Health Canada Santé Canada

Draft Guidance Document

Management of Pre-Market Submissions

Effective Date: (DD/MM/YYYY)

Food Directorate
Health Products and Food Branch
Health Canada

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1.0 Introduction

1.1 Purpose

This document describes the Food Directorate's management of pre-market submissions for food additives, novel foods, and infant formulas pursuant to requirements of the *Food and Drug Regulations*.

This guide provides information on activities and timelines related to the management of submissions, and is intended to improve the predictability and transparency of the process. By adhering to this process, submission deficiencies, omissions or inadequacies will be identified early in the process and procedures will be in place to address any such gaps, thus reducing the overall submission review time.

The process described below is limited to the management of submissions. Other guidance documents have been developed to assist petitioners in meeting the scientific and regulatory requirements for food additive, novel food, and infant formula submissions. This document is intended to be used in conjunction with those documents[1]. [*Note: Some of these documents are in development. For the current consultation on this document and process, they are not needed.*]

1.2 Scope

This document describes each step in the management of submissions by the Food Directorate and associated time lines from the receipt of a submission to the communication of the decision to the petitioner. These steps include:

- **Verification** - to ensure that the submission package is complete and contains all required administrative information.

- **Screening** - to ensure that appropriate scientific information to meet regulatory requirements is included in the submission so that the review can be initiated.

- **Review** - to evaluate whether all scientific information submitted based on regulatory requirements demonstrates the safety, efficacy and/or quality of the food product.

- **Decision** - to notify the petitioner of Food Directorate's decision regarding its submission.

[1] Available on the Health Canada website at: www.hc-sc.gc.ca/fn-an/legislation/guide-ld/index_e.html

Additional information on submission management activities are provided in this document and include:

- Pre-submission consultation
- Withdrawal of a submission
- Refiling a submission
- Dispute resolution

2.0 Instructions for Sending Submissions and Related Information

Submission packages and related information must be directed to:

Submission Management and Information Unit
Food Directorate, Health Products and Food Branch, Health Canada
251, Sir Frederick Banting Driveway
Postal Locator: [*tbd]*
Ottawa, Ontario K1A 0K9
Fax: [*tbd*]
Email address: [*tbd*]

3.0 Pre-Submission Consultation

Before preparing a submission, petitioners may wish to contact the Submission Management and Information Unit to determine whether a pre-submission consultation with the Directorate would be beneficial. Such a consultation would allow the petitioner to seek further guidance on regulatory requirements and specific information that should be included in the submission package. This practice often reduces the number of requests for clarification or additional information needed so a decision can be reached.

4.0 Submission Management Process

A flow diagram outlining the submission management process and related timelines is provided in Appendix 1. The proposed timelines are the Food Directorate's interim performance standards and may be reviewed during the implementation phase. Appendix 2 outlines performance standards for the various types of submissions.

4.1 Verification

The submission package is verified within 7 calendar days of its receipt to ensure the petitioner has provided a complete submission containing all required administrative information. Petitioners whose submissions are accepted are provided a submission number as part of an Acknowledgement Letter confirming the receipt of the submission and the completion of the verification step. The submission number should appear on all correspondence to the Food Directorate.

Significant omissions or inadequacies in administrative requirements will result in the issuance of an "On Hold" Letter. The submission management process will resume only after the petitioner has appropriately responded to the letter within 15 calendar days. If the petitioner's response is unsatisfactory or is not received within the established timeline, the entire submission package will be returned to the petitioner at the petitioner's expense. The submission may be resubmitted at a future date and it will be processed as a new submission.

4.2 Screening

All submissions will be screened within 45 calendar days from the date of receipt of a complete submission package to verify they contain appropriate scientific information based on regulatory requirements so that the review of the submission can be initiated. Petitioners whose submission content is considered acceptable are provided with an Acceptance for Review Letter.

If deficiencies, omissions or inadequacies preventing the review of the submission are identified, a Screening Deficiency Notice will be sent to the petitioner. The submission management process will resume only after the petitioner has submitted all requested additional information within 45 calendar days. The petitioner's response will be verified within a new 14 calendar day screening period.

An unsatisfactory response or no response received within the allocated timeline will result in the submission being returned to the petitioner at the petitioner's expense. The submission may be resubmitted at a future date and it will be processed as a new submission.

4.3 Review

The review of the submission will only begin when the submission is considered to contain all administrative and scientific information based on regulatory requirements and applicable guidelines, and is of suitable quality.

