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**Meeting of Panel on Food Safety and Environmental Hygiene
on 9 May 2006**

Background Brief prepared by Legislative Council Secretariat

Regulation and labelling of genetically modified food

Purpose

This paper summarises the previous discussions by Members since 2000 on the need for a regulatory and labelling system for genetically modified (GM) food in Hong Kong.

Background

GM food and the labelling requirements in overseas places

2. Modern biotechnology makes it possible to alter the genetic make-up of living organisms by means other than traditional selective breeding. There are about 50 kinds of crops for food purposes, such as soya bean, corn and canola, that have been genetically modified. Insect resistance and herbicide tolerance are the most common traits introduced into these crops.
3. There is currently no international consensus on labelling of GM food or on a GM food testing protocol. The United States of America (USA) and Canada only require labelling of GM food that is not substantially equivalent to its conventional counterpart in terms of composition, nutritional value and allergenicity.
4. The European Union (EU), Australia and New Zealand, however, require labelling of all GM food if any ingredient therein contains more than 1% GM material.

5. In Asia, Japan and the Republic of Korea require labelling of certain food products which contain the most common GM agricultural products, such as corn and soybean, as major ingredients. The threshold adopted by Japan is 5% and Korea 3%.

6. In Hong Kong, there is no requirement to label the GM content of pre-packaged or other types of food.

Public concerns

7. Green groups, the Consumer Council and some members of the public have called for the labelling of GM food to provide more information for consumers.

8. Public concerns about GM food mainly include -

- (a) GM food may cause allergic reactions and antibiotic resistance;
- (b) GM food may bring irreversible damage to the environment such as unintended modification of other species in the neighbouring fields of GM crops due to cross-pollination; and
- (c) religious and vegetarian groups are worried that they may consume food containing genes from animals which they do not eat for religious or other reasons.

Motion debate at the Council meeting on 5 January 2000

9. On 5 January 2000, the Legislative Council (LegCo) passed a motion urging Government to introduce a mandatory labelling system for GM food, conduct tests on GM food for sale locally and enhance consumers' knowledge of GM food.

Consultation Paper issued by the Administration

10. On 26 February 2001, the Administration issued a "Consultation Paper on Labelling of Genetically Modified Food". Public views were specifically sought on a number of issues, including -

- (a) whether a voluntary or a mandatory labelling system, or a phased programme of both, should be introduced;
- (b) whether the labelling system should be restricted to pre-packaged food ; and

- (c) whether the threshold of GM content should be set at 5% or lower.

Discussions by the Panel on Food Safety and Environmental Hygiene

The Administration's Consultation Paper

11. The Administration briefed the LegCo Panel on Food Safety and Environmental Hygiene on the Consultation Paper on 26 February 2001. The Administration advised that there was no scientific or medical evidence to date to suggest that GM food was unsafe for human consumption. The Administration also pointed out that any labelling system to be introduced would have implications on food supply and cost for the food trade.

12. The Panel held another meeting on 28 May 2001 to further discuss the proposals in the Consultation Paper, before the consultation period ended on 31 May 2001. The Panel expressed support for putting in place a labelling system for GM food as soon as possible to enhance consumer information. While members did not oppose a voluntary labelling system in the initial stage of implementation, some members considered that a mandatory system should be introduced after a grace period of 18 months. A member suggested that a threshold of 5% could be introduced initially and lowered to 3% gradually. However, some members suggested that a more stringent threshold of GM content, say 1%, should be set.

13. Members also requested the Administration to strengthen publicity and public education on GM food. They were concerned about the enforcement aspect of the system, such as which party should be held responsible for the accuracy of information on the GM content on a food label. A member suggested that the Administration should consider issuing a White Bill on GM food labelling to facilitate the collection of public views.

Outcome of the public consultation

14. The Administration briefed the Panel on the outcome of the public consultation exercise at the meeting on 28 January 2002.

15. According to the Administration, the majority of views collected during public consultation was in support of mandatory labelling, and that the presence of GM content in any ingredient of a food product above a threshold should be labelled. All the professional medical bodies that had expressed views on the Consultation Paper also supported the proposal that there should be additional labelling for GM materials with significantly different characteristics from their traditional counterparts.

16. The Administration's paper also pointed out that the trade considered that it would incur additional costs for compliance with the mandatory labelling requirements. Moreover, if the GM food labelling system in Hong Kong would be very different from those implemented in other markets, overseas food manufacturers might simply give up the Hong Kong market because Hong Kong was a very small market for them. The Administration therefore proposed to conduct an economic assessment on the different options, including the impact on each sector of the food trade and on food prices, and the resource implications for implementation.

17. Some Panel members considered that a mandatory labelling system should be put in place as soon as possible, given that the majority of views collected in the public consultation exercise was in support of a mandatory system. Nevertheless, the Panel did not raise objection to the proposed economic assessment in order to fully evaluate the impact on the food trade. The Administration agreed to report to the Panel the outcome of the economic assessment and the recommendations on the way forward in late 2002.

Findings of the economic assessment

18. The Administration appointed a consultant to conduct a regulatory impact assessment (RIA) in April 2002 to assess the economic impact of introducing a labelling scheme on packaged GM food. The RIA was completed in March 2003 and a copy of the Executive Summary of the RIA report was provided for the Panel meeting on 20 March 2003.

