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Safety Assessment of Genetically Modified Foods and Food Additives in Korea

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ABSTRACT *: Genetically modified foods and food additives are derived from organisms that have been inserted foreign genetic materials by recombinant DNA techniques to improve the quality or any other purposes. The problems such as toxicity, allergenicity and antibiotics resistance in the safety of genetically modified foods are usually concerned. In Korea, the safety of foods is ensured by the Food Sanitation Act. Although there is no specific provision regarding the genetically modified foods in it, any foods that might cause negative effect(s) on public health or human life are prohibited to sell in the market. In order to systematically evaluate safety of genetically modified foods, the Korea Food and Drug Administration (KFDA) promulgated "Guidelines regarding review of safety assessment data for genetically modified foods and food additives (KFDA Notification 1999-46)". The objectives of these guidelines are to ensure safety of genetically modified foods and food additives. In order to evaluate the safety of genetically modified foods, KFDA operates a special expert committee composed by experts from government, universities, research institutes, and consumer's unions. Recently, manufacturers and consumers are interested in the issues on safety and labeling of genetically modified foods, because of increment of imported genetically modified crops and processed foods. Since government and consumers unions have different viewpoints, their positions regarding the issue are different each other. Therefore, the regulation of labeling on genetically modified foods is prepared and should be enforced at July 2000 in Korea.*

I. BACKGROUND

Rising concerns over safety of foods and food additives developed through recombinant DNA technologies, which were not used for food production in the past, necessitate that the Commissioner of the KFDA confirm before they are commercially distributed that such foods or food additives do not pose any health risk to humans.

For this reason, guidelines regarding review of safety assessment data for genetically modified foods and food additives are to be enacted so that food manufacturers and distributors may have safety assessment data of genetically modified foods reviewed for their adequacy by the Commissioner of the KFDA to ensure food safety in a changing domestic and international environment relating to genetically modified foods and to comply with international regulatory standards under the WTO regime.

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II. GIST

The guidelines

· Apply to both genetically modified organisms which are intended for eating as part of foods or food additives and those which are used in production of foods and food additives but are not intended for eating;

· Stipulate submission and review procedures regarding safety assessment data of genetically modified foods, etc. for manufacturers and distributors who want the safety of their foods, etc. reviewed and confirmed by the KFDA Commissioner; and

· Specify the scope of safety assessment data which include, Purpose and method of using recombinant organisms, and data on safety and allergenicity of hosts (recipient organisms), vector systems, introduced DNAs, and recombinant organisms;

· Expected intake amounts, nutritional characteristics, toxicity, allergenicity, safety of antibiotic resistance genes, etc. of genetically modified foods and food ad-

ditives; and,

· Data on manufacturing processes and product safety.

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Chapter 1. General Provisions

Article 1. (Purpose)

These Guidelines aim to establish safety assessment requirements and procedures for genetically modified foods and food additives in accordance of with Article 4 Paragraph 2 of the Food Sanitation Act so that foods and food additives developed through recombinant DNA techniques may be commercially distributed after the Commissioner of the Korea Food & Drug Administration confirms that such foods and food additives do not pose any health risk to humans.

Article 2. (Definitions)

Defines terms used in there Guidelines

1. Recombinant DNA techniques
2. Recombinant DNA molecule
3. A host
4. A vector
5. Inserted DNA
6. A donor
7. Recombinant
8. Food containing recombinant itself
9. Foods made through recombinants
10. Progeny cultivar

Article 3. (Applicability)

1. Foods containing recombinant itself which include agricultural products produced through recombinant DNA techniques and progeny cultivar thereof;

2. Food made through recombinant which include the following:

A. Food additives, food ingredients, etc. derived from recombinants;

B. Recombinants used in the manufacture of foods and then removed from such foods, etc.

Chapter 2. Application and Approval Procedures

Article 4. (Submission of applications)

1. A person who desires to manufacture or import GM foods, etc. should submit to the KFDA Commissioner a review application as per the form with the documents specified below in Article 8.

2. A person who desires to manufacture a food made through recombinant organism should submit an application to the KFDA Commissioner with documents specified below in Article 9.

Article 5. (Review and evaluation)

1. Upon receiving an application to review safety assessment data for GM foods. the KFDA Commissioner should review adequacy of safety assessment based on submitted data.

2. The KFDA Commissioner should complete review within ninety (90) days from submission and may demand the submission of additional data if he deems the data incomplete.

3. The submission of additional data should be required if there is omission or incompleteness in submitted data as follows:

1) If all the data as specified in the review item list are not submitted;

2) If it is suspected that there is a problem with safety assessment.

4. If necessary, spot inspection may be conducted.

5. Safety assessment data for GM foods should be reviewed by the Food Sanitation Deliberation Council.

6. When safety assessment data for foods and food additives are determined adequate, The Decision should be published in an official bulletin.

Chapter 3. Review Data

Article 8. (Supporting documents for foods containing recombinants)

1. To confirm that a food, etc. containing recombinant organism does not pose any health risk to humans, safety of recombinants and foods containing recombinants should be assessed.

