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General Guidance Document for Temporary Marketing Authorization for Foods

May 2013

Food Directorate

Health Products and Food Branch

Canada

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1.0 Introduction

1.1 Purpose

The purpose of this guidance document is to help explain when a Temporary Marketing Authorization (TMA) may be granted by Health Canada for a food and how to prepare a complete submission that fulfills TMA requirements.

Scope

This document provides general guidance for those seeking a TMA for a food. In some circumstances a food category may be eligible for a TMA and separate guidance documents will be published outlining specific criteria and other requirements for these categories of food. Manufacturers or distributors of these foods are directed to these category specific guidance documents.

1.2 What is a Temporary Marketing Authorization (TMA)?

Foods sold in Canada must meet the requirements set out in the *Food and Drugs Act* (FDA) and the *Food and Drug Regulations* (FDR) as they pertain to foods. To permit sale of a food that does not meet the FDR normally requires a regulatory amendment. When applying for an amendment to the FDR, the manufacturer or distributor must provide the information necessary to support the specifics of the change which may include, evidence concerning the safety of the food, the rational for and the suitability of any proposed labelling where these involve a variation from provisions of the FDR.

However, in some specific cases Health Canada (the Department) may allow a non compliant food to be sold before the regulatory amendments are made. There are two key tools in the FDR that can be used to permit this: Temporary Marketing Authorization (TMA) and Interim Marketing Authorization (IMA). These tools are designed for different purposes and for different situations.

> TMA: Sections B.01.054 and B.01.055 of the FDR make provision for the issuance of a Temporary Marketing Authorization Letter (TMAL) for the purpose of generating information in support of an amendment to the FDR.
>
> IMA: Section 30.2 of the *Food and Drugs Act* and section B.01.056 of the FDR provide the authority for Interim Marketing Authorizations (IMA) allowing the sale of a food not in compliance with the Regulations, in a limited set of circumstances, to be marketed while an amendment to permit its ongoing legal sale is being processed.

The possible need for a TMA may arise during the evaluation of a submission for amending the FDR, or during presubmission discussions with industry. At this time, the Department may determine that there are gaps in the information needed to finalize the proposed regulatory amendments that would allow the sale of a food or a food category. If (a) a scientific risk

assessment has determined that the food(s) does not pose a risk to the health of the consumer and (b) the missing information cannot be obtained without real world marketing of the food, then a food or food category may be granted approval to market temporarily and under specified conditions in order to collect this information through a TMA. The information would then be used to propose a regulatory amendment to the Governor in Council through the existing regulation-making processes.

Since the purpose of a TMA is to gather specific data, the manufacturer or distributor is required to gather such data in a manner agreed upon with Health Canada in advance, and to submit the data to Health Canada within a specified period of time. See section 2.3 of this guidance for more information.

In order to obtain a TMA, a manufacturer or distributor must provide the requested information and sign a Letter of Agreement. This Letter of Agreement becomes part of the TMAL, and demonstrates that the manufacturer or distributor has agreed to the terms and conditions including withdrawing the food if asked by Health Canada. See section 1.3.4 for more details.

A TMAL is issued to a manufacturer or distributor for a specific food formulation, and specifies the restrictions and conditions of the TMA as stated in subsection B.01.054(2) of the FDR.

If a petitioner wishes to make a change to the conditions of a TMAL after it has been issued, Health Canada would need to agree on the change and an amendment to the TMAL would be required.

The TMAL is not a tool for test marketing. For information regarding test marketing, consult the Canadian Food Inspection Agency (CFIA) web site or contact the CFIA at:

Director, Consumer Protection
Canadian Food Inspection Agency
1400 Merivale Road
Ottawa, Ontario, K1A 0Y9

Examples of TMALs that Have Previously Been Issued

TMALs are a regulatory instrument that has been used in the past by Health Canada in the following examples:

- Use of Omega-3 nutrition claims (prior to amendments to the FDR to allow “source of Omega-3” claims)
- Addition of calcium and vitamin D to orange juice – to gather data on consumer understanding of the message "specially designed as a source of calcium for people who do not drink milk" on the label, prior to issuance of an IMA for the addition of calcium and vitamin D to orange juice.

