codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5b) **CX/FL 07/35/8**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Thirty-fifth Session
Ottawa, Canada, 30 April - 4 May 2007

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING: PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING : LABELLING PROVISIONS (AT STEP 4)

REPORT OF THE CCFL WORKING GROUP ON LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

Report of the CCFL Working Group on Labelling of Foods and Food Ingredients obtained through certain techniques of Genetic Modification/Genetic Engineering

Oslo 6-7 February 2007

1. The Working Group on Labelling of Foods and Food Ingredients obtained through certain techniques of Genetic Modification/Genetic Engineering established by the 34th Session (May 2006) of the Codex Committee of Food Labelling convened in Oslo, Norway on 6-7 February 2007. The meeting was co-chaired by Professor Josephine Nketsia-Tabiri (Ghana), Mr Federico Alais (Argentina) and Mr Kjetil Andreas Tveitan (Norway), and was attended by 60 delegates representing 25 member governments, 1 member organization (EC), WHO and 6 observer organizations. The list of participants is attached as Appendix I.

2. The Working Group was mandated to assist the Codex Committee on Food Labelling with guidance relating to the further development of the *Draft Proposed Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification-Genetic Engineering.* Within the mandate of Codex, the Working Group should address the following areas:

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification /genetic engineering with particular reference to how Members label these foods.
5. The output CCFL may require to respond to items 1-4 above.

The Committee agreed that in undertaking this work, the Working Group should take into account information presented in:

- Existing proposed draft texts on the labelling of foods and food ingredients obtained from certain techniques of genetic modification/genetic engineering prepared by the Codex Committee on Food Labelling, and associated comments and committee reports.
- Relevant Codex texts such as, but not limited to, the Codex *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account* and the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius,* particularly those sections relating to risk management and risk communication.
- The WHO document *20 Questions on Genetically Modified (GM) Foods.*

3. The co-Chairs reviewed the mandate of the Working Group, informed the group of comments received from 14 member governments and 1 Member Organization (the EC)

following the circular letter[1] and invited open discussion. The group was invited to identify the main problems and share relevant experiences.

Identify the current standards, regulations, acts/decrees, etc.

4. Based on comments submitted and discussions, the working group identified the following approaches in member states to GM labelling [2]:

1. *Mandatory GM[3] labelling as such of all foods derived from or containing ingredients derived from organisms produced using gene technology (food consisting of, containing or produced from GMOs)*
2. *Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food.*
3. *Mandatory GM labelling as such of GM food where it is significantly different from its conventional counterpart and where GM labelling is required in addition to the significant change*
4. *Mandatory labelling of GM foods where it is significantly different from its conventional counterpart and where only the significant difference is labelled, but not the method of production*
5. *Voluntary labelling (Voluntary labelling guidelines for foods that are or are not products of genetic engineering).*
6. *No special labelling requirement for bioengineered foods as a class of foods*
7. *Labelling Requirements Under Development*

5. The working group noted that a country's labelling requirements might be covered by several of the above listed categories and that the discussion did not cover exemptions or exclusions from these regulations. The categories may not fully reflect the situation in different countries and do not reflect the full complexity.

6. Some delegations objected to the inclusion of "labelling requirements under development" given that the working group should only address current regulations, while other delegations believed it should be kept as it reflected their current situation. It was further underlined that the lack of guidance given by Codex was an important reason explaining why some countries, especially developing countries, still had their labelling requirements under development.

Consideration of the rationale for Members' approach

7. The co-Chairs invited members to explain the rationale behind their regulations in the different approaches. For the purpose of ordering the discussion countries were asked to only explain the rationale behind their own approach and not comment upon the approach of other countries. The intention was to identify the various rationales and not seek consensus on this item. Rationales were given during the plenary meeting and handed in during the afternoon.

[1] Attached as Appendix II

[2] Countries may use more than one approach in labelling GM food

[3] "Genetically modified/engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

8. It was noted that when a country chooses a certain labelling regime, it also considers and rejects other possibilities (pros and cons). As there was insufficient time for a country to present its entire rationale the discussion was limited to why a country chose a certain approach and not why another approach was not considered suitable. Further there was no exchange of views regarding technical feasibility, economic costs of implementing labelling regimes, or proportionality of the adopted measures or their impact on the consumers' right and demand to make an informed choice. These subjects could not be explored within the time frame of the WG.

Approach 1

9. Mandatory GM labelling as such of all foods derived from or containing ingredients derived from organisms produced using gene technology (food consisting of, containing or produced from GMOs).

The following views were presented:

I. The main rationale behind this is based on the CAC mandate from 1991 ALINORM 91/40 paragraph 90,[4] and the consumers' right to make an informed choice. The aim is to meet the demands expressed in consumer surveys, and it is the only approach

[4] 88. In considering document ALINORM 91/11, the Commission recalled that the issue of biotechnology was first discussed in 1989 during its 18th Session. At that time, the Commission had been informed of an initiative of WHO to convene, jointly with FAO, a Consultation on the Assessment of Biotechnology in Food Production and Processing as Related to Food Safety. This Consultation had taken place in Geneva in November 1990 and the Report of it would be available, as a formal WHO publication, at the end of 1991. The Consultation had recognized biotechnology as a continuum, embracing traditional breeding techniques and modern techniques based on recombinant DNA - technologies. "Modern" biotechnologies had the potential of revolutionizing the food supply, both in quantity and quality. While the Consultation was of the opinion that foods derived from "modern" biotechnologies were inherently not less safe than those derived from traditional biotechnologies, the issue of safety had to be considered. In addition, nutritional concerns may have to be addressed.

89. Based on scientific and technical advice by Joint FAO/WHO expert committees and consultations, the Codex Committees on Nutrition and Foods for Special Dietary Uses, on Food Labelling, on Food Additives and Contaminants and on Food Hygiene were expected to be the main committees with responsibilities for matters on biotechnologies. In addition, several commodity committees (e.g. Vegetable Protein, Cereals, Pulses and Legumes, Fish and Fishery Products, Fats and Oils) might need to play a role in reaching international consensus on particular novel foods.

90. The Commission endorsed the conclusions and recommendations of the Joint FAO/WHO Consultation. It noted that while consumers would benefit from "modern" food biotechnology, some consumers felt that this technology would pose certain problems. For example, individual consumers might, on ethical or other grounds, not wish to buy foods derived from "modern" biotechnology. The Commission requested the Codex Committee on Food Labelling to provide guidance on how the fact that a food was derived from "modern" biotechnologies could be made known to the consumers.

91. The need to provide consumers with sound, scientifically based information which explained the application of biotechnology in food production and processing and clarified the safety issues was stressed. In this context, the Commission was informed that WHO was exploring possibilities to prepare a book on food biotechnology for the non-technical reader which would be based on the report of the Joint FAO/WHO Consultation.

92. The Commission endorsed the views expressed by its Executive Committee and agreed that the Commission should monitor developments in the field of food biotechnology and that the General Subject Committees identified above should discuss issues related to biotechnology within the context of their Terms of Reference (see ALINORM 91/4, para. 34). The Commission requested WHO to make copies of the Consultation report available to all Codex Contact Points. A progress report is to be presented to the 20th Session of the Commission.

which allows consumers to choose according to the method of production i.e. between GM and non GM foods.

II. This approach secures transparency and facilitates the consumer's right to informed choice. It is enforceable in combination with a traceability system and also in compliance with Codex Standards for labelling.

III. It was stated that the safety assessment is an integral part of the mandatory GM labelling requirements. These requirements are proportionate as they take into account the demands of consumers and the economic concerns of industry and they apply to both locally produced and imported foods.

IV. Mandatory GM labelling also highlights the intrinsic qualities of GM foods in comparison with their conventional counterparts (e.g. fewer pesticides).

Approach 2

10. Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food.

The following views were presented:

I. The main rationale behind this is to allow consumers to purchase food based on its actual content, rather than the process by which it was made. It was stated that it prevents consumer deception by only requiring labelling when GM material is present in the final food and thus allows consumers to make an informed choice. The category provides adequate consumer information commensurate with national demands for information.

II. It is enforceable because it avoids requiring labelling of food that does not contain novel DNA or protein which cannot be verified by analytical methods, since there is no current testing available for distinguishing between GM foods and non-GM foods when there is no novel protein or DNA present in the final food.

III. It does not impose additional costs on industry and enforcement agencies due to tracking origin of ingredients which could not be justified on the basis of a cost benefit analysis.

IV. The mandatory GM labelling requirements are related to full implementation of a safety assessment and are not based on safety.

Approach 3

11. Mandatory GM labelling as such of GM food where it is significantly different from its conventional counterpart and where GM labelling is required in addition to the significant change.

The following views were presented:

I. The main rationale is to state that a food has been genetically engineered or genetically modified and the label specifies the difference (composition, nutritional change, use) and it is mandatory to indicate that it is a GMO product.

II. Novel foods, including those produced through biotechnology or genetic engineering, are subjected to comprehensive health and safety requirements.

Approach 4

12. Mandatory labelling of GM foods where it is significantly different from its conventional counterpart and where only the significant difference is labelled, but not the method of production.

The following views were presented:

I. The main rationale is food safety linked to labelling of the significant difference and not method of production. It does not require the words GM or GE on the label. It was

argued that consumers should be informed about any significant change in the food and not the method of production. The important element of information is the substantial difference a food may have as compared to its conventional counterpart.

II. Novel foods and GM products are subjected to comprehensive health and safety requirements. If the assessment demonstrates that a GM product is found to have undergone a change in composition, nutrition, toxicity or allergenicity consumers need to be informed, and mandatory labelling informs about these changes. This approach informs consumers about material facts related to the use of the product without misleading the consumer when there are no differences between similar foods based on the method of production. It allows use of labelling as a measure to communicate possible risk to consumers, as a result of a scientifically based risk assessment of the food and is the only approach that has a scientific basis.

III. This approach provides consumers with information to manage their diet and ensures transparency to garner consumer trust.

IV. This approach is consistent with existing Codex standards for mandatory labelling and is enforceable.

V. It retains proportionality between the measure and the risk, and is technically and economically viable for developing countries.

Approach 5

13. Voluntary labelling (voluntary labelling guidelines for foods that are or are not products of genetic engineering).

The following views were presented:

I. Voluntary labelling allows the industry to use labelling as a measure to communicate different aspects; for instance if there is a market advantage to provide such labelling. In this regard, food producers and manufacturers may voluntary label their products, provided the label is truthful, not misleading, and in compliance with all domestic regulatory requirements.

II. Voluntary labelling provides guidance that will assist consumers in making an informed choice, while allowing the agri-food industry the flexibility to make appropriate business decisions in response to market demands. It responds to specific niches or groups to be able to differentiate between their products and addresses the potential market demand for GM labelling information. It allows positive and negative labelling on the basis that the claim is factual and not misleading.

III. This labelling can coexist with mandatory labelling (e.g. mandatory positive labelling and voluntary negative labelling). It allows the possibility of using both positive and negative labelling.

IV. This approach allows the development of regulations that provide a net benefit to consumers. Consumer research indicates that mandatory labelling is not required and that voluntary labelling is sufficient for the method of production.

V. The benefits of this approach outweigh the cost, and the regulatory burden authorities introduce is the required minimum to meet regulatory needs.

Approach 6

14. No special labelling requirement for bioengineered foods as a class of foods.

The following views were presented:

I. Codex General Labelling Standards are applicable to all food classes including bioengineered foods.

II. There is no information showing that bioengineered foods differ in any meaningful or uniform way, or as a class present any different or greater safety concern than foods

developed by traditional plant breeding. Therefore standards/ regulations are based on the GMOs' identified characteristics and risks, rather than the process by which the GMOs originated. In other words, the system addresses GMOs in terms of the proposed use, considering only those aspects in the procedures for obtaining them that might mean a risk to the environment, agricultural production or public health.

III. This approach informs consumers about material facts related to the use of the product without misleading the consumer when there are no differences between similar foods based on method of production. It ensures transparency to garner consumer trust.

IV. This approach incorporates criteria that are enforceable. It retains proportionality between the measure and the risk, and is technically and economically viable for developing countries.

Approach 7

15. Labelling requirements under development.

The following views were presented:

I. This category covers members which currently have labelling requirements under development which are yet not established, but may be before parliament or because of administrative procedures, are being worked on.

II. Countries are awaiting a decision by Codex on the development of a GM standard. Their national legislation can be aligned with international standards as these countries are not able to develop regulations alone, and thus they are awaiting a steer from Codex. Countries are afraid they might be sanctioned because they have not complied with recommendations made.[5]

III. Reference was made to report 0629/22 paragraph 91[6].

16. Consumer interests were used as the rationale in several of the approaches and the WG noted that Consumers in each member country may not share the same concerns. Countries have different concerns and so do the different consumers around the world.

17. An observer organization pointed out that a consumer world congress expressed the request for mandatory labelling of all foods derived from or consisting of GMOs.

Identify Members' practical experiences

18. The co-Chairs invited the group to look at practical experiences and suggested that countries share their experience without repeating what had already been submitted (attached appendix II).

19. Delegations informed the working group of their varying practical experiences, and the following elements were presented:

I. Countries have approval systems and the primary aim of these systems is to make sure that GM food on the market is safe through a risk assessment. Details were given about

[5] There is no internal agreement on the thrust of the national legislation or approach. *It was therefore noted that this is not a reason for deferring taking a decision at a national level for countries that want to take a decision to avert any possible risk, e.g. not providing info to consumers on GMs*

[6] "Some delegations stressed the importance of CODEX recommendations in order to provide guidance to developing countries as it would facilitate the establishment of national policy or requirements concerning labelling of GM/GE foods and therefore supported further work in this area"

a consultative process between authorities and the companies wanting to introduce a product derived from biotechnology.

II. The need to provide consumers with comprehensive information.
III. The labelling system has to be economically viable following a cost benefit analysis.
IV. Several countries are monitoring the GM field; reports are available on the Internet (see attached comments to the CL). Members conduct open consultations involving consumers and all stakeholders on different aspects concerning labelling.
V. Countries that are monitoring labelling requirements argued that enforceable legislation meets a high level of compliance. Any action of non-compliance would be in response to complaints to a food inspection agency regarding false and misleading advertising.
VI. Traceability can be used as a tool for monitoring labelling and traceability can be used to monitor the documentation which accompanies food.
VII. The appropriate role of governments should be considered before intervening in labelling. Governments might choose leaving voluntary GM labelling to the industry, however the label must not be false or misleading.
VIII. Some countries informed about having few products on the marketplace.

Identify communication strategies

20. The Co-Chairs invited the Working Group to discuss communication strategies with particular focus on results of information campaigns etc. without repeating details from their written submissions (see appendix II).

21. Members explained their communication strategies which showed a wide range of strategies and measures in the different member countries.
Countries explained that their strategies and measures included:

I. objective information to consumers and stakeholders on techniques of genetic modification, their implication on health (e.g allerginicity, nutrition,) and the legal requirements regarding their production, marketing and labelling;
II. public consultations, surveys and activities in the process of developing guidelines and regulations and publications of official reports on basis of feedback;
III. information and guidance on regulations in terms of lectures, work-shops, multi-stakeholder meetings, conferences and laymen's conferences;
IV. communication materials in terms of fact sheets, booklets, news releases, web sites and web-based information to help the general public gain a better understanding of genetic modification, its use in food production and labelling requirements;
V. Consumer research (public opinion research) as important instruments to review consumer behaviour and as an opportunity to consider whether the authorities are providing consumers with information which is useful to them. It was also pointed out that the authorities have a responsibility to understand how consumers use the information and to ensure they are making correct judgments;
VI. education sessions for industry and stakeholders
VII. industry user guides (which outline labelling requirements and provide information on how industry can determine whether they have a labelling obligation and how they ensure ongoing compliance);
VIII. Labelling is considered as a part of the communication strategy

22. Different views were expressed as to whether GM labelling was misleading or informing the consumer. It was argued that labelling two identical products based only on method of production would be misleading as many consumers would perceive this as a safety or health

warning, even though the food had undergone a safety assessment and been found to be safe. It was also stated that the primary responsibility of the authorities in adopting standards is to protect consumers given that there is no different safety risk in GM food compared to conventional products. Adopting general labelling standards for products derived from GMO may be interpreted as a disproportionate measure. It was also claimed that consumers' negative perception needs to be changed with more education rather than with measures contributing to this perception.

23. On the other hand, it was argued that foods derived from biotechnology have been assessed for safety prior to approval for marketing and thus labelling only informs the consumer of the method of production in order to allow informed choices. It was also stated that the authorities should not decide what information the consumers want.

24. It was argued that "communication strategy" is a complex issue; particularly in some developing countries were you might find a high level of illiteracy and communication has to be adapted for various conditions and regions. One delegation stated that the authorities have to make decisions based on what is in the market place and what information should be provided to the consumer when the public's capacity to understand such complex issues is restricted. Others argued that in this discussion, illiteracy cannot be the basis on which to base guidelines since illiteracy is also associated with a lack of specific knowledge.

