ACFEH Information Paper 10

Advisory Council on Food and Environmental Hygiene

Proposed Guidelines on Voluntary Labelling of Genetically Modified Food

Purpose

This paper briefs Members on the progress of preparing the Guidelines on Voluntary Labelling of Genetically Modified (GM) Food (the Guideline).

Background

2. GM food is any food or food ingredient that is, or is derived from, an organism in which the genetic material has been modified using modern biotechnology. According to the World Health Organization , GM foods currently available on the international market have passed risk assessments and are not likely to present risks for human health. Regarding the labelling of GM food, there is currently no international consensus in the method of GM food labelling. Nevertheless, a number of countries and areas have introduced their own labelling requirements on GM food. The international scenario of GM food labelling is summarized and attached in Annex I.

The International Scenario of GM food labelling

3. At present, policies on GM food labelling vary in different countries and areas, but can be broadly classified into voluntary and mandatory approaches. For the mandatory approach, it is further classified into “labelling of designated GM products only” and “pan-labelling” approach.

The voluntary labelling approach

4. The voluntary labelling approach only requires GM food that is significantly different from its conventional counterpart, in terms of composition, nutritional value and allergenicity, to be labelled. The U.S and Canada are examples of countries adopting this approach.

The mandatory labelling approach for designated GM products only

5. For this approach, only designated food products which contain GM materials are required to be labelled. Countries and areas like Japan, Republic of Korea, Taiwan and Mainland China are adopting this approach.

The mandatory pan-labelling approach

6. The pan-labelling approach requires labelling of any food or food ingredients that contains GM materials exceeding a threshold level. The European Union, Australia and New Zealand are examples of countries and region adopting this approach.

<u>The Codex Alimentarius Commission (Codex) discussion on GM food labelling</u>

7. The issue of GM food labelling falls within the competence of the Codex Committee on Food Labelling (CCFL). A draft guideline for the labelling of GM foods and food ingredients has been proposed for discussion in the CCFL. However, up to 2006, no consensus can be reached within the Committee. Due to the diverse views among its members, it is unlikely that the Codex can reach any consensus on the method of GM food labelling in the near future.

<u>The development of a GM food labelling system in Hong Kong</u>

8. The Administration conducted a public consultation on GM food labelling from February to May 2001 and a regulatory impact assessment (RIA) in April 2002. Members were last briefed at the meeting on 17 March 2003 that barriers were identified in the RIA on

implementation of a mandatory GM food labelling scheme in Hong Kong, including the lack of international consensus on GM food labelling. The idea of voluntary labelling of GM food was initiated by some members of the trade. The Administration supported the initiative and worked closely with the trade to introduce a voluntary GM food labelling scheme in Hong Kong. The working group on voluntary labelling of GM food (the Working Group) comprising representatives from manufacturing, wholesale, retail, trade associations, consumer group and various government departments was established to formulate the guidelines.

The Guideline

9. After five meetings and thorough discussions, the Working Group has agreed on the following four principles on the voluntary labelling scheme of GM food -

(i) Principle 1: the labelling of GM food should comply with the requirement of Hong Kong legislation, in particular the Public Health and Municipal Services Ordinance (Cap. 132) which provides the legislative framework for food safety control in Hong Kong;

(ii) Principle 2: The threshold level applied in the guidelines for labelling purpose is 5%, in respect of individual food ingredient, taking account of adventitious mixing of GM and non-GM crops during harvest, transportation, processing and storage. This threshold level reflects a more pragmatic and realistic level that the trade can achieve at this stage;

(iii) Principle 3: Additional declaration on the food label is recommended when significant modifications of the food, e.g. composition, nutrition value, level of anti-nutritional factors, natural toxicant, presence of allergen, intended use, introduction of an animal gene etc., have taken place; and

(iv) Principle 4: Negative labelling is not recommended for food without GM counterparts, as it would be misleading to consumers.

A copy of the draft Guideline is attached at Annex II for reference.

Response from the Trade

10. We have learnt from the Working Group that some of the trade will follow the Guideline when labelling their products as long as they can obtain the relevant information. There are also views expressed that the small and medium-sized enterprises may not be able to comply with the Guideline at this stage due to the increase in cost.

