

# Philippine Biosafety Regulations: E.O. 430 History, Process and Experience

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# GMO Regulations in the Philippines

- E.O. 430, s. 1990, created the National Biosafety Committee of the Philippines
- DA A.O. No. 8, s. of 2002, provided the guidelines for the importation and use (except contained use) of GM crops.

## Domestic Regulations vis-à-vis International Standards

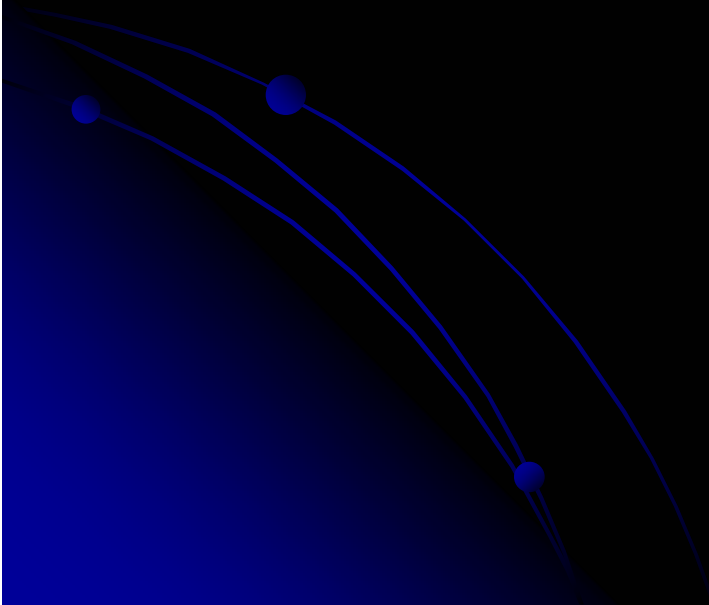
- ❑ **GMO regulations are in compliance with the Cartagena Protocol on Biosafety and the Codex Alimentarius Commission Principles and Guidelines.**
- ❑ **GMO regulations are continuously evaluated, modified to conform to internationally accepted standards and best practices.**

# REGULATORY NODES

Supervision

- **Contained Use**
    - Laboratory
    - Greenhouses, Glasshouses, Screenhouses
  - **Release into the Environment**
    - Planned Field Release
    - Multi-Site Release
  - **Large scale release**
    - Production/Commercial propagation
    - Use for Food or Feed
    - Use for Processing
  - **Transboundary Movement (Import, Export)**
- NCBP, 1991-2003
- NCBP July 1, 2003 to present
- DA-BPI, from July 1, 2003
- DA-BPI, from April 2002
- DA-BPI
-

# Brief History of Modern Biotech Regulations in the Philippines



- 1987 Ad-Hoc Committee on Biosafety  
UPLB, IRRI and DA

- RECOMMENDATIONS:

- creation of a National Committee on Biosafety; and

- formulation of national policies and guidelines on biosafety.

# The National Committee on Biosafety of the Philippines

- ❖ **Inter-agency (DOH, DOST, DA, DENR) committee with 4 scientists and 2 community representatives created in October 1990 (E.O.430)**
- ❖ **Is replicated at the institutional level through the Institutional Biosafety Committee**
- ❖ **Issues Guidelines (for experimental use)**
- ❖ **Conducts risk assessment with the Scientific and Technical Review Committee**
- ❖ **Also evaluates risks relating to Potentially Harmful Exotic Species**

