



Administrative Order No. 8, Series of 2002

Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology

Department of Agriculture



Introduction

- ◆ DA objective is to accelerate agricultural development, enhance production, and diversify products for food security and global competitiveness
- ◆ Safe and responsible use of modern biotechnology could increase farm yield, improve quality of farm products, reduce use of pesticides and other inputs, enhance the environment, and reduce farmer/consumer exposure to pesticides

Introduction

- ◆ Government has recognized the potentials of modern biotech thru EO 430, the AFMA, and the GMA Policy Statement on Modern Biotechnology
- ◆ DA has to address concerns on the risks of GMOs on human health & environment
- ◆ The Rules will further strengthen the existing regulatory system for the importation and use of GMOs

Coverage

1 Any plant which has been altered or produced through the use of modern biotechnology if donor organism, host organism, or vector or vector agent belongs to any of the genera or taxa classified by BPI as meeting the definition of plant pest or is a medium for the introduction of noxious weeds

2 Any plant or plant product altered or produced through the use of modern biotechnology which may pose significant risks to human health and the environment based on available scientific and technical information

Risk Assessment

No person shall be allowed to import or release into the environment any regulated article without a satisfactory risk assessment conducted in accordance with these Rules and Regulations.

Policy

- 1 Carried out in scientific & transparent manner; based on available scientific & technical information
- 2 Lack of scientific knowledge or consensus not to be interpreted as indicating a particular level of risk, absence of risk, or acceptable risk

Principles

3. Identified characteristics of GMO and its use shall be compared to those of non-GMO from which it is derived and its use under the same conditions
4. To be carried out case-by-case and on the basis of transformation event
5. If new information becomes available, risk assessment shall be readdressed

Principles

Responsible Officer

The applicant for the import or release into the environment of GMO shall appoint a Responsible Officer –

- its highest ranking officer *and*
- resident of the Philippines –

who shall ensure that all appropriate measures are taken to prevent adverse effects on human health and the environment.

For communication purposes, RO may designate a duly authorized representative

TYPES OF PERMIT

- 1 To Import for Contained Use
- 2 To Field Test
- 3 To Propagate
- 4 To Import for Direct Use as Food or Feed, or for Processing

WHO CAN APPLY

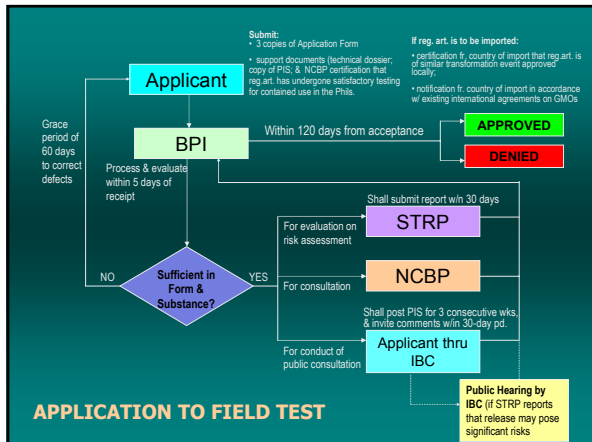
Any Juridical person who has and will maintain control over the importation or release of the GMO. It may be:

- departments or agencies of the Government of the Philippines
- university-based research institutions in the Philippines
- duly recognized international research organization based in the Philippines
- corporations registered with the SEC
- cooperatives registered with the CDA

POLICY ON FIELD TESTING

“No regulated article shall be released into the environment for field testing unless:

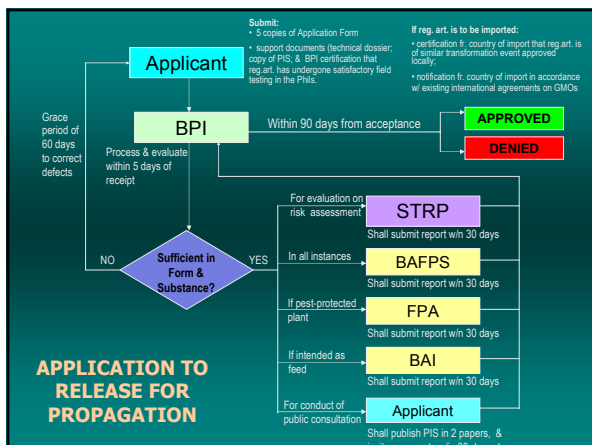
- (i) a *Permit to Field Test* has been secured from the BPI; and,
- (ii) the regulated article has been tested under contained conditions *in the Philippines*.