19. The Panel noted that according to the RIA, there would be no increase in cost to the food trade if a voluntary labelling system was adopted. There would be some increase in costs (ranging from \$16 million to \$91 million) to the food trade if a mandatory labelling system was implemented. The cost implications to the small to medium enterprises would be significant because they would have difficulties in complying with the requirements, including difficulties in securing contractual agreements with product manufacturers with regard to the product's GM status. The RIA also identified some barriers to implementation, such as the lack of international consensus of GM labelling and testing, and the lack of international standards on Identity Preservation and documentation systems for certifying the GM content of products.

20. Having considered the RIA report and the need to address the issue of safety of GM foods in future, the Administration proposed that it would be appropriate to introduce a pre-market safety assessment requirement for GM ingredients, to be supplemented by a system of voluntary labelling.

Views of the Panel and depositions

21. At its meetings on 20 March and 29 April 2003, the Panel gauged the views of the food trade and organisations concerned on the RIA and the Administration's proposal to introduce a voluntary labelling system and a pre-market safety assessment requirement for GM ingredients.

22. The green groups and the Consumer Council supported the introduction of a mandatory labelling system for GM food as soon as possible. Greenpeace considered that a voluntary labelling system would mean status quo because many food importers would not voluntarily label their products as containing GM ingredients. The Consumer Council pointed out that there was consensus internationally on the need for the labelling of GM food, although there were differences in their labelling systems. These depositions were of the view that the costs on the food trade for complying with the mandatory labelling requirements were not that significant, given that the cost would spread over a long period of time, and it would cost more to the food trade if some of the GM products were subsequently found unsafe for human consumption. Some organisations also urged the Government to include seeds and animal feeds in the regulatory system for GM food.

23. Organisations representing the food trade were generally in favour of a voluntary labelling system, and requested for a gradual approach of implementation. They also expressed concern about the additional costs for safety assessment and repackaging, the lack of international consensus on the threshold for labelling of GM food, difficulties in tracing the origin of the GM content in ingredients, and availability of testing facilities in Hong Kong. A summary of the views received by the Panel is in **Appendix I**.

24. The majority of Panel members present at the meetings on 20 March and 29 April 2003 expressed support for introducing a mandatory labelling system for GM food in order to safeguard public health and protect consumers' interest. They shared the views of some depositions that the food trade should be able to comply with the labelling requirements given that many exporting countries already adopted GM food labelling and the additional costs of \$91 million to the industry was not very significant. The Panel passed a motion at the meeting on 20 March 2003 urging the Government to draw reference to the experience of the European Union countries and expeditiously introduce legislation to set up a mandatory GM food labelling system.

Research studies and overseas duty visits

25. To facilitate Panel members to have a better understanding of the practice of GM food labelling in overseas countries, the Panel requested the Research and Library Services Division to conduct a research study on GM food labelling in USA, Australia and Japan (RP05/02-03 and IN25/02-03) in 2003. An information note on the system in EU (IN03/03-04) was also provided to the Panel.

26. A delegation of the Panel visited Australia and Japan in 2003 and 2004 respectively to better understand the food regulatory systems in these countries. During these visits, members also exchanged views with the organisations concerned on the implementation of GM food labelling in their countries. An extract of the relevant findings of the delegations is in **Appendix II**.

Motion debate and Council questions on the subject of GM food labelling since 2003

27. At the Council meeting on 26 June 2003, Hon Fred LI moved the motion on “Establishing a labelling system for genetically modified food”. The motion, which urged the Government to expeditiously establish a genetically modified food labelling system for prepackaged food products by adopting a “voluntary first, and then mandatory” approach, was passed at the meeting.

28. Questions on GM food labelling were raised by Hon Fred LI and Dr Hon LUI Ming-wah at the Council meetings on 2 March 2005 and 1 June 2005 respectively. Concerns were raised on the presence of animal genes found in samples of vegetarian food products, and the importation of GM crops from the Mainland and other places.

29. Hon Fred LI raised a further question on GM food labelling at the Council meeting on 26 April 2006 on the application of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity to Hong Kong, the recent incident of distributing GM papaya seedlings to farmers, and the timetable for implementing a mandatory labelling system for GM food.

Recent developments

30. The Panel on Food Safety and Environmental Hygiene will discuss with the Administration on 9 May 2006 the presence of GM content in infant food and papaya seedlings, the implementation of the Cartagena Protocol on Biosafety, and the timetable for introducing mandatory labelling for GM food.

Relevant papers

31. A list of the relevant papers discussed is in the **Appendix III** for members' easy reference. These documents are available on the Research and Library Information System and the Council's web site at <http://www.legco.gov.hk>.

Council Business Division 2
Legislative Council Secretariat
3 May 2006

LC Paper No. CB(2) 2521/02-03(01)

Panel on Food Safety and Environmental Hygiene

Summary of submissions on labelling of genetically modified food received by the Panel

(as at 17 June 2003)

Organisation [LC Paper No.]	Views/Suggestions
1. The Hong Kong Food Council [CB(2)1565/02-03(01)]	<ul style="list-style-type: none"> - <u>supports</u> implementing voluntary genetically modified (GM) food labelling - <u>suggests</u> that mandatory GM labelling should not be introduced until Codex Alimentarius Commission has established an internationally agreed standard for GM food labelling - <u>considers</u> that the requirement to label all GM food is not easy to enforce because of limitation of detection methods for GM foods and not all GM food products are readily identifiable by end-product analysis. Moreover, the laboratory capabilities in Hong Kong are inadequate to provide the necessary testing for GM foods - approaches in GM food labelling differ from place to place. e.g. Japan, Korea and Taiwan have adopted labelling of designated food items that contain GM ingredients as major components. Canada and USA only require the labelling of GM food that is not substantially equivalent to its conventional counterpart and the trade may label other GM food on a voluntary basis. Moreover, Canada and USA are still drafting guidelines for the voluntary labelling of GM food. In fact, a consensus has yet to be reached in the international community on the labelling approach of GM foods and not all countries have implemented mandatory GM labelling

