

Proposed Act on the Revisions to the 'Labelling Standard for Genetically Modified Organisms'

October 2008

Korea Food and Drug Administration

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Korea Food and Drug Administration Public Announcement No. 2008-193

The Korea Food and Drug Administration is proposing revisions to the 'Labelling Standard for Genetically Modified Organisms'. Thereupon, announcing as follows in accordance with Articles 41 and 46 of the 'Administrative Procedures Act', in order to notify citizens the intent of the revisions, reason for the revisions and the key elements of the proposed Act beforehand and to collect public opinions.

7 October 2008

Commissioner, Korea Food and Drug Administration

Proposed Act on the Revisions to the Labelling Standard for Genetically Modified Food

1. Reason for the revisions

• The reason for revisions is to broaden the labelling scope of genetically modified organisms for consumers' right to know. The scope shall be extended to items that were approved to be imported or developed or produced for human consumption after passing through safety assessment, or foods that manufacturers, processors, producers, packers or importers of such items are selling or import, store, transport or display for the purpose of selling.

2. Key Elements

- Clarify the basis of labelling for food, food additives and health functional food (Article 1).
- Clarify the definition of genetically modified organisms based on the 'Food Sanitation Act', 'Health Functional Food Act' and 'Liquor Tax Act' (Article 2 Paragraph 1), and remove main ingredients (Article 2 Paragraph 4).

- Extend the scope of items that are subjected to be labelled as genetically modified organisms from some foods to all food, food additives, health functional food and liquor (Article 3).
- Reclassify persons responsible for labelling based on the 'Food Sanitation Act', 'Health Functional Food Act' and 'Liquor Tax Act' (Article 4).
- Classify labelling methods for genetically modified organisms (Article 5 Paragraph 1). Establish the basis to label GMO-free (Article 5 Paragraph 2). Enact a provision that foods which are manufactured or produced using agricultural, livestock or fishery products that are not on the list of approved items as raw material, or foods which are manufactured or produced from such products as ingredients shall not be labelled as GMO-free in order to prevent the possibility of consumers' confusing with intentional use of GMO-free labelling (Article 5 Paragraph 3).

3. Enforcement date

This proposed Act shall take effect on the date of announcement.

4. Presenting written opinion

Any group or individuals who have opinion(s) about the Proposed Act on the Revisions to **'Labelling Standard for Genetically Modified Organisms'** (Attachment) are welcome to present written opinion to the commissioner of Korea Food and Drug Administration (Address: 194 Tongilro, Eunpyeong-gu, Seoul (Postal Code: 122-704), CC: Bio Food team Phone 02-380-1331~3, Fax 02-358-2157) by **December 5th**, **2008**. The written opinion should contain followings:

- A. Opinion about the proposed Act (Whether you are for or against it, and the reasoning)
- B. Your name (For groups, the name of the group and name of the representative), address and phone number
- C. Other references

Attachment: Proposed Act on the Revisions to Labelling Standard for Genetically Modified Organisms

Proposed Act on the Revisions to the Labelling Standard for Genetically Modified Organisms

The Korea Food and Drug Administration is revising labelling standard for genetically modified organisms as follows.

Article 1 (Purpose) This proposed Act is intended to provide consumers with proper information about the foods they consume by enacting provisions for labelling genetically modified organisms. The revised standard shall be applied to food or food additives in accordance with the proviso in Article 10 Paragraph 1 of the 'Food Sanitation Act' (referred as "Act" hereinafter), health functional foods in accordance with Article 17 Paragraph 1 Sub-paragraph 6 of the 'Health Functional Food Act', and liquors in accordance with Article 7 of the 'Enforcement Regulation of the Liquor Tax Act'.

Article 2 (Definitions of terms) The definitions of terms that are used in this proposed Act are as follows.

