GRAIN TRADE AUSTRALIA

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17 April 2012

Ms Anna Simonds
A/g Director, Productivity and Food Security Unit
Agricultural Productivity Division
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Dear Ms Simonds

Re: World Trade Organization Notice G/SPS/N/KOR/407 dated 24 February 2012 on the Proposed Amendment to the Guideline for Safety Assessment and Evaluation of Genetically Modified Foods (Food Safety Assessment Amendment) – Korea

Grain Trade Australia or GTA was formed in 1991 to standardise grain standards, trade rules and grain contracts across the Australian grain industry to enable the efficient facilitation of trade across the grain supply chain. GTA's role today is to ensure the efficient facilitation of commercial activities across the grain supply chain. To achieve this, GTA develops and provides the industry with some key tools:

- Commodity Standards
- Contracts
- Trade Rules
- Dispute Resolution Service
- Professional Development
- Australian Grains Industry Conference

GTA Strategic Direction 2011 has been prepared for members and others with an interest in the Australian grains industry. It details GTA's short to medium term strategies and long term vision for the Australian grain supply chain.

GTA is non political, however, issues arise from time to time where there is common agreement amongst members and GTA represents their interests.

GTA is a member of:

- International Grain Trade Coalition (IGTC) – members are drawn from the major grain exporting countries. The IGTC represents their interests at world trade forums such as the UNEP Convention on Biological Diversity, better known as the Cartagena Protocol.
- Australian Quarantine Inspection Service (AQIS) – GTA is on the Grains Industry Consultative Committee.
- Food Chain Assurance Advisory Group – GTA is part of the Committee to the Commonwealth Attorney General's Department

GTA would like to express its appreciation to the Australian Government for the opportunity to provide comment in relation to the Korean Food Safety Assessment Amendment notified to the World Trade Organization on 24 February 2012.

GTA notes that Korea's food and feed industry is heavily dependent on imported commodities to meet its food and feed security needs. The agricultural commodities imported by Korea are primarily products of agricultural biotechnology. Despite a proven record of safety, every genetically modified (GM) crop is subjected to intense global regulatory scrutiny.
Globally, government regulators have independently reached the same conclusion - that cultivation of GM crops poses no greater risk to human health or the environment than cultivation of conventional (non-GM) varieties.

GTA would like to draw the attention of the Australian Government to several provisions of the Korean Food Safety Assessment Amendment (the 'Amendment') that are of concern to our members. These are outlined in the following submission.

Yours Sincerely

Mr. Geoff Honey
Chief Executive Officer
Grain Trade Australia

Grain Trade Australia (GTA) comment on the proposed amendments by Korea Food and Drug Administration (KFDA) to the Guideline for Safety Assessment and Evaluation of Genetically Modified Food
(Advanced notice No.2012-24) Feb 2012

GTA recommend that DAFF incorporate the following amendments in its response to the current review of the Republic of Korea Guidelines for Safety Assessment for Genetically Modified Foods being undertaken by the KFDA.

1. **The definition of GM Food and/or Product**:

Within the current regulations the definition for "GM Food" is a process based definition (i.e. how is the product produced?).

> *"Genetically modified (GM) food etc." means an agricultural/ livestock/fisheries/ microbial product cultivated/raised through genetic modification techniques or a food (including health/functional foods. This definition shall apply hereinafter.) or food additive manufactured/ processed using such a product as a raw material." (Article 2, Paragraph 1)*

It is GTA's position that the definition for GM Food within the regulation be changed so that it is consistent with the regulatory approach taken by Australia and other major international trading partners such as USA, Canada and Brazil. In each case the definition applied by the respective regulators for GM Food relates to the composition of the GM Food. For example the FSANZ definitions which relate to GM Food products are found in Standard 1.5.2 in which the definition relates to "*food produced using gene technology*" and states the following:

> "*it is a food which has been derived or developed from an organism which has been modified by gene technology*".

Within Standard 1.5.2 the specific definition for "genetically modified food" states:

> "*food that is, or contains as an ingredient, including a processing aid, a food produced using gene technology which a) contains novel DNA and/or novel protein; or b) has altered characteristics*".

This latter definition is also intimately tied up with labelling where there is a fundamental difference in the position taken by the EU versus that of the major trading countries such as Australia, USA, Canada and Brazil. In Europe, labelling for GM Food is based on the production process for producing the GM food i.e. cultivated/raised.

By contrast in Australia/NZ, Standard 1.5.2 specifies that labelling of a GM food product/ ingredient is only mandatory when novel DNA/protein is present (detectable) or when the food has altered characteristics. Therefore, GTA propose that the definition for GM Food within the proposed changes to the regulation incorporate the following changes. This will ensure consistency and continuity with Australian GM Food regulation:

> *"Genetically modified (GM) food etc." means an agricultural/ livestock/fisheries/ microbial product food that is, or contains as an ingredient, including a processing aid, a food produced using gene technology which a) contains novel DNA and/or novel protein; or b) has altered characteristics".*

Where the definition for "characteristics" is as follows:

> *The word "Characteristics" means "pertaining to, constituting, or indicating the character or peculiar quality of an agricultural/ livestock/fisheries/ microbial product; (typical; distinctive)."*

GTA recommend to DAFF that it seek a change to the definition for a GM Food and/or product within the Guideline for Safety Assessment and Evaluation of Genetically Modified Food in the Republic of Korea so it parallels the definition applied by FSANZ in its Standard 1.5.2.

2. Amendments to the regulations

1. Additional Definitions:

The following definitions are recommended for inclusion with the regulations:

a. "Species" means the major subdivision of a genus or subgenus, regarded as the basic category of biological classification, composed of related individuals that resemble one another, are able to breed among themselves, but are not able to breed with members of another species. (Article 2 Definitions)

b. "Stack" means the combining through either genetic modification or through crossing two or more unrelated recombinant products in the one product or alternatively the combining of a recombinant product with a non - recombinant product in a product.(Article 2)

c. "Characteristics" means "pertaining to, constituting, or indicating the character or peculiar quality of an agricultural/ livestock/fisheries/ microbial product; (typical; distinctive)." (Article 2 Definitions)

2. Edits to the regulations:

The following amendments are recommended for inclusion with the regulations:

a. "Vector" means DNA used to transfer a foreign gene of a different species or the same species into the host through a genetic modification technique. (Article 2, Paragraph 5)

b. Inserted gene" means a foreign gene of another species or the same species inserted into a vector. (Article 2, Paragraph 8)

c. Which are crossed between different species (Article 3, Paragraph 1.e.2)

GTA recommends to DAFF that it supports the nominated changes and/or additions to the Guideline for Safety Assessment and Evaluation of Genetically Modified Food in the Republic of Korea.

3. Industry Supported Amendments

GTA supports the following comments provided by CropLife Australia and recommends that DAFF supports the amendments in its submission to the KDFA as part of the review of the proposed amendments by Korea Food and Drug Administration (KFDA) to the Guideline for Safety Assessment and Evaluation of Genetically Modified Food.

1. Appropriate Comparable Counterparts for Stacked Events (Article 3 (1) (e) (3))

Excluding exceptional cases where stacks are derived from a parental line that has been intentionally genetically modified, the data for dietary amount, edible parts and processing methods should be compared to the stacked plants' conventional counterparts.

CropLife recommends that the current provisions of the *Guideline for Safety Assessment and Evaluation of Genetically Modified Foods* (the Current Guideline) be retained and that the conventional counterparts continue to be used as the comparator for dietary amount, edible parts and processing methods for plants containing stacked events.

2. Detection Methods (Article 4 (1) (1) (c))

Currently, every dossier submitted to the Korea Food & Drug Administration (KFDA) must include both qualitative and quantitative detection methods. The proposed Amendment revises the language used in the Current Guideline regarding detection methods and now indicates they must "meet standard requirements established by international organisations". Despite CropLife supporting

reference to established international standards, the Amendment is not clear as to which international organisations the Amendment is referring and as a corollary, is unclear as to what additional data may be required.

CropLife recommends that the KFDA need to clarify to which international organisations and standards this new language refers and to avoid confusion, until this is clarified the wording of the Current Guideline be retained.

3. Reference Material Requirements for Re-registration (Article 4 (2) (5))

The Amendment proposes a new requirement for re-registration purposes for reference materials of the host species and recombinant variety be included in the re-registration package. CropLife understands that the KFDA already requires the submission of reference material during the initial application and would have already have developed a detection method during the initial safety assessment. Therefore, there does not seem to be any reasonable explanation for requiring reference material at the re-registration stage.

CropLife recommends that the requirement for reference materials for re-registration purposes be removed from the Amendment.

4. Submission of Samples (Article 4 (4) (4))

Regarding the submission of samples for stacked events, the new language proposed in the Amendment indicates a requirement for "1 kg each of the recombinant variety"; however, it is unclear if this means "1 kg of stack samples".

In order to clarify what is required, **CropLife recommends** the language in this section be altered to state "1 kg of stack samples".

5. Extension of Public Comment Period (Article 5 (3))

The Amendment proposes an extension to the public comment period in respect of the results of a review from 20 to 30 days. CropLife is concerned that such an extension will only serve to further prolong the entire review period, aggravating the current delay.

CropLife recommends that the KFDA retain the 20 day comment period that is in the Current Guideline.

6. Scope of Submitted Data (Article 7 (3) (4))

The Amendment introduces a new requirement that indicates data must be produced from tests conducted according to Good Laboratory Practice (GLP) of the OECD. Typically, data that is included in dossiers submitted to the KFDA is not produced according to specific GLPs of the OECD, but rather according to GLP standards of OECD member countries.

CropLife recommends that the language in the amendment be altered to "Data from tests conducted according to the Good Laboratory Practice (GLP) of OECD or relevant OECD member countries".

Conditional Approval **(Article 9 (2))**

The Amendment introduces a new term "conditional approval" in addition to an approval. However, the Amendment neglects to make any reference to the requirements for, nor definition of exactly what constitutes a "conditional approval". CropLife believes that this new language will only serve to further decrease the transparency and predictability of the Korean regulatory process.

CropLife recommends the KFDA provide a clear definition of and conditions for issuing a "conditional approval"

7. Hazardous Sequence Data in Vector (Article 12 (1) (4))

The Amendment outlines the requirement for three new pieces of data regarding the presence of hazardous base sequences of parts of the transformation vector that are not included in the final product. CropLife believes this is not a scientifically valid request.

CropLife recommends that the additional data requirements in regard to hazardous data sequences in vectors be deleted from **Article 12 (1) (4) (A) (2) (E); Article 12 (1) (4) (B) (5) and Article 12 (1) (4) (B) (6)**.

8. Stability Data from Multiple Generations (Article 12 (1) (5) (A) (5) (B))

The requirement in the Amendment for stability data from multiple generations is considered excessive given that stability data from generation satisfies the requirements of the regulatory system in most other countries. Most technology providers routinely characterise the stability of inserted genes in one generation of a GM product. Standard molecular biology techniques, such as Southern blot analysis, suffice to show the stability of the trait in subsequent generations and therefore meet the requirements on stability of inserted genes.

CropLife recommends that this requirement be deleted.

