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

5 January 2009

ADMINISTRATIVE ORDER
No. 01
Series of 2009

SUBJECT: FOOD SAFETY ASSESSMENT IN SITUATIONS OF LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIALS IN FOOD AND FEED

WHEREAS, products derived from modern biotechnology, including genetically modified (GM) commodities for food and feed or processing are globally traded;

WHEREAS, countries in accordance with their national priorities and needs have adopted biosafety legislation, rules and regulations, and other measures so as to enjoy fully the benefits of modern biotechnology while safeguarding the health of humans and animals and safety of the environment;

WHEREAS, Department of Agriculture Administrative Order No. 8, series 2002 (DA AO 8), "Rules and Regulations on the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology", regulates the use of products of modern agricultural biotechnology that are intended for commercial release including recombinant-DNA products for direct use for food and feed or for processing;

WHEREAS, the cornerstone of a decision making for the issuance of a biosafety permit for direct use as food and feed or for processing under DA AO No. 8 is a food safety assessment / risk assessment conducted in accordance with internationally accepted principles and practices including those of the Cartagena Protocol on Biosafety, the Codex Principles for the Risk Assessment of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) and the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, or otherwise known as the Codex Plant Guideline (CAC/GL 45-2003);

WHEREAS the DA adopted the Codex Principles for the Risk Assessment of Food Derived from Modern Biotechnology (CAC/GL 44-2003) and the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants (CAC/GL 45-2003) on 13 October 2008 through DA AO No. 31 series of 2008;

WHEREAS, DA AO No. 8 has established the Approval Registry of Plant Products for Direct Use as Food and Feed or for Processing, currently maintained by the Department of Agriculture-Bureau of Plant Industry;

WHEREAS, there have been occasions of unauthorized low-level presence of recombinant-DNA plant material in countries of import;

WHEREAS, the unauthorized presence in low levels of recombinant-DNA plant materials in commercial food and feed can be traced to several factors, including natural pollen flow, emergence of volunteer plants from previously harvested GM crops, discontinued GM products where discontinuance is not due to safety reasons, handling, processing and transport of GM commodities. Hence, there is a need to identify the risks posed by such recombinant-DNA plant material;

WHEREAS, such presence in low levels of unauthorized recombinant-DNA plant material in food and feed, by its nature, is transient, temporary or occasional; exists in non-commercial levels; and can be detected and measured through threshold levels;

WHEREAS, the 31st Session of the Codex Alimentarius Commission adopted Annex 3 to the Codex Plant Guideline, *"Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food"*;

WHEREAS, low level presence of recombinant-DNA plant material under Annex 3 refers to the occasional presence in low levels of recombinant-DNA plant material present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined but which have passed a foods safety assessment in one or more countries according to the Codex Plant Guideline;

WHEREAS, Annex 3 to the Codex Plant Guideline provides that food safety assessment in situations of low-level presence may not require a full or complete comparison of the characteristics of a recombinant-DNA plant or plant product with its conventional counterpart as in the Codex Plant Guideline;

WHEREAS, this Administrative Order does not cover recombinant-DNA plant and plant products denied approval by Department of Agriculture's regulatory agencies for the reason that these products pose significant risks to human, animal, plant or the environment health;

WHEREAS, there is a need to ensure consumer protection in terms of human and animal health, environmental safety and food safety, by utilizing the Annex to the Codex Plant Guideline in assessing the safety of low-level presence of recombinant-DNA plant materials in food and feed;

NOW THEREFORE, I, ARTHUR C. YAP, Secretary of the Department of Agriculture, in accordance with the Consumer Act of the Philippines and Section 19, Chapter 4, Title IV, Book IV of Executive Order No. 292, Series of 1987, do hereby issue this Order:

> Adopting Annex 3 to the Codex Plant Guideline, *'Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food'*, for the conduct of food safety assessment in situations of low-level presence of recombinant-DNA plant materials in food and feed;

Directing the concerned policy and regulatory offices of the Department to clarify issues and formulate guidelines necessary to implement this Order under the leadership of the Office of Policy and Planning; and

Implementing an institutional capability building program for DA regulatory agencies to enhance their technical capacities to undertake appropriate regulatory action.

This Order shall take effect thirty (30) days after its publication in a national newspaper of general circulation.

Atty. ARTHUR C. YAP
Secretary

ANNEX 3: FOOD SAFETY ASSESSMENT IN SITUATIONS OF LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

SECTION 1 – PREAMBLE

1. An increasing number of recombinant–DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

2. This Annex describes the recommended approach to the food safety assessment in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances[24].

3. This Annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

4. This Annex can be applied in two different dietary exposure situations:

   a. That involving commodities, such as grains, beans or oil seeds, in which exposure to food from a variety not authorized in the importing country would likely be to dilute low level amounts at any one time. This would likely be the more common situation of low-level presence of recombinant-DNA plant material. Because any food serving of grains, beans or oil seeds would almost necessarily come from multiple plants, and because of how these types of commodities generally are sourced from multiple farms, are commingled in grain elevators, are further commingled in export shipments, at import and when used in processed foods, any inadvertently commingled material derived from recombinant-DNA plant varieties would be present only at a low level in any individual serving of food.

   b. That involving foods that are commonly consumed whole and undiluted, such as some fruits and vegetables like potatoes, tomatoes, and papaya, in which exposure would be rare but could be to an undiluted form of the unauthorized recombinant-DNA plant material. While the likelihood of consuming material from such an unauthorized variety would be low and the likelihood of repeated consumption would be much lower, any such consumption might be of an entire unauthorized fruit or vegetable.