TMAs and Food Additives

In the case of food additives, food manufacturers or distributors must use the food additive submission process established in section B.16.002 of the FDR to request that a new additive or a new use of a permitted additive be enabled. When reviewing the food additive submission, Health Canada may identify additional non-safety data that are required but can only be obtained from testing the additive under actual market conditions. In such a case, in order to obtain the data, Health Canada may authorize the limited sale of the food containing the additive via a TMA. For example, a TMA might be granted for a non-permitted food preservative because the effectiveness must be tested under real-world distribution and market conditions that cannot easily be reproduced in the laboratory. In this case, the TMAL is issued to test the efficacy of the preservative. The TMAL for this purpose is only issued once Health Canada has received a food additive submission and has determined that the food containing the additive will be safe to consume (in accordance with subparagraph B.01.054 (1)(a)(iv)).

1.3 Process for Obtaining a TMA

As noted above, the possible need for a TMA may arise during the evaluation of a submission for amending the FDR, or during presubmission discussions with industry. This section describes the process for obtaining a TMA once it has been determined by the Department that a TMA is appropriate.

1.3.1 How to Prepare a TMA Submission

The petitioner must submit all information requested by the Department and required under section B.01.054 of the FDR. Petitioners should follow the guidelines in section 2.0 below (as well as the specific guidance document for the food category if one exists) to understand what information is needed when preparing their submissions.

In order for Health Canada to process TMA submissions in an efficient manner, complete information should be provided, as outlined in this guidance document. The submission should be concise and include only information relevant to the request for the TMA. Upon receipt of the submission, Health Canada will conduct an initial screening to ensure it is complete. Should information be missing, the petitioner will be notified and the review process will be stopped. It will be re-initiated only once all the necessary information has been provided to Health Canada.

Petitioners are encouraged to organize their submissions as follows:

- Pagination should be sequential for the entire submission.
- Paper copies should be bound or organized in a binder.
- The petitioner's identification (e.g., company names) should be included on all pages.
- Information must be in English or French. Relevant material in other languages must be translated into English or French by petitioners.
- Petitioners are responsible for clearly indicating which information is proprietary or confidential.
- The application must be signed by the person responsible for the submission.

1.3.2 Delivery of the Submission to Health Canada

Three hard copies of the required TMA submission must be forwarded by mail to the address below:
Submission Management and Information Unit
Food Directorate
Health Products and Food Branch, Health Canada
251 Sir Frederick Banting Driveway
Postal Locator 2202E
Ottawa, Ontario, Canada, K1A 0K9

Submissions of less than 20 pages may be sent electronically in Microsoft or PDF format by e-mail to the following address: smiu-ugdi@hc-sc.gc.ca. Please use the words "Temporary Marketing Authorization (TMA) application" in the subject line.

1.3.3 Contact for Questions / Presubmission Meeting

Should there be any questions regarding TMAs or a specific potential need for TMA, please email "smiu-ugdi@hc-sc.gc.ca" or contact the address indicated above.

Petitioners are encouraged to arrange a presubmission consultation with the Food Directorate to discuss any potential issues and questions before submitting a TMA application. To do this they should contact the Submission Management and Information Unit (SMIU), see information above. The petitioner can seek further guidance on the information requirements to ensure that a complete submission is filed at the outset, potentially reducing the number of requests to the petitioner for clarification or additional information. During these meetings the time period and duration of the proposed TMA and the research protocol can be discussed.

1.3.4 TMA Package: Letter of Agreement and TMAL

Once Health Canada completes its assessment of a TMA-submission and is satisfied that the application meets all the requirements of a TMA, including that the food will not pose a risk to the health of consumers, a Letter of Agreement is drafted and sent to the petitioner for signature. Within this agreement, the petitioner agrees to the conditions found in paragraph B.01.054(1)(b) of the FDR, in other words:

i. Describe the food on a label or in an advertisement in a manner that is not false, misleading or deceptive;
ii. Use such marks or statements on the label or in any advertisement as Health Canada may require;
iii. On request, submit to Health Canada, the results of the data gathering conducted during the temporary marketing; and
iv. On request, withdraw the food from sale where Health Canada is of the opinion that it is in the public interest to do so.

