RP05/02-03

Genetically Modified Food Labelling

19 March 2003

Prepared by

Diana WONG

Research and Library Services Division
Legislative Council Secretariat

5th Floor, Citibank Tower, 3 Garden Road, Central, Hong Kong
Telephone : (852) 2869 9372
Facsimile : (852) 2509 9268
Website : http://www.legco.gov.hk
E-mail : library@legco.gov.hk

C O N T E N T S

The Legislative Council Secretariat welcomes the re-publication, in part or in whole, of this research report, and also its translation in other languages. Materials may be reproduced freely for non-commercial purposes, provided acknowledgement is made to the Research and Library Services Division of the Legislative Council Secretariat as the source and one copy of the reproduction is sent to the Legislative Council Library.

Acknowledgements

We sincerely acknowledge the kind assistance given to us by Mr. Dennis Bittisnich, Manager, Standards Management and Information Unit, Food Standards Australia New Zealand. He has provided us with valuable information in the preparation of this research report.

Executive Summary

1. In the United States of America (US), the approach adopted by the regulatory authority towards genetically modified (GM) food can be characterized as assuming the food is safe unless proven otherwise. The labelling of GM food is voluntary. Labelling is only required when the food is significantly different from its conventional counterpart in characteristics, such as composition, nutrition, allergenicity or toxicology.

2. In Australia and Japan, the approach towards GM food can be characterized as seeking proof that the food is safe. The resulting legislation requires strict evaluation of GM crops prior to approval and mandatory labelling of GM food. In Australia, labelling of GM food is mandatory if novel DNA and/or novel protein is present in the final food product by more than 1%. In Japan, labelling of GM food is mandatory if the food product contains any of the designated GM ingredients that is one of its top three ingredients and accounts for 5% or more of the total weight. For food products containing GM ingredients which are not approved, it is illegal to either sell or import them regardless of the content percentage.

3. In all of the three jurisdictions studied, negative labelling (e.g. "Non-GM" and "GM-free") is voluntary. This is because it is difficult, if not impossible, to verify if the food product is indeed "GM-free", i.e. containing "zero" GM materials. The present technology is not equipped to handle the verification of the "GM-free" claims. Hence, manufacturers are required to take measures to substantiate the claims by testing the presence of novel protein and novel DNA, and documentation of the handling practices and procedures.

4. Australia and Japan place great emphasis on the pre-market assessment of new GM food varieties. GM food products are examined and tested by enforcement agencies before they are allowed to be distributed in the market. In contrast, in the US, the pre-market assessment of GM food by the Food and Drug Administration (FDA) is voluntary. Realizing that it is not possible to anticipate all of the novel scientific and regulatory issues that may arise, FDA proposed a mandatory notification system of GM food in 2001. However, the mandatory notification system has not been implemented.

5. In Australia and Japan, enforcement and inspection of GM food labelling are performed by government agencies responsible for food hygiene and safety. However, in the US, FDA maintains an "honour system" approval process, allowing the biotechnology industry to monitor itself, and there is no labelling system which provides standards, testing, certification and enforcement regarding GM food.

Genetically Modified Food Labelling

Part 1 - Introduction

1. Background

1.1 The Legislative Council Panel on Food Safety and Environmental Hygiene at its meeting on 28 January 2003 endorsed the research outline prepared by the Research and Library Services Division on genetically modified (GM) food labelling in the United States of America (US), Australia and Japan.

1.2 The US has a voluntary labelling system for GM food because GM food is presumed to be *generally-recognized-as-safe* (GRAS). Labelling is only required when the food is significantly different from its conventional counterpart in any of its product characteristics. Australia is chosen because there exists a threshold of GM materials above which all GM food is required to be labelled. Japan is chosen because, with regard to GM food, only food items containing designated GM materials as major components are allowed to be sold and required to be labelled.

2. Scope of research

2.1 The scope of research covers international practices, and the following aspects of the selected overseas jurisdictions:

(a) legislative history of GM food labelling;

(b) GM food labelling regulations and policies;

(c) authorities involved in GM food labelling;

(d) enforcement methods; and

(e) cost and benefits of GM food labelling.

3. Methodology

3.1 This research adopts a desk research method which involves Internet research, literature review and analysis, and correspondence with related authorities. Information for this research is obtained from government reports, the Internet and relevant reference sources. Enquiries have also been sent to the relevant authorities in the US, Australia, Japan and Hong Kong, and some of them have responded to our questions.

Part 2 - International practices on genetically modified food labelling

4. International practices

4.1 There is no universally accepted agreement regarding GM food labelling policies in the international community. Countries such as the US and Canada choose a voluntary labelling policy, while others, such as those of the European Union, Australia, New Zealand and Japan, adopt a mandatory labelling policy.

5. Codex Alimentarius Commission

5.1 The Codex Alimentarius Commission (Codex) is an international organization which develops food standards. Established in 1962 by the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO), the functions of Codex are to provide international standards to decrease consumers' perception of risk, promote consumer confidence, and facilitate international trade of food. While the standards themselves are not binding, they serve as benchmarks in negotiations and evaluation of trade disputes in the World Trade Organization.

5.2 A proposed draft recommendation on GM food labelling (the Proposal)[1] was presented at the May 2002 meeting of the Codex Committee on Food Labelling. The drafting group for the Proposal includes representatives from Australia, Brazil, Canada, the European Commission, India, Japan, South Africa, Thailand and the US. The Proposal outlined several provisions for labelling GM food, from the transfer of known allergens to a comprehensive labelling provision. It recommended the establishment of a threshold level for adventitious or accidental inclusion of GM ingredients, and the establishment of exemptions for certain highly processed food. While negative labelling (e.g. "Non-GM" and "GM-free") was discussed at the meeting, it was not included in the Proposal.

5.3 During the May 2002 meeting, the US delegation objected to the inclusion of labelling requirements for GM food which was not different from its conventional counterpart, as it would be misleading to consumers and imply that the product was unsafe, and the practical implications related to the enforcement of such labelling had not been addressed. This position was supported by the delegations of Argentina and Brazil. On the other hand, the delegation of Norway, supported by India, called for comprehensive labelling in all cases for food derived from biotechnology, in order to provide consumer with information and allow consumer to choose.

---

[1] FAO, "Report of the Thirtieth Session of the Codex Committee on Food Labelling", Halifax Canada, 6-10 May 2002, ALINORM 03/22, Rome.

5.4 Since an agreement on GM food labelling was not reached during the May 2002 meeting, the matter will be taken up again at the May 2003 meeting in Rome. According to a study conducted by Zepeda[2], Professor of Consumer Science and Chair of Development Studies at the University of Wisconsin-Madison, given the diverse opinions posed by the member countries, it is unlikely that a consensus will be reached within the next few years.

6. Objectives and goals of genetically modified food labelling

6.1 Summarizing various research studies on GM food labelling,[3] the primary objective of GM food labelling, and food labelling in general, is to provide truthful information to consumers without misleading them. In addition, food labels are generally designed to serve three purposes:

(a) to provide adequate and accurate information related to health and safety concerns;

(b) to protect consumers and industries from fraudulent and deceptive packaging and advertising practices; and

(c) to promote fair competition and product marketability.