9. Request of "omics" data (Article 12 (1) (5) (F))

The Amendment makes reference to requiring additional data on "potential changes in the contents of other components due to genetic modification", however, there is no mention of how the KFDA intend to interpret this requirement. CropLife is concerned that the KFDA may use to requirement to request data that internationally is considered inappropriate to be used for food safety assessments.

CropLife recommends that this requirement be deleted.

10. Exemption of Data Requirements (Article 12 (4))

The Current Guideline includes examples that allow for exemptions of certain data requirements from being included in a product submission (ie. if there is a safe history of food use or if testing of the product is theoretically or technically impossible). The proposed Amendment excludes these examples and includes a generic statement indicating that data may be exempted "if there is a rational reason". However, the Amendment provides no clarity over what the KFDA will consider to a "rational reason".

In order to avoid confusion, **CropLife recommends** the language of the Current Guideline be maintained.

11. Review Period Extension for Stacked Traits (Appendix – Table 7)

The Amendment proposes to extend the review period for stacked events from 30 to 90 days, effectively postponing the KFDAs approval of stacked events for an even greater time period. As the majority of future products reaching the Korean market are likely to contain stacked events, the prospect of increased delays in the regulatory process is of great concern to CropLife members.

CropLife recommends the 30 day period for review of stacked events as found in the Current Guideline be retained.

Current provisions	2012 Revision (Feb 15 2012)	Comments
Regulations concerning Review, etc. of Safety Assessments for Genetically Modified Foods **Chapter 1. General Provisions** **Article 1 (Objective)** The objective of this Notice is to establish the scope of genetically modified agricultural/livestock/fisheries products, etc. subject to the safety assessment requirement, the submissions for safety assessment, review procedures, etc. in accordance with the provisions of Article 15 of the Food Sanitation Act (hereinafter referred to as the "Act") so as to ensure the adequacy and effectiveness of safety assessment review activities and the safety of genetically modified foods, with a view to contributing to the promotion of public health. **Article 2 (Definitions)** For the purpose of this Notice, (The terms used in this Notice shall have the following definitions:) 1. "Genetically modified (GM) food" means an agricultural livestock/fisheries/ microbial product cultivated/raised through genetic modification techniques or a food (including health/functional foods. This definition shall apply hereinafter.) or food additive manufactured/ processed using such a product as a raw material.	**Regulations concerning Review, etc. of Safety Assessments for Genetically Modified Foods** **Chapter 1. General Provisions** **Article 1 (Objective)** The objective of this Notice is to establish the scope of genetically modified agricultural/livestock/fisheries products, etc. subject to the safety assessment requirement, the submissions for safety assessment, review procedures, etc. in accordance with the provisions of Article 18 of the "Food Sanitation Act" so as to ensure the adequacy and effectiveness of safety assessment review activities and the safety of genetically modified foods etc., with a view to contributing to the promotion of public health. **Article 2 (Definitions)** For the purpose of this Notice, (The terms used in this Notice shall have the following meanings:) "Genetically modified (GM) food etc." means an agricultural/ livestock/fisheries/ microbial product ~~cultivated/raised through genetic modification techniques or a food (including health/functional foods.~~ Or *food that is, or contains as an ingredient, including a processing aid, a*	The preferred definition is one that relates to the genetic modification that has been undertaken rather than the agricultural system within which the product was produced. (refer amendment) The word "characteristics" requires a definition: The word "Characteristics" means "pertaining to, constituting, or indicating the character or peculiar quality of an agricultural/ livestock/fisheries/ microbial product; (typical; distinctive)."

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2. "Recombinant DNA technique" means a technique by which a desired gene taken from the genes of an organism is combined with a gene of another organism, etc.	*food produced using gene technology which a) contains novel DNA and/or novel protein; or b) has altered characteristics".*	
3. "Recombinant DNA molecule" means DNA constructed in vitro by combining replicable DNA (vector) with different DNA with the help of enzyme(s), etc.	1. This definition shall apply hereinafter.) or food additive manufactured/ processed using such a product as a raw material.	
4. "Host" means a cell into which a DNA insert is introduced through a genetic modification technique.	2. "Recombinant DNA technique" means a technique by which a desired gene taken from the genes of an organism is combined with a gene of another organism, etc.	
5. "Vector" means DNA used to transfer a foreign gene of a different species into the host through a genetic modification technique.	3. "Recombinant DNA molecule" means DNA constructed in vitro by combining replicable DNA (vector) with different DNA with the help of enzyme(s), etc.	
6. "Gene insert" means gene of a different species inserted into a vector.	4. "Host" means an organism into which DNA is introduced through a genetic modification technique.	
7. "Inserted gene" means a foreign gene of another species inserted into a vector.	5. "Species" means the major subdivision of a genus or subgenus, regarded as the basic category of biological classification, composed of related individuals that resemble one another, are able to breed among themselves, but are not able to breed with members of another species.	Refer edit
8. "Donor organism" means an organism which provides DNA to be inserted into a vector. It also means an organism which provides RNA in the case that DNA to be inserted into a vector is synthesized from the RNA template.	~~4.~~	
9. "Recombinant" means a cell or an organism that has partially changed gene(s) or newly introduced gene(s) as a result of genetic modification or equivalent procedures.	~~5.~~6. "Vector" means DNA used to transfer a foreign gene of a different species or the same species into the host through a genetic modification technique.	Refer edit
10. "Gene product" means a nucleic acid or protein	~~6.~~7. <Deleted>	

Current provisions	2012 Revision (Feb 15 2012)	Comments
resulting from expression of an inserted gene. 11. "Recombinant product" means any material made through a genetic modification technique. 12. "Stack" means a species obtained by crossing a recombinant with another recombinant or a conventional counterpart. **Article 3 (Applicability)** The following shall be subject to the safety assessment requirement in accordance with Article 15 Paragraph 1 of the Act: 1. Genetically modified agricultural products; 2. Genetically modified livestock products; 3. Genetically modified fisheries products; 4. Genetically modified microorganisms; 5. Among those listed in Sub-paragraphs 1 through 3, recombinants which are not produced commercially any longer or which are not developed commercially for human consumption, but which might be detected in foods on the market 6. Among stacks of those listed above in 1 through 3, crosses of different recombinants whose modified traits have changed or crosses between different species or	~~7.~~8. "Inserted gene" means a foreign gene of another species or the same species inserted into a vector. ~~8.~~9. "Donor organism" means an organism which provides DNA to be inserted into a vector. It also means an organism which provides RNA in the case that DNA to be inserted into a vector is synthesized from the RNA template. ~~9.~~10. "Recombinant" means an organism that has partially changed gene(s) or newly introduced gene(s) as a result of genetic modification or equivalent procedures. ~~10.~~11. "Gene product" means a nucleic acid or protein resulting from expression of an inserted gene. ~~11.~~12. "Recombinant product" means any material made through a genetic modification technique. ~~12. "Stack" means a species obtained by crossing a recombinant with another recombinant.~~ **Article 3 (Applicability)** The following shall be subject to the safety assessment requirement in accordance with Article 18 Paragraph 1 of the Food Sanitation Act (hereinafter referred to as the "Act") and Article 9 of the Enforcement Decree of the Food Sanitation Act (hereinafter referred to as the "Decree") : 1. The following genetically modified food etc. that are imported, developed or produced for the first time.	The word "Stack" requires a change of definition: "Stack" means the combining through either genetic modification or through crossing two or more unrelated recombinant products in the one product or alternatively the combining of a recombinant product with a non - recombinant product in a product.

Current provisions	2012 Revision (Feb 15 2012)	Comments
recombinants whose intake amounts, edible parts and processing methods are different from their conventional counterparts; 7. Food ingredients, etc. made by removing genetic material from ingredients listed in 1 through 3 by way of extraction, refinement; 8. Among food additives made using those specified above in 4, enzymes and vitamins, etc. that do not contain ingredients derived from recombinants; 9. Among those listed in 1 through 4 and 6 through 8, commercial GM foods for which 10 years elapsed after safety assessment as specified in Article 3 Sub-paragraph 2 of the Enforcement Decree of the Act but which are still on the market for sale. When the commercial production of products is discontinued before the 10 year registration period concludes, those products are exceptions. 10. Among products for which 10 years have not yet elapsed since safety assessment, those announced by	a. Genetically modified agricultural products; b. Genetically modified livestock products; c. Genetically modified fisheries products; d. Genetically modified microorganisms; e. Among stacks of those listed above in a. through c., crosses of already approved genetic recombinants which apply to one of the following: (1) Whose given characteristics are modified (2) Which are crossed~~bred~~ between different species (3) Whose dietary amount, edible parts and processing method are different from their parental varieties f. Food ingredients, etc. from a. through c. made by extracting and refining specific ingredient and removing the genetic material; g. Among those made using those specified above in d., food additives such as enzymes and vitamins, etc. that do not contain ingredients derived from recombinants; h. A recombinant from a. to c. which is currently not commercially produced but had been produced previously, and detectable in existing foods on the market, or which, although developed and produced with a purpose of research, may be detectable in foods on the market. ~~1.~~2. Among those listed in Clauses a. through g. of Sub-paragraph 1, commercial GM foods etc. for which 10 years elapsed after safety assessment and which are	

Current provisions	2012 Revision (Feb 15 2012)	Comments
the Commissioner of the Korea Food and Drug Administration (hereinafter referred to as the "KFDA Commissioner") after review by the Food Sanitation Review Committee referred to in Article 42 of the Act as having potential hazards to human health such as identification of new hazard factors, etc.	still on the market for sale. When the commercial production of products is discontinued before the 10 year period concludes, those products are exceptions.	
Chapter 2. Review Procedures	2.3. Among GM foods etc. for which 10 years have not yet elapsed since safety assessment, those announced by the Commissioner of the Korea Food and Drug Administration (hereinafter referred to as the "KFDA Commissioner") after review by the Food Sanitation Review Committee referred to in Article 57 of the Act as having potential hazards to human health such as identification of new hazard factors, etc.	
Article 4 (Filing of applications)	**Chapter 2. Review Procedures** **Article 4 (Filing of applications)**	
① A person who desires to have safety assessment data reviewed for those listed in Article 3 Sub-paragraphs 1 through 3, 5 and 6 shall submit to the KFDA Commissioner a review request as per Attachment 1 accompanied by required data specified in Article 12 and a summary thereof as per Attachment 2. In the case of a stack, however, first an application shall be filed as per Attachment 7 for review as to whether the stack in question falls under the category of Article 3 Sub-paragraph 6. If a notification as per Attachment 8 confirms that the stack is subject to the assessment requirement, an application for review of safety assessment data shall be filed.	① A person who desires to have safety assessment data reviewed for those listed in Article 3 Sub-paragraph 1 shall submit to the KFDA Commissioner a review application as per Attachment 1 accompanied by the following data and reference materials: 1. Clauses a, b, c, e, and h of Sub-paragraph 1 of Article 3: a. Data specified in Article 12 (including Attachment 2 form) and a summary b. Data on the analytical information such as the sequence of the inserted gene and surrounding gene (Including Attachment 4 form) c. Quantitative and qualitative detection methods to confirm the subject and validation data of the methods (The detection methods must meet the standard requirements established by international organizations, and test data proving this must also be submitted)	
② A person who desires to have safety assessment data		

