Republic of the Philippines
DEPARTMENT OF AGRICULTURE
Office of the Secretary
Elliptical Road, Diliman, Quezon City

October 11, 2004

MEMORANDUM CIRCULAR
No. 08
Series 2004

Subject: **RISK ASSESSMENT FOR STACKED GENE PRODUCTS IMPORTED FOR DIRECT USE AS FOOD AND FEED OR PROCESSING**

This Memorandum Circular covers the basic procedures for carrying out risk assessment of plant products or commodities carrying stacked genes which are imported for direct use as food and feed or for processing. Risk assessment of stacked gene plant products or commodities imported for direct use as food and feed or for processing shall be consistent with the approval process established in the relevant provisions of existing biosafety polices of the Department of Agriculture such as Administrative Order No. 8 s. 2002 and Memorandum Circular No. 6 s. 2004, "*Risk Assessment of Plants Carrying Stacked Genes for Release into the Environment*".

This Memorandum Circular does not cover food and feed safety risk assessment of plant products derived from locally propagated stacked gene plants. Said process is incorporated in the approval process established for locally released stacked gene plants as per Memorandum Circular No. 6 s. 2004.

I. Plant Products or Commodities Carrying Stacked Genes

Plant products carrying stacked traits are commodities from plants derived from the use of modern biotechnology which have multiple stacked genes encoding different traits. As per Memo Circular No. 6 s. 2004, gene stacking in plants can be conferred either through genetic engineering or conventional breeding.

II. Risk Assessment of Imported Plant Products or Commodities Carrying Stacked Genes

Plant Products Carrying Stacked Genes Conferred through (a) Genetic Engineering or (b) Conventional Breeding, with Individual Traits That Have No Prior Approval

A full risk assessment as to food and feed or processing shall be conducted, consistent with Part V of AO No. 8, "*Approval Process For the Importation of*

Regulated Articles for Direct Use as Food and Feed or For Processing", for plant products with multiple traits conferred through:

(a) genetic engineering, or
(b) conventional breeding, where the individual traits have no prior approval from the Bureau of Plant Industry (BPI) for direct use as food and feed or processing.

Plant Products Carrying Stacked Genes Conferred through Conventional Breeding, with Individual Traits That Have Prior Approval

For plant products with multiple traits conferred through conventional breeding, with all individual events granted prior approval and included in the Approval Registry, a notification shall be submitted by the technology developer to the BPI, which shall conduct an evaluation in accordance with the relevant criteria in Annex I of this Memorandum Circular. The list of data contained in Annex I will not preclude the inclusion of other issue and concerns that will be raised by the BPI and the Scientific and Technical Review Panel (STRP) during the course of the desktop review.

The relevant protocols implemented by the BPI for the risk assessment of plant products for direct use as food and feed or for processing shall likewise apply.

III. Notification Requirement for Plant Products Carrying Stacked Genes

All technology developers shall submit a notification to the Bureau of Plant Industry of their developed plant products carrying stacked genes and shall be required to comply with the relevant approval process listed above.

The Bureau of Plant Industry shall issue a certificate as to the approval of the stacked gene products and shall likewise include the transformation events in the official approval registry of plant products for food and feed or processing.

This Memorandum Circular shall take effect immediately.

ARTHUR C. YAP
Secretary

ANNEX I

Risk Assessment Procedure for Plants Carrying Stacked Genes Conferred Through Conventional Breeding: A Desktop or Documentary Review for Expected or Possible Interactions

For applications for release into the environment (i.e., limited or commercial release) of plants carrying stacked genes conferred through conventional breeding, a desktop or documentary risk assessment on the possible or expected interactions between genes shall be conducted by the BPI. The review will take into account existing data available and will be conducted according to the criteria enumerated below, as relevant. This list does not preclude the inclusion of other issues that will be raised by the BPI and the STRP during the course of the review.

Basic Information Required:

Applicant Name:
Address:
Contact Person and No.:
Transformation Events, Description of Traits, and Approval Dates:
Breeding History:
List of Countries where Individual Traits and/or Plant Carrying Multiple Traits Have Been Approved –
For Food:
For Feed:
For Propagation:

Phase I: Determination of Interaction between/among traits

A. Gene Interaction
   1. Is there any interaction of the resulting products such that a new allergen or a new toxin could be produced?
   2. Will the compartmentalization of the expressed products be affected by stacking?
   3. Other than the introduced trait, will the stacking influence other phenotypic characteristics of the plant?

B. Metabolic Pathways
   1. Is there a complete description of the mode of action of each gene product?
   2. Is the mode of action of each gene product different?
   3. Are the products involved in the same metabolic pathway?

2. Are the marker genes transferred and expressed also in the plants containing the stacked genes?

D. Other Concerns Identified by the STRP or the BPI

Phase II. If inter-action is demonstrated, the plant products carrying stacked genes conferred through traditional breeding shall undergo the appropriate level of risk assessment as per AO 8 s. 2002.

ANNEX I

Risk Assessment Procedure for Imported Stacked Gene Products with the Following Attributes: (a) Multiple traits have been conferred by conventional breeding; (b) Individual traits have prior approval from the Bureau of Plant Industry; and (c) Commodities carrying traits are used directly for food and feed or for processing

For applications for the plant products carrying stacked genes with the above attributes, a desktop or documentary risk assessment on the possible or expected interactions between genes shall be conducted by the BPI. The review will take into account existing data available and will be conducted according to the criteria enumerated below, as relevant. This list does not preclude the inclusion of other issues that will be raised by the BPI and the STRP during the course of the review.

Basic Information Required:

Applicant Name:
Address:
Contact Person and No.:
Transformation Events, Description of Traits and Approval Dates:
Breeding History:
List of Countries where Individual Traits and/or Plant Products Carrying Multiple Traits Have Been Approved –
For Food:
For Feed:

Phase I: Determination of Interaction between/among Traits

A. Gene Interaction
1. Is there any interaction of the resulting products such that a new allergen or new toxin could be produced?
2. Will the compartmentalization of the expressed products be affected by stacking?
3. Other than the introduced trait, will the stacking influence other phenotypic characteristics of the plant?

B. Metabolic Pathways
1. Is there a complete description of the mode of action of each gene product?
2. Is the mode of action of each gene product different?
3. Are the products involved in the same metabolic pathway?

C. Gene Expression and Performance
1. Are the expression levels of the individual protein products the same as the individually approved transformation events?

/ The two or three singles are approved before we approve a stacked one.
/ One STRP member is required to evaluate the gene interaction or only desktop eval is conducted.

C. Gene Expression and Stability

Do the genes perform the same way in the stacked genes as in the plants containing the individual traits? This may be determined by:

1. Gene Expression (and/or 2)
   a. Are the expression levels of the individual protein products the same as the individually approved transformation events?
   b. Are the marker genes transferred and expressed also in the plants containing the stacked genes?

2. Field Performance
   a. Is the field performance of the stacked gene plant equivalent to the relevant field performance of plants with individually approved traits/transformation events?
   b. Are the agronomic characteristics of the stacked plant equivalent to the agronomic characteristics of individually approved traits/transformation events?
   c. Is the expression of the multiple traits based on the field trial performance as stable as those expressed in the same plant when these are individually carried?

D. Agricultural Management

1. Will the presence of the traits cause a change in the cultural management of the crop except for the intended changes? If yes, describe the change.

E. Other Concerns Identified by the Proponent and Scientific Technical Review panel (STRP)

Phase II. If inter-action is demonstrated, the plants carrying stacked genes conferred through traditional breeding shall undergo the appropriate level of risk assessment as per AO 8 s. 2002.