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Draft Consolidated Notice to Implement Cartagena Biosafety Protocol

2007

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Report Highlights:
The Ministry of Commerce, Industry, and Energy (MOCIE) released the draft consolidated notice to enforce the Act on Transboundary Movements of Living Modified Organisms, the legislation to implement the Cartagena Protocol on Biosafety on August1, 2007. This consolidated notice was notified to the WTO under SPS 256 and TBT 148 and 152 repeatedly for international comments. Comments are due by October 3, 2007.

This notice provides details about import inspection, documents required for import clearance and approvals required for import of LMO including LMO for food, feed, and processing (LMO FFP) into Korea. Therefore, this notice will have significant implications for trade of LMO FFP.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Seoul [KS1]
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Consolidated Notice Concerning Transboundary Movements of Living Modified Organisms, etc.

Table of Content

Note: This report provides an unofficial translation of selective chapters of the Consolidated Notice Concerning Transboundary Movements of Living Modified Organisms, which are mainly focused on agricultural LMO and LMO FFP. Chapters included in this report are Chapter 1, 4, 6, 10, Annex, and attached forms.

In accordance with the Act on Transboundary Movements of Living Modified Organisms, etc. and the Presidential Decree of the Act, a "Consolidated Notice Concerning Transboundary Movements of Living Modified Organisms, etc." is established/announced by the competent national administrative authorities as follows:

August 1, 2007

Minister of Science and Technology (MOST Minister)
Minister of Agriculture and Forestry (MAF Minister)
Minister of Commerce, Industry, and Energy (MOCIE Minister)
Minister of Health and Welfare (MOHW Minister)
Minister of Environment (MOE Minister)
Minister of Maritime Affairs and Fisheries (MOMAF Minister)
Commissioner of the Korea Food and Drug Administration (KFDA Commissioner)

Consolidated Notice Concerning Transboundary Movements of Living Modified Organisms, etc. (DRAFT)

Chapter 1
General Provisions

Article 1-1 (Objective)

The objective of this Notice is to establish specific matters pertaining to the development/ production/import/export/sales/transport/storage, etc. (hereinafter referred to as "export/ import, etc.") of living modified organisms in accordance with the "Act on Transboundary Movements of Living Modified Organisms, etc." (hereinafter referred to as the "Act"), the Decree of the Act (hereinafter referred to as the "Decree") and the Ordinance of the Act (hereinafter referred to as the "Ordinance") so as to prevent risks due to living modified organisms to public health and the conservation and sustainable use of biodiversity, to improve the quality of life of the public, and to promote international cooperation.

Article 1-2 (Definitions)

For the purposes of this Notice,

1. "Living modified organism (LMO)" means any living organism that possesses a novel combination of genetic material obtained through the use of the following modern biotechnology:

   A. In vitro recombination of genes or direct injection of nucleic acid into cells or organelles;
   B. Fusion of cells beyond the taxonomic family, which overcomes natural physiological reproductive or recombination barriers and which is not a technique used in traditional breeding and selection.

2. "LMO intended for test/research use" means an LMO used for test/research purposes under the conditions of contained use.

3. “LMO intended for use in the agricultural/forest or livestock industry” (hereinafter referred to as an “agricultural LMO”) means an LMO used in the agricultural/forest/livestock industry and includes the following:

   A. LMO for seeds intended for introduction into the environment;
   B. LMOs in their original shapes and intended for use as feed or for feed processing
   C. Other LMOs intended for use in the agricultural/forest/livestock industry.

4. “LMO for industrial use” means an LMO intended for uses in textile/machinery/ chemical/electronics/energy/resources and other industries excluding those intended for test/research, agricultural, health/medical, environmental purification or maritime/ fisheries uses.

5. “LMO intended for health/medical use” means an LMO used to protect/promote public health and includes the following:

   A. LMOs intended for food use
   B. Other LMOs intended for uses relating to clinical and medical use.

6. “LMO intended for use in environmental purification” means an LMO for intentional introduction into facilities or the environment with a view to reducing/eliminating environmental pollutants or remediating the environment, taking advantage of the organism’s tolerance to environmental pollutants or contaminants.

7. “LMO intended for maritime or fisheries use” (hereinafter referred to as a “LMO for maritime or fisheries use”) means an LMO that inhabits the sea/freshwater and is used in the maritime or fisheries fields and includes those for observation/aquarium uses.

8. “Introduction into the environment” means intentional exposure of LMO into the natural environment without enclosing of facilities/equipment or other structures as defined in Article 2 Paragraph 2 of the Act.

9. “Environmental risk” means any potential negative effect which an LMO may have on the conservation and sustainable use of domestic biodiversity if it is introduced into the environment.

10. “Stack event” means a species obtained by crossing an LMO with another LMO or an LMO with a conventional variety.

11. “Adventitious presence ratio” means the percentage of an LMO adventitiously present in a non-GMO import.

12. “Handling/controlling” means any measure taken by the exporter/importer, etc. of an LMO to ensure safety including any measure to prevent the LMO from being used for non-approved purposes and to comply with the approval conditions, etc.

13. “Handler” means any person who handles an LMO for export/import, etc. or uses an LMO as a raw material.

14. “Information specified in Annex I to the Protocol” means information in Annex 1-1.

15. “Information specified in Annex II to the Protocol” means information in Annex 1-2.

16. “General principles and methodology for risk assessments of LMOs specified in Annex III to the Protocol” means those in Annex 1-3.

17. “Monitoring of transboundary movements” means monitoring activities relating to import inspection and handling within border areas (meaning quarantine areas referred to in Article 6 Paragraph 2 of the Plant Quarantine Act).

18. “Field trial” means cultivation, control, research, environmental impact assessment, and other activities carried out within a contained trial field with a view to the introduction of an LMO into the environment.

19. “Seed” means any organism (seed, mushroom spawn, vegetative body) for propagation or cultivation.

20. “Test zone” means an area consisting of laboratory, corridor, etc. isolated from other areas with an anteroom for access control.

21. “Research facility” means a test zone and its anteroom, which is considered as a unit facility for which a notification or an application for approval should be filed separately.

Article 1-3 (Responsibilities of competent national administrative authorities)

In accordance with Article 2 Paragraph 1 of the Decree, competent national administrative authorities shall be responsible for the following:

1. The MOST shall be responsible for matters pertaining to the export/import, etc. of LMOs for test/research use.
2. The MAF shall be responsible for matters pertaining to the export/import, etc. of agricultural LMOs.
3. The MOCIE shall be responsible for matters pertaining to the export/import, etc. of LMOs for industrial use.
4. The MOHW shall be responsible for matters pertaining to the export/import, etc. of LMOs for health/medical use.
5. The MOE shall be responsible for matters pertaining to the export/import, etc. of LMOs for environmental purification use.
6. The MOMAF shall be responsible for matters pertaining to the export/import, etc. of LMOs for maritime/fisheries use.

Article 1-4 (Delegated/contracted agencies)

The following agencies shall perform responsibilities delegated/contracted out pursuant to the “Regulations on Delegation and Contracting of Administrative Authorities” among those of competent national administrative authorities (hereinafter referred to as “CNAA”) referred to in Article 1-3 (hereinafter referred to as “delegated/contracted agencies”):

1. The MAF Minister shall delegate the following authorities pertaining to agricultural LMOs to the Administrator of the Rural Development Administration (RDA Administrator):

   A. Designation of LMO risk assessment agencies pursuant to Article 8 Paragraph 4 of the Act

B. Consultations on review and matters pertaining to review of risks of LMOs to the crop cultivation environment pursuant to Article 8 Paragraph 5, Article 12 Paragraph 3, and Article 13 Paragraph 1 of the Act
C. Receipt of import notifications for LMOs for fairs or exhibitions and notification of notification information pursuant to Article 9 of the Act
D. Receipt of installation/operation notifications for LMO research facilities and notification of notification information pursuant to Article 22 Paragraphs 1 and 2 of the Act
E. Approval of development/test of LMOs with significant potential risks pursuant to the proviso of Article 22 Paragraph 3 of the Act
F. Suspension of the operation of LMO research facilities and revocation of development/test approval of LMOs with significant potential risks pursuant to Article 23 Paragraphs 1 and 2 of the Act
G. Access, reporting, inspection or demand for submission of data/samples pursuant to Article 36 Paragraph 1 Subparagraph 1 (applicable only to persons who have filed import notifications referred to above in Clause C), Subparagraphs 3 through 6 (in the case of Subparagraph 6, applicable only to importers of LMOs referred to above in Clause C)
H. Access/inspection pursuant to Article 36 Paragraph 2 of the Act (applicable only to those who are suspected of importing without filing import notifications referred to above in Clause C or of operating a research facility without filing a notification referred to above in Clause D)
I. Matters pertaining to the imposition/collection, etc. of penalties pursuant to Article 44 Paragraph 1 Subparagraph 7 (applicable only to those who have imported LMOs referred to above in Clause C and those who have filed research facility installation/operation notifications referred to above in Clause D) and Subparagraph 8 (applicable only to those who refuse/interfere with or evade access, reporting, inspection or demand for submission of data/samples referred to above in Clauses G and H) and Paragraphs 2 through 5 of the Act.

2. The MAF Minister shall delegate the authorities pertaining to LMOs for seed use to the Director General of the National Seed Management Office (NSMO):

A. Import approval for LMOs and notification of approval decisions pursuant to Article 8 Paragraphs 1/5/6 of the Act
B. Production approval for LMOs and notification of approval decisions pursuant to Article 12 Paragraphs 1 and 3 of the Act
C. Public announcement and gathering of public opinions before import/production approval for LMOs pursuant to Article 13 Paragraph 4 of the Act
D. Revocation of import/production approval for LMOs (applicable only to import approval referred to above in Clause A and production approval referred to above in Clause B) and notification of revocation decisions pursuant to Article 17 of the Act
E. Matters pertaining to re-review pursuant to Article 18 of the Act
F. Administrative actions against LMOs including disposal by destruction/return, etc. and notification of the actions pursuant to Article 19 of the Act
G. Access, reporting, inspection or demand for submission of data/samples pursuant to Article 36 Paragraphs 1 and 2 of the Act
H. Public hearings (limited to public hearings pertaining to approval revocation referred to above in Clause D) pursuant to Article 37 Paragraph 1 of the Act
I. Matters pertaining to the imposition/collection, etc. of penalties pursuant to Article 44 of the Act.

3. The MAF Minister shall delegate the following authorities pertaining to LMOs for feed use to the Director General of the National Agricultural Products Quality Management Service (NAQS):

   A. Import approval for LMOs and notification of approval decisions pursuant to Article 8 Paragraphs 1/5 and 6 of the Act
   B. Public announcement and gathering of public opinions before import approval of LMOs pursuant to Article 13 Paragraph 4 of the Act
   C. Revocation of import approval for LMOs (applicable only to import approval referred to above in Clause A) and notification of revocation decisions pursuant to Article 17 of the Act
   D. Matters pertaining to re-review pursuant to Article 18 of the Act
   E. Administrative actions against LMOs including disposal by destruction/return, etc. and notification of the actions pursuant to Article 19 of the Act
   F. Access, reporting, inspection or demand for submission of data/samples pursuant to Article 36 Paragraphs 1 and 2 of the Act
   G. Public hearings (limited to public hearings pertaining to approval revocation referred to above in Clause C) pursuant to Article 37 Paragraph 1 of the Act
   H. Matters pertaining to the imposition/collection, etc. of penalties pursuant to Article 44 of the Act.

4. The MAF Minister shall delegate the following authorities pertaining to agricultural LMOs to the Director General of the National Plant Quarantine Service (NPQS):

   A. Import inspection and actions including disposal by destruction, return, etc. against LMOs imported by mail pursuant to Article 10 Paragraphs 1 and 2 of the Act
   B. Administrative actions against LMOs including disposal by destruction/return, etc. and notification of the actions pursuant to Article 19 of the Act
   C. Access, reporting, inspection or demand for submission of data/samples pursuant to Article 36 Paragraph 1 Subparagraph 2/6 (excluding matters delegated to the RDA Administrator pursuant to Subparagraph 1 Clause G above) and Paragraph 2 (excluding matters delegated to the RDA Administrator pursuant to Subparagraph 1 Clause H above) of the Act
   D. Matters pertaining to the imposition of penalties/administrative actions, etc. pursuant to Article 44 Paragraph 1 Sections 2/3/7/8 (excluding matters delegated to the RDA Administrator pursuant to Subparagraph 1 Clause I above) and Paragraphs 2 through 5 of the Act.

5. The MOHW Minister shall delegate the following authorities pertaining to LMO for food use to the Director of the National Quarantine Station (NQS):

   A. Import inspection, actions including disposal by destruction, return, etc., receipt of notifications and disposal orders for LMOs imported by mail pursuant to Article 10 of the Act (excluding matters delegated to the Director of the Korea Centers for Disease Control and Prevention (KCDC) pursuant to Subparagraph 6 Clause B)
   B. Administrative actions including disposal by destruction/return, etc. and notification of the actions pursuant to Article 19 of the Act (excluding matters delegated to the KCDC Director pursuant to Subparagraph 6 Clause G)
   C. Access/inspection for safety control of import of LMOs pursuant to Article 36 Paragraph 2 of the Act (excluding matters delegated to the KCDC Director pursuant to Subparagraph 6 Clause O).