	<ul style="list-style-type: none">- Hong Kong relies heavily on imported food. Should Hong Kong introduce labelling requirements which are more stringent than those imposed by some of her trading partners, this will not only generate increased costs to importers but also give rise to trade barriers- <u>supports</u> that the Government should adopt a gradual approach in implementing food labelling systems
<p>2. Hong Kong Retail Management Association [CB(2)1836/02-03(04)]</p>	<ul style="list-style-type: none">- <u>welcomes</u> the proposal of implementing voluntary GM food labelling and agrees that the trade should be encouraged to label voluntarily- the lack of an international consensus on threshold level for GM food labelling is the main problem for implementing mandatory GM labelling. The lack of consensus affects all organisations, particularly small and medium sized enterprises, which are faced with the task of complying with multiple laws- it is impractical and costly for Hong Kong to adopt a GM labelling approach which is different from its major trading partners. This will result in higher production costs and retail prices, and reduced choice for consumers as some products may disappear from Hong Kong market- <u>suggests</u> granting blanket approval to products imported from markets which have demonstrated sufficient control over GM labelling- <u>worries</u> that the proposed pre-market safety assessment will result in increased cost of regulation to the Food and Environmental Hygiene Department (FEHD) and entail a lengthy approval process

<p>3. World Wide Fund for Nature [CB(2)1836/02-03(07)]</p>	<ul style="list-style-type: none">- <u>welcomes</u> the proposed introduction of a requirement of pre-market safety assessment for food containing GM ingredients. However, GM food suppliers and manufacturers should still label all the GM ingredients in their food products no matter whether the GM ingredients are on the list of approved GM ingredients or not- <u>suggests</u> a grace period of 12 months be granted to those GM products already in the market- <u>supports</u> the formulation by the Government of a set of guidelines on the labelling of GM foods- <u>demands</u> the Government to implement mandatory labelling of GM food
<p>4. The Democratic Party [CB(2)1875/02-03(01)]</p>	<ul style="list-style-type: none">- <u>demands</u> the Government to implement mandatory labelling of GM food to enable consumers to make informed choice- <u>considers</u> that the Government has already wasted a lot of time in conducting the relevant studies and has lagged far behind in introducing regulation of GM foods compared with our neighbouring places. The Government should provide for mandatory labelling by introducing legislation and the approach should be "voluntary labelling to be followed by mandatory"- <u>suggests</u> setting the threshold at 1% for GM labelling- <u>suggests</u> that FEHD should conduct regular inspections of the prepackaged food items available in the market and publish any of them contain GM ingredients

<p>5. The Consumer Council [CB(2)1836/02-03(03)]</p>	<ul style="list-style-type: none">- <u>supports</u> the introduction of a mandatory labelling system for GM food as soon as practicable. There is already a general consensus in the international community on the need for the labelling of GM food and consumers have the right to know whether the food items they pay for contain GM ingredients- <u>points out</u> that voluntary labelling cannot prevent withholding of GM ingredient information or making false claims about the GM content- <u>supports</u> the implementation of a mandatory pre-market safety assessment of GM food and <u>welcomes</u> the formulation of guidelines on GM labelling- <u>suggests</u> that the use of negative labelling claims should be prohibited- <u>points out</u> that in USA, safety assessment relies on claims advanced by biotech companies and the GM variety is regarded as safe if there is no scientific evidence to the contrary. Consumer organisations worldwide consider such an approach inappropriate and the Consumer Council considers that such an approach should not be followed by Hong Kong- <u>proposes</u> for the introduction of traceability/product tracing technology and the requirement of proper documentation in the production of GM food- <u>suggests</u> that local universities and research institutions should be encouraged to conduct studies on GM food safety to produce data and information directly applicable to the local population
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<p>6. Hong Kong Food Science & Technology Association Limited [CB(2)1906/02-03(02)]</p>	<ul style="list-style-type: none">- <u>supports</u> the implementation of a voluntary GM food labelling system- <u>suggests</u> that mandatory GM food labelling should be introduced at least 5 years later- Problems of implementing mandatory GM labelling include -<ul style="list-style-type: none">a. the production cost will have to increase which will be passed onto customersb. adequate time should be allowed for the trade to allow existing stocks of packaging to be finished before implementing new labelling requirementsc. there is a lack of information on the cost of GM testing and on negative labelling. Laboratories which provide GM testing services are also limited in Hong Kongd. local retailers or manufacturers often buy ingredients from the Mainland through an exporter. It is difficult to trace for which farm or factory has produced the ingredients
<p>7. Hong Kong DNA Chips Limited [CB(2)1836/02-03(05)]</p>	<ul style="list-style-type: none">- <u>suggests</u> the adoption of a "Yes/No" principle for GM labelling while allowing an acceptable level of adventitious contamination- highly sensitive DNA-based tests are available in Hong Kong for detecting the presence of GM ingredients at a level even lower than the threshold of 1% adopted by the European Union- the global trend is towards providing more information to consumers about ingredients derived from GM sources

