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THE PROCESS OF DEVELOPING LABELING STANDARDS FOR GM FOODS IN THE CODEX ALIMENTARIUS

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The Codex Committee on Food Labeling (CCFL) is currently considering the issue of genetically modified (GM) food labeling in an effort to develop guidelines for international harmonization. This paper provides a summary of the CCFL's seven-year effort to develop a standard for the labeling of biotechnology-derived foods. It is hoped that the CCFL will continue to meet its objective of protecting consumers while facilitating trade by developing the best labeling policies for harmonization.

Key words: Codex Alimentarius Commission (Codex); Committee on Food Labeling (CCFL); genetically modified (GM); international harmonization.

The Codex Alimentarius Commission, or "Codex," was created in 1962 to implement the joint United Nations Food and Agriculture Organization (FAO) / World Health Organization (WHO) Food Standards Program. Membership in Codex is open to all member nations of the United Nations (UN) and currently 165 countries participate. The Food Standards Program strives to protect consumer health and ensure fair trade practices involving food as demonstrated by the over 4,000 standards, recommendations, and guidelines that have been accepted to date. The Food Standards Program involves the determination of priorities and provides guidance for the preparation and finalization of standards that are referred to in the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement, and which are published either as regional or worldwide standards.

Once a Codex standard has been adopted, member countries are encouraged to incorporate it into any relevant domestic rules and legislation. However, under the WTO SPS Agreement, member countries retain the right to unilaterally impose more stringent food safety regulations deemed necessary to ensure domestic consumer protection, provided the different standards are scientifically justifiable and otherwise consistent with WTO SPS rules. The Codex Committee on Food Labeling (CCFL) is considering the issue of genetically modified (GM) food labeling in an effort to develop guidelines for international harmonization. This paper provides a summary of the CCFL's seven-year effort to develop a standard for the labeling of biotechnology-derived foods.

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The Codex Committee On Food Labeling

The Codex Committee on Food Labeling, hosted and chaired by Canada, examines international food-labeling issues; drafts labeling provisions that are applicable to all foods; and endorses labeling provisions prepared by Codex Committees charged with drafting standards, codes of practice, and guidelines. The high controversy generated by many issues before the CCFL demonstrates the importance given by member countries to the development of international labeling standards. The CCFL is considering the major issues around the labeling of biotechnology-derived foods.

To date, the CCFL has advanced the Draft Recommendations on Biotechnology Labeling - Section 2, Definition of Terms and Section 4.2.2, Allergens, to Steps 6 and 8[1] of the Codex Acceptance Procedure, respectively (Codex, 2001, pars. 37-38, apps. III & V). The Committee has also agreed to return the Proposed Draft Recommendations on Biotechnology Labeling - Section 5, Additional Mandatory Requirements, to Step 3 for redrafting by the Working Group, which will prepare a revised version for circulation and consideration by the Committee's April 2001 Session (Codex, 2001, par. 49).

The following summary of the CCFL's seven-year effort to develop a standard for the labeling of biotechnology-derived foods demonstrates the laborious process of developing a Codex standard. The principle is to develop a standard that bears the input from all governments. All the meetings discussed below were held in Ottawa, Canada, and were attended by representatives of some of the Codex member countries, international consumer groups, private industries, and by representatives from the Codex Secretariat and observers.

22nd Session (April 1993)

The CCFL agreed that work on the labeling aspects of biotechnology be considered in light of recommendations by the Codex Commission. The CCFL requested the United States (US) prepare a discussion paper for consideration at the next session.

23rd Session (October 1994)

The Committee considered the discussion paper prepared by the US. The paper identified a number of issues as areas where further elaboration and comments should be sought. During these initial discussions, countries either favored mandatory labeling only for the introduction of any potential health or safety concerns to food products, or advocated that labeling be required under all circumstances. Some countries thought that it was too early to determine particular rules for products obtained through biotechnology and that labeling should be required only when the food or ingredient is significantly different from its traditional equivalent, or if safety concerns are involved, such as in the case of the introduction of an allergen.

24th Session (May 1996)

Delegations and observers requested that all food products prepared with the assistance of biotechnology should be subjected to mandatory comprehensive labeling. They reasoned that consumers should be able to make choices based on several considerations, including food origin, production method, agronomic practices, and personal values. Some observers also suggested the public be notified, through labeling, of specific concerns relative to safety, nutrition, and food composition. It was further suggested that these concerns be the subject of scientific evaluation. The European Union (EU) stated that taking a position on such matters would be premature as member countries were still reviewing their respective situations. Canada indicated that its policy on the labeling of biotechnology-derived foods was still being

developed. Noting the lack of consensus, the CCFL agreed to seek guidance from the Codex Executive Committee on how labeling guidelines might be composed.

25th Session (April 1997)

A document based on recommendations made by the Codex Executive Committee was introduced for discussion. Within the Recommendations for the Labeling of Food Obtained Through Biotechnology (Codex, 1997a, app. VI), the Executive Committee proposed that foods that are not equivalent to existing non-biotechnology foods with respect to composition, nutritional value, or intended use, should be labeled. The document also contained suggested approaches for addressing allergens. In order to identify issues and provide direction to the Codex Executive Committee, the CCFL agreed to solicit Codex-member governments' comments. A review comprising these comments was released in February 1998.

26th Session (May 1998)

The Proposed Draft Recommendations (Codex, 1997b, app. VI) were again discussed. The proposal for labeling foods that are non-equivalent to existing foods, based on composition, nutritional value, or intended use, remained intact. This Session provided an opportunity for Codex members to comment as to whether all genetically modified foods, or foods that contain genetically modified material, should be so labeled. The CCFL facilitated constructive discussion among Codex members. This time, progress was made in refining the definition of products obtained through biotechnology and on the mandatory labeling of foods with allergens, with the exception of food products that are non-equivalent compositionally, nutritionally, or in their intended use. Several European countries, along with India, expressed a preference for the mandatory method of production labeling of all biotechnology-derived foods.