The output to CCFL – possible ways forward

25. The co-chairs invited the working group to focus on the output for CCFL and to outline some possible ways forward to deliver to CCFL. The following possibilities were listed by various participants at the working group:

1. *Discontinue work on this agenda item*
2. *Distil common principles and themes which we could agree to take forward*
3. *Develop general horizontal overarching principles which would be consistent with all the GM approaches presented by members.*
4. *Refer back to the CAC*
5. *Share the experience we have gathered in the last two days with CCFL*
6. *Continue working on the draft guidelines taking into consideration the outcome of the working group based on information shared by the working group members*
7. *Discontinue work related to consumer information which should be based on national legislation*
8. *Continue work related to consumer information.*
9. *Focus on guidelines for labelling of GM foods where there is a significant difference from its conventional counterpart where only the significant difference is labelled.*

26. *Discontinue work on this agenda item.* It was stated that this seemed to be one way forward considering CCEXEC 55th session[7]. Work on this item has been going on for the past 15 years without any result and thus continuing this work is wasting the scarce resources of Codex. It is not possible to apply universal labelling standards as consumers are different and

[7] 41. The Executive Committee agreed to give a general recommendation to Codex Committees to make all efforts to achieve progress on controversial issues, and, if progress was slow or consensus was unlikely to be reached, to consider the following options: redefining or narrowing the scope of the text, concentrating on the areas where consensus could be reached; suspending consideration of the issue for a period of time; or discontinuing the work.

they have different concerns. It was further noted that the question of cost-benefit analysis regarding labelling had not been touched on. Another comment presented was that suspension rather than discontinuation of work might be a preferable option leaving then time for science to provide new facts which could facilitate the establishment of a consensus on a certain approach.

27. *Distil common principles and themes which we could agree to take forwar*d. It was requested that the CCFL explore a way to capture information given in this Working Group, make it more widely available and look at common principles which unite rather than divide us.

28. *Develop general horizontal overarching principles which would be consistent with all the GM approaches presented by members. S*ome horizontal principles were presented by a delegation as examples of principles which could be further explored by CCFL and these principles could address issues related to: food safety, e.g. change in composition of nutritional properties, allergenicity etc., different consumer needs and various levels of approaches regarding labelling, the consumer's basic rights to information; appropriate control measures to prevent false and misleading labelling and the limitations of developing countries. The principles were not considered by the Working Group.

29. Refer back to the CAC. It was noted that CCFL would not comply with its mandate from 1991 to provide guidance to governments if they failed to develop relevant guidelines. However reference was made to ALINORM 97/3 1997[8] claiming that the consumer's right to know was "ill defined".

30. Share experience we have gathered in the last two days with CCFL. The experiences gathered on communication strategies during the WG could provide guidance to developing countries.

31. *Continue working on the draft guidelines taking into consideration the outcome of the working group based on information shared by the working group members.* The guidance which the WG can offer CCFL can emerge from the information shared, and can ensure that the draft guideline is continued. Some developing countries indicated this was important for them while other delegations noted that existing Codex labelling texts provided sufficient guidance."

[8] 29. In the matter of the proposal to initiate the preparation of proposed draft guidelines for the labelling of foods prepared with the aid of biotechnology, the Executive Committee stressed that the Four Statements of Principle should be closely adhered to. It noted the opinion claiming that while consumers may claim the right to know whether or not foods had been prepared by such means, it also noted that the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling. The Executive Committee stated that there were certain elements which clearly had to be taken into account when considering the labelling of foods in relation to production processes. Foremost among these was the protection of consumers' health from any risks introduced by the production process, followed by consideration of any nutritional implications which resulted from changes to the composition of the food, by any significant technological changes in the properties of the food itself, and the prevention of deceptive trade practices. To a considerable extent such matters would have to be decided on a case-by-case basis. The Executive Committee noted that there was always the possibility of voluntary labelling.

32. *Discontinue work related to consumer information which should be based on national legislation.* Codex's main objective is to protect health thus the consumers' right to know information should be left to national legislation.

33. *Continue work related to consumer information*. Much of the work in CCFL is about consumer issues, thus CCFL has to continue work on consumer information. The mandate of Codex is to protect the health of consumers and ensure fair practices in the food trade; however, it is important to continue working with questions relating to information for consumers.

34. Focus on guidelines for labelling of GM foods where there is a significant difference from its conventional counterpart where only the significant difference is labelled but not the method of production. One possible way forward could be to identify guidelines for labelling significant differences where there is a change as regards nutrition, use and .composition.

35. There was an extensive discussion on how the working group should move its discussions forward to the CCFL and what should be included in the report. Many regretted that there was not sufficient time to:

- discuss pros and cons with regard to the labelling regimes (see paragraph 4 and paragraph 8),
- discuss and go further into the rationale for members' approach (see paragraph 7),
- discuss further practical experiences with specific reference to cost benefit (paragraph 17 III),
- exchange more views on communication strategies and their effectiveness.

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Argentina

CL 2006/22-FL
LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

COMMENTS FROM ARGENTINA

Argentina is grateful for the opportunity to provide information on the issues requested in agreement with the mandate of the Working Group.

Introduction

Argentina was one of the first countries to develop and apply modern biotechnological techniques to assist the development of primary production, complying with FAO recommendations whose techniques are important for the improvement of food production, the reduction of production costs, the protection of the environment through a substantial reduction in the use of agrochemicals, and the promotion of developments that, according to scientific advances, allow for the production of increasingly larger quantities of safe, harmless and high quality food.

On that basis, Argentina was one of the first countries to develop an adequate regulatory framework, which allowed it to carry out a thorough monitoring process of all GMO production phases, as well as a risk analysis of this process for endorsement and marketing purposes.

In 1991 the National Advisory Committee on Agricultural Biotechnology (CONABIA) was created to advise the Ministry of Agriculture, Livestock, Fisheries and Food on technical requirements and bio security which should bring together all genetic materials obtained through biotechnological procedures, before they are incorporated by whatever procedure or method and in whatever form (trials, dissemination, etc.) into the bio system. This includes a previous food harmlessness evaluation that includes the first field trials, without prejudice to the subsequent independent harmlessness evaluation carried out by SENASA as a requirement for commercial authorization.

CONABIA is an organization made up of representatives from various public and private organizations and associations, directly competent in the subject matter.

In 2004, to support of the management of CONABIA, the Office of Biotechnology was created within the Ministry of Agriculture, Livestock, Fisheries and Food with the aim of advising and assisting in the running of activities linked to biotechnology and bio security. In particular, environmental release authorizations and the marketing of genetically modified vegetable and/or animal organisms originating in agricultural and fishing activities, defining policies and specific regulations, and in the dissemination of information about Ministry activities.
The National Service of Health and Agri-Food Quality (SENASA) is the official organization responsible for the evaluation of food harmlessness of GMOs. A Technical Advisory Committee on Food Bio security made up of professionals from the public and private sectors linked to the subject matter provides SENASA with advice on issues related to the evaluation framework.

Bio security Regulatory Framework for Biotechnology

Since 1991, Argentina has had a regulatory system to evaluate the bio security of genetically modified organisms. This system is implemented by the Ministry of Agriculture, Livestock, Fisheries and Food. The Argentine framework is based on characteristics and risks identified with the GMO, not on the process by means of which it originated. In other words, it is aimed at GMOs according to their proposed use, taking into account only those aspects of the processes used to achieve it, which could cause risks to the environment, agricultural production or public health.

The Ministry of Agriculture, Livestock, Fisheries and Food (SAGPYA) is responsible for applications and the subsequent monitoring of trials. The subsequent monitoring of trials – responsibility of the National Seed Institute (INASE) and the National Service of Health and Agri-Food Quality (SENASA) – evaluate “on site” the execution of the points requested.. They are also trained to apply measures to prevent adverse effects on the environment outside of the trials (such as scattering of weeds). Controls are also carried out on plots of land, prior to the time of harvest; in an attempt to limit the possible transfer of genetic information contained in the genetically modified organism to other conventional organisms.

To obtain the corresponding trade license, a request for the approval of a GMO must comply with the requirements of the National Advisory Committee for Agriculture Biotechnology, The National Service of Health and Agri-Food Quality (SENASA), assisted by the Technical Advisory Committee on Food Bio security and the National Department of Markets of the Ministry of Agriculture, Livestock, Fisheries and Food.

The rigorousness with which the steps for approving a GMO have been applied took the favourable evaluation of the three steps as a basis for approval. This has allowed Argentina to currently cultivate and market 10 transformation programs without there being any negative impact on agro ecosystems, human or animal health.

Taking into account that the regulatory approach for genetically modified organisms in Argentina concentrates on the evaluation of environmental safety and the harmlessness of these organisms as food, and that the specific regulations for labelling at a national level are based on the characteristics and properties of the products when these are technically verifiable, there is no specific law at a national level for the labelling of food produced from raw materials or from ingredients which come from genetically modified organisms.

Regulatory Framework for food labelling

In 1994, the reform to the Argentine National Constitution allowed the protection of consumer rights to be included in Article 42, giving it the status of a constitutional right.
This principle includes the obligation to provide adequate information to the consumer and the obligation of the authorities to facilitate this right; providing education for the consumer and the protection of competition, and to constitute consumer associations able to provide adequate mechanisms to resolve disputes.

Law 24.240 on Consumer’s Defence and its modifications, contains provisions for the protection and defence of consumers; application authority, procedures and sanctions. The law imposes an obligation on those who produce, import, distribute or market any kind of product, to provide consumers with sufficient, truthful, detailed and efficient information on the essential characteristics of a given product. Likewise, it is stipulated that products must present no danger

to the health of consumers and establishes the joint responsibility of the producer, manufacturer, importer, distributor, provider, seller and whoever has put their mark on the item or service, for damage resulting from any health hazard or defect of the product.

The law also seeks to motivate consumers, so that they can play an active role in regulating, guiding and transforming the market by means of their decisions.

Likewise, the Commercial Loyalty Law establishes the prohibition of recording on brochures, containers, labels or packaging, words, phrases, descriptions, marks or any other signs which could cause error, deception or confusion, regarding the nature, origin, quality, purity, mixture or quantity of products, its properties, characteristics, uses, marketing conditions or production techniques. It also establishes the responsibility of the producers and manufacturers of the merchandise, the packers, the people who divide up the product and the importers, for the truthfulness of the instructions recorded on the label.

This Law also prohibits any type of presentation, publicity or advertisement which could lead to error, deception or confusion on the part of the consumer.

In the Republic of Argentina, the regulations linked to the manufacture and control of foodstuffs cover general principles linked to the communication of truthful and reliable information, as well as aspects related to statements which could be made regarding the properties of the foodstuff.

As regards nutritional value, Argentine regulations cover the declaration of properties of food for special diets and also declarations made with interests that do not correspond to specific dietary requirements.

Regarding the first group, the Argentine Food Code and its regulating Decree 2126/71 widely covers regulations referring to diet products. Included in these are those aimed at satisfying the specific nutritional requirements of certain groups of healthy people, comprising food for babies and young children, fortified with essential nutrients. Also included are those foods aimed at people with specific body types, amongst which are found those products with changes in energetic value, glucid content, protein, fat, minerals, hyposodics and gluten-free products. To round off this group is a smaller range of enriched products and diet supplements.

Those who establish properties for additional nutritional information, are regulated nationally, also by the Argentine Food Code, and by means of decisive acts combined between the Ministry of Agriculture, Livestock, Fisheries and Food and the Ministry of Health and Social Affairs (Combined Ruling 40/2004-SPRRS and 298/2004-SAGPyA). which cover essential and comparative properties for macronutrients and micronutrients, as well as their listing on the labels.

On this aspect, products with a high or low content of a particular nutrient, or products that due to the nature of their ingredients can be regarded as sourced from same, are covered. Thus covering products which have a comparatively reduced or increased content in comparison to conventional products. There are no restrictions regarding the manner in which these nutrients are modified, as products, for example those in which the primary production has lead to a high content of a particular nutrient, are covered.

Thirdly, in relation to stating properties on labels, there is the National Program of Food Quality Certification, whose function is to certify quality aspects of products or processes, which carries out reviews on a voluntary basis and applies to all types of products. This Program, created in

2001, stipulates the quality certification by third parties of different types of characteristics of quality and origin at the companies´ request, in a similar way to those traditionally developed for the organic production of food. In general, this alternative is opted for when the property to be declared is not included in the nutrient categories already listed or when there are specific demands by the manufacturer regarding the differentiation of the product. Since the program started there have been no requests for authorizations linked to the biotechnological origin of the products, or for products of that origin whose properties are not linked to their genetically modified nature.

It should be emphasised that in the scope of organic production, this activity is regulated by Law 25127.

Regarding the current issue, the labelling of GMO foods, the regulatory system in Argentina protects labelling in cases where information is given exclusively about differences in composition, nutritional value and anticipated use, as compared to equivalent conventional food, in the sense that it was established in the GENERAL CODEX STANDARD FOR THE LABELLING OF PRE-PACKAGED FOODS (CODEX STAN 1-1985, Rev. 1-1991). We consider that this information is relevant for the consumer.

This approach coincides with the criteria that our regulations, for the most part, are based on, which is the demonstration or substantiation of the qualities which are assigned to the product via the label. For this reason, Argentina does not agree with the criteria that it should be necessary to label food which, having no changes in composition, nutritional value or anticipated use, contains, is composed of, or derives from a genetically modified organism. Given that said information is not stated on the label of conventional products, there is no reason why it is necessary to discriminate food and/or ingredients, by stating the production method on the label.

Regarding this issue, Argentina would like to emphasize the decision of the Appeal Body of the OMC (cases “European Communities – Measures which affect asbestos and products which contain asbestos” –from now on EC-Asbestos and “European Communities – Trade Description of Sardines”- from now on EC-Sardines, in which it was established that there are 3 essential requirements for a ruling to be considered as a technical regulation: through this ruling characteristics are established, which are applicable to identified or identifiable products and that they by compulsory.

From this it can be deduced that technical regulations can establish characteristics about products as well as production methods. Nonetheless, they can only establish conditions for production methods when the results of these are related to the final product. That is to say that if, for whatever reason, the characteristics of a certain production method are not found stated on the final product, they should not be subject to regulations or conditioning factors in order for the product to be sold, and much less within the framework of a technical ruling of compulsory observance by all parties.

The characteristics of a product must be verifiable by the product itself and by transmitting information to the consumer by means of the label; it should guarantee that it relates to information verifiable by the final product.

Other issues considered

As a developing country which has incorporated modern biotechnology into its cultivation methods, Argentina pays special attention to world trends which are followed at a regulatory

level in other countries. Based on this, a plan was developed with the FAO in 2003, to analyze the variable practices which could have a substantial influence on the segregation of LMOs (Living Modified Organisms).

In this respect, the conclusions drawn from the FAO PROJECT-SAGPYA/TCP/ARG/2903 on the "EVALUATION OF CHAINS OF CORN AND SOYA IN ARGENTINA AND NECESSARY ADJUSTMENTS TO MAKE EXPORTATIONS SEGREGATED FROM NON LMOs have been of vital importance in agreement with that established in the Cartagena Protocol and in the regulations of the main importing countries.

From this, it can be deduced that, in order to comply with the demands which could be established relating to labelling by production method, circuits for the reception, internal transport and independent grain despatch or "Exclusive Plant" are necessary. The adaptability of the production and commercialization system (including silo plants, automatic samplers in ports and institutional training and strengthening) will involve in practice, large investments to develop parallel circuits.

This analysis, added to the multiple guarantees given by risk evaluation which is occurring on a national level before a GMO food is launched onto the market, to assure consumers of the harmlessness of the foods derived from it, plus the possibility of labelling any differences that exist between conventional products and a GMO food, in agreement with national labelling regulations, has brought about the decision not to establish specific compulsory regulations for the labelling by production method for foods or food ingredients obtained through certain techniques of genetic engineering/genetic modification.

Based on what has been stated, Argentina, not having a specific regulation on differential labelling for these products, does not have practical experience on its application.

Communication strategies

Biotechnology is a recurrent theme in Argentina's media, not only through information in specialized magazines, but also in those within reach of the public in general.

The public authorities transmit information via various mediums on advances achieved., The biotechnological development taking place in the country is considered to be a competitive advantage, which will allow the country to be at the cutting edge of these developments, which will benefit producers, the environment and consumers.

There have recently been many consumer education campaigns, aimed at raising awareness and educating the population about for example, nutritional labelling of food, the significance of trans fat, products for special diets etc. None of these campaigns make specific reference to the production methods of food, but only to its composition and the interpretation of the information on the label, etc. which, as far as the health authorities are concerned represents useful, truthful and necessary information so that the consumer can make healthy options from a nutritional point of view.

On the other hand, the of Biotechnology Agency of the Ministry of Agriculture, Livestock, Fisheries and Food has an institutional website where information can be found on authorizations granted for the use of GMOs (http://www.sagpya.mecon.gov.ar/new/0-

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Subject: Australian comments on Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering CL 2006/22-FL

Australia would like to provide the following comments in response to CL 2006/22 - FL

It should be noted that Australia and New Zealand operate an integrated food regulatory system in which joint food standards are set for both countries and are maintained in the *Australia New Zealand Food Standards Code*. However the implementation and enforcement of the labelling requirements are done at the level of the States and Territories in Australia and at the national level in New Zealand. Hence the Australian response in relation to questions 1 and 2 will be similar to that supplied by New Zealand, reflecting the joint food standards operating in Australia and New Zealand, but there are differences in response to questions 3 and 4, reflecting differences at the national level in implementation, enforcement and communication strategies.

Australian Response

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Australia requires that genetically modified (GM) foods and food ingredients must be labelled if there is novel DNA and/or novel protein in the final food, or if the food has 'altered characteristics'. An altered characteristic means that a food or food ingredient must be identified on the label as being 'genetically modified' if it is significantly different from its non-GM counterpart with respect to allergenicity, toxicity, nutritional impact or end use. The rationale for this regulatory approach is the provision of consumer information to allow informed food choice.