- 1. "Genetically Modified Organisms" indicates agricultural, livestock and fishery food products that are produced or reared with recombinant DNA techniques, which take only useful genes from an organism and recombine them into genes of another organism. It also indicates food or food additives (Including health functional food and liquor. The same shall apply hereinafter) that manufacturers, processors, producers, packers or importers of above mentioned products are selling or import, store, transport or display for the purpose of selling.
- 2. "Non-Genetically Modified Organisms (GMO-Free)" indicates product that is manufactured or produced without using 'genetically modified organisms'.
- 3. "Ingredients" indicates substances that are used to manufacture or process or cook food or food additives, except purified water, and are contained in the final products.
- 4. "Main surface" indicates a side of container or package that has a trademark or logo of the product printed on it, and normally is shown to consumers when they purchase food or food additives.

Article 3 (Subject to labelling) Foods subject to labelling are those that were approved to be imported or developed or produced for human consumption after passing through safety assessment pursuant to Article 15 of the Act, or genetically modified foods that manufacturers, processors, producers, packers or importers of such food products are selling or import, store, transport or display for the purpose of selling. However, agricultural products which contain a lower GMO rate than defined in Article 3 paragraph 3 of 'Methods to indicate genetically modified agricultural products (Issued by the Ministry for Food, Agriculture, Forestry and Fisheries)' or food or food additives that are

manufactured or produced from such agricultural products are not legally required to be labelled as genetically modified organisms.

Article 4 (Persons responsible for labelling) Businesses subject to labelling genetically modified organisms are as per paragraphs below.

- 1. Food manufacturers and processors, manufacturers and processors of foods for immediate sale, food additives manufacturers, food packers, food distribution retailers or food importing retailers in accordance with Article 7 of the 'Enforcement Decree of Food Sanitation Act'.
- 2. Health functional food manufacturers, importers or distribution retailers in accordance with Article 2 of the 'Enforcement Decree of Health Functional Food Act'.
- 3. Licensed liquor manufacturers in accordance with Article 6 of the 'Liquor Tax Act', and licensed liquor importers and exporters in accordance with Article 8 of the 'Liquor Tax Act' and Article 9 Paragraph 2 Sub-paragraph 4 of the 'Enforcement Decree of Liquor Tax Act'.

Article 5 (Labelling methods) Labelling methods for genetically modified organisms subject to labelling pursuant to Article 3 are as below.

- 1. Genetically modified organisms shall be labelled in letters that are greater than 10 point and the colour shall be distinguishable from the background of the corresponding product's container or package with indelible ink, imprint or stamp for consumers to easily recognize.
- 2. Genetically modified organisms shall be displayed on the corresponding product for consumers to easily recognize as each of the following.

a. On the main surface, the words "Genetically modified organisms" or "Genetically modified $\circ\circ$ was used" shall be displayed in conjunction with the name of the food.

b. The words "Genetically modified" shall be displayed in parentheses after the name of the ingredient that was used for the genetically modified food.

"Non-genetically modified organisms (GMO-Free)" can be emphasized as below applying the method in -1.

1. Display the words "Non-genetically modified organisms (GMO-Free)" on the main surface.

2. Display the words "GMO-Free" in parentheses after the name of the ingredient that was used for the product.

3. Food or food additives which have no remaining modified genes after manufacture or production, and therefore are unable to be inspected, are excluded.

Food that was manufactured or produced using an agricultural, livestock or fishery product that is not on the list of subjects for safety assessment complying with Article 15 of the Act as raw materials, or food that was subsequently manufactured or produced from such product shall not be displayed with emphasis on "GMO-Free food" as described in

Article 6 (Exceptions in applying the labels) In the case which corresponds to one of subparagraphs below, labelling would be done as follows regardless of the provisions in Article 5.

- 1. In the case that food manufacturers or processors of food for immediate sale are displaying and selling genetically modified foods that were manufactured or processed by themselves, indication of each product can be omitted when they are displaying the relevant facts of genetically modified organisms on the showcase or on a separate signpost.
- 2. In the case of selling tofu or similar products in a portable sanitized container, indication of each product can be omitted when they are displaying the relevant facts of genetically modified organisms on the container or on a separate signpost.
- 3. When it is not possible to print the facts of genetically modified organisms with ink, imprint or stamp due to the specific characteristics of the package, and for imported food and food additives, stickers that would not fall off can be affixed to the package.