Canada, US, Australia, New Zealand, Peru, and Brazil supported the labeling of foods based on safety, composition, intended use, and nutrition, which was consistent with their respective labeling laws. The CCFL agreed to forward to the Commission for adoption at Step 5, the definitions related to biotechnology and the provisions on allergens and to return all other sections of the Proposed Draft Recommendations (Codex, 1999a, pars. 41-49, app. VII) for further consideration.

27th Session (April 1999)

The CCFL considered a rewrite of the Proposed Draft Recommendations (Codex, 1999b, pars. 40-49) and established an Ad Hoc Working Group for this purpose. Canada was selected to coordinate and chair the group that comprised representatives from 23 member countries, the European Union, and nine international non-governmental organizations (NGOs). The Committee also recommended that a smaller Drafting Group (consisting of Japan, Brazil, the United States, Australia, Canada, and two representatives from the European Union) be formed within the Working Group to "hold the pen." The approach taken was for the Drafting Group to draft the document and circulate it to the full-member working group for review and comment. The final draft of the recommendations was to be discussed at the CCFL meeting in May 2000. The Drafting Group reviewed and revised the texts for the following:

- The definition of biotechnology-derived foods.
- The two labeling options being considered by the CCFL.

It must be emphasized that the mandate given to the Working Group was to develop more fully the two options in front of the CCFL. The first option requires labeling of products when they are obtained through biotechnology and differ significantly from the corresponding food with regard to composition,

nutritional value, or intended use. The second option requires the declaration of the method of production.[2]

The Working Group also agreed that consideration should be given to the following:

- The establishment of a threshold level in food or in food ingredients for the presence of food or food ingredients obtained through modern biotechnology, below which labeling would not be allowed.
- The establishment of a minimum threshold level for "adventitious" or accidental inclusion in food or food ingredients, of food or food ingredients obtained through biotechnology.[3]

28th Session (May 2000)

Recognizing the diversity of opinions among member countries, the CCFL engaged in lengthy debate and decided to return the proposed draft for further consideration. The CCFL also agreed that the Working Group would continue its deliberations to combine Options 1 and 2 into a Codex Guideline, (Codex, 2001, pars. 46-48) in light of the proposal from member countries, and to circulate it for consideration by the next session.

The Working Group was also asked to table a paper on key issues and questions associated with the labeling of these foods. A Draft Discussion Document of this nature has since been developed by the US. Three new members (South Africa, Thailand, and India) were added to the Drafting Group, which met in India in late October 2000. At that meeting, some additional options were developed for consideration during the April 2001, 29th Plenary Session.

29th Session (May 2001)

Consistency regarding the definition of terms became the major topic of debate when the Committee met in Ottawa. Two substantive matters were considered with respect to food biotechnology labeling. In the first instance, the Committee agreed to use the definition of "modern biotechnology" adopted by the Cartagena Protocol and moved the definitions to stage eight for decision, which is a critical step. However, upon consideration by the Codex Alementarius Commission Meeting in July 2001, and after considerable debate, the definition section was returned at step 5 for further consideration by the CCFL. The committee, however, was not able to proceed further with its consideration of the Guidelines for the Labeling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering, and returned the current text to step three for further comments. The following terms were agreed upon:

- *"Food and food ingredients obtained through certain techniques of genetic modification/genetic engineering"* means food and food ingredients composed of or containing genetically modified/engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified/engineered organisms obtained through modern biotechnology.

- *"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.

- *"Modern biotechnology"* means the application of
  a) *in vitro* nucleic acid techniques,[4] including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles, or
  b) fusion of cells[5] beyond the taxanomic family, that overcome natural physiological, reproductive,

or recombination barriers and that are not techniques used in traditional breeding and selection.

Conclusion

The GM labeling issue is a good example of the complexity of the Codex process; it also demonstrates how narrow technical issues, once only of interest to specialists, have become public policy issues of huge economic importance, imbued with differing social, cultural, and political values. Standard setting and dispute resolution are particularly difficult where science is relevant but not determinative, and where an international standard will clearly create economic winners and losers.

The current debate within Codex concerning labeling of foods derived from biotechnology is clearly indicative of how biotechnology is perceived from country to country. The Codex process for standards development is based on reaching international consensus. Building upon its past accomplishments in developing labeling standards for other food products, it is hopeful that the CCFL will continue to meet its objective—to protect the consumer and facilitate trade by developing the best labeling policies for harmonization.

Endnotes

[1] There are 8 steps taken in the setting of Codex standards (Codex, 1997c, pp. 20-21). These steps are as follows,

Step 1	The Commission decides to elaborate a Standard and assigns the work to a Committee. A decision to elaborate a Standard may also be taken by a Committee.
Step 2	The Codex Secretariat arranges preparation of a Proposed Draft Standard.
Step 3	The Proposed Draft Standard is sent to governments and international organizations for comment.
Step 4	The Secretariat forwards comments to the Committee.
Step 5	The Proposed Draft Standard is then sent to the Commission through the Secretariat for adoption as a Draft Standard.
Step 6	The Draft Standard is then sent back to governments and international organizations for comment.
Step 7	The Secretariat forwards comments to the Committee.
Step 8	The Draft Standard is returned to the Commission for adoption as a Codex Standard to be sent to governments for final acceptance.

[2] See Stull (2000) in this issue for a more detailed exposition of Options 1 and 2.

[3] See Stull (2000) in this issue for further discussion of alternative threshold levels from an industry perspective.

[4] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organisms of hereditary materials prepared outside the organisms such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion.

[5] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxanomic family.

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