## Present COMPOSITION OF NCBP

- \* **CHAIRMAN:**

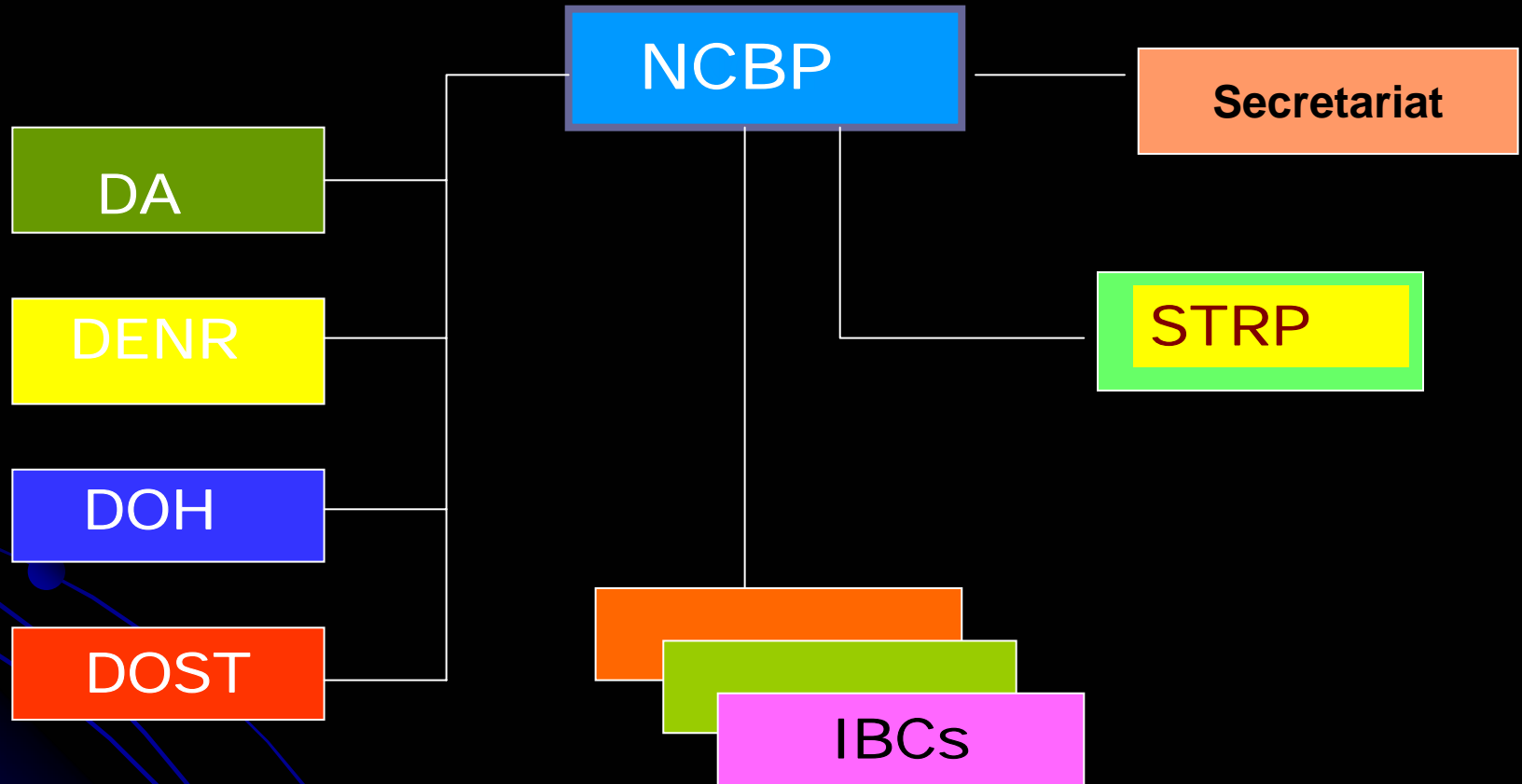
- DOST Undersecretary for R & D (Ex-officio)

- \* **MEMBERS :**

- 4 Scientists representing the Biological, Physical, Social and Environmental Sciences
- 1 Representative each from DA, DENR and DOH (Ex officio)
- 2 Community Representatives