Within 90 calendar days (45 calendar days for novel food submissions) from the date of issuance of the Acceptance for Review Letter, submissions will be reviewed to determine if the safety, efficacy, and/or quality issues of the proposed food product have been clearly addressed in the submission and a decision can be made.

During the review step, two types of information may be requested. Where there are major deficiencies preventing the continuation of the submission review, and the type of information requested may require new studies or data, the review stops and a Deficiency Notice will be issued. The submission review will resume only after the petitioner has appropriately responded to the letter within 90 calendar days. The petitioner's response will be incorporated into the submission package and the review of the submission will be resumed in a new 90 calendar day period.

If the petitioner's response to the Deficiency Notice is unsatisfactory or is not received within the established timeline, the entire submission package will be returned to the petitioner at the petitioner's expense. The submission may be resubmitted at a future date and it will be processed as a new submission.

The Food Directorate may also request additional information or clarification to facilitate the submission review through a Minor Information Request. The type of information requested should not require new studies or data and the petitioner is expected to be able to provide all requested information within 15 calendar days from the date of issuance of the Minor Information Request. The submission review continues during this time. If the petitioner fails to provide the requested information within the above mentioned timeline, the remaining issues will be addressed through a Deficiency Notice.

4.4 Decision

Upon completion of the review, the review findings and recommendations are presented to senior management for decision. The petitioner will then be sent a letter stating the Food Directorate's decision with respect to the submission.

For infant formula and novel food submissions, the letter will state whether or not the submission satisfies the requirements of the *Food and Drug Regulations*.

For food additive submissions, the letter will state the Food Directorate's intention to either begin or not the process to amend the *Food and Drug Regulations,* and to issue an Interim Marketing Authorization, if applicable.

4.4.1 Amendments to the *Food and Drug Regulations*

Food additives must be listed in the Tables to section B.16.100 of the *Food and Drug Regulations* before they may be used in foods sold in Canada. Consequently, the process to amend the Regulations is initiated after the Food Directorate has communicated its intention to proceed to enable the use of a food additive to the petitioner. Publication in *Canada Gazette*, Part I allows a period of a minimum of 75 days for the public to comment on the proposed amendments. Once approved by the Governor-in-Council, the amendments are registered as regulations and published

in *Canada Gazette*, Part II. When the amendments are registered, the food additive may legally be used in foods sold in Canada. The regulatory amendment process is undertaken in cooperation with several other federal departments including the Department of Justice, Privy Council Office and Treasury Board. The process usually takes 24 months to complete.

When a submission involves a new or a higher level of use for a permitted food additive, the petitioner may be eligible for an Interim Marketing Authorization (IMA) provided that the submission meets the requirements set out in the *Food and Drug Regulations* [2]. When applicable, an IMA will be published in *Canada Gazette*, Part I within 60 calendar days from the date the Food Directorate has informed the petitioner of its intent to initiate the process to amend the Regulations. The publication of such notice permits the immediate use of the food additive under conditions set out in the notice, while the regulatory process is undertaken to formally amend the Regulations.

5.0 Withdrawal of a Submission

Petitioners may withdraw their submission at any time during the submission management process. The entire submission package will be returned to the petitioner at the petitioner's expense. If the submission is to be re-submitted at a future date, it will be processed as a new submission.

6.0 Refiling a Submission

Any submission that has been previously withdrawn by the petitioner, or returned by the Food Directorate to the petitioner during a previous review, can be re-submitted at a future date. It will be considered a new submission and assigned a new submission number. When refiling a submission, the petitioner should make reference to the previous submission number.

7.0 Dispute Resolution

In accordance with the Health Products and Food Branch's Guiding Principles on Dispute Resolution[3], the Food Directorate will make every effort to identify, manage, and resolve disputes at the level at which they take place. Dispute prevention and early resolution will primarily take place through improved communication among Food Directorate staff, and between the Directorate and petitioners. A formal dispute resolution process is available should other mechanisms fail to

