



September 16, 2004

Memorandum Circular

No. 016
Series of 2004

**Subject: RISK ASSESSMENT OF PLANTS CARRYING STACKED GENES FOR
RELEASE INTO THE ENVIRONMENT**

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This Memorandum Circular covers the basic biosafety policies in carrying out the risk assessment of plants carrying stacked genes particularly for applications for limited and/or commercial release into the environment.

The risk assessment principles of AO No. 8, s. 2002, "Rules and Regulations on the Importation and Release Into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology", provide that risk assessment shall be carried out case-by-case and on the basis of the transformation event. The required information may vary in nature and level of detail from case to case depending on the regulated article concerned, its intended use and the receiving environment (DA AO No. 8 s. 2002, Section 3.C.4).

I. Stacked Genes

Stacked gene products refer to plants improved through the use of modern plant biotechnology using multiple genes encoding several traits. Stacked gene plants are produced through the following methods: (1) Insertion of an additional transgene by transformation of an existing biotech plant; (2) Insertion of multiple genes into a non-transgenic plant with a vector containing two or more genes; and (3) Traditional breeding approach that combines genes previously introduced by plant biotechnology.

II. Risk Assessment of Stacked Traits

Plants Carrying Stacked Genes Conferred Through Genetic Engineering

Plants carrying stacked genes in categories (1) and (2) above, i.e., those produced by transformation of an existing biotech product or transformation with a vector containing two or more genes or traits, are considered novel or new transformation events. Hence they are required to undergo the full step-by-step, phase-by-phase risk assessment procedure of AO No. 8, which covers food, feed, and environmental safety assessment.

Plants Carrying Stacked Genes Conferred Through Conventional Breeding

Products with multiple traits conferred through conventional breeding of plants with one or more transgenes – that have been earlier approved individually by the Bureau of Plant Industry (BPI) under AO No. 8 for commercial propagation – are not considered new events. Hence they may not be required to undergo the full food, feed, and environmental safety assessment. An initial evaluation and risk assessment will focus on the possible or expected interaction effects between/among the multiple traits conferred in the plant.

For these stacked-gene plants, the Biotech Core Team of the BPI shall convene a Scientific and Technical Review Panel (STRP) to conduct a preliminary assessment as to the potential interaction between/among the multiple traits. An element of desktop evaluation will be performed to determine if any interaction is likely.

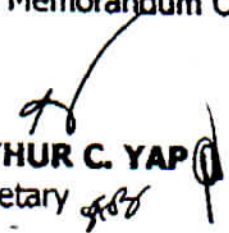
If the STRP determines that there is no potential interaction resulting to an adverse effect among the traits and the environment, the BPI will formally notify the technology developer of its findings.

If, on the other hand, the STRP determines that there is potential interaction resulting to an adverse effect, the BPI will require the application to undergo the step-by-step, phase-by-phase risk assessment procedures for biotech plant introduced into the environment, as per AO 8.

Annex I of this Memorandum Circular provides guide questions for consideration in the conduct of risk assessments for plants carrying stacked genes conferred through conventional breeding. Annex I will not however preclude other relevant issues or concerns that the BPI or the Scientific Technical Review Panel will raise during the course of the desktop review.

Field testing of products with multiple traits conferred through conventional breeding still to be approved individually for commercial propagation by the BPI is allowed for the purposes of collecting data or verifying existing field test data, for as long as the particular event(s) has been tested under contained conditions in the Philippines and has obtained a certificate of satisfactorily passing the test from the National Committee on Biosafety of the Philippines (NCBP).

This Memorandum Circular shall take effect immediately.


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Secretary