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**Reaffirmed
May 2016**

National Standard of Canada

Voluntary labelling and advertising of foods that are and are not products of genetic engineering

Canadian General Standards Board 



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NATIONAL STANDARD OF CANADA

CAN/CGSB-32.315-2004

Reaffirmed
May 2016

Voluntary labelling and advertising of foods that are and are not products of genetic engineering

CETTE NORME NATIONALE DU CANADA EST DISPONIBLE EN VERSIONS
FRANÇAISE ET ANGLAISE.

ICS 55.020

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Acknowledgment is made for the translation of this National Standard of Canada by the Translation Bureau of Public Services and Procurement Canada.

Preface to the National Standard of Canada

This National Standard of Canada has been reaffirmed by the CGSB Committee on Voluntary Labelling of Foods Obtained or not Obtained Through Genetic Modification.

Editorial changes have been made by the correction of the following paragraphs.

Introduction, par. 2.1 and 4.1.1 g: There is a reference to the *Guide to Food Labelling and Advertising* which is no longer available. It has been replaced by the Industry Labelling Tool (ILT) which can be obtained from the Canadian Food Inspection Agency Web site at www.inspection.gc.ca.

Section 3 – Definitions and terminology

Item a. of the Genetic engineering definition has been modified and should now read:

Genetic engineering (Génie génétique):

Refers to techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination. Examples of the techniques used in genetic engineering include but are not limited to the following:

- a. recombinant DNA (rDNA) techniques that use vector systems or other mechanisms involving direct manipulation of the genome

NOTE This standard does not apply to genetic engineering techniques that give rise to genetic material and products, which also occur naturally as a result of multiplication and/or natural recombination, and are otherwise indistinguishable from them. For example, use of genome editing and other new breeding technologies to introduce characteristics which could also be achieved by the above excluded techniques, would not be treated as products of genetic engineering.

CANADIAN GENERAL STANDARDS BOARD

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INTRODUCTION

In recognition of heightened interest regarding foods that are and are not products of genetic engineering, countries and international bodies have examined approaches for identifying such foods through labelling, to assist consumers in making informed food choices.

Canada has in place a regulatory framework for the food, feed, and environmental safety assessment of products of biotechnology, including for *novel foods*,¹ which include but are not limited to foods that have been developed through the use of *genetic engineering* as defined in this standard. Under the *Food and Drugs Act*, mandatory labelling of all foods, including novel foods, is required where the foods have significant nutritional or compositional changes, or where potential health and safety risks exist that could be mitigated through labelling. The label must state, for example, the nature of a nutritional or compositional change, or the presence of an allergen. It is not required to indicate that the food is a product of genetic engineering.

Food label and advertising claims pertaining to the use or non-use of genetic engineering are permissible in Canada, provided such claims are truthful; not misleading; not deceptive; not likely to create an erroneous impression of a food's character, value, composition, merit or safety; and in compliance with all other regulatory requirements set out in the *Food and Drugs Act*, the *Food and Drug Regulations*, the *Consumer Packaging and Labelling Act* and *Consumer Packaging and Labelling Regulations*, the *Competition Act* and any other relevant legislation, as well as the *Guide to Food Labelling and Advertising*. If claims related to the health, safety, nutrition and/or environmental impacts of foods are made, such claims must be truthful, verifiable, not misleading, and in compliance with all Canadian regulations.

The National Standard of Canada *Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* was developed to ensure that any such claims are consistent with an appropriate set of parameters, including being informative, understandable, verifiable, and not false or misleading. Should a claim be made pursuant to this standard, it must meet the requirements applicable to the type of claim being made, as outlined in this standard. This standard was developed to provide consumer choice and does not imply the existence of health or safety concerns for products within its scope.

It is important to note that the standard permits verification of claims by several processes including audit tracking (identity preservation) as well as chemical analysis. However, acceptable Canadian or international verification processes or methods for validating ingredient claims, as outlined in section 7 of the standard, may not be available at the time of issuing this standard. As with all labelling claims, where acceptable verification processes, including such systems as audit tracking, do not currently exist, voluntary claims will not be made until an acceptable verification process is developed. Currently work is underway internationally and domestically to develop these processes.

It has been recognized that the term *genetic modification* is sometimes used as a synonym for *genetic engineering* as defined in this standard. However, to *genetically modify* a plant, animal, or micro-organism implies making any change to the genetic makeup of the organism by any intentional means whatsoever and is defined in this manner in the *Food and Drug Regulations*. Because of the broad nature of this definition, many food products would be considered *genetically modified*, and very few could be considered *non-genetically modified*. In order to meet the needs of consumers for information about the application of specific techniques of biotechnology, the standard limits itself to claims about the use of *genetic engineering* in the production of foods and food ingredients.

The standard was developed by a Committee, with representation from food producers, manufacturers, distributors, consumers, general interest, and government groups. While mindful of international implications, including ongoing Codex Alimentarius work towards a labelling guideline, the Committee reached a consensus based on a voluntary code for products available in Canada.