The mandatory requirement to label GM food and food ingredients is not based on safety. Any new GM foods or food ingredients are required to undergo a pre-market safety assessment and established analytical procedures to verify the presence of approved novel DNA and/or novel protein must be available. FSANZ follows guidelines for assessing GM foods developed by the Codex Alimentarius Commission, FAO/WHO and OECD. Only those foods or food ingredients that are found to be safe are approved for sale and must be labelled accordingly if they contain novel protein or DNA. Foods or food ingredients that are found to contain unapproved DNA and/or novel protein are prohibited for sale in Australia.

Australia considers that GM-derived foods which are produced from gene technology, but do not contain novel DNA and/or novel protein in the final food, may not be significantly different from their conventional counterpart. Given that there are no analytical methods to determine whether a food is GM-derived (unless it contains novel DNA and/or novel protein), no safety concerns relating to approved GM foods and that there are no currently agreed standards for export certification and traceability/product tracing, Australia does not require mandatory labelling on the basis of method of production where there is no novel DNA or novel protein.

2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Standard 1.5.2 – Food Produced Using Gene Technology contains provisions for labelling of GM foods and food ingredients. This Standard sits within the *Australia New Zealand Food Standards Code* (the Code), which has the force of law under the Food Acts of the Australian Commonwealth, States and Territories. An electronic version of the Standard is available from the FSANZ website at: http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm#_FSCchapter1

The Standard requires that food and food ingredients (including food additives and processing aids) must be labelled with the words 'genetically modified', if it contains novel DNA and/or novel protein, or where the food has 'altered characteristics' (refer to previous answer for definition of 'altered characteristics').

Certain exclusions to the food labelling requirements for GM foods are permitted, primarily for highly processed foods, in which all novel DNA and/or novel protein is removed as a result of processing (e.g. highly refined oils and minor ingredients, including processing aids and food additives, unless they contain novel DNA and/or protein). Flavours that are present in amounts of no more than 1g/kg are also excluded from the labelling requirements. In addition, labelling requirements do not apply to food intended for immediate consumption that is prepared and sold from food premises such as restaurants and takeaways, caterers or self-catering institutions and vending machines. The Standard permits a food in which an approved GM food or food ingredient is unintentionally present in a quantity of no more than 10g/kg per ingredient to remain unlabelled.

Standard 1.5.2 is silent on the use of negative claims such as 'GM free' and 'non-GM'. The manufacturer might be called on to substantiate the claim and ensure that it is not false or does not mislead or deceive consumers. If a food product contains novel DNA and/or novel protein and a negative claim leads consumers to believe that it does not, a manufacturer may be in breach of the Australian Commonwealth, State and Territory fair trading legislation and food laws.

In Australia, in addition to regulation under the Code, all information on food labels must comply with Section 52 of the *Trade Practices Act 1974.* This section prohibits a corporation in trade or commerce from engaging in conduct which is 'misleading or deceptive or is likely to mislead or deceive'. It is mirrored in fair trading legislation in each State or Territory. The *Trade Practices Act* is enforced by the Australian Competition and Consumer Commission.

It is the responsibility of the State and Territory governments in Australia to enforce the requirements of the Code. In addition, the Australian Quarantine Inspection Service (AQIS) holds jurisdictional responsibility for enforcing the Code in relation to foods imported into Australia.

Where concerns exist about the veracity of compliance decisions made by manufacturers, especially with regard to those products that are either not positively labelled in terms of GM status or have made a negative claim such as 'GM free', enforcement agencies may undertake product testing to verify compliance.

In these circumstances, qualitative testing, which provides a yes or no answer for the presence of GM material in a food is carried out in the first instance. If the product tests negative for GM material, no further action by the enforcement agency is required. If the product tests positive for the presence of an approved GM variety, the manufacturer would be advised of the results and has the option of re-labelling the product as containing GM ingredients or demonstrating that the food falls into one of the exclusion categories for flavours or for the unintentional presence of GM food.

With regard to the exclusion status "a food, ingredient, or processing aid in which genetically modified food is unintentionally present in a quantity of no more than 10g/kg per ingredient", the manufacturer would need to demonstrate that they intended to purchase non-GM ingredients by having in place adequate traceability systems and produce quantitative data to show that the level of GM material detected is less than the 10g/kg permitted for the unintentional presence of GM food in an ingredient of non-GM food. If either of these requirements is not met it would be difficult for the manufacturer to argue that the presence of GM material is unintentional.

3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Australia was among the first countries in the world to adopt a mandatory labelling regime for GM food. After gazettal in December 2000, the Standard came into effect in December 2001. When the conditions were agreed, the Ministerial Council requested a review of industry compliance with the labelling requirements to be conducted after three years.

An industry compliance survey was undertaken by enforcement agencies (State and Territory jurisdictions) to ascertain the level of compliance with the GM labelling requirements of Standard 1.5.2 and to assess the systems that food businesses have in place to ensure ongoing compliance. This review was completed at the end of 2003.

Compliance was assessed in the survey through product testing and document audit. To ascertain whether there was a labelling requirement, validated qualitative and quantitative analyses were used to determine the presence and amount of GM material in final 'off the shelf' products. Commonly eaten foods containing soy and corn were targeted, as there is widespread use of minimally processed ingredients from these crops throughout the food supply. The survey found that 10 out of the 51 samples

tested in Australia were found to contain traces of GM material. In all cases the quantity was less than the amount of 10g/kg of novel DNA and/or novel protein permitted in an ingredient of a non-GM food where the presence is unintentional.

A total of 36 small (17), medium (5) and large (14) manufacturers were document audited to assess the adequacy of any management systems that had been implemented to determine the GM status of foods and food ingredients. The survey results indicated that although more (86%) of the larger manufacturers were able to demonstrate the GM status of foods and food ingredients, only 40% of medium manufacturers audited were able to demonstrate this whilst none of the smaller businesses audited had management systems in place. The lack of business processes or documentary evidence could increase the risk of non-compliance with labelling requirements. However, the cost of introducing supply chain management systems may also impact disproportionately on small manufacturers.

The 'Report on the Review of Labelling of Genetically Modified Foods' is available on the FSANZ website at:
http://www.foodstandards.gov.au/newsroom/publications/gmlabellingreviewrep2460.cfm

4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods.

A number of resources have been developed to assist industry implementation of the labelling requirements for GM foods, including business processes that should be in place to ensure compliance. The GM Standard came into effect in December 2001. Compliance requirements for labelling were included in industry and stakeholder education sessions in all jurisdictions during the transition period.

The industry user guide '*Labelling Genetically Modified Food'* was published by FSANZ and developed by an intergovernmental working group representing enforcement agencies from the jurisdictions. This user guide outlines the labelling requirements of the Standard and provides information as to how industry can determine whether they have a labelling obligation and how they ensure ongoing compliance.

In addition, FSANZ has developed fact sheets, which also outline the labelling requirements for GM Foods. FSANZ has an established telephone Advice Line that provides information to industry about the requirements of the Code, including those relating to GM foods.

FSANZ published an information booklet entitled 'GM Foods: Safety Assessment of genetically modified foods', in 2005. The purpose of the document was to provide consumers with up-to-date information on the processes undertaken by FSANZ for safety assessment and approval of GM Foods in Australia and New Zealand. The booklet includes information on the labelling requirements set out in Standard 1.5.2.

Electronic versions of the *Australia New Zealand Food Standards Code*, User Guide to Standard 1.5.2, fact sheets and the 'GM Foods: Safety Assessment of genetically modified foods' booklet are available from the FSANZ Website at www.foodstandards.gov.au . Hard copies of these resources are also available.

5. The output CCFL may require to respond to items 1-4 above.

In order to do a comprehensive evaluation of Method of Production labelling, the working group would need to investigate the practicalities of enforcement and impact on industry, which would arise from a regulatory system which requires labelling of GM-derived food which are compositionally identical to non-GM derived food.

Yours sincerely

Rose Hockham
Assistant Manager
Codex Australia

Brazil

BRAZIL COMMENTS ON THE CL 2006/22-FL

Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering

The Brazilian Delegation thanks for the opportunity to present the following comments:

In Brazil, the Law 11.105, of March 24, 2005 provides the safety norms and inspection mechanisms for activities that involve genetically modified organisms and their by-products, implements the National Biosafety Council (*CNBS*), re-structures the National Biosafety Technical Commission (*CTNBio)* and provides for the National Biosafety Policy (*PNB*),

1 – Consideration of the rationale for Member's approach to the labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

In Brazil, the labeling of foods and food ingredients containing or consisting of organisms obtained by certain techniques of genetic modification / genetic engineering is mandatory, as established in the Decree 4.680 of April 24, 2003.

This decree regulates the right to information, insured by the Law 8.078, of September 11, 1990, for foods and food ingredients destined to human or animal consumption that contain or are produced from genetically modified organisms. The Law 8.078/1990 disposes about the protection and defense of consumer, also known as Code of Defense of the Consumer.

In this sense, the main reason for the labeling of the foods and food ingredients obtained through certain techniques of genetic modification, in Brazil, is to guarantee the legitimate consumer right to information, in order to favor his/her conscious choice of foods.

The warranty of this right is in consonance with the third statement of principles of the Codex Procedural Manual, 15.Ed. - Appendix: General Decisions of the Commission: "When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade".

Furthermore, the mandate requested by the Codex Alimentarius Commission, in the 19th Session, to the CCFL was to "provide guidance on how the fact that a food was derived from modern biotechnology could be made known to the consumer".

2 – *Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labeling of foods and foods ingredients obtained through certain techniques of genetic modification/genetic engineering.*

Decree 4.680 of April 24, 2003 - it regulates the right to information for foods and food ingredients destined to human or animal consumption that contain or are produced from genetically modified organisms. This decree states that labels must inform about the presence of genetically modified organisms when they are found above the limit of 1% in the food product;

Interministerial Normative Instruction no. 1, of April 1, 2004 - it defines the complementary procedures for the application of the Decree 4.680/03 and approves the Technical Regulation on the Labeling of Foods and Food Ingredients that that contain or are produced from genetically modified organisms" (D.O.U. April 2, 2004, Section 1, p.5);

Portaria (Regulation) 2.658, of December 22, 2003 - published by the Ministry of Justice, it approves the "Regulation about the utilization of the Transgenic Symbol" (D.O.U. 06/12/03, Section 1, p.13).

3 – *Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of and foods ingredients obtained through certain techniques of genetic modification/genetic engineering.*

The Department of Consumer Defense of the Ministry of Justice analyzed, in 2004, 294 (two hundred and ninety four) food products in order to verify its genetically modified soy content, as well as the eventual use of genetically modified soy without informing the consumer, according to the accusations presented by entities of consumer's defense with actuation in the national territory.

The analysis revealed that the products presented RR soy in smaller quantity than 0,1%. These results demonstrated that the companies were using RR soy in the formulation of their products, but in smaller concentration than the limit established in the Decree 4.680/2003. In this sense, the companies were exempted of labeling their products about the presence of genetically modified organisms. The soy oil was not analyzed because its processing makes the detection of modified protein or ADN/ARN above 1% impossible, and, therefore, it is not included in the Brazilian rule for labeling of genetically modified organisms.

It is worth to explain that in Brazil the genetically modified soy with tolerance to the herbicide glifosato is the only genetically modified organism inserted in the alimentary chain and that only 1% of the national soy production (conventional and genetically modified) is used for the production of foods that are covered by the Brazilian rule for labeling of genetically modified organisms.

4 – *Identify communication strategies in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods.*

In Brazil, the communication strategy to the public has been developed by segments of the society, such as consumers' organizations, academy, the media and others. The Government does not have, in the moment, a program for the information to the public. The private sector develops the communication strategies to the public about the genetic modified food. These communications cannot mislead the consumer. The Government acts in order to prohibit misleading information and advertising.

Canada

COMMENTS FROM THE GOVERNMENT OF CANADA

On the

Comments from Canada on Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification / Genetic Engineering (CL 2006/22-FL)

Canada would like to thank Norway, Argentina and Ghana for co-chairing the upcoming physical working group meeting and is pleased to provide comments on the following areas agreed to at the 34th Session of the Codex Committee on Food Labelling.

1. **Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.**

   The Government of Canada established a regulatory policy to ensure its regulatory powers are used in a manner that provides the greatest net benefit to Canadians. The policy has a number of requirements including an obligation for regulators to demonstrate that federal intervention is justified in order to manage a problem or a risk. The regulators must be able to show that a mandatory approach is the best alternative, taking into consideration that the benefit outweighs the costs associated with a regulation being implemented and the regulatory burden be minimized while respecting international agreements.

   Existing requirements for the pre-market notification under *Food and Drug Regulations* for novel food products along with existing labelling requirements in the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* and their respective *Regulations* affords Canada the leeway to adopt a voluntary approach to the labelling of food and food ingredients obtained through genetic modification.

   The Canadian approach to biotechnology labelling consists of both mandatory labelling requirements, when there is a health and safety change or a significant change in nutrition or composition in the novel food (including products of genetic engineering), and voluntary labelling requirements for method of production labelling.

   Novel foods, including those produced through biotechnology or genetic engineering, are subject to comprehensive health and safety requirements. The *Food and Drug Regulations* require that before a novel food can be advertised or sold, Health Canada be provided with sufficient accompanying information to enable it to undertake a safety assessment to demonstrate that the novel food is considered to be safe and nutritious as foods already on the Canadian marketplace.

   In keeping with these regulatory requirements, Health Canada established a clear and stringent process for evaluating the safety of foods derived through genetic modification[1]. The specific criteria for the safety assessment of such foods are outlined in the Health Canada publication "Guidelines for the Safety Assessment of Novel Foods" (http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lingesdirectrices_e.html).

   In principle, food products derived from genetic modification that are demonstrated to be safe and nutritious are treated in the same manner as non-genetically modified foods with regard to labelling requirements. If the assessment demonstrates that a food product derived from genetic

[1] Genetically modified, as defined in Division 28 of the FDR, means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation.

modification is found to have undergone a change in composition, nutrition, toxicity or allergencity that the consumer needs to be informed of, then mandatory labelling is required to inform Canadians about these changes in the food. Health Canada, in consultation with the Canadian Food Inspection Agency (CFIA), would determine what type of information is needed on the label to highlight how the novel product differs from its non-modified counterpart.

Health Canada and the CFIA share the responsibility for food labelling policies under the *Food and Drugs Act*. Health Canada is responsible for developing policy and setting standards related to the health and safety aspects of labelling under the *Food and Drugs Act and Regulations*, whereas the CFIA applies these policies and enforces the regulations. The CFIA also has the mandate to develop basic food labelling policies and regulations not related to health and safety. In particular, the CFIA is responsible for protecting consumers from misrepresentation and marketplace deception with respect to food labelling, packaging and advertising, and promoting fair market practices by prescribing and enforcing standards related to food labelling and advertising requirements.

For method-of-production labelling, such as biotechnology, the Government of Canada has traditionally supported market-driven initiatives. In this regard, food producers and manufacturers may voluntarily label their products, provided the label is truthful, not misleading, and in compliance with all domestic regulatory requirements set out in the *Food and Drugs Act and Regulations*, the *Consumer Packaging and Labelling Act and Regulations*, the *Competition Act* and all other relevant legislation.

This approach to labelling has been supported by a number of consultations, in which the Government of Canada has carried out and participated in, related to biotechnology labelling. The outcomes of these consultations[2] indicated that there was general consensus:

- to build on current food safety approach: mandatory labelling for health & safety, nutritional, compositional changes;
- that labelling is understandable, truthful and not misleading
- that the approach chosen must take into account domestic and international considerations
- that information for consumer choice can be facilitated through voluntary labelling by food manufacturers
- to permit voluntary positive and negative labelling on the condition that the claim is not misleading or deceptive and the claim itself is factual

All of these outcomes could be achieved within Canada's current regulatory framework for food.

This approach was supported by the Royal Society of Canada Expert Panel on the Future of Food Biotechnology, the Canadian Biotechnology Advisory Committee (CBAC) and the House of Commons Standing Committee on Agriculture and Agri-Food. In particular, the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology identified that it did not, on the basis of scientifically established health hazards, find a justification for the mandatory labelling of biotechnology-derived foods. However, the Panel did call for the implementation of a reliable and informative system of voluntary labelling. In addition, CBAC recommended that the voluntary system be evaluated 5 years after its implementation to ensure adequate choice was provided for consumers.

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[2] Workshop on Regulating Agricultural Products of Biotechnology (Nov 1-10, 1993)
Technical Workshop on the Labelling of Novel Foods Derived Through GE (Nov 24-25, 1994)
Communiqué: Labelling of Novel Foods Derived through Genetic Engineering (Dec 1, 1995)
Food Biotech and Consumer Information: Do we need to label? (Dec 6-7, 1995)

This voluntary approach to biotechnology labelling offers Canada the opportunity to support and enable Canadian social, environmental and economic priorities, achieve high standards of protection for citizens and to enhance business confidence and public trust in Canada's regulatory system

2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

The following are key pieces of food labelling legislation. The onus is on the manufacturer to comply with these requirements whenever a food product is sold in Canada. The authority to delete, amend or add regulations is provided under the *Food and Drugs Act* should it be necessary and appropriate.

Subsection 5.1 of the *Food and Drugs Act*

5(1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Section 7 of the *Consumer Packaging and Labelling Act*
7. (1) No dealer shall apply to any prepackaged product or sell, import into Canada or advertise any prepackaged product that has applied to it a label containing any false or misleading representation that relates to or may reasonably be regarded as relating to that product.