Once the signed Letter of Agreement is received by Health Canada, a TMAL will be issued to the petitioner. The TMAL, along with the Letter of Agreement will specify the following information:

(a) The common name and description of the food to be sold;
(b) The name and address of the manufacturer or distributor of the food;
(c) The purpose for which the temporary marketing of the food is authorized;
(d) The quantity of the food that is authorized for sale;
(d.1) The type of packaging, labelling or advertising authorized with respect to the food where the Letter is intended to authorize a variation from a requirement of any provision of the Regulations respecting packaging, labelling or advertising;
(e) The period of time during which the food may be sold; and
(f) The designated area within which the food may be sold.

The petitioner will receive a TMA package which includes the TMAL signed by Health Canada and a copy of the Letter of Agreement. In order to be transparent, Health Canada intends to post on its website a list of all foods that have been issued a TMAL. The relevant information will be provided to the Canadian Food Inspection Agency to assist with compliance and enforcement activities.

1.3.5 Results of Temporary Marketing Research

The purpose of the TMA is to allow the marketing of a food so that specific data can be gathered as needed by Health Canada to finalize an amendment to the FDR. These are data that can only be obtained under actual market conditions**.** For example, depending on the specific amendment(s), data may be gathered on the effectiveness of a proposed label or advertising in ensuring that the food reaches the intended target population. Data may also be gathered on food consumption or use patterns to better estimate intake of certain ingredients such as added vitamins and minerals that are the subject of the TMA. As required under subparagraph B.01.054(1)(b)(iii) of the FDR, the petitioner must submit to Health Canada the data collected within the time period set out in the TMAL (see section 2.3 for further information on the type of data that may be requested to be collected). The information gathered will enable Health Canada to complete its assessment and refine various components related to the final regulatory decisions (for example, formulation, labelling requirements, etc.).

1.3.6 End of the TMA

Upon analysis of the data gathered through the research process, the Department will work to finalize its regulatory decisions pertaining to the food or category of food. It is important to note that the specific requirements in the final proposed regulation(s) may be different from the specifications in the TMAL. Manufacturers or distributors will need to be in compliance with the final regulation(s) when it comes into force.

2.0 Information Requirements

This section outlines mandatory requirements for a complete submission. The Temporary Marketing Authorization Submission Form provided in the appendix should be used to help ensure the submission is complete and to support an efficient and timely review of the application. A fillable PDF version of the form is available upon request by contacting smiu-ugdi@hc-sc.gc.ca .

2.1 Contact Information for the Manufacturer or Distributor *(Part A of TMA Form)*

The TMA submission should include the name and address of the principal place of business of the manufacturer or distributor and, if the address is outside Canada, the name and address of the principal place of business of the importer. Please include a telephone number with extension if applicable, a fax number and email address for all contacts listed within the submission.

2.2 Requirements under B.01.054 FDR *(Part B of TMA Form)*

2.2.1 The Purpose for which the TMA is Requested [B.01.054(1)(a)(i) FDR]

The submission must include an indication of the type of amendment to the FDR that is considered necessary (for example, an amendment that would permit an added vitamin not currently permitted and indicating the sections to be amended, if known) and the reason why information and/or data gaps must be addressed through marketing before an amendment can be made. A description of the nature of the data gaps should also be included, where possible. The needed information can be clarified during presubmission discussions with Health Canada's Food Directorate officials.