<p>8. Hong Kong Organic Farming Association [CB(2)1906/02-03(03)]</p>	<ul style="list-style-type: none">- <u>supports</u> introducing a mandatory labelling system for GM food to protect consumers' right to know and enable them to make their choices taking religious, cultural or ethical issues into consideration- without a mandatory labelling system for GM food, organic food producers may inadvertently use GM ingredients in their food production process and this problem has already posed a serious threat to organic farming- since legislation on GM food labelling has already been introduced in our neighbouring places such as Japan, South Korea, Mainland China and Taiwan, Hong Kong will become a dumping ground for GM food not approved to be sold in other countries
<p>9. Green Women Current - Tuen Mun Yan Oi Tong Women's Development Centre [CB(2)1906/02-03(01)]</p>	<ul style="list-style-type: none">- <u>supports</u> introducing a mandatory labelling system for GM food to protect consumers' right to know and enable them to make informed choices- since the long-term effect of consumption of GM food on human health is still uncertain, consumers should not be used as guinea-pigs for testing the safety level of GM food
<p>10. Hong Kong Organic Resource Centre [CB(2)1891/02-03(01)]</p>	<ul style="list-style-type: none">- <u>welcomes</u> the introduction of a requirement of pre-market safety assessment for food containing GM ingredients and the proposal of issuing a set of guidelines on the labelling of GM food by the Government. However, no conclusion on the health impact of GM food can be drawn even though the food passes the assessment- <u>supports</u> introducing a comprehensive, stringent and mandatory labelling system for GM food as soon as possible

	<ul style="list-style-type: none">- GM labelling will not incur extra testing cost to the trade since they anyway have to go through the proposed pre-market safety assessment. To meet GM labelling requirement, they simply have to set out in food labels the outcome of the safety assessment
11. Greenpeace [CB(2)1511/02-03(03) CB(2)1836/02-03(06)]	<ul style="list-style-type: none">- <u>supports</u> introducing as soon as possible a stringent, mandatory labelling system for all food which is produced, processed, cultivated or grown by using genetic modifications- <u>suggests</u> setting the threshold at 1% and a grace period of not more than 18 months should be allowed for the food trade before the relevant legislation taking effect- the proposed pre-market safety assessment for food containing GM ingredients cannot address consumers' concern about the safety problem of GM food- the implementation of mandatory GM food labelling will not have serious impact on people's livelihood as supported by the findings of the regulatory impact assessment (RIA) report, which points out that "for most manufacturers these costs were unlikely to be significant and if the costs could be diluted over a longer period of time (more than one year), then the actual impact on the company's revenues and profits might not be significant" and "it is unlikely that the costs incurred will be recoverable from retailers"- the RIA report also points out that the financial implications to the food trade in implementing mandatory labelling only "ranges between HK\$16 million to HK\$91 million". Even the most costly option (HK\$91 million) is not substantial as the cost can be shared out by the different sectors of the food trade

	<ul style="list-style-type: none">- mandatory GM food labelling has been implemented in about 39 places and it was not known any economies or food traders/manufacturers have been negatively impacted by the implementation of mandatory GM food labelling- Greenpeace has surveyed 80 local food manufacturers and agents, of which 49 have confirmed in writing that they do not use GM ingredients and 3 have undertaken to avoid using GM ingredients. So GM labelling will not incur much extra costs to these food traders and it is only fair to them by requiring their counterparts using GM ingredients to label their products as containing GM ingredients- Greenpeace has also written to local food manufacturers in January and September 2002 and many of them have responded positively to the introduction of mandatory GM labelling. Extracts from the responses are set out in the submission of Greenpeace [LC Paper No. CB(2)1836/02-03(06)]- a position paper jointly signed by 27 community organisations, political parties and green groups is attached to the submission of Greenpeace
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**Extract from the report of the delegation of
the Panel on Food Safety and Environmental Hygiene
to study the food regulatory systems in Australia
from 20 to 25 July 2003**

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Chapter 4 : Safety assessment of genetically modified food

Foods requiring a safety assessment in Australia

4.1 According to the Organisation for Economic Co-operation and Development in 1993 (OCED 1993), "the safety of food for human consumption is based on the concept that there should be reasonable certainty of no harm from the intended use". Food is considered to be safe based on experience, for example, there is no history of adverse effects or there is adequate knowledge in the community to address any hazards.

4.2 The following categories of food for sale in Australia require a safety assessment -

- (a) novel foods (including those with dietary macro-components; extracts of plants, animals or micro-organisms; single ingredient foods; and viable micro-organisms - probiotics);
- (b) foods produced using gene technology; and
- (c) irradiated foods.

Food produced using gene technology

4.3 Food produced using gene technology (GM food) is regulated by Standard 1.5.2 - Food Produced Using Gene Technology. The Standard prohibits the sale and use of a GM food unless it is included in the Table to clause 2 of the Standard and complies with any special conditions specified by that Table. The Standard requires FSANZ to assess the safety for human consumption of each food or class of food prior to their inclusion in the Table. Mandatory pre-market safety assessment is imposed on all kinds of GM food. The goal of such assessment is not to establish absolute safety but to consider whether the GM food is as safe as its traditional counterpart, where such counterpart exists.

4.4 The safety assessment for GM food is characterised by -

- (g) use of scientific, risk-based methods;
- (h) case-by-case assessment;
- (i) consideration of both the intended and unintended effects; and
- (j) comparisons with conventionally produced food.