Current provisions	2012 Revision (Feb 15 2012)	Comments
reviewed for those listed in Article 3 Sub-paragraph 4 shall submit to the KFDA Commissioner a review request as per Attachment 1 accompanied by required data specified in Article 13 as per Attachment 2-2 and a summary thereof. ③ A person who desires to have safety assessment data reviewed for those listed in Article 3 Sub-paragraphs 7 and 8 shall submit to the KFDA Commissioner a review request as per Attachment 1 accompanied by required data specified in Article 14 as per Attachment 3 and a summary thereof. ④ A person who desires to have safety assessment data reviewed for those listed in Article 3 Sub-paragraph 9 shall submit, to the KFDA Commissioner before 9 years elapses after safety assessment, a review request as per Attachment 1 accompanied by the notification advising of the previous review results for the safety assessment data, data evidencing whether the product is commercialized or not, evidencing data on safety issues raised during the commercialization period, and other data on changes.	d. 1kg each of host species and recombinant variety (However, in case of Clauses a, e, and h, original shapes of reference material have to be maintained, or no contamination with other biotech event(s) has to be certified). 2. For Clause d of Sub-paragraph 1 of Article 3: a. Data as per Article 13 (including Attachment 2-2 form) and a summary b. Data on the analytical information such as the sequence of the inserted gene and surrounding gene (Including Attachment 4-2 form) c. Quantitative and qualitative detection methods to confirm the subject and validation data of the methods (The detection methods must meet the standard requirements established by international organizations, and test data proving this must also be submitted) d. 10 reference samples of the microorganism (must be fit for long term storage) 3. For Clauses f. and g of Sub-paragraph 1 of Article 3, data according to Article 14 (Including Attachment 3 form) and a summary. ② A person who desires to apply for a safety assessment review for those listed in Article 3 Sub-paragraph 2 shall submit, to the KFDA Commissioner before 9 years elapses after safety assessment, a review application as per Attachment 1 form accompanied by the following data: 1. Notification advising of the previous review results for the safety assessment data, 2. Data confirming whether the product is commercialized or not, 3. New data regarding safety such as toxicity,	This would appear to be an unusual request and one which does not appear to have a precedent in any other major jurisdiction. For what purpose are these physical samples being requested given the food safety assessment is based on the provision of quantitative and qualitative data. The certification for no contamination with other biotech events can at best be only limited to those events which have been approved within a jurisdiction and where a suitably approved sampling and testing methodology is available to the exporter. The imposition of such a requirement would add significant cost to product and/or shipment verification.

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⑤ A person who desires to have safety assessment data reviewed for those listed in Article 3 Sub-paragraph 10 shall submit to the KFDA Commissioner a review request as per Attachment 1 accompanied by the notification advising of the previous review results for safety assessment data, data relevant to new risk factors found to have potential hazards on human health, and other data on changes.	allergenicity and nutrition data generated during the commercialization period. 4. Data on other changes 5. 1kg each of the host species and the recombinant variety (original shapes of reference material have to be maintained, or no contamination with other biotech event(s) has to be certified). ③ A person who desires to apply for a safety assessment review for those listed in Article 3 Sub-paragraph 3 shall submit to the KFDA Commissioner a review application as per Attachment 1 form accompanied by the following data: 1. Notification advising of the previous review results for safety assessment data 2. Data relevant to new risk factors found to be potentially harmful to human health 3. Data on other changes ④ In the case of a stack, a person who desires to apply for a review as to whether the stack in question falls under the category of Article 3 Sub-paragraph 1 Clause e., shall submit to the KFDA Commissioner an application as per Attachment 7 form accompanied by the following data. 1. Data proving no change in the given characteristics 2. Data proving crosses between different species did not occur 3. Data proving that dietary amount, edible parts and processing method are not different from their parental varieties 4. 1kg each of the recombinant variety (original shapes of reference material have to be maintained, or no contamination with other biotech event(s) has to be certified)	This would appear to be an unusual request and one which does not appear to have a precedent in any other major jurisdiction. For what purpose are these physical samples being requested given the food safety assessment is based on the provision of quantitative and qualitative data. This would appear to be an unusual request and one which does not appear to have a precedent in any other major jurisdiction. For what purpose are these physical samples being requested given the food safety assessment is based on the provision of quantitative and qualitative data.
⑥ A person who desires to receive safety assessment shall submit data on analytical information enabling the identification of the product under assessment and a form as per Attachment 4 or Attachment 4-2 together with reference standards at the time of submission of required data for review as follows. In the case of a stack, however, such data, etc. shall be submitted at the time of application for review as per Attachment 7 as to whether the stack in question falls under the category of Article 3 Sub-paragraph 6:		

Current provisions	2012 Revision (Feb 15 2012)	Comments
1. In the case of those listed in Article 3 Sub-paragraphs 1 and 5, 1 Kg each of the host species and the recombinant variety (original shapes of reference material shall be **identifiable or** absence of commingling other biotech events has to be certified); 2. In the case of a stack: 1 Kg of the product (the original shape shall be identifiable); 3. In the case of those listed in Article 3 Sub-paragraph 4, 10 samples of microorganism reference materials suitable for long-term storage; 4. In the case of those listed in Article 3 Sub-paragraph 8: 100 g of the product; 5. In the case of others subject to the requirement, amounts as specified under "Chapter 2. Sample Collection and Handling Methods" of the "Food Code." **Article 5 (Safety review)** ① The KFDA Commissioner shall set up a review committee, and, upon receiving a review request for safety assessments of GM foods filed pursuant to Article 4, shall review the adequacy of safety assessments based on the review reports by the review committee. ② The KFDA Commissioner may demand explanations or conduct on-site investigations, etc. if deemed necessary for review based on submitted data.	**Article 5 (Safety review)** ① In the case of a review application for safety assessment of GM foods etc, the KFDA Commissioner	

Current provisions	2012 Revision (Feb 15 2012)	Comments
③ The results of review by the review committee referred to in Article 6 shall be made public for opinions for 20 days or longer.	shall have the application reviewed in a review committee according to Article 18 Paragraph 2, and the safety assessment result is reviewed based on the reports submitted for review.	
④ Within 270 days from the date that an application for safety assessment is received, the KFDA Commissioner shall complete the review and announce the results.	② The KFDA Commissioner may demand explanations or conduct on-site investigations, etc. if deemed necessary for review based on submitted data.	
⑤ The disclosure of information concerning data and reference standards submitted for review shall be in accordance with the "Act on Information Disclosure by Public Institutions (Act #8171)" and the "Regulations concerning Information Disclosure (KFDA Rules)."	③ The results of review by the review committee shall be made public for opinions for 30 days or longer.	
	④ Within 270 days from the date that an application for safety assessment is received, the KFDA Commissioner shall complete the review and announce the results.	
Article 6 (Review committee)		
The KFDA Commissioner shall set up a GM food safety assessment review committee at the KFDA for review of safety assessments for GM foods, etc., and the specifics on the composition and operation of the committee shall be established separately.	⑤ The disclosure of information concerning data and reference standards submitted for review shall be in accordance with the "Act on Information Disclosure by Public Institutions" and the "KFDA Regulations concerning Information Disclosure."	
Article 7 (Instructions for submission of review requests)	**<Deleted>**	
① A review request shall be submitted in duplicate accompanied by required data and a summary thereof. In this case, a copy of the documents shall also be submitted in diskette (3 1/2) or CD, paginated and accompanied by the list and index numbers thereof in the sequence specified in the applicable form of Attachment 2, 2-2 or 3.	**Article 7 (Instructions for submission of review applications)**	

Current provisions	2012 Revision (Feb 15 2012)	Comments
② If the summary of a review request is in a foreign language, both the original and the translation (certified with a seal by the translator and verifier knowledgeable about the field) shall be submitted. ③ Submissions shall meet the following criteria: 1. Data published in a relevant scientific journal; 2. Data based on tests carried out by a domestic/overseas professional organization such as a university or research institution, etc. and issued by the head of the organization, which may be recognized as acceptable (in this case, test equipment, key facilities, research personnel organization, testing personnel's experiences, etc. of the research institution shall be described); 3. Data submitted and evaluated when the relevant GM food was assessed for safety in the country of development. <Addition> 4. In the case of an approval in a country, data evidencing the approval by the government of the country (permitting/approval or verifying authorities). 5. <Addition> **Article 8 (Complementation of the review request, etc.)**	① One copy of the review application shall be submitted accompanied by required data and a summary thereof. In this case, a copy of the documents shall also be submitted in CD, accompanied by the name of data and data requirement thereof in the sequence specified in the applicable form of Attachment 2, 2-2 or 3. ② If the summary of a review application is in a foreign language, both the original and the translation shall be submitted. ③ Among submissions specified in Articles 12 through 14, test data shall meet one of the following criteria: 1. Data published in a scientific journal listed in the Science Citation Index (SCI), SCI Expanded; 2. Data based on tests carried out by a domestic/overseas professional organization such as a university or research institution, etc. and issued by the head of the organization, which may be recognized as acceptable (in this case, test equipment, key facilities, research personnel organization, testing personnel research experiences, etc. of the research institution shall be described); 3. Data submitted and evaluated when the relevant GM food was assessed for safety in the country of development or country of import with the confirmation by the government of the country that safety is approved or with notarized data attached 4. Data from tests conducted according to the Good Laboratory Practice (GLP) of OECD	

Current provisions	2012 Revision (Feb 15 2012)	Comments
① If any of the following is applicable to documents of a review request received in accordance with Article 4, submission of supplementary data may be required:	5. Reports prepared by international organizations **Article 8 (Supplementary data for a review application, etc.)** ① If any of the following is applicable to documents of a review application received in accordance with Article 4, submission of supplementary data may be required:	

Current provisions	2012 Revision (Feb 15 2012)	
1. If submitted data are incomplete; 2. If it is suspected that safety assessment is faulty. ② If any of the following is applicable to a review request, revision of documents may be required: 1. If the general contents are not prepared pursuant to the guidelines; 2. If items are not specified under the guidelines or it is determined as having minor errors as a result of examination. ③ If any of the following is applicable to a review request, the request may be rejected: 1. If submitted data do not comply with the guidelines;	1. If submitted data are incomplete; 2. If it is suspected that safety assessment is faulty. ② If any of the following is applicable to a review application, the application may be rejected: 1. If submitted data is not acceptable with these guidelines; 2. If review is not possible due to the incompleteness of the supplementary data.	

