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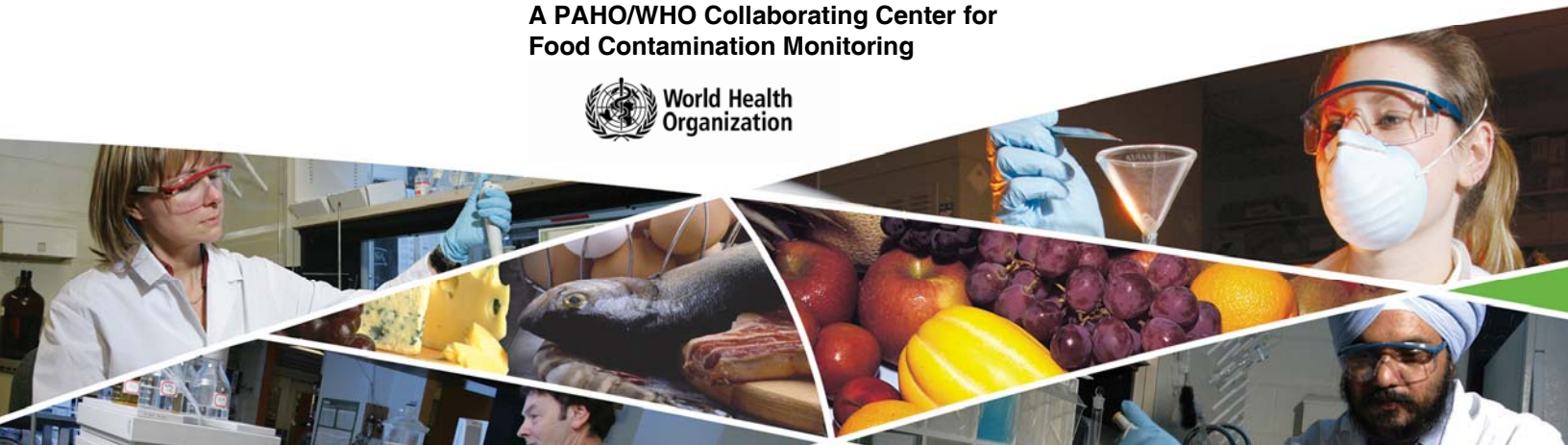
Policy for Differentiating Food Additives and Processing Aids

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch

A PAHO/WHO Collaborating Center for Food Contamination Monitoring

World Health Organization



Our Mission

To ensure chemicals are not present in foods at levels that may cause adverse health effects to Canadians.

Notre Mission

Veiller à ce que les produits chimiques ne soient pas présents dans les aliments à des niveaux pouvant entraîner des effets néfastes sur la santé des canadiennes et des canadiens.

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. *We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.*

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Publications
Health Canada
Ottawa , Ontario K1A 0K9
Tel.: (613) 954-5995
Fax: (613) 941-5366
E-Mail: info@hc-sc.gc.ca

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Purpose

This document sets forth the Food Directorate's policy for differentiating food additives and food processing aids. It provides systematic guidance for determining the status of a substance as a food additive or a processing aid in a given context of use.

Background

In Canada, the *Food and Drugs Act* (the "Act")[1] is the basis for the oversight of all substances used in food processing and manufacture. Under the Act, the *Food and Drug Regulations* (the "Regulations")[2] enable control of the use of additives in foods.

The Regulations define "food additive". The definition describes what a food additive is, and lists certain types of substances that are not included in the meaning of "food additive".[3] However, there are substances that are used during food processing and manufacture that do not meet the definition of food additive and are not on the list of exclusions. These substances include those commonly referred to as food "processing aids".
There is no regulatory definition of food processing aid in Canada. Canadian regulators have typically used "processing aid" in an informal manner for substances used as adjuncts in food processing and manufacture. Most processing aids are not mentioned in the Regulations.[4] And, unlike food additives, there is no regulatory requirement for preclearance of new processing aids by the Minister of Health. Like all substances used with food, the use of a processing aid is ultimately controlled by section 4, part I of the Act.[5]

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[1] The *Food and Drugs Act* can be viewed at
http://laws.justice.gc.ca/en/showtdm/cs/F-27///en

[2] The *Food and Drug Regulations* can be viewed at
http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/index.html

[3] In this policy document the list of substances not included in the meaning of "food additive" is referred to as the "list of exclusions".