6. The MOHW Minister shall delegate the following authorities to the KCDC Director:
   A. Import approval and notification of approval decisions for LMOs for test/research use or for fairs/exhibitions referred to in Article 9 of the Act and Article 12 Paragraph 1 of the Decree
   B. Import inspection, administrative actions including disposal by destruction/return, etc., receipt of notifications and disposal orders for LMOs for test/research use or for fairs/exhibitions subject to the approval requirement and imported by mail pursuant to Article 10 of the Act
   C. Matters pertaining to review of risks of LMOs (excluding those for health/medical use) to human health pursuant to Article 13 Paragraph 1 of the Act
   D. Prohibition or restriction of import and notification of such decisions for LMOs for test/research use or for fairs/exhibitions subject to the approval requirement pursuant to Article 14 Paragraphs 1 and 2 of the Act
   E. Revocation of import approval for LMOs for test/research use or fairs/exhibitions and notification of revocation decisions pursuant to Article 17 of the Act
   F. Matters pertaining to re-review of import approval revocation for LMOs for test/research use or fairs/exhibitions pursuant to Article 18 of the Act
   G. Administrative actions including disposal by destruction/return, etc. and notification of the actions against LMOs for test/research use or for fairs/exhibitions subject to the approval requirement pursuant to Article 19 of the Act
   H. Permission of installation/operation, permission/receipt of notification of modifications, and notification thereof for research facilities subject to the permission requirement pursuant to Article 22 of the Act and Article 23 Paragraphs 1 through 3 of the Decree
   I. Receipt of notifications of installation/operation and notification thereof for research facilities of national research institutions under the MOHW pursuant to Article 22 of the Act and the proviso of Article 23 Paragraph 4 of the Decree
   J. Approval of development/test of LMOs pursuant to the proviso of Article 22 Paragraph 3 of the Act and Article 23 Paragraph 6 Subparagraph 1 through 4 and Subparagraph 6 of the Decree
   K. Revocation of permission and suspension of operation of research facilities pursuant to Article 23 Paragraph 1 of the Act (applicably only to matters pertaining to research facilities referred to above in Clauses H and I)
   L. Revocation of development/test approval for LMOs pursuant to Article 23 Paragraph 2 of the Act (applicable only to development/test approval referred to above in Clause J)
   M. Receipt of notification on adverse effects of LMOs (excluding health/medical LMOs) on public health pursuant to Article 27 Paragraph 2 of the Act
   N. Access, reporting, inspection and demand for submission of data/samples pursuant to Article 36 Paragraph 1 Subparagraph 1 (applicable only to those who have obtained import approval referred to above in Clause A)/Subparagraph 5 (applicably only to those who install/operate research facilities referred to above in Clauses H/I)/Subparagraph 6 (applicable only to those who import LMOs referred to above in Clauses A/B and those who install/operate research facilities referred to above in Clauses H/I) of the Act
   O. Access/inspection pursuant to Article 36 Paragraph 2 of the Act ((applicable only to those who are suspected of importing products considered as LMOs referred to above in Clause A for which approval is not obtained and LMOs referred to above in Clause B for which a notification is not filed or those who are suspected of operating research facilities referred to above in Clause H or I without permission or notification)
   P. Public hearings with regard to revocation of import approval for LMOs for test/research use or for fairs/exhibitions and revocation of permission for human health risk research facilities pursuant to Article 37 of the Act

Q. Matters pertaining to the imposition/collection, etc. of penalties pursuant to Article 44 Paragraph 1 Subparagraph 2 (applicable only to those who fail to file a notification or implement an order for LMOs referred to above in Clause B)/Subparagraph 6/Subparagraph 7 (applicable only to those who import LMOs referred to above in Clauses A/B and those who install/operate research facilities referred to above in Clauses H/I)/Subparagraph 8 (applicable only to those who refuse/interfere with or evade access, reporting, inspection or demand for submission of data/samples referred to above in Clauses N/O), and Paragraphs 2 through 5 of the Act.

7. The MOHW Minister shall delegate the following authorities pertaining to LMOs for health/medical use to the KFDA Commissioner:

A. Import approval, etc. for LMOs pursuant to Article 8 of the Act
B. Receipt of import notifications and notification thereof for LMOs for fairs/exhibitions pursuant to Article 9 of the Act
C. Production approval, etc. for LMOs pursuant to Article 12 of the Act
D. Matters pertaining to review of risks of LMOs to human health pursuant to Article 13 of the Act
E. Prohibition or restriction of import/production of LMOs and notification thereof pursuant to Article 14 Paragraphs 1 and 2 of the Act (excluding matters delegated to the KCDC Director pursuant to Subparagraph 6 Clause D)
F. Revocation of import/production approval and notification thereof for LMOs pursuant to Article 17 of the Act (excluding matters delegated to the KCDC Director pursuant to Subparagraph 6 Clause E)
G. Matters pertaining to re-review pursuant to Article 18 of the Act (excluding matters delegated to the KCDC Director pursuant to Subparagraph 6 Clause F)
H. Receipt of notifications on adverse effects of LMOs on public health pursuant to Article 27 Paragraph 2 of the Act
I. Access, reporting, inspection or demand for submission of data/samples pursuant to Article 36 Paragraph 1 of the Act (excluding matters delegated to the KCDC Director pursuant to Subparagraph 6 Clause N)
J. Public hearings on revocation of import/production approval for LMOs pursuant to Article 37 Paragraph 1 of the Act (excluding matters delegated to the KCDC Director pursuant to Subparagraph 6 Clause P).

8. The MOHW Minister shall delegate the following authorities pertaining to LMOs for health/medical use to the head of the competent regional KFDA:

A. Import inspection, administrative actions including disposal by destruction/return, etc., receipt of notifications, and disposal orders for LMOs imported by mail pursuant to Article 10 of the Act (excluding matters delegated to the NQS Director pursuant to Subparagraph 5 Clause A and to the KCDC Director pursuant to Subparagraph 6 Clause B)
B. Administrative actions including disposal by destruction/return, etc. and notification of the actions for LMOs pursuant to Article 19 of the Act (excluding matters delegated to the NQS Director pursuant to Subparagraph 5 Clause B and to the KCDC Director pursuant to Subparagraph 6 Clause G)
C. Access/inspection pursuant to Article 36 Paragraph 2 of the Act (excluding matters delegated to the NQS Director pursuant to Subparagraph 5 Clause C and to the KCDC Director pursuant to Subparagraph 6 Clause O)
D. Matters pertaining to the imposition/collection, etc. of penalties pursuant to Article 44 of the Act (excluding matters delegated to the KCDC Director pursuant to Subparagraph 6 Clause Q).

9. The MOE Minister shall delegate the following authorities to the Chief of the National Institute of Environmental Research (NIER):

   A. Import approval, etc. for LMOs pursuant to Article 8 Paragraphs 1 through 6 of the Act
   B. Receipt of import notifications and notification thereof for LMOs for fairs/exhibitions pursuant to Article 9 of the Act
   C. Import inspection, administrative actions including disposal by destruction/return, etc., receipt of notifications, and disposal orders for LMOs imported by mail pursuant to Article 10 of the Act
   D. Production approval, etc. for LMOs pursuant to Article 12 of the Act
   E. Review consultations/review of risks, designation of risk review agencies and public announcement and gathering of public opinions prior to import/production approval pursuant to Article 13 Paragraphs 1/3 and 4 of the Act
   F. Prohibition or restriction of import/production of LMOs and notification thereof pursuant to Article 14 Paragraphs 1 and 2 of the Act
   G. Revocation of import/production approval and notification thereof for LMOs pursuant to Article 17 of the Act
   H. Matters pertaining to re-review pursuant to Article 18 of the Act
   I. Administrative actions including disposal by destruction/return, etc. and notification thereof for LMOs pursuant to Article 19 of the Act
   J. Receipt of notifications on adverse effects of LMOs pursuant to Article 27 Paragraph 2 of the Act
   K. Access, reporting, inspection or demand for submission of data/samples pursuant to Article 36 of the Act
   L. Public hearings pursuant to Article 37 Paragraph 1 of the Act
   M. Matters pertaining to the imposition/collection, etc. of penalties pursuant to Article 44 of the Act.

10. The MOMAF Minister shall delegate the following authorities to the Director General of the National Fisheries Products Quality Inspection Service (NFPQIS):

    A. Import inspection, administrative actions including disposal by destruction/return, etc., receipt of notifications and disposal orders for LMOs imported by mail pursuant to Article 10 of the Act
    B. Administrative actions such as disposal by destruction/return and notification of such actions pursuant to Article 19 of the Act (excluding matters delegated to the Chief of the National Fisheries Research & Development Institute (NFRDI))
    C. Access, reporting, inspection or demand for submission of data/samples pursuant to Article 36 Paragraph 1 Subparagraphs 1/2/6 and Paragraph 2 (applicable to those who are suspected of being engaged in export/import, etc. of products considered as LMOs without obtaining an approval or filing a notification) of the Act
    D. Matters pertaining to the imposition/collection, etc. of penalties pursuant to Article 44 Paragraph 1 Subparagraphs 2/3/7 (applicable only to those who fail to prepare/keep controlling/operating records pertaining to production/import/export/sale and transport/storage)/ Subparagraph 8 (applicable only to those who refuse/interfere with or evade access, reporting, inspection or demand for submission of data/samples referred to above in Clause C) and Paragraphs 2 through 5 of the Act.

11. The MOMAF Minister shall delegate the following authorities to the NFRDI Chief:

    A. Import approval, etc. for LMOs pursuant to Article 8 Paragraphs 1 through 6 of the Act

B. Receipt of import notifications and notification thereof for LMOs for fairs/exhibitions pursuant to Article 9 of the Act
C. Production approval, etc. for LMOs pursuant to Article 12 of the Act
D. Review consultations/review of risks, designation of risk review agencies and public announcement and gathering of public opinions prior to import/production approval pursuant to Article 13 Paragraphs 1/3 and 4 of the Act
E. Prohibition of import or production of LMOs and notification thereof pursuant to Article 14 Paragraphs 1 and 2 of the Act
F. Revocation or import approval or production approval and notification thereof for LMOs pursuant to Article 17 of the Act
G. Matters pertaining to re-review pursuant to Article 18 of the Act
H. Administrative actions including disposal by destruction/return, etc. and notification thereof pursuant to Article 19 Paragraph 1 Subparagraph 3, and Paragraphs 2 and 3 of the Act
I. Receipt of notifications of installation/operation of LMO research facilities and notification thereof and approval of development/test of LMOs with significant potential risks pursuant to Article 22 of the Act
J. Suspension of the operation of research facilities and revocation of development/test approval of LMOs with significant potential risks pursuant to Article 23 Paragraphs 1 and 2 of the Act
K. Receipt of notifications of adverse effects of LMOs pursuant to Article 27 Paragraph 2 of the Act
L. Access, reporting, inspection or demand for submission of data/samples pursuant to Article 36 of the Act (excluding matters delegated to the NFPQIS Director General pursuant to Subparagraph 10 Clause C)
M. Public hearings pursuant to Article 37 Paragraph 1 of the Act
N. Matters pertaining to the imposition/collection, etc. of penalties pursuant to Article 44 Paragraph 1 Subparagraphs 1/4 and 6 through 8 (excluding matters delegated to the NFPQIS Director General pursuant to Subparagraph 10 Clause D) and Paragraphs 2 through 5 of the Act.

Article 1-5 (Risk review consultations)

. In the case that risk review is conducted for import approval or production approval for an LMO or that risk review is to be conducted upon an application for advance risk review filed by a person who desires to import or produce an LMO, the head of the NCAA or the delegated/contracted agency (hereinafter referred to as the “head of the NCAA, etc.”) shall have prior consultations with the KCDC Director with regard to effects of the LMO on human health and the head of one of the following agencies if the LMO is to be introduced into the environment or has the potential to be introduced into the environment pursuant to Article 13 Paragraph 1 of the Act:

1. The NIER Chief with regard to effects of the LMO on natural ecosystem
2. The RDA Administrator with regard to effects on the crop cultivation environment
3. The NFRDI Chief with regard to effects on the marine ecosystem.

? By the request of the head of the CNAA, etc. to the NIER Chief, RDA Administrator, or NFRDI Chief for prior consultations as to the necessity, if he is notified of review results upon request for prior consultations pursuant to Paragraph 1 above, risk review shall be deemed as completed pursuant to Article 8 Paragraph 5, Article 12 Paragraph 3 of the Act and Article 9 Paragraph 3, Article 5 Paragraph 1 Subparagraph 1 of the Decree.

Article 1-6 (Gathering of public opinions)

- The head of the NCAA, etc. shall publicize information on an LMO and gather public opinions before approving the import or production of the LMO pursuant to Article 13 Paragraph 4 of the Act. In the case that public opinions are gathered during the risk review process, however, this requirement may not apply.

- In the case that the head of the NCAA, etc. is to gather public opinions pursuant to Paragraph 1, information on the applicable LMO shall be provided along with the methods for submitting opinions on the web site of the NCAA or the delegated/contracted agency for 30 days or longer.

Article 1-7 (Detailed rules and implementation guidelines)

If necessary for the efficient implementation of this Notice, the head of the NCAA, etc. may establish detailed rules and implementation guidelines provided that such rules and guidelines shall not violate the applicable statutes and this Notice.

Chapter 4
Approval for Import and Production, Risk Assessment, Labeling and Management of Agricultural LMO

Section 1
Import/Production Approval

Article 4-1 (Applications for approval and submission requirements, etc.)

. An application for import or production approval for an LMO intended for agricultural use (an agricultural LMO) shall be as follows. In the case that an application is for the same LMO as the one which is reviewed for risks to human health and the environment, however, documents on human health and environmental risk review may not be required:

1. A person who desires to obtain import approval for an LMO for feed use shall submit an "Application for LMO Import Approval" as per Attachment 1 of the Ordinance and required documents to the Director of the competent Experiment and Research Station of the NAQS (hereinafter referred to as the "ERS Director").

2. A person who desires to obtain import or production approval for an LMO for use as seed shall submit the following documents to the NSMO Director:

A. A person who desires to obtain import approval for an LMO for seed use shall submit an "Application for Import Approval of LMO Intended for Environmental Release" as per Attachment 4 of the Ordinance accompanied by required documents.

B. A person who desires to obtain production approval for an LMO for seed use shall submit an "Application for LMO Production Approval" as per Attachment 13 of the Ordinance accompanied by required documents.

. An environmental risk review may be requested by submitting environmental risk review documents to the RDA Administrator before filing an application for import or production approval.