Way Forward

11. Members are requested to note the content of this paper.

Health, Welfare and Food Bureau
Food and Environmental Hygiene Department
Centre for Food Safety
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Annex I

Labelling of GM Food – International Scenario

Labelling system	**Voluntary labelling**		**Mandatory labelling**					
			Pan-labelling		**Designated products only**			
Places	**United States**	**Canada**	**Australia and New Zealand**	**EU**	**Mainland China**	**Korea**	**Taiwan**	**Japan**
Labelling requirements	1. If the composition of GM food differs significantly from its conventional counterpart. 2. Presence of an unexpected allergen.	GM foods with health or safety concern. Labelling threshold -- 5%	GM food products on sale – either as a whole food or as an ingredient – must have their GM status identified if modified genetic materials or protein is present in the final food. Labelling threshold -- 1%	All foods produced from GM organisms (GMO), irrespective of whether DNA or protein of GM origin is detectable in the final products, have to be labelled. Labelling threshold -- 0.9%	Labelling of designated agricultural GM products (including food products): soybean, corn, rape, cotton and tomato, is regulated by Ministry of Agriculture. Labelling of GM food is also regulated by Ministry of Health No threshold limit listed.	Predetermined agricultural products: soybean, corn, bean sprouts and potato. Predetermined processed food which contain GM soybean, corn or bean sprouts as a major food ingredient (i.e. one of the top five ingredients) Labelling threshold -- 3%	Soybean and corn products, including soybean meal (flour), corn grit/meal (flour). Labelling threshold -- 5%	Designated agricultural products: soy bean (including soybeans and bean sprouts), corn, potato, rapeseed and cottonseed. Labelling threshold -- 5%
Exemption	Nil	Nil	1) Highly refined food, processing aids and food additives, flavours in a concentration less than or equal to 0.1%; 2) Food prepared at the point of sale.	Nil	Nil	GM agricultural or processed food products other than the designated items and processed food products with undetectable amount of GM materials.	Processed food made of soybean and corn such as soy sauce, soybean oil (salad oil), corn oil, corn syrup, corn starch and other highly processed food products which the final products do not contain traces of GM material or protein.	Nil
Negative labelling	1. The term “free” should not be used in label statements. 2. To be misleading if it suggests that a food with no GM counterpart is not genetically modified.	Absolute terms such as “free” were not allowed.	Voluntary negative claims must be accurate, unambiguous and substantiated.	“GM free” labelling is allowed as long as the claims are truthful and not misleading.	Nil	Non-GMO or GMO free claims were not allowed for processed food products.	Food products made of non-GM soybean or corn might be labelled as “non-GM” or “not GM”.	Food made from non-GMOs that have been segregated from GMOs during the production /distribution process by identity preservation.

Format of the labelling statement	Pending. Effective date not known.	Prescribed statement in conjunction with the name of that food or food ingredient. e.g. “Product of genetic engineering” or “Genetically engineered”	Prescribed statement in conjunction with the name of that food or food ingredient.	“Genetically modified” or “produced from genetically modified [name of organism] but not containing a genetically modified organism” should appear when appropriate.	Prescribed statement in conjunction with the name of that food or food ingredient. Examples: “轉基因 XX” “轉基因 XX 加工品” “轉基因 XX 食品” “以轉基因 XX 食品為原料”	Prescribed statement in conjunction with the name of that food. For agricultural products: “genetically modified soybeans” “bean sprouts cultivated from GM soybeans” For processed foods: “Genetically Modified Foods” or “Use Genetically Modified *name of ingredient* Foods” in the main display panel.	“Genetically Modified (GM) soybean (or corn)” or “Containing Genetically Modified soybean (or corn)” should appear when appropriate.	Prescribed statement in conjunction with the name of that food. Examples: "soybeans (genetically-modified)" "soybeans (genetically modified soybean NOT segregated)" "not genetically modified"

Annex II

GUIDELINES ON VOLUNTARY LABELLING OF GENETICALLY MODIFIED (GM) FOOD

PURPOSE

This guidance note sets out the principles underlying the recommended labelling approaches for GM food, and provides reference for the trade to make truthful and informative labels in a consumer-friendly manner.

BACKGROUND

2. The international community is working towards a consensual system on GM food labelling. However, there is no consensus on GM food labelling in the Codex Alimentarius Commission (Codex) and it is unlikely that internationally agreed standards can be established in the near future. Nevertheless, a number of countries have introduced their own labelling requirements on GM food. In order to enhance consumers' knowledge and right to make an informed choice on GM food, the Centre for Food Safety (CFS) supports the local food trade's initiative in setting up a voluntary labelling system for GM food. A Working Group comprising representatives from the food trade, the Consumer Council and the relevant Government departments was set up by the Centre for Food Safety (CFS) to formulate the relevant guidelines.