POLICY ON RELEASE FOR PROPAGATION

“No regulated article shall be released for propagation unless:

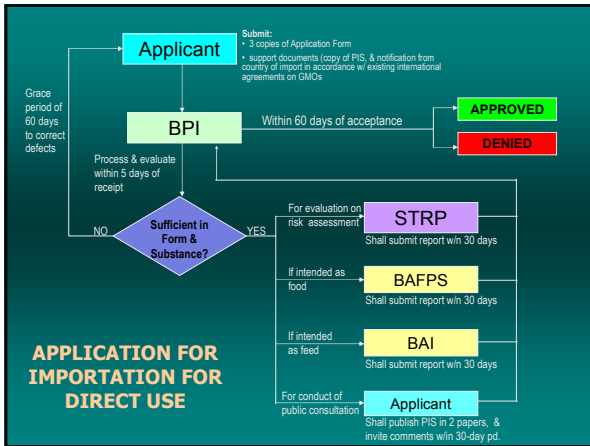
- (i) a *Permit for Propagation* has been secured from BPI;
- (ii) it can be shown that based on field testing conducted in the Philippines, the regulated article will not pose any significant risks to the environment;
- (iii) food and/or feed safety studies show that the regulated article will not pose any significant risks to human and animal health; and,
- (iv) If the regulated article is a pest-protected plant, it has been duly registered with the FPA.”



POLICY ON IMPORTATION FOR DIRECT USE

“No regulated article shall be allowed importation for direct use as food or feed, or for processing, unless:

- (i) the importation has been duly authorized by BPI;
- (ii) the regulated article has been authorized for commercial distribution as food or feed, as the case may be, in the country of origin; and
- (iii) regardless of the intended use, the regulated article poses no significant risks to human and animal health.”



TRANSITION PERIOD - on FIELD TESTING

- Until June 30, 2003
- *Applications to Field Test* shall be filed with and processed by the NCBP in accordance with its Guidelines
- *Provided:* That the conduct of the field testing shall be subject to the control and supervision of BPI.

TRANSITION PERIOD - on DIRECT USE

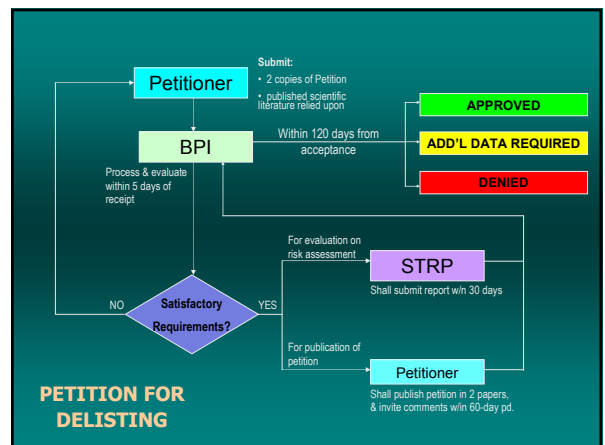
- Until June 30, 2003
- No permit requirements to import for direct use a regulated article which *must also approved for commercial distribution as food or feed by the regulatory authorities in the country of origin*
- Provided: in case regulated article is intended as feed or for processing into feed, importation is allowed *only if regulatory authorities in country of origin have likewise determined that the regulated article poses no significant risks to human health.*

TRANSITION PERIOD - on DIRECT USE

- During transition period, BPI to create an *Ad Hoc STRP* to review available scientific risk assessment data and information on regulated articles likely to be imported.
- If *Ad Hoc STRP* determines that a regulated article poses no significant risks, BPI shall register it in the approval registry; otherwise, it shall immediately ban its importation and advise the public accordingly.

DELISTING OF REGULATED ARTICLE

If based on the nature of a regulated article and its use, the regulated article will not pose any significant risks to human health and the environment, BPI may remove it from the coverage of this Order.



CONFIDENTIAL BUSINESS INFORMATION

Upon prior consultation with the applicant, the BPI can declare and designate certain portions of the application, which contain trade secrets or confidential business information, as such.

OUTSIDE EXPERTS AND ACCREDITATION OF LABS

In implementing this AO, including evaluation of risk assessment studies and risk management measures, BPI may coordinate, seek services of, and consult with international or governmental agencies and public or private research institutes or laboratories, educational establishments and individuals or entities with expertise relevant to biosafety.