. Applications for import or production approval for agricultural LMOs and required documents shall be submitted as follows:

1. The importer or producer of the applicable LMO or a representative thereof may submit an application.

2. Documents accompanying an application shall be prepared in Korean, and, if necessary, the name of the LMO, etc. may be stated in the original language or English.

Article 4-2 (Approval of modifications to an approval, etc.)

. A person who desires to have an import/production approval for an agricultural LMO modified shall submit an "Application for Approval of Modifications to LMO Import Approval (Modification Notification)" as per Attachment 3 of the Ordinance accompanied

by required documents or an "Application for Approval of Modifications to LMO Production Approval (Modification Notification)" as per Attachment 15 of the Ordinance accompanied by required documents to the ERS or NSMO Director.

. Upon receiving an application referred to above in Paragraph 1, the ERS and NSMO Director shall make a decision as to modification approval within 10 days and notify the applicant of the decision as per Attachment 2 of the Ordinance "Certificate of LMO Import Approval" or as per Attachment 14 of the Ordinance "Certificate of LMO Production Approval."

Article 4-3 (Processing of applications, etc.)

. Upon receiving an application referred to above in Article 4-1, the ERS and NSMO Director shall make a decision as to approval after receiving advice from the Advisory Committee referred to in Article 4-6 or having responsible government officers perform on-site verification to verify application documents, etc., and notify the applicant of the decision as per Attachment 2 of the Ordinance "Certificate of LMO Import Approval" or as per Attachment 14 of the Ordinance "Certificate of LMO Production Approval." In the case that the same LMO as an agricultural LMO which has completed prior human health and environmental risk review is to be imported again, however, a decision as to import approval shall be made within 10 days and notified to the applicant. On-site verification by responsible government officers may be conducted in the presence of the applicant or a representative thereof.

. In the case that an import or production approval application and required documents are incomplete, the ERS or NSMO Director may specify a period not exceeding 30 days and require that the applicant submit additional data within the period, and the period for supplementary submission, etc. shall be as follows:

1. In the case that the applicant fails to submit supplementary data within a specified period, the ERS and NSMO Director may again require submission of additional data. In this case, the period for submission shall be 10 days.

2. Upon being required by the ERS or NSMO Director to submit additional data, the applicant may request for an extension of the supplementary submission period as per Attachment 3-3 "Request for Extension of Supplementary Submission Period" specifying the period required, and in this case, the ERS or NSMO Director may set the period considering the reasons for extension.

3. In the case that additional data are not submitted within the period specified above in Subparagraphs 1 and 2, the ERS or NSMO Director may reject the application specifying the reasons for rejection.

. Upon receiving an application for import/production approval requiring environmental risk review, the ERS and NSMO Director shall transfer environmental risk review data to the RDA Administrator within 10 days.

. Upon receiving data referred to above in Paragraph 3, the RDA Administrator shall, within 250 days, conduct environmental risk review, and report the review results to the MAF Minister and notify the ERS and NSMO Director of the results.

. The ERS and NSMO Director shall report "LMO Import/Production Approval Results" as per Attachment 4-1 to the MAF Minister every quarter.

Article 4-4 (Approval revocation)

. In any of the following cases, the ERS and NSMO Director may revoke import approval or production approval. In the case specified below in Subparagraph 1 or 2, approval shall be revoked:

1. In the case that an agricultural LMO approved for import or production is found to pose risks or potential risks to public health and the conservation and sustainable use of biodiversity

2. In the case that approval is obtained in a fraudulent or otherwise false manner

3. In the case that an agricultural LMO approved for import or production is used for non-approved purposes

4. In the case that the Act or an order or administrative action pursuant to the Act is not complied with

5. In the case that safety management personnel and facilities, etc. fall significantly below the levels at the time of approval

6. In the case that documents evidencing import or production approval for an agricultural LMO are transferred or lent to another person.

. Upon revoking approval pursuant to Paragraph 1, the ERS and NSMO Director shall report promptly to the MAF Minister.

Article 4-5 (Re-review)

. A person who desires to request for re-review in protest against a decision as to import approval, production approval or approval revocation shall submit a “Request for Re-assessment as per Attachment 18 of the Ordinance accompanied by documents evidencing the reasons for re-review request to the ERS or NSMO Director.

. Upon receiving a request for re-review referred to above in Paragraph 1, the ERS or NSMO Director shall report to the MAF Minister, and notify the applicant of the results as per Attachment 2 of the Ordinance “Certificate of LMO Import Approval” or Attachment 14 of the Ordinance “Certificate of LMO Production Approval” within 90 days.

Article 4-6 (Composition, etc. of the Advisory Committee)

. The NAQS Director General and NSMO Director may set up/operate an advisory committee to consider potential social/economic effects on domestic biodiversity when a decision is to be made as to import/production approval for agricultural LMOs.

. Specific matters pertaining to the composition and operation of the Advisory Committee shall be specified by the NAQS Director General and NSMO Director.

Article 4-7 (Standards and verification procedures for adventitious presence, etc.)

. The standards for LMOs for feed use which are imported unintentionally commingled

with and present in agricultural products during distribution including export/import, etc. shall be as follows:

1. In the case of adventitious presence not exceeding 3% of LMOs for feed use approved through domestic risk review

2. In the case of adventitious presence not exceeding 0.5% of LMOs for feed use with the approval of the country of export or development, without the domestic approval. Its testing methods and reference materials shall be submitted to be applicable. As standards for submissions, Subparagraph 13 Clause A of Attachment 10-1 "LMO Risk Assessment Data" shall apply *mutatis mutandis*.

. In the case that an LMO is detected in a product not approved for import or notified during inspection referred to in Article 4-17, the head of the competent NPQS regional or branch office may request the ERS Director to conduct a test by sending a sample to determine whether the limit for adventitious presence is exceeded.

. Upon receiving a request for test pursuant to Paragraph 2, the ERS Director shall perform verification promptly and make notification of the results within 15 days.

Section 2
Risk Assessment and Review

Article 4-8 (Environmental risk review, etc.)

. The RDA Administrator may establish and implement review procedures and other specific matters required to conduct environmental risk review responsibilities.

. A person who desires to proactively receive environmental risk review for an agricultural LMO (hereinafter in Chapter 4 referred to as an "applicant") shall file a prior application on the Internet, and submit an "Application for Environmental Risk Review for Agricultural LMO" as per Attachment 4-2 accompanied by required documents to the RDA Administrator.

. As review data among required documents referred to above in Paragraph 2, 20 paper copies and 2 electronic copies in the diskette or CD or other digital format of the LMO risk assessment data in Annex 10-1 shall be submitted to the RDA Administrator. In the case that review data are from other countries, the original data and a summary thereof translated into Korean shall be submitted together.

. Review data referred to above in Paragraph 3 shall meet any of the following requirements:

1. Scientifically proven data published in scientific journals

2. Data derived from tests conducted by domestic/overseas professional institutions including biotechnology-related universities or research institutions, etc., and issued by the head of such an institution (in this case, an overview of test facilities, major equipment, composition of research personnel, credentials of researchers, etc. shall be described)

3. All data submitted at the time of risk review in the country of development and export of the applicable agricultural LMO. The data shall certify that approval is

granted by the government of the country of development and export (licensing, authorizing or certifying authorities) or be notarized.

- In the case that the RDA Administrator determines that consultations are necessary for risk review of an applicable LMO pursuant to Article 13 Paragraph 1 of the Act, the RDA Administrator shall request the head of the NCAA, etc. for consultations.

- The RDA Administrator shall, within 250 days from the receipt of an application for environmental risk review referred to above in Paragraph 2, scientifically review/investigate/analyze submitted review data (hereinafter referred to as "environmental risk review") to decide as to risks pertaining to introduction into the environment, and notify the applicant of the results as per Attachment 4-4 "Environmental Risk Review Notification for Agricultural LMO."

- In any of the following cases pertaining to environmental risk review referred to above in Paragraph 2, submission of additional data may be requested. In this case, the risk review period shall be the period required for supplementary submission added to the period of 270 days from the date of receipt:

  1. In the case that submissions do not meet the requirements for review data specified in Annex 10-1

  2. In the case that the Expert Review Committee referred to in Article 4-11 (hereinafter referred to as the "Expert Review Committee") decides that detailed test data should be reviewed due to suspected problems in review data

  3. In the case that scientific evidence negatively affecting environmental risks of the applicable agricultural LMO or data justifying suspicion are discovered after the preparation of review data.

- In any of the following cases with regard to an application for review, documents may be rejected:

  1. In the case that submitted data do not comply with these regulations

  2. In the case that risks to the domestic environment are suspected due to lack of safety and soundness, etc. or due to difficulty in verification

  3. In the case that a review is impossible due to inadequacy of supplementary data.

- To gather public opinions concerning environmental risk review, the RDA Administrator shall disclose information on the agricultural LMO for which an application for environmental risk review is filed for 30 days or longer on the Internet, in the official government gazette, etc. The scope and timing of information disclosure, however, may be restricted upon a recommendation from the Expert Review Committee.

- Upon receiving an application for environmental risk review referred to above in Paragraph 2, the RDA Administrator shall report application information to the MAF Minister within 10 days.

Article 4-9 (Review of stack event, etc.)

- A person who desires to apply for environmental risk review for stack event bred

through artificial breeding between LMOs approved through the environmental risk review process within the country shall submit an “Application for Environmental Risk Review for Stack event for Agricultural Use” as per Attachment 4-3 accompanied by required documents and each of the following:

1. Information necessary to determine whether there is any interaction occurred between traits on inserted nucleotides in the parental lines

2. Other available (collectible) information relating to characteristics of stack event

3. A comprehensive assessment based on information on parental organisms specified above in Subparagraphs 1 and 2

4. A certificate of the identity of variety and an agreement for the review of assessment data of approved LMO event, which are issued by the applicant of stack event or by the developer of LMO event with domestic approval for environmental risk assessment.

. Upon receiving an application for review for stack event referred to above in Paragraph 1, the RDA Administrator shall conduct environmental risk review within 90 days from the receipt, taking into account the likelihood of interactions between the organisms, anomalies, etc.; and notify the applicant of the review results as per Attachment 4-5 “Notification of Environmental Risk Review for stack event.”

. In the case that environmental risk review conducted pursuant to Paragraph 2 determines the presence of interactions and anomalies, the RDA Administrator shall perform environmental risk review on the applicable stack event according to the review procedures specified in Article 4-9.

Article 4-10 (Re-review)

. A person who desires to request for re-review in protest against the results of environmental risk review for an agricultural LMO shall submit a “Request for Re-review of Environmental Risks of Agricultural LMO” as per Attachment 4-7 to the RDA Administrator within 30 days from the date of the decision or within 15 days from becoming aware of the decision.

. Upon receiving a request for re-review referred to above in Paragraph 1, the RDA Administrator shall report to the MAF Minister and notify the applicant of the results within 90 days as per Attachment 4-4 “Environmental Risk Review Notification for Agricultural LMO.”

Article 4-11 (Expert Review Committee, etc.)

. To secure expertise with regard to environmental risk review for agricultural LMOs, approval of environmental release trials, and designation of environmental risk assessment agencies, the RDA shall have government official(s) responsible for reviews and set up and operate an expert review committee.

. The RDA Administrator shall appoint up to 30 review committee members among experts in the academia and the related fields for environmental risk review for LMOs, and form a committee consisting of up to 15 members with the expertise required to perform review for individual review applications.

. The review committee shall review each of the following:

1. Environmental risk submissions, submissions for approval of environmental release trials, submissions for designation as an environmental risk assessment agency submitted by applicants;

2. Adjustment of environmental risk review items;

3. Decision as to the necessity of field trials and on-site inspections;

A. In the case of LMOs for use as seed to be released into the environment, a review shall consider the results of field trial(s) within the country and if an additional field trial is deemed necessary, a decision shall be made as to the environmental risk assessment agency and items, and methods, etc. of the trial (microorganisms are excluded from field trials);

B. In the case of agricultural products in the original shape intended for use as food, feed, and for processing, a review shall consider environmental risk review data derived from field trial(s) in the country of development or export; and if a field trial within the country is deemed necessary, a decision shall be made as to the environmental risk assessment agency and items, methods, etc. of the trial.

4. Exemptions from the data provision for environmental risk assessment;

5. In the case that a re-review as referred to in Article 4-10;

6. The scope and timing of disclosure of submitted data;

7. Designation for risk assessment agencies and the revocation of its designation;

8. Other necessary matters which is requested by RDA administrator or chairman of advisory expert committee.

. A committee member shall not disclose confidential information obtained in the course of reviews, sign a confidentiality agreement and abide by the agreement.

. Allowances and travel expenses for committee members, election of the chair, and other specific matters necessary for the operation of the committee shall be specified by the RDA Administrator.

Article 4-12 (Designation, etc. of environmental risk assessment agencies)

. A person who desires to be designated as an environmental risk assessment agency for agricultural LMOs shall submit an “Application for Designation as Environmental Risk Assessment Agency as per Attachment 8 of the Ordinance accompanied by required documents to the RDA Administrator.

. Upon receiving an application referred to above in Paragraph 1, the RDA Administrator shall scientifically review submitted documents and the “Basic Personnel, Facilities and Equipment Requirements for Environmental Risk Assessment Agencies” in Annex 4-2 within 60 days, and, in the case of compliance, shall issue a “Certificate of Risk Assessment Agency Designation” as per Attachment 9 of the Ordinance to the applicant.

. In the case that a person is designated as a risk assessment agency pursuant to Paragraph 2, the RDA Administrator shall announce each of the following on the Internet, in the official government gazette, etc.:

1. The name/address of the risk assessment agency and the name of the representative thereof
2. Place of business (all places of business including the main office/regional offices and overseas offices, etc.)
3. Scope of risk assessment work
4. Designation date

. After an assessment agency referred to above in Paragraph 2 is designated, the RDA Administrator shall check every year whether the agency continues to meet the requirements as an assessment agency, and may revoke the designation in case of non-compliance which prevents the agency from properly performing its environmental risk assessment activities. In the case of a failure to take corrective actions by 60 days from the receipt of a corrective order, however, the designation as an assessment agency shall be revoked.