[4] Exceptions include certain substances listed as fining agents in the standards for wine, honey wine, cider and beer (sections B.02.100, B.02.106, B.02.120 and B.02.130 in Division 2 of the Regulations), ion exchange resins used in manufacturing wine (B.02.100), and sodium methyl sulphate for use in pectin (Item S.15, Table VIII, Division 16). Only sodium methyl sulphate is referred to as a "processing aid" in the Regulations.

[5] Section 4 states: "No person shall sell an article of food that (*a*) has in or on it any poisonous or harmful substance; (*b*) is unfit for human consumption; (*c*) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; (*d*) is adulterated; or (*e*) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions."

It is important that a substance is appropriately identified as a food additive or processing aid. In the case of food additives, which usually are present in finished foods, appropriate identification will help ensure that the use of an additive (1) undergoes a safety evaluation, when necessary,[6] by Health Canada, and (2) complies with the regulatory provisions governing its use. Regulatory provisions can include a list of foods in which the additive may be used and a limitation on the level of use in each food, as well as a requirement that the additive be declared on the label of a prepackaged food.

Appropriate identification will also support a level playing field for the food industry if principles for identification are consistently applied.

For many years the Food Directorate has had a general approach for identifying food additives and processing aids stemming from the regulatory definition of food additive. The policy set forth in this document has been developed based on that approach.

Primary basis for differentiating food additives and processing aids

The regulatory definition of "food additive" is the primary basis for differentiating food additives and processing aids. Quite simply, a substance is a food additive if it is used in a manner that would cause it to meet this definition. A substance in and of itself is not necessarily a food additive or a processing aid; however, the conditions surrounding its use may cause it to be one or the other.

"Food additive" is defined in section B.01.001 of the Regulations:

> "food additive" means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include:
>
> (*a*) any nutritive material that is used, recognized or commonly sold as an article or ingredient of food;
> (*b*) vitamins, mineral nutrients and amino acids, other than those listed in the tables to Division 16,
> (*c*) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives;
> (*d*) agricultural chemicals, other than those listed in the tables to Division 16,
> (*e*) food packaging materials and components thereof; and
> (*f*) drugs recommended for administration to animals that may be consumed as food;

[6] A safety evaluation is not required for a food additive that is listed in Division 16 of the Regulations and is used according to its regulatory provision(s).

Decision tree to identify food additives and processing aids

Figure 1 is a decision tree to identify food additives and processing aids based on the regulatory definition of food additive. The questions in the tree should be answered by following the principles outlined under "Principles for using the decision tree".

