



***Taming the Double Helix:***  
**Twenty-Five Years of**  
**Biosafety Regulations in the**  
**Philippines**

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Photo source:  
[www.quotesandsmiles.com](http://www.quotesandsmiles.com)

**THE ONLY TIME  
YOU SHOULD EVER  
LOOK BACK,  
IS TO SEE HOW  
FAR YOU'VE COME.**

**CHAIRPERSONS  
NATIONAL COMMITTEE ON BIOSAFETY OF THE PHILIPPINES**



**Dr. Ricardo M. Lantican**  
Oct. 1990 to Dec. 1992



**Dr. William G. Padolina**  
Jan. 1993 to Dec. 1994



**Dr. Estrella F. Alabastro**  
Jan. 1995 to Nov. 1998;  
Jan. 2006 to June 2010



**Dr. Raymundo S. Punongbayan**  
December 1998-March 1990



**Dr. Rogelio A. Panlasigui**  
April 1999 to Dec. 2005



**Hon. Mario G. Montejo**  
July 2010 to date

**CHAIRPERSONS  
DOST BIOSAFETY COMMITTEE**



**Dr. Reynaldo V. Eborá**  
Jan. 2009 to July 2010



**Dr. Fortunato T. de la Peña**  
Nov. 2010 to Nov. 2014



**Dr. Jaime C. Montoya**  
Dec. 2014 to date

## **Scientist-Pillars of Biosafety in the Philippines**



**Dr. Dolores A. Ramirez**  
Biological Scientist



**Dr. Flerida A. Cariño**  
Physical Scientist

# Discussion Points

- **The Foundation Years: The First Fifteen**
- **The Last Ten Years**
- **Thoughts for the Next Five**



Photo source: [www.ayay.co.uk](http://www.ayay.co.uk)



# **THE FOUNDATION YEARS: THE FIRST FIFTEEN**

Photo source: [www.depositphotos.com](http://www.depositphotos.com)

# The Beginnings

- UPLB Chancellor Raul P. de Guzman and IRRI Director-General M.S. Swaminathan created the *Joint Committee on Biosafety*.
  - Objectives were, among others, (i) to review and approve/deny research proposals submitted by UPLB and IRRI scientists for experiments requiring safety arrangements; (ii) to provide guidelines for experimental protocols in cases when a proposed experiment is considered to be potentially beneficial.
  - Composition: 8 scientists from UPLB, 6 from IRRI and 1 each from DA Bureau of Plant Industry and DOST-PCARRD
- The Committee studied the biosafety guidelines of several countries, including Australia, Japan, United Kingdom, and USA and the quarantine laws of the Philippines.
- Biosafety guidelines were drafted, presented in several international conferences, and submitted to NAST.
- Recommendation was for NAST to take the lead having the guidelines adopted nationally.

Source: Mendoza, E.M.T, *et al.*, Biosafety Regulations in the Philippines: A Review of the First Fifteen Years, Preparing for the Next Fifteen (2009).



# **Executive Order No. 430 (1990)**

- Issued by Pres. Corazon C. Aquino.
- Mandate of NCBP:
  - Identify and evaluate potential hazards in GE experiments
  - Formulate and review national policies on biosafety and guidelines in risk assessment
  - Develop working arrangements with quarantine services in evaluation, monitoring & review of projects
  - Assist in development of technical expertise for quarantine services & risk assessment

- Recommend development and promotion of research programs to establish risk assessment protocols and assessment of long-term effects of bio research
- Publish results of internal deliberation and agency reviews
- Provide assistance in formulation, amendment or pertinent laws, rules and regulations
- Call upon the assistance of any government agency or GOCC.

# **Early Mandate Issues**

- **Inclusion of Potentially Harmful Exotic Species**
- **Authority to regulate**
- **Relationship with line agencies, particularly with the Plant Quarantine Service**
- **Access to best available science**
- **Extent of public participation**
- **Sharing of costs with other agencies**

# **Defining Moments in Early NCBP History**

- 1. Bt Corn Field Testing**
- 2. Issuance of D.A.-A.O. No. 8 (2002)**
- 3. Issuance of E.O. 514 (2006)**
- 4. Ratification of Cartagena Protocol**

