Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Bureau of Chemical Safety
Food Directorate

Bureau d'innocuité des produits chimiques
Direction des aliments

Priority Scheduling and Expedited Handling of Submissions that have the Capacity to Enhance Food Safety

A PAHO/WHO Collaborating Center for Food Contamination Monitoring

World Health Organization

January 2011

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

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Background

In July 2009, the Government of Canada released a report[1] prepared by an independent investigator, key collaborators, and an expert advisory group, regarding the analysis of the 2008 listeriosis outbreak that occurred in Canada. The purpose of the study was to explore how and why the outbreak occurred, and to make recommendations about how a similar incident could be prevented in the future. Health Canada's Food Directorate is committed to implementation of Recommendation 12 of the report, which states:

> **"Health Canada should review its approval processes and fast track, where appropriate, new food additives and technologies that have the potential to contribute to food safety giving particular attention to those that have been scientifically validated in other jurisdictions (provinces or countries)."**[2]

The substances and technologies that have the potential to contribute to the microbiological safety of foods are encompassed in four principal categories: food additives, food irradiation, novel foods / novel food processes, and food processing aids. Food additives are regulated in Canada under the *Food and Drug Regulations* and associated Marketing Authorizations (MAs). Approved food additives and their permitted conditions of use are set out in the Lists of Permitted Food Additives that are incorporated by reference in the MAs. Health Canada approves food irradiation treatments by amending the *Food and Drug Regulations* (the Regulations). Health Canada also authorizes the sale of novel foods, including foods produced through novel processes, by issuing letters of no objection under Division 28 of the Regulations. All of these pre-market processes require that Health Canada conduct an assessment of the food additive, food irradiation treatment, or novel food / novel food process prior to recommending a regulatory amendment be made or issuing a letter of no objection. As well, Health Canada issues advisory opinions on the use of certain processing aids upon request from, and as a service provided to, the food industry.

The pre-market assessment process for food additives, food irradiation, novel foods / novel food processes, and food processing aids is initiated when Health Canada receives a request from industry and an accompanying information package that can be evaluated by Departmental scientists. Together, the request and information are referred to as either: a *food additive submission*, a *food irradiation submission*, a *novel food submission*, or a *food processing aid submission*.

The pre-market assessment is the first phase of a two-phase approval process for food additives, food irradiation, and novel foods / novel food processes. During the pre-market assessment, Health Canada's Food Directorate evaluates the proposed use of the substance or technology to

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[1] Weatherill, S. *Final Report: Report of the Independent Investigator into the 2008 Listeriosis Outbreak* (Ottawa, Government of Canada: July, 2009) (http://www.listeriosis-listeriose.investigation-enquete.gc.ca/lirs_rpt_e.pdf)
2 Weatherill, 2009, page 41 (emphasis in original)

ensure that the use will not result in an unsafe food. Where necessary, the Directorate also reviews data on the efficacy of the substance or technology.

With respect to food additives, the second phase of the approval process is modification of the Lists of Permitted Food Additives. This follows an established administrative procedure, which always includes public notification on Health Canada's website and, in certain cases, a comment period. The food additive is permitted to be used in or upon food sold in Canada the day on which the Lists of Permitted Food Additives are modified. For food irradiation, the second phase of the approval process is the amendment of the *Food and Drug Regulations* to authorize the use of the irradiation treatment.[3] The food irradiation treatment is permitted in/on food to be sold in Canada when the final regulatory amendments are published in Part II of the *Canada Gazette*.

In the case of a novel food, the second phase of the approval process is the issuance of a letter of no objection, by Health Canada's Food Directorate, authorizing the sale of the novel food. Novel foods that have successfully undergone a safety evaluation may be sold as soon as the Food Directorate issues the letter of no objection.

The Regulations do not require pre-market assessment of most food processing aids.[4] However, Health Canada's Food Directorate will conduct a pre-market safety assessment of processing aids upon request from, and as a service provided to, the food industry. This is done on a case-by-case basis, and will result in the issuance of a letter of opinion expressing no objection for those processing aids that are considered acceptable for use in food manufacture or processing. A letter of opinion is not an approval of the processing aid; rather, it is the Food Directorate's comments concerning the acceptability (from a food safety perspective) of a processing aid for its proposed use(s).

Policy for priority scheduling and expedited handling

To address Recommendation 12 of the independent investigator's report, Health Canada's Food Directorate is implementing a policy for moving eligible food additive submissions, food irradiation submissions, and novel food submissions through the pre-market safety evaluation phase and, where possible, the authorization phase, more quickly. The policy does not abbreviate or compromise the safety evaluation conducted by the Food Directorate. Rather, it is an administrative system for *priority scheduling* and *expedited handling* of eligible submissions.

The policy applies to food additives, food irradiation treatments, and novel foods / novel food processes that have a *demonstrated capacity* to *enhance food safety*. The Directorate will also apply the policy when handling food processing aid submissions if the processing aids have a demonstrated capacity to enhance food safety, although manufacturers are not required under the

3 More correctly, the regulatory amendment(s) authorize(s) the sale of the food that has been irradiated.

4 There are a few processing aids, such as fining agents permitted for use in making wine and beer, that are regulated under the *Food and Drug Regulations* and that may require approval by Health Canada.

