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Guidance Document – The Use of Probiotic Microorganisms in Food

Food Directorate
Health Products and Food Branch
Health Canada

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Canada

I. Introduction

Purpose

1. The purpose of this Guidance Document is to clarify the acceptable use of health claims about microorganisms represented as “probiotics” on food labels and in advertising.

It also provides guidance on the safety, quality (stability) and labelling aspects of food products containing probiotic microorganisms.

This Guidance Document will be used by the Canadian Food Inspection Agency (CFIA) to administer and assess compliance of food products containing probiotic microorganisms with the *Food and Drugs Act* and with the food provisions of the *Food and Drug Regulations*.

Terms

2. In this Guidance Document,

Health claim means any representation in labelling or advertising that states, suggests, or implies that a relationship exists between consumption of a food or food constituent (including an ingredient in the food) and a person’s health.

Function claims are health claims that describe the physiological effects of foods or food constituents on normal functions or biological activities of the body associated with health or performance.

Therapeutic claims are claims that would bring a food into the definition of a drug or a natural health product (drug claims). These are claims about the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans, or restoring or correcting organic functions in humans, or modifying organic functions in humans. Products that carry such claims are considered to be represented for “therapeutic use”.

Scope

3. This Guidance Document applies to products that are manufactured, sold, or represented for use as food as defined in Section 2 of the *Food and Drugs Act*.

It should be read together with applicable provisions of the *Food and Drugs Act* and its regulations and all other legislation and regulations applicable to food, as well as their associated policies and guidelines. Manufacturers are responsible for compliance with all relevant food legislation and regulations and for the accuracy of all information on the labels and in advertisements of their products.

4. This Guidance Document does not apply to natural health products (NHPs) - whether in a food format or not¹ - containing probiotic microorganisms. A product in food format is generally classified as an NHP when a probiotic microorganism in the product is represented as having a therapeutic use. Such a product is governed by the *Natural Health Product Regulations*. Refer to the Guidance Document “*Classification of Products at the Food-Natural Health Product Interface: Products in Food Format*” (<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php>).
5. However, therapeutic claims that would otherwise bring a food product into the definition of an NHP or a drug may be made for a food if the *Food and Drug Regulations* are amended to permit the claim. See section III of this Guidance Document for information on how to make a submission for such a regulatory amendment.

II. Health claims about probiotic microorganisms in food

6. Health claims made in respect of probiotic microorganisms in food² are subject to Subsection 5(1) of the *Food and Drugs Act* and should be scientifically validated. Subsection 5(1) of the *Food and Drugs Act* states as follows:

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

The following paragraphs in section II provide guidance in complying with Subsection 5(1) of the *Food and Drugs Act*.

“Probiotic” and similar terms

7. The term “probiotics” and similar terms or representations (e.g. “with beneficial probiotic cultures”; “contains bacteria that are essential to a healthy system”; and a Latin name of a microbial species modified to suggest a health benefit) in text or graphics on food

¹ A product is in food format if it is sold in a format and serving size consistent with food use. Examples of products in a food format include chewing gums, hard candies, candy bars, tea, juices and beverages. Capsules, pills and tablets are considered non-food formats.

² According to the Expert Consultation (2001) conducted by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), probiotics are: “Live microorganisms which when administered in adequate amounts confer a health benefit on the host.” In the case of foods, the FAO/WHO Expert Consultation limited the scope of the definition to: “Live microorganisms which when consumed in adequate amounts as part of food confer a health benefit on the host”.

labels and in advertising that suggest a food confers a health benefit are examples³ of health claims.

8. It is recommended that the term “probiotic(s)” and similar terms or representations described in paragraph 7 only be used when accompanied by specific, validated statements on the benefits or effects of the probiotic microorganism contained in the food. This will also provide more information to the consumer about the expected benefit.

Acceptable Use of Function claims

9. Function claims may be made about the physiological effects of probiotic microorganisms in foods. (e.g. “promotes regularity” and “improves nutrient absorption and aids in digestion”).
10. A function claim is limited to a role in maintaining or supporting the functions of the body associated with good health or performance.
11. Acceptable function claims are those that state a specific and scientifically supported physiological effect associated with good health or performance. Claims about a specific effect provide more useful information for the consumer.
12. Further, claims that state a general effect (e.g. improves gut health; supports immune function/system) are not recommended. A broad, non-specific claim is acceptable only for the generally recognized role for energy and essential nutrients in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

Validation of claims

13. A health claim may be less likely to be interpreted as contravening Subsection 5(1) of the *Food and Drugs Act* when it is scientifically supported as follows:
 - (a) A systematic review of the relevant scientific evidence is used to support the claimed or implied effects of each of the probiotic strain(s) at their claimed intake levels; and
 - (b) When evidence from markers is used to support the claimed or implied health benefit, the markers should be recognized as being valid and biologically relevant to the claim being made.

For example, function claims (e.g. promotes normal transit time) on foods are not considered to be scientifically supported when the evidence is based only on therapeutic (treatment) effects in sick populations (e.g. treatment of diarrhea).

³ The claims provided as the examples in this document are for illustrative purposes only and are not necessarily acceptable or valid claims.

14. The *Guidance Document for Preparing a Submission for Food Health Claims* (http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allégations-santé-eng.php) should be consulted. It provides current guidance for identifying and evaluating the available evidence and the validity of claims.

Publication of validated claims

15. The Food Directorate may, on request, provide advice regarding the acceptability of function claims prior to their use. Advice that a particular claim is scientifically supported will be made publicly available through a strain-specific list of acceptable function claims for probiotic microorganisms in foods. The CFIA will include the list in the *CFIA Guide to Food Labelling and Advertising* (<http://www.inspection.gc.ca/english/fssa/labeti/guide/tab8e.shtml>).