2.2.2 The Description of the Food Including a Sample and Proposed Label [B.01.054(1)(a)(ii) FDR]

A description of the food and its ingredients must be provided. This should include information such as the following:

A. A list of all ingredients in the food, and their components, stated quantitatively per serving of stated size and container size. For herbal ingredients with an intended physiological effect, a description and specifications must be provided with detailed information to confirm the identity, potency, purpose and purity of the ingredient.
B. Maximum number of container(s)/serving(s) not to be exceeded per day, if applicable.
C. The format of the food (for example, beverage, bar, powder, etc).
D. The intended target population(s), if any.
E. Proposed nutrient content claims associated with the food where the labelling or claims proposed involve a variation from a requirement of the FDR respecting the labelling or advertising or claims as well as the amount per stated serving size of the nutrient associated with the claim.
F. Any suggested statements that may inform and mitigate risks to consumers, where applicable.

A copy of the proposed label must be provided with the submission. This label should include all required label information, including a complete Nutrition Facts table, allergen labelling (in effect August 2012), and ingredients, as well as proposed voluntary information. Once the wording has been reviewed by Health Canada, a copy of the final label, or a "mock-up" of the label must be provided before a TMAL will be issued.

While a copy of the label must be provided to Health Canada, it is the responsibility of the manufacturer or distributor to ensure that the label is compliant with the relevant provisions in the Act and Regulations.

2.2.3 A Description of any Proposed Variation from the Requirements of the Food and Drug Regulations [B.01.054(1)(a)(iii) FDR]

A description of how the proposed food is not compliant with the FDR must be provided. For example, the description should indicate whether the food varies from current labelling requirements, or contains added nutrients outside of current food fortification provisions. Specific sections of the FDR with which the food does not comply should be identified. The proposed variation described in this section of the submission must be consistent with the proposed purpose of the TMA (see section 2.2.1 of this document or subparagraph B.01.054(1)(a)(i) of the FDR).

2.2.4 Adequate Data to Show that the Use of the Food will not be Detrimental to the Health of the Purchaser or User [B.01.054(1)(a)(iv) FDR]

The safety of the proposed food and/or its ingredient(s) must be demonstrated. Any novel foods or food additives that are included in the food must have undergone the premarket notification and approval process required under Division 28 or 16 of the FDR, respectively, before submission of the TMA request. However, some exceptions may be made where Health Canada has determined the safety of specific food ingredients included in certain food categories covered by TMAs.

As an example, where the TMA is required to support an amendment for the addition of a vitamin or mineral, information must be included to support the safety of the proposed level of addition. The types and quality of information provided should be sufficient to support safety (for example, information from the Institute of Medicine of the National Academies, peer-reviewed published articles, information on interactions), and would include information on estimated intakes. Documents such as scientific abstracts, newspaper and magazines articles, and website material are not considered appropriate references. A statement of the nutritional or health purpose for the addition is requested, where applicable.

2.2.5 The Proposed Quantity of Food to be Sold [B.01.054(1)(a)(v) FDR]

The proposed quantity of food to be sold in Canada, within the proposed time period for the TMA must be provided. For example, 10,000 units of 355 ml cans over a one year TMA. This figure may be revised when the duration of the TMA is determined.

2.2.6 The Proposed Period of Time Required for Such Sale [B.01.054(1)(a)(vi) FDR]

Since the intent of the TMA is to collect data in support of a potential regulatory amendment, a rationale should be submitted for the quantity of food to be sold and the period of time for the TMA. The required period of time for a TMA could be discussed during a presubmission meeting. This period will be dependent on a number of considerations, including but not limited to the time required for the food to gain sufficient market access, the collection of data, the analysis of data by the petitioner, submission of this data to Health Canada, the analysis of data by Health Canada, and the time required for Health Canada to decide whether and how to proceed with a regulatory amendment related to these products.

2.2.7 The Proposed Area Designated for Such Sale [B.01.054(1)(a)(vii) FDR]

The geographic region, for example, national or the provinces and/or territories, where the food will be sold within Canada must be provided.

2.3 Research to Be Conducted During the TMA

The TMA submission must provide details of the research to be conducted during the temporary marketing period, including protocols for the proposed studies, a clear statement of the objective and intended outcome, and details of the methodology that will be used to conduct the study and analyze the data.

