codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
THIRTY-FOURTH SESSION
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PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: LABELLING PROVISIONS

REPORT OF THE ELECTRONIC WORKING GROUP

The 33rd Session of the Committee agreed to return the Proposed Draft Guidelines for redrafting by the electronic working group (E-WG) led by Canada, for comments at Step 3 and consideration at it's next session. The E-WG could not reach consensus on the proposed restructured guidelines, therefore, comments are not being requested as originally agreed to by the Committee. The attached summary report and draft restructured guidelines of the E-WG are provided for information and consideration at the 34th Session.

Report of the Electronic Working Group on the Restructuring of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering

Electronic Working Group Members: Argentina, Australia, Austria, Brazil, Canada, Denmark, European Community, France, Germany, Ghana, Guatemala, Guyana, India, Indonesia, Japan, Kenya, Korea, Malaysia, Mexico, Norway, Papua New Guinea, Paraguay, Poland, Sweden, Switzerland, Thailand, United States of America, Biotechnology Industry Organization, Consumers International, 49th Parallel Biotechnology Consortium, Institute of Food Technologists, International Council of Grocery Manufacturers Association, International Dairy Federation

I. Background

Advancement of the Draft Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering remains a challenge for the Codex Committee on Food Labelling (CCFL). Strong differences in perspectives of CCFL members have resulted in a lack of consensus on the method of production provisions within the Guidelines. As a result, the Draft Guidelines have remained at Step 3 of the development process since 1996.

At the Thirty-First Session of the CCFL, the Chair proposed to establish a Group of "Friends of the Chair" as an inter-session mechanism to break through the difficulty the Committee had been facing, in order to develop options to manage the issue for consideration at its next session. The CCFL had agreed to establish a Working Group with the mandate for management of this agenda item and to circulate to all Codex members the proposals submitted to the Group and a summary of the Group's discussions.

The Working Group met in October 2003 in Calgary, Canada. The report of the Working Group indicated that there was considerable interest in maintaining a single document with a mandatory component and other provisions that would be considered optional.

These findings were presented to the Committee at the 32nd Session of the CCFL. After a lengthy discussion, the Committee recognized that there was no consensus to convene a working group between sessions and agreed to return the Proposed Draft Guidelines to Step 3. It was agreed that at the next session, there would be a day dedicated to reviewing the text section by section, taking into account all comments received.

At the last Session (33rd) of the CCFL, the Committee, after considerable discussion, agreed to maintain the Proposed Draft Guidelines at Step 3 and establish an electronic working group (E-WG), hosted by Canada to reconstruct the Guidelines to include mandatory provisions for health and safety-related labelling and optional method of production labelling provisions. It was agreed that the restructured text would take into account the discussion of the 33rd session and the written comments received in response to CL 2004/22-FL, including those of countries not present at the session. The Committee confirmed that the revised text was to include the same content as the current Proposed Draft Guidelines, including provisions for both health and safety and method of production labelling. It was agreed that the reconstructed Proposed Draft Guidelines would be circulated for consideration prior to the next session.

In June 2005, the Office of the Codex Contact Point for Canada invited all those members of CCFL interested in participating in the E-WG to provide contact information. The invitation was accepted by 26 member countries, 1 member organization, and 6 non-government organizations. Canada reconstructed the Guidelines, taking into account the discussion held at the 33rd Session and the comments received including those of countries not present in the session (Attachment #1). Canada circulated the restructured guidelines and a roll up of the comments received prior to the 33rd Session to the E-WG for their consideration and comment by October 24, 2005. Canada again rolled up all the comments received and circulated them to the E-WG on December 12th, 2005 with a request to review and provide final comments by January 16, 2005.

In reviewing and analyzing the comments, it was evident that there was no consensus on the restructured Guidelines.

II. Observations

Members of the E-WG were unable to come to consensus on how to appropriately address the issue of method of production labelling.

Some members felt that Canada had gone beyond the mandate of the E-WG as they felt that parts of the guidelines had been removed and that new language had been added.