4.5 The assessment aims to identify if a hazard is present in a GM food. Such assessment applies to food derived from a GM organism, and not the organism itself (e.g. oil, sugar, seed, fruit). The assessment process is based on internationally developed concepts and principles developed over the past 12 years. The process is constantly reviewed and updated to take into account new developments.

4.6 The safety assessment process is conducted in two phases -

- (a) identification of similarities and differences (e.g. identification of the source of donor DNA/genes and the molecular characteristics); and
- (b) further scrutiny of the identified differences (e.g. to assess the toxicity/allergenicity of any novel protein, the safety of any transferred antibiotic resistance gene, and the safety and nutritional impact of any compositional changes).

Decisions on the safety of GM foods are based on the totality of the evidence gathered.

4.7 According to FSANZ, the first GM food safety assessment was conducted in 1998. Up to 2003, 21 food safety assessments have been completed, and all GM foods assessed to date are found to be "as safe as their non-GM counterpart".

Development of the GM food labelling requirements

4.8 In 1998, the Inter-governmental GM Food Labelling Taskforce was formed at the request of the Ministerial Council (paragraph 2.2) to develop options for labelling of GM food, and to provide the approximate costing for each option. A consultancy company was subsequently engaged to advise on the options and the estimated costs on the Government and the industries under each option. During the public consultation period, thousands of submissions

were received. In November 2000, the Health Ministers approved the Standards for implementation of the new labelling provisions concerning presence of novel DNA or novel protein in final food. The new requirement was gazetted on 7 December 2000 and put in force a year later, i.e. on 7 December 2001.

GM food labelling requirements

4.9 The labelling requirements apply to GM food where -

- (a) novel DNA and/or protein is present in the final food; and/or
- (b) the food has altered characteristics when compared with its conventional counterpart.

4.10 There are several exemptions to the labelling requirements -

- (a) highly refined food where the effect of the refining process removes novel DNA and/or protein;
- (b) processing aids and food additives except those where novel DNA and/or protein is present in the final food;
- (c) flavours which are present in a concentration less than or equal to 0.1% in the final food;
- (d) 1% threshold or accidental contamination where the manufacturer has sought to obtain non-GM ingredients; and
- (e) food prepared at the point of sale (i.e. restaurants and take-way food).

4.11 Food or food ingredients produced using gene technology where GM material is present in the final food must be labelled with the words "genetically modified". This information must appear on the label of packaged food or in connection with the display of the food if it is unpackaged.

4.12 If the GM food or ingredient has altered characteristics when compared to its conventional counterpart, there are additional labelling requirements, which are specified in Standard 1.5.2. These altered characteristics are -

- (a) composition or nutritional values;
- (b) anti-nutritional factors or natural toxicants;
- (c) factors known to cause allergic responses;

- (d) difference in the intended use; and
- (e) factors that may raise significant ethical, cultural or religious concerns.

4.13 Standard 1.5.2 is silent with regard to negative claims such as "GM free" or "non-GM". The Standard does not prescribe statements to be used for negative claims nor does it prohibit the use of negative claims. Negative claims are made by food businesses on a voluntary basis. However, such claims are subject to the fair trading requirements of the Australian Trade Practices Act 1974. Food businesses must ensure that any such claims are not false, misleading or deceptive.

Enforcement

4.14 FSANZ only sets the regulatory standards and enforcement in Australia is carried out by the State/Territory Governments. In Australia, the inspection and enforcement of food labelling of processed food at retail level are undertaken by Environmental Health Officers (EHO) of local councils, or Senior Food Officers of the State health authorities, depending on their jurisdictions. For imported food, the inspection and enforcement of the food labelling requirement are undertaken by AQIS (paragraphs 3.14 - 3.15 refers). Complaints concerning non-compliance with the labelling requirements could be made to the consumer organisations or the relevant enforcement agency.

4.15 Dr Paul Brendt, Manager, Biotechnology Products Standard Program of FSANZ has advised that only a limited amount of enforcement activity has taken place in Australia due to manpower constraints. Nevertheless, a recent survey on compliance to the GM food labelling requirements in Australia (see paragraphs 4.16 - 4.24) reveals that the GM food labelling requirements of Standard 1.5.2 are in general complied with by the food businesses surveyed. FSANZ is also conducting a review of the GM food labelling standard which has been in place for almost three years. The review is expected to be completed by the end of 2003.

Australian GM food labelling survey

4.16 The State and Territory Governments in Australia have recently collaborated to conduct a pilot survey of corn and soy derived food products in Australia aiming to determine -

- (a) how food businesses are adapting to comply with GM food labelling requirements, and the need to determine the GM status of their ingredients; and

- (b) the usefulness of document surveys to regulatory authorities in determining compliance or non-compliance with the mandatory GM food labelling requirements, as an alternative to undertaking expensive laboratory tests.

4.17 The survey tested a representative range of soy and corn derived food products (soy milk, bread, cornflakes, corn chips and tacos) for the presence of novel DNA. These products have the potential for the inclusion of GM ingredients, because of international trade and the commercial cultivation of GM crops overseas. Three rounds of Polymerase Chain Reaction (PCR) testing were conducted to detect the presence of DNA in 51 samples collected in the survey. 36 manufacturers, importers and retailers (supermarkets with generic products) providing such samples were also asked to present evidence on how they determined the GM status of their food products. The document survey covered a mixture of small, medium and large food businesses.