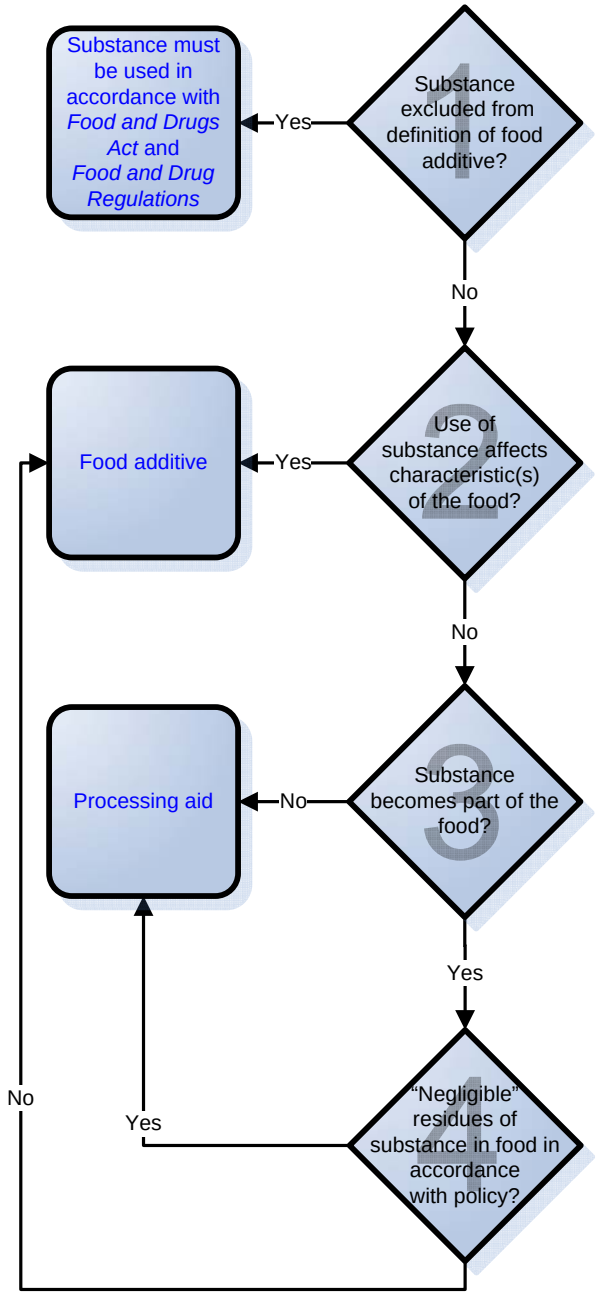

Figure 1 – Decision tree to identify food additives and processing aids based on the regulatory definition of food additive. The questions in the tree should be answered by following the principles outlined under "Principles for using the decision tree".

Principles for using the decision tree

Question 1: Does the definition of food additive exclude the substance from being a food additive?

Principle 1: If a substance is on the list of exclusions in the regulatory definition of food additive, then it is neither a food additive nor a processing aid.

The list of exclusions is made up of those substances in parts (*a*) to (*f*) of the definition. Their use in food is subject to the *Food and Drugs Act* and any applicable Regulations, but these substances are neither food additives nor processing aids. These substances are not addressed further in this document. Enquiries concerning them can be directed to the appropriate group within Health Canada.[7]

Question 2: Does use of the substance affect one or more characteristics of the food?

Principle 2: A substance is a food additive if its use affects the characteristics of the food. Generally, this means that a substance is a food additive if its use causes a technical effect on the finished food.[8]

For example, the addition of chlorine to flour to bleach the flour would be considered a food additive use of chlorine. This would be the case whether or not the chlorine becomes part of the flour, since bleaching is a technical effect on the flour that alters its characteristics. In contrast, chlorine would be viewed as a processing aid if it were to be added at a low level to poultry chiller water to reduce the pathogen load in the water and/or on the poultry carcass, provided there are negligible residues of the chlorine and its by-products on the finished poultry product(s). Here, the technical effect of the chlorine is considered to be on the water, not the poultry.

Question 3: Does the substance become part of the food?

Principle 3: A substance is a food additive if it or its by-product(s) becomes part of the food, unless it can be demonstrated that any residues of the substance in or on the finished food are "negligible".

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[7] Enquiries concerning agricultural chemicals or veterinary drugs can be sent to Health Canada's Pest Management Regulatory Agency (http://www.pmra-arla.gc.ca/english/index-e.html) or Veterinary Drugs Directorate (http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/vdd-dmv/index-eng.php), respectively. Enquiries concerning any of the remaining substances can be sent to the Food Directorate (see "For further information").

[8] The finished food is the food that is offered for sale to consumers. It could also include the food that is shipped to the retailer prior to processing, preparation and/or packaging by the retailer.

Question 4: Are residues of the substance in the food "negligible" in accordance with this policy?

Principle 4: "Negligible" means there are no residues of public health significance in or on the finished food, and any residues that are present are at levels that are too low to have a technical effect in or on the finished food.[9]

The Directorate determines, on a case-by-case basis, whether residues are negligible. Evidence supporting that residues are negligible might include (but is not limited to): (1) deliberate or inadvertent measures in food processing or manufacturing that remove or reduce residues of the substance and its by-products from the food;[10] (2) analytical data showing that residue levels are near the limit of detection of the most sensitive method available; and/or (3) efficacy data showing that residue levels are too low to have any technical effect in or on the finished food.