It is recommended that petitioners contact Health Canada's Food Directorate for a presubmission consultation to discuss the proposed research to ensure that the type of research is appropriate for their food and will provide the desired data in order to move forward with a regulatory amendment.

The data collected should relate to actual market use of the food - data which is not available other than through the sales and marketing of the food. For example, research on a beverage containing added vitamins and minerals may address questions such as who uses the food (for example, consumption patterns and demographics) and the consumption of vitamin and mineral supplements in addition to the food.

The proposed area designated for the sale of the food indicated in the TMA submission should also be reflected in the data to be collected. For example, a TMA submission requesting national distribution should collect data pertinent to the purpose of the TMA on a national level. The sample size for the research should also be appropriate based on the proposed distribution and should ensure that meaningful results are obtained. A sampling plan should be developed in a manner that will address all these aspects.

2.4 Nutrient Data for Foods under TMAs *(Voluntary)*

Petitioners are strongly encouraged to provide a full nutrient profile for the food for which a TMA is requested that can be included in the Canadian Nutrient File (CNF). This would be especially desirable for foods for which the TMA extends beyond one year and covers a large geographic distribution or all of Canada. The CNF is a computerized, bilingual food composition database containing average values for nutrients in foods available in Canada. This Canadian resource includes levels of fortification and regulatory standards specific to Canada, Canadian only foods, and, where appropriate, some brand name foods. Data in the CNF are recorded per 100 g of the edible portion of the food.

Data could include various nutrients as well as quality control indicators for each nutrient such as limit of detection, limit of quantification, and method information. For further information, please refer to the *Guide to Developing Accurate Nutrient Values* or contact the Food Composition Manager at:

Nutrition Research Division
Sir Frederick G. Banting Research Centre
AL 2203E
251 Sir Frederick Banting Driveway
Ottawa, Ontario K1A 0K9
cnfusers@hc-sc.gc.ca

3.0 Labelling, Advertising and Claims

3.1 Basic Requirements

In general, all requirements for labelling and advertising for food in the *Food and Drugs Act* and Part B of FDR and in the *Consumer Packaging and Labelling Act* and *Regulations* will apply, other than those aspects that are the subject of the TMA. Basic labelling requirements include:

- Common name;
- Net quantity;
- Company name and principal place of business;
- Ingredient list, in descending order by weight;
- Allergen labelling requirement (coming into force in August 2012);
- Nutrition Facts table; and
- Any other information required to be shown on the label (for example, declaration of the presence of a non nutritive sweetener, such as aspartame).

Further information on the food labelling and advertising requirements can be found in the Food Labelling and Advertising section of the Canadian Food Inspection Agency's website.

There may be specific situations where the TMA may exempt the food from some of the FDR labelling requirements.

3.2 Claims

Certain statements may be made on the label or in advertisements for foods on a voluntary basis. When they are made, they must comply with applicable regulations or guidance. All claims are subject to subsection 5(1) of the *Food and Drugs Act* and must not be false, misleading, or deceptive. These statements include:

- Quantitative statements
- Nutrient content claims
- Health claims
- Other claims

3.2.1 Quantitative Statements

As part of the terms and conditions of the TMA, there may be a requirement to provide quantitative labelling for some ingredients, substances or components. Simple quantitative declarations of food ingredients, components, or food constituents may be made on a voluntary basis on a food label provided the information is truthful and not misleading.

Quantitative declarations of non-nutrients may be declared elsewhere on the label outside the Nutrition Facts table. Absolute amounts of vitamins and minerals (for example, milligrams (mg)), other than for sodium and potassium, may only be declared outside the Nutrition Facts table. Voluntary quantitative declarations, when made, should preferably be grouped together with other required quantitative declarations immediately below the Nutrition Facts table or adjacent to the ingredient listing. This will assist consumers in consistently locating quantitative information.