¹ *Government of Canada, Food and Drug Regulations. C.R.C., c. 870, s. B.28.001.*

CANADIAN GENERAL STANDARDS BOARD

**VOLUNTARY LABELLING AND ADVERTISING OF FOODS
THAT ARE AND ARE NOT PRODUCTS OF GENETIC ENGINEERING****1. SCOPE**

- 1.1 The standard applies to the voluntary labelling and advertising of food in order to distinguish whether or not such foods are products of genetic engineering, or contain or do not contain ingredients that are products of genetic engineering, irrespective of whether the food or ingredient contains DNA or protein.
- 1.2 The standard defines terms, and sets out criteria for claims and for their evaluation and verification.
- 1.3 The standard applies to food sold to consumers in Canada, regardless of whether it is produced domestically or imported.
- 1.4 The standard applies to the labelling and advertising of food sold prepackaged or in bulk, as well as to food prepared at the point of sale.
- 1.5 Under this standard, processing aids, enzymes below 0.01% by weight in a food as offered for sale (exception, see par. 6.2.7 a.), veterinary biologics, animal feeds, and substrates for micro-organisms (where the substrate itself is not present in the finished food product) do not affect whether a food or ingredient is considered to be or not to be a product of genetic engineering.
- 1.6 This standard does not preclude, override, or in any way change legally required information, claims or labelling, or any other applicable legal requirements.

2. REFERENCED PUBLICATIONS

- 2.1 As in the case of all foods sold in Canada, the labelling and advertising of foods that are and are not products of genetic engineering must be truthful and not misleading, as required by subsection 5(1) of the *Food and Drugs Act* and section 7 of the *Consumer Packaging and Labelling Act*, and in compliance with all other regulatory requirements as set out in the *Food and Drug Regulations*, the *Consumer Packaging and Labelling Regulations*, the *Competition Act* and any other relevant legislation, as well as the *Guide to Food Labelling and Advertising*. The definition for genetic engineering is adapted from the Report of the 28th Session of the Codex Committee on Food Labelling, Ottawa, Canada, May 5 to 9, 2000.
- 2.2 A reference to an act, regulation, or guide is always to the latest amendment.

3. DEFINITIONS AND TERMINOLOGY

- 3.1 The following definitions and terms apply in this standard:

Advertisement (Publicité ou annonce)

Any representation, by any means whatever, for the purpose of promoting directly or indirectly the sale or disposal of any food. (*Food and Drugs Act*)

Audit procedure (Procédure d'audit)

A control procedure that is sufficiently documented to determine the origin and supply chain of any food or food ingredient labelled in accordance with this standard.

Claim (Allégation)

Any statement made in labelling or advertising about a food or food ingredient that is intended to highlight the presence or absence of a specific characteristic of a food or an ingredient or the food or ingredient itself.

Enzyme (Enzyme)

A protein of animal, vegetable, or microbial origin that acts as a catalyst to increase the speed of a biological reaction without being altered, consumed, or destroyed during the reaction stage.

Food (Aliment)

Includes any article manufactured, sold, or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food, for any purpose whatever. (*Food and Drugs Act*)

Genetic engineering (Génie génétique)

Refers to techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination. Examples of the techniques used in genetic engineering include but are not limited to the following:

- a. recombinant DNA (rDNA) techniques that use vector systems
- b. techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism
- c. cell fusion (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

Unless the donor/recipient organism is derived from any of the above techniques, examples of excluded techniques include but are not limited to the following:

- a. in vitro fertilization
- b. conjugation, transduction, transformation, or any other natural process
- c. polyploidy induction
- d. mutagenesis
- e. cell fusion (including protoplast fusion) or hybridization techniques where the donor cells/protoplasts fall within the same taxonomic family.

(Descriptions of most of these techniques are found in Appendix A.)

Genetically engineered material (Matériel modifié par génie génétique)

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

Ingredient (Ingrédient)

An individual unit of food that is combined with one or more other individual units of food to form an integral unit of food.

Inspection (Inspection)

Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing, gauging, or documentation.

Label (Étiquette)

Includes any legend, word, or mark attached to, included in or on, belonging to, or accompanying any food or package containing food. (Adapted from the *Food and Drugs Act*)

Micro-organism (Micro-organisme)

An organism visible only under magnification. Includes bacteria, fungi, protozoa, microscopic algae, and viruses.

Multi-ingredient food (Aliment pluri-ingrédients)

An integral unit of food that consists of a combination of more than one ingredient.

Organism (Organisme)

Any biological entity capable of reproducing, of replicating or of transferring genetic material.

Person (Personne)

Includes a person and a corporation. (Adapted from the *Interpretation Act*)

Processing aid (Auxiliaire de fabrication)

Any substance that is intentionally used in the course of manufacturing or manufacture of a food unit, food ingredient, or food itself to fulfill a certain technological purpose during treatment or processing and which does not result in residues of the substance or its derivatives therein.

Product of genetic engineering (Issu du génie génétique)

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.

Sell (Vente)

Includes offer for sale, expose for sale, have in possession for sale, and distribute, whether or not the distribution is made for consideration. (*Food and Drugs Act*)

Single-ingredient food (Aliment mono-ingrédient)

An individual unit of food.

Source (Source)

A quantity of food, produced under conditions that are uniform (that is, a bin of potatoes, a field of corn, or a shipment of canola), the whole or a portion of which may be used for production or processing.

Standard (Norme)

The standard *Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering*, CAN/CGSB-32.315.

Substrate (Substrat)

Materials used to provide the nutritional requirements for growing cells or micro-organisms.

Verifiable (Vérifiable)

The ability to establish the correctness of a claim by examination or demonstration.

Verification (Vérification)

The process by which the correctness of a claim is established by examination or demonstration.