(2) For the purposes of this section, “false or misleading representation” includes

(a) any representation in which expressions, words, figures, depictions or symbols are used, arranged or shown in a manner that may reasonably be regarded as qualifying the declared net quantity of a prepackaged product or as likely to deceive a consumer with respect to the net quantity of a prepackaged product;

(b) any expression, word, figure, depiction or symbol that implies or may reasonably be regarded as implying that a prepackaged product contains any matter not contained in it or does not contain any matter in fact contained in it; and

(c) any description or illustration of the type, quality, performance, function, origin or method of manufacture or production of a prepackaged product that may reasonably be regarded as likely to deceive a consumer with respect to the matter so described or illustrated.

National Standard for the Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering (National Standard)

To facilitate the development of voluntary labelling scheme with respect to biotechnology claims, Agriculture and Agri-Food Canada (AAFC) provided funding to the Canadian Council of Grocery Distributors to develop a standard for the voluntary labelling of biotechnology-derived foods under the guidance of the Canadian General Standards Board (CGSB).

The voluntary labelling standard was developed through a committee comprised of a balanced representation of interested stakeholders (the Committee), including consumer groups, food processors, manufacturer and retailer associations, grocery distributors, provincial and federal government representatives and farm organizations so that claims about biotechnology and its use in food production would be consistent with an appropriate set of parameters, including being informative, understandable, verifiable, and not false or misleading. This Standard is meant to provide for consumer choice and does not imply the existence of health or safety concerns for these types of products.

It should be noted that approval of a draft standard is achieved by consensus, which is defined as substantial agreement by those involved in the preparation of the standard. An attempt must be made to resolve all objections to the Draft Standard. Once there is approval of a draft standard, the Standards Council of Canada reviews the process before approving the Draft Standard as a National Standard of Canada. A voluntary standard is meant to complement existing regulatory requirements.

The standard applies to the voluntary labelling and advertising of food sold pre-packaged or in bulk, in order to distinguish whether or not such foods are products of or not of genetic engineering, irrespective of whether the food or ingredient contains DNA or protein. It applies to food sold to consumers in Canada, regardless of whether it is produced domestically or imported.

It defines terms, and sets out criteria for claims and for their evaluation and verification.

This standard does not preclude, override, or in any way change legally required information, claims or labelling, or any other applicable legal requirements.

The new National Standard (Appendix 1) is meant to assist manufacturers in making claims about their products and provides guidance to help them comply with regulatory requirements. Claims that follow provisions set out in the National Standard are considered to be in compliance with Canadian regulations that apply to food.

The National Standard provides guidance that will assist consumers in making informed choices, while allowing the agri-food industry the flexibility to make appropriate business decisions in response to market demands. For consumers who want additional details about a specific food product, the Standard requires that labels provide a toll-free telephone number or Internet address from which such information can be obtained.

3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtain through certain techniques of genetic modification/genetic engineering.

As Canada has recently implemented its voluntary labelling standard, very little experience has been gained with respect to the application and implementation of the voluntary standard.

The Canadian government conducted two studies on labelling of GE foods in 2005: one on how many foods were labelled using Canada's voluntary labelling standard, and the other on consumers' understanding and attitudes towards such labels. These preliminary studies meant to establish the baseline against which future information will be compared in order to determine trends and evaluate the "success" of the voluntary standard.

Inventory of foods labelled as GE

In February 2005, the Canadian government commissioned a study called the "Inventory of Foods Bearing Labelling Relating to Genetic Engineering in Canada." Its purpose was to:

- benchmark the current range and quantity of GE-referenced food products, currently available in the Canadian marketplace
- provide an estimate of the current consumer demand for these foods
- identify the type and form of claims being made on product labels and to establish whether consumers had access to additional information about the claims being made on the product itself

Findings of the study include:

- 117 food products in 22 out of 261 unique food product categories had some type of GE reference.
- Most of these food categories did not have large numbers of active items.
- Soya-based products (tofu and soya drinks) dominated and account for 56% of all GE references.
- In this initial study, 36 different references were found, all "non-GE" in nature.

The study was repeated in February 2006 and found 225 products across 38 unique product categories bearing some type of GE reference. A total of 53 different GE-related claims were found, all but one indicated that the product was non-GE in nature. As in the earlier study, soya drinks and tofu products were found to be the largest umber of GE-referenced items.

As a complementary study, we conducted the "The Exploration of Consumer Understanding and Attitudes Towards GE-Related Label Statements" study in March 2005. Its objectives were to test:

- opinions and reactions towards 27 GE-related food label statements
- clarity and understanding of the statements
- ancillary attitudes towards GE

Participants were shown a series of 27 different label statements which had been drafted in accordance with the Standard Council of Canada's *National Standard for the Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering*. They were then led through a series of questions which were designed to gauge their understanding of, as well as attitudes and opinions towards, each statement.

Results of the study:

- Participants easily accepted the term "GE"
- Participants showed little concern that the standard is voluntary
- GE labelling is identified as being important to people, but is not a top of mind issue such as nutrition labelling and nutrition information which is mandatory under the *Food and Drugs Regulations* since December 12, 2005.
- Participant's purchase behaviour is unlikely to change with GE labels
- Education should accompany labelling of GE products
- Consumers appreciate clear and simple labels, and view rationale statements positively

In September 2005, a study was undertaken to obtain information on the *"Importance of GE Labelling to Canadian Consumers."* This study consisted of telephone interviews to determine the relative importance of GM/GE information compared to other types of information that could be added to a food label.

Findings indicated that:

- Top-of-mind, the majority of grocery shoppers (59%) were unable to identify anything that needs to be added to a food label that is not already there.
- Small percentages of respondents overall suggested GM/GE ingredients (6%), nutritional value (6%), all ingredients in general (6%) and trans fat content (5%). Other smaller mentions included preservatives/additives, fat

content, potential allergens, complete/accurate information, sugar content, country of origin, calorie content, salt content and expiry date.

- When specifically asked about items that could be on a food product, nutritional content was the most important, followed by potential allergens, certification that the product meets specific recognized quality standards and GM/GE ingredient information. Nutritional content information was found to be nearly twice as important to grocery shoppers as the next item, information about a potential allergen, and more than twice as important as certification that the product meets a certain quality standard and information about whether or not the product is genetically modified.

These preliminary studies will be used as a baseline in future years to provide information with which to assist in analyzing whether:

- industry is voluntarily providing Canadians with information concerning biotechnology via labelling claims which respects the national standard.
- the information being provided to Canadian consumers is sufficient to permit them to make an informed choice.

4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label their foods.

Canada's approach to communication has been to focus on biotechnology and the issues related to it, rather than biotechnology labelling itself. The communication strategies related to genetically engineered (GE) food have been shaped by numerous consultations and activities over the years. The Government of Canada's communication approach to GE foods has been one of continual improvement in understanding and responding to public and stakeholder information needs. These activities include:

Mechanisms Used to Collect Information

Public engagement through consultations has helped develop guidelines and regulations. The consultation process includes conducting workshops, convening multi-stakeholder meetings, and distributing draft documents for the general public's review and comment. Another form of consultation employed is the citizens' conference, also known as a consensus conference. This form of consultation provides Canadians with a forum to voice any concerns they may have with respect to policy or regulatory decisions which may be taken by the Government.

As an example, the Health Products and Food Branch (HPFB) of Health Canada have organized a Public Advisory Committee (PAC), comprised of 16 to 20 Canadians. The committee meets three times a year as a public / consumer involvement forum, to advise on issues and initiatives as requested by HPFB[3].

Public Opinion Research (POR) is another mechanism commonly used by the Government of Canada to gather information regarding important issues to stakeholders, including consumers.

Since 1999, the Canadian Biotechnology Secretariat and its partners have maintained a large-scale tracking program of public opinion research (POR). Results have been consistent since the inception of the research program. The cumulative research shows a clear upward pattern in

[3] Minutes from previous the committee meetings can be found on the Health Canada website at: www.hc-sc.gc.ca/hpfb-dgpsa/ocapi-bpcp/index_e.html

Canadian support for biotechnology in general, with the caveat that people do not offer blanket support or opposition to any area of this technology. GE foods have lower support, and lower perceived overall benefits, than other biotechnology applications.

The program currently produces one wave of research each year. Each wave has a large tracking component, along with sections of more intensive inquiry into specific issues like genetic privacy, GE food, molecular farming, GE trees, and stem cell research.

The CBS Communications Working Group has published all of its POR reports on the Government of Canada's BioPortal website[4].

A more formal mechanism available to the Government of Canada is to request **expert advice** from various independent organizations.

In 1998, the CFIA funded an independent study by the National Institute on Nutrition (NIN), to see what type of information Canadians actually wanted on labels[5]. It is important to do such studies, to move beyond anecdotal "evidence." The knowledge garnered from the NIN study, set the stage for how the CFIA would communicate information to consumers about GE labelling, in order to assist them in their food choices. The key findings of the NIN study were that consumers wanted simple labels, linked to agriculture and government regulatory approval—although product labelling was not viewed as the only way to provide information. The study also found that product labelling was not viewed as the only way to provide information.

In 2000, an expert panel was formed under the auspices of the Royal Society of Canada to study the future of food biotechnology and the federal regulatory capabilities and capacities to deal with these issues. The panel's report, titled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*[6] was made available to the Government of Canada for consideration and response.

The panel discussed Canada's labelling policy for genetically engineered food products. They conclude that there are not currently sufficient reasons to adopt a system of general mandatory labelling of GM foods. They do not lead necessarily to the same conclusion about voluntary labelling. Many of the concerns voiced in favour of mandatory labelling can be addressed, at least in part, by voluntary labels.

The final independent organization that provides advice to the Government of Canada regarding labelling of biotechnology derived products was the Canadian Biotechnology Advisory Committee (CBAC). CBAC provides advice to federal ministers on social, economic, regulatory, scientific, ethical, regulatory, and environmental and health aspects related to biotechnology. In its report tabled in 2004 titled "*Improving the Regulation of Genetically Modified Foods and other Novel Foods in Canada*", CBAC made several recommendations[7] regarding labelling GE food.

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[4] www.biotech.gc.ca or www.biostrategy.gc.ca/english/view.asp?x=524

[5] More details on the study can be found on the CFIA website, at "National Institute of Nutrition Study on Voluntary Labelling of Foods from Biotechnology": www.inspection.gc.ca/english/sci/biotech/labeti/ninintroe.shtml

[6] www.rsc.ca/index.php?page_id=119

[7] The report on food biotechnology, titled *Improving the Regulation of Genetically Modified Foods and other Novel Foods in Canada*, is posted at: http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00186e.html *(html version)*

The most formal mechanism available to the consumers to participate and for the Government of Canada to collect information is by participation in **parliamentary activities**.

The Government of Canada has participated in numerous hearings by Parliamentary Committees such as:

- the Standing Committee on the Environment and Sustainable Development
- the Standing Committee on Agriculture and Agri-Food
- the Senate Standing Committee on Energy, the Environment and Renewable Resources

The bulk of work done by Members of Parliament is in these standing committees. There they study and amend bills, and examine important issues and departmental spending plans (known as the Estimates) in depth. Committee work requires Members to read background documents and meet experts in various fields, including lawyers, economists, special interest groups, business persons and senior government officials. Committee work enables Members to study issues and legislation in greater detail than is possible in the Chamber. Minutes are made public via posting on the internet[8].

Though labelling of genetically engineered foods was discussed in the three Standing Committees listed above, the most significant recommendations came from the Standing Committee on Agriculture and Agri-Food. In their report titled "Labelling of Genetically Modified Food and its Impacts on Farmers: Report of the Standing Committee on Agriculture and Agri-Food contained four recommendations on labelling, as follows:

- That the government continue to develop a standard for the voluntary labelling of food derived from biotechnology. That standard should use a narrow definition of GMOs, as proposed in the draft standard produced by the Canadian General Standards Board.
- That the government intensify research into the benefits and risks to human health and the environment of agricultural products derived from biotechnology, and bring forward a public information program.
- That the government assess the additional costs, particularly for farmers and consumers, of implementing segregation and tracking systems, which are necessary for the labelling of GM foods, and report to the Committee and the House of Commons.
- That the government assess the trade implications of mandatory versus voluntary labelling of GM foods, and report the results of this assessment to the Committee and the House of Commons.

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http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/Improving_Regulation_GMFoodAug02.pdf/$FILE/Improving_Regulation_GMFoodAug02.pdf *(pdf version)*

[8] Minutes from the Standing Committee on the Environment and Sustainable Development are found at: www.parl.gc.ca/35/Archives/committees352/sust/minutes/sust_issue-03_19-29/sust_03_covE.html
The report from the Standing Committee on Agriculture and Agri-Food, (June 2002) can be found at: www.parl.gc.ca/InfoComDoc/37/1/AGRI/Studies/Reports/agrirp23-e.htm
Proceedings of the Standing Senate Committee on Energy, the Environment and Natural Resources can be found at: www.parl.gc.ca/36/2/parlbus/commbus/senate/Com-e/enrg-e/09cv-e.htm?Language=E&Parl=36&Ses=2&comm_id=5

In addition, the Government of Canada responds to correspondence received from Canadians, on the topic of GE food labelling. While there has been a decline in the numbers of letters from the late 1990s, there is still a certain volume of letters received every year. By supporting the Minister of Agriculture and Agri-Food in his or her communications in the House of Commons, and in ministerial correspondence, the CFIA is able to explain labelling policy to the Canadian public.

The final mechanism is the **environmental petition process**. The petition process provides an opportunity for Canadians to ask the government questions concerning activities being undertaken by the government with respect to sustainable development.

The Government of Canada has responded to petitions regarding request for information concerning the Government of Canada position on labelling and transparency[9]. In Petition 23, the petitioners asked the federal government to review its laws, regulations, and policies on a number of fronts, and to adopt a series of suggested measures aimed at protecting the health, safety, and environment of Canadians from genetically modified organisms (includes labelling). In addition, the government has responded to questions related to human, social, and environmental impact of genetic engineering, including questions about the production and licensing of GE crops, and the impact of GE crops on human health, biodiversity, and sustainable farming (includes labelling)[10].

Communication Strategies

As demonstrated above, the Government of Canada, using various means, gathered a great deal of information regarding Canadians views on issues related to genetically engineered foods through the various activities. However the key design to effective communication strategies is taking that information and developing materials which provide information to a specific audience in a manner that they can understand and use to make decisions.

For instance the information gathered from the consultations the government participated in and conducted, and expert advice provided by the National Institute of Nutrition were used as a basis for the development of the Voluntary National Standard. Recognizing the importance of transparency and making the National Standard available, the CFIA established a five year web licensing agreement with the CGSB so the public and industry have free access to the voluntary standard. The voluntary standard is available via the Canadian General Standards Board web site at: http://www.pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html and is available, without charge, in hard-copy format. You can also request a copy from the: CGSB Sales Centre (Sales Centre, Canadian General Standards Board, Gatineau, Quebec, K1A 1G6).

In a second communication initiative, the government took into consideration the Royal Society of Canada and CBAC reports, as well as the labelling and biotechnology recommendations of the fourth and fifth reports by the Standing Committee of Agriculture and Agri-food. This communication strategy was developed to drive further work on transparency for biotechnology at the CFIA, some of which was about labelling in particular.

One transparency project undertaken provides a way for the public to look, in detail, at the assessment process for biotechnology-derived food crops, showing a product assessment's beginning, middle, and end. Each component is available on the CFIA website, in text and graphical form.[11] In the first component, the Biotechnology Notices of Submission Project,

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[9] Petition 23: *Review of Federal Laws, Regulations and Policies on Genetically Modified Organisms* (9 May 2000): www.oag-bvg.gc.ca/domino/petitions.nsf/viewe1.0/099F91DB55C481EE85256C5600689A94

[10] Petition 108: *Social, Health and Environmental Concerns of Genetic Engineering* (7 April 2004): www.oag-bvg.gc.ca/domino/petitions.nsf/viewe1.0/B8F93B1077687CAB85256FB40050F95A

[11] For all three projects, see the graphic “Looking inside the Assessment Process”, at http://www.inspection.gc.ca/english/sci/biotech/trans/approve.shtml

summaries of biotechnology-derived plant product submissions are posted to the CFIA website, and the public is invited to provide comments on the submissions[12].

Other transparency work, which took into consideration public opinion research, recommendations from the Standing Committees and expert advice, included:

- Improvement of the shared Government of Canada information kit for GE foods
- Delivery of further information about CFIA regulation of biotechnology to consumers via development of fact sheets, and info kit and poster distribution
- delivery of public presentations, for example to the United Church of Canada, for some of its congregational consultations (the CFIA also provided information to the United Church for its consultations across Canada)
- delivery CFIA-wide training on biotechnology to our Operation staff
- focus testing of biotechnology factsheets and then applying what was learned when writing new factsheets
- development of the Biotechnology Highlights report which was made publicly available
- development of an educator's resource for post-secondary instructors titled *Regulation of Agricultural Biotechnology in Canada: Post-Secondary Educator's Resource*

In addition to these initiatives, the Government of Canada has developed communication material, which has resulted and benefited from the information gathering activities. Communication material on GE food labelling included:

- Information brochures
- Magazine supplement
- Information kits
- Posters
- Factsheets
- News releases

A key consideration in developing effective communication material is the principle of risk communication. Older views on how to communicate with the public about risk focussed on public misperception of risk and how to educate the public about the “real” risk. But more modern approaches stress the importance of factoring in public reaction to risk, and this has led to the view that there needs to be a real two way interaction between experts and lay people in order to achieve a common view on risk. These principles are considered at the root of all communication material produced by the Government of Canada.

Through the Government On-Line initiative, the Government of Canada committed itself to being the government that is the most connected to its citizens, with Canadians being able to access government information and

[12] www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml

services on-line (www.ged-gol.gc.ca/rpt2006/rpt/rpt00_e.asp). Government of Canada departments and agencies put a great deal of their information on their websites, for public access.