The Food Directorate's definition of food processing aid

A food processing aid is a substance that is used for a technical effect in food processing or manufacture, the use of which does not affect the intrinsic characteristics of the food and results in no or negligible residues of the substance or its by-products in or on the finished food.

This definition of processing aid differs from the one used by the Codex Alimentarius Commission (CAC). The CAC definition does not have a limitation on residue levels and does not refer to affecting the characteristics of the food.[11] These restrictions must be included in the Directorate's definition because a substance is a food additive, under the Canadian regulatory definition of food additive, if use of the substance results in residues in the food or affects the characteristics of the food.

Examples of food additive and processing aid uses

[9] Although the Food Directorate frequently refers to the food quality specifications given in the *Food Chemicals Codex*, "negligible" in the context of identifying food additives and processing aids does not have the same meaning as "negligible" as used in the *Food Chemicals Codex*. Also, the Food Directorate reserves the right to determine what constitutes negligible on a case-by-case basis, with consideration given to previous decisions to ensure consistency.

[10] Examples of these measures are: (1) use of the substance early in food processing where subsequent processing reduces or removes residues; (2) trimming beef carcasses or rinsing them with potable water such that residues of a sanitizing chemical, sprayed on the carcass, are eliminated from the finished retail meat cuts; (3) use of immobilizing agents (for example, to immobilize enzymes); and (4) extraction solvent removal.

[11] The definition in the *Codex Alimentarius Commission Procedural Manual* is: "***Processing aid*** means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product." *Codex Alimentarius Commission Procedural Manual*, Seventeenth edition, pp 41-42. Accessible at http://www.codexalimentarius.net/web/procedural_manual.jsp

The following examples show how the decision tree and the principles outlined in this policy can be used to identify food additive and processing aid uses of substances. The examples are for illustration purposes only and should not be taken as the Food Directorate's "approval" of these substances for the uses mentioned. It is recommended that the Directorate be consulted about uses of substances that are not addressed by provisions in the *Food and Drug Regulations*.

Antimicrobial substances for use on meat or poultry

Antimicrobial substances for use on meat or poultry are not on the list of exclusions in the regulatory definition of food additive. These substances are either processing aids or food additives.

Treatments that result in a one-time reduction in the microbial load of meat or poultry but do not have an ongoing antimicrobial effect are not considered to affect the characteristics of the meat or poultry. An antimicrobial substance that exerts such a reduction (and does not exert any other technical effect) will be identified as a food additive or processing aid depending on the residue(s) of the substance and/or its by-products that remain(s) in/on the finished food product.

The stage in meat or poultry processing at which this type of antimicrobial substance is applied does not generally determine whether the substance is a food additive or a processing aid. For example, the substance can be used as a carcass rinse early in processing or as a treatment applied to final meat or poultry cuts. The substance will be a processing aid in accordance with this policy if there are no or negligible residues of the antimicrobial substance or its by-products remaining in/on the finished food.

Note that an antimicrobial substance that results in the addition of water to meat or poultry meat may be ineligible to be a processing aid because the addition of water may be considered to be an effect on the characteristics of the food. But regardless of whether the antimicrobial substance is a processing aid or a food additive, any addition of water resulting from use of the substance must not cause the minimum meat protein requirement for the finished food product to be violated, where such a requirement exists. There may also be labeling requirements for meat or poultry meat to which water has been added in this manner.[12]

Antifoaming Agents

Antifoaming agents can also be food additives or processing aids depending on the context of use.