. The head of a risk assessment agency shall obtain prior approval on assessment items from the RDA Administrator, and, in the case that unapproved items are discovered, the designation of the assessment agency may be revoked pursuant to Paragraph 4.

. The RDA Administrator may establish and implement necessary matters pertaining to the requirements for risk assessment agency designation referred to above in Paragraph 2.

Section 3
Labeling and Handling

Article 4-13 (Labeling methods, etc.)

An exporter/importer, etc. of an agricultural LMO shall label the LMO as follows:

1. In the case that an agricultural LMO is imported as bulk commodity shipments on board a vessel or in a container, etc., labeling information specified in Article 24 of the Decree shall be stated on the letter of credit (L/C) or the commercial invoice, and, for distribution on the domestic market, the information shall be stated on individual containers/packages as specified below in Subparagraph 2.

2. If an agricultural LMO is imported in a packaged form in jute bags, plastic bags, cans, etc., labeling information shall be stated on the surface of the packaging materials pursuant to Article 24 of the Decree. In this case, labeling information shall be stated using easy-to-read typefaces for final purchasers at an easy-to-find location in a manner that the information is not erasable or detachable, and the type sizes shall be conspicuous and prominent enough for purchasers. In addition, labeling information shall be stated in the Korean language, and if deemed necessary, the name of the LMO, etc. may be additionally stated in the original or English language.

3. In the case that an agricultural LMO is transported as a bulk commodity within the country, labeling information specified in Article 24 of the Decree may be stated on the transport documents, etc.

Article 4-14 (Handling/controlling standards, etc. for export/import, etc.)

. The handling/controlling standards, etc. for agricultural LMOs referred to in Article 25 Paragraph 2 of the Act shall be as follows:

1. A production operation shall meet each of the following requirements for production operation facilities:

A. Signs identifying the production operation facilities and bearing warnings against unauthorized access, etc.
B. Containment facilities such as washing facilities for machinery used in the production operation to prevent unintentional movement of genetically modified crops out of the production operation
C. In the case there is a concern over pollen drift over a wide area from LMOs for use as feed, environmental containment facilities such as windbreak forests, windscreen, etc. to reduce pollen drift.

2. The controlling methods for production operations shall be pursuant to the methods specified by activity type in Annex 4-3 applicable to the agricultural LMO in question.

3. General handling/controlling

A. Cautions shall be taken during the harvesting, packaging, loading, processing, etc. of an agricultural LMO to prevent unintentional commingling with conventional agricultural products.

B. At a place where an agricultural LMO is handled, sign cards and frames, information panels, placards, etc. shall be placed in a conspicuous location so as to ensure that relevant personnel be aware of the presence of the LMO.

C. If an LMO is stored in a packaged form, cautions shall be taken to ensure that the packaging material not be damaged.

D. If an LMO is stored in a non-packaged form, specific facilities, structure, etc. shall be used to prevent environmental release.

E. If an agricultural LMO is transported in a packaged form, cautions shall be taken to prevent the content of the package from being leaked out or otherwise exposed due to damage or defect of the packaging material.

F. If an agricultural LMO is transported in a non-packaged form, grain-tight special grain transport vehicles, conveyor belts, or other facilities and structures (hereinafter referred to as “grain-tight facilities”) shall be used to prevent unintentional environmental release of the LMO.

G. Once an LMO for use as feed is harvested from a production operation, plants or products thereof obtained from cultivation shall be inactivated.

. A person who was received import/export, etc. approval for an agricultural LMO shall report the actual results of import/export and business before 15th of next month every quarter to the head of the competent NAQS regional/branch office in the case of an LMO for use as feed; and to the NSMO Director in the case of an LMO for use as seed.

. If an agricultural LMO is released into the environment due to damage to grain-tight facilities, etc. the exporter/importer, etc. of the LMO shall report to the head of the competent NAQS regional/branch office in the case of an LMO for use as feed; and to the NSMO Director in the case of an LMO for use as seed.

. Upon receiving a report referred to above in Paragraph 2, the head of the NAQS regional/branch office and the NSMO Director shall ensure that the exporter/importer, etc. of the LMO take necessary actions including the recovery of the LMO, check the site, and report the results to the MAF Minister.

Article 4-15 (Handling/controlling personnel, etc.)

Personnel specializing in the handling/controlling of agricultural LMOs and management guidelines shall be as follows:

1. A handler of agricultural LMOs shall designate and manage specialized personnel including responsible persons or supervisors, etc. capable of meeting the handling/controlling standards referred to in Article 25 Paragraph 1 of the Decree using the form in Attachment 4-6 “LMO Controlling Personnel Designation Report.”

2. Specialized LMO personnel shall prepare agricultural LMO controlling records and other relevant documents, periodically check the controlling status, and take necessary corrective actions in case of non-compliance with safety control measures specified in this Notice.

3. Specialized LMO personnel shall be familiar with handling instructions and safety control measures for agricultural LMOs to prevent hazards, and provide education/training for related personnel.

Section 4
Reporting and Inspection, etc.

Article 4-16 (Applications for import inspection)

. A person who desires to import an agricultural LMO (importer or a representative thereof) shall apply for inspection by submitting an "Application for Import Inspection for Agricultural LMO" as per Attachment 4-8 to the head of the competent NPQS regional or branch office at the port of entry of the applicable product, and, if two or more products are imported, a "List of Plants Subject to Import Inspection" shall be attached as per Attachment 4-9. In a case referred to in Article 4-8, however, an application for import inspection may not be required.

. The provision above in Paragraph 1 notwithstanding, a person who desires to import a product specified in Annex 4-1 as a carryon may submit a carryon luggage item declaration specified by the Commissioner of the Korea Customs Service (KCS) or declare the product verbally instead of submitting an application for LMO import inspection in Attachment 4-8.

Article 4-17 (Import inspection at borders, etc.)

. If deemed necessary to verify whether an imported agricultural LMO accompanied by a certificate of import approval (notification) is an approved/notified product as declared in the certificate, the NPQS Director General may collect a sample from the applicable LMO and conduct inspection.

. In accordance with Article 36 of the Act, the NPQS Director General may, if deemed necessary with regard to an item subject to inspection specified in Annex 4-1 for which import approval is not obtained from the MAF Minister or a notification is not filed, get access to the applicable storage location, warehouse, vessel, vehicle or aircraft, etc. or question related persons; and collect a minimum amount of samples necessary for testing free of charge.

. Inspection of international mail referred to in Article 10 Paragraph 2 of the Act shall be conducted pursuant to Paragraphs 1 and 2 above *mutatis mutandis*.

. In the case that a verification certificate is submitted with regard to inspection specified above in Paragraphs 1 through 3 which is issued by an LMO verification agency of the government of the exporting country, an LMO verification agency recognized by the government of the exporting country, or a designated domestic verification agency, on-site and laboratory inspection, etc. may be exempted. As for a verification certificate issued by a designated domestic verification agency, however, exemption shall be applicable only when the sample for verification is collected by the NPQS Director General or a sample collection permit issued by the head of the competent Customs Office is attached, etc. to prove the representativeness of the sample.

. Specific matters pertaining to inspection of agricultural LMOs at borders including inspection applications, inspection procedures, inspection of labeling information before customs clearance, actions based on inspection findings, etc. shall be established and implemented by the NPQS Director General.

. Upon receiving a transit notification for an agricultural LMO in transit to another country of import pursuant to Article 21 of the Act, the MAF Minister may notify and have the

NPQS Director General verify the notification.

Article 4-18 (Actions based on import inspection results)

. In each of the following cases as determined by inspection results pursuant to Article 4-17, the NPQS Director General shall issue a “Certificate of Agricultural LMO Import Inspection.” Issuance of an import inspection certificate may not be required, however, if the fact that inspection is passed is notified electronically to the head of the competent Customs Office:

1. In the case that import approval is obtained from the MAF Minister or notification is filed pursuant to Articles 8 and 9 of the Act

2. In the case that an import notification is filed for an LMO announced pursuant to Article 15 Paragraph 3 of the Act as an LMO without risks

3. In the case that a product is confirmed as a non-LMO

4. In the case that the adventitious presence of an agricultural LMO detected is below the level specified in Article 4-8

5. In the case that the adventitious presence of an agricultural LMO exceeds the level specified in Article 4-8 but an import approval certificate is issued within the specified period and submitted.

. The NPQS Director General may require the submission of an import approval certificate pursuant to Paragraph 1 Subparagraph 5. In this case, the submission period shall be 15 days. In the case that submission is not made within the specified period, the NPQS Director General may again require that submission shall be made within 7 days.

. The proviso of Paragraph 1 notwithstanding, the NPQS Director General shall issue a certificate on request from a person who desires to import an LMO specified above in Paragraph 1 Subparagraph 1/2.

. In the case that an agricultural LMO without import approval obtained or notification filed is detected during inspection referred to above in Article 4-17, the NPQS Director General may order that the importer shall destroy, return, or take other actions for the applicable agricultural product, and report the results to the MAF Minister.

Article 4-19 (Approval for environmental release experiment such as field trial, etc.)

. A person who desires to conduct an environmental release experiment such as field trial, etc. shall notify the quarantine field specified in Attachment 4-11, “Notification for experimental quarantine field of an agricultural LMO” and submit Attachment 25, “Application for development/experiment approval of LMO” and Attachment 4-3, “Review of environmental release experiment of LMO”. Notification of quarantine field is available for the first time and re-notification shall be done in the case of a presence of change.

. Upon receiving an application pursuant to Paragraph 1, the RDA Administrator shall conduct a review scientifically and notify the applicant of the result with Attachment

26, “Approval for development/experiment of LMO”.

. In case that environmental release experiment such as field trial, etc. is conducted by development/experiment approval of an LMO, the experiment may be conducted specified in Attachment 4-4, “Requirements as an adequate place for environmental release experiment of an agricultural LMO” or in Attachment 4-5, “Management methods of an agricultural LMO”.

. The RDA Administrator may cancel the approval of experiment in the case that inadequate thing was appeared in the check-ups every year for a person who conduct the environmental release experiment pursuant to Paragraphs 2/3. In the case that the experiment was not amended even after 60 days from a revise order, the RDA Administrator shall revoke the approval.

. In the case that requirements need to conduct environmental release experiment such as field trial, etc of an agricultural LMO pursuant to Paragraph 1, the RDA Administrator may set the details.

Article 4-20 (Designation of port of entry, etc.)

. In the case that a port or airport of entry is designated pursuant to Article 11 Paragraph 1 of the Act, a person who desires to import an agricultural LMO shall do so through the designated place of entry.

. If deemed necessary, the NPQS Director General may request the MAF Minister to designate a port or airport of entry.

Article 4-21 (Disposal by destruction, etc.)

. The NAQS, NSMO and NPQS Director General may order the destruction/return, etc. of an agricultural LMO to an importer or representative thereof in any of the cases specified in Article 19 Paragraph 1 of the Act.

. In the case that an order of destruction/return, etc. is issued, the NAQS, NSMO and NPQS Director General shall make notification/report to the KCS Commissioner and the MAF Minister pursuant to Paragraph 1.

. In the case that an order of destruction/return, etc. is issued, the importer or representative thereof shall complete the destruction/return, etc. within 30 days from the order. However, In the case that disposal of LMO by destruction/return, etc. is not possible to do because of inevitable situations such as severe weather condition, the owner of LMO may request the extension of disposal period within 30 days to the head of regional/branch office and the head of the regional/branch office may extend the period on condition that the request is believed to be adequate.

. In the case that an order of destruction/return, etc. is issued specified in Paragraph 1, the NAQS, NSMO and NPQS Director General shall let a responsible public servant confirm the result.

. Destruction shall, in principle, be implemented by way of incineration. Crushing/heat application or other methods may be used instead which can completely eliminate the germination or propagation capabilities of an agricultural LMO.

. In the case that an agricultural LMO is returned, a billing of lading, etc. may be used as a proof of return.

Article 4-22 (Preparation/retention, etc. of related documents)

A person who is engaged in the export/import, etc. of an agricultural LMO shall prepare and keep LMO control records at the storage location or administrative office, etc. for the LMO as per Attachments 27/28/29/30 of the Ordinance.

Article 4-23 (Information sharing, etc.)

. The NAQS Director General may request the RDA Administrator for analytical information among environmental risk review data and standard materials to develop verification methods for agricultural LMOs.

. Upon receiving a request referred to above in Paragraph 1, the RDA Administrator shall provide the requested information and standard materials unless there are justifiable reasons not to do so.

. Once verification methods are developed for agricultural LMOs, the NAQS Director General shall provide relevant information for the NPQS and NSMO Director General, and may provide education on verification techniques for government officers responsible for verification activities.

Article 4-24 (Follow-up monitoring, etc.)

. The RDA Administrator and the NAQS, NSMO, and NPQS Director General may have responsible government officers of their respective agencies enter the applicable offices/establishments/storage locations, etc. and inspect the handling/controlling or other status including relevant documents or facilities/equipment and storage conditions, etc. for the purpose of safety control of agricultural LMOs in accordance with Article 36 of the Act.

. To prevent the use of agricultural LMOs with import/production approval for non-approved uses, the responsible agencies may conduct joint follow-up monitoring activities.

. During investigative processes referred to above in Paragraphs 1 and 2, necessary samples may be collected, and verification may be performed on samples. Specific matters pertaining to sample collection and verification methods may be established and implemented by the NAQS and NSMO Director General.

. Even after an agricultural LMO is approved through a notification of environmental risk review results pursuant to Articles 4-8 and 4-9, the RDA Administrator may conduct follow-up monitoring activities with regard to environmental risks of the agricultural LMO.