Term of three years to end on 30 June 2006


# Biosafety Organizational Structure in the Philippines



# LEGAL MANDATE OF THE NCBP

- **Identify & evaluate potential hazards in GE experiments**
- **Formulate & review national policies on biosafety & guidelines in risk assessment**
- **Assist in development of technical expertise for quarantine services & risk assessment**
- **Recommend development & promotion of research programs to establish risk assessment protocols & assessment of long-term effects of bio research**

# BIOSAFETY REVIEW IS CONDUCTED BY:

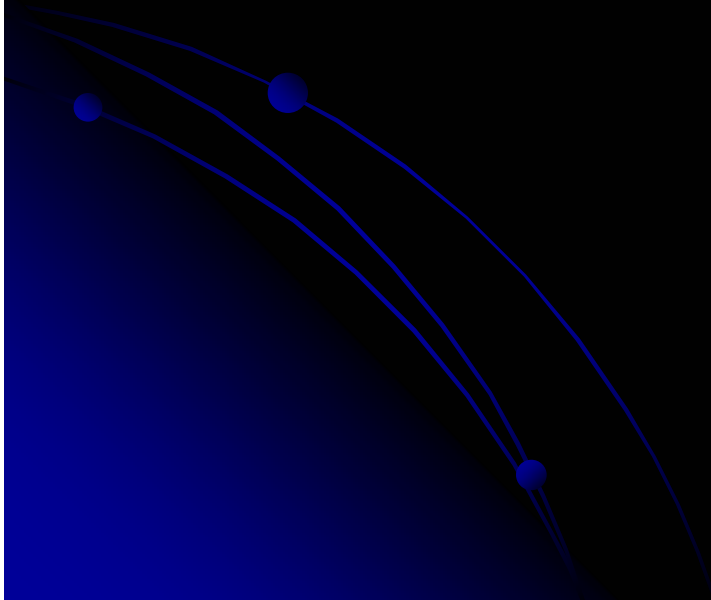
- ❑ Institutional Biosafety Committee
  - ❑ Scientific & Technical Review Panel  
(case by case)
  - ❑ National Committee on Biosafety of the  
Philippines
- 

# NCBP Approval: is necessary IF:

✉ Organism is genetically modified by recombinant DNA techniques, whether produced locally or imported from abroad.

✉ Organism is **not genetically modified, but is exotic** or non-indigenous to the Philippines and maybe potentially harmful.

# Biosafety Guidelines



# PHILIPPINE BIOSAFETY GUIDELINES (First Edition-1991)

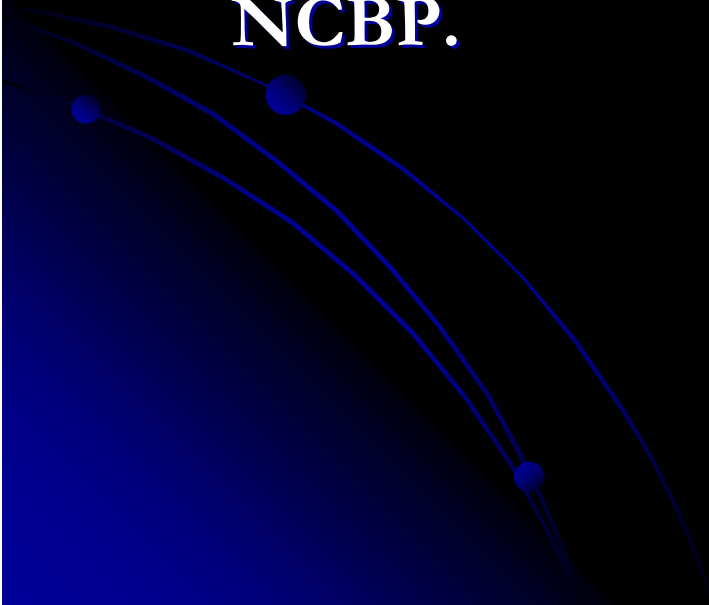
**Scope:** work involving genetic engineering; activities requiring importation, introduction, field release & breeding of non-indigenous organisms that may be potentially harmful to the public & the environment even though these are not genetically modified.