4.18 At the time of the delegation's visit, the results of the survey had not yet been considered by the Ministerial Council. The survey report was subsequently released in August 2003. The full report is now available on Australian Commonwealth Government's web site at <http://www.foodstandards.gov.au>.

4.19 According to the survey report, all the 51 samples tested in the survey were found to have complied with the GM food labelling requirements of Standard 1.5.2. In 10 samples, the GM material detected was within the 1% limit of the labelling exemption for unintentional presence of an approved GM food in non-GM food.

4.20 The report also revealed that the large food businesses covered by the document survey had management systems (documentation or testing) in place to demonstrate the GM status of ingredients used in their products. However, the smaller food businesses surveyed were unable to provide evidence that their products did not contain GM ingredients because they had not implemented management systems.

4.21 Examples of documents included in the management systems of large and medium food businesses are -

- (a) supplier's product specification sheets;
- (b) supplier certification or declaration statements (assurances may be validated by audits or testing);

- (c) independent third party certification;
- (d) an "Approved Supplier Program" requiring suppliers to meet certain requirements; and
- (e) a database classifying the GM status of all raw materials and ingredients used, such as "GM", "GM derived/contain novel DNA or protein", "GM derived/DNA negative", " Non-GM sourced" and "GM free".

4.22 Standard 1.5.2 does not require a food business to establish a management system to determine the GM status of ingredients used in its products to demonstrate the basis of decisions to label or not label products as GM. The Standard is also silent on documentation. However, documentation has been proposed as a method to determine the GM integrity of products.

4.23 In general, the findings of the survey indicate that large food businesses have adapted to the need to label food products which are GM or contain GM ingredients, and the consequential need to determine the GM status of ingredients used in the products. They have also implemented management systems for the purpose. On the other hand, the smaller food businesses do not appear to have adapted. However, from the samples which were subject to testing and document survey, there have not been non-compliance with the GM labelling requirements.

4.24 According to the report, the document survey is a useful tool for regulatory authorities as an alternative to expensive testing to determine compliance or non-compliance with GM food labelling requirements if the food business has implemented a management system to demonstrate the GM status of ingredients used in its products.

AgriQuality - genetically modified organisms testing services

4.25 The delegation visited one of the laboratories operated by AgriQuality which is a New Zealand-based company wholly owned by the New Zealand Government. The organisation provides internationally accredited certification services on food safety and biosecurity through a network of laboratories.

4.26 AgriQuality offers testing services for the detection of genetically modified organisms (GMOs) in food and animal feed. Its technical experts use PCR technology to detect the presence of DNA sequences typical of GMOs.

With highly sophisticated equipment and using real-time PCR, AgriQuality can also quantify the amount of target DNA that has been genetically modified. During the meeting with representatives of AgriQuality in Victoria, the delegation was told that the current PCR testing could detect the presence of up to 0.1% DNA in food.

4.27 According to AgriQuality, about 63% of soy, 21% of maize, 11% of cotton and 5% of canola grown worldwide were genetically modified. The major countries growing commercial GM crops include USA, Mexico, Canada, Argentina, China and Australia.

4.28 In 2002, GMO tests were conducted by AgriQuality on flours (53%), mixes (41%), final products (31%), seed/grain (19%) and oil/lecithin (10%). These included soybean, maize, rice, rape seed, sugar beet, tomato, potato and cotton.

4.29 According to AgriQuality, the following issues would continue to receive attention worldwide -

- (g) emerging technology for GMO testing;
- (h) acceptance of GMO testing worldwide;
- (i) extended application of GMO testing to the whole food spectrum including animals;
- (j) control of the supply chain to ensure that consumer has choice;
- (k) better identification system for GM food; and
- (l) development of GM-free zones.

The new labelling system in the European Union (EU)

4.30 Dr Paul Brendt of FSANZ advised the delegation that the European Parliament had adopted a new legislation on 2 July 2003, and the new legislation would have to be ratified by the European Council before the Regulations could come into force. The new legislation provides for :

- (a) a single approval process for GMOs, e.g. seeds, and feeds derived from those GMOs;
- (b) traceability across production and distribution chains; and
- (c) extensive mandatory labelling of GMOs in food and feed.

4.31 Under the new legislation, all foods produced from GMOs irrespective of whether there is DNA or protein of GM origin in the final product (e.g. highly refined oils and sugars) must be labelled. In addition, all genetically modified feed have to be so labelled and a 0.9% threshold has been adopted for adventitious presence of approved events.

4.32 According to Dr Paul Brendt, the new EU legislation recognises that accidental or unintended presence of minute traces of GMOs in products is largely unavoidable. The EU recognises that such situation already exists and affects products originating both in EU and in other countries. While EU has adopted an across-the-board threshold of 0.5%, a technically unavoidable presence of GMOs not formally authorised but scientifically assessed could be permitted. This exemption applies for a limited time period of three years. This is less strict than the FSANZ requirements, which apply a nil tolerance for unapproved GM foods.

4.33 In comparing EU's new legislation with the Australian requirements, Dr Paul Brendt of FSANZ explained that EU's regulatory system covered seeds, while the Australian system regulated the crops but not the seeds. Moreover, EU adopted a threshold of 0.9% while Australia maintained the 1% threshold for GM labelling. As regards accidental contamination, EU accepted 1% while Australia adopted "zero tolerance" at the moment.

4.34 The Research and Library Services Division of LegCo Secretariat has prepared an information note on the GM food labelling system in the EU (IN 25/02-03).