3. This guidance note is advisory in nature and has no legal effect. Adoption is entirely voluntary and is not binding. Nevertheless, members of the trade are encouraged to adopt these guidelines which have been jointly developed by representatives of the trade, consumer bodies and government departments. Members of the trade are reminded that they should not falsely describe their food products, which section 61 of the Public Health and Municipal Services Ordinance (Cap 132) will apply. [An extract of this section is attached at Appendix.]

These guidelines will be updated as and when necessary to reflect changes in technology and the international developments of GM food labelling requirement.

BASIC PRINCIPLES

4. The guidelines embody the following basic principles:

5. **Principle 1:** The Public Health and Municipal Services Ordinance (Cap. 132) provides the legislative framework for food safety control in Hong Kong. As stipulated in section 61, no person shall give any food sold by him or display with any food exposed for sale by him, a label, which falsely describes the food. In addition, the Food and Drugs (Composition and Labelling) Regulations require that any prepackaged food shall be marked and labelled in the prescribed manner.

6. **Principle 2:** The threshold level currently applied in the guidelines for labelling purpose is 5%, in respect of individual food ingredient, taking account of adventitious mixing of GM and non-GM crops during harvest, transportation, processing and storage. This threshold level reflects a more pragmatic and realistic level that the trade can achieve at this stage.

7. **Principle 3:** Additional declaration on the food label is recommended when significant modifications have taken place under the following conditions –

(a) the composition or nutritional [1] value is significantly different from that of its conventional counterpart;
(b) the level of anti-nutritional factors or natural toxicants is significantly different from that in its conventional counterpart;
(c) the presence of an allergen that is not found in its conventional counterpart;

[1] The Government put forward the original and revised proposals on Labelling Scheme on Nutrition Information in November 2003 and April 2005 respectively. Labelling requirement of nutrition information under the proposed scheme is irrespective of labelling of GM food ingredients.

(d) the intended use of the food is significantly different from that of its conventional counterpart; or
(e) an animal gene has been introduced into food of plant origin.

8. **Principle 4:** Negative labelling is not recommended for food without GM counterparts, as it would be misleading to consumers.

SCOPE

9. These guidelines are applicable to prepackaged food that contains food or food ingredients that are known to have a GM counterpart.[2]

DETAILED GUIDELINES

Interpretation

10. The following definitions are applicable to this guidance note.

"genetically modified (GM) food"（基因改造食物） refers to any food or food ingredient that is, or is derived from, an organism in which the genetic material has been modified using modern biotechnology;

"GM free"（不含基因改造成分） refers to any food ingredients absolutely free (i.e. zero) of GM materials;

"genetically modified organism (GMO)" （基因改造生物） means any organism in which the genetic material has been modified using modern biotechnology;

"ingredient"（配料）means any substance, including any additive and any constituent of a compound ingredient, which is used in the manufacture or preparation of a food

[2] Negative labelling is not recommended for food of which no GM varieties have been produced, as it would be misleading to consumers.

and which is still present in the finished product, even if in altered form;

"labelling"（標籤、加上標籤）, in relation to a food, includes any words, particulars, trade mark, brand name, pictorial matter or symbol relating to the food and appearing on the packaging of the food or on any document, notice, label, ring or collar accompanying the food;

"modern biotechnology"（現代生物科技） refers to the application of the following techniques that overcome natural physiological reproductive or recombination barriers and that are not used in traditional breeding and selection:

(i) *in vitro* nucleic acid techniques, including but not limited to recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(ii) fusion of cells beyond the taxonomic family;

"prepackaged food"（預先包裝食物） means any food packaged, whether completely or partially, in such a way that –

(a) the contents cannot be altered without opening or changing the packaging; and

(b) the food is ready for presentation to the ultimate consumer or a catering establishment as a single food item.

Positive Labelling

11. Any food items with 5% or more GM materials in their respective food ingredient(s) should be labelled as "genetically modified" in parenthesis following the name of the food/food ingredient in the list of ingredients. Alternatively, the words "genetically modified" may appear in a prominently display footnote to the list of ingredients, whereas the ingredient concerned would be marked with an asterisk "*". However, the font size of the footnote should be at least the same size as the list of

ingredients. Examples are,

For whole food or food with single ingredient: [3]
List of Ingredients: soya beans (genetically modified)
配料表：大豆（基因改造）

For processed food:

List of Ingredients: flour, soya flour (genetically modified), water, sugar, butter, and walnut

配料表：麵粉，大豆粉（基因改造），水，糖，牛油，合桃

or

List of Ingredients: flour, soya flour*, water, sugar, butter, and walnut

*genetically modified

配料表：麵粉，大豆粉*，水，糖，牛油，合桃

***基因改造**

Note:

If both the English and Chinese Languages are used in the labelling of prepackaged food, the name of the food and the list of ingredients shall appear in both languages.

