Structure



- **NCBP Series No. 3 (1998):** Guidelines on Planned Release of GMOs and PHES
 - Scope of E.O. 430 for contained & confined use only
 - NCBP developed these new guidelines in anticipation of field testing and release of GM corn
 - Subjected to public consultations
 - Stakeholders from academe, industry, NGOs, and gov't
 - Pioneer Hi-Bred and Cargill (Monsanto) submitted first two applications for limited field tests of GM corn

Evolution of the Regulatory Structure



- **DA A.O. No. 8 (2002):** Rules for Importation and Release of GMOs
 - Prompted by near completion of field tests for GM corn
 - DA developed guidelines for commercialization and subjected it to public consultations
 - Considered procedures for risk assessments
 - Ensured socio-economic considerations included in decision-making
 - 2003: Bt corn approved for commercialization

Evolution of the Regulatory Structure



- **E.O. 514 (2006):** National Biosafety Framework of the Philippines
 - Formalized regulatory framework already in place and established “expanded” NCBP
 - Enhanced risk assessment procedures
 - Clarified roles of various agencies
 - DOST for contained use, DA-BPI for field tests
- E.O. 514 & consequent AOs made Philippines biosafety regulations consistent with the **Cartagena Protocol** and **Codex Alimentarius Guidelines**

Experience with Bt Corn and Bt Eggplant



- **Bt Corn Approval process (1996-2003)**
 - First encounters with anti-biotech groups
 - Forced NCBP to explain biotech to public
 - Recognize the multi-dimensional nature of biotech (not just science-based risk assessment)
- **Bt Eggplant Supreme Court Decision (12/2015)**
 - Halt field testing of GMOs and void A.O. No. 8 (2002)
 - Prompted **Joint Dept. Circular No. 1 (2016)**
 - Extensive public consultations with stakeholders
 - SC reversed decision 7/2016

Experience with Bt Corn and Bt Eggplant



- **Joint Department Circular No. 1 (2016):**
Updated DA A.O No. 8 (2002)
 - Made more “stringent” (i.e., environmental impact assessments, risk assessments, more public consultations)
 - Clarified roles of other government agencies (DA, DOST, DENR, DOH, DILG)
 - Addressed issues in first Bt Eggplant Supreme Court decision

Regulatory Process



1. Prepare a project proposal for submission to the Institutional Biosafety Committee (IBC)
2. Submit a proposal to the IBC, which conducts a risk assessment & endorses to NCBP
3. Apply to the NCBP for a permit to conduct contained testing
4. Apply to DA-BPI for a field testing permit after contained testing is complete and successful, conditional on the endorsement by the NCBP

Regulatory Process



5. DA-BPI creates a STRP concurrent with public notification by the IBC, and the STRP evaluates potential adverse effects to humans and the environment
6. Risk assessment by STRP and the BPI-Core Biotechnology team (BPI-BCT)
7. Conduct single field test and then multi-location field tests (after receipt of field test permit and each field is evaluated)
8. Obtain permit for release (propagation & commercialization)

Previous Assessments

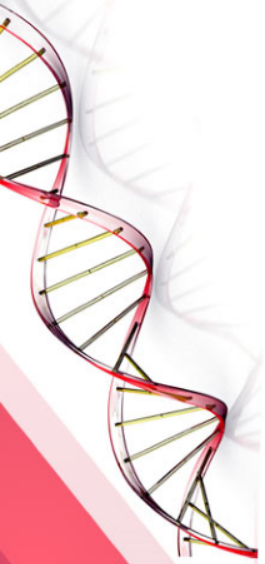


- Richmond (2006)
 - Lack of enforcement power, recommend legislation (with one regulatory agency)
- Mendoza et al. (2009)
 - Too strict & difficult/long application process
 - NCBP committee size and agency costs
- Manalo & Ramon (2007), Bayer et al. (2010)
 - Direct regulatory costs (borne by applicant) are significant
 - High opportunity costs of delay in product release

Lessons for Building a Regulatory Framework for GE Pests



- Regulation of GE insects likely under current Philippine biosafety regulations
- Importance of transparent & meaningful public consultations (i.e., awareness/perceptions)
- Balance stringency with opportunity cost of regulatory delay
 - Role of *ex ante* economic & env. impact assessment
 - Consider resources needed for ↑ stringency
 - Using real options approach (irreversible decision)
 - Transparency of risk assessments & scientific evidence at each step



Thank You!

Question and/or Comments?

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Pertinent Regulations



- **E.O. 514 (2006):** Established the National Biosafety Framework of the Philippines
- **Other DA A.O.'s (2007, 2008, 2009):** Amendments to make consistent with Codex
- **Joint Department Circular No. 1 (2016):** Updated DA A.O No. 8 (2002)
 - Made more “stringent” and clarified roles of other government agencies (DOST, DENR, DOH, DILG)
 - Response to Bt Eggplant Supreme court case nullifying DA A.O. No. 8

Lessons for Building a Regulatory Framework for GE Pests



- Regulation of GE insects likely under current biosafety regulations
- Importance of meaningful public consultations (i.e., awareness/perceptions)
- Balance stringency with opportunity cost of regulatory delay
 - Role of *ex ante* economic & env. impact assessment
 - Understanding market for GE pests (i.e. agricultural, public health)
 - Incentives for academe-NGO-Govt partnership (allowing them to carry regulatory costs/burden)

Organizational Structure