□ **CONTAINS** procedures for: evaluation of project proposals; introduction, movement & field release of regulated materials; and

◆ **REQUIRED** levels of containment (physical/biological)

# Policy on Importation for Contained Use

No regulated article intended for contained use shall be allowed importation or be removed from the port of entry unless duly authorized by BPI upon the endorsement of NCBP.



# Flow of procedures for evaluation of proposals for work under containment (laboratory/greenhouse/screen/glasshouse)

■

Researcher/Proponent



Thru the Head of Institution



IBC for biosafety evaluation



NCBP  
(approval/disapproval)



Recommends to  
BPI-PQS the issuance of  
Permit to import the regulated  
article

## CRITERIA FOR EVALUATING WORK UNDER CONTAINMENT

- ❑ Transformation protocol
- ❑ Genetic & physiological characteristics of donor organisms & GMOs
- ❑ Adequacy of the facility, laboratory to ensure that no viable material escapes into the environment (level of containment will depend on the type of work to be conducted)
- ❑ Biosafety measures, i.e. disposal procedures, etc.



**Number of R & D Projects  
Approved by the NCBP for  
Implementation in the  
Laboratory or Greenhouses  
with Proper Containment:  
168**



# Guidelines on Planned Release of Genetically Modified Organisms (GMOs) and Potentially Harmful Exotic Species (PHES)

Ratified by the NCBP – 13 May 1998

□ Effectivity: 9 September 1998

□ **SCOPE:** Apply to deliberate release of GMOs and PHES into the Philippine environment



## EXCLUSIONS:

- ❑ work in containment
- ❑ accidental release from contained facilities;
- ❑ pharmaceuticals, processed food, animal feed, industrial & other products already being regulated by other departments, agencies or instrumentalities of the Philippine government;
- ❑ work on organisms resulting from natural reproduction or use of traditional breeding practices; and
- ❑ such other activities as the NCBP may in the future declare to be excluded

# Process flow of procedures for field release applications

(1998 – 30 June 2003)





Assess the physical environment:  
location, area, topography, climatic  
conditions, proximity to bodies of  
water, ECA, etc

Biological environment  
vegetation, other crops, pest profile,  
weed species, livestock, migratory  
species

Social environment  
population, cultural profile and  
economic activities in the area



Proposed field test site for Bt  
corn, Bgy. Maltana, Tampakan,  
South Cotabato

- To give the public/residents in the area the opportunity to be informed & comment on the proposed activity
- Posting of NCBP approved PIS for 3 consecutive weeks
  - Starts on the last day of posting of NCBP-approved PIS or last publication date in newspaper, whichever comes later

All comments - sent to the proponent thru the NCBP Secretariat, by registered mail

Proponent given 15 days within which to respond to comments.

