Regulatory Framework for GMOs in Korea: Food Safety Approval Processes

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ABSTRACT

In Korea, GM foods are regulated under the Food Sanitation Act by Korea Food and Drug Administration. The safety evaluation of GM foods is based on "Regulation on Safety Evaluation of GM Foods" and the Division of Nutritional Evaluation of the Center for Food Standard Evaluation handles the enactment and evaluation operations of the safety evaluation system. The labeling system of GM foods and overall the management of GM foods is supervised by the Imported Food Division of the Food Safety. In this manuscript, we explained the organizations responsible for management, the safety evaluation system, the labeling system, the post-market monitoring system of the mandated labeling and safety evaluation system, and the analytical method of GM foods.

1. INTRODUCTION

Korea's supply and demand of food has a high import dependency rate with the exception of rice. In the case of soybean and corn, over 90% of the domestic supply is imported and mostly imported from US. However, genetically modified (GM) soybean and corn started to be produced and distributed, from the mid-1990's and centering in the US, demanding a safety

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management system for these crops. Hence, in 1998, Korea Food and Drug Safety Administration (KDFA) was established as a new government organization. In addition, in 1999, by the notification of the KFDA, “Guidelines for the Safety Assessment of GM Foods and Food Additives” was prepared, enabling the safety evaluation of GMO foods in Korea. As mentioned above, with the officiating of market distribution according to GMO safety evaluation system, the Food Sanitation Act of 2001 was amended and the “GMO labeling System” was induced, not only for safety evaluation, but to also guarantee the consumer’s right to choose. Meanwhile, in 2000, because of such international problems as the mixing of GM “Starlink” corn, the strengthening of GM food safety management was demanded. So, in 2002, the Food Sanitation Act was amended and a mandatory safety inspection clause was newly established and has been enforced since February of 2004. So far, the safety evaluation on 26 types of GM foods including soybean, corn, potato, cotton and canola along with 6 food additives such as amylase are in the process of being completed.

2. MANAGEMENT ORGANIZATIONS FOR GM FOODS

In Korea, in regards to food control, the Ministry of Agriculture and Forestry (MAF) supervises the agricultural foods (dairy and meat products) while the other foods are supervised by the Ministry of Health and Welfare (MOHW) and the Korea Food and Drug Administration (KDFA). MOHW exercises the right to enact and amend the Food Sanitation Act while the other substantial food management operations are handled by KDFA. The management of GM foods is also handled by KDFA: the Imported Food Division of the Food Safety Bureau supervises the enactment and the post management of the labeling system, while the Division of Nutritional Evaluation of the Center for Food Standard Evaluation handles the safety evaluation regulation enactment/revision and the conduct of the safety evaluation system.

3. SAFETY EVALUATION SYSTEM FOR GM FOODS

At present (2004) in Korea, the safety evaluation of GM foods is based on Article 15: “GM Foods Safety Assessment etc” of the Food Sanitation Act. The Commissioner of KDFA determines the scope of evaluation and other requirements of submitted data necessary for evaluation with the evaluation process stipulated by KDFA Notification No. 2003-37 (2003.9.1): “Regulation on Safety Evaluation of GM Foods”. According to this notification, safety evaluation should be based on sound science and amended according to the international standards in line with WTO Agreement with the various domestic and other international food safety considerations regarding GM foods. Also, It is also harmonized with the principles of risk analysis and the guideline for conduct of food safety assessment of GMOs that was developed by the Ad hoc Working Group on Foods derived from Modern Biotechnology under the scheme of Codex Alimentarius Commission held in Japan for four year since 2000, where the scope of the scientific assessment data has been decided upon. The list of data for safety evaluation by “Regulation on Safety Evaluation of GM Foods” is shown in table 1.