One member felt that voluntary method of production guidelines were meant only to provide guidance to the private sector, while other members felt that they were to provide guidance to governments and still others felt mandatory labelling provisions should apply for both health and safety and method of production. One delegation questioned whether Codex has the mandate to draft guidelines for the private sector.

Other members felt that a guideline that contained both mandatory and optional elements would be open to inconsistent operational interpretation. There was some concern that should a dispute arise relating to GM/GE labelling in the World Trade Organization, no distinction would be made between the mandatory and optional elements.

Another member felt that as most of the information provided in section 4 of the restructured guidelines was already covered by the Codex *General Standard for the Labelling of Prepackaged Foods* (i.e. allergen labeling, non-food safety claims, presentation of mandatory information on a food label, etc.) and by the Codex *General Guidelines on Claims and* therefore questioned the need for separate guidance relating to process-based labelling as these needs are already met in existing Codex texts.

III. Conclusion

The electronic working group members had an open exchange on the restructured guidelines and the implications of the text. Canada attempted to restructure the Guidelines based on the instructions provided by the Committee for the E-WG's consideration. At this time the E-WG cannot provide an agreed-upon set of restructured Guidelines to the CCFL for further consideration, as consensus was not achieved.

ATTACHMENT #1

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS [DERIVED THROUGH MODERN BIOTECHNOLOGY ~~OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING~~]

(For Discussion)

PURPOSE OF THE GUIDELINES

To provide guidelines to ensure that the labelling of food and food ingredients [derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~] provides factual, verifiable, understandable and non-misleading information to protect consumer's health and to ensure fair practices in food trade. [~~Food labelling plays an important role in providing information to consumers and thereby facilitating consumer choice.~~]

[In order to accomplish this goal, the guidelines are split into two components.

- Section 3.0 contains mandatory labelling provisions for food and food ingredients derived through modern biotechnology which have an impact on consumer health and safety; and
- Section 4 contains voluntary labelling provision for food and food ingredients derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~ with respect non-health and safety matters ~~in nature and would be used~~ applied by the private sector when responding to the market. ~~are meant to provide industry guidance so~~ The voluntary provisions are meant to protect consumers from false or misleading claims concerning the method in which the product was produce when industry chooses to make such claims.]

[Sections 1 and 2 apply to both mandatory and voluntary labelling. Section 3 outlines mandatory labelling provisions which apply when there is an impact on consumer health and safety, while Section 4, which now includes the exemptions and thresholds, covers the voluntary method of production labelling provision to be applied by industry. Finally Section 5 applies to both mandatory and voluntary labelling.]

[~~These guidelines set out a number of approaches and related information that could be used for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.~~]

1.0 SCOPE

These guidelines recommend procedures for the [mandatory and voluntary labelling] of food and food ingredients [derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~.]

1.1 These guidelines apply to the labelling of such food and food ingredients:

1.1.1 when it is demonstrated [through scientific evidence, ~~through an appropriate analysis of data~~] that the composition, nutritional value, or intended use of the food and food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation[1]; and/or

[1] This would include products such as oils with altered fatty acid levels, but would not include products such as those with agronomic modifications which contain recombinant DNA and/or protein but no further overall change to composition, nutritional value or intended use.

1.1.2 when they are composed of or contain a genetically modified/engineered organism or contain protein or DNA resulting from gene technology[2]; and/or; [in those cases when the presence of genes of genetically modified/engineered foods is proven to be present;] and/or

1.1.3 [when they are specifically indicated in the appropriate Codex standards or in the national legislation of countries ~~when they are produced from, but do not contain, genetically modified/ engineered organisms, protein or DNA resulting from gene technology~~.]

[1.2 These guidelines apply to the labelling of such food and food ingredients that deliberately exclude food and food ingredients that are described by section 1.1.1, 1.1.2, and 1.1.3 to ensure fair practices in food trade and to protect consumers from false or misleading claims concerning the method in which the product was produced ~~and thereby facilitate consumer choice~~.]