Veterinary biologic (Produit biologique vétérinaire)

Means

- a. a helminth, protozoan, or micro-organism;
- b. a substance or mixture of substances derived from animals, helminths, protozoa, or micro-organisms; or
- c. a substance of synthetic origin that is manufactured, sold, or represented for use in restoring, correcting, or modifying organic functions in animals or for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in animals. (*Health of Animals Act*)

4. GENERAL REQUIREMENTS FOR CLAIMS

4.1 Unless otherwise specified, these requirements apply to claims about single-ingredient foods as well as to ingredients in a multi-ingredient food.

4.1.1 Claims shall

- a. be permitted pursuant to the scope of the standard as identified in section 1;
- b. be understandable, informative, not false, and not misleading;
- c. comply with all requirements of section 7;
- d. refer to ingredient(s) in a multi-ingredient food rather than to the multi-ingredient food itself; (For examples, see Appendix B, par. B2.1)
- e. contain a reference to an external, readily accessible source of further information, such as a toll-free telephone number or a Web-page address, unless all the mandatory information required in par. 5.3.2 and 6.3.2 accompanies the claim;

- f. be accompanied by an explanatory statement if the claim alone is likely to result in misunderstanding or misinformation; (For examples, see Appendix B, par. B2.2)
- g. be presented in a manner so that the claim is grouped together with any explanatory statements and sources of additional information. Explanatory text shall be placed in close proximity to the claim with no intervening material, a format consistent with that specified in the *Guide to Food Labelling and Advertising*;
- h. be based upon a percentage by weight as offered for sale unless otherwise stated;
- i. not imply directly or indirectly an improvement that does not exist nor exaggerate the aspect of the food to which the claim relates;
- j. not imply that the food is endorsed or certified by an independent third-party organization, when it is not;
- k. not be made using absolute terms such as *free* or *100% or all*;
- l. use such terms as *entirely*, *completely* and *absolutely* with care. When claims are modified by these terms, allowances for unintentional or unverifiable food or ingredients, as described in sections 5 and 6, cease to exist; (For examples, see Appendix B, par. B1.3)
- m. not make use of signs or emblems. Abbreviations of well-known phrases or words are permitted. Symbols such as asterisks are permitted to draw consumers' attention to additional words or statements;
- n. be re-assessed and updated as necessary to reflect changes in technology or other circumstances that could alter the accuracy of the claim;
- o. use the terms *genetically engineered* (name of product), *(derived) from genetically engineered* (name of product), or the term *product of genetic engineering*, which refers to either of the preceding terms and shall conform, in intent, to the examples and guidance found in Appendix B;
- p. not be carried on the principal display panel of a product or made in advertising unless the requirements of par. 5.2.5 or 6.2.6 are met.

5. CLAIMS THAT FOODS ARE PRODUCTS OF GENETIC ENGINEERING

5.1 Claims about Single-Ingredient Foods (For examples, see Appendix B, par. B2.3)

- 5.1.1 If a claim is made that a **single-ingredient food** is a product of genetic engineering, it must comply with the requirements of section 4, and par. 5.1 and 5.3 of this standard.
- 5.1.2 Claims that a **single-ingredient food** is a product of genetic engineering shall be made only when more than 95% of the source of the single-ingredient food is a product of genetic engineering.
- 5.1.3 Claims that a **single-ingredient food** is a mixture of products of and not of genetic engineering shall be made only when 5 to 95% of the source of the single-ingredient food is a product of genetic engineering.
- 5.1.4 Claims that a **single-ingredient food** is a product of genetic engineering or is a mixture of products of and not of genetic engineering shall not be made when less than 5% of the single-ingredient food is a product of genetic engineering.

5.2 Claims about Ingredient(s) in a Multi-Ingredient Food (For examples, see Appendix B, par. B2.3 and B2.4)

- 5.2.1 If a claim is made that an **ingredient** is a product of genetic engineering or is a mixture of products of and not of genetic engineering, it must comply with the requirements of section 4, and par. 5.2 and 5.3 of this standard.
- 5.2.2 Claims that an **ingredient** in a multi-ingredient food is a product of genetic engineering shall be made only when more than 95% of the source of the ingredient is a product of genetic engineering.
- 5.2.3 Claims that an **ingredient** in a multi-ingredient food is a mixture of products of and not of genetic engineering shall be made only when 5 to 95% of the source of the ingredient is a product of genetic engineering.
- 5.2.4 Claims that an **ingredient** in a multi-ingredient food is a product of genetic engineering or is a mixture of products of and not of genetic engineering shall not be made when less than 5% of the source of the ingredient is a product of genetic engineering.

- 5.2.5 When a claim is made pursuant to par. 5.2.2 or 5.2.3 that one or more **ingredients** in a multi-ingredient food are products of genetic engineering or are a mixture of products of and not of genetic engineering,
- a. the manufacturer shall undertake steps to investigate the origin of all ingredients that each make up 1% or more of the total weight of the multi-ingredient food as offered for sale; and
 - b. the label shall indicate, within the list of ingredients, all known ingredients that are products of genetic engineering, or are mixtures of products of and not of genetic engineering.

- 5.2.6 Claims made pursuant to par. 5.2.2 and 5.2.3 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 multi-ingredient food as offered for sale; and
 - b. they are accompanied by explanatory text indicating that they should be read together with the information in the list of ingredients.