6.2 The consensus among the researches mentioned in the previous paragraph is that the fundamental goal of a GM food labelling policy is to balance the costs and benefits of implementing such a policy. Some of the other goals quoted are:

(a) Consumers have a right to know what is in their food, especially concerning products for which health and environmental concerns have been raised.[4]

(b) Labelling allows problems to be easily identified, traced and verified, should they occur.[5]

(c) More informed choices on food and health will be available, leading to an increase in consumer confidence in product quality.

(d) Average quality of food will increase because labelling makes food producers responsible for their products and producers do not want an adverse label put on their food.

---

2 Zepeda, L., "Genetically Engineered Food Labeling: Consumers, Policies and Trade", August 2002.

3 For instance, see Byrne, P., "Labeling of Genetically Engineered Foods", Colorado State University Cooperative Extension; and Matthew, R., and W. Huffman, "GM Food Labeling Polices of the U.S. and Its Trading Partners", Department of Economics, Iowa State University, 30 September 2001.

4 Consumers International, Consumers International Position Paper on the proposed draft "Recommendations for the Labelling of Foods Obtained From Biotechnology", 1998.

5 In the UK, 80% of all British physicians advocate mandatory labelling for this reason. Weiss, R., "British Medical Association Warns of Health Hazards of Genetically Engineered Foods", Washington Post, 18 May 1999.

7. Costs associated with genetically modified food labelling

Supply chain tracking

7.1 To ensure non-GM and GM products can be accurately labelled, producers and suppliers should be able to separate and trace the production of agricultural food products throughout the supply chain, i.e. from seed production to food products on supermarket shelves. In tracking food products through the supply chain, there are two important procedures:

(a) Segregation
Products are kept separate as they travel through the supply chain. If facilities and handling equipment are used for both GM and non-GM products, they have to be thoroughly cleaned as the change over takes place from one to the other.

(b) Identity preservation (IP)
Facilities are set up to preserve the identity by physical separation of products and processes throughout the supply chain to prevent commingling. This may extend to the use of separate processing and manufacturing lines in separate facilities.

GM food labelling cost

7.2 In both segregation and IP, certification of production is expected to enable producers and suppliers to demonstrate that the systems are consistent with best practices and industry standards. All in all, the cost of GM food labelling involves far more than the paper and ink required to print the actual labels. Frequent testing and detailed record-keeping need to be done at various steps along the supply chain. All these steps have cost implications. In fact, according to the study conducted by Golder et al of KPMG Consulting,[6] it is difficult and costly to trace every use of GM technology along the supply chain, especially when the ingredients come from various sources.

7.3 To prevent adventitious commingling of GM and non-GM materials, tolerance level is a major factor in determining the cost of segregation systems. As the tolerance threshold decreases, the cost of ensuring products being compliant increases exponentially.[7]

---

6 Golder, G., F. Leung, and S. Malherbe, "Economic Impact Study: Potential Costs of Mandatory Labelling of Food Products Derived from Biotechnology in Canada", KPMG Consulting, Ottawa, 2000.

7 Ibid.

Import and export

7.4 At present, some countries have developed their own rules and regulations for the labelling of GM food. The differences between the regulation of individual countries may result in disparate export and import restrictions which, in certain situations, may cause trade barriers between countries. For example, if Country A, which has no mandatory labelling policy, wants to export food to Country B, which has strict mandatory labelling on all GM food, Country B may not accept the GM products of Country A if they have not been labelled appropriately. Conversely, the issue of exporting GM labelled food may not be a problem for Country B to Country A, which does not have laws requiring GM food labelling.

Part 3 - The United States of America

8. Regulatory authority

8.1 The regulation of GM food labelling in the US is administered by the Food and Drug Administration (FDA). FDA, an agency of the Department of Health and Human Services (HHS), is responsible for enforcing the food labelling laws and regulations to safeguard the safety of food and food additives under the Federal Food, Drug, and Cosmetic Act (the Act).

9. Regulatory framework

9.1 The US is the first country to develop a policy towards GM food. In 1992, FDA issued regulations that GM food did not have to be labelled if the food products had the same characteristics as their non-GM counterparts. This approach was consistent with recommendations made by FAO/WHO joint consultation for assessing the safety of food produced by biotechnology, and principles for the evaluation of food products driven by modern biotechnology by the Organisation for Economic Co-operation and Development (OECD) in 1993.[8] The FDA policy did not require pre-market approval for GM crops.[9] Nevertheless, FDA determined that there could be circumstances that would require special review and labelling of GM food, including:

(a) when the gene transfer produced unexpected genetic effects;

(b) when the levels of toxicants in the food were significantly higher than those present in other edible varieties of the same species that had not been modified;

(c) when the nutrients in the bioengineered food differed from those in traditional varieties; or

(d) when the sources of the newly introduced genetic materials came from a food plant associated with allergies found in humans.

---

8 WHO, "Application of the Principles of Substantial Equivalence to the Safety Evaluation of Foods or Food Components from Plants Derived by Modern Biotechnology", Report of a WHO workshop, 1995, (WHO/FNU/FSO/95.1); and OECD, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles", Paris, 1993.

9 HHS, FDA, *Federal Register*, Vol. 57 No. 104, "Statement of Policy: Foods Derived from New Plant Varieties", 29 May 1992: p. 22984.

9.2 When FDA first introduced the 1992 policy, interested parties were invited to submit comments. A number of public interest groups and consumers expressed concerns about the policy, while others opposed the regulatory guidance articulated in the policy, particularly regarding the ability of the regulated industry to make market entry decisions. In addition, FDA was aware that biotechnology continued to evolve and that it was not possible for the agency to anticipate all of the novel scientific and regulatory issues that might arise.

9.3 As a consequence, in January 2001, FDA proposed modifications to the 1992 policy. In particular, the agency proposed to make mandatory a notification system, the Pre-market Biotechnology Notice (PBN)[10], whereby a food company should notify the agency 120 days prior to the initiation of commercial distribution[11] of a bioengineered food, and supply the agency with safety test data regardless of the amount of GM contents.[12] In addition, FDA proposed to include in the regulation a voluntary step that any prospective notifier might consider consulting the agency regarding the safety, nutritional, or other regulatory issues of the bioengineered food before submitting a PBN.

9.4 In the proposed regulation, FDA has the right to inform a notifier that the PBN submitted does not provide a basis for the notifier's view that the bioengineered food is as safe as comparable food. In this case, the agency expects the bioengineered food not to be marketed. If a notifier initiates commercial distribution of a bioengineered food after being informed that PBN is not adequate, FDA can exert its authority under section 704 of the Act to conduct inspections and investigations, collect samples, and perform analyses. When the agency concludes that the food is adulterated, misbranded, or otherwise not in full compliance with the Act, FDA can utilize the Act's legal sanctions to seize violative food and order criminal prosecution of those responsible for distributing such food.

9.5 The proposed regulation of PBN will also be applicable to imported GM food when it is enacted. At present, the US has no special import regulations applying to GM food, and federal officials are not required to know which imports are genetically modified.[13]

---

10 PBN will be exempt if the following conditions are satisfied:
(a) the bioengineered food derives from a plant line representing a transformation event that has been addressed in a PBN previously submitted to FDA;
(b) the use or application of the bioengineered food has been addressed in a PBN previously submitted to FDA; or
(c) a letter from FDA demonstrates that FDA has evaluated the use or application of the bioengineered food and has no questions about it.