**PUBLIC COMMENT PERIOD ( THE process will take about 60 days (minimum)**



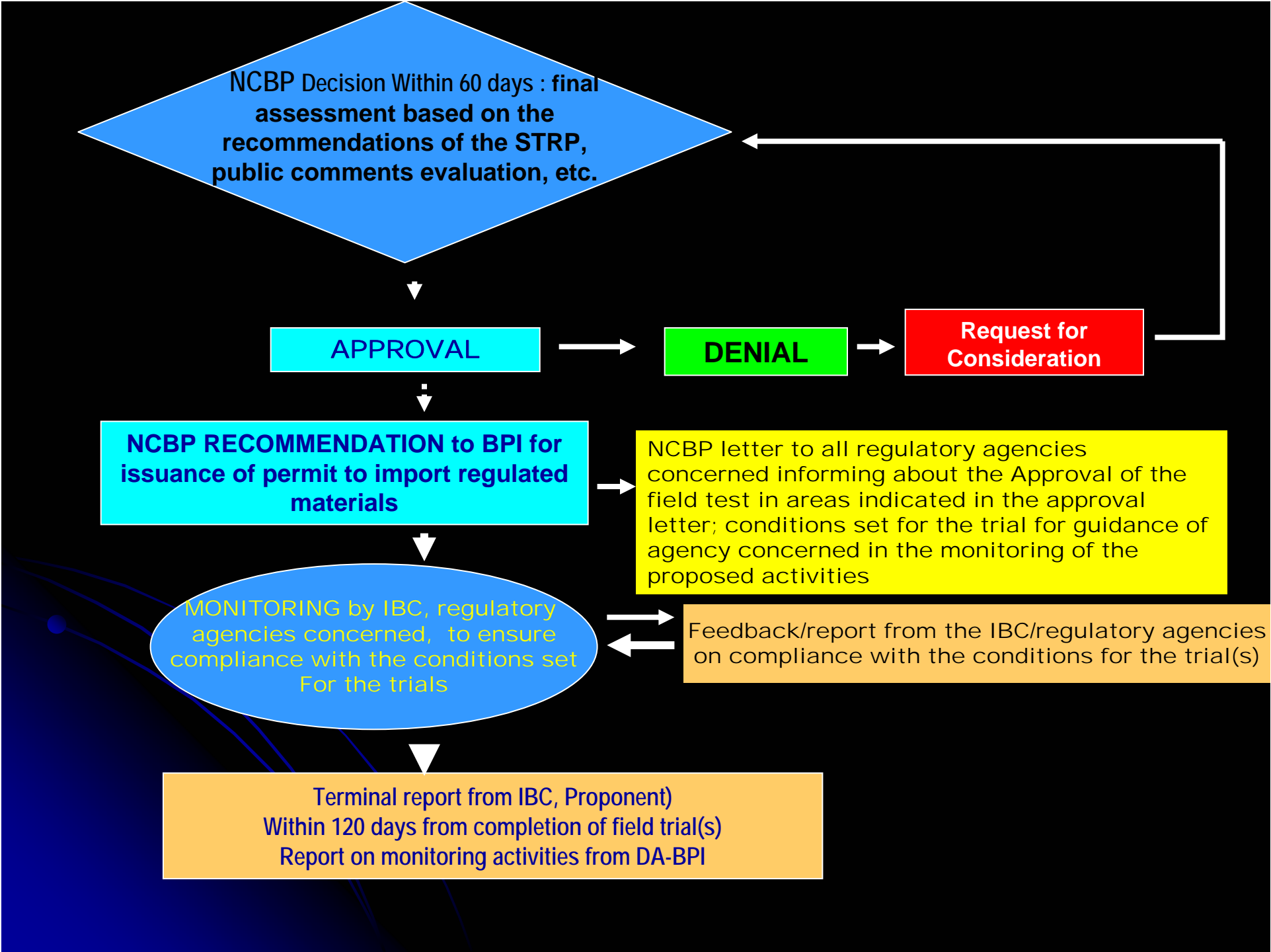
Inspection report, maltana, tampakan, s. cotabato (Monsanto)

23 Sept. 2001

Inspection report, maltana, tampakan, s. cotabato (Monsanto)

23 Sept. 2001

Warning sign outside the Church in Maltana, Tampakan, South Cotabato on the way to inspect the field testing site





NCBP inspection of field test Sites for Bt corn, Tigaon, Camarines Sur



**Project proposal, including  
amendments and attachments  
(i.e. scientific studies, etc)**

**IBC assessment/**

**FINAL ASSESSMENT NCBP decision  
(APPROVAL/DISAPPROVAL)**

**Comments and  
recommendations of the  
STRP**

**Public comments**

**such other documents or  
information, from whichever  
source deemed relevant by the  
NCBP**

## Case-by-case assessment

Trials may be used to assess benefit and impact, prior to approval for commercial release

human safety

+

Environmental  
safety

Allergenicity

Toxicity

Pathogenicity

Digestibility

Unexpected products

Stability

Etc.