Meanwhile, in Korea, the Ministry of Commerce, Industry and Energy (MOCIE) has enacted the “Transboundary Movement of LMOs Act” as the domestic abiding law on bio-safety protocol. This law stipulates the roles of each ministry and the observance of the Food Sanitation Act in regards to the safety as foods. However, for the overall harmony of the law, in accordance to this law, the period for safety evaluation as food was stipulated as 270 days as in the guideline mentioned above.

Table 1. Scope of Data Submission on Safety Assessment by Article 12 of "Regulation on Safety Evaluation of GM Foods".

1) Any applicant who wants to undergo inspection on safety assessment in accordance with regulations in Article 3 Paragraph 1 to 4 should submit data specified below

(1) Data on the purpose and type of the modification

(2) Description on host organism(s)

① Taxonomic classification (common name, scientific name, taxonomic classification, etc.)

② History of cultivation and development through breeding

③ Known toxicity or allergenicity

④ History of safe use for consumption as food

(3) Description on donor organism(s)

① Taxonomic classification (common name, scientific name, taxonomic classification, etc.)

② History of cultivation and development through breeding

③ Toxicity, anti-nutritional properties, and allergenicity of the donor organism and its relatives (For microorganism, additional information on pathogenicity and the relationship to known pathogens)

(4) Description on genetic modification

① Description of the transformation process

i. Information on the specific method used for the transformation (Agrobacterium-mediated transformation, particle bombardment method, and photoplasma, etc.)

ii. Description on vector used in modification

a. Source

b. Confirmation from the host

c. Function in the host

iii. Description on intermediate host

iv. Description on gene tranfer

② Description on inserted gene

i. Traits of genetic components

a. Selectable marker gene

b. Regulatory elements

c. Other elements affecting the function of the DNA

ii. Size and identity

iii. Location and orientation of the sequence in the final vector/ construct

iv. Function of genetic components

v. Existence of hazardous sequence

vi. Identification of any open reading frames within inserted DNA

vii. Identification of sequence other than intended genes (purity of genes)

(5) Characterization of recombinant DNA plants

① Information on gene introduced into recombinant DNA plants

i. Characterization and description of the inserted gene materials

ii. The number of insertion sites

iii.Organization of the inserted genetic material at each insertion site

a. Copy number, and sequence data of the inserted materials and of the surrounding region

b. Description on gene which is not encoding any known toxin or anti-nutrients

iv. Identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion proteins

v. Information on Stability

a. Sequence and size of genes inserted at multi-generations

b. Site, time, and level of expression at multi-generations

① Description on gene products

i. Chemical characteristics of gene products (a protein or an untranslated RNA)

ii. Function of gene products

iii. Description of post-translational modification of the expressed protein

iv. Description of structural changes in the expressed proteins

v. Phenotypic description of the new trait(s)

vi. Level and site of gene products

③ Toxicity

i. Expressed substance (protein)

a. History of safe use for consumption as food

b. Amino acid similarity between the protein and known protein toxins and anti-nutrients

c. Stability to heat or processing and to degradation in appropriate representative gastric and intestinal model system (For alternative products, additional information on biochemical, structural and functional homogeneities)

d. Appropriate oral toxicity studies may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safety in food, and taking into account its biological function in the plant where known

ii. Expressed substance (others)

a. Biological function

b. Dietary exposure (quantity)

c. History of safe use for consumption as food

d. Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed. The type of assessments to be performed may include studies on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/carcinogenicity, reproduction and development toxicity according to the traditional toxicological approach

④ Allergenicity

i. Data on whether genetic products are known to be allergens

ii. Stability to heat or processing and to degradation in appropriate representative gastric and intestinal model system (For alternative products, additional information on

biochemical, structural and functional homogeneities)

iii. Data on homology if gene products to known allergens

iv. Data on gene products accounting for a significant ratio to the daily protein intake

v. The following data in the event allergenicity is difficult to determine according to documents provided under Paragraphs (1) to (4)

a. Data on the assessment of binding to IgE in sera of individuals with clinically validated allergic responses to broadly-related categories of food with sequence homology to a known allergen

b. Data on the assessment of the binding to IgE in sera of individuals with clinically validated allergic responses to broadly-related categories of food