Current provisions	2012 Revision (Feb 15 2012)	
2. If there is concern about risks to human health due to the lack or unverifiability of safety, soundness, etc. 3. If review is not possible due to the incompleteness of the complemented data. ④ As for the duration of time required for supplementation, the applicant shall notify of the date of submission in advance, and the period for supplementation shall be excluded from the calculation of the review period.		
Article 9 (Notification of review results) ① Once review of safety assessment for a GM food is completed, the Commissioner shall notify the applicant of the review results as per the form in Attachment 5 and publish the review results in an official bulletin as well. ② Starting on the date of publication in an official bulletin, etc. pursuant to Paragraph 1 above, GM foods approved for import/development/production with the notification of the review results may be imported/ developed/ produced for human consumption. ③ If a product approved as "Other" under Paragraph 19 of Attachment 5 is to be commercially imported/ produced for human consumption, a new approval for import/production shall be obtained. ④ In the case of a product approved for "Development" or	**Article 9 (Notification, of review results)** ① Once review of safety assessment for a GM food etc. is completed, the Commissioner shall notify the applicant of the review results as per the form in Attachment 5, and publish the review results in the Gazette and the Website. ② Starting on the date of publication in the website, etc. pursuant to Paragraph 1 above, GM foods etc. approved (including conditional approval) for import/development/production with the notification of the review results may be imported/ developed/ produced for human consumption. ③ If a product approved as "Other" under Paragraph 19 of Attachment 5 is to be commercially imported/ produced for human consumption, a new approval for import/production shall be obtained. ④ In the case of a product approved for "Development" or as "Other" pursuant to Paragraphs 2 and 3, only	

Current provisions	2012 Revision (Feb 15 2012)	
as “Other” pursuant to Paragraphs 2 and 3, only adventitious presence may be recognized as such a product is not for commercial production. A decision as to adventitious presence shall be made pursuant to Article 12 Paragraph 2 and based on data evidencing adventitious presence submitted by the importer or the company of development.	adventitious presence may be recognized as such a product is not for commercial production. A decision as to adventitious presence shall be made pursuant to Article 12 Paragraph 2 and based on data evidencing adventitious presence submitted by the importer or the company of development.	
Article 10 (Changes to items of review results notifications) If a change is to be made to an item of a review results notification received in accordance with Article 9, an application of changes as per the form in Attachment 6 shall be submitted. In this case, changeable items shall be limited to applicant, developer, or brand name.	**Article 10 (Changes to items of review results notifications)** If a change is to be made to an item of a review results notification received in accordance with Article 9, an application of changes as per the form in Attachment 6 shall be submitted. In this case, changeable items shall be limited to applicant, developer, event name or brand name.	
Chapter 3. Scope of Data Submission on Safety Assessment	**Chapter 3. Scope of Data Submission on Safety Assessment**	
Article 12 (Scope of Safety assessment of GM agricultural/livestock/fisheries products and data submissions) ① A person who desires to have safety assessment reviewed in accordance with Article 3 Sub-paragraphs 1 through 3, 5 and 6 shall submit the following data: <Additional proviso> 1. Data on development purpose and using method of the recombinant	**Article 12 (Scope of Safety assessment of GM agricultural/livestock/fisheries products and data submissions)** ① A person who desires to have safety assessment reviewed in accordance with Article 3 Sub-paragraph 1 Clauses a, b, c, e and h shall submit the following data. However, if there is a rational reason, part of the data may be exempted from submission. 1. Data on purpose of development and uses of the recombinant 2. Data on the host	

Current provisions	2012 Revision (Feb 15 2012)	
2. Data on the host A. Taxonomical characteristics (common name, scientific name, taxonomic classification, etc.) B. History of cultivation and improvement of variety C. Known toxins or allergenicity D. History of safe use as a source of food E. <Addition>	A. Taxonomical characteristics (common name, scientific name, taxonomic classification, etc.) B. History of cultivation, breeding and development of new varieties (in particular, characterization of traits with the potential of having hazardous effects on human health) C. Known toxicity, allergenicity, or relatedness to pathogenic exogenous elements (in the case of an animal, including the possibility of symbiosis with a toxin-producing organism , potential of creating colonies by human pathogens) D. History of safe use as a source of food E. Information on effects of feed, movement, and breeding environments on foods (applicable only to animals)	
3. Data on the donor organism A. Taxonomical characteristics (common name, scientific name, taxonomic classification, etc.) B. History of safe use as a source of food C. Toxicity, anti-nutritional factors, allergenicity of the donor organism and its relatives (for a microorganism, pathogenicity and relationship to known pathogens)	3. Data on the donor organism A. Taxonomical characteristics (common name, scientific name, taxonomic classification, etc.) B. History of safe use as a source of food, routes of exposure other than through consumption as food (e.g., possible presence as contaminants) C. Toxicity, anti-nutritional factors, allergenicity of the donor organism and its relatives (for a microorganism, pathogenicity and relationship to already known pathogens)	
4. Data on DNA recombination A. Information on transformation procedures (1) Transformation methods (Agrobacterium-mediated transformation, particle gun transformation, protoplast transformation, etc.) (2) Information on the vector used in the genetic modification (A) Source	4. Data on the genetic modification A. Information on the transformation process (1) Transformation methods (Agrobacterium-mediated transformation, particle gun transformation, protoplast transformation, microinjection etc.) (2) Information on the vector used in the genetic modification (A) Source (B) Identification in the host	

Current provisions	2012 Revision (Feb 15 2012)	
(B) Identification in the host (C) Function in the host <addition> <addition> <addition> (3) Information on the intermediate host (4) Information on transmissibility B. Information on inserted gene(s) (1) Characterization of components (A) Selectable marker gene (B) Regulators (C) Other factors affecting DNA functions (2) Size and name (3) Location and orientation of the gene sequence in the constructed vector (4) Functions of the components of the gene (5) Presence of hazardous base sequences (6) Presence of exogenous open reading frames and potential of transcription and expression thereof (7) Introduction of unintended base sequences other than the target gene (purity of the gene) 5. Data on characterization of the recombinant A. Information on introduced gene(s) in the recombinant (1) Characteristics and functions of the genes inserted into the recombinant genome (2) Number of insertion sites (3) Composition of the inserted gene at each insertion site (A) Number of copies, base sequences (including adjacent base sequences)	(C) Function in the host (D) Restriction enzyme map (E) Presence of hazardous base sequences (F) Information on transferability (3) Information on the intermediate host (4) Method of producing the first genetically modified animal and information on manufacturing process of genetically modified animals for use in food B. Information on the introduced gene(s) (1) Characterization, base sequence, restriction map of genetic components (A) Selectable marker gene (B) Regulators (C) Other factors affecting DNA functions (2) Size and name (3) Location and orientation of the gene sequence in the constructed expression vector (4) Functions of the components of the gene (5) Presence of hazardous base sequences (6) Presence of exogenous open reading frames and potential of transcription and expression thereof (7) Introduction of unintended base sequences other than the target gene (purity of the gene) 5. Data on characterization of the recombinant A. Information on introduced gene(s) in the recombinant (1) Characteristics and functions of the gene(s) inserted into the recombinant genome (2) Number of insertion sites (3) Composition of the inserted gene at each insertion site (A) The copy number, sequences (including sequences of the surrounding regions) (B) Data on evidence that there are no genes	

Current provisions	2012 Revision (Feb 15 2012)	
(B) Data on evidence that there are no genes encoding known toxicity or anti-nutrients	encoding already known toxins or anti-nutrients	
(4) Presence of exogenous open reading frames in the inserted gene(s) and adjacent genes of the host genome and potential of transcription and expression thereof	(4) Presence of exogenous open reading frames in the inserted gene(s) and adjacent genes of the host genome and potential of transcription and expression thereof	
(5) Data on stability	(5) Data on stability	
(A) Sequences and sizes of the inserted gene(s) in multiple generations	(A) Sequences and sizes of the inserted gene(s) in multiple generations	
(B) Sites, time, levels of expression in multiple generations	(B) Sites, time, levels of expression in multiple generations	
B. Information on gene products	B. Information on the gene product(s)	
(1) Chemical properties of gene products (proteins or non-tranlated RNA)	(1) Chemical properties of the gene product(s) (proteins or untranslated RNA)	
(2) Functions of gene products	(2) Functions of the gene product(s)	
(3) Changes after translation of amino acid sequences of expressed protein	(3) Post-translational modification of the expressed protein	
(4) Structural change in expressed protein	(4) Structural change in the expressed protein	
(5) Phenotype with new characteristics	(5) Phenotype with new traits	
(6) Expression sites and levels of gene product	(6) Expression sites and levels of gene product	
C. Toxicity	C. Toxicity	
(1) If the product is a protein:	(1) If the gene product is a protein:	
(A) History of safe use as source of food	(A) History of safe use of expressed protein as source of food	
(B) Similarity of amino acid sequences to known toxicity and anti-nutrients	(B) Similarity of amino acid sequences of the expressed protein to already known toxins and anti-nutrients	
(C) Sensitivity of gene product to physio-chemical treatment (for a product made by way of substitution, including data on biochemical, structural, functional homology to gene product)	(C) Sensitivity of the expressed protein to physio-chemical treatment (for a product made by way of substitution, including biochemical, structural, functional homology to the gene product)	

Current provisions	2012 Revision (Feb 15 2012)	
(D) Single-dose toxicity of expressed protein (E) If safety cannot be verified through (A)~(D), other oral toxicity tests and biological functions of the protein in an organism known to have the protein (2) If the product is not a protein: (A) Biological functions (B) Dietary exposure (C) History of safe use as source of food (D) Data on general toxicity tests if there is no history of safe use as food D. Allergenicity (1) Data on whether the gene product is known as an allergen (2) Sensitivity of the gene product to physio-chemical treatment (for a product made by way of substitution, including data on biochemical, structural, functional homology to the gene product) (3) Data on homology to known allergens of the gene product (4) Data on whether the gene product accounts for a significant portion of the daily protein intake (5) The following data if data in (1) through (4) are not sufficient to determine as to allergenicity: (A) Data on the binding strength between gene product and patients' IgE antibody formed due to an allergen confirmed to have structural similarity (B) Data on the binding strength between gene product and patients' IgE antibodies formed due to key allergens	(D) Single-dose toxicity of the expressed protein (E) If safety cannot be verified through (A)~(D), other oral toxicity tests and biological functions of the protein in an organism known to have the protein (2) If the gene product is not a protein: (A) Biological functions of the gene product (B) Dietary exposure of the gene product (C) History of safe use of the gene product as source of food (D) Data on general toxicity tests if there is no history of safe use of the gene product as food D. Allergenicity (1) Whether the gene product is known as an allergen (2) Sensitivity of the gene product to physio-chemical treatment (for a product made by way of substitution, including biochemical, structural, functional homology to the gene product) (3) Homology of the gene product to known allergens (4) Whether the gene product accounts for a significant portion of the daily protein intake (5) The following data if (1) through (4) are not sufficient to determine as to allergenicity: (A) Cross-reactivity between the gene product and patients' IgE antibodies for an allergen confirmed to have structural similarity (B) Cross-reactivity between the gene product and patients' IgE antibodies for key allergens	