12. For any GM food with significant modifications that have taken place under the following conditions –

(a) the composition or nutritional value is significantly different from that of its conventional counterpart;
(b) the level of anti-nutritional factors or natural toxicants is significantly different from that in its conventional counterpart;
(c) the presence of an allergen that is not found in its conventional counterpart;
(d) the intended use of the food is significantly different from that of its conventional counterpart; or

[3] Food with single ingredient is exempted from the requirements of "List of Ingredients" as stipulated in the Food and Drugs (Composition and Labelling) Regulations. Should the trade wish to label a GM food with single ingredient by means of the "List of Ingredients", such list shall conform in all respects with the requirements of the Marking and Labelling of Pre-packaged Foods of the said regulations.

(e) an animal gene has been introduced into food of plant origin,

the label should provide additional words in conjunction with the name of the food or food ingredients to inform consumers the changed characteristics. For example, product containing soya bean that is genetically modified to contain high oleic acid as an ingredient, the ingredient should be labelled as "high oleic acid soya bean (genetically modified)" with the necessary nutrient declaration indicated on the label.

13. If any GM food and their products of plant origin contain animal gene, additional information regarding the origin of animal gene[4] following the name of food ingredient is recommended. For example, a GM food "xx" with gene from animal "A" can be labelled as:

List of Ingredients: water, sugar, xx (genetically modified, contains gene(s) from A)
配料表：水，糖，xx (基因改造，含有來自 A 的基因)

Negative Labelling

14. "GM free" and similar labels (e.g. GMO free, free from GM ingredients, etc.) will give consumers the impression that the food products so labelled are totally free of GM content. Since there is the possibility of unintentional mixing of GM and non-GM crops, a truly "GM free" status is very difficult to attain. Such absolute terms may therefore be misleading to consumers and are not recommended to be used.

15. Should the trade wish to apply negative labelling other than "GM free" and similar labels to any food ingredients derived from non-GM sources (which contains less than 5% of GM content), the trade should ensure that there should be documentation to substantiate such declaration. The trade is also reminded to comply with the provisions laid down in Section 61 of the Public Health and Municipal Services Ordinance (Cap 132).

[4] No GM crops available in the international market at present contain any animal genes.

16. In addition, any such negative labelling is not recommended to appear following the name of the food, unless all of the concerned ingredients in the product are derived from non-GM sources and have fulfilled the requirement stated in paragraph 15.

EFFECTIVE DATE

17. These guidelines will be published on a date to be notified and thereupon for adoption.

Centre for Food Safety
Food and Environmental Hygiene Department

dd-mm 2006

CHAPTER 132
PUBLIC HEALTH AND MUNICPAL SERVICES ORDINANCE

Section 61 - False Labelling and Advertisement of Food or Drugs

(1) If any person gives with any food or drug sold by him, or displays with any food or drug exposed for sale by him, a label, whether or not the same is attached to or printed on the wrapper or container, which –

(a) falsely describes the food or drug; or

(b) is calculated to mislead as to its nature, substance or quality,

he shall be guilty of an offence, unless he proves that he did not know, and could not with reasonable diligence have ascertained, that the label was of such a character as aforesaid.

(2) Subject to the provisions of subsection (3), if any person publishes, or is partly to the publication of, an advertisement, other than a label to which the provisions of subsection (1) apply which –

(a) falsely describes any food or drug; or

(b) is likely to mislead as to the nature, substance or quality of any food or drug,

he shall be guilty of an offence, and, in any proceedings against the manufacturer, producer or importer of the food or drug, it shall rest on the defendant to prove that he did not publish, and was not a party to the publication of, the advertisement.

(3) In any proceedings for an offence under subsection (2), it shall be a defence for the defendant to prove either –

(a) that he did not know, and could not with reasonable diligence have ascertained, that the advertisement was of such a character as is described in that subsection; or

(b) that, being a person whose business it is to publish, or arrange for the publication of, advertisements, he received the advertisement in the ordinary course of business.

(4) For the purposes of this section, a label or advertisement which is calculated to mislead as to the nutritional or dietary value of any food is

calculated to mislead as to the quality of the food.

(5) In any proceedings under this section, the fact that a label or advertisement in respect of which the offence is alleged to have been committed contained an accurate statement of the composition of the food or drug shall not preclude the court from finding that the offence was committed.

(6) In this section, save in so far as it relates to drugs, references to sale shall be construed as references to sale for human consumption.