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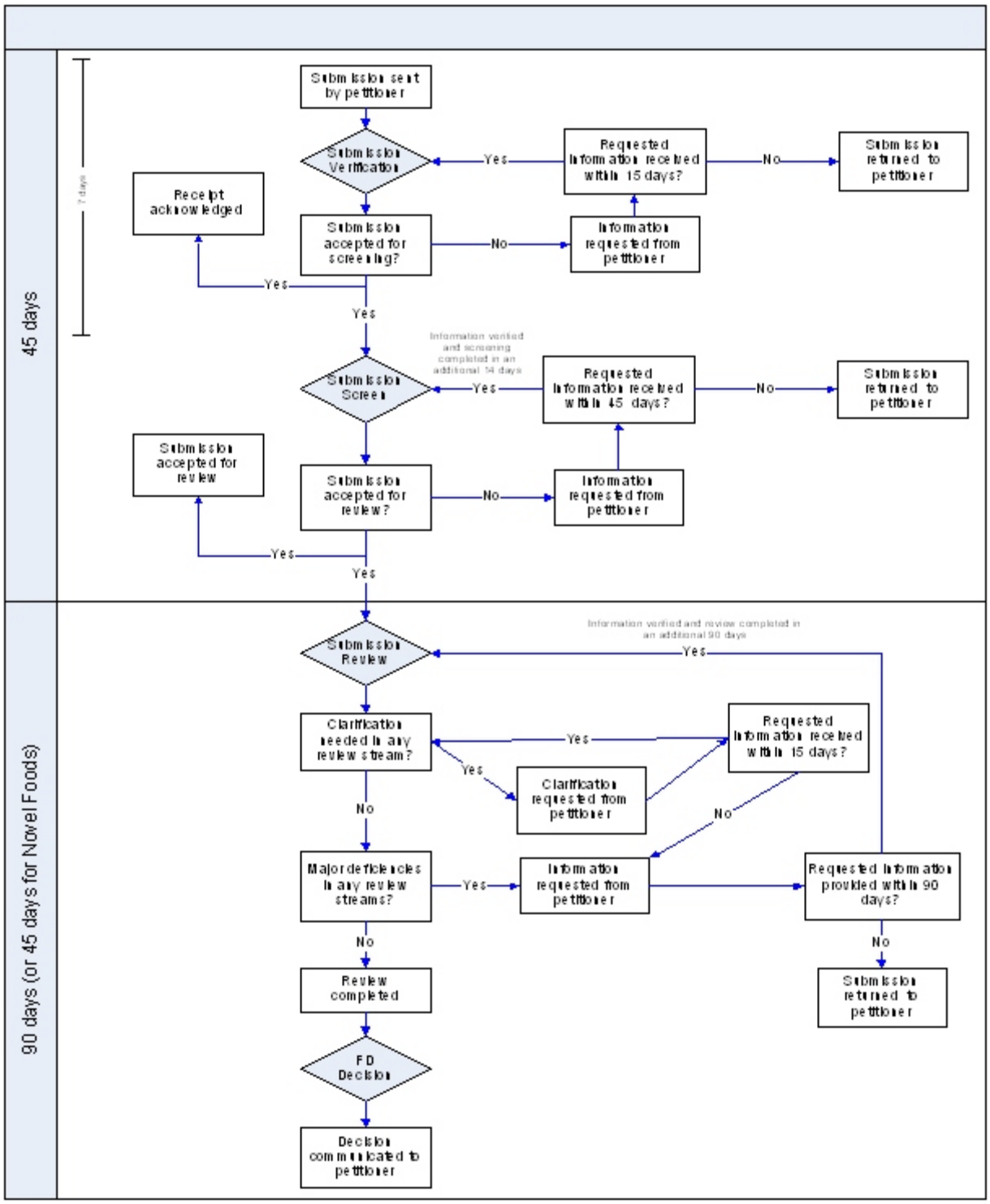
[2] More information available on the Health Canada's website at: www.hc-sc.gc.ca/fn-an/legislation/ima-amp/interim_market_authorization-autorisation_mise_marche_e.html

[3] Available on the Health Canada website at: www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/guiding_principles_principes_directeurs_dr-rd_e.html

resolve the issues(s). [*Note: The formal process for dispute resolution is under development.*]

8.0 Appendix 1: Overview of the Submission Management Process



9.0 Appendix 2: Performance Standards

Target = 90% of the submissions in a category to be processed within the time shown

Submission Type	Food Directorate's Performance Standards (in calendar days)				
	Screening[1]	Review[2]	2nd Screen [3]	2nd Review [4]	IMA[5]
Food Additive	45	90	14	90	60
Infant Formula	45	90	14	90	n/a
Novel Food	45	45	14	90	n/a

1 Verification within the first 7 days.
2 From date of acceptance of a submission for review.
3 If required, for a response to a Screening Deficiency Notice.
4 If required, for a response to a Deficiency Notice.
5 If required, for an Interim Marketing Authorization Notice.