3.2.2 Nutrient Content Claims

Nutrient content claims are statements or expressions which describe, directly or indirectly, the level of a nutrient[1] in a food or a group of foods. Nutrient content claims (for example, sugar-free) are limited to those that are permitted by the FDR (section B.01.503, the table following section B.01.513, subsections D.01.004(1), and D.02.002(1) of the FDR). Only the wording permitted in the regulations may be used. The regulations also prescribe the compositional criteria for each claim and any related additional labelling requirements. The compositional criteria for most of the nutrient content claims are based on regulated standardized "reference amounts" for foods as well as the "serving of stated size" for the particular food. Refer to the Nutrient Content Claims section of the CFIA's website for more information.

[1] The term "nutrient" is not defined in the Food and Drug Regulations for the purposes of food labelling and advertising. Health Canada considers a substance to be a nutrient if it is recognized as such by the Institute of Medicine of the National Academies, Washington, DC.

3.2.3 Health Claims

A **health claim** is any representation in labelling or advertising that states, suggests or implies that a relationship exists between the consumption of a food[2] and health. All health claims are subject to subsection 5(1) of the *Food and Drugs Act*, which prohibits false, misleading or deceptive food representations.

Regulatory requirements vary depending on the type and nature of the claim. For example, under the FDA, claims about the prevention or treatment of diseases and disorders listed in Schedule A are prohibited for foods unless specifically allowed by regulation, whereas permitted claims about nutrient functions are not specified in the FDR but are subject to general requirements set out in the FDR.

Generally, **disease risk reduction claims** are statements that link a food to a reduced risk of developing a diet-related disease or condition in the context of the total diet. For example, "[Naming the food or food constituent] may reduce the risk of cardiovascular disease".

Therapeutic claims refer to the treatment or mitigation of a disease or health-related condition, or about restoring, correcting or modifying body functions. For example, "[Naming the food or food constituent] lowers blood cholesterol".

Health claims about the specific beneficial effects that the consumption of a food or food constituent has on normal functions or biological activities of the body are referred to as **function claims**. Such claims relate to a positive contribution to health or performance. For example, "[naming the food or food constituent] promotes regularity or laxation".

Statements or claims to the effect that a food's energy (Caloric) value or a nutrient contained in the food is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development are a subset of function claims referred to as **nutrient function claims**.

Scientific Substantiation of Health Claims

Detailed information on the substantiation of health claims can be found in the *Guidance Document for Preparing a Submission for Food Health Claims*. These guidance documents are applicable to all food health claims, with the exception of nutrient function claims. Submissions[3] for health claims made on food sold in Canada can be made to the Food Directorate of Health Canada to ensure that claims are adequately substantiated and are compliant with applicable sections of the *Food and Drugs Act* and its associated regulations. Consultation with the Food

[2] The term "food" refers to a food category, a food (whole or processed) or a food constituent, added or inherent.

[3] The term "submission" usually refers to a stand-alone dossier containing all of the information required to substantiate a health claim.

Directorate is encouraged before preparing a health claim submission. See contact information in section 1.3.2.

3.2.4 Other Claims

Examples of other claims include, but are not limited to:

- Healthy
- "Supplement" and variations of this term
- Organic

Trade marks, brand names, logos and slogans are also subject to subsection 5(1) of the *Food and Drugs Act* and subsection 7.1 of the *Consumer Packaging and Labelling Act and Regulations*. Any trade mark, brand name, logo or slogan that suggests or implies a health benefit by any means, including through nuance, double meanings, or implied meanings, is generally considered a health claim. For more information, refer to the Food Labelling and Advertising section on the Canadian Food Inspection Agency's website.

3.3 Planned Advertising

In addition to the proposed food label, information as to the planned advertising and marketing of the food should also be included. The TMA request should indicate the population groups to whom the food will be targeted, if any.

Appendix: Temporary Marketing Authorization Submission Form

The Temporary Marketing Authorization (TMA) Submission Form should be used to help ensure that a TMA submission is complete and to support an efficient and timely review of the application. A fillable PDF version of the form is available upon request by contacting smiu-ugdi@hc-sc.gc.ca .