5.3 **Additional Information Requirements**

- 5.3.1 Information appearing on the label and in advertising may include but is not limited to
- a. information regarding the method(s) used to verify claims made pursuant to section 5;
 - b. in the case of recombinant DNA technology, information about the origin of external genetic material (for example, plant, animal, fish, human, bacteria);
 - c. information about the method(s) used to produce the genetic change (for example, recombinant DNA technologies, cell fusion);
 - d. details of why genetic engineering was used, provided that the information meets all the requirements of sections 4 and 7, in addition to all other regulatory requirements; and
 - e. information on the genetically engineered material content of a single-ingredient food or ingredient, in the form of only the following explanatory statements: *contains no genetically engineered material* or *contains less than 0.1% genetically engineered material*, as long as the ingredient has been processed to arrive at a purified substance or class of substances, and which contain no more than 0.1% crude protein.

Such information must meet all requirements of section 4 and applicable clauses of section 7 in addition to all regulatory requirements.

The statement that such an ingredient *contains no genetically engineered material* shall be made only using an internationally accepted, validated testing method, the results of which demonstrate an undetectable level of genetically engineered material.

- 5.3.2 Information available at the external source of information (described in par. 4.1.1 e.), if not on the label,
- a. shall include
 - i. information about the method(s) used to verify claims made pursuant to section 5;
 - ii. in the case of recombinant DNA technologies, information about the origin of external genetic material (for example, plant, animal, fish, human, bacteria);
 - iii. information about the method(s) used to produce the genetic change (for example, recombinant DNA technology, cell fusion); and
 - b. may include details of why genetic engineering was used, provided that the information meets all the requirements of sections 4 and 7, in addition to all other regulatory requirements.

6. **CLAIMS THAT FOODS ARE NOT PRODUCTS OF GENETIC ENGINEERING**

6.1 **Claims About a Single-Ingredient Food** (For examples, see Appendix B, par. B2.5)

- 6.1.1 If a claim is made that a **single-ingredient food** is not a product of genetic engineering, it must comply with all the requirements of section 4, and par. 6.1 and 6.3 of this standard.

- 6.1.2 Claims that a **single-ingredient food** is not a product of genetic engineering shall be made only for a single-ingredient food that is obtained from sources of which less than 5% are products of genetic engineering.²
- 6.1.3 Claims that a **single-ingredient food** is not a product of genetic engineering shall not be made for a single-ingredient food obtained from sources to which food that is a product of genetic engineering has been intentionally added (for example, to meet the maximum permitted allowance identified in par. 6.1.2).
- 6.1.4 Claims that a **single-ingredient food** is not a product of genetic engineering shall not be made for a single-ingredient food of which no genetically engineered strains have been offered for sale, unless accompanied by an explanatory statement, for example, *like all other oranges, these oranges are not a product of genetic engineering*. Other examples are found in Appendix B, par. B2.5.
- 6.2 **Claims About Ingredient(s) in a Multi-Ingredient Food** (For examples, see Appendix B, par. B2.5 and B2.6)
- 6.2.1 If a claim is made that an **ingredient** is not a product of genetic engineering, it must comply with all the requirements of section 4, and par. 6.2 and 6.3 of this standard.
- 6.2.2 Claims that an **ingredient** in a multi-ingredient food is not a product of genetic engineering shall be made only when less than 5% of the source of the ingredient is a product of genetic engineering.²
- 6.2.3 Claims that an **ingredient** in a multi-ingredient food is not a product of genetic engineering shall not be made for an ingredient obtained from sources to which food that is a product of genetic engineering has been intentionally added (for example, to meet the maximum permitted allowance identified in par. 6.2.2).
- 6.2.4 Claims that an **ingredient** in a multi-ingredient food is not a product of genetic engineering shall not be made for an ingredient of which no genetically engineered strains have been offered for sale, unless accompanied by an explanatory statement, for example, *like all other oranges, these oranges in this fruit salad are not a product of genetic engineering*. Other examples are found in Appendix B, par. B2.5.
- 6.2.5 When a claim is made that one or more (but not all) **ingredients** in a multi-ingredient food are not products of genetic engineering,
- the manufacturer shall undertake steps to investigate the origin of all ingredients that each make up 1% or more of the total weight of the multi-ingredient food as offered for sale;
 - the label shall indicate, within the list of ingredients, all known ingredients that are products of genetic engineering or that are mixtures of products of and not of genetic engineering; and
 - ingredient(s) of unverifiable origin shall not make up 5% or more of the total weight of the multi-ingredient food as offered for sale.
- 6.2.6 Claims made pursuant to par. 6.2.5 that one or more (but not all) **ingredients** in a multi-ingredient food are not products of genetic engineering may also appear on the principal display panel, provided that
- the highlighted ingredients each make up 5% or more of the total weight of the multi-ingredient food as offered for sale;
 - the claim is accompanied by explanatory text indicating that other ingredients are products of genetic engineering, if that is the case; and
 - the claim is accompanied by explanatory text indicating that it should be read together with information in the list of ingredients.
- 6.2.7 Claims implying that a multi-ingredient food is made solely or completely from ingredients that are not products of genetic engineering
- shall not be made when ingredients, including enzymes, that are products of genetic engineering have been added to the multi-ingredient food; and
 - shall not be made when ingredients, including components of ingredients, are of unverifiable origin.

² Refer to Appendix C — Explanation for an Adventitious Material Allowance of Less Than 5%.