## Defining Moments

# The Bt Corn Experience

- August-December 1996: First greenhouse evaluation of Bt corn expressing Bt CryIIA(b) gene under CL4 confinement facility at IRRI using transgenic hybrid materials from Pioneer Hi-Bred
- 1997-1998: Second greenhouse evaluation with Event 176 with materials from CIMMYT under CL4 confinement facility
- December 1999-March 2000: Limited field trial evaluation in General Santos City by IPB-UPLB and Agroseed Corporation
- 2001-2002: Multi-location field trials by Monsanto and Pioneer Hi-Bred
- [2003: *Bt* corn approved for commercialization]\*

\* By the Department of Agriculture

# Lessons from the Bt Corn Approval

- The Bt Corn episode:
  - Was NCBP's first encounter with anti-biotech groups
  - Forced NCBP and scientists to explain biotechnology to laymen
  - Highlighted the fact that biosafety is not only science-based risk assessment, but involves other issues which NCBP was ill-equipped to handle
- NCBP was later criticized because:
  - Risk management measures required of the applicant were too strict
  - It took a long time to approve the application
  - It was very expensive for the applicant

# **D.A.-A.O. No. 8, Series of 2002**

- Issued by DA Secretary Leonardo Q. Montemayor.
- Served to formalize existing arrangements between NCBP and Department of Agriculture
- Transferred field testing decision-making to the agency most equipped to handle it.
- Ensures that socio-economic considerations are included in decision-making process.

# **Executive Order No. 514 (2006)**

- Issued by Pres. Gloria Macapagal-Arroyo. A UNEP-funded project
- Established the National Biosafety Framework, which was essentially a description of a regulatory framework that was already in existence.
- Created a New NCBP, a super-body with policy-making powers and expanded membership
- Identifies the national competent authorities for purposes of the Cartagena Protocol



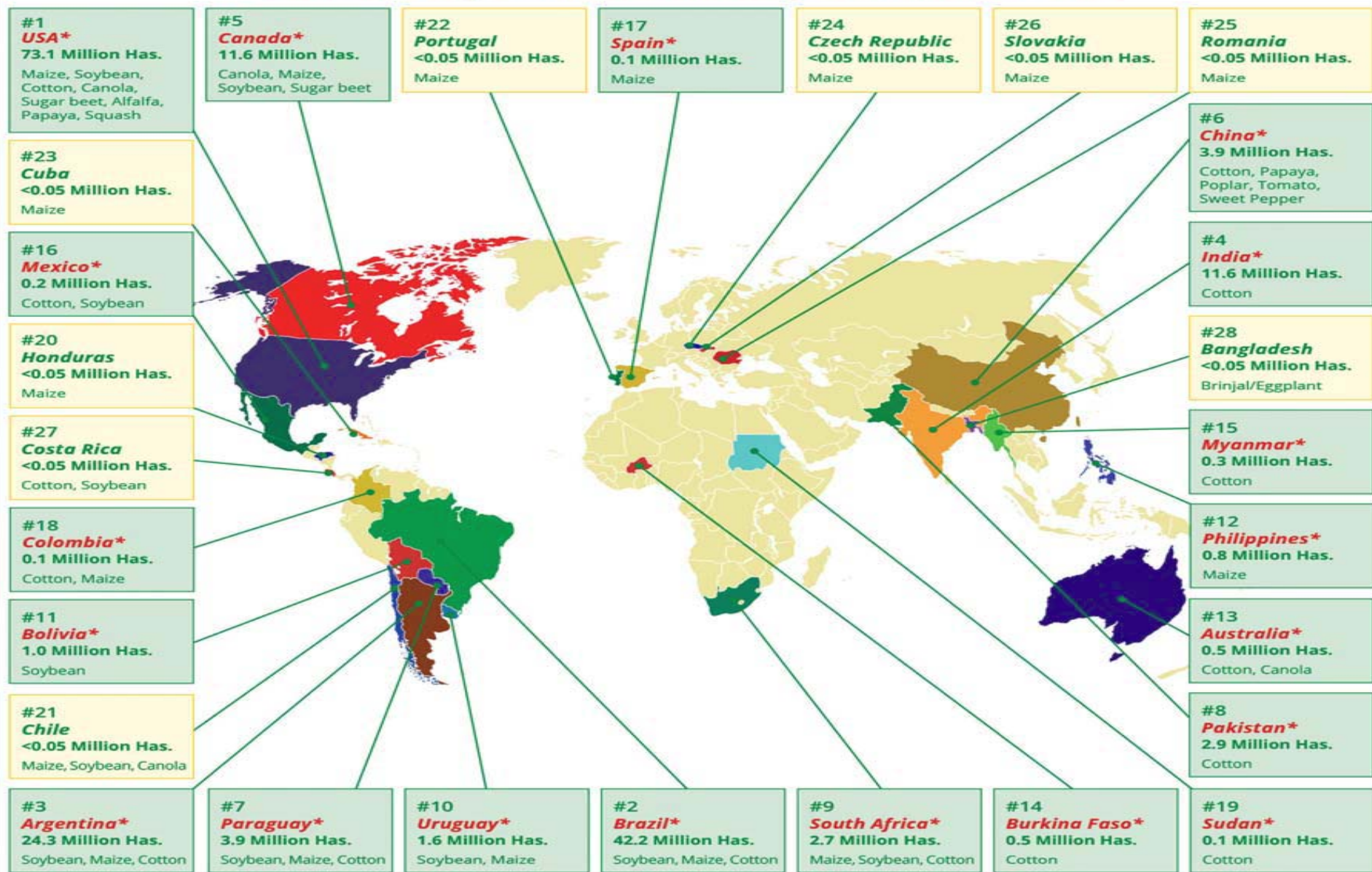
# **Ratification of Cartagena Protocol**