Regulations to request the pre-market assessment of a processing aid. This document provides general guidance to industry regarding the information and data required to be provided to Health Canada in order to enable Health Canada scientists to evaluate the public health benefit, and thereby determine whether priority scheduling and expedited handling of a submission should be granted.

Scope

Food safety is a broad term and there could be a number of substances and processes that have the capacity to enhance the safety of foods. However, the independent investigator's report was provided in response to an outbreak of a food-borne pathogenic microorganism. While Health Canada's Food Directorate does not wish to restrict the definition of "enhance food safety", **the initial focus of this policy will be on substances and processes that improve the microbiological safety of foods by reducing or eliminating pathogens.** Health Canada's Food Directorate considers antimicrobial substances and technologies, used in particular on meat, poultry, fish, and fruits and vegetables, to be measures that should be eligible for priority scheduling and expedited handling. The Directorate will consider expanding the scope of the policy on a case-specific basis for substances and processes which could be used to mitigate, for example, a nutritional or chemical health risk.

Definitions

For this policy, the terms *demonstrated capacity*, *enhance food safety*, *expedited handling* and *priority scheduling* are defined below.

Demonstrated capacity means supported by acceptable scientific evidence.

Enhance food safety refers to an appreciable, measurable and statistically-significant improvement in the safety of a food containing, processed with, or processed by a food additive, irradiation, novel food / novel food process or processing aid.

Expedited handling means application, where possible, of accelerated administrative processes or procedural tools, such as priority scheduling, for a submission that is assigned priority.

Priority scheduling refers to moving a submission that has not entered the Food Directorate's evaluation queue ahead of those submissions that do not "enhance food safety". A new eligible priority submission will be placed in the queue after any other submissions that have already been priority-scheduled.

Timelines for priority scheduling and expedited handling of submissions

The Food Directorate's proposed performance standards for the management of food additive submissions and novel food submissions are outlined in the publication *Draft Guidance Document - Management of Pre-market Submissions*.[5] These standards include the timelines that apply to the Verification, Screening, and Review stages of submission evaluation. The main targeted standards are to complete Verification within seven calendar days, Screening within 45 calendar days, and Review of food additive submissions within 90 calendar days and Review of novel food submissions within 45 calendar days.[6]

These performance standards, when implemented, will normally apply only to the management of food additive submissions and novel food submissions, not submissions for processing aids or food irradiation. However, the Food Directorate will apply the timelines to all submissions assigned priority status under the present policy, including submissions for processing aids and food irradiation.

The Directorate will determine a submission's eligibility for priority status during the 45 day Screening period (i.e., within 45 days of receipt of the submission). If the submission is acceptable for Review,[7] the Directorate will issue an Acceptance for Review Letter that will also notify the petitioner whether the submission has been assigned priority status. The Directorate will then evaluate the submission within the 90 day Review period (45 days for novel foods / novel food processes), which begins following issuance of the Acceptance for Review Letter. Priority submissions in the Review period will be evaluated, in queue, ahead of submissions in the same Review period that have not been assigned priority status.

While this policy is intended to reduce the time required for the assessment of substances and technologies that have the potential to enhance food safety, there is still a limit to the rate at which certain processes can proceed. Health Canada's Food Directorate will apply this policy to the evaluation of eligible submissions while maintaining the following three general principles:

1) Health Canada's Food Directorate will remain committed to conducting a rigorous pre-market safety assessment of all submissions to ensure that foods treated with new substances or technologies will be safe for consumption;

2) Health Canada's Food Directorate will continue to operate within the confines of existing regulatory and operational frameworks; and

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[5] The reader is encouraged to refer to the discussion of performance standards set out in the draft guidance document, which is available at: http://www.hc-sc.gc.ca/fn-an/consult/blueprint_food-plan_aliments/pre_mark_sub-dem_pre-eng.php

[6] Performance standards for Screening or Review of additional material submitted to the Food Directorate in response to a Screening Deficiency Notice or Deficiency Notice, respectively, are addressed in the *Draft Guidance Document - Management of Pre-market Submissions*.

[7] Acceptable for Review means that no deficiencies in the content of the submission were identified during Screening of the submission. See the *Draft Guidance Document - Management of Pre-market Submissions* for the process and timelines that will apply to incomplete submissions.

3) Health Canada's Food Directorate will continue to conduct pre-market assessments of processing aids upon request by industry. This will be done within the constraints of operational resources since most processing aids are not subject to mandatory pre-market assessment.

Food additives and technologies validated in other jurisdictions

The second part of Recommendation 12 of the independent investigator's report states that particular attention should be given to food additives and technologies "**that have been scientifically validated in other jurisdictions (provinces or countries).**" As part of its evaluation process, Health Canada's Food Directorate already considers current international food additive evaluations that have been conducted by the independent expert advisory group known as the Joint FAO / WHO Expert Committee on Food Additives (JECFA) and, in the case of novel foods, uses international guidance developed by the Codex Alimentarius Commission and takes into account food/feed safety consensus documents generated by the Organisation for Economic Cooperation and Development (OECD).