11 "Commercial distribution" refers to the introduction, or delivery for introduction, into interstate commerce for sale or exchange for consumption in any form by humans or other animals.

12 HHS, FDA, *Federal Register*, Vol. 66 No. 12, "Premarket Notice Concerning Bioengineered Food", 18 January 2001: p. 4706.

13 OECD, "Report for the Task for the Safety of Novel Foods and Feeds", May 2002.

9.6 To solicit comments and suggestions from the industry, FDA issued a "Draft Guidance for Industry" (the Draft Guidance) for labelling GM products in January 2001.[14] In this document, while the agency reiterated its opposition to mandatory labelling of GM food, it provided guidance on languages it deemed appropriate for voluntary labels. FDA reaffirmed its decision that it would not require special labelling of all bioengineered foods because it believed the use of bioengineering, or its absence, did not itself cause a material difference in the food.

9.7 At present, manufacturers can choose to provide more information on GM food on a voluntary basis. Companies have the option of voluntarily indicating whether or not their food is genetically modified. For companies that choose to label their GM food, FDA has suggested certain guidelines under the Draft Guidance that must be followed. For example, FDA prefers that food be labelled as "made through biotechnology" instead of "genetically modified" or "genetically engineered".[15]

10. Negative labelling

10.1 Negative labelling is voluntary. To avoid false or misleading statements about the absence of bioengineered ingredients, or to avoid implying that one food is superior to others, FDA suggests that statements such as "GM-free" or "biotech-free" should not be used in label statements, unless they are used in a context that makes clear that zero level of bioengineered materials is not implied. Consumers may assume that "free" of bioengineered materials means that "zero" bioengineered materials is present, but this is almost impossible to verify.

10.2 For manufacturers who claim that their food or ingredients, including raw agricultural commodities, are not bioengineered, they should substantiate that the claim is truthful and not misleading. Validated testing and documentation of the handling practices and procedures are required to support such claim.

[14] Center for Food Safety and Applied Nutrition, FDA, "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering", January 2001.

[15] Consumer surveys by FDA found that the label of "genetically modified" misled consumers into thinking that the product had different characteristics.

10.3 In determining whether a "GM-free" claim is misleading, FDA proposes that it will review label statements about the use of bioengineering to develop a food or its ingredients under sections 403(a) and 201(n) of the Act. "GM-free" labelling will be considered misleading if it fails to disclose:

(a) facts that are material in light of representation made about a product; or

(b) facts that are material with respect to the consequences that may result from the use of the product.

10.4 Under the Draft Guidance, detection of misleading "GM-free" claims will be considered violation of the Act. [16]

10.5 According to FDA, it has the necessary controls to ensure that it obtains the safety data needed for its evaluation on GM food. However, biotechnology experts, such as the Council for Agricultural and Science Technology[17], state that the agency's overall evaluation process could be enhanced by randomly verifying the test data that companies provide and by increasing the transparency of the evaluation process. FDA officials acknowledge that the agency will do more to increase the level of transparency in its work to enhance the public's confidence in the evaluation process.[18]

11. Enforcement

11.1 While the FDA policy identifies specific potential risks of GM food to public and animal health, it places the responsibility for investigation and reporting these risks on the companies developing GM food. Meanwhile, there is no labelling system which provides standards, testing, certification and enforcement regarding GM food.[19]

---

16 As of the publication date of this report, the Draft Guidance has not yet been adopted.

17 The Council for Agricultural and Science Technology is a group of universities and companies established to provide a more scientific basis for analyzing and prioritizing agricultural issues.

18 United States General Accounting Office, "Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced", GAO-02-566, May 2002.

19 Golan, Elise, F. Kuchler, and L. Mitchell, "Economics of Food Labeling", United States Department of Agriculture, 2000.

12. Public views

12.1 In the US, recent surveys indicate that a high proportion (82% - 93%) of American consumers want GM food labelling.[20] Politicians have proposed mandatory labelling legislation in Congress and within the state legislatures of California, Minnesota, Nebraska, Vermont and Wisconsin. However, political support has not been sufficient to pass the legislation.

12.2 According to the Council for Responsible Genetics, a non-profit bioethics organization, FDA "[does not] *have a complete set of information regarding GM food on the market,* [and there is] *no way to trace who or what is responsible should a problem occur.*" FDA maintains an "honour system" approval process, allowing the biotechnology industry to monitor itself.[21]

[20] Program on International Policy Attitudes, Biotechnology, available at http://www.americans-world.org/digest/global_issues/biotechnology/biotech3.cfm.

[21] Ticciati, Laura, and R. Ticciati, *Genetic Engineered Foods*, Chicago: Keats Publishing, 1998.

Part 4 - Australia

13. Regulatory authority

13.1 The regulation of GM food labelling in Australia is administered by the Food Standards Australia New Zealand (FSANZ)[22]. FSANZ is a partnership among the Australian Commonwealth Government, Australia's State and Territory governments and the New Zealand Government. Board members of FSANZ are selected by appointment. They include government officials having responsibility for matters relating to public health, and experts in the fields relating to consumer rights, public health, food science, food production, and public administration.

13.2 As an independent statutory body, FSANZ is responsible for developing and reviewing food standards for both Australia and New Zealand. Its primary role is to conduct research, develop codes of practice, and co-ordinate national food surveillance and recall arrangements.

14. Regulatory framework

14.1 Australia, together with New Zealand, implemented a new set of GM food labelling standards on 7 December 2001. According to FSANZ, "*Australia and New Zealand now have one of the most rigorous and progressive labelling requirements for GM food in the world.*" All GM food is subject to pre-market safety assessment and approval, which involves consultation and peer review. The FSANZ safety assessment process focuses on four main parts: the description of the genetic modification, general safety issues, toxicological issues and nutritional issues.

14.2 The regulation of GM food labelling is prescribed by Standard 1.5.2, titled "Food Produced Using Gene Technology", in the Australia New Zealand Food Standard Code (the Standard). The Standard requires labelling of food and food ingredients if the food product contains more than 1% of GM materials. If a product ingredient is genetically modified, the ingredient must be labelled in the list of ingredients. For a single-ingredient GM food, the phrase "genetically modified" must be printed on the front of the package, next to the name of the food.

[22] FSANZ was formerly known as the Australia New Zealand Food Authority (ANZFA). The change of name took place in 2002.

14.3 The 1% threshold is adopted by FSANZ based on the following factors[23]:

(a) the threshold appears to be a level above which novel Deoxyribonucleic Acid (DNA) and/or novel protein can be reliably detected so that food manufacturers can comply with the standard, and enforcement agencies can take reasonable legal actions for non-compliance; and

(b) the threshold is in use in some other countries (such as members of the European Union) which are major trading partners of Australia.

14.4 Food of uncertain status must be labelled with the prescribed statement "may be genetically modified" or "may contain genetically modified [ingredient name]" if the manufacturer, having taken all reasonable steps to ascertain the genetic status of that food, is uncertain as to whether the food has been produced from GM sources.

14.5 There are several exemptions to the labelling requirements:

(a) food that contains less than 1% of GM materials. This allows for some inadvertent mixing of GM and non-GM sources in the supply chain;

(b) highly refined food[24] that does not contain DNA or protein. There are no known methods to test for the presence of GM ingredients if DNA or protein is not present;

(c) food which uses GM processing aids that are not present in the final food products; or

(d) food prepared at the point of sale (i.e. restaurants).