⑤ Difference from the host

i. Major nutrients
ii. Trace nutrients
iii.Intrinsic toxin
iv.Anti-nutrients
v. Allergens
vi.Metabolites of inserted gene
vii.Nutritional properties

⑥ Effect of gene products on any other metabolic pathways (any possibility of reaction with unique ingredient as a substrate)

⑦ Information on survival and proliferation of recombinant DNA plants

⑧ Methods to inactivate recombinant DNA plants

⑨ Information on the present state of approval and use for dietary purposes in other countries

(6) In the event safety assessment under 1), (1) to (5) above is difficult, additional safety assessment will be conducted with experimental data on the following. However, some may be exempted if there are compelling reasons

① Acute toxicity
② Sub-chronic or chronic toxicity
③ Data on hereditary toxicity, reproductive and development toxicity, carcinogenicity, and other toxicities, in case it is deemed necessary as the result of sub-chronic or chronic toxicity

2) For genetically modified products not being grown or marketed any more that may be detected in food, official document authenticating the documents under 1), (1) to (4) above as well as documents proving the commercial sales of the products have been discontinued should be submitted. If necessary, documents under 1), (5) to (6) may be attached

3) For genetically modified food products that traits of the stacks ate altered, or stacks are developed by crossing different subspecies, or food processing methods and nutrients intake are altered their parental line, documents specified under 1), (1) to (6) should be submitted. Whether the product is stacked specified in the paragraphs should be confirmed through submission of documents as per the form in Attachment 6

4) If testing is not possible to be conducted from a theoretical and technical point of view, or testing is deemed impractical even if possible, or there are other proper reasons, some descriptions or information specified 1) above may not be submitted

5) If three years have passed after commercialization in the country of development and (an) other country (countries) are using such food, etc., data in support of such facts may replace some of the data specified 1) above.

The evaluation process for GM food and food additives is as follows: The developer submits the necessary data in accordance to the guideline upon requesting safety evaluation. The Division of Nutritional Evaluation, Center for Food Standard Evaluation at KFDA registers the request and conducts the initial examination of the data. Then, a twenty-member review committee

composed of academia, research and research related government workers in various fields such as food science, nutrition, molecular biology, medicine, immunology, toxicology, and microbiology examines the submitted data. This review committee is formed and operated according to KDFA Regulation No. 102: “Guideline on Operation of GM Foods Evaluation Committee”. On an average of one monthly meeting, safety issues are reviewed centered on each expert ’s examined data and a final decision is reached after 4-8 meetings. Additional necessary data or information needed during the review process is requested to the submitter; also, because the period until the additional data is submitted is exempt from the total number of inspection days, the final decision can take as long as 1-2 years. Upon the completion and submission of the review result report by the review committee, it is announced officially on the KFDA’s homepage to gather public opinion in order to seek clarity. (Figure 1)