6.3 **Additional Information Requirements**

6.3.1 Information appearing on the label and in advertising

- a. may, in all cases, include information regarding the method(s) used to verify claims made pursuant to section 6;
- b. may, if a claim has been made pursuant to par. 6.2.5 and with reference to those ingredients that are products of genetic engineering, include
 - i. information about the origin of external genetic material (in the case of recombinant DNA technology, for example, plant, animal, fish, human, bacteria);
 - ii. information about the method(s) used to produce the genetic change (for example, recombinant DNA technology, cell fusion); and
 - iii. details of why genetic engineering was used, provided that the information meets all the requirements of sections 4 and 7, in addition to all other regulatory requirements.

6.3.2 Information available at the external source of information (described in par. 4.1.1 e.), if not on the label,

- a. shall, in all cases, include information regarding the method(s) used to verify claims made pursuant to section 6;
- b. when a claim has been made pursuant to par. 6.2.5 and with reference to those ingredients that are products of genetic engineering,
 - i. shall include
 - A. information about the origin of external genetic material (in the case of recombinant DNA technology, for example, plant, animal, fish, human, bacteria); and
 - B. information about the method(s) used to produce the genetic change (for example, recombinant DNA technology, cell fusion);
 - ii. may include details of why genetic engineering was used, provided that the information meets all the requirements of sections 4 and 7, in addition to all other regulatory requirements.

7. **VERIFICATION**

7.1 Verification for claims about foods that are and are not products of genetic engineering may include but are not limited to testing, detection methods, inspection, and audit tracking. No claim is permitted if it cannot be verified.

7.2 **Requirements of Verification**

7.2.1 A person making a claim in accordance with this standard shall ensure compliance with the requirements in section 4 and section 5 or 6, as appropriate.

7.2.2 The person making the claim shall be responsible for securing data necessary for the verification of the claim.

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

7.2.4 Retention of documents shall be for the period that the claim for the food or ingredient is being made, and for a reasonable period thereafter, taking into account the patterns of use of the food.

7.3 **Systems for Verification**

7.3.1 Prior to making a claim, verification methods shall be used to confirm the validity of the claim.

7.3.2 A person seeking to make a claim in accordance with the standard shall prepare a plan covering all the activities within his or her control, and ensure that his/her suppliers do the same. Where applicable, the plan shall include

- a. a detailed description of the source(s) of food and/or ingredient;
- b. a description of the management system used to maintain the identity of the food or ingredient. This plan shall include the specifications and steps under the control of the person including, but not limited to, the planting, harvesting, preparation, processing, packaging, transportation, storage, testing, detection or audit methods as well as distribution of the food or ingredient. It shall include steps needed to communicate the appropriate control

measures required at other levels in the supply chain. Such a plan should follow, in order of preference, Canadian standards, international standards, recognized standards that have international acceptability (these may include regional or national standards), and industry or trade standards.

7.4 **Testing**

- 7.4.1 Where testing methods are chosen for verification purposes, the results from these testing methods shall document the presence or absence or levels, as appropriate, of substances that verifiably identify the presence or absence of the application of processes defined in this standard.
- 7.4.2 Where testing and detection methods are used, validated methods of sampling and analysis are to be used as appropriate for the product in question. These methods shall follow, in order of preference, Canadian standards, international standards, recognized standards that have international acceptability (these may include regional or national standards) and industry or trade standards.
- 7.4.3 Where there are no methods already in existence, the person making the claims may develop a method, provided it meets the other requirements of this section and is subject to peer review.

(This appendix forms a mandatory part of the standard.)

ADDITIONAL DEFINITIONS

Cell fusion (Fusion cellulaire)

The fusing of two cells to form a single cell.

Chemoporation (Chimioporation)

The process of exposing a cell to a chemical (typically, calcium chloride) and heat, thereby allowing the cell to take up DNA molecules.

Conjugation (Conjugaison)

The temporary contact between two unicellular organisms (for example, bacteria) during which DNA is transferred from the donor to the recipient organism.

Electroporation (Électroporation)

The electrical treatment of cells to induce the formation of transient pores through which DNA is taken up into the cell.

Helminth (Helminthe)

A parasitic worm (for example, tapeworm, liver fluke, ascarid, or leech), often an intestinal worm.

Hybridization (Hybridation)

A process of interbreeding to form a hybrid, by sexual or asexual methods.

In vitro fertilization (Fécondation *in vitro*)

The union of male and female gametes taking place in an artificial environment.

Liposome fusion (Fusion par liposome)

The encapsulation of DNA into a liposome (phospholipid vesicle or fat globule), which incorporates the DNA into the cell.

Macroinjection (Macro-injection)

The introduction of larger molecules into single cells.

Microencapsulation (Micro-encapsulation)

The enclosure of small DNA molecules into a capsule, which could be any fatty, fibrous, or membranous structure.

Microinjection (Micro-injection)

The introduction of DNA or other compounds into single cells with a microscopic needle.

Mutagenesis (Mutagenèse)

The induction of genetic mutation through chemical, physical, or radiation treatment, causing nucleotide(s) of the exposed organism's DNA to be altered. This occurs naturally at a very low rate of occurrence, or can be accelerated with *in vitro* methods.

Plasmid (Plasmide)

A circular DNA molecule found in bacteria. Plasmids can transfer genes between bacteria and are important transformation tools.

Polyploidy (Polyploidie)

The condition where more than two copies of chromosomes are present within a cell — this is caused either by the prevention of cell division or by reproduction of extra copies of chromosomes.