14.6 Additional labelling is required for GM food that has the following altered characteristics when compared to conventional food:

(a) composition or nutritional values;

(b) anti-nutritional factors or natural toxicants;

(c) factors known to cause allergic responses;

(d) its intended use; or

(e) factors that may raise significant ethical, cultural or religious concerns.

---

23 Information provided by FSANZ.

24 Examples are oil, sugar and starch that undergo refining processes to produce purified products. Processes that may be used to purify food or ingredients include, but are not limited to, high temperature extraction, filtration and centrifugation, distillation, and crystallization.

15. Negative labelling

15.1 FSANZ supports voluntary labelling of "GM-free" products, and a growing number of producers have opted for this form of labelling. Non-GM food may be labelled with the prescribed statement:

(a) "not sourced from genetically modified ingredient"; or

(b) "free from genetic modification".

15.2 Negative labelling is required to fulfill a more stringent standard: "GM-free" products should contain no mixture or highly processed ingredients from GM crops. The food suppliers are required to take steps to substantiate the claim with evidence and ensure that it must not be misleading or deceptive.

15.3 An IP system is designed to ensure the absence of GM components in a food or ingredients by separating non-GM from GM components throughout the supply chain. While such use is appropriate when voluntary negative claims on labelling are made, the Standard does not make the use of IP system mandatory.

16. Enforcement

16.1 FSANZ only sets regulatory standards and has no enforcement powers. However, with authority to co-ordinate enforcement of the Standard in each of the Australian states and territories, FSANZ has warned producers that abusing the Standard is liable to lawsuits or civil penalties.

16.2 In Australia, the inspection and enforcement of food labelling of processed food at the retail level are undertaken by Environmental Health Officers (EHO) at local councils and Senior Food Officers (SFO) at state health authorities, depending on the jurisdiction.

16.3 For imported food, the inspection and enforcement of food labelling are undertaken by the Australian Quarantine Inspection Service (AQIS).

16.4 At present, there are two methods to verify whether the food is genetically modified:

(a) Documentation

- Process-based verification entails detailed record-keeping of seed source, field location, harvest, transport and storage.

(b) Testing

- Content-based verification requires testing the food product for the physical presence of foreign DNA or protein.

Documentation

16.5 Verifiable documentation is needed to constitute a reliable paper trail regarding the GM status for the food from the seller to the buyer along the supply chain. The paper trail includes written documentation regarding requests on order forms, and declarations on invoices and packing slips. Growers, processors, suppliers and importers are expected to pass on documentation to the manufacturer if the food is genetically modified.

16.6 At each step of the supply chain, responsibility falls on successive suppliers to provide accurate information. Enforcement agencies review documentation provided by suppliers in assessing compliance with the Standard. Businesses are expected to retain documentation for an appropriate period, depending on the durable life of the food.

Testing

16.7 Testing for the presence of novel DNA and/or novel protein is needed if the GM status of the food:

(a) varies from batch to batch; or

(b) cannot be established through a paper trail (e.g. documents are unreliable or unavailable).

16.8 Occasional testing by enforcement agencies at various stages of production may be necessary to confirm the validity of the paper trail to satisfy the requirement of due diligence. In the case of highly refined food, an one-off test may be required to confirm that novel DNA and/or novel protein is removed.

16.9 There are two tests for the determination of the presence of GM ingredients and the measurement of the level of such materials. They are:

(a) polymerase chain reaction (PCR) test for DNA[25]; and

(b) enzyme-linked immunosorbent assay (ELISA) for protein[26].

16.10 At present, enforcement of labelling standards is considered to be a low priority by food enforcement officers when compared to other food safety issues. According to a research study conducted by FSANZ in February 2002[27], a typical EHO spent 60% - 80% of his time on food-related issues, and of which between 5% - 10% was spent on food labelling issues. The study attributed the explanation of this finding to the inspection workload being too heavy to dedicate resources to labelling enforcement.

16.11 In the same study, food enforcement officers indicated that they operated primarily on a reactive rather than a proactive basis. In other words, they investigated labelling issues only when they had received a specific query from a consumer or manufacturer.[28]

---

25 The PCR test is the most commonly used method to determine the presence of DNA in GM food. It is a laboratory-based technique requiring a trained staff and specialized equipment. Sensitivity of the test decreases with further processing of the food product. However, for most products, the detection range is between 0.1% to 1%. Testing cost per sample ranges from US$200 - US$600 and it takes five to 14 days to produce the result. The way that PCR works is to generate billions of copies of a single DNA molecule in a matter of hours. Through biochemical processes, a sample of DNA is scanned to locate target sequences of DNA which are amplified billions of times. The amplification allows detection of a specific sequence and quantification of the proportion of DNA molecules in the sample. (American Crop Protection Association, "Methods for Detection of GMO Grain in Commerce", September 2000).

26 The ELISA test is designed to detect the presence of protein in GM food. Similar to PCR, conducting ELISA test requires trained personnel and specialized equipment. Testing cost per sample ranges from US$75 - US$100 and it takes two to four days to produce the result. The way that ELISA works is to use antibodies specific for the protein of interest. ELISA uses one antibody to bind the specific protein, a second antibody to amplify detection, and a third antibody conjugated to an enzyme whose product generates a colour that can be easily visualized and quantified. (American Crop Protection Association, "Methods for Detection of GMO Grain in Commerce", September 2000).

27 ANZFA, "Qualitative Research with Stakeholders - Food Labelling Issues", April 2002.

28 Ibid.

17. Public views and cost studies

17.1 The Australian Consumer Association (ACA) queries the decision that labelling is not required for food additives and food processing aids, highly refined food, and food preparing at the point of sale. ACA advocates a comprehensive labelling policy with zero threshold allowed. It argues that the 1% threshold is ineffective and in fact allows up to 70% of food on sale to remain unlabelled.

17.2 The Australian Food and Grocery Council (AFGC), an association representing food manufacturers, agrees to some degree of the claim of labelling to ensure food safety. AFGC is pleased with the labelling exemptions but is concerned about the costs of implementing GM food labelling. According to the executive director of AFGC, "*This* [is] *never an argument about whether the food should be labelled. It* [is] *an argument of how you actually do it.*"[29]

17.3 In 1999, FSANZ commissioned a study to estimate the economic impact of its proposed labelling policy and associated enforcement requirements based on its draft standard[30] on GM food labelling.[31] The study suggested that a food system-wide testing and certification system to track GM food could increase the cost of food production by 6% (approximately AU$3 billion) in the first year, and 3% (approximately AU$1.5 billion) in the following years - a burden that would likely be borne by consumers.[32] However, FSANZ did not accept the findings of the study, arguing that it did not take into consideration:

(a) the changes made to the draft standard after the study was commissioned; and

(b) the exercise of due diligence[33] in compliance should lower the cost of labelling.[34]

---

29 Website of the Australian Broadcasting Corporation, available at http://www.abc.net.au/worldtoday/s156867.htm.

30 ANZFA, "Standard A18, Food Produced Using Gene Technology".

31 ANZFA, "Report on the Compliance Costs Facing Industry and Government Regulators in Relation to Labelling Genetically Modified Foods", Canberra, October 1999.