Labelling of foods for which health claims for probiotics are made

16. The following apply to the labelling of foods for which health claims about probiotics are made.
- (a) The term “probiotic(s)” and similar terms or representations should be accompanied by a statement of the demonstrated effect of the probiotic;
 - (b) The claimed effect of the probiotic microorganism in a food should be clearly stated in a manner that is not false, misleading, deceptive, or likely to create an erroneous impression with respect to the effect of or benefit from the probiotic microorganism(s) in the food;
 - (c) Where a health claim is made, the Latin name (i.e., genus and species) and the strain of the probiotic microorganism or mixed culture that is the subject of the claim should be declared;
 - (d) The level of the probiotic strain expressed in colony forming units (cfu) in a serving of stated size of the food should be declared; and
 - (e) If more than one probiotic strain is added to a food, the above recommendations apply to the mixed culture.

III. Representations about therapeutic use expressly permitted in Part B of the Food and Drug Regulations

17. Certain representations about therapeutic use, including drug claims, that would bring the food within the definition of an NHP or drug and therefore classified as an NHP or drug may be permitted in the *Food and Drug Regulations* (B.01.601 to B.01.603). These regulations expressly permit such claims to be made in relation to foods by

exempting those foods from the provisions of the *Food and Drugs Act* and its regulations with respect to drugs and from the advertising prohibitions in Section 3 of the *Food and Drugs Act*. To seek additional or new claims of this type to be made for a food, manufacturers must make a submission to the Food Directorate that proposes a regulatory amendment to the *Food and Drug Regulations* to permit the claim.

18. For Health Canada to consider such a proposed regulatory amendment, scientific evidence acceptable to Health Canada that supports the claimed effect must be submitted. The *Guidance Document for Preparing a Submission for Food Health Claims* (http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allégations-santé-eng.php), also referenced in paragraph 14, is available to assist persons wishing to prepare such submissions.

IV. Safety of probiotic microorganisms contained in foods

19. It is the responsibility of the food manufacturer to ensure that the food or food ingredients produced are not unsafe. Section 4 of the *Food and Drugs Act* provides as follows:

“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.”

20. Live bacterial cultures added to foods are food ingredients under the food provisions of the *Food and Drug Regulations*. If the culture(s) does not have a history of safe use in foods, or the strain is genetically modified, or otherwise falls within the definition of a novel food under Division 28 of Part B of the *Food and Drug Regulations* (see endnote 1), it would be subject to the requirements set out in that Division.
21. Food manufacturers interested in using novel technology (e.g. microencapsulation) to help deliver a viable microorganism in food are advised to contact the Food Directorate prior to commercialization or marketing to discuss whether the use of the technology for food application would meet the definition of novel food.
22. If food additives are used in the manufacture of the encapsulation material (such as enzymes), they must comply with Division 16 of the *Food and Drug Regulations*.
23. Common microorganisms claimed to be probiotic include bacteria belonging to a group broadly defined as lactic acid bacteria (LAB) and to the genus *Bifidobacterium*. Even though many species of LAB and *Bifidobacterium* are commonly used in various food

applications, it is well recognized that these species may also be resistant to various antibiotics and could be a potential reservoir of antimicrobial resistance. When using these species as a probiotic, the food manufacturer must ensure that the strain proposed for use does not pose a significant risk with regards to transferable antimicrobial resistance. The Food Directorate will require this information if it is to provide an opinion on the safety of the strain used.

V. Stability of probiotic microorganisms contained in foods

24. The food manufacturer is responsible for the stability and viability of the probiotic strain or mixed-culture in the food product so that the product delivers the declared level in a serving of stated size throughout product shelf life. Documentation to support these quality aspects of the product should be maintained.

VI. Contact information

The following types of inquiry may be directed to the Food Directorate of Health Canada.

Questions about health claim substantiation:

Nutrition Evaluation Division

E-mail: healthclaims-allegationssante@hc-sc.gc.ca

Questions about novel foods:

Novel Foods Section

Food Directorate, Health Products and Food Branch

Health Canada

251, Sir Frederick Banting Driveway

Postal Locator: 2204E

Ottawa, Ontario K1A 0K9

Submissions related to novel food or health claims:

Submission Management and Information Unit

E-mail: smiu-ugdi@hc-sc.gc.ca

Tel : 613-960-0552

Fax : 613-946-4590

Mailing address:

Food Directorate, Health Products and Food Branch

Health Canada

251, Sir Frederick Banting Driveway

Postal Locator: 2202E

Ottawa, Ontario K1A 0K9

Questions about compliance with this Guidance Document and with other applicable food legislation and associated regulations may be directed to the Canadian Food Inspection Agency.

Consumer Protection Division
Canadian Food Inspection Agency
1400 Merivale Road, Tower 2
Ottawa, Ontario
K1A 0Y9

<http://www.inspection.gc.ca/english/tools/feedback/commene.shtml>

Endnotes

1. 'Novel food' means
 - (a) a substance, including a microorganism, that does not have a history of safe use as a food;
 - (b) a food that has been manufactured, prepared, preserved or packaged by a process that:
 - (i) has not been previously applied to that food, and
 - (ii) causes the food to undergo a major change; and
 - (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
 - (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
 - (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
 - (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

References

FAO/WHO. 2001. Health and nutritional properties of probiotics in food including powder milk with live lactic acid bacteria. Report of a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food Including Powder Milk with Live Lactic Acid Bacteria. Córdoba, Argentina, October 1-4, 2001.

FAO/WHO. 2002. Guidelines for the evaluation of probiotics in food. Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, April 30 - May 1, 2002.