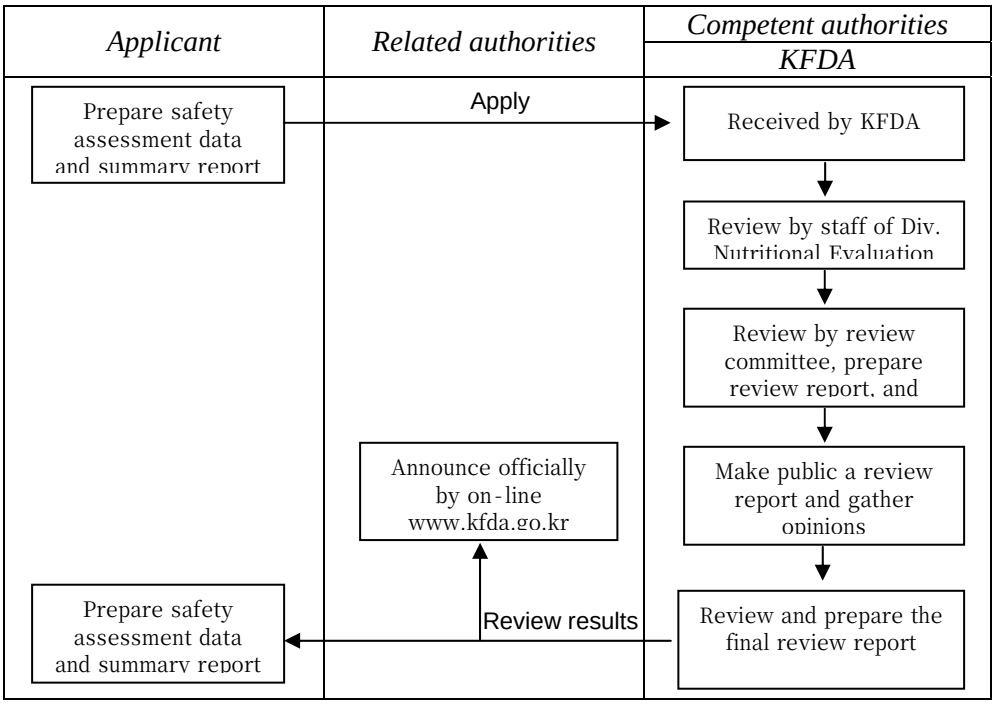

Figure 1. Procedure of GM food Safety evaluation.

The list of GM foods that have completed review as of September 2004 are shown in table 2.

Table 2. Current Status on the Safety Regulation of GM Foods (As of May, 2004).

No.			Submitter	Characteristics
1	Type Corn	Product RRS	Monsanto Korea Co.	Herbicide (glyphosate) Resistance
2	Corn	MON810	Monsanto Korea Co.	Pesticide (Cry1A (b)) Resistance
3	Corn	1507	DuPont	Herbicide (glufosinate) Resistance and Pesticide (Cry1F) Resistance
4	Corn	GA21	Monsanto Korea Co.	Herbicide (glyphosate) Tolerance
5	Corn	NK603	Monsanto Korea Co.	Herbicide (glyphosate) Tolerance
6	Corn	Bt11	Syngenta	Pesticide (Cry1A(c)) Resistance
7	Cotton	531	Monsanto Korea Co.	Pesticide (Cry1A(c)) Resistance
8	Cotton	757	Monsanto Korea Co.	Pesticide (Cry1A (b)) Resistance
9	Cotton	1445	Monsanto Korea Co.	Herbicide (glyphosate) Tolerance
10	Canola	GT73	Monsanto Korea Co.	Herbicide (glyphosate) Tolerance
11	Corn	T25	Aventis	Herbicide (glufosinate) Tolerance
12	Cotton	15985	Monsanto Korea Co.	Pesticide (Cry2Ab) Resistance
13	Corn	MON863	Monsanto Korea Co.	Pesticide (Cry3Bb1) Resistance
14	Corn	Event 176	Syngenta	Pesticide (Cry1Ab) Resistance
15	Potato	SPBT 02-05	Monsanto Korea Co.	Colorado Potato Beetle (mCry3A) Resistance

(Table 2. Continued)