32 Another study commissioned by the Canadian government in 2000 showed similar results. The report of the study estimated that mandatory labelling of GM food would increase retail prices of food products by a minimum of 9% - 10% and producer prices by 35% - 41%. Producer prices refer to prices associated with food production, handling, processing and manufacturing. Golder, G., F. Leung, and S. Malherbe, "Economic Impact Study: Potential Costs of Mandatory Labelling of Food Products Derived from Biotechnology in Canada", KPMG Consulting, Ottawa, 2000.

33 Due diligence relies on appropriate documentation throughout the supply chain and not continual testing of products at each step in the chain. Testing is only required if the paper trail fails.

34 According to FSANZ ministers, the report was essentially a worst case scenario and they did not accept that the amount of tracking and testing proposed was required to ensure accurate labelling of products of GM sources. They commissioned another study based on the due diligence approach. The new study reduced the cost to AU$106 million in compliance costs and AU$209 million in additional ingredient costs, and most of which was the cost of finding out whether food ingredients contained altered DNA or protein, rather than changing the labels.

Part 5 - Japan

18. Regulatory authority

18.1 The regulation of GM food labelling is shared between two Ministries in Japan:

(a) The Ministry of Health, Labour and Welfare (MHLW)

- MHLW is responsible for conducting scientific reviews to assess the safety of new biotechnology varieties and carrying out safety assessment of GM food labelling under the Food Sanitation Law.

(b) The Ministry of Agriculture, Forestry and Fisheries (MAFF)

- MAFF is responsible for regulating the Law Concerning Standardization and Proper Quality Labelling of Agricultural and Forestry Products (the JAS Law) to enable consumers to make informed choices on food selection.

19. Regulatory framework

19.1 Pre-market assessment for new biotechnology varieties is required for companies developing new biotechnology products. These companies must first submit their application through the Inspection and Safety Division under MHLW to the Expert Panel of the Biotechnology Subcommittee within the Food Sanitation Committee under MHLW. The Expert Panel reviews the application and makes a recommendation to the Biotechnology Subcommittee regarding the application's approval. Based on the Panel's recommendation, the Subcommittee provides its judgement to the Food Sanitation Committee which reviews the application and then makes a recommendation on approval to the Minister of MHLW. Approved applications are published in the Japanese Government's Gazette.

19.2 On 1 April 2001, a new set of GM food labelling policies was implemented. A list of 24 raw products made from corn and soybeans (the List) is designated to be subject to labelling requirements.[35] For a food product that contains any of the designated GM ingredients, labelling is required if the GM ingredient is one of its top three ingredients and accounts for 5% or more of its total weight.

[35] On 22 February 2002, MAFF announced a further revision of the GM food labelling scheme to include potato products with introduced DNA or protein. As of December 2002, the List has been expanded to contain 44 GM food varieties. Please refer to Appendix I for more details.

19.3 For food products containing GM ingredients which are not approved by MHLW, it is illegal to either sell or import them regardless of the content percentage.[36]

19.4 Labelling of food products can be classified as:

(a) "Genetically modified"

- This label is for prepackaged food products[37] which are required to be labelled under both the Food Sanitation Law and the JAS Law. Labelling is mandatory for this category;

(b) "Not segregated from GM products"

- This label is for food products which have not been handled according to the identity preserved basis[38] and may contain GM ingredients. Labelling is mandatory for this category; or

(c) "Non-GM"

- Labelling is optional for this category. Please refer to paragraph 20.1 for further details.

19.5 There are exemptions to the labelling requirements for some GM food. Labelling is voluntary for:

(a) food in which recombinant DNA and the resulting protein from such DNA have been eliminated or broken down; or

(b) food that has GM content accounting for less than 5% of the total weight. This only refers to unintentional contamination by GM crops after proper identity preserved handling. In other words, this exemption of labelling is not applicable to cases where the contamination is 5% or less but identity preserved handling has not been verified, or where GM ingredients have been intentionally mixed with non-GM ingredients.

---

36 Unapproved GM ingredients include StarLink corn, 55-1 papaya and New Leaf Y potato.

37 Policy Planning Division, Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW, "Mandatory Labeling of Genetically Modified Foods and Foods Containing Allergens", available at http://www.mhlw.go.jp/english/topics/qa/gm-food/gm4.html.

38 For details regarding identity preservation, please refer to paragraph 7.1(b).

19.6 MAFF originally excluded oil and other highly processed food made with GM ingredients from the List because the absence or presence of GM content could not be verified through testing, with foreign DNA being destroyed during processing. Nonetheless, on 3 September 2001, MAFF revised the labelling proposal to require high oleic acid soybean oil made from high oleic acid GM soybeans be labelled as "GM high oleic soybean oil."

20. Negative labelling

20.1 Negative labelling is voluntary. In order for a product to be labelled "Non-GM", certification must be provided to show that ingredients are handled on an identity preserved basis at each step of the production and distribution process. If such documentation cannot be confirmed, identity preserved handling is assumed to be inadequate. Such products must be labelled "Not segregated from GM products".

21. Enforcement

21.1 Japan has a zero tolerance for unapproved biotechnology varieties in food. To ensure compliance, a sampling programme is in place to test both import shipments and processed food products at the retail level. Any detection of an unapproved biotechnology variety in a food product is deemed violation of the Food Sanitation Law.

21.2 In Japan, the inspection and enforcement of food labelling for processed food at the retail level are undertaken by local health authorities. If a food product is detected to be in violation of the Food Sanitation Law or the JAS Law at the retail level, the manufacturer of the product must issue an immediate recall.

21.3 For imported food, the inspection and enforcement of food labelling are undertaken by MHLW. If a food product is detected to be in violation of the Food Sanitation Law or the JAS Law at the port, the shipment must be returned, destroyed, or diverted for non-food use.

21.4 Both documentation and testing are used to verify whether the food is genetically modified.

Documentation

21.5 Documents are required to show that food products are identity preserved handled during the entire food processing cycle. The procedures for identity preserved handling are detailed in the Distribution Manual created by the Japan Food Industry Center. Food producers and suppliers are encouraged to follow the Manual which indicates checkpoints, control methods and records to be kept in each stage of production, distribution, and processing. Nonetheless, procedures other than those proposed in the Manual may be used, provided that they must be equivalent or superior in reliability and traceability to those described in the Manual.

Testing

21.6 The evaluation of the presence of GM ingredients is done using PCR and ELISA testing. If the quantitative test indicates that a food product is contaminated with 5% or more of GM ingredients, reconfirmation of the accuracy of identity preserved handling may be required, even if documents are available certifying that ingredients have been identity preserved.

21.7 All testings are performed according to sampling and testing criteria set by MHLW. The focus of testings is currently on products which are made of soybeans, corn, papayas and potatoes. As of January 2003, MHLW has found one unapproved biotechnology variety of potatoes, two unapproved biotechnology papaya cases and one unapproved StarLink corn.[39]

21.8 If the test result proves that measures taken to ensure proper GM food labelling have been inadequate, the following actions may be taken:

(a) Instruct the manufacturer to label as required; or

(b) If the manufacturer does not comply with (a) above, the business license may be withdrawn and all or part of the operations may be banned or suspended for a specified period. The manufacturer may be subject to fines and imprisonment as well.