- NCBP Guidelines pre-dated the Cartagena Protocol, but it was guided by internationally-accepted standards, including the draft Cartagena Protocol.
- NCBP supported the Cartagena Protocol to help strengthen the regulation of trans-boundary movement, but has been protective of matters relating to sovereignty.



# **THE LAST TEN YEARS**

## Biotech Crop Countries and Mega-Countries\*, 2014



■ \*19 biotech mega-countries growing 50,000 hectares, or more, of biotech crops.

Source: Clive James, 2014.

Figure 1. Global Map of Biotech Crop Countries and Mega-Countries in 2014

## SUMMARY OF PROJECT PROPOSALS AND ACTION TAKEN

RECEIVED PROPOSAL		CONTAINED						CONFINED TEST			PLANNED RELEASE		
		Approved	Deferred	Not within the purview	W/drawn by the proponent	Dis-approved	Under Evaluation	Approved	Dis-approved	Not within the purview	Approved	Dis-approved	
<b>NCBP (1991-2008)</b>													
<b>TOTAL (NCBP)</b>	<b>246</b>	<b>188</b>	<b>24</b>	<b>13</b>	<b>1</b>	<b>6</b>	<b>-</b>	<b>4</b>	<b>-</b>	<b>-</b>	<b>10</b>	<b>-</b>	
<b>DOST-BC (2009-2015)</b>													
<b>TOTAL (DOST-BC)</b>	<b>59</b>	<b>37</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1</b>	<b>20</b>	<b>-</b>	<b>1</b>			
<b>GRAND TOTAL</b>	<b>305</b>	<b>225</b>	<b>24</b>	<b>13</b>	<b>1</b>	<b>6</b>	<b>1</b>	<b>24</b>	<b>-</b>	<b>1</b>	<b>10</b>	<b>-</b>	

# HIGHLIGHTS (2006-2015)

- Implementation of E.O. 514 with the convening of NCBP and formation of agency BCs.
- Issuance of *Manual on Biosafety Decision Making Process under E.O. 514*.
- Applications for national priority crops (e.g., rice, eggplant, cotton, tomato)
- Draft of the *Guidelines for Risk Assessment of Experiments on GM Arthropods*
- **Establishment of BCH Pilipinas.** Launched Aug. 7, 2008 to facilitate exchange of scientific, technical, environmental and legal information and experience with LMOs. For transparency, DOST and NCBP website also created.



**Some  
Thoughts  
on the  
Next Five**

# **Performance Metrics for the Biosafety Regulatory System**

- 1. Identification and evaluation of potential hazards in GE experiments.** All risks have been properly assessed and managed. Science-based policies on biosafety and guidelines in risk assessment.
- 2. Collaborative inter-agency arrangements in evaluating, monitoring & review of projects.**
- 3. Research programs to establish risk assessment protocols and assessment of long-term effects of research.**
- 4. Public trust in the robustness of the biosafety regulatory system.**
- 5. Capacity building for the next generation of regulators.** Development of technical expertise for biosafety risk assessment.