2. For safety assessment of recombinants, the data specified below should be attached.

1) Purpose and methodology of using a recombinants

2) Host

A. Taxonomy (scientific name, variety, phylogenic name, *etc.*)

B. History of being used in foods

C. Whether to create physiologically active hazardous materials

D. Whether its closely related species produce physiologically active hazardous substances

E. Allergenicity

F. Contamination by pathogens and external factors (viruses, *etc.*)

G. Ability to survive and reproduce, and conditions limiting these abilities

3) Vector

A. Name

B. Source

C. Traits

(1) Molecular weight of DNA

(2) Restriction Map

(3) Existence of hazardous base sequences

(4) Number and stability of replicated vectors in a host

D. Traits of selectable market genes (drug-resistance, *etc.*)

E .Transferability

F. Host-dependency

G. Method to create expressed vectors

H .Method and location to insert expressed vectors into a host.

4) Inserted DNA

A. Donor

(1) Name and taxonomic properties (scientific name, variety, phylogenic name, *etc.*)

(2) History of being used in foods

(3) Whether the donors and their related species produce physiologically active hazardous substance

(4) Allergenicity

(5) Contamination by pathogens and external factors (viruses, *etc.*)

B. Inserted DNA

(1) Structure

(A) Promoter

(B) Terminator

(C) Inserted base sequences and surrounding DNA sequences

(2) Traits

(A) Functions of inserted DNA

(B) Restriction Map

(C) Molecular weight

(D) Existence of hazardous base sequences (Known hazardous base sequences should not be included.)

(3) Purity

(4) Stability

(5) Number of replicated DNA

(6) Location, time, and quantity of expression

(7) Existence, transcription, and expressability of an external open reading frame

5) Recombinants

A. Newly added traits due to recombinant manipulations

B. Toxicity

C. Metabolic pathway

D. Difference from the host

E. Allergenicity

(1) History of donors being used as foods

(2) Data as to whether genetic products are known as allergens

(3) Sensitivity of genetic products to physio-chemical processing

(4) Whether any genetic product has structural properties identical to those of known food allergens

(5) Whether a genetic product accounts for a significant quantity in per diem protein intake

(6) Methods to inactivate recombinants

(7) Data on approval and use for eating purposes in other countries.

3. For safety assessment of GM foods

1) General data

A. Usage methods

B. Manufacturing processes

2) Safety assessment data based on subtantial equivalence

A. History of being used as foods

B. Ingredient data

(1) Main nutrients

(2) Nutrients in trace concentrations

(3) Intrinsic toxins

(4) Anti-Nutrients

(5) Allergens

(6) Metabolites of introduced DNA

C. Expected intake amounts

3) Nutritional experiment data (dietary intake quantities, weight increase, *etc.* based on animal tests)

4) Toxicological testing data

A. acute toxicity

B. chronic toxicity

C. Reproductive/oncologenic toxicity

D. Hereditary toxicity

E. Carcinogenicity

F. Gastrointestinal toxicity

5) Allergenicity experiment data

A. Binding force between genetic products and IgE antibodies of a patient formed due to an allergen with structural similarities

B. Binding force between genetic products and IgE antibodies of a patient formed due to major allergens

6) Testing data on antibiotic resistant genes and metabolites

A. Changes due to cooking or processing

B. Changes within gastrointestinal environments

C. Expected intake amounts

D. Data on use of related antibiotics

E. Comparison with ordinary antibiotic resistant bacteria

F. Estimated quantities of inactivated antibiotics which are orally administered, and possible problems

7) Data on nutritional influences on Infants, children, pregnant and breast-feeding women, aged people, patients suffering from chronic diseases

4. If testing cannot be conducted from a theoretical and technical point of view, testing is deemed impractical even if possible, or there are other proper reasons, some items of data specified above in Paragraphs 2 and 3 may not be submitted.

5. If three years have passed after commercialization in the country of development and other countries are using such food, data in support of such facts may replace some of the data specified above in Paragraphs 2 and 3.

Article 9. (Supporting documents for foods which do not contain recombinant organisms themselves)

1. For safety assessment of foods, food additives which are manufactured through recombinants but do not contain recombinants because such organisms are removed after manufacturing, safety of recombinants, manufacturing methods (including facility requirements), and products should be assessed.

2. During the manufacturing of foods, *etc.* which do not contain recombinant organisms themselves, hosts, vectors, inserted DNA, recombinants, *etc.* as provided above in Article 8 Paragraph 2 should be used.

3. For verification of manufacturing methods, the following data should be attached.

1) Raw materials other than recombinants

A. Usage of raw materials

B. Safety of raw materials

C. If there are no safety data exist for such materials, safety assessment should be conducted based on toxicity testing results

2) Purification of products

Assessment should be made on the methods and effects of purification of products.

4. Product safety assessment should be conducted on all factors added to the products.

1) Data proving non-existence of recombinants in the product

2) Data on safety of impurities derived from the manufacturing processes

3) Data on purification methods and effects thereof4.

4) Data on changes to general ingredients lead to hazards

5) If safety assessment based on the data specified above in Clauses 1 to 4 is difficult to conduct, safety assessment should be conducted based on testing results specified above in Article 8 Paragraph 3 Clauses 4 to 7. If there are proper reasons, however, some of the assessment items may be exempted.