In order to enhance the availability of information related to biotechnology, the Canadian Biotechnology Secretariat developed the Government of Canada BioPortal, a unique one-stop window to government and biotechnology. The portal has a section on labelling, and it also has a section on governments and international organizations (www.biotech.gc.ca).

Evaluating the effectiveness of communication strategies and material

Over the years, the Government of Canada has evaluated the effectiveness of these messages. For instance the CFIA had factsheets tested by the public in focus groups, and discussed by media experts, for clarity and comprehension. The focus testing indicated that readers want the following in factsheets:

- question and answer format
- clarity on definitions
- why the new product was developed
- risks and benefits
- how much research has been done
- how long the research took and where it took place
- who evaluates it (government, universities, or companies)
- long-term impacts
- other websites to go to for further information

Another way the CFIA has had its products evaluated is through a forum on the challenges of communicating science to non-scientific audiences. The forum, entitled “Biotechnology: Plain Language for a Complex Subject,” brought together scientists, researchers, lab technicians, evaluators, policy officers, managers and communicators, along with three media panellists to discuss biotechnology communications. The forum gave scientists and researchers an opportunity to meet media panellists face-to-face, ask questions, and discuss issues and challenges that they face as government communicators and scientists. Panellists also had the opportunity to critique some of the CFIA's biotechnology news releases and fact sheets. While the panellists had praise for two of the factsheets, they had some advice on changing the CFIA news releases. The CFIA has used this advice to improve its information products.

These evaluations provide information that can be used to improve communication material being reviewed, and the findings are used in the development of subsequent communication material.

Conclusion

Communicating about GE foods and labelling in Canada has meant using a variety of methods to continually improve the understanding of the information needs of the public, stakeholders, and parliamentarians. It has also meant improving how the Government of Canada responds to those needs. Through this on-going work, the Government of Canada continues to contribute information to help Canadians make informed food choices.

EC

European Community Comments on

Codex Circular Letter CL 2006/22-FL

Subject: Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering

The European Community and its 25 Member States are pleased to provide comments on the labelling of foods and foods ingredients obtained through certain techniques of genetic modification/genetic engineering in response to Codex Circular Letter 2006/22-FL.

1. Consideration of the rationale for Member's approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification / engineering

Article 153 of the Treaty establishing the European Community stipulates that the Community is to contribute to promoting the right of consumers to information. In addition to other types of information to the public provided by the European legislation on genetically modified organisms, the labelling of genetically modified food enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.

Accordingly, Article 2 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[13] provides that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing.

The labelling should thus include objective information to the effect that a food consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.

In addition, the labelling should give information about any characteristic or property which renders a food different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.

[13] OJ L 109, 6.5.2000, p. 29–42 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2000/l_109/l_10920000506en00290042.pdf

The EC recognises thus the consumers' right to information and labelling as a tool for making an informed choice as regards genetically modified food.

2. Identify the current standards, regulation, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification / genetic engineering

The two major pieces of legislation that govern the labelling and traceability of genetically modified organisms and genetically modified food in the European Community are:

- Regulation (EC) N° 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC14. This Regulation ensures that relevant information concerning any genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced therefrom and should thereby facilitate accurate labelling.
- Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed15. This Regulation lays down, inter alia, specific provisions regarding the labelling of genetically modified food and feed.

Products consisting of or containing GMOs and food products produced from GMOs which are authorised under the European Community legislation are subject to the labelling and traceability requirements laid down by these two Regulations.

Labelling of GMOs and GM food

Regulation (EC) N° 1829/2003 lays down specific labelling requirements for genetically modified food.

Genetically modified foods (that is foods that contain or consist of GMO or are produced from GMO or contain ingredients produced from GMO) which are delivered as such to the final consumer or mass caterers (restaurants, hospitals, canteens and similar caterers) must be labelled in accordance with the provisions outlined below, regardless of whether DNA or proteins derived from genetic modification are contained in the final product or not:

1(a) where the food consists of more than one ingredient, the words "genetically modified" or "produced from genetically modified (name of the ingredient)" shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;

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[14] OJ L 268, 18.10.2003, p. 24–28 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_268/l_26820031018en00240028.pdf

[15] OJ L 268, 18.10.2003, p. 1–23 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_268/l_26820031018en00010023.pdf

(b) where the ingredient is designated by the name of a category, the words "contains genetically modified (name of organism)" or "contains (name of ingredient) produced from genetically modified (name of organism)" shall appear in the list of ingredients;

(c) where there is no list of ingredients, the words "genetically modified" or "produced from genetically modified (name of organism)" shall appear clearly on the labelling;

(d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling;

(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^2, the information required under this paragraph must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

2. In addition to the labelling requirements referred to in paragraph 1, the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:

(a) where a food is different from its conventional counterpart as regards the following characteristics or properties:

(i) composition;

(ii) nutritional value or nutritional effects;

(iii) intended use of the food;

(iv) implications for the health of certain sections of the population;

(b) where a food may give rise to ethical or religious concerns.

3. In addition to the labelling requirements referred to in paragraph 1 and as specified in the authorisation, the labelling of foods falling within the scope of this Section which do not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the foods concerned.

The labelling requirements set out above do not apply to food containing material, which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 % of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

Similar requirements are laid down for feed in order to provide final uses, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.

Traceability of GMOs and GM food

In order to facilitate accurate labelling of GMO and GM food, traceability requirements were established as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of the labelling claims.

These traceability rules make it mandatory on the operators concerned, i.e. all persons who place a product on the market or receive a product placed on the market within the Community, to be able to identify their supplier and the companies to which the products have been supplied.

The traceability requirement varies depending on whether the product consists of or contains GMOs (Article 4 of Regulation (EC) N° 1830/2003) or has been produced from GMOs (Article 5 of Regulation (EC) N° 1830/2003). Hence, two different scenarios must be distinguished:

1. In the case of a product consisting of or containing GMOs operators must ensure that the following two particulars are transmitted in writing to the operator receiving the product:

- an indication that the product – or some of its ingredients – contains or consists of GMOs
- the unique identifier(s) assigned to those GMOs, in the case of products containing or consisting of GMOs.

In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or for processing, the information relating to the unique identifiers may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

Operators must ensure that the information received is transmitted in writing to the operator receiving the product.

2. In the case of products produced from GMOs operators must ensure that the following particulars are transmitted in writing to the operator receiving the product:

- an indication of each of the food ingredients which are produced from GMOs;
- in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

In these two scenarios (products consisting of or containing GMOs; products produced from GMOs), operators must hold the information for a period of five years from each transaction and be able to identify the operator by whom and to whom the products have been made available. In order to respect these traceability requirements, it is important that each operator has in place a system to allow the information to be kept and to make it available to the public authorities on demand.

3. Identify Member's practical experience in applying/implementing mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification / genetic engineering

As mentioned in the previous section, the two major pieces of legislation that govern the labelling and traceability of genetically modified organisms and genetically modified food in the European Community are Regulation (EC) N° 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and Regulation (EC) N° 1829/2003 on genetically modified food and feed.

According to the provision of Regulation (EC) N° 1829/2003, the European Commission is required to monitor the application of the Regulation and its impact on human and animal health, consumer protection, consumer information and the functioning of the internal market. In addition, the Commission is to forward to the European Parliament and to the Council a report on the implementation of this Regulation.

In order to gain more insight on the implementation of the Regulation, the Commission compiled a questionnaire comprising questions on its different provisions. The questionnaire was submitted to all competent authorities under the Regulation, as well as to relevant stakeholders from all involved sectors. The responses, as well as other information received and retrieved by the Commission from the date of application of the Regulation to the current time, were carefully analysed, and on this basis a report on the implementation of Regulation (EC) N° 1829/2003 was adopted on 25 October 2006[16].

Also Regulation (EC) N° 1830/2003 contains a requirement for the Commission to produce a report concerning experiences gained with this regulation. This report was adopted on 10 May 2006[17]. The Commission has taken account of the above interplay between the two regulations and has attempted to avoid duplication in the two reports.

In addition, given the fact that a number of general aspects of the labelling legislation are scheduled for review in 2006-2008, the Commission estimated that there was a need to identify as far as possible a coherent overall approach to labelling. This took place in the political context of the renewed Lisbon Strategy and where the Commission focuses on better regulation as a means to contribute to achieving growth and jobs and on broad dialogue as a contribution to better regulation.

The Commission's Directorate-General for Health and Consumer Protection (DG SANCO) launched a dialogue with key stakeholders on how far there is scope to rethink the way the EU deals with labelling issues[18]. A document was produced which set out the context for considering a change, identified the strategic goal, and gave an overview of the current situation for specific labelling issues. This was a consultative document which was designed to facilitate discussion at

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16 COM(2006) 626 final (http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0626en01.pdf)

17 COM(2006) 197 final (http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0197en01.pdf)

18 http://ec.europa.eu/food/food/labellingnutrition/betterregulation/index_en.htm

established DG SANCO stakeholder fora, but was also the basis for individual stakeholders to respond with views.

A public consultation was launched on March 15th and formally closed on June 16th 2006 (responses were accepted till the end of the month). A total of **247** responses were registered, of which 73 were essential the same having come from one organisation. These were counted as one response, so it was considered that **175** contributions were received. Out of these contributions, **34** dealt with the legislative requirements on GM labelling.

The main conclusions regarding GM labelling of the two reports and of the labelling consultation are given below:

1. Report on the implementation of Regulation (EC) N° 1829/2003

In its section on labelling of GM food, the report on the implementation of Regulation (EC) N° 1829/2003 concludes the following:

Range of products that should be subject to compulsory GM labelling

The range of products that should be subject to compulsory GM labelling was the result of an extensive exchange of views during the legislative process that led to the adoption of the Regulation. Even though the majority of replies does not question this range, it is for some stakeholders still considered to be either too extended (i.e. products that do not contain DNA or proteins should not be labelled as GM) or too restricted (i.e. products of animal origin fed with GM feed such as meat, milk or eggs should be labelled as genetically modified).

Occurrence on the market of food labelled as genetically modified:

According to different reports, few food products labelled as genetically modified are at the present time on the Community market. The situation is however not uniform throughout the EU since in some Member States the number of GM products is negligible while in others their number is more significant.

The Regulation as such did not have an impact on the sale of food labelled as genetically modified. The sale of this type of products is mainly governed by factors that are not related to the legislative framework, such as consumer demand and the policies of food producers and retailers.

According to the results of the sample analysis reported by Member States, the frequency of non compliance to the food labelling requirements of the Regulation across the EU may be estimated below 2% (113 out of 7129 analysed samples). It must be further stressed that this figure is related to controls that often are targeted to products that are likely to contain GMOs or their derivatives and that the number of reported tests as well as the percentage of non compliance varied significantly from one Member State to another.

2. Report on the implementation of Regulation (EC) N° 1830/2003

The main conclusions of the report on the implementation of Regulation (EC) N° 1830/2003 are the following:

The food production and distribution chains:

The European food and retailing industries remain reticent to market GM food and food products due to the perception of negative consumer reaction. As a result, only a limited number of products are currently being marketed and imported GM material is currently not utilised in food products to any great extent.

The European industry recognises that consumer and public perception drives market forces and that a high level of health and environmental protection must be ensured in order to be able to market GM products. The industry currently appears to be responding to retailer/consumers demands of non-GM products and is, therefore, attempting to avoid purchasing ingredients containing or produced from GMOs.

Trading partners do not appear to share this view. Indeed, a large third country food exporter has stated that it no longer exports any processed food products to the European Union. It alleges that this is due to the burden of the regulatory framework, which specifically includes the traceability provisions of the Regulation, rather than to market demand. A third country industry association has stated that many companies marketing food products in the European Union have stopped using internally produced GM soybean oil and protein ingredients to avoid what are perceived as onerous and costly mandatory traceability requirements of the Regulation. It has also stated that the requirements have allegedly led to a decrease in the export of certified organic commodities containing soybean material. This problem has been attributed to the ‘restrictive’ 0.9% threshold for adventitious presence.

A second food association also argues that an additional layer of administrative and financial costs is imposed by the labelling and traceability requirements and highlights, in particular, that this has created an unacceptable burden on small food exporters. It also suggests that conflicting national regulations and different approaches to enforcement in individual Member States adds to the regulatory burden of business transactions.

An overseas Government Department, in its response to the questionnaire, similarly claims that the Regulation is a barrier to trade arguing that it is too restrictive and provides a disincentive for manufacturers to place GM products on the market. However it should be noted that available data - and in particular the relevant market share of GM products in the feed distribution chain - do not confirm this view, indicating, on the contrary, that GM food trade patterns are largely market (consumers) driven.

This Government Department also alleges that the reluctance of European industry to offer GM products to consumers, the lack of implementation of the Regulation by certain Member States and delays in new product approvals have provided major obstacles in obtaining relevant information in terms of implementation of the Regulation, notably with respect to its Article 4(3). The Department further suggests in its response that it is difficult for stakeholders to provide practical input to this report (as a means to improve the consistency of the Regulation) given that they do not have the necessary experience with its implementation as yet.

In particular, the US Government (and certain third country food associations) has urged that the European Commission joins with trading partners to work towards harmonisation and some form of mutual recognition of the trade of GM products that relieves small enterprises of such administrative burdens. They suggest, in particular, a need for guidance on documentary requirements to address the issue of consistent implementation. It should be noted that the Commission has actively engaged in and remains open to international discussions with trading partners but since 2002, the US Government has been reticent to engage in bi-lateral discussions on issues pertaining to GMOs.

In terms of the limited number of food products that are currently marketed, certain NGO groups express that in general, the labelling rules have a positive effect in facilitating informed choice.

However, they also state that it is not acceptable and misleading that the traceability of products (milk, meat, eggs, wool etc) derived from animals fed with GM material is excluded from the scope of the Regulation. They perceive this as a 'loophole' that undermines the credibility of the whole labelling system. It should be noted that the labelling and traceability of such products was extensively discussed by both the Council and European Parliament during preparation of the Regulation but their inclusion was not adopted.

3. Labelling consultation

In the context of the public consultation on labelling carried by DG SANCO, 34 replies have expressly dealt with the legislative requirements on GM labelling. These replies can be summarised as follows.

Consumers

Consumer NGOs express their strong support for the existing legislative requirements on GM labelling. These requirements are considered as a successful response to the request of European consumers to be informed about the GM content of food products. Some of the organizations also express the hope to obtain in the future a much wider international acceptance of the principle of the GM labelling through the discussions held in international fora such as the Codex Alimentarius.

Concerning the developments of the labelling requirements in this sector, two elements are considered as crucial:

- the 0.9% threshold should be maintained only for unintentional and accidental presence of GM and not interpreted as a tolerance level
- the Commission should clarify the notion and requirements of "GM free" labelling scheme in order to avoid any misleading or confusing information to be passed to the consumers.

Finally some of the received replies stress the need for further information in this domain. Some proposals make reference to the opportunity to extend the scope of the legislation to cover also products obtained with the use of a GMO (for instance the meat of animals fed with GM feed)

while others pledge for a more straightforward indication of consumers, for example with the use of visible symbols on the front of the package.

Food producers

The food industry is generally very critical towards the existing legal framework for the labelling of GM food. In particular they concentrate their criticism on three major aspects:

- the existing labelling obligation is based upon the specified "dedicated system of traceability" and covers products derived from GMOs but which do not contain any GM material. This approach is considered unjustified, difficult to enforce and open to fraud because the implication that an ingredient or product is "non-GM", by virtue of the absence of GM labelling, cannot be checked by analysis. According to some of the replies the previous system, which was based upon detectability, provided a more easily enforceable requirement.
- the existing labelling regime is costly and burdensome for the industry with the consequence that these costs are transferred down to European consumers.
- these labelling rules do not facilitate consumers' informed choice nor they provide consumers with a clear benefit. The outcome of the existing regime has been the almost total exclusion of food ingredients of GM origin from the EU market with a reduction of consumers' effective choice.

Retailers and farmers

Retailers and farmers are supportive of the existing system to which they adapted their market or production strategies.

Member States

Only a minority of Member States expressed their view on GM labelling. Member States generally agree with the existing system, although they are open to discuss the practical implementation of the GM regulations and the possibility to further improvements in specific areas.

4. Identify communication strategies used in communicating information to the public on foods and food ingredients with particular reference on who Members label these foods

On the website of the Commission Directorate-General for Health and Consumer Protection (DG SANCO) information related to GMOs can be found (http://ec.europa.eu/food/food/biotechnology/index_en.htm) as for example on authorizations granted for the use of GMOs in the EU, "Questions and Answers on the Regulation of GMO in the EU", etc.

Moreover, it is the national authorities that attempt to provide objective information to consumers on techniques of genetic modification of food and food ingredients, their implications on health, the legal requirements regarding their production, marketing and labelling on their respective

homepages and via informative brochures. Some EC Member States (e.g. Spain) have also put in place information modules in school programmes.

5. The output CCFL may require to respond to items 1-4 above

During previous discussions at CCFL level, it appeared that there was a consensus on the labelling provisions related to the protection of the health of consumers (allergens, modification of nutritional properties, etc) but that there was no consensus on the labelling linked to the mode of production, although the mandate given in 1991 by the Codex Alimentarius Commission to the CCFL is to *"provide guidance on how the fact that a food was derived from "modern" biotechnology could be made known to the consumer"*[19].