2.0 DEFINITION OF TERMS[3]

(At Step 6 of the Procedure)

For the purpose of these guidelines:

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

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"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 direct injection of nucleic acid into cells or organelles, or

b Fusion of cells[5] beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

["Product of Genetic Engineering" means a food composed of or containing organisms whose genetic material has been changed through genetic engineering, as herein defined, and foods derived from, but not necessarily containing or composed of, those organisms.]

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2 [Gene technology: Means a collection of techniques which are used to alter the heritable genetic material of living cells or organisms in a way that does not occur naturally by multiplication and/or recombination.]

3 The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels.

4 These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism 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 taxonomic family.

[“Genetic Material” means deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) that has been changed by the process of genetic engineering, together with its resulting expression product(s).]

[3.0 MANDATORY LABELLING OF FOOD AND FOOD INGREDIENTS DERIVED THROUGH MODERN BIOTECHNOLOGY ~~OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/ GENETIC ENGINEERING~~ WHICH HAVE AN IMPACT ON CONSUMER HEALTH AND SAFETY]

[3.1 Scope]

In adopting a specific approach to the labelling of food and food ingredients [derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~], the following provisions could be used:

[~~3.1When food and food ingredients derived through modern biotechnology obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2, [are no longer equivalent to / differ significantly from] the corresponding existing food and food ingredients, as regards:~~

~~- composition; and/or~~
~~- nutritional value; and/or~~
~~- metabolizing; and/or~~
~~- intended use;~~

~~the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 4.l on label declarations.~~]

[3.1.1 (a) When a food and food ingredient derived from modern biotechnology differs in composition as compared to the appropriate conventional counterpart such that a new common/usual name is required, the new name should convey the characteristic or properties which make the food and food ingredient different in a manner that is accurate and understandable, and/or;]

[(b) When a food and food ingredient derived through modern biotechnology differs from the conventional counterpart in nutritional value and/or intended use such that there is an identifiable consequence for the consumer, the characteristic or properties which make it different from the appropriate conventional counterpart should be clearly identified on the label as described in Section 4.5.2, label declarations.]

[~~3.2~~3.1.2 The presence in any food and food ingredients [derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~] of an allergen transferred from any of the products listed in Section 4.2.1.4 of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985 (Rev.1-1991, Amended 1999) shall be declared[6].]

[~~3.3~~3.1.3 The presence of substances[(s), in comparison to the corresponding existing food, which may trigger the onset or increase the severity of symptoms of pre-existing ~~result in~~]physiological or metabolic disorders for certain sections of the population and that are absent in corresponding existing foods [should] [shall] be [~~labeled~~ indicated]].

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[6] This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

[~~3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2);~~

~~(a) When they are composed of or contain a genetically modified/engineered organism or contain protein or DNA resulting from gene technology; and/or~~

~~(b) When they are produced from, but do not contain, genetically modified/engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value and, intended use.~~]

[~~3.5 Notwithstanding Section 4.2.2.2 4.2.3.2 of the General Standard[7], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary considerations, will be decided and implemented in a manner that is fair, transparent and consistent.~~]

[3.1.4 In addition to the provisions of Subsection 3.1.1 to 3.1.3, the labelling of food and food ingredients derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~ as defined in Section 2 which do not have a corresponding existing food and food ingredient shall contain appropriate information about the nature and characteristics of the food and food ingredients concerned.]

[**3.2] Label Declaration [For Food And Food Ingredients Derived Through Modern Biotechnology ~~Obtained Through Certain Techniques of Genetic Modification/ Genetic Engineering~~ Which Have An Impact On Consumer Health And Safety]**

In accordance with the *General Principles* section of the *Codex General Standard for the Labelling of Prepackaged Foods* and the *Codex General Guidelines on Claims*, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or likely to create an erroneous impression regarding its character or safety in any respect.