Bylaws

Article 1 (Enforcement date) This proposed Act shall take effect on the date of announcement. However for those among the foods subject to labelling which are designated in Article 3, if they were manufactured or produced with genetically modified agricultural, livestock or fishery products as ingredients and do not have remaining genes, this proposed Act will take effect three years after the date of enforcement.

Article 2 (Transitional measures for the labelling standard for genetically modified foods) If persons who were licensed or registered for the business at the time this proposed Act came into effect, the previous 'Labelling Standard for Genetically Modified Foods' shall be applied until December 31, 2009 to genetically modified foods they manufacture, process, produce, import and sell.

Comparison T	Table of New	w and Old Provision	S
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Current Provisions	Proposed Provisions
Article 1 (Purpose) This Act is intended to provide consumers with proper information about the foods they consume by enacting provisions for labelling genetically modified organisms and similar materials in accordance with the proviso in Article 10 Paragraph 1 of 'Food Sanitation Act'.	Article 1 (Purpose) This proposed Act is intended to provide consumers with proper information about the foods they consume by enacting provisions for labelling genetically modified organisms. The revised standard shall be applied to food or food additives in accordance with the proviso in Article 10 Paragraph 1 of the 'Food Sanitation Act' (referred as "Act" hereinafter), health functional foods in accordance with Article 17 Paragraph 1 Sub-paragraph 6 of the 'Health Functional Food Act', and liquors in accordance with Article 7 of the 'Enforcement Regulation of the Liquor Tax Act'.
Article 2 (Definitions of terms) The definitions of terms that are used in this Act are as follows. <u>1. "Genetically Modified Food" indicates</u> food (Including health functional food. The same shall apply hereinafter) or food additives that were manufactured or processed using agricultural, livestock and fishery food products that were produced or reared with recombinant DNA techniques.	Article 2 (Definitions of terms) The definitions of terms that are used in this proposed Act are as follows. <u>1. "Genetically Modified Organisms"</u> indicates agricultural, livestock and fishery food products that are produced or reared with recombinant DNA techniques, which take only useful genes from an organism and recombine them into genes of another organism. It also indicates food or food additives (Including health functional food and liquor. The same shall apply hereinafter) that manufacturers, processors, producers, packers or importers of the above mentioned products are selling or import, store, transport or display for the purpose of selling.
< <u>Added></u> 2. "Ingredients" indicates substances that are used to manufacture or process or cook food or food additives, except purified water, and are contained in the final	 <u>2. "Non-Genetically Modified Organisms</u> (GMO-Free)" indicates product that is manufactured or produced without using <u>'genetically modified organisms'</u>. <u>3. (The same as current Paragraph 2)</u>

product.

3. "Main surface" indicates a side of container or package that has a trademark or logo of the product printed on it, and normally is shown to consumers when they purchase food or food additives.

<u>4. "Main ingredients" indicates 5 most used</u> ingredients to manufacture or process food or food additives.

Article 3 (Subject to labelling) Foods or food additives (including imported food or food additives. The same shall apply hereinafter) subject to labelling are foods that come under any one of sub-paragraphs below. The foods and food additives should be manufactured or processed using one or more of items that approved to import or produce for human consumption after passing through safety assessment pursuant to Article 15 of the Act as the main ingredients, and still have recombinant DNA or the resulting protein even after manufactured or processed. Classification of foods subject to labelling are by the food standard pursuant to Article 7 of the Act and health functional food standard pursuant to Article 14 of the Health Functional Food Act.

1. Soybean flour in processed soybean products group in general nonstandard processed foods

2. Corn flour in processed grain products group in general nonstandard processed foods

 <u>3. Processed soybean products that contain</u> soybean or soybean flour in nonstandard general processed foods.
 4. Processed grain products that contain

corn or corn flour in nonstandard general processed foods.