The European Community is therefore still of the opinion that two levels of labelling should be included in the Codex output: first mandatory labelling provisions in relation to health and consumer protection, and second optional provisions linked to the mode of production according to national requirements. This approach is in line with the conclusions of the Working Group which met in Calgary in October 2003.

A proposed approach could be first to develop general overarching principles which could later be declined into guidelines.

Ghana

Response to Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering

Ghana proposes the following:

A. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Ghana recommends that foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering be labeled. This should be mandatory to enable the consumer make informed choices.

B. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labeling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Comments:

Currently there are no Ghana Standards or regulations, but the National Biosafety bill is currently before Parliament for debate and subsequent legislation. In the handling of Labelling of GM foods we are also guided by the need for requisite documentation and are therefore following on-going and current discussions on handling, transport and identification of Living Modified

[19] ALINORM 91/40, Report of the 19th Session of the Codex Alimentarius Commission, Paragraph 90.

Organisms for Food, Feed and Processing. And as per the last meeting of the Parties decision (COP/MOP3), no decision has been taken yet in either using existing commercial invoices or develops stand alone invoices with requisite information as spelled out in Schedule III of the Biosafety Bill

Relevant Extracts from the Biosafety Bill

THIRD SCHEDULE (*Sections 12, 13)*
INFORMATION REQUIRED IN APPLICATIONS FOR RELEASE, IMPORTATION AND PLACING ON THE MARKET

1. Name, address and contact details of the exporter

2. Name, address and contact details of the importer

3. Name and identity of the genetically modified organism as well as the domestic classification of the biosafety level of the genetically modified organism in the country of export.

4. Intended date of the transboundary movement.

5. Taxonomic status, scientific and technical names, common name, unique identifier, transformation code or event, point of collection or acquisition and characteristics of the recipient organism or parental organism related to biosafety.

6. Center of origin and center of genetic diversity, of the recipient organism and the parental organism and the description of the habitat where the organism is related to biosafety

7. Taxonomic status, common name, point of collection or acquisition and characteristics of the modification introduced, the technique used and the resulting characteristics of the genetically modified organism.

8. Intended use of the genetically modified organism and the products of the genetically modified organism

9. Quantity or volume of the genetically modified organism to be transferred and released

10. The appropriate risk assessment report.

In addition to the foregoing, the Labelling of food and food ingredients would be addressed through subsidiary legislation to the Biosafety bill and existing food and drug legislations with an amendment if it does not cover Novel foods. Ghana's Biosafety bill makes room for subsidiary legislation so related issues of labelling can be developed to handle foods made using GM/GE techniques

Relevant Extracts from the Biosafety Bill , Section 13 and 19

Application to import or place on the market

13. (1) A person shall not, without the written approval of the Authority, import or place on the market a genetically modified organism.

(2) An application under subsection (1) shall include

(a) the information set out in the Third Schedule,

(b) a risk assessment as set out in the Fourth Schedule, and

(c) any other information that the applicant may consider necessary for an assessment of the potential risks and benefits of the requested activity.

To assess safety of GM Foods

Risk assessment and risk management

19. (1) where an application is screened and found to be complete, the Board shall act in accordance with the advice of the Technical Advisory Committee in respect of a risk assessment as set out in the Fourth schedule.

(2) Risk assessment shall be carried out taking into account available information concerning a potential exposure to the genetically modified organism.

(3) On completion of the risk assessment, the Board shall

(a) make a report giving its decision and the justification on the disposition of the application, and

(b) indicate the measures to be taken to ensure the safe use of the genetically modified organism.

(5) The Board shall liaise with the appropriate regulatory agency to ensure that measures are in place to manage and control risks identified during the risks assessment process.

The technical advisory committee has technical expertise and institutional representation from the regulatory agencies including the food regulatory agency and thus would lead issues related to food safety matters

C. Identify Members practical experiences in applying/implementing mandatory and voluntary labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

We do not have any practical experience in applying /implementing mandatory labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

D. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods.

Communication strategies such as electronic and print have been developed. The media has also been trained.

The Biosafety Bill covers public participation and awareness and recommends measures in article 42. In addition a guideline on Public Participation on GMOs has been developed; additional measures are being developed through training on risk communication. The Food & Drugs Board has a public awareness agenda though it has to be strengthened.

Communication strategies have been developed under biosafety framework of Ghana. The media, farmers and other relevant stakeholders are being educated in the continous engagement process.

India

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/ genetic engineering.

In every country, developing or developed, consumers hold the right to choose to buy and or consume a category of food. In making such a choice the composition of food plays a major role. However, in the case of genetically modified (FM) food certain key issues are yet to reach a stage of global consensus. These issues include availability of data base of all the potentially harmful components in the GM food e.g. antinutrients, allergens and toxins, selection of appropriate comparator for determination of equivalence, consensus on the maximum level of GM material allowed to be considered as inadvertent contamination etc. In addition, it may be relevant for the consumers as well as scientists in the country to know the procedure adopted for incorporation of genetic material towards production of GM food. It has been considered that till such time these key issues are resolved, it may be prudent for India to introduce mandatory labelling of GM food already approved by the appropriate national approval committee in this country (Genetic Engineering Approval Committee).

2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

The text of the proposed regulation on labelling of GM food which is at the stage of draft notification and is considering comments from stake holders is as follows:-

(i) In the Prevention of Food Adulteration Rules, 1955 (hereinafter referred to as the said rules), after rule 37D, the following shall be inserted, namely, -

"37 E Labelling of Genetically Modified Food: – Genetically engineered or modified Foods means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through biotechnology, or food and food ingredients produced from but not contained genetically modified or engineered organisms obtained through biotechnology;

In addition to the labelling provisions as prescribed under these rules, the Genetically Modified Food shall also conform to the following labelling requirements: -

(a) a GM Food, derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall be compulsorily labelled, without any exceptions;

(b) the label of all package (s) of GM Food(s) or foods containing ingredients, derived from Biotechnology or Bioengineering or food additives or any food product that may contain GM material shall indicate that they have been subject to genetic modification. These provisions will be applicable to all such products both imported or domestically produced; and

(c) the label of imported GM Food or derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall also indicate that the product has been cleared for

marketing and use in the country of origin so that the verification, if needed can be taken up with that country without having to resort to testing."

(ii) After rule 48-E of the said rules, the following shall be inserted, namely,-

"**48-F Restriction on Sale of Genetically Modified Food: -** No person shall except with approval of and subject to the conditions that may be imposed by the Genetic Engineering Approval Committee (GEAC) constituted under the Environment Protection Act, 1986, manufacture, import, transport, store, distribute or sell raw or processed food or any ingredient of food, food additives or any food product that may contain GM material in the country.

Provided that in case of imported genetically modified foods, the importer shall submit documents supporting the purported clearance at the time of import."

3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

The concept of requirement for mandatory labelling of GM food was considered and approved by the relevant Sub-Committee followed by approval of Central Committee for Food Standards (CCFS), the highest statutory body for approving regulation of food safety in India. The draft for mandatory labelling of GM food was then notified for general public and various stake holders for inviting comments. The various organisations offering their comments included American Chamber of Commerce in India, USFDA, CII, Consumer organisations in India, Ministry of Commerce and Industry, Farmers organisation in India as well as a number of domestic industries. The comments broadly covered the concerns about the need for availability of infrastructure and technology reliable for detection of GM food in the country, practical feasibility of attaining zero threshold limits, lack of consensus on threshold limits and harmonisation with WTO agreement. All of these issues raised by stake holders were considered by an expert group following which has initiated the process of finalization of the draft notification.

4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/ genetic engineering with particular reference to how Members label these foods.

Number of meetings/ symposia/ seminars are being organised from time to time by Governmental and Non-governmental organisations, industry, academic institutions etc. to disseminate information on genetically modified foods ranging from basic concepts to the issue of labelling with special emphasis on the impact of mandatory labelling of GM food on the domestic production as well as on import of food. In addition, as a support to the activities mentioned, numerous documents on GM food have been produced by the same organisations on wide range of topics. Proceedings of the discussions held in various Codex meetings on labelling of GM food are circulated to the members of relevant shadow committees (Food Labelling) in India which is represented by most of the concerned stake holders whose inputs are discussed in meetings. Many laboratory based trainings have been organized recently in order to disseminate the technology on detection of GM food.

In order to provide requisite support to the regulatory guidelines in India on GM food under Prevention of Food Adulteration Act, a Joint Working Group (JWG) constituted by Department of Biotechnology, Ministry of Science and Technology, has identified several institutions, including few as reference centres, for detection of various crop specific transgenes employing various levels of technologies depending on infrastructure and expertise available with the institutions. The working group also discussed R & D related issues e.g. development and validation of detection kits as well as methodologies for sampling.

Japan

Japan's Response to CL 2006/22-FL

We are pleased to respond to CL2006/22-FL. We would like to express our appreciations for Norway's hosting a physical working group on labeling of genetically modified foods as a chair, and Argentina's and Ghana's serving as co-chairs at the group. We look forward to fruitful discussions at the physical working group in February 2007.

1. The Rationale for Japan's Approach to the Labeling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering

There are two rationales for Japan's introducing labeling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering (hereafter "GM foods") in 2000.

The primary rationale is to enable consumers to make informed choices, because the majority of them pleaded for labeling of GM foods in the situation that GM foods were expected to be imported and distributed in Japan. The second rationale is to ensure that only GM foods which have been confirmed as safe by the mandatory safety assessment shall be distributed in Japan.

2. The Current Standards, Regulations, Acts/Decrees, etc. with Respect to the Mandatory and Voluntary Labeling of Genetically Modified Food in Japan

Labeling of GM foods is provided for and systematically enforced by:
a). Article 21 of *the Enforcement Regulation* of *the Food Sanitation Law*; and
b). *The Labeling Standard for Genetically Modified Foods* (Notification No. 517 of the Ministry of Agriculture, Forestry and Fisheries of March 31st, 2000) under *the Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products* (hereafter the "*JAS Law*").

The objective of a) is to ensure that only GM foods which have been confirmed as safe by the mandatory safety assessment shall be distributed in Japan, and the objective of b) is to provide consumers with information.

To fulfill both objectives of these two laws, labeling is required for the products in which genetically modified DNA or protein is present and detectable. Products subject to labeling are 7 agricultural products and 32 processed food categories.[20]

Non-GM products may be voluntarily labeled as "non-GM," if certification is provided to show that the non-GM ingredients were under the identity preserved handling at each step of production, transportation, and distribution. Processed foods in which DNA or protein is undetectable are not subject to mandatory labeling, which include soy sauce, vegetable oils, cornflakes and high fructose corn syrup. Voluntarily labeling as "non-GM" to those processed foods is permitted if certification is provided to show that the non-GM ingredients were under the identity preserved handling.

The provisions in a) and b) above are the same except for labeling of GM foods whose compositions or nutritional values are significantly different from their conventional counterparts. The details of the provisions are attached as Annex to this response.

3. Practical Experiences in Applying/Implementing Mandatory and Voluntary Labeling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering

We have introduced the labeling system in 2000, but have not made any substantial changes to the system since then and only added items subject to labeling, responding to the safety assessment in Japan and the commercialization of GM products in the world market. We have been working to improve our GM labeling system so that the labeling system would be well understood by consumers.

We also believe that the GM labeling must be utilized as a tool so that consumers are able to make informed choices and the safety assessment is thoroughly conducted, and that the similar tool should be applied to the Draft Guidelines for the Labelling of Foods and Foods Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering, in order to make labeling feasible.

4. Communication Strategies used in Communicating Information to the Public on Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering

We believe that disseminating information of the labeling of GM foods is highly important so that consumers, as well as operators in charge of labeling, are better informed. We provide information to the public through websites and brochures.

[20] Labeling of sugar beet and products containing sugar beet became mandatory from November 8th, 2006.

Items subject to labeling in the labeling standards are reviewed annually, taking into account the distribution of GM foods in the world market, the advancement of detection technologies of DNA in foods and consumers' concerns. The public are provided with opportunities to make comments on the review itself and new items to be added before the amendment to the labeling standard is adopted. The public are able to get permissions to present and express their views at the committee for deliberating the standard.

(Annex)

I. Method of labeling of GM foods under the Food Sanitation Law and the JAS Law

The labeling should be as follows:

1. GM foods whose compositions or nutritional values are significantly different from their conventional counterparts[21].

   High oleic soybeans or oils made from them ⇨ Mandatory Labeling "Soybeans (high oleic, genetically modified)" etc.

2. GM foods whose compositions or nutritional values are equivalent to their conventional counterparts.

   (i) Agricultural products and processed foods in which recombinant DNAs or the resulting proteins still exist even after processing (such as *Tofu*)

   a. GM agricultural products under the identity preserved handling[3] or processed foods made form those ⇨ Mandatory Labeling "GMO segregated from non-GMO," "GMO" etc.

   b. Agricultural products, not segregated GM products and non-GM products, or processed foods made from those the identity preserved handling[3] or processed foods made form those ⇨ Mandatory Labeling "Not segregated from GMO" etc.

   c. non-GM agricultural products under the identity preserved handling or processed foods made from those ⇨ Voluntary Labeling "Non-GMO segregated from GMO," "Non-GMO" etc.

   (ii) Processed foods such as edible oils or soy sauce in which recombinant DNAs or the resulting proteins do not remain after processing

   ⇨ Not subject to labeling

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[21] The labeling is provided only by *the Labeing Standard for Genetically Modified Foods* under *the JAS Law* for providing consumers with information for informed choices.

3 Identity preserved handling is a management method in which GM products and non-GM products are not commingled each other at each stage of production, distribution and processing from farms to food manufacturers. It shall be verified by documents indicating that the management has been conducted. If the identified preserved handling is properly conducted, the adventitious presence of GMO is accepted up to 5%.

II. Items subject to labeling

1. Agricultural products (7 items):

Soybean (including green soybean and soybean sprouts); corn; potato; rapeseed; cottonseed; alfalfa and sugar beet.

2. Processed foods 32 food categories

Items subject to labeling	Ingredient to be labeled
1. *Tofu* (soybean curd) and fried *tofu*	Soybean
2. Dried soybean curd, soybean refuse, *yuba*	Soybean
3. *Natto* (fermented soybean)	Soybean
4. *To-nyu* (soy milk)	Soybean
5. *Miso* (soybean paste)	Soybean
6. Cooked soybean	Soybean
7. Canned or bottled soybean	Soybean
8. *Kinako* (roasted soybean flour)	Soybean
9. Roasted soybean	Soybean
10.Item containing food of items 1 to 9 as a main ingredient	Soybean
11.Item containing soybeans (for cooking) as a main ingredient	Soybean
12.Item containing soybean flour as a main ingredient	Soybean
13.Item containing soybean protein as a main ingredient	Soybean
14.Item containing *edamame* (green soybean) as a main ingredient	*Edamame*
15.Item containing soybean sprouts as a main ingredient	Soybean sprouts
16.Corn snacks	Corn
17.Corn starch	Corn
18.Popcorn	Corn
19.Frozen corn	Corn
20.Canned or bottled corn	Corn
21.Item containing corn flour as a main ingredient	Corn
22.Item containing corn grits as a main ingredient (except corn flakes)	Corn
23.Item containing corn (for cooking) as a main ingredient	Corn
24.Item containing food of items 16 to 20 as a main ingredient	Corn
25.Frozen potato	Potato
26.Dried potato	Potato
27.Potato starch	Potato

28.Potato snacks	Potato
29. Item containing food of items 25 to 28 as a main ingredient	Potato
30. Item containing potatoes (for cooking) as a main ingredient	Potato
31. Item containing alfalfa as a main ingredient	Alfalfa
32. Item containing sugar beet as a main ingredient	Sugar beet

1. 10 to 15, 21 to 24, and 29 to 32 in the table above represent food categories and processed foods containing them as ingredients. Each item includes no less than one kind of processed food.
2. Main ingredients are ingredients which are within top 3 constituents in weight, which account for no less than 5 percent of the total weight.

Malaysia

MALAYSIA COMMENTS

CODEX COMMITTEE ON FOOD LABELLING

CL 2006/22 –FL

Labelling of Foods and Food Ingredients Obtained through Certain Techniques Of Genetic Modification / Genetic Engineering

Within the mandate of Codex, the Working Group shall address the following areas:

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Comments :

Malaysia is of the view that the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering should be made mandatory for both consumer and health concerns AND to indicate their methods of production in order to allow consumer to make informed choices.

2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Comments :

No current regulation. Malaysia is in the process of drafting regulations on GM foods.

3. Identify Members practical experiences in applying/implementing mandatory and voluntary labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Comments:

No Comments

4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods.

Comments :

Malaysia will emphasize on consumer awareness so that informed choices can be made. The industry is encouraged to label their products accordingly.

Mexico

Mexican Position regarding Circular Letter (CL 2006/22-FL)

Mexico appreciates the opportunity to issue its opinion with respect to this topic.

Mexico has previously rendered its opinion in the sense that the Codex must only work in drafting a document that includes mandatory guidelines in compliance with the mandate given to the Codex Committee on Food Labeling by the Commission.

1. – Consideration of the rationale for Members' approach to the labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

From the legal point of view, the essential argument is that Mexico has in place a Genetically Modified Organisms Biosafety Law that provides for the events where the labelling of Genetically Modified Organisms (GMOs) and of products containing them is required, namely:

In the events where their traits are significantly different than those of conventional products. In such events, an explicit reference must be made to "genetically modified organisms" and the label must state their food composition or such nutritional properties that are different from their conventional counterparts.

Conversely, such legal ordinance fails to provide the obligation to carry out such labelling in the events where the GMO is not different from its conventional counterpart. Likewise, it fails to provide to carry out such labelling based solely on the Process or Method of Production.