[~~6.1~~3.2.1 Where food and food ingredients derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~ are labelled to indicate final product characteristics, the following requirements should apply]:

[(a) if the composition differs in comparison to the appropriate conventional counterpart such that a new common/usual name is required, the new name should convey the characteristics or properties which make the food and food ingredient different in a manner that is accurate and understandable in accordance with Section 4.1 of the General Standard; and/or ~~if the composition or nutritional value of food and food ingredients [is no longer equivalent to/differs significantly from] the corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Sections 4.1 and 4.2.2 of the *General Standard*. In addition, nutrient declaration should be provided in conformity with the *Codex Guidelines on Nutrition Labelling*.~~]

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[7] Section 4.2.3.2 requires that pork fat, lard, and beef fat shall always be declared by their specific names

[(b) if nutritional value and/or intended use (including mode of storage, preparation or cooking) differs in comparison to the appropriate conventional counterpart such that there is an identifiable consequence for the consumer, the characteristic or properties which make it different from the appropriate conventional counterpart should be clearly identified on the label. ~~if the mode of storage, preparation or cooking [is no longer equivalent to/differs significantly from] the corresponding existing food and food ingredients, clear instructions for use should be provided.~~]

[4.0 VOLUNTARY LABELLING PROVISIONS OF FOOD AND FOOD INGREDIENTS DERIVED THROUGH MODERN BIOTECHNOLOGY ~~OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING~~ TO INDICATE METHOD OF PRODUCTION]

[Without prejudice to the acceptance of the approach to method of production labelling as a "legitimate concern[13bis]" of governments in establishing their national legislation, the following is provided to be considered as voluntary labelling provisions.]

[The provisions found in Section 4 of the guidelines would be voluntarily applied by the private sector when responding to market-driven decision to protect consumers from false or misleading claims concerning the method in which the product was produced.]

[~~In accordance with the *General Principles* section of the *Codex General Standard for the Labelling of Prepackaged Foods* and the *Codex General Guidelines on Claims*, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or likely to create an erroneous impression regarding its character or safety in any respect.~~]

[In adopting a specific approach to the labelling of food and food ingredients derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~, the following provisions could be used.]

[4.1 Scope]

[~~3.~~4 4.1.1 [The guidelines apply to the voluntary labelling of food and food ingredients in order to distinguish whether or not such foods are derived through modern biotechnology, irrespective of whether the food or ingredient contains genetically modified/engineered organisms, DNA or protein resulting from gene technology.]

[~~In addition to the provisions of Subsection 3.1 to 3.3, When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2 are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2):~~

~~(a) When they are composed of or contain a genetically modified/engineered organism or contain protein or DNA resulting from gene technology; and/or~~

~~(b) When they are produced from, but do not contain, genetically modified/ engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value and intended use.~~]

[13bis] Include a statement of principle concerning the role of science and the extent to which other factors are taken into account in the Codex decision making process.

[~~3.5~~ 4.1.2[Notwithstanding Section [4.2.3~~2~~.2] of the General Standard[8]], the presence of substances [in] a [food derived through modern biotechnology] ~~modified through certain techniques of genetic modification/genetic engineering~~ [but] that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, [may] be labelled.]

[~~6.0~~ 4.2 Label Declarations To Indicate Method Of Production]

[In accordance with the General Principles section of the *Codex General Standard for the Labelling of Prepackaged Foods* and the *Codex General Guidelines on Claims*, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.]

[~~6.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to indicate final product characteristics, the following requirements should apply:~~]

[~~(a) if the composition or nutrition value of food and food ingredients is [no longer equivalent to/ differs significantly] from the corresponding existing food and food ingredients, the label shall provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional workds or pharases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Sections 4.1 and 4.2.2 of the General Standard. In addition, nutrient declarations should be provided in conformity with the Codex Guidelines on Nutrition Labelling.~~]

[~~(b) if the mode of storage, preparation or cooking is [no longer equivalent to/ differs significantly] from the corresponding existing food and food ingredients, clear instructions for use should be provided.~~]

[4.2.1 When food and food ingredients are labelled to indicate whether it is derived through modern biotechnology, consideration may be given to the following claims.

a. A claim to indicate that a food and food ingredient is or is not derived through modern biotechnology shall only be made when more than 95% of the source of that food and food ingredient is derived from that method of production.