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Chapter 7 : Observations

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Testing of GM food

7.7 There are several laboratories in Australia which provide GMO testing services for industries and organisations. The delegation is given to understand that with advance technology, it is now possible for the PCR testing to identify the presence of up to 0.1% DNA in food (paragraph 4.26).

7.8 According to Australia's recent GM food labelling survey (paragraphs 4.16 to 4.24), the large food businesses surveyed have put in place management systems (documentation and testing) to demonstrate the GM status of ingredients used in their products, but the smaller food businesses do not have such systems and they generally rely on the information provided by suppliers. The survey report also suggests that document survey is a useful tool to regulatory authorities as an alternative to expensive laboratory testing in determining compliance or non-compliance with the GM labelling requirements.

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**Extract from the report of the delegation of
the Panel on Food Safety and Environmental Hygiene
to study the food regulatory systems in Japan
from 15 to 21 January 2004**

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Chapter 4 - Food labelling

General

4.1 The Food Sanitation Law requires that food, food additives, food apparatus and containers/packages intended for sale must be labelled with information such as contents, best-before date, manufacturer and storage methods.

Foods containing allergic substances

4.2 In April 2001, the Food Sanitation Law was amended to include provisions on labelling of foods containing allergic substances, in order to provide necessary information to customers to prevent health risk. Mandatory labelling is required for five types of foods which can cause severe allergic symptoms, i.e. eggs, milk, wheat, buckwheat and peanuts. In addition, the food trade is also encouraged to provide necessary information on the labels of 19 types of foods which can cause symptoms of allergy of a lower degree of severity. These foods include abalone, squid, salmon roes, prawn, oranges, crabs, beef, walnuts, soybeans, chicken, pork, etc.

Foods for specified health or dietary uses

4.3 Foods for specified health uses refer to all foods intended to maintain or enhance the health conditions, or for special health uses by people who wish to control health conditions such as blood pressure or level of cholesterol. Manufacture or distribution of these foods requires permission of the national government. Permission will be given after evaluation of the safety and efficiency of the health functions claimed.

4.4 Foods for special dietary uses refer to all foods intended for special dietary uses, e.g. food for the ill and aged, milk powder for pregnant women and infants, and foods for specified health uses. These foods must be labelled to the effect that they are intended for any of the special uses and that permission or approval for the food has been given. The food label must also include information as prescribed in the Ministerial Ordinance under the Health Promotion Law, e.g. name and address of manufacturer, permitted health claim, amount of nutrients, calories, ingredients, use-by date, recommended daily intake and methods of consumption/preservation.

Nutrition information

4.5 Foods with nutrition claims refer to all foods intended to supply or supplement nutrients that are liable to deficiencies in daily life. Such foods can be manufactured or distributed without specific permission from or notification to the national government, subject to their meeting the prescribed standards and labelling requirements.

4.6 Foods labelled with information on calories or nutrients (other than foods for specified health uses) must comply with the Nutrition Labelling Standards prescribed by Ministry of Health, Labour and Welfare (MHLW) in the Health Promotion Law. Information on the five core nutrients, i.e. protein, fat, carbohydrate, minerals and vitamins, must be included in these food labels. Information on these nutrients must be written in Japanese on the container or package in a manner that is easy to read. The delegation was informed that the five core nutrients were selected after a survey on the health conditions and nutrient deficiencies among the Japanese.

4.7 There are specific labelling requirements concerning description of the amount of, or the level or range of such nutrients. For example, the amount of each nutrient must be shown in terms of per 100g or 100ml, or per serving or package. A minimum or maximum level is also prescribed for claims using terms like "high" protein, "rich" in Vitamin A, "low" fat, "reduced" sodium, "containing" iron, etc.

4.8 According to MHLW officers, the food trade does not have much objection to the nutrition information labelling requirements, because not much additional costs are involved and the manufacturers also want to include such information as a marketing tactic.

4.9 The nutrition labelling standards of Japan are given in **Appendix VII**.

(not attached)

GM food

4.10 In April 2001, labelling of GM food also became mandatory in Japan. Ministry of Agriculture, Forestry and Fishery (MAFF) and MHLW are responsible for monitoring compliance with the GM labelling requirements. MAFF is responsible for enforcing the Japanese Agricultural Standards Law with an aim to enable customers to make informed food choices. MHLW is responsible for conducting safety assessments on GM food under the Food Sanitation Law.

4.11 As at July 2001, five crops (i.e. soybeans, corns, rape seeds, potatoes and cotton seeds) and 30 types of processed foods containing ingredients made from these crops are subject to mandatory labelling. However, voluntary labelling applies to the following processed foods -

- (a) products from which recombinant DNA and protein are removed; and
- (b) products in which the crops are not used as major ingredients (major ingredients refer to the three major ingredients of the product in terms of weight, and the proportion of each ingredient is 5% or more by weight).

4.12 Certain GM ingredients, such as Starlink corn, 55-1 papaya and New Leaf Y potato are prohibited in Japan.

4.13 According to MHLW officers, very few GM food products are imported into Japan. Although negative labelling is entirely voluntary, almost all manufacturers have labelled their non-GM food as such.

4.14 As regards adopting a 5% threshold for mandatory labelling of GM food. MHLW officers informed the delegation that Japan had taken into consideration the actual manufacture and distribution process of crops, and noted that inadvertent mixture of GM ingredients was sometimes inevitable in the process. Japan has also made reference to the situation in other countries such as the United States of America, conducted public consultation and carried out scientific analysis before deciding on the 5% threshold.