Protoplast fusion (Fusion de protoplastes)

The fusing of two protoplasts (a bacterial or plant cell deprived of its cell wall but having an intact plasma membrane).

Protozoan (Plural: **protozoa** or **protozoans**) (Protozoaire)

A type of single-celled or colonial micro-organism.

Recombinant DNA (rDNA) techniques (Techniques de l'ADN recombinant)

The transfer, in vitro, of spliced genes between different organisms of the same or different species, or the transfer of synthetic genes, which in turn changes the heritable traits of the organism. Such transfer of genes can be accomplished using vector systems or by direct introduction using a number of techniques including but not limited to chemoporation, electroporation, liposome fusion, macroinjection, microencapsulation, microinjection, and transduction.

Taxonomic family (Famille taxonomique)

An orderly classification of living organisms according to their presumed natural relationships, in which a group of related living organisms form a category ranking above a genus and below an order, and usually comprising several to many genera.

Transduction (Transduction)

The transfer of DNA from one micro-organism to another via a virus that infects bacteria.

Transformation (Transformation)

A process whereby a cell incorporates foreign DNA into its genome.

Vector (Vecteur)

An organism, plasmid, or virus that is used to deliver selected foreign DNA into a host cell.

(This appendix forms a mandatory part of the standard.)

CLAIM STATEMENTS

Introduction

This appendix contains explanatory text and examples of claims that are acceptable and unacceptable according to the standard. Claims made in accordance with the standard shall conform in intent to the examples and guidance found in this Appendix.

The examples provided are meant to be illustrative of the consideration discussed in each section, and unless otherwise noted, are not meant to take into consideration all the requirements of the standard. These examples do not necessarily reflect foods genetically engineered at the time this standard was published. This Appendix does not contain an exhaustive list of the requirements of the standard and is therefore not meant to serve as a replacement for the text of the standard.

Claims shall appear in the list of ingredients. In addition, a claim may appear in advertising and on the principal display panel, provided the requirements of par. 5.2.5 and 6.2.6 are met. Not all claims in this appendix are appropriate for the principal display panel or for advertising.

B1. USE OF TERMS

- B1.1 Product of Genetic Engineering** — The expression *product of genetic engineering* refers to food consisting of organisms that have undergone genetic engineering and to foods derived from these organisms. Care must be taken when using the terms *genetic engineering*, *genetically engineered*, or *from genetically engineered*.

Examples:

These potatoes are a product of genetic engineering, this corn oil is a product of genetic engineering, and canola oil (from a GE/non-GE blend of canola) are acceptable claims if they are made in accordance with the standard.

Genetically engineered corn oil, however, is unacceptable, since it is the corn that is actually genetically engineered.

- B1.2 Use of Terms Other Than Those Identified in This Standard** — Certain terms are not used in this standard. For example, claims that a food does not contain genetically engineered organisms are misleading in many cases, since most foods do not contain organisms. Seeds, nuts, and micro-organisms such as live bacterial cultures in yogurt are exceptions. It is also important to consider whether acronyms such as GEO are commonly understood by the consumer, before using them in claims.

Examples:

Non-GEO corn starch and *non-GEO canola oil* are unacceptable statements, since neither cornstarch nor canola oil are, or contain, organisms.

- B1.3 Modifying Statements** (par. 4.1.1 1.) — Care should be taken when using such terms as *entirely*, *completely*, and *absolutely*. Claims that are modified by these terms ignore the allowances for unintentional or unverifiable food or ingredients described in sections 5 and 6. Claims using such terms should not be made when ingredients in a multi-ingredient food are of unverifiable origin, or when it cannot be verified that there are no unintentionally present and/or undeclared products of, or not of, genetic engineering in this food.

Examples:

Made entirely from non-genetically engineered ingredients and *ingredients used are absolutely not genetically engineered* are unacceptable claims if some of the ingredients used are of unverifiable origin.

This corn is completely non-genetically engineered and *these corn chips contain absolutely no genetically engineered ingredients* are also unacceptable claims if it could not be verified that there is no product of genetic engineering unintentionally present in these foods.

B2. GUIDANCE RELATED TO SPECIFIC SECTIONS OF THE STANDARD

- B2.1 Claims About Ingredients in A Multi-Ingredient Food** (par. 4.1.1 d.) — A statement that a multi-ingredient food is or is not a product of genetic engineering is misleading, since it is actually the ingredients that are or are not products of genetic engineering.

Examples:

This cake is not a product of genetic engineering, non-genetically engineered pizza, and genetically engineered potato chips are unacceptable statements.

These chips are made from potatoes that are not a product of genetic engineering and made with oil from canola that is a product of genetic engineering are acceptable statements.

- B2.2 Explanatory Statements** (par. 4.1.1 f.) — In some cases, explanatory statements are required to ensure that a claim is truthful and not misleading. In other cases, a manufacturer may want to provide further details. Any information provided in such statements must also be truthful and not misleading, must meet all the requirements of sections 4 and 7, and must apply specifically to the food being labelled, unless given an appropriate context.

Examples:

Canola oil from canola genetically engineered to increase crop yield, corn: product of genetic engineering, this type of corn requires less pesticide use, and our potatoes are genetically engineered to reduce our use of pesticide are acceptable statements about why genetic engineering was used (par. 5.3.1 d., 5.3.2 b., 6.3.1 b. iii., and 6.3.2 b. ii.), as long as they are truthful and not misleading. Scientific data about specific crops may be required to support claims that, for example, pesticide use was reduced for the crop being sold.