The antifoaming agent dimethylpolysiloxane (DMPS) is not on the list of exclusions in

[12] Enquiries about labeling and other requirements for meat and poultry should be directed to the Canadian Food Inspection Agency (CFIA). Contact information for the CFIA's Area and Regional Offices can be found at http://www.inspection.gc.ca/english/directory/offbure.shtml

the regulatory definition of food additive. It is either a processing aid or a food additive. If, for example, DMPS were to be used to prevent foaming in the water used to process potatoes, then the technical effect is considered to be on the water, not the potatoes. If there are no or negligible residues of the DMPS on the finished potato product then the DMPS can be considered to be a processing aid.

However, DMPS would be a food additive when added directly to a jam or jelly, a fruit or vegetable juice, a lecithin- or vegetable oil-based pan spray, or to any other food for which, in the final filling stage, foaming could occur. A food additive provision in Table VIII, Division 16 of the *Food and Drug Regulations* would be required for any of these uses. If the Regulations contain a standard of identity and composition for the food in question, the standard would also need to provide for DMPS to be present in the food.

Adsorbents and ion exchange resins

Adsorbents and ion exchange resins are not listed with the substances excluded from the meaning of food additive. In general, deliberate removal of undesirable substances from food, whether by use of these agents or a filtration process, is not considered to be an effect on the characteristics of the food. Provided there are no or negligible residues of the adsorbent or ion exchange resin in the finished food, and use of the agent does not deleteriously affect the food (for example, by substantially altering nutrient profiles), these agents would be considered to be processing aids.[13]

Fining agents

Fining agents are not on the list of exclusions in the regulatory definition of food additive. The technical effect of a fining agent is consistent with that of a processing aid. However, whether a fining agent is a processing aid or a food additive depends on the residue(s) of the agent in the finished beverage.

The standards of identity and composition for certain alcoholic beverages list which fining agents are permitted for use in manufacturing those beverages.[14] Also, some fining agents are listed with food additives in Table VIII, Division 16 of the Regulations and must be used within their Table VIII provision.

Enzymes

Historically in Canada, the use of most enzymes in food has been regulated by a listing of the enzyme in Table V, Division 16 of the Regulations, and by provision in the standard of identity and composition for the food (where a standard exists). However, for certain uses enzymes may be more consistent with the Directorate's definition of a processing aid than with the regulatory definition of a food additive. Examples might include the use of an enzyme in the

[13] Note that the standard for wine in section B.02.100, Division 2 of the Regulations, specifies two types of ion exchange resin that may be used to treat wine prior to final filtration.

[14] See, for example, the standards for wine (section B.02.100), honey wine (section B.02.106), cider (B.02.120) and beer (B.02.130) in Division 2 of the Regulations.

production of a food ingredient derived from starch, or to assist with extracting juice from fruit, or to facilitate the mashing process in manufacturing a distilled beverage.

Modified atmosphere packaging (MAP) systems

A reactive gas that can interact with a food constituent is an example of a substance that is considered to be a food additive because of the technical effect on the food, even if there is no residue of the gas in or on the finished food. The gas affects the characteristics of the food such that the finished food that is offered to the consumer is not in the same state it would have been if the gas had not been used.

The use of such a system must not lead to a violation of section 5, part I of the *Food and Drugs Act*. This section prohibits packaging, treating or processing a food in a manner that is likely to create an erroneous impression regarding the character of the food. It is recommended that consultation with the Food Directorate occur prior to using MAP systems.

The seller of a food is responsible for offering for sale a safe food

The sale of all foods in Canada is subject to section 4, part I of the *Food and Drugs Act*.[15] The use of a food processing aid, like all substances used in manufacturing food, must not lead to a violation of this section. The Food Directorate requires, based on section 4, that a processing aid be of suitable food-grade quality and safe for its intended use. This means the processing aid meets suitable food-grade specifications, and the manner in which the processing aid is used does not lead to toxicological, nutritional, microbiological, or other safety concerns.

Labelling for Processing Aids

Processing aids fall outside the regulatory definitions of "food additive" and food "ingredient".[16] As a result, processing aids are not required under the *Food and Drug Regulations* to be declared on prepackaged food labels.[17] Processing aids differ from food additives and food ingredients in that they are not present in the finished food, or are present in a negligible amount.

Letters of Opinion

[15] See footnote 5 on page 4.