   Claims indicating that a food and food ingredient is or is not derived through modern biotechnology shall not be made for a food and food ingredient when its counterpart is intentionally added.

b. A claim indicating that a food and food ingredient is a "mixture of product of and not a product of genetic modification/genetic engineering" shall only be made when 5 to 95% of the food and food ingredients is a product of genetic modification/genetic engineering.

c. Claims regarding whether a food and food ingredient is derived through modern biotechnology (is or is not derived through modern biotechnology) shall be accompanied by an explanatory statement if the claim alone is likely to result in misunderstanding or misinformation.[9]]

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[8] Section 4.2.2.2 requires that pork fat, lard, and beef fat shall always be declared by their specific names

[9] Claims that a food and food ingredients is not derived from modern biotechnology, when no similar food and food ingredients are derived from modern biotechnology has been offered for sale, would be considered misleading because the claims creates the false impression that the product is unique. In such cases, it is appropriate to use a statement which includes an explanatory statement to avoid misunderstanding.

[~~6.~~2 4.2.2]In accordance with [Section ~~6.0~~ 4.0], [~~and in addition to the provisions of subsection 6.1 4.5.1~~,] food labels should be meaningful to the [intended] consumer. Where food and food ingredients [~~obtained through certain techniques of genetic modification/genetic engineering~~] are labelled to declare [whether they have been derived through modern biotechnology ~~the method of production, examples of~~ the] label declaration(s) [should ~~which may be adopted in accordance to national legislation,~~] include [an indication or a reference to genetic modification/genetic engineering. ~~but are not limited to:~~ A product will be regarded as bearing indications referring to genetic modification/genetic engineering where in the labelling or claims, including advertising material or commercial documents, the product or its ingredients is defined by the terms "genetically engineered", "genetically modified", "modern biotechnology", "plant/animal biotechnology", "gene technology", "recombinant DNA technology" or words of similar intent including diminutives which, in the country the product is placed on the market, suggests to the purchaser that the product or its ingredients were or were not derived through modern biotechnology ~~certain techniques of genetic modification/genetic engineering~~.

~~(a) (i) ["Produced from genetically modified (naming the source)"] e.g. "produced from genetically modified soya"~~

~~(b) If the ingredient is already listed as produced from the source, ["genetically engineered (naming the food)"], e.g. "genetically engineered maize flour"~~

~~(c) ["Grown from seeds obtained through [modern] plant biotechnology"]~~

~~(d) (i) If the ingredient is designated by the name of a category, ["contains (name of the ingredient) produced from genetically modified (source)"], e.g. starch ("contains starch produced from genetically modified maize")~~

~~(e) ["Genetically engineered (naming the characteristic) (naming the food)"] e.g. "genetically engineered high oleic soybean oil"~~

~~(f) ["Product of plant/animal biotechnology"]~~

~~(g) (i) ["Naming the food/food ingredient (genetically modified)"] e.g. "soybean (genetically modified)"~~

~~(h) ["Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)"] e.g. "soybean (genetically modified soybean not segregated)"~~

~~(i) ["Product of gene technology"]]~~

[4.2.3 When labelling] the presence of substances [in] a [food derived through modern biotechnology but] that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, [member countries ~~should~~ may establish criteria on how labelling decisions, based on dietary considerations, will be decided and implemented in a manner that is fair, transparent and consistent.]

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e.g. Like all [food and food ingredients], these are not derived from modern biotechnology.]