5. Canned, bottled and retort-pouched soybean in preserved foods.

4. (The same as current Paragraph 3)

<Rescinded, 2008>

Article 3 (Subject to labelling) Foods subject to labelling are those that were approved to be imported or developed or produced for human consumption after passing through safety assessment pursuant to Article 15 of the Act, or genetically modified foods that manufacturers, processors, producers, packers or importers of such food products are selling or import, store, transport or display for the purpose of selling. However, agricultural products which contain a lower GMO rate than defined in Article 3 paragraph 3 of 'Methods to indicate genetically modified agricultural products (Issued by the Ministry for Food, Agriculture, Forestry and Fisheries)' or food or food additives that are manufactured or produced from such agricultural products are not legally required to be labelled as genetically modified organisms.

<u>6. Canned, bottled and retort-pouched corn</u>	
in preserved foods.	
7. Cookies in confectionery group.	
8. Breads or rice cakes.	
9. Regular tofu, whole tofu, tofu skin	
(yuba), processed tofu in soybean curd	
group or jelly group.	
10. Soybean milk in beverages group.	
11. Infant formulas in special use foods.	
12. Growing children's formulas in special	
use foods.	
13. Cereal formulas for infant/baby in	
special use foods.	
14. Other infant and baby foods in special	
use foods.	
15. Foods for special dietary uses in special	
use foods.	
16. Diet formulas in special use foods.	
17. Cereal formulas for pregnant women	
and nursing mothers in special use foods.	
<u>18. Fermented soybeans in paste group.</u>	
<u>19. Traditional soybean paste, soybean</u>	
paste, flavoured soybean paste in paste	
group.	
20. Hot pepper paste, flavoured hot pepper	
paste in paste group.	
21. Cheonggukjang in paste group.	
22. Mixed paste in paste group.	
23. Hard-boiled foods.	
24. Cornstarch in starch group in other	
foods group.	
25. Processed corn product for popcorn in	
other foods group.	
26. Dietary supplemental products in other	
foods group.	
27. Other foods that use soybean, corn,	
<u>cottonseed, canola, sugar beet (including</u> bean sprouts and alfalfa) as a main	
ingredient.	
28. Foods containing food of items 1 to 27 as a	
main ingredient.	
Article 4 (Dersons responsible for	Article 1 (Persons responsible for
Article 4 (Persons responsible for labelling) Ecod manufacturers and	Article 4 (Persons responsible for
labelling) Food manufacturers and	labelling) Businesses subject to labelling

processors, food manufacturers and processors of food for immediate sale, food additives manufacturers, food packers, food distribution retailers or food importing retailers in accordance with Article 7 of the 'Enforcement Decree of Food Sanitation Act' and Health functional food manufacturers, importers or distribution retailers in accordance with Article 2 of the 'Enforcement Decree of Health Functional Food Act' are responsible for labelling genetically modified organisms and similar materials.	genetically modified organisms are as per paragraphs below.
< <u>Added></u>	 1. Food manufacturers and processors, manufacturers and processors of foods for immediate sale, food additives manufacturers, food packers, food distribution retailers or food importing retailers in accordance with Article 7 of the 'Enforcement Ordinance of Food Sanitation Act'. 2. Health functional food manufacturers, importers or distribution retailers in accordance with Article 2 of the 'Enforcement Decree of Health Functional Food Act'.
	3. Licensed liquor manufacturers in accordance with Article 6 of the 'Liquor Tax Act', and licensed liquor importers and exporters in accordance with Article 8 of the 'Liquor Tax Act' and Article 9 Paragraph 2 Sub-paragraph 4 of the 'Enforcement Decree of Liquor Tax Act'.
Article 5 (Labelling methods) <u>Labelling</u> <u>methods for genetically modified</u> <u>organisms and similar materials are as</u> <u>below.</u>	Article 5 (Labelling methods) <u>Labelling</u> methods for genetically modified organisms subject to labelling pursuant to <u>Article 3 are as below.</u>
1. <u>Genetically modified organisms and</u> <u>similar materials</u> shall be labelled in letters that are greater than 10 point and the colour shall be distinguishable from the	<u>1. Genetically modified food</u>