5. In both cases, the dietary exposure will be significantly lower than would be considered in a food safety assessment of the recombinant-DNA plant according to the Codex Plant Guideline. As a result, only certain elements of the Codex Plant Guideline will be relevant and therefore are included in this Annex.

6. This Annex does not:

   - address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate;
   - preclude national authorities from conducting a safety assessment according to the Codex Plant Guideline; countries can decide when and how to use the Annex within the context of their regulatory systems; or
   - eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material.

SECTION 2 – GENERAL AND OTHER CONSIDERATIONS

7. For the food safety assessment in situations of low-level presence of recombinant DNA plant materials in food, sections 4 and 5 of the Codex Plant Guideline apply as amended as follows. The applicable paragraphs are specifically indicated. Those paragraphs of the Codex Plant Guidelines that are not listed can be omitted from consideration.

DESCRIPTION OF THE RECOMBINANT-DNA PLANT

8. Paragraph 22 of the Codex Plant Guideline applies.

DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD

9. Paragraphs 23, 24 and 25 of the Codex Plant Guideline apply.

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[24] This guidance is not intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

DESCRIPTION OF THE DONOR ORGANISM(S)

10. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor organism(s) should include:

A. its usual or common name;

B. scientific name;

C. taxonomic classification;

D. information about the natural history as concerns food safety;

E. information on naturally occurring toxins and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and,

F. information on past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants)[25].

DESCRIPTION OF THE GENETIC MODIFICATION(S)

11. Paragraphs 27, 28 and 29 of the Codex Plant Guideline apply.

CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

12. Paragraphs 30 and 31 of the Codex Plant Guideline apply.

13. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include:

A) the gene product(s) (e.g. a protein or an untranslated RNA);

B) the gene product(s)' function;

C) the phenotypic description of the new trait(s);

D) the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the edible portions of the plant; and

E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.[26]

14. Paragraph 33 of the Codex Plant Guideline applies.

SAFETY ASSESSMENT

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity

15. The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values.[27]

16. Information should be provided to ensure that genes coding for known toxins present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate toxicants.[28]

17. Paragraph 37 of the Codex Plant Guideline applies.

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25 The text of this paragraph was adapted from paragraph 26 of the Codex Plant Guideline.

26 The text of this paragraph was adapted from paragraph 32 of the Codex Plant Guideline.

27 The text of this paragraph was adapted from paragraph 35 of the Codex Plant Guideline.

28 The text of this paragraph was adapted from paragraph 36 of the Codex Plant Guideline.

18. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. appropriate oral toxicity studies[29] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.[30]

19. Paragraphs 39 and 40 of the Codex Plant Guideline apply.

Assessment of possible allergenicity (proteins)

20. Paragraphs 41, 42 and 43 of the Codex Plant Guideline apply.

Analyses of Key Toxicants and Allergens

21. Analyses of key toxicants[31] and allergens are important in certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted, such as potatoes, tomatoes, and papaya). Analyses of concentrations of key toxicants and allergens of the recombinant-DNA plant typical of the food should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.[32]

22. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of key toxicants and allergens over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimize environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key toxicants and allergens.[33]

Evaluation of Metabolites

23. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Food safety assessment in situations of low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).[34]

Food Processing

24. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.[35]

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29 Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

30 The text of this paragraph was adapted from paragraph 38 of the Codex Plant Guideline.

31 Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased).

32 The text of this paragraph was adapted from paragraph 44 of the Codex Plant Guideline.

33 The text of this paragraph was adapted from paragraph 45 of the Codex Plant Guideline.

34 The text of this paragraph was adapted from paragraph 46 of the Codex Plant Guideline.

35 The text of this paragraph was adapted from paragraph 47 of the Codex Plant Guideline.

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

25. Some recombinant-DNA plants may exhibit traits (e.g. herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g. those that are commonly consumed whole and undiluted), the risk assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g. procedures for assessing the human safety of chemicals) should be applied.[36]

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

26. Paragraphs 55, 56, 57 and 58 of the Codex Plant Guideline apply.

SECTION 3 – GUIDANCE ON DATA AND INFORMATION SHARING

27. In order for Codex Members to use this Annex, it is essential that they have access to requisite data and information.

28. Codex Members should make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline. This information should be presented in accordance with the following format:

a. name of product applicant;

b. summary of application;

c. country of authorization;

d. date of authorization;

e. scope of authorization;

f. unique identifier;

g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate;

h. summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline;

i. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained[37]; and

j. contact details of the competent authority(s) responsible for the safety assessment and the product applicant.

29. This process should facilitate rapid access by importing Codex Members to additional information relevant to the assessment of food safety assessment in situations of low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.

30. The authorizing Codex Members should make available complementary information to other Codex Members on its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.

31. The product applicant should provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method suitable for low level situations and appropriate reference materials (non-viable, or in certain circumstances, viable). This is without prejudice to legitimate concerns to safeguard the confidentiality of commercial and industrial information.

32. As appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline by the authorizing Codex member should be made available.

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36 The text of this paragraph was adapted from paragraph 54 of the Codex Plant Guideline.

37 This information may be provided by the product applicant or in some cases by Codex members.