[39] StarLink corn is an insect-resistant genetically modified corn which is approved by FDA to be grown for animal feed, but is not approved for direct human consumption because it "exhibits some characteristics of known allergens." Positive test for StarLink was found during a monitoring test performed on 19 324 tons of US corn for corn starch in December 2002. MHLW has found StarLink to be commingled in a 1 200 ton lot with the corn shipment. As a result of the finding, the monitoring testing on imported US corn has been raised from the sampling rate of 5% to 50% of all the corn shipments from the US.

21.9 In the fiscal year 2002 (from 1 April 2002 to 31 March 2003), MHLW announced its plan to strengthen the inspection of food. The Ministry requested a budget of 269 million yen to increase the number of testing both at the ports and retail levels. MHLW planned to test 1 199 food samples for unapproved GM traits and another 163 for approved GM food, such as corn and soybeans, to ensure compliance with the labelling requirements.[40]

22. Public views

22.1 Consumer groups, including the Consumers Union of Japan and the No! GMO Campaign, support the existing mandatory labelling policy on GM food but they call for a more restrictive framework. Their primary concern is regarding the effectiveness of the GM labelling system where food products with GM ingredients less than 5% are not required to be labelled.

[40] USDA Foreign Agricultural Service, GAIN Report #JA2017, "Biotechnology Product Monitoring Plan by Japan's Health Ministry During 2002-2003", 16 April 2002.

Part 6 - Analysis

23.1 The labelling of GM food has become a paramount concern in the international community. This part analyzes the differences in GM food labelling regulatory frameworks of the US, Australia and Japan. The situation of GM food labelling in Hong Kong and the Government's current proposal on GM food labelling will also be discussed. Appendix II summarizes the various attributes of the GM food labelling systems in these three jurisdictions.

24. Production of genetically modified crops

24.1 In a study conducted by Zepeda[41], the food labelling policies were found to be correlated with the economic interest in GM crops of each jurisdiction. The contrasting positions of countries regarding labelling requirements seem to correspond closely to the production of GM crops for commercial sale.

24.2 According to a study conducted by Buttel[42], Professor of Rural Sociology and Environmental Studies at the University of Wisconsin-Madison, the US, together with Canada and Argentina, grow roughly 98% of all GM crops, and these three countries do not require mandatory labelling of GM food. With a significant economic stake in GM food production and sales, the US adopts a reactive labelling policy. The labelling of GM food is voluntary because GM food is presumed to be GRAS. Labelling is only required when the food is significantly different from its conventional counterpart in characteristics, such as composition, nutrition, allergenicity or toxicology.

24.3 In contrast, Australia grows a very small amount of GM crops[43], while Japan does not grow any GM crops.[44] The relevant authorities in these two countries have taken the lead in implementing mandatory labelling of GM food. In Australia, labelling of GM food is mandatory if novel DNA and/or novel protein is present in the final food product by more than 1%. In Japan, labelling of GM food is mandatory if the food product contains any of the designated GM ingredients that is one of its top three ingredients and accounts for 5% or more of its total weight.

---

41 See Note 2.

42 Buttel, F.H., "The Adoption and Diffusion of GM Crop Varieties: The "Gene Revolution" in Global Perspective, 1996-2001." University of Wisconsin-Madison, Program on Agricultural Technology Studies paper series, paper no. 6, March 2002.

43 Ibid.

44 Policy Planning Division, Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW, "FAQs on Labeling System for Genetically Modified Foods", available at http://www.mhlw.go.jp/english/topics/qa/gm-food/gm1.html.

25. Regulatory policy

25.1 In the US, the approach towards GM food can be characterized as assuming the food is safe unless proven otherwise. FDA lists some likely suspects that pose public health risk, and proposes self-regulation by manufacturers. The recent policy proposal modifies this stance and recommends pre-market approval, but it is still far from the position of the precautionary principle adopted by Australia and Japan.

25.2 In Australia and Japan, the approach towards GM food can be characterized as seeking proof that the food is safe. The primary purpose is to provide convincing evidence of safety to consumers and thereby enhance public confidence. The resulting legislation requires strict evaluation of GM crops prior to approval of distribution to consumers and mandatory labelling of GM food. The mandatory labelling policy in these two countries aims at addressing consumer concerns and allowing consumers to exercise choice. In all of the three jurisdictions studied, GM food labelling is not required for food prepared at the point of sale.

26. Negative labelling

26.1 In all of the three jurisdictions studied, negative labelling is voluntary. This is because it is difficult, if not impossible, to verify if the food product is indeed "GM-free", i.e. containing "zero" GM materials. The present technology is not equipped to handle the verification of the "GM-free" claims. Hence, manufacturers are required to take measures to substantiate the claim by testing the presence of novel protein and novel DNA, and documentation of the handling practices and procedures.

27. Pre-market assessment

27.1 As part of the GM food regulatory policy, Australia and Japan place great emphasis on the pre-market assessment of new GM food varieties. GM food products are examined and tested by enforcement agencies before they are allowed to be distributed in the market.

27.2 In contrast, the pre-market assessment of GM food in the US is voluntary, but the stance of FDA seems to be shifting. After receiving public views regarding its 1992 GM food labelling policy, FDA admitted that it was not possible to anticipate all of the novel scientific and regulatory issues that might arise. Therefore, it has proposed a mandatory notification system of GM food. Nonetheless, the proposal has not been implemented as of the publication date of this report.

28. Enforcement

28.1 In Australia and Japan, enforcement and inspection of GM food labelling are performed by government agencies responsible for food hygiene and safety. On the other hand, in the US, the biotechnology industry, rather than FDA, is responsible for monitoring the labelling of GM food.

28.2 The enforcement of GM food labelling is stricter in Australia and Japan when compared to the US. In Japan, all testings are performed according to criteria set by MHLW. However, in the US, FDA does not have information regarding GM food on the market, thus it is difficult to trace who or what is responsible should a problem occur. The approach of FDA is to maintain an "honour system" approval process, allowing the biotechnology industry to monitor itself and to investigate and report problems to the agency and the public.

29. Situation in Hong Kong

29.1 In Hong Kong, the regulation of food labelling is administered by the Health, Welfare, and Food Bureau. Under Part V of the Public Health and Municipal Services Ordinance (Chapter 132), food intended for sale in Hong Kong must be fit for human consumption. The Ordinance applies to all food including GM food.[45]

29.2 On 5 January 2000, the Legislative Council supported a motion demanding mandatory labelling of GM food products. The response of the then Secretary for Environment and Food was that the Administration was in the process of studying the feasibility of introducing legislation to set up a GM food labelling system. It was suggested that the Food and Environmental Hygiene Department (FEHD) would include GM food as a topic for public education.

29.3 Public consultation was conducted on the labelling of GM food in February 2001.[46] Public views were specifically sought on a number of issues, including:

(a) whether a voluntary or 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.

---

45 Website of the Food and Environmental Hygiene Department, available at http://www.info.gov.hk/fehd/safefood/gmf/info6.html.

46 Environment and Food Bureau, "Labelling of Genetically Modified Food, Consultation Paper", February 2001. The consultation period ended on 31 May 2001.