Identity preservation systems are used to ensure that the soybeans we use are not genetically engineered and non-genetically engineered corn (tested) are also acceptable statements about the methods used to verify claims that foods are not products of genetic engineering (par. 6.3.1 a. and 6.3.2 a.) provided that they are truthful and not misleading.

Canola oil. Product of genetic engineering. Contains no genetically engineered material is an acceptable statement for a product of genetic engineering that contains no genetically engineered material (par. 5.3.1 e.).

High fructose corn syrup. Product of Genetic Engineering. Contains less than 0.1% genetically engineered material is an acceptable statement for a product of genetic engineering that contains less than 0.1% genetically engineered material (par. 5.3.1 e.).

- B2.3 Claims About Foods That Are Products of Genetic Engineering** (par. 5.1 and 5.2) — In addition to the considerations described above, the choice of appropriate expressions for claims about single-ingredient foods and ingredients that are products of genetic engineering will depend on how much of the specific food has been produced through genetic engineering.

Examples:

Papaya (product of genetic engineering) and genetically engineered potatoes are acceptable claims only if the food is obtained from sources (for example, a farmer's crop) that are more than 95% product of genetic engineering (par. 5.1.2 and 5.2.2).

Potatoes (partly a product of GE), tomatoes (combination of GE and non-GE), and squash (mixed non-GE and GE sources) are acceptable claims when between 5% and 95% of the source of the food or ingredient is a product of genetic engineering (par. 5.1.3 and 5.2.3).

- B2.4 Claims About Ingredients in A Multi-Ingredient Food** (par. 5.2)

- B2.4.1** When a claim is made that one or more ingredients in a multi-ingredient food are products of genetic engineering or are a mixture of products of and not of genetic engineering, the standard requires a) that the manufacturer undertake steps to investigate the origin of all ingredients that each make up 1% or more of the total weight of the multi-ingredient food as offered for sale, and b) that all known ingredients that are products of genetic engineering be identified in the list of ingredients (par. 5.2.5).

Example:

The following is an acceptable claim and format. (The percentages listed refer to the weight of ingredients in the product as offered for sale. These are included here for instructional use and are not a requirement of the standard.)

Corn chips snack food: ingredients: corn⁺ (70%), hydrogenated canola oil (25%), seasonings (4%), calcium hydroxide*

⁺Not a product of genetic engineering.

**From GE/non-GE crops.*

Toll-free line XXX XXX-XXXX

- B2.4.2 Should claims about specific ingredients that are products of genetic engineering be made on the front panel of a multi-ingredient food panel, the highlighted ingredient must make up 5% or more by weight of the multi-ingredient food as offered for sale and must draw the readers attention to the additional information found in the list of ingredients (par. 5.2.6).

Example:

Brand Name: contains genetically engineered corn (see ingredient panel) is an acceptable claim for the front panel of the multi-ingredient food described in the previous example.

B2.5 Claims That A Food Is Not A Product of Genetic Engineering (par. 6.1 and 6.2)

- B2.5.1 Claims about single-ingredient foods or ingredients that are not products of genetic engineering may not be made when the single-ingredient food or ingredient is obtained from sources of which 5% or more are products of genetic engineering (par. 6.1.2 and 6.2.2).

Examples:

Corn (not a product of genetic engineering) and *non-genetically engineered potatoes* are acceptable claims when it has been verified that each of these contains less than 5% product of genetic engineering.

- B2.5.2 Claims that a food is *not a product of genetic engineering*, when no similar foods that are products of genetic engineering have been offered for sale, are considered misleading because they create the false impression that the product is unique. In such cases, it is appropriate to use an alternate statement or to include an explanatory statement to avoid misunderstanding (par. 6.1.4 and 6.2.4).

Examples:

These onions are not a product of genetic engineering, non-genetically engineered chicken, and non-genetically engineered asparagus are unacceptable statements, since they imply that onions, chicken, or asparagus that are products of genetic engineering have been offered for sale.

Like all apples, these are not a product of genetic engineering; like all poultry, our turkey is not a product of genetic engineering; meat is not produced using genetic engineering; and brussel sprouts are not a product of genetic engineering are acceptable statements, since it is clear that no genetically engineered meat, poultry, apples, or brussel sprouts have been offered for sale.

B2.6 Claims About Ingredients in a Multi-Ingredient Food (par. 6.2)

- B2.6.1 In addition to previously described considerations, when a claim is made about ingredients in a multi-ingredient food that are not products of genetic engineering, the manufacturer is also required a) to undertake steps to investigate the origin of all ingredients that each make up 1% or more of the total weight of the multi-ingredient food as offered for sale; and b) to indicate within the list of ingredients, all known ingredients that are products of genetic engineering, or are mixtures of products of and not of genetic engineering. Claims cannot be made if 5% or more of the multi-ingredient food as offered for sale consists of ingredients of unverifiable origin.

Examples:

The following are acceptable claims and formats. (The percentages listed refer to the weight of ingredients in the product as offered for sale. These are included here for instructional use and are not a requirement of the standard.)

Home-style soup: ingredients: chicken broth (50%), red kidney beans (20%), corn (10%), enriched flour (8%), potato* (5%), canola oil* (3%), soya margarine* (2%), salt, herbs and spices*

**Not products of genetic engineering.*

Call 1-800-XXX-XXXX for more information.