. Approval may be revoked in the case that new scientific information becomes available through follow-up monitoring activities referred to above in Paragraph 4 on the risks or potential risks of an approved LMO to the environment.

. The RDA Administrator, the NAQS, NSMO, and NPQS Director General may impose/collect penalties in each of the cases specified in Article 44 Paragraph 1 of the Act with regard to the safe handling/controlling, etc. of agricultural LMOs.

Article 4-25 (Detailed implementation guidelines, etc.)

. The NAQS and NSMO Director General shall establish detailed matters for the efficient implementation of this Notice, oversee the implementation of safety control measures by those who have obtained import or production approval for agricultural LMOs, and check whether handlers comply with the standards for handling/controlling.

. The NPQS Director General may establish and implement detailed implementation guidelines on inspection procedures, etc. for the effective and efficient implementation of this Notice.

Chapter 6
Approval for Import and Production, Risk Assessment, Labeling and Management of LMO Intended for Health/Medical Use

Section 1
Import/Production Approval

Article 6-1 (Applications, etc. for import/production approval)

. An application for import or production approval for an LMO intended for health/medical use referred to in Articles 8 and 12 of the Act shall be filed in the following manner:

1. A person who desires to obtain import or production approval for an LMO for health/medical use shall apply to the KFDA Commissioner with an application and documentation as per Attachment 5/6/7 and 13/14/15 of the Ordinance. The data for human health risk assessment of food LMO may be replaced by the documents specified in Article 15 of the Food Sanitation Act or regulations on LMO safety assessment, etc.

2. A person who desires to request for re-review pursuant to Article 18 of the Act shall submit a "Request for Re-review" as per Attachment **19** of the Ordinance accompanied by documents evidencing the reasons for re-review request to the KFDA Commissioner.

. The requirements for submissions referred to above in Paragraph 1 shall be as follows:

1. Documents may be submitted by the importer or producer (manufacturer) of the applicable LMO for health/medical use or a representative thereof.

2. All submissions shall, in principle, be prepared in Korean. If necessary, however, the name of the LMO, etc. may be stated in the original or English language.

3. In the case that an application is to be filed for environmental risk assessment referred to in Article 13 Paragraph 1 of the Act, risk related data, etc. required by consultation agencies shall be attached.

. In the case that an application is to be filed for continued import of the same LMO as an LMO for use as food which has completed safety assessment review referred to in Article 15 of the Food Sanitation Act and environmental risk review referred to in Article 13 Paragraph 1 of the Act, the risk assessment report and related documents may not be required.

Article 6-2 (Processing of applications, etc.)

. Upon receiving an application and required documents referred to above in Article 6-1 Paragraph 1, the KFDA Commissioner shall decide as to approval from the receipt of an application, and notify the applicant of the decision as per the criteria or procedure of the Decree and Section 2 (Article 6-3 through 6-8). Review of risks to human health of LMOs for food use, however, shall be pursuant to the "Regulations on Review, etc. of Safety Assessments of Genetically Modified Foods" established pursuant to Article 15 of the Food Sanitation Act.

- In the case of an application requiring environmental risk review under Article 13 Paragraph 1 of the Act, the KFDA Commissioner shall request the head of the NCAA, etc. for consultations pursuant to the consultative procedures specified in Article 1-5 within 30 days.

- The KFDA Commissioner may request for submission of additional data in the case of an incomplete application, and submission of additional data and rejection of applications shall be pursuant to the "Act on Processing of Civil Applications"

- If deemed necessary for the verification of applications, the KFDA Commissioner may have responsible government officers conduct on-site verification (the presence of the applicant or a representative thereof may be possible), etc.

- The KFDA Commissioner shall report import or production approval results to the MOHW Minister as per Attachment 6-1 every quarter.

Section 2
Human Health Risk Assessment and Review

Article 6-3 (Receipt of applications)

- A person who desires to import or produce an LMO for health/medical use may apply for the risk assessment before applying for import/production approval pursuant to Article 5 Paragraph 2 Subparagraph 1 of the Decree.

- A person who desires to import or produce an LMO for health/medical use (hereinafter in Chapter 6 referred to as an "applicant") shall submit an request as per Attachment 6-2 (including a request in an electronic format) accompanied by each of the following documents (including electronic documents) to the Commissioner of the Korea Food and Drug Administration (hereinafter referred to as the "KFDA Commissioner") for review of risks to human health of the LMO:

  1. The Risk Assessment Submission Table as per Attachment 10-1 (hereinafter in this Chapter referred to as "assessment data")

  2. An executive summary (summary of key points)and human health risk assessment report containing risk assessment data specified in Annex 10-1

- When review data are submitted, data on analytical information enabling the identification of the assessed product and standard materials shall also be submitted.

Article 6-4 (the requirements of submitted data)

- Data for submission shall be any of the following:

  1. Data published in professional journals

  2. Data derived from tests conducted according to the Good Laboratory Practice (GLP) standards

  3. Data derived from tests conducted by domestic/overseas professional institutions

including universities or research institutions, etc., issued by the head of such an institution (in this case, an overview of test facilities, major equipment, composition of research personnel, credentials of researchers, etc. shall be described), and recognizable as appropriate through review

4. Assessment data submitted at the time of risk review in other countries for the applicable LMO. In this case, data certifying that safety is approved by the government of the country shall be attached.

Article 6-5 (Review methods)

. Upon receiving a request for review of risks to human health of an LMO referred to in Articles 5 and 13, the KFDA Commissioner may decide as to human health risks, taking into account opinions from the Expert Review Committee on Human Health Risks referred to in Article 10 (hereinafter in Chapter 6 referred to as the “Committee”).

. If deemed necessary for review of submissions, the KFDA Commissioner may require explanation from the applicant or conduct on-site investigation, etc.

Article 6-6 (Composition and operation of the Committee)

. The Committee shall be set up at the KFDA to provide advice on human health risk review for the KFDA Commissioner.

. The Committee shall provide advice on the following for the KFDA Commissioner:

1. Review of assessment data

2. Other necessary matters for human health risk review.

. The Committee shall consist of up to 15 members including the chair and the vice chair.

. The Chair shall be appointed by the KFDA Commissioner among the Committee members, and the Vice Chair shall be appointed by the Chair among the Committee members.

. Committee members shall be appointed by the KFDA Commissioner among those who majored in molecular biology, microbiology, toxicology, immunology, biotechnology, pharmacology, or medicine, etc. and meet each of the following qualifications:

1. A person who is an assistant professor or holds a higher rank at a college/university referred to in the Higher Education Act or used to be so for at least 3 years

2. A person recommended by the relevant academic society or national/public research institution in the fields of biology, biotechnology, pharmacology, or medicine, etc.

. A Committee member shall be appointed to a two-year term and may be reappointed. A new member appointed to fill a vacancy, however, shall serve for the remainder of the term for which his/her predecessor is appointed.

. The Chair shall represent the Committee and be responsible for overall business of the Committee.

. The Vice Chair shall assist the Chair and act for the Chair when the Chair is unable to carry out the responsibilities in inevitable circumstances.

. A Committee member shall not disclose confidential information obtained in the course of or by reason of his/her membership on the Committee.

. Committee members may be paid allowances and travel expenses for their attendances at Committee meetings within the budget.

. The Committee may appoint a manager for paperwork and the manager shall make a record the content of Committee meeting and set aside the related data.

Article 6-7 (Submission of supplementary data, etc.)

. In each of the following cases, the KFDA Commissioner may require that the applicant submit additional data.

1. In the case that submissions are inadequate

2. In the case that assessment data have problems requiring the review of detailed data.

. In the case that any of the following is applicable to a request for review, the KFDA Commissioner may return the documents:

4. In the case that submitted data do not comply with these regulations

5. In the case that risks to human health are suspected due to lack of safety and soundness, etc. or due to difficulty in verification

6. In the case that an applicant fails to submit supplementary data within the period specified above in Paragraphs 2 and 3.

Article 6-8 (Notification of review results, etc.)

The KFDA Commissioner shall, within 250 days from the receipt of an application, complete review and issue a notification to the applicant as per Attachment 6-3. In the case of non-compliance and rejection, a description of reasons for rejection shall be attached to the notification.

Article 6-9 (Designation of risk assessment agencies)

. A person who desires to be designated as a human health risk assessment agency for LMOs for health/medical use pursuant to Article 8 Paragraph 4 of the Act shall submit an “Application for Risk Assessment Agency Designation” accompanied by required documents to the KFDA Commissioner pursuant to Article 10 of the Decree.

. Upon receiving an application for designation as a human health risk assessment agency for LMOs for health/medical use pursuant to Paragraph 1, the KFDA Commissioner shall issue a “Certificate of Risk Assessment Agency Designation” or notify the reasons for rejection after making a decision as to the designation within 60 days. In this case, the requirements for manpower/facilities/equipments of risk assessment agencies are

specified in Attachment 6-1.

. The KFDA Commissioner shall monitor every year whether a designated agency continues to meet the requirements as an assessment agency, and may revoke the designation in the case of non-compliance which prevents the agency from adequately performing its human health risk assessment activities as the risk assessment agency specified in Article 8 paragraph 4 of the Act.

. The KFDA Commissioner shall announce the following information on the Internet and in the official government gazette in the case of risk assessment agency designation or revocation of designation referred to above in Paragraphs 2 and 3:

. A person designated as a risk assessment agency pursuant to Paragraph 2 shall report risk assessment results to the KFDA Commissioner every quarter.

Section 3
Labeling and Handling

Article 6-10(Labeling)

. The labeling methods for LMOs for health/medical use referred to in Article 24 Paragraph 3 of the Act shall be as follows:

4. In the case that an LMO for health/medical use is imported as bulk commodity shipments on board a vessel or in a container, etc., labeling information shall be stated on the letter of credit (L/C) or the commercial invoice, and before being placed on the domestic market, the information shall be stated on individual containers/packages as specified below in Section 2.

5. If an LMO for health/medical use is imported in a packaged form in jute bags, plastic bags, cans, etc., labeling information shall be stated on the surface of the packaging materials. In this case, labeling information shall be stated using easy-to-read typefaces for final purchasers at an easy-to-find location in a manner that the information is not erasable or detachable, and the type sizes shall be conspicuous and prominent enough for purchasers. In addition, labeling information shall be stated in the Korean language, and if deemed necessary, the name of the LMO, etc. may be stated in the original or English language.

6. In the case that an LMO for health/medical use is placed on the market as a bulk commodity within the country, labeling information shall be stated on transport documents, etc.

7. Information pertaining to the developer, producer, exporter and importer may be stated in the language of the country of export (producing country) of the product.

. With regard to detailed matters not specified in these Regulations including exemption from the labeling requirement for LMOs for health/medical use and adventitious presence referred to in Article 5 Paragraph 5 of the Decree, the regulations on the labeling of genetically modified agricultural products pursuant to Article 16 of the “Agricultural Products Quality Management Act” shall apply *mutatis mutandis*.

Article 6-11 (Handling/controlling)

. In accordance with Article 25 Paragraph 2 of the Act, exporters/importers, etc. of LMOs for health/medical use shall comply with the following standards for handling/controlling:

1. Dedicated personnel or supervisors capable of handling/controlling LMOs (hereinafter referred to as "LMO personnel") shall be designated/managed using the "LMO Controlling Personnel Designation Report" in Attachment 4-6.

2. The packaging, storage, loading, transport, etc. of LMOs shall be conducted with necessary facilities and equipment in place to prevent the commingling and adventitious presence of LMOs in non-LMOs.

3. At a place where LMOs are handled, signs, information panels, placards, etc. shall be installed at a conspicuous location so as to ensure that related personnel be aware of the presence of LMOs.

4. In the case that LMOs are stored/transported in packaged forms, cautions shall be taken to prevent the content of a package from being leaked or exposed due to damage or defect of the packaging material.

5. In the case that LMOs are stored in unpackaged forms, specific facilities and structure, etc. shall be used to prevent leakage and exposure.

6. In the case that LMOs are transported in unpackaged forms, grain-tight special grain transport vehicles, conveyor belts, or other facilities and structures (hereinafter referred to as "preventive facilities") shall be used to prevent unintentional environmental release of the LMOs.

. The responsibilities of LMO personnel referred to above in Paragraph 1 Subparagraph 1 shall be as follows:

1. LMO personnel shall prepare relevant documents including control records for LMOs for health/medical use, periodically check the controlling status, and take necessary corrective actions in case of non-compliance with safety control measures specified in these Regulations.

2. LMO personnel shall maintain/control handling/controlling facilities for LMOs for health/medical use appropriately so as to ensure the intended performance of such facilities.

3. LMO personnel shall be familiar with safety control measures and train/educate relevant personnel if handling instructions and hazard prevention measures are required for the handling of LMOs for health/medical use.

. The exporter/importer, etc. of LMOs for health/medical use shall promptly report to the head of the regional KFDA and the National Quarantine Station in the case that an LMO for health/medical use is released into the environment due to the damage to preventive facilities, etc.

. Upon receiving a report referred to above in Paragraph 3, the head of the regional KFDA and the NQS shall ensure that the export/importer of the LMO take necessary actions

including the recovery of the LMO, check the site, and report the results to the KFDA Commissioner.

Section 4
Reporting and Inspection, etc.

Article 6-12 (Procedures and methods, etc. of import inspection during customs clearance)

. At the time of import notification referred to in Article 16 Paragraph 1 of the Food Sanitation Act (FSA), a person who desires to import an LMO for use as food (importer or a representative thereof) shall submit an import notification accompanied by the "Certificate of Import Approval" and relevant documents to the head of the competent regional KFDA or the National Quarantine Station (hereinafter referred to as the "head of the regional KFDA" or "head of the NQS") at customs.

. The inspection, etc. on notified LMOs for use as food pursuant to Paragraph 1 by the head of the regional KFDA or NQS shall be referred to in this Chapter and Article 16 of the Food Sanitation Act (FSA).