Current provisions	2012 Revision (Feb 15 2012)	
E. Differences from the host (1) Proximates (2) Micronutrients (3) Intrinsic toxins (4) Anti-nutritional factors (anti-nutrients) (5) Allergens (6) Metabolites of inserted genes (7) Nutritional characteristics	E. Differences from the host (1) Proximates (2) Micronutrients (3) Intrinsic toxins (4) Anti-nutritional factors (anti-nutrients) (5) Allergens (6) Metabolites of the inserted gene products (7) Nutritional characteristics	
F. Effects of the gene product on metabolic pathways (potential of reaction using, as substrates, endogenous elements of the host)	F. Effects of the gene product on metabolic pathways (potential of reaction using, as substrates, endogenous elements of the host, potential changes in the contents of other components due to the genetic modification, etc.)	
<Addition>	G. Health conditions of a recombinant animal	
<Addition>	H. Description regarding storage and processing as food	
G. Approval status for distribution as a food and use for human consumption, etc. in other countries	I. Approval status for distribution as a food and use for human consumption, etc. in other countries	
6. If Sub-paragraphs 1 through 5 are not sufficient for safety assessment, safety shall be assessed based on the results of the following tests. If there are justifiable reasons, however, some of the tests may be exempted if there are justifiable reasons: A. Single-dose toxicity B. Repeated-dose toxicity C. If deemed necessary for a decision as to safety based on the results of repeated-dose toxicity tests, data on genetic toxicity, reproductive/developmental toxicity, carcinogenicity, and other necessary toxicity tests	6. If Sub-paragraphs 1 through 5 are not sufficient for safety assessment, safety shall be assessed based on the results of the following tests. If there are justifiable reasons, however, some of the tests may be exempted if there are justifiable reasons: A. Single-dose toxicity B. Repeated-dose toxicity C. If deemed necessary for a decision as to safety based on the results of repeated-dose toxicity tests, data on genetic toxicity, reproductive/developmental toxicity, carcinogenicity, and other necessary toxicity tests	
② If commercial production of a GM food referred to in	② If commercial production of a GM food referred to in Article 3 Sub-paragraph 1 Clause h is discontinued,	

Current provisions	2012 Revision (Feb 15 2012)	
Article 3 Sub-paragraph 5 is discontinued, data specified in Paragraph 1 Sub-paragraphs 1 through 4 shall be submitted together with official document(s) evidencing the discontinuation of commercial production. If appropriate, data in Sub-paragraphs 5 and 6 may be attached.	data specified in Paragraph 1 Sub-paragraphs 1 through 4 shall be submitted together with official document(s) evidencing the discontinuation of commercial production. If appropriate, data in Sub-paragraphs 5 and 6 may be attached.	
③ For a GM food referred to in Article 3 Sub-paragraph 6, data specified in Paragraph 1 Sub-paragraphs 1 through 6 shall be submitted; and a decision as to whether it is a stack referred to in this Sub-paragraph shall be obtained by submitting data as per Attachment 7.	③ For a GM food referred to in Article 3 Sub-paragraph 1 Clause e, data specified in Paragraph 1 Sub-paragraphs 1 through 6 shall be submitted; and a decision as to whether it is a stack referred to in this Sub-paragraph shall be obtained by submitting data as per Attachment 7.	
④ Some of the information specified above in Paragraph 1 may be exempted if there are justifiable reasons such as; there has been history of safe use as food, testing is theoretically/technically impossible or testing is meaningless even if it is possible.	④ <Deleted>	
⑤ If three years has elapsed since a product is commercialized in the country of development and the product is used in other country (countries) than the country of development, data evidencing this may be submitted instead of some of the information specified in Paragraph 1.	⑤ <Deleted>	
Article 13 (Safety assessment of genetically modified microorganisms and scope of information submissions)	**Article 13 (Safety assessment of genetically modified microorganisms and scope of information submissions)**	
① A person who desires to have safety assessment reviewed in accordance with Article 3 Sub-paragraph 4 shall submit the following data: <Additional proviso>	① A person who desires to have safety assessment reviewed in accordance with Article 3 Sub-paragraph 1 Clause d shall submit the following data. However, if there is a rational reason, a part of the data may be exempted from submission.	

Current provisions	2012 Revision (Feb 15 2012)	
1. Data on GM microorganism A. Purpose of development B. Uses C. Whether it is deposited at publically recognized type culture collection or other culture collection D. Standard cultivation method E. Whether the microbe survive in the final product 2. Data on the host A. Taxonomic status (scientific name, common name, strain bank accession number, etc.) B. History of food use and strain development C. Genotypes and phenotypes of which safety concerns have been raised D. History of safe use as source of food E. Optimal cultivation conditions F. Presence of transmissible genes 3. Data on the donor organism A. Taxonomic status (scientific name, common name, strain bank accession number, etc.) B. History of safe use as source of food C. Genotypes and phenotypes of which safety concerns have been raised D. Food risk-related information of the donor organism and its relatives 4. Data on genetic modification A. Strain development process (1) Methods used for genetic modification (2) Recombinant DNA (A) Source (B) Identification and functions in the recombinant DNA microorganisms (C) Copy number for plasmids	1. Data on GM microorganism A. Purpose of development B. Uses C. Whether it is deposited at publically recognized type culture collection or other culture collection D. Standard cultivation method E. Whether the microbe survive in the final product 2. Data on the host A. Taxonomic status (scientific name, common name, strain bank accession number, etc.) B. History of food use and strain development C. Genotypes and phenotypes of which safety concerns have been raised D. History of safe use as source of food E. Optimal cultivation conditions F. Presence of transmissible genes 3. Data on the donor organism A. Taxonomic status (scientific name, common name, strain bank accession number, etc.) B. History of safe use as source of food C. Genotypes and phenotypes of which safety concerns have been raised D. Food risk-related information of the donor organism and its relatives 4. Data on genetic modification A. Strain development process (1) Methods used for genetic modification (2) Recombinant DNA (A) Source (B) Identification and functions in the recombinant DNA microorganisms (C) Copy number for plasmids (D) Intermediate host	

Current provisions	2012 Revision (Feb 15 2012)	
(D) Intermediate host B. Information on added, deleted, inserted, or modified DNA (1) Characteristics of genetic components (A) Selectable marker gene (B) Vector gene (C) Regulators (D) Other factors affecting DNA functions (2) Size and name (3) Location and orientation of sequences in the constructed vector (4) Functions of genes 5. Characterization of the recombinant A. Information on DNA recombination in the recombinant (1) Description of addition, insertion, deletion, other modification, etc. due to the insertion of the recombinant DNA (2) Location of recombinant genetic material (on a chromosomal or extra-chromosomal location) (3) Insertion sites and number of insertions (4) Organization of the inserted DNA at each insertion site (the copy number, sequence, and surrounding sequences, etc.) (5) Presence of foreign open reading frames within inserted DNA and within surrounding host genomic DNA and potential of transcription and expression thereof (6) Presence of hazardous sequences B. Information on gene product (1) The gene product (proteins or untranslated RNA) and analytical methods thereof (2) The gene product's functions (3) Phenotypes with new traits (4) Sites and levels of expression of gene products and metabolites thereof	B. Information on added, deleted, inserted, or modified DNA (1) Characteristics of the genetic components (A) Selectable marker gene (B) Vector gene (C) Regulators (D) Other factors affecting DNA functions (2) Size and name (3) Location and orientation of sequences in the constructed vector (4) Functions of the genetic components 5. Characterization of the recombinant A. Information on DNA recombination in the recombinant (1) Description of addition, insertion, deletion, other modification, etc. due to the insertion of the recombinant DNA (2) Location of recombinant genetic material (on a chromosomal or extra-chromosomal location) (3) Insertion sites and number of insertions (4) Organization of the inserted DNA at each insertion site (the copy number, sequence, and surrounding sequences, etc.) (5) Presence of foreign open reading frames within the inserted DNA and within the surrounding host genomic DNA and potential of transcription and expression thereof (6) Presence of hazardous sequences B. Information on gene product(s) (1) The gene product (proteins or untranslated RNA) and analytical methods thereof (2) The gene product's functions (3) Phenotypes with new traits (4) Sites and levels of expression of gene products and metabolites thereof (5) The amount of the inserted gene product(s) if the	

Current provisions	2012 Revision (Feb 15 2012)	
(5) The amount of the inserted gene product(s) if the function of the expressed gene(s) is to alter the level of a specific endogenous mRNA or protein (6) Presence of gene product(s), or alterations in metabolites C. Information on changes, etc. in inserted DNA (1) Realignment of the inserted gene (when inserted into a cell, used as food, during storage) (2) Change(s) in amino acid sequence of expressed protein (3) Structural change(s) in the expressed protein after translation (4) Data on intended effects, expression levels, stability of gene (5) Whether the traits are expressed at the correct site or secreted (6) Any effects of genetic modification on host genes (7) Presence of new fusion protein D. Toxicity and pathogenicity (1) Dietary exposure (2) Dietary intake (3) Functions and concentration of expressed material in the food (4) Number of viable microorganisms remaining in the foods (in comparison to a conventional counterpart) (5) If the gene product is a protein (A) History of safe use as food (B) Structure and functions of the protein (C) Similarity of amino acid sequence to known toxins and anti-nutrients (D) Sensitivity of the gene products to physio-chemical treatment (for a n alternative product, data on biochemical, structural, functional homology to genetic material shall be included)	function of the expressed gene(s) is to alter the level of a specific endogenous mRNA or protein (6) Presence of gene product(s), or alterations in metabolites C. Information on changes, etc. in inserted DNA (1) Realignment of the inserted gene (when inserted into a cell, used as food, during storage) (2) Change(s) in amino acid sequence of the expressed protein (3) Structural change(s) in the expressed protein after translation (4) Data on intended effects, expression levels, stability of gene (5) Whether the characteristics are expressed at the correct site or secreted (6) Any effects of genetic modification on host genes (7) Presence of new fusion protein D. Toxicity and pathogenicity (1) Dietary exposure (2) Dietary intake (3) Functions and concentration of expressed material in the food (4) Number of viable microorganisms remaining in the foods (in comparison to a conventional counterpart) (5) If the gene product is a protein (A) History of safe use as food (B) Structure and functions of the protein (C) Similarity of amino acid sequence to known toxins and anti-nutrients (D) Sensitivity of the gene products to physio-chemical treatment (for a n alternative product, data on biochemical, structural, functional homology to genetic material shall be included)	

Current provisions	2012 Revision (Feb 15 2012)	
(E) Single-dose toxicity of expressed protein (F) If the safety cannot be confirmed based on the information (A)~(E), other oral toxicity tests and biological functions of the protein in an organism known to have the protein. (6) If the gene product is not a protein: (A) Detection methods (B) Biological functions (C) Concentration (D) Dietary exposure (E) History of safe use as food (F) Data on ordinary toxicity tests if there is no history of safe use as food (G) Production of expressed material, toxic metabolites, and antibiotics due to genetic modification E. Allergenicity (1) Data on whether the gene product is known as an allergen (2) Sensitivity of the gene product to physio-chemical treatment (for a n alternative product, data on biochemical, structural, functional homology to genetic material shall be included) (3) Similarity of the gene product to known allergens (4) Data as to whether gene products accounts for a significant portion of the daily protein intake (5) The following data if data in (1) through (4) are not sufficient in interpreting as to allergenicity: (A) Data on the cross-reactivity between the gene product and patients' IgE antibodies for an allergen that was confirmed to have structural similarity (B) Data on the cross-reactivity between the gene products and patients' IgE antibodies for key allergens	(E) Single-dose toxicity of expressed protein (F) If the safety cannot be confirmed based on the information (A)~(E), other oral toxicity tests and biological functions of the protein in an organism known to have the protein. (6) If the gene product is not a protein: (A) Detection methods (B) Biological functions (C) Concentration (D) Dietary exposure (E) History of safe use as food (F) Data on ordinary toxicity tests if there is no history of safe use as food (G) Production of expressed material, toxic metabolites, and antibiotics due to genetic modification E. Allergenicity (1) Data on whether the gene product is known as an allergen (2) Sensitivity of the gene product to physio-chemical treatment (for a n alternative product, data on biochemical, structural, functional homology to genetic material shall be included) (3) Similarity of the gene product to known allergens (4) Data as to whether gene products accounts for a significant portion of the daily protein intake (5) The following data if data in (1) through (4) are not sufficient in determining as to allergenicity: (A) Data on the cross-reactivity between the gene product and patients' IgE antibodies for an allergen that was confirmed to have structural similarity (B) Data on the cross-reactivity between the gene products and patients' IgE antibodies for key allergens F. Differences with the host	