No.	Type	Product	Submitter	Characteristics
16	Potato	RBBT 06	Monsanto Korea Co.	Colorado Potato Beetle (Cry3A) Resistance
17	Potato	Newleaf Y (RBMT15-101, SEMT15-02, SEMT15-15)	Monsanto Korea Co.	Colorado Potato Beetle (Cry3A) and Potato Virus Y Resistance
18	Potato	Newleaf PLUS (RBMT21-129, RBMT21-350, RBMT22-82)	Monsanto Korea Co.	Colorado Potato Beetle (Cry3A) and Leafroll Virus Resistance
19	Corn	DLL25	Monsanto Korea Co.	Herbicide (glufosinate) Tolerance
20	Corn	DBT418	Monsanto Korea Co.	Insect Pest (Cry1A(c)) Resistance
21	Cotton	281-3006	Dow AgroSciences	Herbicide (glufosinate) Tolerance and Insect Pest (Cry1F,1Ac) Resistance
22	Corn	MON863 X NK603	Monsanto Korea Co.	Herbicide Tolerance and Insect Pest Resistance (Future Generation Crossbreed)
23	Corn	MON863 X MON810	Monsanto Korea Co.	Insect Pest Resistance (Future Generation Crossbreed)
24	Corn	MON810 X GA21	Monsanto Korea Co.	Herbicide Tolerance and Insect Pest Resistance (Future Generation Crossbreed)
25	Corn	MON810 X NK603	Monsanto Korea Co.	Herbicide Tolerance and Insect Pest Resistance (Future Generation Crossbreed)
26	Corn	1507 X NK603	DuPont	Insect Pest Resistance and Herbicide Tolerance (Future Generation Crossbreed)

4. LABELING SYSTEM FOR GM FOODS

Labeling system is a sensitive subject worldwide. In Korea, GM food labeling system became a social issue in 1998 and especially 1999. Labeling

control in Korea is as follows: the quality control of farming and marine products is handled by the National Agricultural Products Quality Management Service (NAQS) of the Ministry of Agriculture and Forestry (MAF); while the labeling management of processed foods is handled by Imported Food Division of the Food Safety Bureau in KFDA. Hence, MAF has completed an examination from the standpoint of labeling the country of origin in accordance to the Agricultural Products Quality Management Act. In the cases of soybean, corn and soybean sprout, MAF decided that if the added quantity of GMO was more than 3%, then the "GM Soybean or Corn" label was required. In accordance, KDFA also decided to label the ingredient labeling part of the processed foods, in which it would be mandated to add "GM Soybean or Corn" in parenthesis after the name of the main ingredient (1 of the top 5 in terms of blending ratio) listed if it was GM soybean or corn. Four months after mandated raw ingredient labeling and preparation time, the mandated labeling for processed foods was initiated in July of 2001.

The difference between Japanese and Korean GMO labeling system is the tolerant quantity of non-intentional blending. In contrast to 5% in Japan, in Korea, it has been lowered to 3% because of the non-governmental organizations' strong demand. Regarding the "non GMO label", as for processed foods, this label is only allowed in the cases where only GMO free ingredients are used. This label is not utilized in the following cases: 1) when the GMO is completed dissolved or eliminated in the manufacturing process; 2) when the manufacturer uses ingredients which he/she independently-controlled in accordance to the consumer's non-preference for GM products; and 3) when a utilized GMO is not the main ingredient. Therefore, with the non-existence of GMO-labeled products in the market, if a product is labeled "non GMO", the products that were not labeled in compliance to the above regulation can be mistaken as GM foods. So, considering the matter of fairness, when a future labeling system is fixed and when there is a public consensus on GM food, this matter will be re-examined.

The subjects of GMO labeling in processed foods are 26 foods that are

separate from the manufacturing process in which soybean or corn may be used and 27 cases in which these main ingredients may be used during the manufacturing and processing of foods.

From 2003, potato is also a subject of GMO labeling at MAF. However, at KDFA, because international production of GM potato has discontinued as of 2000, the application of a labeling system for potato-processed food was thought to be unnecessary.

5. POST MANAGEMENT OF THE MANDATED LABELING AND SAFETY EVALUATION SYSTEM

With the enforcement of the GM labeling system, at KDFA, as a part of post management, importers are asked to state when submitting import food declaration document whether the foods are subject of the GM labeling system in the cases of GM labeling system applicable foods. In the cases when the foods are not declared, importers are asked to also submit as proof data IP Certification or another approved certificate from the government of the producing country that is equally valid. Yet, because this labeling system is targeted at GM DNA or foreign proteins in the final product, the submitting of a result document that proves the non-existence of these DNA or proteins in the foods that he/she wants to import is also permitted.