. Upon receiving a notice/notification concerning an LMO for use as food and imported by mail referred to in Article 10 Paragraph 1 of the Act, the head of the regional KFDA or NQS shall conduct inspection on the applicable international mail, and, within 10 days, take necessary actions such as disposal by destruction/return, etc.

. With regard to methods or procedures of import inspection during customs clearance of the rest of LMO intended for health/medical use, the KFDA commissioner shall prescribe mutatis mutandis.

Article 6-13 (Inspection of samples, etc.)

. If deemed necessary to verify whether an imported LMO for health/medical use accompanied by a certificate of import approval (notification) is an approved/notified product as declared in the certificate, the head of the regional KFDA or NQS may collect a sample from the applicable LMO free of charge and conduct inspection on the sample in accordance with Article 36 of the Act.

Article 6-14 (Disposal by destruction, etc.)

- The head of the regional KFDA or NQS may issue an order of disposal by destruction/return, etc. within 30 days as per Attachment 6-4 to the owner of an LMO for health/medical use specified in Article 19 Paragraph 1 of the Act.

- In the case that disposal of LMO by destruction/return, etc. is not possible to do because of inevitable situations such as severe weather condition in spite of Paragraph 1, the owner of an LMO may request the extension of disposal period within 30 days and the head of the regional KFDA or NQS may extend the period on condition that the request is adequate.

- In the case that an order of destruction/return, etc. is issued pursuant to Paragraph 1, the head of the regional KFDA or NQS shall promptly make notification/report to the KCS Commissioner (only in the case of imported LMOs) and the KFDA Commissioner.

- Destruction shall, in principle, be implemented by way of incineration. Crushing/heat application or other methods may be used instead which can completely eliminate the germination or propagation (reproductive) capabilities of an LMO for health/medical use.

Article 6-15 (Preparation/retention of related documents)

- In accordance with Article 26 of the Act, a person who is engaged in the export/import, etc. of a LMO for health/medical use shall prepare and keep LMO control records at the storage location or administrative office, etc. for the LMO.

- A person who is engaged in the export/import, etc. of a LMO for health/medical use pursuant to Paragraph 1 shall notify the KFDA Commissioner of the actual results of production/import/business of an LMO for health/medical use before 15th of next month every quarter.

- Upon request from responsible government officers pursuant to Article 36 of the Act, such documents shall be presented.

Article 6-16 (Emergency measures for hazard prevention, etc.)

- In the case that an exporter/importer, etc. of an LMO for health/medical use becomes aware of adverse effects of an LMO for health/medical use, s/he shall promptly report the information to the KFDA Commissioner pursuant to Article 27 Paragraph 2 of the Act.

- In the case that a report is given pursuant to Paragraph 1 or any of the following is applicable to a request for review, the head of the KFDA may conduct the review in virtue of his or her authority.

- The head of the KFDA Commissioner may request the relevant information from the engaged person or applicant of the LMO in the case of a review pursuant to Paragraph 2.

- After the head of the KFDA Commissioner complete the assessment, s/he shall notify the applicant of the result.

Article 6-17 (Detailed guidelines, etc.)

The KFDA Commissioner shall establish detailed guidelines for the efficient implementation of this centralized Notice, and oversee the implementation of safety control measures by those who have obtained import or production approval for LMOs for health/medical use, and check whether handlers comply with the standards for handling/controlling.

Chapter 10
Risk Review Consultations

Section 1
Consultations on Human Health Risk Review

Article 10-1 (Scope of review consultations)

The regulations in this Chapter shall apply to review consultations on human health risks of all imported or produced LMOs (including stacks). The consultation pursuant to Article 13 of the Act shall not be applied to LMOs which fall under any of the following categories.

1. LMOs imported solely for test/research use or for fair/exhibition use pursuant to Article 9 Paragraph 1 of the Act

2. LMOs intended for health/medical use

Article 10-2 (Request for review consultations)

. In the case that the head of the National Competent Administrative Authority (NCAA), etc. is to request for human health risk review consultations for an LMO, s/he shall request the KCDC Director General for review within 30 days from the receipt of an application for LMO import approval, production approval or risk review referred to in Article 5 Paragraph 2 Subparagraph 1 of the Decree (hereinafter in Chapter 10 referred to as “risk review”).

. In the case that the head of the NCAA, etc. is to request for LMO human health risk review pursuant to Paragraph 1, a request as per Attachment 10-2 (including a request in an electronic format) shall be submitted accompanied by each of the following documents:

1. Risk assessment submission table as per Attachment 10-1

2. Risk assessment report containing a summary in Korean (a summary of key points) and risk assessment data specified in Attachment 10-1 (hereinafter in this Chapter referred to as “assessment data”).

3. Analytical data or standard materials for specific detection of the LMO specified in Attachment 10-1.

Article 10-3 (Submission requirements)

. Submissions shall be in the order of appearance in Annex 10-1, and indexed and paginated. In the case that submissions are exempted pursuant to Article 10-4 Paragraph 1, the reasons shall be described in detail.

. Assessment data shall be any of the following:

5. Data published in professional journals
6. Data derived from tests conducted according to the Good Laboratory Practice (GLP)

standards

7. Data derived from tests conducted by domestic/overseas professional institutions including universities or research institutions, etc., issued by the head of such an institution (in this case, an overview of test facilities, major equipment, composition of research personnel, credentials of researchers, etc. shall be described), and recognizable as appropriate through review

8. Assessment data submitted at the time of risk review in other countries for the applicable LMO. In this case, data certifying that safety is approved by the government of the country shall be attached.

Article 10-4 (Exemption of submissions, etc.)

. The provision above in Article 10-2 Paragraph 2 notwithstanding, stacks meeting all of the following criteria may be exempt from the submission of the documents specified in Article 10-2 Paragraph 2, provided that data be submitted evidencing that all criteria are met:

1. Stacks without changes in introduced traits
2. Stacks which do not breed with other species
3. Stacks without changes in biochemical metabolism.

. Notwithstanding Annex 10-1, if it is recognized that the preparation of a submission is theoretically/technically impossible or is meaningless even if it is possible, the applicable submission may be exempted.

. A person who desires to apply for import approval, production approval or risk review (hereinafter in Chapter 10 referred to as an “applicant”) may request the KCDC Director General for a prior meeting concerning the scope of assessment submissions, etc. or for an opportunity to explain the prepared data.

Article 10-5 (Review methods)

. Upon receiving a request for review of risks to human health of an LMO referred to in Article 10-2, the KCDC Director General may decide as to human health risks, taking into account opinions from the Advisory Committee on Human Health Risk Assessments referred to in Article 10-6 (hereinafter in Chapter 10 referred to as the “Committee”).

. If deemed necessary for review of submissions, the KCDC Director General may require explanation from the applicant or conduct on-site investigation, etc.

Article 10-6 (Composition/operation of the Advisory Committee on Human Health Risk Assessments)

. The Committee shall be set up at the KCDC to provide advice on human health risk review for the KCDC Director General.

. The Committee shall provide advice on the following for the KCDC Director General:

3. Review of assessment data

4. Other necessary matters for human health risk review.

. The Committee shall consist of up to 15 members including the chair and the vice chair.

. The Chair shall be appointed by the KCDC Director General among the Committee members, and the Vice Chair shall be appointed by the Chair among the Committee members.

. Committee members shall be appointed by the KCDC Director General among those who majored in molecular biology, microbiology, toxicology, immunology, biotechnology, pharmacology, or medicine, etc. and meet each of the following qualifications:

3. A person who is an assistant professor or holds a higher rank at a college/university referred to in the Higher Education Act or used to be so for at least 3 years

4. A person recommended by the relevant academic society or national/public research institution in the fields of biology, biotechnology, pharmacology, or medicine, etc.

. A Committee member shall be appointed to a two-year term and may be reappointed. A new member appointed to fill a vacancy, however, shall serve for the remainder of the term for which his/her predecessor is appointed.

. The Chair shall represent the Committee and be responsible for overall business of the Committee.

. The Vice Chair shall assist the Chair and act for the Chair when the Chair is unable to carry out the responsibilities in inevitable circumstances.

. A Committee member shall not disclose confidential information obtained in the course of or by reason of his/her membership on the Committee.

21 Committee members may be paid allowances and travel expenses for their attendances at Committee meetings within the budget.

Article 10-7 (Submission of supplementary data, etc.)

. In each of the following cases, the KCDC Director General may specify a period not exceeding 105 days and require that the applicant submit additional data within the period. In this case, the KCDC Director General shall notify the head of the NCAA, etc. of the fact that supplementary submission is required:

3. In the case that submissions do not meet the requirements specified in Articles 10-2 through 10-4 and Annex 10-1

4. In the case that assessment data have problems requiring the review of detailed data.

. In the case that additional data are not submitted within the period specified above in Paragraph 1, the KCDC Director General shall again require the submission of supplementary data and notify the head of the NCAA, etc. of the fact. In this case, the supplementary submission period shall be 10 days.

. The provisions above in Paragraphs 1 and 2 notwithstanding, in the case that the applicant requests for an extension of the period specifying the period required, the KCDC Director General shall decide on the supplementary submission period, taking into account the reasons for extension, and, if the period is extended, notify the head of the NCAA, etc. of the extension.

. In each of the following cases, the KCDC Director General may return the application of review to the head of the NCAA, etc., stating the reasons for return...

A. In the case that the submitted supplementary data do not meet the standards specified in Article 10-2 Paragraph 2 or Article 10-3 Paragraph 2.
B. In the case that an applicant fails to submit supplementary data within the period specified above in Paragraphs 2 and 3.

Article 10-8 (Notification of review results, etc.)

. The KCDC Director General shall, within 210 days from the receipt of a review request, complete review and issue a notification as per Attachment 10-3 to the head of the NCAA, etc. In this case, the period of preparing supplementary data does not be included in the period of review.

Article 10-9 (Re-review)

. In the case that the head of the NCAA, etc. is to request for re-review with regard to LMO human health risk review results upon receiving a request for re-review referred to in Article 18 of the Act, the head of the NCAA, etc. shall submit a description of reasons for re-review request accompanied by supporting documents (including electronic documents) to the KCDC Director General within 10 days from the receipt of a request for review.

. Upon receiving a request for re-review referred to above in Paragraph 1, the KCDC Director General shall, within 60 days, perform re-review on matters specified for re-review in the request pursuant to Article 10-5 *mutatis mutandis* and issue a notification as per Attachment 10-3 to the head of the NCAA, etc.

Article 10-10 (Follow-up monitoring)

. Pursuant to Article 27 Paragraph 2 of the Act, in the case that new information pertaining to risks to human health of a reviewed LMO has become available, the exporter/importer, etc. of the LMO or the applicant shall report such information to the KCDC Director General.

. In the case that a report referred to above in Paragraph 1 is made concerning matters reviewed pursuant to these Regulations or that any of the following is applicable, the KCDC Director General may perform review by virtue of his/her office. In this case, review methods shall be pursuant to Article 10-5 *mutatis mutandis*:

1. In the case of an occurrence which may affect human health risk review results

2. In the case that new scientific or technical information has become available.

. To perform review referred to above in Paragraph 2, the KCDC Director General may request the exporter/importer, etc. of the applicable LMO or the applicant for submission of relevant data.

. In the case that review referred to above in Paragraph 2 is performed, the KCDC Director General shall notify the head of the NCAA, etc. of the results.

Section 2
Environmental Risk Review Consultations

Article 10-11 (Request for review consultations)

. In the case that the head of the NCAA, etc. is to have consultations with regard to environmental risk review for an LMO pursuant to Article 15 Paragraph 1, s/he shall request the head of the Chief of the National Environmental Research Institute(NERI), the RDA Administrator, and the Chief of the National Fisheries Research and Development Institute(NFRDI) (hereinafter referred to as the "head of the consultative agency") for review consultations specified in Attachment 10-4 within 30 days from the receipt of an application for risk assessment and notify the applicant of the fact.

. The head of the NCAA, etc. may require a prior consultation to the head of the consultative agency on need for consultation, procedure, and scope of data submission after judging whether it is possible to be released to environment.

Article 10-12 (Period of review, etc.)

. The head of the consultative agency shall, within 210 days, complete review and issue a notification as per Attachment 10-5 to the head of the NCAA, etc.

. If deemed necessary for environmental risk review, the KFDA Commissioner may require explanation from the applicant or conduct on-site investigation, etc.

Article 10-13 (Submission of supplementary data, etc.)

. The head of the consultative agency may require supplementary data from the applicant in the case of any of the following...

1. In the case that submitted data was not adequate specified in Attachment 10-1
2. In case that it is necessary to conduct a review in detail due to the fault in assessment data.
3. In case that scientific evidences proved to be doubtful are newly appeared.

. In the case that the applicant do not submit the supplementary data within the period specified in Paragraph 1, the head of the consultative agency may require the supplementary data from the applicant again. The period of submission of supplementary data is within 10 days.

. In the case that the applicant requests an extension for supplementary data in spite of

Paragraphs 1/2, the head of the consultative agency may set the period of extension after considering the reasons.

. The period of submission of supplementary data specified in Paragraph 1 through 3 does not be applied to the period of review pursuant to Article 10-12 Paragraph 1.

. Upon requesting supplementary data to the applicant, the head of the consultative agency shall notify the head of the NCAA, etc. of the fact.

. In case that the applicant did not submit the supplementary data within the period specified in Paragraph 1 through 3, the head of the consultative agency may return the application for review of risk assessment to the head of the NCAA, etc. with the reasons for return.

Article 10-14 (Re-review)

. Upon receiving a request for re-review referred to above in Article 18 of the Act, the head of the NCAA, etc. shall submit ,within 10 days from the day requested, reasons for re-review and verification documents (include electric format) to the head of the consultative agency.

. In the case that an re-review is filed pursuant to Paragraph 1, the head of the consultative agency shall, within 60 days, complete the review and notify the head of the NCAA, etc. of the result.