From the technical point of view, the policy followed by health authorities in Mexico regarding the safety assessment of foods that are or contain GMOs for human consumption has been the systematic assessment based on a case-by-case and step-by-step basis of the genetic events submitted by developers and to render a positive expert opinion only when, on the basis of available scientific evidence, it is proved that such food is as safe as its conventional counterpart.

Consequently, taking into account the health risk there is the need to carry out the labelling only in the event where the genetic modification results in a product substantially different from its conventional counterpart; that is to say, in those cases where the GMO presents significant changes in its composition or in its nutritional properties, or in the event that it may pose a risk for the health of specific sectors of the population, as compared with its conventional counterpart..

2. - Identify the laws, regulations, standards, decrees, etc., with respect to the mandatory and voluntary labelling of foods obtained through certain genetic modification/ genetic engineering:

- Genetically Modified Organisms Biosafety Law (Ley de Bioseguridad de Organismos Genéticamente Modificados),

Particularly, Article 101, paragraphs one, two and four.

- General Health Law (Ley General de Salud),

Particularly, Article 282 Bis 2.

- Statute for the Sanitary (safety) Control of Products and Services (Reglamento de Control Sanitario de Productos y Servicios),

Particularly, Article 166 thereof provides that labels of biotech products must include information regarding their characteristics and the health risks posed by them in accordance with the provisions and specifications set forth by the Secretariat of Health.

- Mexican Official Standards (Technical Regulations)

It is worth mentioning that the Genetically Modified Organisms Biosafety Law anticipates the issuance of a Mexican Official Standard regarding this issue, and the drafting of which has not started as yet.

Each and any of such provisions are mandatory.

3. – Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Hitherto, the events submitted to approval by the health authority have reported no substantial differences with respect to their conventional counterparts. Thereforethere is no experience with such kind of labelling.

There is, however, experience as to the application of precautionary statements for foods posing risks only for specific sectors of the population.

4. – Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods

The Health Authority makes available through its web page (www.cofepris.gob.mx) the positive list of GMOs released for merchandizing. Such products have already been subjected to a safety assessment process and may be regarded as suitable for consumption.

In addition, there is information available on such issue by the Inter-sectorial Biosafety Commission of Genetically Modified Organisms and the Federal Consumers Attorney's Office, and also available in the Biosafety Clearing House web page and that of the Biological Diversity Convention.

5. – The output CCFL may require to respond to items 1-4 above.

Over the years this issue has been included in the CCFL agenda, the different approaches by Codex members are evident and have derived in opposing positions that hardly will come to an agreement with each other in the current situation, and allow to reach a decision by consensus[22].

Due to the above statements, Mexico supported the motion proposed by the CCFL presidency to suspend the discussions about the aforesaid issue until such time when there are suitable circumstances that may allow progress by consensus.

[22] See recommendations by the 55th session of the Executive Committee

New Zealand

5 October 2006

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Re: New Zealand response to CL 2006/22-FL

New Zealand is pleased to submit the following comments in response to *CL 2006/22-FL: Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering.*

In May 2000 the New Zealand government established the Royal Commission on Genetic Modification to look into and report on the issues surrounding genetic modification in New Zealand. The full report is available at: http://www.mfe.govt.nz/publications/organisms/royal-commission-gm/index.html

The Royal Commission was directed to receive representations upon, inquire into, investigate, and report upon certain matters relating to genetic modification, including, in principal: the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products; and any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products.

An overview of the government's response to the Royal Commission on Genetic Modification is available at: www.mfe.govt.nz/issues/organisms/law-changes/commission/summary.html

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Comment:

New Zealand has a joint food standard setting system with Australia for primarily food labelling and composition standards, as well as standards requiring the pre-market assessment of GM foods. The Australia New Zealand Food Standards Code (the Code) came fully into force in New Zealand in December 2001. Only Chapters 1 and 2 of the Code apply in New Zealand. The Code is available from the FSANZ website at:
http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm

There is a very clear process in the development of joint Australia New Zealand food standards. This includes public announcement of any standard being developed followed by two rounds of public consultation on the draft standard. The FSANZ process includes a requirement to undertake a risk assessment of any new food or component of food being proposed in a standard.

Before any GM food or food ingredient can be sold in New Zealand it is required to undergo a pre-market safety assessment. FSANZ is responsible for conducted this assessment and follows guidelines for assessing GM foods developed by the Codex Alimentarius Commission, FAO/WHO and OECD.

To allow consumer choice Food Standard 1.5.2 'Food Produced using Gene Technology' in the Code requires all foods, food ingredients or additives sold in New Zealand to be labelled at point of sale, where novel DNA or protein is present in the final food, or the food has altered characteristics as a result of genetic modification processes. This approach allows consumers to purchase food based on its actual content, rather than by the process by which it was made. The mandatory GM labelling requirements are not based on safety.

There are exceptions to the labelling requirements for genetically modified material in flavourings making up less than 0.1 percent of a final food, or for the inadvertent presence of trace amounts of GM material (less than 1%) in ingredients. However, in all cases the GM material must be of a type that has been approved for human consumption by the regulators.

The GM labelling requirements apply to all packaged and bulk foods, but do not apply to food prepared in restaurants, cafes and takeaways.

Standard 1.2.9 'Legibility Requirements' of the Code sets out general and specific legibility requirements for the labelling of packaged and unpackaged foods.

New Zealand does not require mandatroy labelling for method of production, where a food has been derived from gene technology, but does not contain novel DNA and/or novel protein. This is based on the fact analytical tests cannot distinguishable such foods from conventional foods and there are no food safety concerns relating to the consumption of approved GM foods.

2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Comment:
GM food labelling is regulated under Standard 1.5.2 of the Code (see response to question 1).

The Code is silent on negative claims such as 'GM Free'. Such claims can be made voluntarily by food manufactures and are subject to the provisions regarding false and misleading conduct under the New Zealand Fair Trading Act 1986. If a food product contains novel DNA and/or novel protein and a negative claim leads consumers to believe that it does not, a manufacturer may be in breach of the Fair Trading Act and liable for a fine of up to $60,000 for an individual, or $200,000 for a body corporate.

The Fair Trading Act prohibits a food businesses from engaging in conduct that is misleading or deceptive or likely to mislead or deceive in relation to the advertising, packaging or labelling of food, to falsely describe food, or to provide food not of the nature or substance or quality demanded by the purchaser.

The report of the Royal Commission on Genetic Modification recommended that the government facilitate the development of a voluntary label indicating that food had not been genetically modified, contains no genetically modified ingredients and had not been manufactured using a process involving genetic modification.

In response, the government convened a stakeholder working group in 2003 attended by consumer and industry groups to investigate the development of a voluntary GM-free labelling system for food. Following the working group it was concluded that none of the options considered would provide a workable labelling system that meets stakeholder expectations and the requirements of the New Zealand Fair Trading Act. Under the Fair Trading Act "GM-free" has been interpreted as being absolute (i.e. a product cannot in any way result from a GM process or contain any GM material). Suppliers are free to voluntarily label their products "GM-free" if they are confident that such a claim is true. However, if that claim is found to be untrue, the supplier would be in breach of the Fair Trading Act 1986. The report from the working group meeting can be found on the New Zealand Food Safety Authority (NZFSA) website at: http://www.nzfsa.govt.nz/consumers/food-safety-topics/genetically-modified-foods/gmfreelabellingwebreport.htm

The New Zealand Ministry of Consumer Affairs (MCA) and the Commerce Commission have since been charge with the responsibility of facilitating the development of a guideline intended to provide guidance to industry regarding requirements for labelling a product GM-free. Work in this regard is ongoing.

In New Zealand, genetic modification is, in the main, controlled under the Hazardous Substances and New Organisms (HSNO) Act 1996, which regulates the use of "new" organisms (including genetically modified organisms). Anyone proposing to develop or use in containment, or release to the environment, any new (including genetically modified) organism has to apply to the Environmental Risk Management Authority (ERMA New Zealand) and go through a rigorous assessment process. Assessment of all applications for use of genetically modified organisms in field tests or for release includes opportunity for public submissions.

To date there have been no applications to release any GM organisms into the New Zealand environment, for either research purposes or for commercial production.

Before any viable GM food is introduced into New Zealand it must first have ERMA approval for environmental release and FSANZ approval to be added to food.

3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Comment:
Standard 1.5.2 of the Australia New Zealand Food Standards Code requires that foods containing genetically modified ingredients be adequately labelled. In December 2003, the NZFSA completed a survey examining the level of compliance with Standard 1.5.2 and to assess the systems that food businesses have in place to ensure ongoing compliance.

A total of 726 manufacturers and 196 importers that could potentially use or import GM ingredients/foods were identified. A subset of 337 manufacturing businesses and 69 importers were selected and contacted because of their potential to use, or handle, soy or corn ingredients. Food products derived from soy and corn were considered the category of foods most likely to require labelling as being genetically modified and were therefore the highest priority for monitoring and enforcement.

A cross-section of the subset of businesses was then chosen for audit. In total, 269 manufacturers and 38 importers were audited. Depending on the ingredients used and whether steps had been taken to demonstrate due diligence, a statutory sample was taken and submitted to the New Zealand Crown

Research Institute of Environmental Research and Science (ESR) to verify compliance with Standard 1.5.2. 14 samples were collected in the course of auditing businesses with one imported product found to be non-compliant. This was followed up with the importers concerned and labelling rectified.

Businesses were also informed that NZFSA was testing a range of unspecified soy and corn product in New Zealand retail arena for compliance. An additional 103 food products were tested. None of these food products were found to be non-compliant with Standard 1.5.2.

The survey revealed a high level of compliance with the presence based labelling laws for GM foods in New Zealand, with all but one of the 117 samples complying with the Standard. No GM food/ingredient was found that had not been subject to pre-market food safety and therefore lawfully permitted to be on sale in New Zealand.

Two products labelled as "GM Free" were found to contain an inadvertent presence of an approved GM ingredient at a level of less than 1%. Although both products complied with Standard 1.5.2 in the Code, they did not comply with the Fair Trading Act 1986 because these products carried claims stating that they were "GM free" when clearly they were not. These cases were referred to the Commerce Commission for investigation and one case was eventually prosecuted.

The survey demonstrated that the GM labelling requirements in New Zealand can be effectively enforced using strategies which examine compliance plans and documentation held by manufacturers, supplemented by quite limited product testing where appropriate to confirm compliance.

The full report "Assessment of Compliance with Standard 1.5.2 – Food Produced Using Gene Technology' can be found on the NZFSA website at: http://www.nzfsa.govt.nz/consumers/food-safety-topics/genetically-modified-foods/compliance-assesment.htm

Ongoing compliance efforts focus on audit trails and this is supplemented with analytical testing when required to verify compliance.

4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods.

Comment:
The NZFSA periodically updates web-based information for consumers on the use of gene technology in the production of food; including a fact sheet on GM labelling that further explains the labelling regime of GM foods in New Zealand. Information of GM food can be found on the NZFSA website at:
http://www.nzfsa.govt.nz/consumers/food-safety-topics/genetically-modified-foods/index.htm

NZFSA hosts a Consumers Forum on Food Safety which gives consumers an opportunity to become involved in New Zealand's food safety regulatory programme. The meetings provide an opportunity for good quality two-way communication about food regulations and the way these are developed. The meetings also provide a useful sounding board for the NZFSA on food safety matters, and a constructive forum for sharing information and ideas. Consumers attending the forums represent national bodies that are interested in the effects of food and food safety on the health and welfare of New Zealanders. The Consumers Forum has considered GM labelling issues in the past.

The New Zealand government has also produced and disseminated information to help the general public gain a better understanding of genetic modification and its use in food. In 2002, an information pack was released that contained pamphlets on genetic modification, explaining how it is used, how it is controlled in New Zealand and specifically its use in food. The GM food pamphlet explained the New Zealand GM food labelling requirements (and what is exempt), what the label looks like and labelling requirements in situations such as food prepared at restaurants.

The NZFSA commissions ESR to provide an independent source of current information on issues related to genetically modified foods, including international developments in food safety and food quality. These reports are completed approximately every 6 months and made available to the public via the NZFSA website at:
http://www.nzfsa.govt.nz/consumers/food-safety-topics/genetically-modified-foods/compliance-assesment.htm

FSANZ has published an industry user guide 'Labelling Genetically Modified Food' developed collaboratively by an intergovernmental working group. The guide outlines the labelling requirements of Standard 1.5.2 and the means by which manufactures can comply with the requirements. The guide is available from the FSANZ website at:
http://www.foodstandards.gov.au/thecode/assistanceforindustry/userguides/labellinggeneticallymodifiedfooduserguide/index.cfm

Yours Sincerely

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Your ref: CL 2006/22-FL
Our ref: 2006/2781
Date: 2.10.2006
Org.no: 985 399 077

Norwegian Food Safety Authority

Mattilsynet

Norwegian answers to the circular letter CL 2006/22-FL (June 2006) regarding *Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering*

In the following document we address the areas in paragraph 1 – 4 in the CL as asked for.

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

The Norwegian GM labelling regulations main purposes are to:

- Meet consumers' desires to make informed choices
- Help consumers choose between GM and non GM products
- Secure transparency to garner consumers trust

Consumer choices may amongst several other aspects be based on ethical and environmental values. It is the consumers' right to have their own views, and these views are acknowledged by the authorities in this regard. Our aim is to accommodate consumer scepticism about GM products by having openness and comprehensive information.

2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

The first Norwegian labelling requirements on GM food and food ingredients entered into force in 1997 to ensure the interests of Norwegian consumers. Today, the regulations contain rules for the authorisation, labelling and traceability of both GM food and feed. The regulations are based upon EU Regulations (EC) Nos1829/2003 on GM food and feed and 1830/2003 on traceability and labelling, pending full incorporation. The labelling regulations apply to all GM foods including GMOs and food derived from GMOs, whether their properties or characteristics be different from those of comparable conventional food or not.

The labelling requirements are considered to be satisfied if products containing genetically modified ingredients are labelled as such if the genetically modified component constitutes more than 0.9% of the ingredient.

Further on, Norway has *Regulations relating to the labelling, transport, import and export of genetically modified organisms (GMOs).* See chapter 4 in the following link:
http://odin.dep.no/md/english/doc/legislation/acts/022031-200051/dok-bn.html

For your information, we have attached the translation of current regulations in annex 1 to this letter.

3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

Up to now there has been no applications for authorisation to be considered by the authorities, and therefore there has not been granted any authorization to GM products. Due to this, we have no practical experience from supervision of the present labelling requirements.

4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods

In 1991 the Norwegian government appointed an independent body "The Norwegian Biotechnology Advisory Board" The main tasks of this board are to identify and examine the ethical questions raised by applications of modern biotechnology on humans, animals, plants and micro organisms, provide advice that can assist policy-making and stimulate public debates on the issues. This board has conducted several conferences with active participation from the public, so called laymen's conferences.

The authorities has over the years given information on GM food in general, and information and guidance on regulations. We have given conferences for consumers, lectures for stakeholders,

consumers and other interested groups where we among others, have communicated the fact that labelling GM food does not imply that the product has adverse effects.

ANNEX 1

Regulation Amending the General Regulation of 8th July 1983 no. 1252 concerning the Production and Sale etc of Foodstuffs

Laid down by the Ministry of Health pursuant to §§ 9 and 15 of the Food Act

I

The following amendments are made to the General Regulation of 8th July 1983 no. 1252 concerning the Production and Sale etc of Foodstuffs:

§ 16a shall read:

§ 16a. Foodstuffs and foodstuffs' ingredients including additives, flavourings and extraction solvents for use in foodstuffs containing, consisting of or produced from genetically modified organisms, may not be sold or marketed unless the Norwegian Food Safety Authority has granted its authorisation for this. This does not apply to:

1. products covered by the Act of 2nd April 1993 no. 38 (The Gene Technology Act),
2. products which are produced with genetically modified organisms, but where the final product does not contain material from the original genetically modified material, including genetically modified processing aids and foodstuffs which have been treated with genetically modified processing aids.

The obligation to be authorised pursuant to the first paragraph does not apply to adventitious or technically unavoidable presence of genetically modified material provided that the establishment can document this, and provided that:

1. the occurrence does not exceed 0.9 % if the genetically modified material has been authorised in the EU, or
2. the occurrence does not exceed 0.5 % if the genetically modified material has been subject to a risk assessment and has been deemed to be safe from the point of view of health by either the EFSA/EU's Scientific Committees or the Norwegian Scientific Committee for Food Safety and that the method of analysis is publicly available.

In connection with the application or authorisation the Norwegian Food Safety Authority may require methods of analysis, test material and traceability, etc.

It is an obligation to indicate a unique identification code for genetically modified organisms in the accompanying documentation for products that consists of or contain such organisms as set out in Regulation no. 1009 of 2 September 2005 on labelling, transport, import and export of genetically modified organisms.

Food additives, flavourings and extraction solvents which shall be authorised in accordance with the first subsection above, and which already exist on the Norwegian market as of 15 September 2005, can still be sold provided that within six months of 15 September 2005 a notification has been sent to the Norwegian Food Safety Authority containing information concerning the substances. Within three years after 15 September 2005 an application for authorisation concerning these substances must be made pursuant to § 16a.

The Norwegian Food Safety Authority may pass supplementary regulations regarding the implementation of the provisions in this section.

II

This regulation enters into force immediately.

Regulation Amending the Regulation of 21st December 1993 no. 1385 concerning Labelling of Foodstuffs etc.