These types of imported food declaration operations are undertaken at the six regional offices of KDFA and at nine National Quarantine Station (NQS) in Kunsan, Yeosu and etc. For imported foods that were declared, the provisional and city offices work as a network to check whether the foods are labeled exactly and correctly distributed while regularly pursuing and checking the actual state of the labeling system. In the case of soybean import, except for those imported into Korea for oil extracting, the raw ingredients for soybean curd and soybean paste are separately imported to prevent GMO mixing; also, only those soybeans with less than 3% non-intentional blending

rate are imported through the government-operated import company, the Agricultural and Fishery Marketing Corporation (AFMC). Hence, because commercially distributed soybean sprout, curd and milk are all manufactured with less than 3% non-intentional blending rate raw material, labeling is exempt. Also, because in reality, the existence of GMO in these commercial products is not labeled, it is mistaken by the consumer protection organization from time to time that the labeling system is not implemented. Also, this is the same reason why it is hard to find “GMO” labels showing its existence in other processed foods in Korea.

Every year KDFA buys and conducts analytic inspection on commercially distributed foods that utilize soybean and/or corn as raw material. As a result of monitoring 2,461 cases of soybean or corn containing foods for two years starting from 2002, GMO was detected in 719 cases, showing a 29.2% detection rate. However, upon verification, the manufacturing company possessed all IP Certifications; so, as of the end of 2003, there have been no cases of prosecution. However, in the cases where GMO is detected in products labeled as “non GMO”, the importer/manufacturer is subject to administrative disposition for false labeling; so, there was one case in which administrative measures were imposed.

6. KOREA’S EVALUATION LAW (METHOD) ON GM FOODS

In accordance to the enforcement of the 2002 GMO labeling system, KDFA prepared an evaluation guideline for GM foods. In this guideline, in regards to processed foods, methods for gene extraction and on qualitative and quantitative analyses were presented on 1 type of GM soybean (herbicide tolerant GTS 40-3-2 soybean, Monsanto Co.) and 5 types of corn (MOM810 and GA21, Monsanto Co.; Bt11 and Even176, Syngenta Co.; and T25, Aventis Co.) However, because only qualitative analysis is implemented on processed foods, there is quantitative analysis of only raw materials. Because

the analytical results not only greatly affect food distribution but also food trade, the establishment of an evaluation method is critical. With the premise that the primer and promo necessary for the evaluation of GMOs has to be a verified method, KDFA is collaborating with the National Food Research Institute in Japan and will select the verified method.

7. FURTHER COMMENTS

Because there has been no case in which GM foods were developed or domestically produced in Korea, the current subjects of management are imported foods or feeds. Also, although there is mandatory safety evaluation as food, safety evaluation as feeds is currently being reviewed by MAF. Also, MAF is also evaluating on environmental harmfulness during distributing process to guarantee safety in non-intentional environmental emission.

With international agreement on the bio-safety protocol, in Korea, MOCIE is aiming to establish a comprehensive management system by amending the 2002 “Transboundary Movement of LMOs Act”. If Korea ratifies the bio-safety protocol, this law can go into effect after three months while MAF’s the environmental risk evaluation becomes mandated by this law.

8. REFERENCES

Ministry of Health and Welfare (2002.8.26) Food Sanitation Act, www.kfda.go.kr

Korea Food and Drug Administration (2001.7.9) Guideline for Labeling on genetically modified food, Notification No.2001-43, www.kfda.go.kr

Korea Food and Drug Administration (2003.9.1) Regulation on safety evaluation of genetically modified food, Notification No.2003-37, www.kfda.go.kr

Korea Food and Drug Administration (2001.7.13) Guideline for detection method of genetically modified food, www.kfda.go.kr

Ministry of Commerce, Industry and Energy (2002) Transboundary Movement of LMOs Act