Addenda

. This Notice shall take effect on the date of entry into force of the “Act on Transboundary Movements, etc. of Living Modified Organisms.”

. The “Guidelines for Review of Environmental Risk Assessments for Genetically Modified Agricultural Products” (MAF Notice #2002-2) shall be abolished with the establishment by the MOCIE Minister of the integrated (centralized) notice containing regulations on matters pertaining to environmental risk review of agricultural LMOs.

[Annex 1-1]

Information Specified in Annex I to the Protocol

(A) Name, address and contact details of the exporter.

(B) Name, address and contact details of the importer.

(C) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(D) Intended date or dates of the transboundary movement, if known.

(E) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(F) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(G) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(H) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(I) Intended use of the living modified organism or products thereof (processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology).

(J) Quantity or volume of the living modified organism to be transferred.

(K) A previous and existing risk assessment report consistent with Annex III.

(L) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(M) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(N) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(O) A declaration that the above-mentioned information is factually correct.

[Annex 1-2]

Information Specified in Annex II to the Protocol

(A) The name and contact details of the applicant for a decision for domestic use.

(B) The name and contact details of the authority responsible for the decision.

(C) Name and identity of the living modified organism.

(D) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(E) Any unique identification of the living modified organism.

(F) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(G) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(H) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(I) Approved uses of the living modified organism.

(J) A risk assessment report consistent with Annex III.

(K) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

[Annex 3-3]

**Information Required in the Documents
Regarding the Name/Characteristics and Uses of the LMO
(Related to Article 3-1 Paragraph 2 Section 4)**

1. Name of the LMO

2. Characteristics of the LMO

A. Modern biotechnology used for the genetic modification

B. Trait(s) derived from inserted gene(s)

C. Functions and characteristics of inserted gene(s) (if applicable)

(1) In the case of an LMO referred to in Article 3-1 Paragraph 1 Subparagraph 1: functions, characteristics and risk potential of the inserted gene(s)

(2) In the case of an LMO referred to in Article 3-1 Paragraph 1 Subparagraph 2: toxicity values, applicable scope, and physiochemical characteristics of toxins produced by the inserted gene(s)

(3) In the case of an LMO referred to in Article 3-1 Paragraph 1 Subparagraph 3: antibiotics whose sensitivity is reduced due to the expression of the inserted gene(s) and types of antibiotics subject to cross-resistance, therapeutic uses and the frequency of use of such antibiotics

(4) In the case of an LMO referred to in Article 3-1 Paragraph 1 Subparagraph 4: disease(s) caused by the inserted gene(s), susceptible population, and infectivity data (route of transmission, etc.)

D. Differences in biological characteristics from the host or its relative(s)

E. Pathogenicity, toxogenicity, allergenicity and capability of generating other harmful physiologically active substances

F. The site(s) and number of copies of the inserted gene(s) within the LMO

G. Expression level of the protein(s) encoded by the inserted gene(s) and measurement methods

H. The presence of the vector used during genetic modification and methods for its elimination

I. Detection and verification methods

J. Name, taxonomic classification and pathogenicity, toxogenicity, allergenicity, and other biological characteristics of the host

K. Name, taxonomic classification and pathogenicity, toxogenicity, allergenicity and other biological characteristics of the donor

3. Uses of the LMO

   A. Key uses

   B. Countries where its use is authorized, and authorized uses

[Annex 4-1]

List of Agricultural LMOs Subject to Inspection at Borders

Products	Scientific name
Soybean	*Glycine max*
Lentil	*Lens culinaris*
Maize	*Zea mays*
Cotton	*Gossypium hirsutum*
Canola	*Brassica napus* *Brassica rapa*
Potato	*Solanum tuberosum*
Tobacco	*Nicotiana tabacum*
Melon	*Cucumis melo*
Wheat	*Triticum aestivum*
Rice	*Oryza sativa*
Sugar beet	*Beta vulgaris*
Flax	*Linum usitatissimum L.*
Alfalfa	*Medicago sativa*
Creeping bentgrass	*Agrostis stolonifera*
Chicory	*Chichorium intybus*
Carnation	*Dianthus caryophyllus*
Tomato	*Lycopersicon esculentum*
Papaya	*Carica papaya*
Sunflower	*Helianthus annuus*
Squash	*Cucurbita pepo*

* The list consists of agricultural LMOs which are or have the potential of being placed on the market after development/approval and have the potential for introduction into the environment in the original shape when imported for use as seed or feed.

<Sources>

- BCH LMO Database (http://bch.biodiv.org/organisms/defaults.html)
- OECD Biotech Database (http://webdomino1.oecd.org/ehs/bioprod.nsf)
- Agbios GM Database (http://www.agbios.com/dbase.php)

[Annex 4-3]

Review Submissions for Environmental Release Trials of Agricultural LMOs

1. Name of the agricultural LMO (scientific name, common name, variety/line, etc.)
2. Purpose of the environmental release trial
3. Name of the donor organism (scientific name, common name, variety/line, etc.) 4. Vector A. Name and source (GenBank Accession No., etc.) B. Vector structure (1) Molecular weight of the DNA and restriction map (2) Types and characteristics of selectable markers 5. Inserted gene(s) A. Name and source (GenBank Accession No., etc.) B. Sequence of the inserted gene(s) and modifications 6. Characteristics of the agricultural LMO A. Introduced traits B. Gene introduction methods and breeding methods
7. Trial plan A. Duration B. Description of the trial (1) Scale (area) of the trial (2) Methods and intended research items
8. Safety control measures A. Transferability of inserted gene(s) and measures for prevention thereof B. Seed harvesting and controlling measures C. Measures for disposal of waste/residues from field trial

[Annex 10-1]

LMO Risk Assessment Data

Data		Reviewing Authorities					
		RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
1. general data	A. Purpose of development	O	O	O	O	O	O
	B. Benefits of development and uses	O	O	O	O	O	O
2. Data on the host organism	A. Taxonomic status (scientific name, common name, variety/line, etc.)	O	O	O	O	O	O
	B. Distribution in nature	O	O	O	O	O	O
	C. History of use (including use with the country and other countries, history of cultivation and development through breeding, etc.)	O	O	O	O	O	O
	D. Biological characteristics	O	O	O	O	O	O
	(1) Viability and reproduction/ propagation capabilities in the natural environment or under test conditions simulating the natural environment	O	O	O		O	O
	(2) Mode/cycle of reproduction/ propagation and likelihood of cross-hybridization (3) Interactions with other species in the natural ecosystem (natural enemy, pathogenic organisms, competitors, predators, etc.) (4) Other genetic characteristics (including source) (5) Mode of reproduction and reproductive compatibility with other species or relatives (6) Dissemination (dissemination characteristics of pollen/seed, environmental factors affecting dissemination)	O	O	O			

Data		Reviewing Authorities					
		RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
	<For maritime/fisheries use> (7) Life cycle (generation time) (8) Natural habitats (9) Wild predators and preys (10) Parasites and competitors (11) Symbionts and hosts (12) Environmental factors affecting survival and LD values (13) Sexual maturation and spawning time, number of eggs per spawn, etc. (14) Fertilization rate, survivability of posterity (15) Respiratory and nutritional metabolism (16) Phenotypic and genetic markers (17) Presence of relatives and cross-hybridizable varies of the same species in the habitats				O		
	E. Capability of producing hazardous materials (including the capability of relatives)	O	O	O	O	O	O
	F. Reports on toxogenicity and allergenicity of the host and relatives					O	O
	G. Contamination by pathogenic and foreign agents (viruses, etc.)	O	O	O	O	O	O
	H. Centers of origin and genetic diversity	O	O	O	O	O	O
	I. Other important physiological characteristics including parasitism	O	O	O	O	O	O
	J. Research data on pathogenicity or relationship to known pathogens in the case of microorganisms					O	O
	K. Potential to become a weed (become wild)	O	O	O	O	O	O
3. Data on the donor organism	A. Taxonomic status (scientific name, common name, variety/line, etc.)	O	O	O	O	O	O
	B. History of use	O	O	O	O	O	O
	C. Biological characteristics	O	O	O	O	O	O
	D. Toxogenicity	O	O	O	O	O	O
	E. Data on reported toxogenicity and allergenicity of the donor and relatives					O	O
	F. Research data on pathogenicity or relationship to known pathogens in the case of microorganisms					O	O
4. data on the vector	A. Name and source (GenBank Accession No. etc.)	O	O	O	O	O	O

Data		Reviewing Authorities					
		RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
	B. Molecular weight of DNA	O	O	O	O	O	O
	C. Restriction map (including genetic elements in the vector, loci, orientation, sequences, etc.)	O	O	O	O	O	O
	D. Presence of hazardous sequence, etc.	O	O	O	O	O	O
	E. Vector structure	O	O	O	O	O	O
	F. Potential of vector being transferred to other cells or dependency on the host					O	O
	G. Identification and functions of genetic elements in the intermediate host					O	O
	H. Data on intermediate hosts					O	O
5. data on introduced gene(s)	A. Functions (GenBank Accession No., etc.) and characteristics of introduced gene(s)	O	O	O	O	O	O
	B. Sources and sequences of components in an introduced gene (1) Size, name and functions of the introduced gene (2) Regulators (promoters and terminators) (3) Selectable marker genes (4) Other promoters and other factors affecting the DNA functions	O	O	O	O	O	O
	C. Modifications to the gene for use	O	O	O	O	O	O
	D. Presence of hazardous sequences	O	O	O	O	O	O
	E. Sites and orientation of gene sequences in the finalized vector	O	O	O	O	O	O
	F. Presence of exogenous open reading frames and potential of transcription and expression thereof	O	O	O	O	O	O
6. Data on LMO develop-ment	A. Genetic modification methods (transgenic methods)	O	O	O	O	O	O
	B. Description on the development process for LMO (cultivation, breeding, etc.)	O	O	O	O	O	O
	C. Stability of phenotypes of an inserted gene through multiple generations	O	O	O	O	O	O
	D. Specifications of materials used in development						O
	E. Storage and control of the developed LMO						O
7. Molecular	A. Identification results for an inserted gene in LMO	O	O	O	O	O	O

Data		Reviewing Authorities					
		RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
Molecular character-ization of LMO	B. Insertion site of a gene (chromosome or cellular organelle) and adjacent sequences	O	O	O	O	O	O
	C. Number of copies of an inserted gene	O	O	O	O	O	O
	D. Methods to detect and to verify the expression of an inserted gene	O	O	O	O	O	O
	E. Data on stability (1) Changes in the sequences and size of an introduced gene through multiple generations (2) Changes in expression sites, timing, and level of an introduced gene through multiple generations					O	O
	F. Data proving that an inserted gene in the LMO genome does not encode toxins and allergens					O	O
	G. Data on genetic product (1) Traits/characteristics of genetic product (proteins, non-coding RNA, etc.) (2) Post-translational modification of an inserted gene				O	O	O
	(3) Functions of genetic product (4) Expression level, timing and site of a marker protein due to an inserted gene or the insertion, and measurement methods and sensitivity thereof (5) Effects of genetic product on metabolic pathways (6) Structure and functions of the selectable marker gene and the mechanism of resistance and metabolite(s) thereof (7) LMO detection and identification methods					O	O
8. Comparison between LMO and non-LMOs	A. Enhanced characteristics and traits after modification	O	O	O	O	O	O
	B. Difference in viability and propagation between the host and the LMO					O	O
	C. Differences from the host or the species of the host	O	O	O	O		
	(1) Viability and reproduction/ propagation capabilities in the natural environment or under test conditions simulating the natural environment	O	O	O	O		

Data		Reviewing Authorities					
		RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
	(2) Mode/cycle of reproduction/ propagation and likelihood of cross-breeding (3) Interactions with other species in the natural ecosystem (natural enemy, pathogenic organisms, competitors, predators, etc.) (4) Other genetic characteristics (including source) (5) Mode of reproduction and reproductive compatibility with other species or relatives (6) Dissemination (dissemination characteristics of pollen/seed, environmental factors affecting dissemination) (7) Production of hazardous materials and residual effects on ecosystem	O	O	O			
	<For maritime/fisheries use> (8) Life cycle (9) Natural habitats (10) Wild predators and preys (11) Parasites and competitors (12) Symbionts and hosts (13) Environmental factors affecting survival and LD values (14) Sexual maturation and spawning time, number of eggs per spawn, etc. (15) Fertilization rate, survivability of posterity (16) Respiratory and nutritional metabolism (17) Phenotypic and genetic markers (18) Potential of genetic transferability to other organisms (hybridization)				O		
9. Detailed data on adverse effects	A. Generation of toxic materials (presence of toxic materials secreted by an organism, etc.)	O	O	O	O		
	B. Potential to become a weed	O	O	O	O		
	C. Potential effects on organisms in the vicinity and the ecosystem	O	O	O	O		

Data	Reviewing Authorities					
	RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
D. Information on the environment to which the LMO is to be introduced (1) Distance from the center of origin of the LMO (2) Geographic and climatic characteristics and ecological characteristics of flora in the vicinity	O	O	O	O		
E. In the case of LMOs for environmental purification (1) Information on specific targets of environmental purification (2) Effects of target materials on the host (3) The mechanism of action of the LMO on target materials (4) Potential of the host and the LMO to change non-target materials (5) Effects on physiochemical characteristics of the adjacent ecosystem (air, soil and water) (6) Effects of concentration of LMO metabolites in the food chain on other organisms		O				
F. For maritime/fisheries use (1) Disturbance on the food chain and threats to biodiversity due to an increase in population (2) Competitive threats to wild varieties of the same species and relatives (3) Movement of an inserted genes into the gene pool of the wild varieties of the same species and relatives (4) Expansion of habitats (5) Occurrence and propagation of diseases (6) Changes in habitat environment and material cycles (7) Effects on parasites and predators (8) Other unintended effects				O		