In addition, Health Canada's Food Directorate liaises, where possible, with national regulatory agencies and sometimes exchanges evaluation summaries to assist in the decision-making process. However, Health Canada's Food Directorate cannot rely entirely on evaluations undertaken by other national authorities. For example, Health Canada must favour the use of Canadian food consumption data, when available, in the exposure assessments that are the basis of safety evaluations fitting the Canadian context.

Ultimately, Health Canada must be in a position to assure Canadians that due diligence and scientific rigour have been applied to the evaluation of all submissions filed with Health Canada.

Guidance to industry on how to request priority scheduling and expedited handling of submissions

Demonstration of capacity to enhance food safety:

Petitioners can request in their covering letter that their submission be considered for priority

scheduling and expedited handling. **The submission should include acceptable scientific evidence to demonstrate that the substance or technology in question will improve the microbiological safety of the food product(s) under the proposed conditions of use.**

For example:

- statistically-analysed data from challenge studies done as part of an experimental trial, designed in collaboration with the Food Directorate, at the facility where the substance or technology would be used; or

- published scientific literature linking the proposed substance or technology to improvement in the microbiological safety of a food, and in-house validation data demonstrating such improvement for the food product(s) of interest to the petitioner.

While onus is on the petitioner to request priority scheduling and expedited handling of a submission, the Food Directorate may itself determine that there is a potential food safety benefit from the use of a particular food additive, irradiation process, novel food / novel food process, or food processing aid. In such cases the Directorate can assign priority scheduling and expedited handling to the submission even if the petitioner has not requested it. Decisions in this regard will be made on a case-specific basis and will be communicated to the petitioner.

General criteria for eligibility for priority scheduling and expedited handling

The submission package should include data to demonstrate its eligibility for priority scheduling and expedited handling against the following criteria:

a) For Food Additives and Food Irradiation

- The substance which is the subject of a food additive submission must meet the regulatory definition of a food additive found in paragraph B.01.001, Division 1, Part B of the *Food and Drug Regulations*;
- The food irradiation treatment which is the subject of a food irradiation submission must meet the regulatory definition of irradiation found in paragraph B.26.001, Division 26, Part B of the *Food and Drug Regulations*;
- The food additive, or the food irradiation treatment, must demonstrate capacity to enhance food safety through data provided in the submission package.

b) For Novel Food Notifications

- The food which is the subject of a novel food notification (novel food submission) must meet the regulatory definition of a novel food found in paragraph B.28.001, Division 28, Part B of the *Food and Drug Regulations*;
- The novel food or novel food process must demonstrate capacity to enhance food safety through data provided in the submission package.

c) For Processing Aids

- The substance which is the subject of a request for a letter of opinion expressing no objection (processing aid submission) must meet the definition of a processing aid set out in the Food Directorate's *Policy for Differentiating Food Additives and Processing Aids*;
- The processing aid must demonstrate capacity to enhance food safety through data provided in the submission package.

If the conditions specified for each category of substance or technology are met, the Food Directorate will confer priority scheduling and expedited handling status upon the submission, and will commit to completing the evaluation within 90 days from issuance of the Acceptance for Priority Review Letter - provided the Directorate is not required to issue a Deficiency Notice to the petitioner.

For food processing aids and novel foods / novel food processes, the 90 day period includes issuance of the letter of opinion expressing no objection, and the letter of no objection, respectively. However, for food irradiation, the 90 day period does not include amendment of the *Food and Drug Regulations*. In the case of food additives it also does not include the time required to modify the *Lists of Permitted Food Additives*. The time required to add a new additive to an existing list is typically six months following the determination of safety and senior management approval, while the time to enable an extension of use of an already approved additive is typically three months.

Guidance on Submission Preparation

Guidance on preparing submissions for food additives, novel foods / novel food processes (i.e. novel food notifications) and food processing aids can be found via the following Health Canada webpages:

Food Additives - Submission Preparation

A Guide for Preparing Food Processing Aid Submissions

Guidelines for the Safety Assessment of Novel Foods

For information on food irradiation submissions, please contact the Bureau of Chemical Safety.

Completed submissions should be sent to:

Submission Management Information Unit
Food Directorate
Health Products and Food Branch, Health Canada
Postal Locator 2201C

251 Sir Frederick Banting Driveway
Ottawa, Ontario K1A 0K9
E-mail: smiu-ugdi@hc-sc.gc.ca

Comments about this policy

Health Canada's Food Directorate invites comments and feedback on this policy from all stakeholders, including members of the public. Comments can be submitted in writing, either electronically or by regular mail. If you are submitting your comments electronically, please use the words "Policy for priority scheduling and expedited handling" in the subject box of your e-mail.

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch, Health Canada
Postal Locator: 2202C
251 Sir Frederick Banting Driveway
Ottawa, Ontario K1A 0L2
E-mail: bcs-bipc@hc-sc.gc.ca