background of the corresponding product's	
container or package with indelible ink,	
imprint or stamp for consumers to easily	
recognize.	
2. Genetically modified organisms and	2. Genetically modified organisms shall be
similar materials shall be displayed on the	displayed on the corresponding product for
main surface of corresponding product for	consumers to easily recognize as each of
consumers to easily recognize as	the following.
"Genetically modified organisms "or	
"Genetically modified oo was used", and	a. On the main surface, the words
shall be displayed as "Genetically	"Genetically modified organisms" or
modified" or "Genetically modified oo" in	"Genetically modified oo was used"
parentheses after the name of the ingredient	shall be displayed in conjunction with
of the transgenic agricultural product.	the name of the food.
	b.The words "Genetically modified"
	shall be displayed in parentheses after
	the name of the ingredient that was used
	for the genetically modified food.
<u><added></added></u>	"Non-genetically modified organisms
	(GMO-Free)" can be emphasized as below
	applying the method in -1.
	1. Display the words "Non-genetically
	modified organisms (GMO-Free)" on
	the main surface.
	2. Display the words "GMO-Free" in
	parentheses after the name of the
	ingredient that was used for the
	product.
	3. Food or food additives which have
	no remaining genes after manufacture
	or production, and therefore are unable
	to be inspected, are excluded.
	Food that was manufactured or produced
<u><added></added></u>	using an agricultural, livestock or fishery
	product that is not on the list of subjects for
	safety assessment complying with Article
	15 of the Act as raw materials, or food that
	was subsequently manufactured or produced
	from such product shall not be displayed
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	with emphasis on "GMO-Free food" as
	described in
	< Pasaindad>
	< <u>Rescinded></u>
3. If it is not possible to confirm whether	
the product is genetically modified or not, it can be displayed as "It is possible that	
this product contains genetically modified	
$\circ\circ$ " on the main surface or "It is possible	
that this product contains genetically	
modified $\circ \circ$ " in parentheses after the name	
of the corresponding ingredient that was	
used for the product.	Article 6 (Exceptions in applying the
Article 6 (Exceptions in applying the	labels) (The same as at present)
labels) In the case which corresponds to	
one of subparagraphs below, labelling	
would be done as follows regardless the	
provisions in Article 5.	1 (The same as at present)
	1. (The same as at present)
1. In the case that food manufacturers or	
processors of food for immediate sale are displaying and selling genetically modified	
foods that were manufactured or processed	
by themselves, indication of each product	
can be omitted when they are displaying	
the relevant facts of genetically modified	
organisms on the showcase or on a separate	
signpost.	2. (The same as at present)
2. In the case of selling tofu or similar	
products in portable sanitized container,	
indication of each product can be omitted	
when they are displaying the relevant facts	
of genetically modified organisms on the	
container or on a separate signpost.	3. (The same as at present)
	5. (The same as at present)
3. When it is not possible to print the facts of genetically modified organisms with ink,	
imprint or stamp due to the specific	
characteristics of the package, and for	
imported food and food additives, stickers	
that would not fall off can be affixed to the	
package.	
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	Bylaws

Article 1 (Enforcement date) This proposed Act shall take effect on the date of announcement. However for those among the foods subject to labelling which designated in the Article 3, if they were manufactured or produced with genetically modified agricultural, livestock or fishery products as ingredients and do not have remaining genes, this proposed Act will take effect three years after the date of enforcement. Article 2 (Transitional measures for
Article 2 (Halistional measures forlabelling standard for genetically modifiedfoods) If persons who were licensed orregistered for the business at the time thisproposed Act came into effect, the previous'Labelling Standard for GeneticallyModified Foods' shall be applied untilDecember 31, 2009 to genetically modifiedfoods they manufacture, process, produce,import and sell.