Enforcement

4.15 While MHLW is mainly responsible for setting standards, conducting safety assessment and monitoring the hygiene standard of imported food, sample checks and surveillance are carried out by the Health Inspectors under the prefecture or local governments. Foods for sale at food premises, including supermarkets, have to comply with the requirements under the Food

Sanitation Law and other relevant legislation.

4.16 Where discrepancies are found in the amount of nutrients, the food business operators will be advised to rectify the discrepancies. If no improvement is made, ministerial orders may be issued, and non-compliance with the orders may lead to a fine of 500,000 yen.

4.17 As regards the sale of food beyond the "best-before" or "use-by" date, MHLW officers advised that Article 4 of the Food Sanitation Law stipulates that no person shall sell foods that are rotten, decomposed or immature, but this does not apply to food that have no adverse effects on human health and are deemed to be fit for human consumption. As a general practice, food premises are advised not to sell food beyond its expiry date. Enforcement action will be taken if the food for sale has perished and is unfit for human consumption.

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Chapter 9 - Observations

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Food labelling

9.6 The delegation has noted that food labels in Japan provide very comprehensive information on the ingredients and their quantities. There are also detailed guidelines and standards on food labelling such as those related to nutrition claims (paragraphs 4.5 to 4.8 and Appendix VII). According to government officials in Japan, the five core nutrients subject to mandatory labelling were selected after a survey on the health conditions and nutrient deficiencies among the nationals in Japan. There was not much controversy over the labelling requirement on nutrition claims because not much additional costs for nutrition information labelling were involved, and the food industry in Japan also wanted to include such information as a marketing tactic (paragraph 4.8).

9.7 Labelling of GM food is mandatory (subject to certain exemptions) in Japan. The 5% threshold is adopted by Japan having regard to its own situation and overseas experience, and after scientific research and public consultation. There are very few GM food for sale in Japan, and almost all non-GM foods are so labelled although negative labelling (i.e. non-GM food labelling) is entirely voluntary (paragraphs 4.10 to 4.14).

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Appendix III

Relevant Papers

<u>Meetings</u>	<u>Meeting Dates</u>	<u>Papers/Motion Passed/Council Question</u>
Legislative Council	5 January 2000	A motion was passed urging Government to introduce a mandatory labelling system for GM food, conduct tests on GM food for sale locally and enhance consumers' knowledge of GM food.
	5 December 2001	Motion on "Reviewing the labelling system for prepackaged food" moved by Hon CHAN Kam-lam
	12 December 2001	Written question on "Labelling system for GM food" raised by Hon Cyd HO
	8 May 2002	Written question on "Control of 'roundup ready' soya bean" raised by Hon Cyd HO
	26 June 2003	Motion on "Establishing a labelling system for genetically modified food" moved by Hon Fred LI
	2 March 2005	Written question on "Genetically modified food" raised by Hon Fred LI
	1 June 2005	Oral question on "Food labelling requirements for food products sold in Hong Kong" raised by Dr Hon LUI Ming-wah

	21 December 2005	Oral question on “Genetically modified foods” raised by Dr Hon LUI Ming-wah
	26 April 2006	Written question on “Application of the Cartagena Protocol on Biosafety to Hong Kong” raised by Hon Fred LI
Panel on Food Safety and Environmental Hygiene	26 February 2001	<p>Government Consultation Paper entitled "Labelling System for Genetically Modified Food"</p> <p>Submission from Greenpeace LC Paper No. CB(2) 951/00-01(01)</p> <p>Submission from Hong Kong DNA Chips Ltd. LC Paper No. CB(2) 920/00-01(06)</p> <p>Administration's paper LC Paper No. CB(2) 920/00-01(05)</p> <p>Minutes of meeting LC Paper No. CB(2) 1328/00-01</p>
	28 May 2001	Minutes of meeting LC Paper No. CB(2) 2314/00-01
	28 January 2002	<p>Administration's paper LC Paper No. CB(2) 713/01-02(05)</p> <p>Minutes of meeting LC Paper No. CB(2) 1260/02-03</p>
	20 March 2003	<p>Administration's paper and executive summary on regulatory impact assessment on labelling of genetically modified food LC Paper No. CB(2)1511/02-03(04)</p> <p>Submission from Greenpeace LC Paper No. CB(2) 1511/02-03(03)</p>

		<p>Press release provided by the Secretariat of Legislative Councillors of the Democratic Party LC Paper No. CB(2) 1511/02-03(05)</p> <p>Research report prepared by Research and Library Services (RLSD) of the Legislative Council (LegCo) on "Genetically modified food labelling" LC Paper No. RP05/02-03</p> <p>Minutes of meeting LC Paper No. CB(2) 1835/02-03</p>
	<p>29 April 2003</p>	<p>Summary of submissions on labelling of genetically modified food received by the Panel – LC Paper No. CB(2)2521/02-03(01)</p> <p>Minutes of meeting LC Paper No. CB(2) 2169/02-03</p>
	<p>27 May 2003</p>	<p>Information note prepared by RLSD of LegCo on “Supplementary information on genetically modified food labelling” LC Paper No. IN25/02-03</p>
	<p>25 November 2003</p>	<p>Information note prepared by RLSD of LegCo on “Genetically modified food labelling in European Union” LC Paper No. IN03/03-04</p>