29.4 During the consultation period, the Government received more than 6 000 responses from members of the public, the food industry, green groups and professional bodies. The majority of the views supported mandatory labelling on all food items (not only on pre-packaged food) and the establishment of a threshold of GM content above which food product should be labelled. Professional medical bodies also supported additional labelling for GM materials with significantly different characteristics from their traditional counterparts. In response, the Government promised to conduct a detailed economic assessment on the impact of a GM food labelling system on the food trade and on food prices before deciding on the way forward.[47]

29.5 In April 2002, the Government appointed a consultant to conduct a regulatory impact assessment (RIA) to assess the economic impact of introducing a labelling scheme on packaged GM food in Hong Kong. The RIA was completed in March 2003.[48] The executive summary of the assessment indicates that there will be no increases in cost to the food trade under a voluntary labelling scheme. However, there will be some cost increases to the trade if a mandatory scheme is to be implemented. The cost implications to the small and medium enterprises would be significant because they would have difficulties, among others, in securing contractual agreements with product manufacturers with regard to the products' GM status.[49]

29.6 Having considered the results of the RIA, the Government proposes to introduce a mandatory pre-market safety assessment for GM ingredients to be supplemented by a system of voluntary labelling of GM food.

29.7 Under the proposed pre-market safety assessment scheme, importers or manufacturers of food containing GM ingredients will be required to submit documents and certificates to FEHD, prior to importing the food to Hong Kong, detailing the safety assessments that have been conducted by the developers of the GM ingredients. To minimize the impact on the trade, a grace period would be granted to those GM products that are already in the market.

29.8 Regarding voluntary labelling of GM food, the Government proposes that it will issue a set of guidelines on the labelling of GM food and encourage the trade to adopt voluntary labelling in accordance with the guidelines. The proposed guidelines would provide reference to the trade in making truthful positive and negative labels. Standardized terminologies and fundamental principles underlying the recommended labelling approaches would be included in the guidelines.

---

47 Information from LC Paper No. CB(2) 713/01-02(05).

48 FEHD, "Regulatory Impact Assessment on Labelling of Genetically Modified Food, Executive Summary", March 2003.

49 Information from LC Paper No. CB(2) 1511/02-03(04).

Issues to be considered

29.9 The study of the GM food labelling systems of the US, Australia and Japan has provided references to the implementation of GM food labelling policies in Hong Kong. In view of the Government's proposal on the regulation of GM food, Members may wish to consider the following issues.

29.10 The Government proposes a voluntary labelling framework for GM food. The proposed approach appears to be different from the majority of the views supporting mandatory labelling on all food items during the public consultation conducted in February 2001. Members may wish to consider the experience of the mandatory labelling practices in Australia and Japan.

29.11 The proposal does not have any provision of additional labelling requirement for GM materials with significantly different characteristics from their conventional counterparts. Members may wish to draw reference from the additional labelling requirements in the US and Australia where labelling is required when the food is significantly different from its conventional counterpart in characteristics, such as composition, nutrition, allergenicity or toxicology.

29.12 The proposal does not have any provision of penalty involved when the food manufacturers or suppliers do not adhere to the pre-market safety assessment requirement. Members may wish to draw reference from the proposed mandatory notification system in the US under FDA.

29.13 The proposal states that *"FEHD will take food samples from the market for testing of unapproved GM varieties from time to time."* Members may wish to consider how the testing will be conducted and the sampling frequency conducted by FEHD.

Appendix I

List of Currently Approved GM Food in Japan (as of December 2002)

Plant Species	Trait/Variety	Developer	Year of Approval
Canola	RT73	Monsanto	2001
	HCN92	AgrEvo	2001
	HCN10	AgrEvo	2001
	PGS1	Plant Genetic Systems (PGS)	2001
	PHY14	PGS	2001
	PHY35	PGS	2001
	T45	AgrEvo	2001
	PGS2	PGS	2001
	PHY36	PGS	2001
	PHY23	PGS	2001
	Westar-Oxy-235	Rhone Poulanc	2001
	MS8RF3	PGS	2001
	MS8	PGS	2001
	RF3	PGS	2001
	RT200	Monsanto	2001
Corn	T-14	AgrEvo	2001
	T-25	AgrEvo	2001
	MON810	Monsanto	2001
	Bt11	Northlap King	2001
	Event176	Ciba Seed	2001
	GA21	Monsanto	2001
	DLL25	Dekalb	2001
	DBT418	Dekalb	2001
	NK603	Monsanto	2001
	Sweet corn, Bt11	Novartis	2001
	MON863	Monsanto	2002
	1507	Dow Chemicals	2002

Appendix I (cont'd)

List of Currently Approved GM Food in Japan (as of December 2002)

Plant Species	Trait/Variety	Developer	Year of Approval
Cotton	531	Monsanto	2001
	757	Monsanto	2001
	1445	Monsanto	2001
	10211	Monsanto	2001
	10215	Monsanto	2001
	10222	Monsanto	2001
	15985	Monsanto	2002
Potato	BT6	Monsanto	2001
	SPBT02-05	Monsanto	2001
	RBMT21-129 (NLP)	Monsanto	2001
	RBMT21-350 (NLP)	Monsanto	2001
	RBMT22-82 (NLP)	Monsanto	2001
Soybean	40-3-2	Monsanto	2001
	260-05	DuPont	2001
	A2704-12	AgrEvo	2002
	A5547-127	Aventis	2002
Sugar beet	T120-7	AgrEvo	2001

Source: USDA Foreign Agricultural Service, GAIN Report #JA3002, "Update on Japan's Biotechnology Safety Approval and Labeling Policies", 13 January 2003.

Appendix II

Comparison of the GM Food Labelling Systems

	The US	**Australia**	**Japan**
General Information			
Definition of GM Food	Food derived from plant varieties that are developed using in vitro manipulations of DNA. Plants genetically modified through other techniques are not considered under this definition.	Food which is derived or developed from an organism which is modified by gene technology[50], and includes any substance regulated as a food additive or processing aid.[51]	Food that is produced using genetic recombination techniques which consist of introducing into a crop or other organisms a gene extracted from another organism that gives characteristics to the crop or organism.
Regulatory Authority	Food and Drug Administration (FDA).	Food Standards Australia New Zealand (FSANZ).	Ministry of Health, Labour and Welfare (MHLW) and Ministry of Agriculture, Forestry and Fisheries (MAFF).
Legislation	Federal Food, Drug, and Cosmetic Act.	Australia and New Zealand Food Standard Code.	Food Sanitation Law and the Law Concerning Standardization and Proper Quality Labelling of Agricultural and Forestry Products (the JAS Law).
Growing of GM crops	The US, together with Canada and Argentina, grow roughly 98% of all GM crops.	Grows a very small amount of GM crops.	Grows no GM crops.

[50] "Gene technology" refers to recombinant DNA techniques that alter the heritable genetic materials of living cells or organisms.

[51] This definition does not include a food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or organism itself is a product of gene technology.