Current provisions	2012 Revision (Feb 15 2012)	
F. Differences with the host (1) Macronutrients (2) Micronutrients (3) Endogenous toxins (4) Anti-nutrients (enzyme inhibitors, etc.) G. Metabolites H. Effects of food processing I. Viability in gastrointestinal tract J. Genes with antibiotic resistance and gene transfer K. Information on survival/proliferation of the recombinant L. Methods to inactivate the recombinant M. Approval for distribution as food and use for human consumption, etc. in other countries	(1) Macronutrients (2) Micronutrients (3) Endogenous toxins (4) Anti-nutrients (enzyme inhibitors, etc) G. Metabolites H. Effects of food processing I. Viability in gastro-intestinal tract J. Genes with antibiotic resistance and gene transfer K. Information on survival/proliferation of the recombinant L. Methods to inactivate the recombinant M. Approval for distribution as food and use for human consumption, etc. in other countries	
② If consumed as killed microorganism, some of the information in Paragraph 1 may be exempted. In this case, data confirming that viable microorganism does not exist in the product for consumption shall be submitted	② If consumed as killed microorganisms, some of the information in Paragraph 1 may be exempted. In this case, data confirming that viable microorganism does not exist in the product consumption shall be submitted.	
③ Some of the information specified above in Paragraph 1 Sub-paragraphs 1 through 5 may be exempted if there are justifiable reasons such as; there has been history of safe use as food, testing is theoretically/technically impossible or testing is meaningless even if it is possible.	<Deleted>	
Article 14 (Safety assessment of food ingredients or food additives, etc. and scope of submissions)	**Article 14 (Safety assessment of food ingredients or food additives, etc. and scope of submissions)**	
① A person who desires to have safety assessment reviewed in accordance with Article 3 Sub-paragraph 7 or 8 shall submit the following data. <Additional proviso>	① A person who desires to have safety assessment reviewed in accordance with Article 3 Sub-paragraph 1 Clauses f and g shall submit the following data. However, if there is a rational reason, a part of the data is exempted from submission.	

Current provisions	2012 Revision (Feb 15 2012)	
1. Data specified in Article 12 or Article 13 Paragraph 1 Sub-paragraphs 1 through 4 2. Data on the recombinant A. Data on traits newly acquired due to the inserted gene B. Data on viability and propagation capabilities C. Data on restriction of viability and propagation of the recombinant D. Data on methods to inactivate the recombinant 3. Data on raw materials other than recombinants used in manufacture A. Data on use of foods and food additives as raw materials or auxiliary raw materials in manufacture B. Data on safety of foods and food additives as raw materials or auxiliary raw materials in manufacture 4. Data on safety of recombinant product A. Data proving that the recombinant product is the same as the conventional counterpart B. Data proving that the recombinant is not present C. As for refinement of the recombinant product, data on refinement methods and the effects thereof D. Data on changes in ordinary ingredients which become hazardous when the content changes <Addition> <Addition>	1. Data specified in Article 12 Paragraph 1 Sub-paragraphs 1 through 4 or Article 13 Paragraph 1 Sub-paragraphs 1 through 4 2. Data on the recombinant A. Data on traits newly acquired due to the inserted gene B. Data on viability and propagation capabilities C. Data on restriction of viability and propagation of the recombinant D. Data on methods to inactivate the recombinant 3. Data on raw materials other than recombinants used in manufacture A. Data on use of foods and food additives as raw materials or auxiliary raw materials in manufacture B. Data on safety of foods and food additives as raw materials or auxiliary raw materials in manufacture 4. Data on safety of recombinant product A. Data proving that the recombinant product is the same as the conventional counterpart B. Data proving that the recombinant is not present C. As for refinement of the recombinant product, data on refinement methods and the effects thereof D. Data on changes in ordinary ingredients which become hazardous when the content changes E. Data on toxicity and allergenicity F. Current status of market approval and commercial use as food for food and food additives in other countries 5. If Sub-paragraphs 1 through 4 are not sufficient for	

Current provisions	2012 Revision (Feb 15 2012)	
5. If Sub-paragraphs 1 through 4 are not sufficient for safety assessment, safety shall be assessed based on the results of the following tests: A. Single-dose toxicity B. Repeated-dose toxicity C. If deemed necessary for a decision as to safety based on the results of repeated-dose toxicity tests, data on genetic toxicity, reproductive/developmental toxicity, carcinogenicity, and other necessary toxicity tests	safety assessment, safety shall be assessed based on the genetic toxicity, reproductive and developmental toxicity, carcinogenicity, and other necessary toxicity data.	
② Some of the submissions specified in Paragraph 1 may be exempted if testing is theoretically/technically impossible, if testing is meaningless even if it is possible, or if there are other justifiable reasons.	② <Deleted>	
③ If three years has elapsed since a product is commercialized in the country of development, and the product is used in other country (countries) than the country of development, data evidencing this may be submitted instead of some of the submissions specified in Paragraph 1.	③ <Deleted>	
Article 15 (Due date for Re-review) Pursuant to "Regulations on Announcement and Administration of Directives and Rules"(Presidential Directive No.248), after the announcement of the Notice, the due date to review the legislation or changes in the actual conditions and take action such as termination or revision of the notice is set to Aug.24, 2012.	**Article 15 (Due date for Re-review)** Pursuant to "Regulations on Announcement and Administration of Directives and Rules"(Presidential Directive No.248), after the announcement of the Notice, the due date to review the legislation or changes in the actual conditions and take action such as termination or revision of the notice is set to Aug. 1, 2015.	

[Attachment 1]

(Front)

Application for Review of Safety Assessment for Genetically Modified Food				Processing time: 270 days
Applicant	① Company		② Business registration No.	
	③ Address			
	④ Representative		⑤ Telephone	
Developer	⑥ Company of development			
	⑦ Address			
⑧ Classification	Article 3 __			
⑨ Organism		⑩ Event/line		⑪Brand

⑫ Introduced traits	
⑬ Inserted gene	
⑭ Country and year of approval for placing on the market for the first time	
⑮ Other countries and years of approval for placing on the market	
⑯ Countries where safety assessment is under review and date of application	
⑰ Commercialization status	New ( ), Commercialized ( ), Commercial production discontinued ( )
⑱ Use (as food)	Import ( ), Development ( ), Production ( ) Other ( )

I hereby apply for review of safety assessment for the genetically modified food specified above in accordance with Article 4 of the “Regulations concerning Review, etc. of Safety Assessments for Genetically Modified Foods.”

Year Month Day

Applicant (seal)

To the Commissioner of the Korea Food and Drug Administration

Fee
4 million won

Required documents, etc.

1. 1 copy each of summary (the original and the translation in the case of data in a foreign language)
2. Data specified under Articles 12 through 14
3. Data on detection methods and reference materials

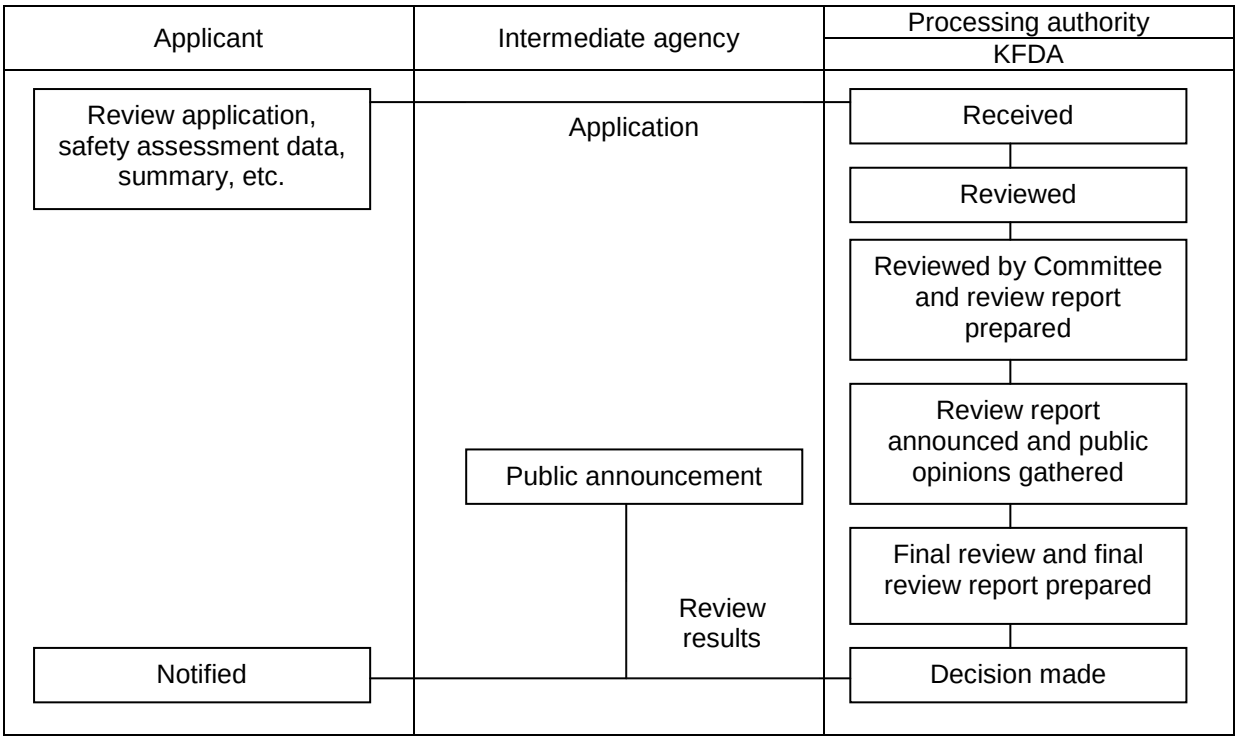
4. In the case of Article 3 Sub-paragraph 2 and Article 3 Sub-paragraph 3, however, the following data shall be submitted:
   A. Article 3 Sub-paragraph 2: notification of review results, data on commercialization, new data regarding safety such as toxicity, allergenicity, and nutrition generated during commercialization of the product, and other changes.
   B. Article 3 Sub-paragraph 3, notification of review results, data on new risk factors found to have potential harm on human health, and other changes

Instructions for preparation of the application form:

1. Any change in ① through ⑦ is recognized as a notification item.
2. For the classification in ⑧, use one of the following numbers in the clauses set in Article 3:

Sub-paragraph 1 Clause a. Genetically modified agricultural products;
Sub-paragraph 1 Clause b. Genetically modified livestock products;
Sub-paragraph 1 Clause c. Genetically modified fisheries products;
Sub-paragraph 1 Clause d. Genetically modified microorganisms;
Sub-paragraph 1 Clause e. Among stacks of those listed above in 1 through 3, crosses of different recombinants whose modified traits have changed or crosses between different species , recombinants whose intake amounts, edible parts and processing methods are different from their conventional varieties;
Sub-paragraph 1 Clause f. Food ingredients, etc. made by removing genetic material from ingredients listed in Clauses a through c by way of extraction, refinement;
Sub-paragraph 1 Clause g. Among food additives made using those specified above in Clause d, enzymes and vitamins, etc. not containing elements derived from recombinants;
Sub-paragraph 1 Clause h. A recombinant from Clauses a. through c. which is currently not commercially produced but had been produced previously, and detectable in existing foods on the market, or which, although developed and produced with a purpose of research, may be detectable in foods on the market.
Sub-paragraph 2. GM foods etc. from Sub-paragraph 1 Clause a through g, which 10 years elapsed after safety assessment and which are still on the market for sale
Sub-paragraph 3. Among GM foods etc. for which 10 years have not yet elapsed since safety assessment, those announced by the Commissioner of the Korea Food and Drug Administration (hereinafter referred to as the “KFDA Commissioner”) after review by the Food Sanitation Review Committee referred to in Article 57 of the Act as having potential hazards to human health such as identification of new hazard factors, etc

This application will be processed as follows:


Applicant
Intermediate agency
Processing authority
KFDA
Review application, safety assessment data, summary, etc.
Application
Received
Reviewed
Reviewed by Committee and review report prepared
Review report announced and public opinions gathered
Public announcement
Final review and final review report prepared
Review results
Notified
Decision made

[Attachment 2]

Safety Assessment Submissions

(Relating to Article 12)

Submission No.					Name of Data	Data Requirement
①	1					
	2	A				
		B				
		C				
		D				
		E				
	3	A				
		B				
		C				
	4	A	(1)			
			(2)	(A)		
				(B)		
				(C)		
				(D)		
				(E)		
				(F)		
			(3)			
			(4)			
		B	(1)	(A)		
				(B)		
				(C)		
			(2)			
			(3)			
			(4)			
			(5)			
			(6)			
			(7)			
	5	A	(1)			
			(2)			
			(3)	(A)		
				(B)		
			(4)			
			(5)	(A)		
				(B)		
		B	(1)			
			(2)			
			(3)			
			(4)			
			(5)			
			(6)			
		C	(1)	(A)		
				(B)		
				(C)		
				(D)		
				(E)		

Submission No.					Name of Data	Data Requirement
	5	C	(2)	(A)		
				(B)		
				(C)		
				(D)		
		D	(1)			
			(2)			
			(3)			
			(4)			
			(5)			
		E	(1)			
			(2)			
			(3)			
			(4)			
			(5)			
			(6)			
			(7)			
			(8)			
		F				
		G				
		H				
		I				
		J				
	6	A				
		B				
		C				
②						
Other				Data on detection methods		
				Qualitative detection methods		
				Quantitative detection methods		

* The submission numbers are those used in Article 12 Paragraphs 1 through 2; and Information condition(s)is related to Article 7 Paragraph 3.

[Attachment 2-2]

Safety Assessment Submissions

(Relating to Article 13)

Submission No.					Name of Data	Data Requirement
①	1	A				
		B				
		C				
		D				
		E				
	2	A				
		B				
		C				
		D				
		E				
		F				
	3	A				
		B				
		C				
		D				
	4	A	(1)			
			(2)	(A)		
				(B)		
				(C)		
				(D)		
		B	(1)	(A)		
				(B)		
				(C)		
				(D)		
			(2)			
			(3)			
			(4)			
	5	A	(1)			
			(2)			
			(3)			
			(4)			
			(5)			
			(6)			
		B	(1)			
			(2)			
			(3)			
			(4)			
			(5)			
			(6)			
		C	(1)			
			(2)			
			(3)			
			(4)			
			(5)			
			(6)			
			(7)			

Submission No.					Name of Data	Data Requirement
5	D	(1)				
		(2)				
		(3)				
		(4)				
		(5)	(A)			
			(B)			
			(C)			
			(D)			
			(E)			
			(F)			
		(6)	(A)			
			(B)			
			(C)			
			(D)			
			(E)			
			(F)			
			(G)			
	E	(1)				
		(2)				
		(3)				
		(4)				
		(5)	(A)			
			(B)			
	F	(1)				
		(2)				
		(3)				
		(4)				
	G					
	H					
	I					
	J					
	K					
	L					
	M					
②						
Other					Data on detection methods	
					Qualitative detection methods	
					Quantitative detection methods	

* The submission numbers are those used in Article 13 Paragraphs 1 through 2; and information condition is related to Article 7 Paragraph 3.

[Attachment 3]

Safety Assessment Submissions

(Relating to Article 14)

<table>
<tr><td colspan="3">Submission numbers</td><td>Name of Data</td><td>Data Requirement</td></tr>
<tr><td rowspan="16">①</td><td>1</td><td>Attachment 2 or 2-2</td><td></td><td></td></tr>
<tr><td rowspan="4">2</td><td>A</td><td></td><td></td></tr>
<tr><td>B</td><td></td><td></td></tr>
<tr><td>C</td><td></td><td></td></tr>
<tr><td>D</td><td></td><td></td></tr>
<tr><td rowspan="2">3</td><td>A</td><td></td><td></td></tr>
<tr><td>B</td><td></td><td></td></tr>
<tr><td rowspan="6">4</td><td>A</td><td></td><td></td></tr>
<tr><td>B</td><td></td><td></td></tr>
<tr><td>C</td><td></td><td></td></tr>
<tr><td>D</td><td></td><td></td></tr>
<tr><td>E</td><td></td><td></td></tr>
<tr><td>F</td><td></td><td></td></tr>
<tr><td rowspan="3">5</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="2"></td><td></td><td></td></tr>
<tr><td></td><td colspan="2"></td><td></td><td></td></tr>
<tr><td></td><td colspan="2"></td><td></td><td></td></tr>
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<tr><td></td><td></td><td></td><td></td><td></td></tr>
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<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">* Among the submission numbers, those relating to Article 14 Paragraph 1 Sub-paragraph 1 correspond to those under Article 12 Paragraph 1 Sub-paragraphs 1 through 4 or Article 13 Paragraph 1 Sub-paragraphs 1 through 4; and the requirements are related to Article 7 Paragraph 3.</td></tr>
</table>

[Attachment 4]

Submissions Relating to Reference Materials and Detection Methods for Genes

(Relating to Article 3 Sub-paragraph 1 Clauses a, b, c, e, and h)

No.	Reference materials				Detection methods			
	Event/line	Classification[1)]	Inserted gene	Quantity (Kg, harvest year)	Classification[2)]	Target gene	Primer or probe sequence	Amplicon length (bp)[3)]
1							Forward:	
							Reverse:	
							Probe	
2							Forward:	
							Reverse:	
							Probe	
3							Forward:	
							Reverse:	
							Probe	
4							Forward:	
							Reverse:	
							Probe	

[1)] Host species, recombinant variety, or stack event
[2)] Qualitative or quantitative test
[3)] In principle, a primer shall be designed so that the amplicon size is 100bp to 150 bp.
* Detailed descriptive data and validation data on the detection methods stated above as well the sequence data of the inserted gene and the surrounding genes, etc. shall be attached.

[Attachment 4-2]

<table>
<tr><td colspan="6">Reference Materials and Related Information for Recombinant Microorganism
(Relating to Article 3 Sub-paragraph 1 Clause d)</td></tr>
<tr><td rowspan="3">① Strain</td><td>Genus</td><td colspan="2"></td><td colspan="2">② No. of reference materials (No. of ampoule, etc.)</td></tr>
<tr><td>Species</td><td colspan="2"></td><td colspan="2">_____ ampoules (CFU/ampoule:)</td></tr>
<tr><td>Strain</td><td colspan="2"></td><td colspan="2">Production date of ampoule:</td></tr>
<tr><td rowspan="2">③ Inserted gene</td><td>Characteristics</td><td colspan="3"></td><td></td></tr>
<tr><td>Name</td><td colspan="2"></td><td>Length</td><td></td></tr>
<tr><td rowspan="4">④ Target gene</td><td>Name</td><td></td><td colspan="3"></td></tr>
<tr><td rowspan="2">Verification primer sequence</td><td>Forward</td><td colspan="3"></td></tr>
<tr><td>Reverse</td><td colspan="3"></td></tr>
<tr><td colspan="2">Length of amplicon (bp)</td><td colspan="3"></td></tr>
<tr><td rowspan="8">⑦ Recovery conditions</td><td>Medium composition</td><td colspan="4"></td></tr>
<tr><td>Temperature (℃)</td><td colspan="4"></td></tr>
<tr><td>pH</td><td colspan="4"></td></tr>
<tr><td>Incubation time</td><td colspan="4"></td></tr>
<tr><td>Oxygen requirement</td><td colspan="4">Aerophilic ( ), microaerophilic ( ), facultatively anaerobic ( ), obligatorily anaerobic ( )</td></tr>
<tr><td>Specific gas requirement</td><td colspan="4"></td></tr>
<tr><td>Culturing conditions</td><td colspan="4">Shaking ( ), static liquid ( ), static solid ( )</td></tr>
<tr><td>Culturing methods</td><td colspan="4"></td></tr>
<tr><td rowspan="3">⑪ Optimal long-term storage</td><td colspan="5">Lyophilization ( )</td></tr>
<tr><td colspan="5">Storage in glycerol [-20℃ ( ), -80℃ ( ), liquid nitrogen tank ( )]</td></tr>
<tr><td colspan="5">Other ( )</td></tr>
<tr><td>⑫ Precautions during storage</td><td colspan="5"></td></tr>
<tr><td>⑬ Suggestions</td><td colspan="5"></td></tr>
<tr><td colspan="6">Attached: patent or reference literature</td></tr>
</table>

[Attachment 5]

(Front)

<table>
<tr><td colspan="5">Notification of Safety Assessment Review Results for Genetically Modified Food</td><td>Notification No.
#</td></tr>
<tr><td rowspan="3">Applicant</td><td>① Company</td><td colspan="2"></td><td>② Business registration No.</td><td></td></tr>
<tr><td>③ Address</td><td colspan="4"></td></tr>
<tr><td>④ Representative</td><td colspan="2"></td><td>⑤ Telephone</td><td></td></tr>
<tr><td rowspan="2">Developer</td><td>⑥ Company name</td><td colspan="4"></td></tr>
<tr><td>⑦ Address</td><td colspan="4"></td></tr>
<tr><td>⑧ Classification</td><td colspan="5">Article 3 __</td></tr>
<tr><td>⑨ Organism</td><td></td><td>⑩ Event/line</td><td></td><td>⑪Brand</td><td></td></tr>
<tr><td colspan="2">⑫ Introduced traits</td><td colspan="4"></td></tr>
<tr><td colspan="2">⑬ Inserted gene</td><td colspan="4"></td></tr>
<tr><td colspan="2">⑭ The first country and year approved for commercialization</td><td colspan="4"></td></tr>
<tr><td colspan="2">⑮ Other countries and years approved for commercialization</td><td colspan="4"></td></tr>
<tr><td colspan="2">⑯ Country and year on applying and pending</td><td colspan="4"></td></tr>
<tr><td colspan="2">⑰ Production status</td><td colspan="4">New ( ), Commercialized for 10 years ( ), Commercial production discontinued ( )</td></tr>
<tr><td colspan="2">⑱ Review results</td><td colspan="4">Approved ( ), Approved with conditions ( ), Non-compliant ( )</td></tr>
<tr><td colspan="2">⑲ Use approved (as food)</td><td colspan="4">Import ( ), Development ( ), Production ( ), Other ( )</td></tr>
<tr><td colspan="6">I hereby notify of the results of the review of the safety assessment for the genetically modified food specified above in accordance with Article 9 of the “Regulations concerning Review, etc. of Safety Assessments for Genetically Modified Foods.”