Data	Reviewing Authorities					
	RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
G. Data on pathogenicity of the LMO (in the case of a microorganism) (1) communicability (2) Infective dose (3) Research data on host range of the LMO and possibility of alteration (4) Survivability outside of human host (5) Presence of vectors related to pathogenicity or other means of dissemination (6) Biological stability (7) Resistance to antibiotics (8) Capacity for colonization (9) Toxogenicity					O	O
H. Toxicity of the LMO (1) Literature (A) Potential toxicity of genetic product or metabolites thereof (B) Structural similarity of genetic material and metabolites thereof, etc. to known toxic proteins (C) Average LMO exposure levels for operators, end users through inhalation, ingestion, etc. (2) Toxicity test data if necessary (A) Single-dose toxicity (B) Other toxicity data					O	O
I. Allergenicity of the LMO (1) Literature (A) Potential allergenicity of genetic product (B) Structural similarity of genetic product and metabolites thereof, etc. to known allergens (2) Allergenicity tests if necessary					O	O

Data		Reviewing Authorities					
		RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
10. Data on environ-mental release of LMO	A. Data on environmental release (1) Duration and date of release (2) Site (geographic, geological characteristics, relationship to environmental conservation areas and other biologically important conservation areas) (3) Receiving ecosystem (types and distribution of species including relatives in the site) (4) Methods of release (5) Quantities to be released (6) Information on previous release approvals (approving countries, approval dates, approval numbers) (7) Information on environmental release trials (trial plan including the placement of trial groups, release area by trial group, etc. and treatment at completion)		O	O	O		
	B. Field trial results (in the case of an agricultural LMO) (1) In the case of LMO for use as <u>Seed</u> (A) Duration and time (B) Methods (C) Scale (D) Treatment at completion (2) LMO in original shape for use as food/feed or for processing (A) Duration and time (B) Methods	O					
	C. Contained cultivation results (in the case of aquaculture) (1) Duration and time (2) Methods (3) Scale (4) Treatment methods at completion				O		
11. Data on monitoring, waste manage-	A. Monitoring plan (methods, time, frequency)	O	O	O	O		O
	B. LMO inactivation methods	O	O	O	O	O	O
	C. Emergency plan (containment)	O	O	O	O		O
	D. Treatment of waste	O	O	O	O	O	O

Data	Reviewing Authorities					
	RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
E. LMO for maritime/fisheries use (1) Escape prevention and control (A) Description of escape prevention/containment facilities (B) Procedures and methods to prevent or minimize the escape of marine LMOs (C) Procedures and methods to control intrusion of unauthorized persons and external predator animals (D) Procedures and methods to control intrusion of other organisms (E) Sterilization and other risk reduction methods (2) Monitoring techniques (A) Effective monitoring methods (B) Specificity differentiating from normal organisms and sensitivity and reliability of monitoring techniques (C) Verification techniques in case of transfer of genetic material into other organisms (D) Duration and frequency of monitoring (E) Reporting mechanism (3) Emergency plan (A) Capturing, containment procedures and methods in case of accidental, intentional release of LMOs (B) Isolation of the areas affected by release (C) Emergency plan in case of urgencies such as typhoons, storms, fire, flood, intrusion of predators, etc. (4) Implementation/control plan (A) Facility inspection and maintenance plan (B) Supervisory personnel and facility operation record inspection plan (C) Facility and trial field improvement/maintenance plan				O		

Data		Reviewing Authorities					
		RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
	F. In the case that LMO poses risks to human health (1) Data on availability of adequate preventive and therapeutic methods and data on clinical or animal tests using such methods (2) Medical monitoring methods capable of detecting and verifying the exposure to the LMO and hazards derived from such exposure (3) Physical methods to protect operators, etc. from exposure to hazardous LMOs					O	O
12. Approvals and uses in other countries	A. Country B. Competent authorities C. Risk assessment agency D. Approval number E. Approval data F. Use data, etc.	O	O	O	O	O	O
13. Submission of standard materials	A. LMOs for agricultural, industrial, environmental purification use Gene sequences and standard materials for qualitative and quantitative verification of the LMO (standard materials shall be submitted in the original shape per seed, etc. so as to be used in the state's SPS, distribution monitoring activities) (1) 50 inactivated seeds each of the LMO and the host organism and 1kg of a mixed sample (2) In the case of a trophosome, 50 inactivated trophosomes each of the LMO and the host (3) In the case of a microorganism, a specific quantity of inactivated LMO (4) Sequences of single-copy endogenous genes specific to the host (5) For specific detection of the LMO, 5'- and 3'-end flanking sequences of the genes of the host genome and introduced genes (6) Other genetic information necessary for the development of detection methods	O	O	O			

Data	Reviewing Authorities					
	RDA	NERI	MOCIE	NFRDI	KCDC	KFDA
B. LMOs for maritime/fisheries use Gene sequences and standard materials for LMO verification (standard materials shall be submitted in the original shape)-MOMAF (1) 50 inactivated units each of the LMO and the host organism (2) Sequences of single-copy endogenous genes specific to the host (3) For specific detection of the LMO, 5'- and 3'-end flanking sequences of the genes of the host genome and introduced genes (4) Other genetic information necessary for the development of analytical methods				O		
C. In the case of LMOs for health/medical use, analytical information and standard materials necessary of the identification of the LMO subject to assessment						O

[Attachment 4-2]

Application for Environment Risk Review for Agricultural LMO

<table>
<tr><td colspan="5">Application for Environmental Risk Review for Agricultural LMO</td><td>Processing time
270 days</td></tr>
<tr><td rowspan="3">Applicant</td><td>? Company</td><td></td><td>? Business registration No.</td><td></td></tr>
<tr><td>? Address</td><td></td><td></td><td></td></tr>
<tr><td>? Representative</td><td></td><td>? Contact info</td><td></td></tr>
<tr><td rowspan="2">Developer</td><td>? Name</td><td colspan="3"></td></tr>
<tr><td>? Address</td><td colspan="3"></td></tr>
<tr><td>? Names</td><td colspan="2">Common name</td><td>Scientific name</td><td>Strain/line</td></tr>
<tr><td>? Use</td><td colspan="2"></td><td></td><td></td></tr>
<tr><td colspan="6">I hereby apply for environmental risk review in accordance with Article 4-8 Paragraph 2 of the “Centralized Notice Concerning Transboundary Movements of Living Modified Organisms, etc.”

Year/Month/Day

Applicant (Seal)

To the Administrator of the Rural Development Administration</td></tr>
<tr><td colspan="6">. Required documents

1. LMO risk assessment data specified in Annex 10-1
2. A risk review certificate issued by the government agency of the developer or the exporter
3. List of confidential information including trade secrets, etc. among submissions
4. Data relating to analytical methods and standard materials
- LMOs for use as seed including soybean, maize, cotton, etc.: 50 seeds (inactivated) and 1 kg (mixed) each
- Trophosomes including potatoes: 50 trophsomes (inactivated)
5. Modifications to ? through ? are recognized as notification items.</td></tr>
</table>

[Attachment 4-3]

Application for Environment Risk Review for Agricultural LMO Stacks

<table>
<tr><td colspan="5">Application for Environment Risk Review
for Agricultural LMO Stacks</td><td>Processing time
90 days</td></tr>
<tr><td rowspan="3">Applicant</td><td>? Company</td><td></td><td>? Business registration No.</td><td></td><td></td></tr>
<tr><td>? Address</td><td colspan="4"></td></tr>
<tr><td>? Representative</td><td></td><td>? Telephone</td><td></td><td></td></tr>
<tr><td rowspan="2">? Developer</td><td>? Company</td><td colspan="4"></td></tr>
<tr><td>? Address</td><td colspan="4"></td></tr>
<tr><td>? Organism</td><td>? Event</td><td></td><td>Brand</td><td></td><td></td></tr>
<tr><td colspan="2">Country and date of commercialization</td><td colspan="4"></td></tr>
<tr><td colspan="2"></td><td colspan="2">Parent variety 1</td><td colspan="2">Parent variety 2</td></tr>
<tr><td colspan="2">Event/line</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="2">Brand</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="2">Introduced traits</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="2">Inserted gene(s)</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="2">Country and date of approval for placing on the market</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="2">Country when applications are filed and application year</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="2">Changes in characteristics</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="2">Breeding between subspecies</td><td colspan="4">Yes ( ), No ( )</td></tr>
<tr><td colspan="6">I hereby apply for environment risk review in accordance with Article 4-9 Paragraph 1 of the “Centralized Notice Concerning Transboundary Movements of Living Modified Organisms, etc.”

Year/Month/Day

Applicant (Seal)

To the Administrator of the Rural Development Administration</td></tr>
<tr><td colspan="6">. Required documents
5. Information on stacks necessary to determine whether interactions occur among traits expressed by DNAs inserted into the parental organisms

6. Other available (collectible) information relating to characteristics of stacks

7. A comprehensive assessment based on information on parental organisms specified above in Subparagraphs 1 and 2

8. A certificate of recognition for the applicable variety and a review consent for approval-completed review data by the applicant with the authority over matters pertaining to domestic approval or the company of ownership.
9. Modifications to ? through ? are recognized as notification items</td></tr>
</table>

[Attachment 4-8]

Application for Import Inspection for Agricultural LMO

Application for Import Inspection for Agricultural LMO					Processing time
					10 days
1. Application details					
Importer	Name		Resident number		
	Address				
	Business name		(Telephone:)		
Exporter	Name		Business name		
	Address				
B/L number					
Cargo control number					
Inspection (receipt site)			Code		

2. Inspected product control number and import approval details					
Product name	HS code	Unit	Quantity	Use for import	Inspection certificate
					? Attached ? Not attached

Scientific name	Event/line	Approval number	Approval certificate issuance date		
			Year	Month	Day

I hereby apply for inspection of the LMO in accordance with Article 4-16 Paragraph 1 of the "Centralized Notice Concerning Transboundary Movements of Living Modified Organisms, etc."

Year/month/day

Applicant (Signature or seal)

To the Head of the National Plant Quarantine Service/Regional Office/Branch Office

	Fees
	None

. Required documents

1. A copy of certificate of import approval for agricultural LMO
2. A copy of inspection certificate issued by the government of the exporting country, government-recognized agency, or a government-designated verification agency (applicable only when such a certificate is issued)
3. A copy of letter of credit or commercial invoice (applicable only when labelling information is stated on the L/C or the commercial invoice)
4. List of plants subject to import inspection as per Attachment 4-9 (applicable only in the case of two or more products)

. Instructions

1. The applicant should not fill in the bold-lined sections.
2. Enter the applicable number in the "Use for Import" section (? for planting, ? for feed, ? for food, ? for processing, ? for other).

[Attachment 4-9]

List of Plants Subject to Import Inspection

List of Plants Subject to Import Inspection					
Product name	HS Code	Unit	Quantity	Use for import	Inspection certificate
					? Attached ? Not attached
Scientific name	Strain/line	Approval number	Approval certificate issuance date		
			Year	Month	Day
Product name	HS Code	Unit	Quantity	Use for import	Inspection certificate
					? Attached ? Not attached
Scientific name	Strain/line	Approval number	Approval certificate issuance date		
			Year	Month	Day
Product name	HS Code	Unit	Quantity	Use for import	Inspection certificate
					? Attached ? Not attached
Scientific name	Strain/line	Approval number	Approval certificate issuance date		
			Year	Month	Day
Product name	HS Code	Unit	Quantity	Use for import	Inspection certificate
					? Attached ? Not attached
Scientific name	Strain/line	Approval number	Approval certificate issuance date		
			Year	Month	Day

. Instructions

1. The list is used only when an inspection application is filed in writing for two or more products.
2. The applicant should not fill in the bold-lined sections.

[Attachment 6-2]

<table>
<tr><th colspan="6">Request for Human Health Risk Review for LMO</th></tr>
<tr><td rowspan="5">Applicant</td><td>? Business name</td><td colspan="2"></td><td>? Business registration No. (Corporate registration number)</td><td></td></tr>
<tr><td rowspan="3">? Place of business</td><td rowspan="3" colspan="2"></td><td>? Telephone</td><td></td></tr>
<tr><td>? Fax</td><td></td></tr>
<tr><td>? E-mail</td><td></td></tr>
<tr><td>? Representative</td><td colspan="2"></td><td>? Resident No.</td><td></td></tr>
<tr><td rowspan="2">Developer</td><td>? Company name</td><td colspan="2"></td><td>? Telephone</td><td></td></tr>
<tr><td>? Place of business</td><td colspan="4"></td></tr>
<tr><td rowspan="4">LMO</td><td>? Classification</td><td colspan="4">LMO ( ) Stacks ( )</td></tr>
<tr><td rowspan="2">? Name</td><td>Organism</td><td>Event/line</td><td colspan="2">Brand</td></tr>
<tr><td></td><td></td><td colspan="2"></td></tr>
<tr><td>? Introduced traits</td><td colspan="4"></td></tr>
<tr><td>? Inserted gene</td><td colspan="4"></td></tr>
<tr><td colspan="2">Purpose of human health risk review</td><td colspan="4">Import approval ( ) Production approval ( )</td></tr>
<tr><td colspan="2">Final use</td><td colspan="4"></td></tr>
<tr><td colspan="2">Country where placing on the market is approved and approval year</td><td colspan="4"></td></tr>
<tr><td colspan="2">Country where risk review is in process</td><td colspan="4"></td></tr>
<tr><td colspan="6">I hereby request for human health risk review for the LMO in accordance with Article 6-3 Paragraph 1 of the “Centralized Notice Concerning Transboundary Movements, etc. of Living Modified Organisms.”

Year/month/day

To the Commissioner of the Korea Food and Drug Administration</td></tr>
<tr><td colspan="6">. Required documents
1. Risk Assessment Submission Table as per Attachment 10-1
2. Risk assessment report containing a summary in Korean (summary of key points) and risk assessment data specified in Annex 10-1</td></tr>
<tr><td colspan="6">. Note: The “Applicant” means the person who applies for import approval, production approval or risk review.</td></tr>
</table>