Home-style soup: ingredients: chicken broth (50%), red kidney beans (20%), corn (10%), enriched corn flour* (8%), potato* (5%), canola oil* (3%), soya margarine* (2%), salt, herbs and spices*

**Not products of genetic engineering.*

+Mixture partly a product of genetic engineering.

Call 1-800-XXX-XXXX for more information.

Home-style soup: ingredients: chicken broth (50%), red kidney beans* (20%), corn** (10%), wheat flour* (8%), potato+ (5%), canola oil+ (3%), soy protein++ (2%), salt*, herbs* and spices**

**Like all types of these ingredients, not genetically engineered (GE).*

***Not a product of GE.*

+GE and non-GE sources not segregated.

++Product of GE.

Call 1-800-XXX-XXXX for more information.

- B2.6.2 Should a claim that specific ingredients that are not products of genetic engineering be made on the front panel of a multi-ingredient food, the identified ingredient(s) must contribute 5% or more to the weight of the multi-ingredient food as offered for sale, and the claim must draw the reader's attention to the additional information found in the list of ingredients (par. 6.2.6). A front panel claim about a non-genetically engineered ingredient must also indicate that other ingredients are products of genetic engineering if that is the case.

Examples:

This soup contains non-GE corn (Also contains GE ingredients. See ingredient panel for more information.) is an acceptable claim for the front panel of the multi-ingredient food described in the third example in B2.6.1.

These corn chips are made with non-genetically engineered corn (See ingredient panel) is also an acceptable claim if corn contributed 5% or more to the weight of the multi-ingredient food as offered for sale and if no other genetically engineered ingredients were contained in the chips.

Does not contain oil from genetically engineered canola is unacceptable if the product in question contains less than 5% canola oil. The claim is also unacceptable, since it does not direct the reader to additional information in the ingredient list. If other genetically engineered ingredients are present in the formula, then these will also need to be confirmed on the front panel.

(This appendix does not form a mandatory part of the standard.)

EXPLANATION FOR AN ADVENTITIOUS MATERIAL ALLOWANCE OF LESS THAN 5%

Par. 6.1.2 and 6.2.2 of this standard provide for an adventitious (accidental) inclusion of food from a genetically engineered crop of less than 5% when making claims that a food or food ingredient is not genetically engineered. Under no circumstances can a non-genetically engineered claim be made for a food to which a genetically engineered variety of the same food has been intentionally added. The amount of accidental inclusion is permitted both for single ingredient foods like potatoes or tomatoes, and for individual ingredients in a multi-ingredient food like corn meal in a corn meal muffin.

Adventitious levels of genetically engineered food in food claiming not to be a product of genetic engineering has been the source of much Committee discussion. Committee members concluded, however, that an amount substantially lower than 5% would not currently be practical or achievable in Canada across a range of commodity groups.

In the production of field crops, adventitious material can be introduced by natural factors such as the wind, insects, and other animals spreading seed from another crop, or by exposure to other crops through bulk handling systems. Even in the case of certified seeds, the purity of the seed is guaranteed at only 98 to 99%. Under current Canadian circumstances, the Committee felt that a lower level would make it virtually impossible for most field crops to qualify for a non-genetically engineered claim and would limit consumer choice of foods that have been grown intentionally to meet the non-genetically engineered market. However, the Committee heard that with diligence a level of less than 5% is achievable and verifiable in food grown today by Canadian farmers.

The Committee recognizes that for food-chain-production stakeholders to stay below the 5% level they will, in practice, need to target zero content of genetically engineered product. These stakeholders need to identify and define processes for minimizing the potential of unintended presence of genetically engineered material. Where deviations occur resulting in genetically engineered material at levels within or above the threshold for non-genetically engineered products, the stakeholders should identify and take corrective measures for the purpose of continuous improvement. If stakeholders fail to do this, the product runs a high risk of failing to meet the test for a non-genetically engineered claim. To reduce this risk, the stakeholders should review and change practices as appropriate.

Finally, the Committee heard that the level found in this standard is consistent with international practice for adventitious material of all sorts, including the inclusion of other classes of wheat or barley in shipments of a single class offered for sale in the world market. In this example, like in the case of genetically engineered commodities, the classes are not visually distinguishable, thus requiring rigorous segregation techniques to ensure compliance. Japan has set a level of adventitious genetically engineered food of 5% in its regulations, and a scientific committee of the European Union (EU) has expressed concern that the low adventitious level adopted by the EU is likely unworkable.

The Committee also noted that the level of adventitious genetically engineered food in a food made up of ingredients would be far less than 5% of the total food. For example, a corn meal muffin may have ten ingredients, only one of which (the corn) is a crop that has both genetically engineered and non-genetically engineered classes. If the corn in the muffin claims not to be from genetic engineering and comprises 10% of the weight of the muffin, the total amount of adventitious genetically engineered foodstuff (corn) in the muffin will be a less than 0.5%. In addition, the Committee notes that foods derived from genetically engineered crops like corn, soy and canola oil contain virtually undetectable amounts of genetic material or protein made from the genetic material.

The Committee considered, with respect, the comments it received during the public review period. Many of these comments recommended that no adventitious material be permitted in foods making a non-genetically engineered claim. However, the Committee considered all the information presented to it and was cognizant of the Canadian food growing and processing situations available today in our country. It recommends a review of the adventitious level set by this standard within five years.