Year Month Day

Commissioner of Korea Food and Drug Administration (seal)</td></tr>
<tr><td colspan="6">Attached:
1 copy of the report on review result of safety assessment</td></tr>
<tr><td colspan="6">The results of the review are based on the submitted data, and all responsibilities for all other matters belong to you. Please notify to KFDA when any new information on safety is occurred and have consultations with the KFDA.</td></tr>
</table>

(Back)

Changes		
Date	Description	Position/name of the contact person (signature or seal)

[Attachment 6]

Application for Modification on Notification of Safety Assessment Review Results for Genetically Modified Food					Duration 1 day
Applicant	① Company		② Business registration No.		
	③ Address				
	④ Representative		⑤ Telephone		
Developer	⑥ Company name				
	⑦ Address				
Classification	Article 3 __		Notification No. of Review result		#
Organism		Event/line		⑦ Brand name	
Introduced traits					

Modifications

Item to be changed	Current entry	Modification	Reason	Remarks

I hereby apply for modification as described above with regard to the genetically modified food for which the review of safety assessment is completed in accordance with Article 10 of the “Regulations concerning Review, etc. of Safety Assessments for Genetically Modified Foods.”

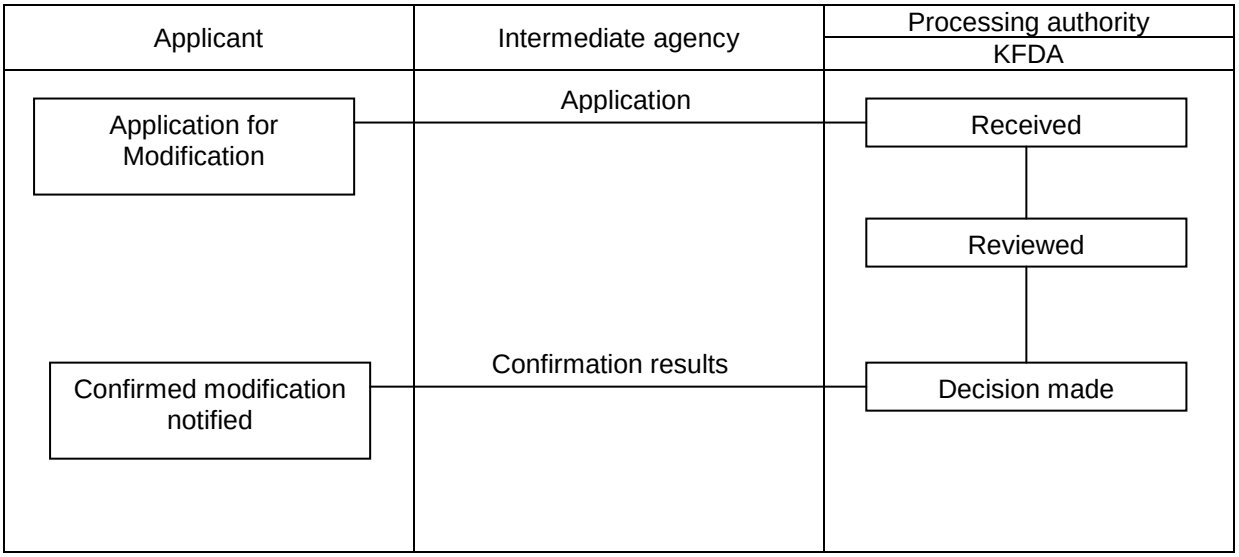
Year Month Day

Applicant (seal)

To Commissioner of Korea Food and Drug Administration

Attached: a copy of the safety assessment review result notification

This application will be processed as follows:



[Attachment 7]

<table>
<tr><td colspan="6">Application for Review
of Safety Assessment Scope for Stack</td><td>Processing time
(30→) 90 days</td></tr>
<tr><td rowspan="3">Applicant</td><td colspan="2">① Company name</td><td colspan="2"></td><td>② Business registration No.</td><td></td></tr>
<tr><td colspan="2">③ Address</td><td colspan="4"></td></tr>
<tr><td colspan="2">④ Representative</td><td colspan="2"></td><td>⑤ Telephone</td><td></td></tr>
<tr><td rowspan="2">Developer</td><td colspan="2">⑥ Company name</td><td colspan="4"></td></tr>
<tr><td colspan="2">⑦ Address</td><td colspan="4"></td></tr>
<tr><td>⑧ Organism</td><td></td><td>⑨ Event/line</td><td></td><td>⑩ Brand name</td><td colspan="2"></td></tr>
<tr><td colspan="3">⑪ Country and year of commercialization</td><td colspan="4"></td></tr>
<tr><td colspan="3"></td><td colspan="2">Parent variety 1</td><td colspan="2">Parent variety 2</td></tr>
<tr><td colspan="3">⑫ Event/line</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑬ Brand</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑭ Introduced traits</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑮ Inserted gene</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑯ Country and year approved for commercialization</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑰ Country and year on applying and pending</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑱ Changes in characteristics</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="3">⑲ Hybridization between different species</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="3">⑳ Differences in intake quantity, edible parts and processing methods compared with the conventional counterpart</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="7">I hereby apply for review as to whether the stack described above falls under the category specified in Article 3 Sub-paragraph 1 Clause e in accordance with Article 4 Paragraph 4 of the “Regulations concerning Review, etc. of Safety Assessments for Genetically Modified Foods.”

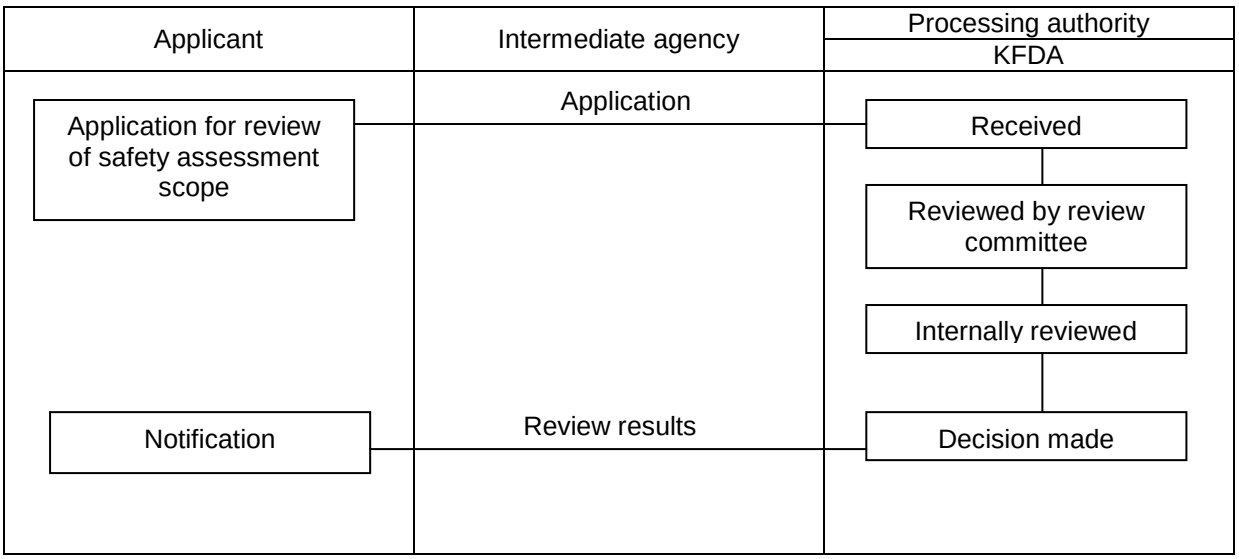
Year Month Day

Applicant (seal)

To Commissioner of Korea Food and Drug Administration</td></tr>
<tr><td colspan="7">Required documents, etc.

1. Data evidencing that no changes occurred to characteristics
2. Data evidencing that hybridization between different species has not occurred
3. Data evidencing that the stack is not different from the conventional counterpart in terms of intake quantity, edible parts, and processing methods.
4. Any change in ①~⑦, ⑨ and ⑩ is recognized as a notification item.
5. Data on Detection methods and Reference materials (Attachment 4 form)</td></tr>
</table>

This application will be processed as follows:



[Attachment 8]

<table>
<tr><td colspan="6">Notification of Results of Review
of Safety Assessment Scope for Stack</td><td>Notification No.
#</td></tr>
<tr><td rowspan="3">Applicant</td><td colspan="2">① Company</td><td colspan="2"></td><td>② Business registration No.</td><td></td></tr>
<tr><td colspan="2">③ Address</td><td colspan="4"></td></tr>
<tr><td colspan="2">④ Representative</td><td colspan="2"></td><td>⑤ Telephone</td><td></td></tr>
<tr><td rowspan="2">Developer</td><td colspan="2">⑥ Company name</td><td colspan="4"></td></tr>
<tr><td colspan="2">⑦ Address</td><td colspan="4"></td></tr>
<tr><td>⑧ Organism</td><td></td><td>⑨ Event/line</td><td></td><td>⑩ Brand name</td><td colspan="2"></td></tr>
<tr><td colspan="3">⑪ Country and year of commercialization</td><td colspan="4"></td></tr>
<tr><td colspan="3"></td><td colspan="2">Parent variety 1</td><td colspan="2">Parent variety 2</td></tr>
<tr><td colspan="3">⑫ Event/line</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑬ Brand</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑭ Introduced traits</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑮ Inserted gene</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑯ Country and year approved for commercialization</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑰ Country and year on applying and pending</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">⑱ Changes in characteristics</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="3">⑲ Hybridization between different species</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="3">⑳ Differences in intake quantity, edible parts and processing methods compared with the conventional counterpart</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="3">㉑ Whether subject to safety assessment requirement</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="7">I hereby notify of the decision as to whether the stack described above is subject to the safety assessment requirement in accordance with Article 4 of the “Regulations concerning Review, etc. of Safety Assessments for Genetically Modified Foods.”

Year Month Day

Commissioner of Korea Food and Drug Administration (seal)</td></tr>
<tr><td colspan="7">The results of the review are based on the submitted data, and all responsibilities for all other matters belong to the applicant company. Please notify to KFDA when any new information on safety is happened and have consultations with KFDA.</td></tr>
</table>