Laid down by the Ministry of Health pursuant to The Food Act's § 10

I

The following amendments are made to the Regulation Amending the Regulation of the 21st December 1993 no. 1385 regarding the Labelling of Foodstuffs etc:

New § 4a no. 4 shall read:

4. Genetically modified foodstuffs shall be accompanied by information as laid down by § 10 c.

New § 7 fourth subsection, first sentence shall read:

The information in § 4a no. 1, 2 and 4 shall be provided on signs, notices or similar.

New § 10 c shall read:

§ 10c. *Labelling of genetically modified foodstuffs*

Genetically modified foodstuffs including additives, flavourings and extraction solvents shall in the product's name or in connection with the actual ingredient be labelled with either "genetically modified (name of organism)" or "produced from genetically modified (name of organism)" if:

1. the foodstuff consists of or contains genetically modified organisms, or
2. the foodstuff is produced from, but does not contain genetically modified organisms. This obligation to label also applies to genetically modified foodstuffs, including additives, flavourings and extraction solvents, in which DNA and protein cannot be demonstrated.

The obligation to label pursuant to the first paragraph does not apply to:

1. adventitious or technically unavoidable presence of genetically modified material not exceeding 0,9 % provided that the genetically modified material has been authorised in Norway or the EU,
2. products which are produced with genetically modified organisms, but where the final product does not contain material from the original genetically modified material, including genetically modified processing aids and foodstuffs which have been treated with genetically modified processing aids.

II

This regulation enters into force immediately.

Regulations relating to the labelling, transport, import and export of genetically modified organisms

Laid down by Crown Prince Regent's Decree of 2 September 2005 pursuant to section 10, third and fourth paragraphs, and section 14 of Act No. 38 of 2 April 1993 relating to the production and use of genetically modified organisms (the Gene Technology Act). Submitted by the Ministry of the Environment.

Chapter 4. Labelling

Section 19. Labelling

Products consisting of or containing genetically modified organisms shall be labelled in Norwegian and/or English with the words “Inneholder (contain) genmodifiserte organismer (GMOs)” alternatively “Inneholder (contain) (name of organism(s))” and/or “Contains genetically modified organisms” alternatively “Contains genetically modified (name of organism(s))”. On packaged products, the information shall be given on a label on each packaged unit. For other products, the information shall be given on an accompanying document or notice.

The product’s commercial name, name and address of the person in the European Economic Area responsible for the sale of the product and information about where further information can be obtained about the genetically modified organism of which the product consists or which the product contains must also be given on the label or accompanying document.

In the case of genetically modified organisms which are approved for sale, a unique identification code shall also be stated in the accompanying document, if such code exists. For combinations of genetically modified organisms which can only be used directly as food or feed or for processing, the unique identification code may be substituted with a declaration that the combination is intended for such use, and a list enclosed of the unique identification codes for all the genetically modified organisms that have been used to make the combination.

Peru

comisión del codex alimentarius

ORGANIZACIÓN DE LAS NACIONES UNIDAS PARA LA AGRICULTURA Y LA ALIMENTACIÓN

ORGANIZACIÓN MUNDIAL DE LA SALUD

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CL 2006/22-FL

JOINT FAO/OMS PROGRAM
ON FOOD STANDARDS
CODEX COMMITTEE ON FOOD AND FOOD INGREDIENTS LABELLING
35th Meeting
Ottawa, Canada, April 30 to May 4 2007

SUBJECT: Labelling of Foods and Food Ingredients Obtained through Certain Techniques of

1. **Peru is in agreement with the terms of reference raised by the Working Group´s tasks.**
2. **Given that Peru does not produce genetically modified food and food ingredients, we do not have sufficient material to contribute to the points referred to at 1, 2, 3, 4**

USA

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

October 2, 2006

Codex Contact Point Norway
Norwegian Food Safety Authority – Head Office
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Dear Sir,

The United States is pleased to respond to CL 2006/22-FL regarding the labeling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering. Specifically, CL 2006/22-FL invited member countries to provide information on the following four items identified in the CL:

1. Rationale for Members' approach to the labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

3. Identify Members practical experiences in applying/implementing mandatory and voluntary labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

4. Identify communication strategies used in communicating information to the public on food and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods.

I. Current labeling requirements

The United States does not have special labeling requirements for bioengineered foods as a class of foods. The labeling requirements that apply to all foods in general also apply to foods produced using biotechnology. Each food is required by law to bear a common or usual name or, in the absence of such a name, an appropriately descriptive term. In addition, the label of the food must reveal all material facts about the food. Thus:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.
- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made in the labeling to describe the issue.
- If a bioengineered food has a significantly different nutritional property, its labeling must reflect the difference.
- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed in the labeling.

All statements made on a food label or in the labeling of a food must be truthful and not misleading.

II. Rationale

The United States Food and Drug Administration (FDA) is the federal agency that is responsible for the safety and labeling of all foods and animal feeds derived from crops, including bioengineered plants. FDA derives its authority for the labeling of foods, in part, from the Federal Food, Drug, and Cosmetic Act (FFDCA or the act). Under section 403(a)(1) of the FFDCA (21 U.S.C. 343(a)(1)), a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act (21 U.S.C. 321(n)) further defines misleading labeling. Under the act, labeling is misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. While the legislative history of section 201(n) of the act contains little discussion of the word "material," there is precedent to guide the United States in its decision regarding whether information on a food is in fact material. Historically, the United States has generally interpreted the scope of “materiality” to mean information about the attributes of the food itself. FDA has required special labeling on the basis of it being "material" information in cases where the absence of such information may: 1) pose special health or environmental risks (e.g., warning statement on protein products used in very low calorie diets); 2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional

characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying)[23].

The United States does not consider the methods used in the development of bioengineered foods to be "material" information within the meaning of section 201(n) of the act, as explained above. The US government's position that the act does not mandate special labeling of the entire class of foods simply on the basis that the food is or is not genetically engineered has been upheld in court. See Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d. 166 (D.D.C. 2000) ("ABI"). In ABI, the court found that the lack of a FDA requirement for special labeling of bioengineered foods, as a class, was not arbitrary or capricious. The court upheld FDA's interpretation of what constitutes a "material" change that would warrant labeling under section 201(n) of the act and agreed with FDA that the process of genetic modification is not a material fact under section 201(n) of the act. Id.

Further, the United States considers the new methods of genetic modification to be extensions at the molecular level of traditional methods that will be used to achieve the same goals as pursued with traditional plant breeding. The United States is not aware of any information showing that bioengineered foods differ in any meaningful or uniform way, or, as a class, present any different or greater safety concern than foods developed by traditional plant breeding. In 2004, the United States' Institute of Medicine (IOM) published a report on the safety assessment of bioengineered foods[24], in which it stated, "All evidence evaluated to date indicates that unexpected and unintended compositional changes arise with all forms of genetic modification, including genetic engineering. Whether such compositional changes result in unintended health effects is dependent upon the nature of the substances altered and the biological consequences of the compounds. To date, no adverse health effects attributed to genetic engineering have been documented in the human population." The IOM report further advised that the genetic modification method used should not be the sole criterion for suspecting and subsequently evaluating possible health effects associated with unintended compositional changes. In addition, a report published in 2000 by the National Research Council of the National Academy of Sciences[25] stated, "The committee is not aware of any evidence that foods on the market are unsafe to eat as a result of genetic modification." The United States is confident that the bioengineered plant foods on the U.S. market today are as safe as their conventionally bred counterparts. Under the FFDCA, manufacturers have a legal obligation to ensure that any food they market is safe. This applies equally to conventional foods and bioengineered foods.

Furthermore, the Report of the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology: Safety Aspect of Genetically Modified Foods of Plant Origin (WHO, 2000) concluded that "safety assessment of food and food ingredients obtained using recombinant-DNA techniques does not require new scientific principles or methodology. Similar principles for the

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[23] United States Food and Drug Administration (2001). Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering. Draft Guidance. *Accessible on the internet at* http://www.cfsan.fda.gov/~dms/biolabgu.html.

[24] Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects (2004). Food and Nutrition Board, Institute of Medicine. The National Academies Press, Washington, DC.

[25] Genetically Modified Pest-Protected Plants: Science and Regulation (2000). Board on Agriculture and Natural Resources, National Research Council. National Academy Press, Washington, DC.

assessment of the safety and wholesomeness of the genetically modified foods should be applied as practiced for conventional food."

Therefore, the United States has no basis under the act or implementing regulations to require that all genetically engineered foods, as a class, be labeled as "genetically engineered" or as containing or produced with "genetically engineered material," nor could it require such labeling, under the act, on the basis of consumer interest alone.

III. Relevant statutes, regulations, policies, and decrees

As noted above, FDA derives its authority for the labeling of foods, in part, from the FFDCA. Under this authority, FDA adopts regulations and develops policies or guidance, as warranted, for the labeling of foods. The FFDCA and FDA's policies, procedures, and guidance that are of specific relevance to the labeling of bioengineered foods are explained below.

The Federal Food, Drug, and Cosmetic Act

The relevant labeling provisions in the FFDCA govern what information must be present in the labeling of a food. Section 403(a)(1) of the FFDCA provides that a food is deemed to be misbranded if its labeling is false or misleading in any particular. Section 403(i) of the FFDCA requires that each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term. In addition, under section 201(n), the label of the food must reveal all material facts about the food. In determining whether the labeling or advertising of a food is misleading, section 201(n) of the FFDCA requires FDA to take into account "the extent to which the labeling or advertising [of a food] fails to reveal facts material in the light of . . . representations [made or suggested] or material with respect to consequences which may result from the use" of the food to which the labeling or advertising relates.

Statement of Policy

In 1992, FDA issued a Statement of Policy: Foods Derived From New Plant Varieties (the 1992 policy) to clarify the agency's interpretation of the act with respect to new technologies, including recombinant DNA techniques, used to develop new varieties of plants that will be sources of foods (57 FR 22984; May 29, 1992). The 1992 policy discusses the safety and regulatory status of such foods. Under this policy, foods such as fruits, vegetables, grains, and their byproducts, derived from plant varieties developed by the new methods of genetic modification are regulated within the existing framework of the act, FDA's implementing regulations, and current practice. FDA's regulatory approach to foods developed using new methods of genetic modification is the same as its approach to foods developed by older methods of genetic modification, i.e., traditional plant breeding. Under the 1992 Policy, the regulatory status of a food is dependent on the objective characteristics of the food and the intended use of the food (or its components) and not on the fact that a new method is used to produce or develop the food.

Consultation Procedures

In the 1992 policy, FDA recommended that developers consult with FDA about bioengineered foods under development that are intended for commercialization; since issuance of the 1992

policy, developers have routinely done so. In June 1996, FDA provided additional guidance to industry on procedures for these consultations. The procedures describe a process in which a developer who intends to commercialize a bioengineered food initially meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues such as labeling regarding the bioengineered food and then later submits to FDA a summary of its scientific and regulatory assessment of the food; FDA evaluates the submission and responds to the developer by letter. Since 1994, FDA has evaluated data and information on more than 60 other products, ranging from herbicide-resistant soybeans to a canola plant with modified oil content. Information about completed consultations is posted on FDA's website at http://www.cfsan.fda.gov/~lrd/biocon.html.

FDA held a series of public meetings in 1999 to seek comments from industry and consumers on its policy, its consultation procedures, and any emerging scientific information related to the safety of bioengineered foods. As a result of the meetings and the request for comments, the agency received more than 35,000 written comments. Upon evaluation of the comments, there was no new scientific information that questioned the safety of any bioengineered foods currently marketed.

Draft Voluntary Labeling Guidance

In 2001, FDA provided draft guidance to manufacturers for the voluntary labeling indicating whether foods have been developed using genetic engineering (Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering. Draft Guidance, 2001; *Accessible on the internet at* http://www.cfsan.fda.gov/~dms/biolabgu.html). While the use of genetic engineering is not a material fact in itself, the US government provided this draft guidance in response to industry and consumer requests regarding the nature of voluntary labeling options. In this draft guidance, FDA also articulated appropriate approaches to making truthful and non-misleading labeling statements about foods that are developed using bioengineering as well as foods that are not bioengineered or that do not contain ingredients produced from bioengineered foods.

IV. Practical Experiences with Labeling

FDA has completed more than 60 consultations (as described above) on bioengineered foods. Where the genetic engineering resulted in any "material" changes to the food, FDA has relied on section 201(n) of the act to evaluate labeling. For example, "laurate canola oil" and "high-oleic acid soybean oil" are bioengineered foods that were developed through the use of bioengineering to differ in composition and intended use from their traditional counterparts and are labeled to distinguish these foods from those counterparts. "Laurate canola oil" is the oil produced from a new canola variety that is modified to produce significantly increased levels of lauric and myristic acids in the seed oil[26]. High-oleic acid soybean oil is produced from new soybean varieties that are modified to produce significantly increased levels of oleic acid in the seed oil.[27]

[26] See Biotechnology Consultation response letter and summary memo for BNF No. 000025. Available online at http://www.cfsan.fda.gov/~lrd/biocon.html

[27] See Biotechnology Consultation response letter and summary memo for BNF No. 000039. Available online at http://www.cfsan.fda.gov/~lrd/biocon.html

Thus the foods must be labeled to point out that, as a result of their compositional change, their identity is different from their traditional counterparts rather than to simply note that they are derived through genetic engineering.

However, the fact that a food is or is not bioengineered does not itself warrant special labeling under the act, where genetic engineering results in no "material" changes to the food within the meaning of section 201(n) of the act. For example, FDA reviewed submissions related to the FLAVR SAVR™ tomato and certain other tomatoes with modified ripening or softening characteristics. FDA did not have any questions about the food developers' conclusions that foods derived from the new tomato varieties are not materially different in composition, safety, or other relevant parameters from traditional tomatoes on the market[28] and, therefore, FDA did not impose special labeling requirements. Specifically with respect to the FLAVR SAVR™ tomato, FDA determined that the appropriate common or usual name of the tomato is "tomato" because the tomato is not significantly different from the range of commercial varieties referred to by that name and because there is no safety or usage concern to which consumers must be alerted by special labeling.[29] Similarly, with respect to bioengineered foods such as glufinosinate-tolerant corn and glyphosate-tolerant corn, FDA determined that these changes, by themselves, do not constitute "material" changes that require labeling under section 201(n) of the act. Increased tolerance of the corn crop to insects or herbicides does not constitute material change unless such changes also result in an alteration in the basic nature or nutritional, organoleptic, or functional characteristics of the corn. Therefore, characteristics such as increased tolerance to insects or herbicides, by themselves, do not warrant special labeling under the act.

V. Communication Strategies

The US Government communicates with its stakeholders in a number of ways. The United States Regulatory Agencies Unified Biotechnology Website, http://usbiotechreg.nbii.gov, provides comprehensive information about the regulation of biotechnology products in the United States and the role of different government agencies. In addition, information about FDA's regulations, policies, and guidance related to bioengineered foods is available to the public via the Internet at http://www.cfsan.fda.gov/~lrd/biotechm.html, where links are provided to current and past FDA activities related to bioengineered foods.

In addition, the US federal rulemaking process offers ample opportunity for the public to provide their comments and bring to the forefront any concerns they may have on the issue. By way of background, federal rulemaking involves a process that includes the publication of a series of notices in the Federal Register seeking public input at every step prior to the adoption of any final rule. The process may be initiated with an advance notice of proposed rulemaking (ANPRM) followed by a notice of proposed rulemaking (NPRM) and then a final rule. Notices may be issued between any of these steps, for example, to extend the comment period (as needed, in response to requests by stakeholders), re-open the comment period (to seek input in response to relevant new or emerging information), or announce public meetings or hearings. Public

[28] See Biotechnology Consultation response letters and summary memos for BNF Nos. 000002, 000003, 000007, and 000014. Available online at http://www.cfsan.fda.gov/~lrd/biocon.html

[29] See Food Master File 526 response letter and summary memo. Available online at http://www.cfsan.fda.gov/~lrd/biocon.html

meetings or hearings may be held during or prior to the initiation of the rulemaking process to bring together stakeholders and seek comment on relevant issues (for example, FDA held a series of public meetings in 1999 to seek comments from industry and consumers on its 1992 policy on the regulation of bioengineered foods). The US Government considers all comments it receives and, in the adoption of any final rule, explains the agency's position in response to these comments. Federal Register notices may be also used to inform stakeholders of its policies or to announce draft guidance and seek comment prior to the issuance of the guidance. In addition, for technical regulations and sanitary and phytosanitary measures within the scope of the TBT and SPS Agreements, notification of proposals are made to WTO members, and inquiry points for information are established as required by these Agreements. Through these processes, all interested persons are informed and given an opportunity to provide input in the adoption of FDA's regulations and the development of its policies and guidance related to bioengineered foods, as in the case of any other food[30].

Additionally, FDA communicates with consumers through its official magazine, *FDA Consumer*, which reports on current FDA activities related to the products the agency regulates, including foods. FDA previously informed consumers about the safety and labeling of genetically engineered foods and, as appropriate, responded to consumer inquiries through publications in the *FDA Consumer*[31].

Thank you for the opportunity to provide these comments.

/S/

F. Edward Scarbrough
U.S. Manager for Codex

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[30] FDA's Federal Register documents are available online at: http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm

[31] See "Genetic Engineering: The Future of Foods?," November-December 2003 (http://www.fda.gov/fdac/features/2003/603_food.html); "Letters to the Editor. Biotechnology and Foods," July-August 2002 (http://www.fda.gov/fdac/departs/2002/402_ltrs.html); and "Are Bioengineered Foods Safe?" January-February 2000 (http://www.fda.gov/fdac/features/2000/100_bio.html).