Appendix II (cont'd)

Comparison of the GM Food Labelling System

	The US	**Australia**	**Japan**
GM Food Labelling Policy			
Focus of labelling policy	The focus is not on consumers or their choices but the food itself. Food is assumed to be safe unless proven otherwise.	The focus is on consumers' concerns and choices.	The focus is on consumers' concerns and choices.
Mandatory or Voluntary Labelling	Labelling is voluntary.	Labelling is mandatory.	Labelling is mandatory for designated GM ingredients.
Threshold Requirement	Not applicable.	1%.	For any of the designated GM ingredients if it is one of the top three ingredients by weight and composes at least 5% of the total weight.
Labelling Exemption/ Requirement	Labelling is required for GM food which is significantly different from its conventional counterpart.	Labelling is exempt for highly refined food, food which used GM processing aids that are not present in the final food products, and food prepared at the point of sale.	Labelling is exempt for food in which recombinant DNA and resulting protein from DNA have been eliminated or broken down.
Negative Labelling	Voluntary.	Voluntary.	Voluntary.

Appendix II (cont'd)

Comparison of the GM Food Labelling System

	The US	**Australia**	**Japan**
Pre-Market Assessment and Enforcement			
Pre-Market Assessment	FDA has proposed to make mandatory a notification system whereby a food company should notify the agency 120 days prior to the initiation of commercial distribution of a bioengineered food, and supply the agency with safety test data.	All GM food is subject to pre-market safety assessment and approval.	A biotechnology company first submits its application through the Inspection and Safety Division to the Expert Panel of the Biotechnology Subcommittee. The application will be submitted to the Minister of MHLW for final approval.
Enforcement	The biotechnology industry is responsible for investigating and reporting problems to FDA and the public. There is no labelling system which provides standards, testing, certification and enforcement regarding GM food.	Inspection and enforcement of food labelling of processed food at the retail level are undertaken by Environmental Health Officers at local councils and Senior Food Officers at state health authorities. For imported food, inspection and enforcement of food labelling are undertaken by the Australian Quarantine Inspection Service. Documentation and testing are used to verify whether the food is genetically modified.	Inspection and enforcement of food labelling for processed food at retail level are undertaken by local health authorities. For imported food, inspection and enforcement of food labelling are undertaken by MHLW. Documentation and testing are used to verify whether the food is genetically modified.

References

Books

1. Anderson, Luke, *Genetic Engineering, Food and Our Environment*, Chelsea Green Publishing Company, 1999.

2. Blanchfield, J. Ralph, MBE, *Food Labelling*, England: Woodhead Publishing Limited, 2000.

3. Nottingham, Stephen, *Eat Your Genes*, Zen Book Limited, 1998.

4. Teitel, Martin, and K. A. Wilson, *Genetically Engineered Food: Changing the Nature of Nature*, Vermont: Park Street Press, 1999.

5. Ticciati, Laura and R. Ticciati, *Genetic Engineered Foods*, Chicago: Keats Publishing, 1998.

Articles

The United States of America

1. American Crop Protection Association, "Methods for Detection of GMO Grain in Commerce", September 2000.

2. Center for Food Safety and Applied Nutrition, FDA, "Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, Draft Guidance", January 2001.

3. CRS Report for Congress, "Food Biotechnology in the United States: Science, Regulation, and Issues", RL30198, Updated 19 January 2001.

4. CRS Report for Congress, "Labeling of Genetically Modified Foods", RS20507, 20 March 2000.

5. Golan, Elise, F. Kuchler, and L. Mitchell, "Economics of Food Labeling", United States Department of Agriculture, 2000.

6. HHS, FDA, *Federal Register*, Vol. 57 No. 104, "Statement of Policy: Foods Derived from New Plant Varieties", 29 May 1992: p. 22984.

7. HHS, FDA, *Federal Register*, Vol. 66 No. 12, "Premarket Notice Concerning Bioengineered Food", 18 January 2001: p. 4706.

8. United States Foreign Agricultural Service, "US Agricultural, Fish and Wood Products Exports", July 1999.

9. United States General Accounting Office, "Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced", GAO-02-566, May 2002.

Australia

1. ANZFA, "Report on the Compliance Costs Facing Industry and Government Regulators in Relation to Labelling Genetically Modified Foods", Canberra, October 1999.

2. ANZFA, "Qualitative Research with Stakeholders - Food Labelling Issues", April 2002.

3. ANZFA, "Labelling Genetically Modified Food. Compliance Guide to Standard A18", available at http://www.foodstandards.gov.au/whatsinfood/gmfoods/complianceguidea18gm.cfm.

Japan

1. Policy Planning Division, Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW, "Genetically Modified Foods", available at http://www.mhlw.go.jp/english/topics/qa/gm-food.

2. USDA Foreign Agricultural Service, GAIN Report #JA3002, "Update on Japan's Biotechnology Safety Approval and Labeling Policies", 13 January 2003.

3. USDA Foreign Agricultural Service, GAIN Report #JA2017, "Biotechnology Product Monitoring Plan by Japan's Health Ministry During 2002-2003", 16 April 2002.

4. USDA Foreign Agricultural Service, GAIN Report #JA2010, "MAFF's Biotech Food Labeling Standards", 14 March 2002.

Hong Kong

1. Environment and Food Bureau, "Labelling of Genetically Modified Food, Consultation Paper", February 2001.

2. FEHD, "Regulatory Impact Assessment on Labelling of Genetically Modified Food, Executive Summary", March 2003.

Others

1. AgBiotech Reporter, February 2001.

2. AgBiotech Reporter, May 2001.

3. Byrne, P., "Labeling of Genetically Engineered Foods", Colorado State University Cooperative Extension

4. Buttel, F.H., "The Adoption and Diffusion of GM Crop Varieties: The "Gene Revolution" in Global Perspective, 1996-2001", University of Wisconsin-Madison, Program on Agricultural Technology Studies Paper Series, Paper No. 6, March 2002.

5. Cornell University, Genetically Engineered Organisms - Public Issues Education Project, "Case Study: GMO Labeling in Australia and New Zealand".

6. Consumers International, Consumers International Position Paper on the proposed draft "Recommendations for the Labelling of Foods Obtained From Biotechnology", 1998.

7. Codex, "Proposed Draft Recommendations for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Food)", Twenty-ninth Session, Ottawa Canada, 1-4 May 2001, CX/FL 01/7, February 2001.

8. FAO, "Report of the Thirtieth Session of the Codex Committee on Food Labelling", Halifax Canada, 6-10 May 2002", ALINORM 03/22, Rome.

9. Golder, G., F. Leung, and S. Malherbe, "Economic Impact Study: Potential Costs of Mandatory Labelling of Food Products Derived from Biotechnology in Canada", KPMG Consulting, Ottawa, 2000.

10. Matthew, R., and W. Huffman, "GM Food Labeling Polices of the U.S. and Its Trading Partners", Department of Economics, Iowa State University, 30 September 2001.

11. Newsweek Magazine, Vol. CXLI, No. 4, 27 January 2003.

12. OECD, "Report for the Task for the Safety of Novel Foods and Feeds", May 2002.

13. OECD, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles", OECD, Paris, 1993.

14. Weiss, R., "British Medical Association Warns of Health Hazards of Genetically Engineered Foods", Washington Post, 18 May 1999.

15. WHO, "Application of the Principles of Substantial Equivalence to the Safety Evaluation of Foods or Food Components from Plants Derived by Modern Biotechnology", Report of a WHO workshop, 1995, (WHO/FNU/FSO/95.1).

16. Zepeda, L., "Genetically Engineered Food Labeling: Consumers, Policies and Trade", August 2002.

17. Zurek, A., C. Bozzo, B. Edwards, N. Fortino, and J. Miller, "Labelling of Genetically Modified Food", 3 December 2001.