[~~6.3~~ 4.2.4 When a claim is made regarding whether a food and food ingredient is ~~the presence of food and food ingredients~~ derived from modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~ ~~is declared~~]on the label, the following would apply:

(a) In the case of single-ingredient foods, or where there is no list of ingredients, the information should appear clearly on the label of the food; or

(b) In the case of a food ingredient(s) in a multi-ingredient food, the information should be shown in the list of ingredients or in parentheses immediately following the ingredient(s). Alternately, the ingredient(s) may be identified by an asterisk and the required wording should appear in a statement immediately following the list of ingredients.

[4.2.5 Claims related to whether a food and food ingredients has been derived through modern biotechnology may appear on the principal display panel, provided that:

a. The highlighted ingredients each make up 5% or more of the total weight of the food as offered for sale;
b. The label shall indicate within the list of ingredients, the method of production of all known ingredients (e.g. derived from and not from biotechnology and mixture of products of and not of GE/GM); and
c. They are accompanied by an explanatory statement indicating that they should be read together with the information in the list of ingredients.]

4.2.6 [Claims shall contain a reference to an external, readily accessible source of further information, such as a toll-free telephone number or a Web-page address to provide additional information concerning:

a. the method(s) used to verify claims made pursuant of Section 5;
b. the origin of external genetic material (for example, plant, animal, fish, human, bacteria) in cases where modern biotechnology techniques have been applied;
c. the method(s) used to produce the genetic change (for example, recombinant technology, cell fusion); and
d. details as to why modern biotechnology was used.]

[~~4.0~~ 4.3 Threshold Levels

[~~4.1~~4.3.1]Where food and food ingredients [derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~], are labelled to declare the method of production, consideration may be given to:

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients [derived through modern biotechnology ~~obtained from certain techniques of genetic modification/ genetic engineering~~], below which labelling would not apply[10]] and/or

[Establishment of a *de minimis* threshold level for adventitious or accidental inclusion in food and food ingredients, of food and food ingredients [derived through modern biotechnology ~~obtained through certain techniques of genetic modification/genetic engineering~~, that corresponds to the limit of detection for the modified/engineered food ingredient] ~~below which labelling would not apply~~]**]**

[10] Consideration of a threshold must address existing provisions of the *Codex General Standard for the Labelling of Prepackaged Foods*, e.g. Section 4.2.1.3 (Compound Ingredients)

[~~5.0~~ **4.4 Exemptions**

[~~5.~~14.4.1]Notwithstanding the provisions of [~~Subsection~~ Section 3.0 ~~3.1 and to 3.2 3.3~~,] consideration may be given to the exemption from labelling of specific categories [~~(for example highly processed food ingredients, processing aids, food additives, flavours)~~] of food and food ingredients derived [through modern biotechnology according to national legislation ~~obtained through certain techniques of genetic modification/genetic engineering~~.]]

[~~7.0~~ [5.0 ~~IMPLEMENTATION~~ VERIFICATION

~~Consistent with the approach(es) adopted under Section 3, additional consideration should be given to procedures and methodologies for the identification of food and food ingredients~~ derived through modern biotechnology ~~produced using certain techniques of genetic modification/genetic engineering and verification of label declarations. These include, but are not limited to: development of validated detection methods; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure.~~]

5.1 [Verification for claims about foods that are or are not derived through modern biotechnology may include but are not limited to testing, detection methods, inspection, and audit tracking. No claim is permitted if it cannot be verified.]

5.2 [When making a claim in accordance with these guidelines shall ensure compliance with the requirements outlined in Section 3, 4 and 5, as appropriate.]

5.3 [The claimant making the claim shall be responsible for securing data necessary for verification of the claim.]

5.4 [The verification shall be fully documented, and the documentation shall be retained by the claimant for the purposes of information disclosure.]

5.5 [The claimants seeking to make a claim in accordance with these Guidelines shall prepare a plan covering all the activities within his/her control and ensure that their suppliers do the same.]

5.6 [Where testing and detection methods are used, validated methods of sampling and analysis and certified reference material are to be used as appropriate for the product in question.]]