[16] Section B.01.001 of the Regulations states: "'ingredient' means an individual unit of food that is combined as an individual unit of food with one or more other individual units of food to form an integral unit of food that is sold as a prepackaged product".

[17] The requirement to declare ingredients, including food additives, is in section B.01.008 of the Regulations.

Food additives currently permitted in Canada are listed in the tables of Division 16 in the Regulations or are enabled for use through the issuance of an Interim Marketing Authorization (IMA).[18] A petitioner can request amendment of the Regulations to enable the use of an additive for which provision does not presently exist. For guidance on how to make this type of request, please see *A Guide for the Preparation of Submissions on Food Additives*.[19]

At the time of developing this document, Health Canada did not maintain a list of all food processing aids for which it has issued a positive letter of opinion although work to develop such lists for certain types of processing aids was under consideration. As a service and upon request, the Food Directorate's Bureau of Chemical Safety will conduct a pre-market assessment and offer advisory comments on the status of a substance as a food additive or a processing aid, and its acceptability for use in food manufacturing or processing.

The assessment is based on a case-by-case consideration of the unique circumstances surrounding the use of the substance. The substance is considered to be a food additive or a processing aid in accordance with this policy, regardless of how the substance may have been classified in the past, except where use of the specific substance has already been enabled by the Regulations. In cases where the status of a substance is not clear under this policy, the decision regarding status rests with the Food Directorate.[20]

Petitioners who request a letter of opinion should provide information that adequately demonstrates the substance should be considered to be a processing aid in accordance with this policy. It is recommended that the information include analytical data for residues of the substance in the finished food, when the food has been prepared with and without the substance.

Petitioners who receive a letter of opinion expressing no objection may present the letter to prospective customers or others at the petitioner's discretion. However, a letter of no objection does not constitute an "approval" of the product under the Act and Regulations. It is simply an advisory opinion expressed by the Food Directorate at a given point-in-time on the acceptability of the product, based on the information available and provided at that time. Such a letter does not relieve the food seller of responsibility under section 4 of the Act or applicable regulations. Opinions issued by the Directorate are based on particular contexts of use and

[18] A food additive for which an IMA has been issued is permitted for use in the interim period between the decision to enable its use and the registration and final publication in the Canada Gazette of the enabling regulation(s). IMAs are listed at the following website: http://www.hc-sc.gc.ca/fn-an/legislation/ima-amp/index-eng.php

[19] http://www.hc-sc.gc.ca/fn-an/pubs/guide-eng.php

[20] The Bureau of Chemical Safety will submit the case to the Food Rulings Committee for consideration. The Food Rulings Committee is a senior management committee that serves as an advisory body to the Director General of the Food Directorate.

typically include conditions under which the Directorate takes no objection.

Alignment with the Regulatory Modernization Strategy for Food and Nutrition[21]

Adoption of this policy for differentiating food additives and processing aids is expected to relieve some of the longstanding pressure associated with the regulatory accommodation of food additives since any substance that can be handled as a processing aid will not require a regulatory amendment or an IMA prior to use. This specifically addresses, in part, one of the objectives under Health Canada's goal of "*Improving Predictability, Effectiveness, Efficiency, and Transparency in Health Canada's Food Regulatory System*".

For further information

Questions and comments concerning this document, and requests for Letters of Opinion, can be addressed to:

Chief
Chemical Health Hazard Assessment Division
Bureau of Chemical Safety, Food Directorate
Health Products and Food Branch
Health Canada
Address Locator: 2201C
Sir Frederick G. Banting Research Centre
251 Sir Frederick Banting Driveway
Ottawa, Ontario
K1A 0K9

They can also be sent electronically to the Bureau of Chemical Safety (bcs-bipc@hc-sc.gc.ca). Please include "Questions or comments on policy document" or "Request for letter of opinion", as applicable, in the email subject line.

[21] *Towards a Regulatory Modernization Strategy for Food and Nutrition*
http://www.hc-sc.gc.ca/fn-an/consultation/blueprint_food-plan_aliments/rmsfn-smran-eng.php