Impact on living components:

- gene flow

- biodiversity

- weediness potential

Impact on non-living components:

- air, water, soil

Stability

Etc.

IBC

NCBP

MONITORING OF  
FIELD TESTING ..

Regulatory Agencies

DA - movement and effects of GMOs for release

DENR - environmental effects

DOH - monitoring the effects of such release to human health.

**DA-BPI does the monitoring of field testing of GMOs**

# NCBP "APPROVAL"

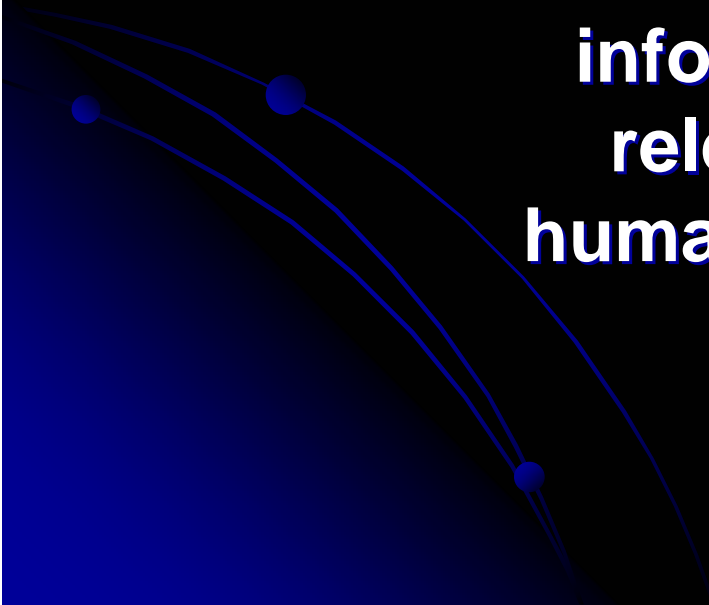
- ❑ Product solely of scientific and technical risk assessment
- ❑ Does not excuse the proponent from complying with the requirements of other agencies of the government before actually conducting the experiment

*At present, only the Plant Quarantine Service of the DA has these legal requirements in place*

# REPORTS

- Annual Report - IBC
- Terminal Report - Proponent to the IBC within 90 days after completion of the activity, indicating
  - whether or not the objectives of the field test were achieved?
  - nature and consequences of adverse effects of the release, if any; and
  - fate of GMOs after the release

# WITHDRAWAL OF NCBP APPROVAL

- ❑ Due to non-compliance with all the conditions set by the NCBP.
  - ❑ Receipt of new reliable data or information indicating that the release may pose a threat to human health of the environment.
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# Number of Completed Field Trials in the Philippines: 8

Corn: all Mon810

2 supercontained, detasseled trials

Monsanto

Pioneer

2-season multilocation trials

Monsanto

Pioneer

Rice: 2 seasons in PhilRice  
(Xa21, 3 events)



# Recently approved/ON-going Field Trials in the Philippines:

## Ongoing:

2 season multi-location trials of Bt11 hybrid corn by Syngenta Phils. (Completed 1<sup>st</sup> season)

2 season multi-location trials of Herculex 1 (cryl(f)) by Pioneer Hi-Bred Phils (Completed 1<sup>st</sup> season)

2nd Season of the 2-season multi-location detasseled trials -Round-up Ready corn by Monsanto Phils (Will be completed by 2nd week July 2004)



## *How we measure up:*

**→ Philippine GMO regulations are in compliance with Cartagena Protocol on Biosafety and Codex Alimentarius Commission Principles and Guidelines.**

**→ The regulations are continuously evaluated and modified to conform to internationally accepted standards and best practices.**



**In the meantime.....**

***The NCBP shall continue to perform its legal mandates UNTIL such time that a permanent BODY to replace NCBP has been created .....***

***Thank you***

*Thank you*

