Health Canada Santé Canada

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

Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods

August 30 2016

Food Directorate

Health Products and Food Branch

Canada

Table of Contents

Background

Health Canada's Food Directorate held a Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods. The consultation closed on December 6, 2014.

The Food Directorate's *Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods* complements other published guidance documents which are specific to Food Additives, Infant Formula, or Novel Food applications. Submission specific processes are outlined within the respective guidance documents. This document describes administrative processes but not the regulatory and scientific processes associated with specific submission types. The Food Directorate has developed these administrative processes to be applicable to all three submission types, in an effort to harmonize the overall submission management process. These processes are a part of the ongoing commitment by the Food Directorate to improve predictability, effectiveness, efficiency, and transparency of its premarket review processes.

Consultation Summary from the Food Directorate

The Food Directorate received comments from ten different stakeholders (companies and industry associations). The comments consisted of a mixture of positive comments as well as areas for further improvement. In general, stakeholders found the timeline of up to 90 days for a petitioner to respond to a formal deficiency letter to be sufficient. They were also supportive that this time should not be counted within the Food Directorate's "clock counting time".[1] Positive comments were also received about the effectiveness of the pre-submission consultation process, and how it can lead to possible improvement. Overall, petitioners acknowledged the Food Directorate's effort to improve timelines, predictability and transparency of the submission review process.

The responses to the consultation did include some common concerns. These concerns have been grouped below, along with the Directorate's response. Comments received which were outside the scope of the consultation or were specific to only one pre-market submission stream will be answered directly by the Food Directorate in discussions with the specific respondent.[2]

Wherever possible, stakeholder suggestions have been incorporated into the Food Directorate's submission management process. Other comments which would require significant change will continue to be a part of future discussions as well as our continuing efforts to ongoing improvements.

[1] The stop the clock provisions have not been implemented and Section 3.2 has been revised accordingly. The performance standard of 410 days from receipt of the submission.

[2] For example: web-posting timelines, concerns with product labelling.

The submission management document supports a key deliverable in the Food Directorate Key Commitments and Business Plan. Specifically, Theme 1: Effectively deliver and transform the business of food pre-market activities; which is aligned with the Branch Strategic Pillars (1) Regulatory Modernization and (2) Operational Excellence. The Food Directorate is committed to the development and implementation of improved business processes for pre-market review and approvals; as well as providing updated guidance and improved predictability for pre-market review and approvals.

Comments Groups

Comment Group 1: Submission streams should be dealt with in separate documents

1A: The respective submission types and their processes should appear in separate documents (i.e. Food Additives, Infant Formula, Novel Foods).

This document outlines administrative processes that are common to the three relevant submissions types; it is intended to complement other published guidance. Comprehensive, submission specific guidance is available from Health Canada for Food Additives, Infant Formula and Novel Foods.

Comment Group 2: The Performance Standard of 410 days from submission receipt to decision

2A: The submission performance standard of 410 days is too long.
2B: How was the time standard of 410 days calculated and why is it different from that proposed in 2007?
2C: The Submission Management Information Unit's (SMIU's) role should be expanded to include a contact person who is accountable for the timelines within the submission management process.
2D: More predictability within the submission management process would be beneficial.

The 410 day performance standard will provide petitioners with a predictable timeframe for expecting the Food Directorate's decision on a well-prepared submission because it is an achievable target. It was identified through process mapping, consideration of resources and historical timeframes for completing submission reviews, and comparisons with the submission review timeframes of like-minded food regulatory agencies.

Based on past experience a small percentage of submissions are expected to be complex and, as a result, to be completed outside the performance standard. Others may be completed in less than 410 days. The Directorate will be monitoring its performance relative to the 410 day standard

and will consider reducing the timeframe if the majority of submissions can consistently be evaluated and decided upon in less than 410 days.

Each submission is now assigned to a Regulatory Project Officer ("RPO") within the Submission Management Information Unit (SMIU) who is responsible for certain administrative aspects of the submission. The RPO contacts the petitioner to acknowledge that the Directorate has received the submission and to provide the petitioner with the submission's case number. The RPO also assists the lead evaluator by handling administrative file management tasks, and will provide status updates to petitioners upon request.

The Food Directorate established a pre-market submission management body that meets regularly to monitor the progress of food additive, infant formula and novel food submissions. The Directorate's performance relative to the 410 day standard is submitted monthly to senior management in the Health Products and Food Branch. The Food Directorate continues to explore and implement best practices in the review and management of submissions.

Comment Group 3: Tiering

3A: Each submission type should have a developed tiering system; for Food Additives, Infant Formulas, and Novel Foods (i.e. a short track system for less complex submission types).

The Food Directorate completed an analysis of the current process and its resources. The analysis indicated that the Food Directorate, and petitioners, would be best served by a time standard that was realistic and achievable to allow for better predictability for the submission management processes. The Food Directorate concentrated its efforts on the service standard for now, recognizing that long-term, other mechanisms including tiering could possibly improve the system. The Food Directorate will investigate and consider possible process changes in the future as part of its efforts to gain more efficiency.

The complexity of a submission may not be apparent until some point during the review, so it would be difficult at submission receipt to assign a submission to a "track" for less complex submissions. However, once the review begins, less complex submissions can already progress more quickly than complicated ones.

Comment Group 4: Transparency

4A: More transparency is needed within the review process, in particular those submissions that are highly innovative, complex submissions that may exceed the 410 day service standard.

The submission management process document has been revised to indicate that the petitioner will be notified if during the submission review it becomes apparent that the 410 day standard will not be met.

As discussed in the consultation document, potential reasons for the Food Directorate not providing a decision within 410 days include, but are not limited to, the complexity of the submission, or new science, technology or datasets which need to be reviewed. In some cases, additional steps may also be required for the Food Directorate to come to a decision, such as addressing scientific uncertainties. To keep the review as predictable and as transparent as possible, the Food Directorate will advise petitioners during the Review Phase if the submission will not be completed within 410 days.

Appendix 1 of the consultation document outlines the Revised Submission Management Process; which outlines the various steps (e.g. Administrative Verification, and for certain types of submissions: Scientific Screening). The revised process provides more formal communication with petitioners as their submission progresses through the submission management steps. During these steps, the Food Directorate will be in contact with the petitioners to communicate any deficiencies.

The Food Directorate remains committed to being transparent with petitioners throughout the review process. As with current practices, for information concerning submission status, petitioners are directed to contact the Submission Management Information Unit. In the event a submission is rejected during the administrative verification stage, the Submission Management Information Unit will list the required data/information in their notification to the petitioner. For technical scientific questions regarding the submission, petitioners are directed to the Lead Evaluator of their submission.

Comment Group 5: Pre-submission Consultation

5A: A suggestion was received to reform the voluntary pre-submission consultation process to ensure the consultations are considered a priority by the Food Directorate and to better formalize any decisions (on aspects of the submission review) made at the meetings.

The Food Directorate has guidance for petitioners on submission preparation on Health Canada's website. Petitioners who require assistance in addition to this guidance have the option of a pre-submission consultation with the Food Directorate. Such consultations can be in the form of an email, phone call, or a face-to-face meeting.

Meetings can be arranged upon request through the Submission Management Information Unit (SMIU). They are informal in nature and are not decision-making fora. For novel foods, specific guidance on setting up a pre-submission consultation is available.

Comment Group 6: Dispute Resolution/ Reconsideration Process

6A: Guidance/ clarification was requested concerning a formal Dispute Resolution / Reconsideration Process

Staff within the Food Directorate will make every effort to identify, manage, and resolve disputes at the level at which they take place and to be available to discuss concerns regarding submissions before disputes arise.

Stakeholders may also seek assistance from Health Canada's alternate dispute resolution services offered by the Food and Drugs Act Liaison Office (FDALO). The FDALO is available as a neutral and impartial dispute resolution resource for stakeholders when they experience problems with the regulatory process or with the application of policies or procedures related to the *Food and Drugs Act*.

Comment Group 7: Review Phase

7A: What is involved in the 368 day scientific review?

The scientific review phase consists primarily of a safety evaluation and consultation with appropriate parties, and varies depending on the complexity of the submission. Further details on the data considered/required of the scientific review may be found in the specific guidance documents for Food Additives, Infant Formulas, and Novel Foods.

Comment Group 8: Web-posting Timelines

8A: Web-posting timelines are lengthy and a challenge for stakeholders

Timelines for web-posting are sometimes subject to other Departmental and Government of Canada priorities. However, the Food Directorate has noted comments received regarding web-posting timelines and will include these concerns in moving forward in Branch and Department initiatives on publication of decisions. In the meantime, some reductions in web-posting timelines have already been realised, in particular, for food additives.
The Department as well as the Branch have identified openness and transparency as a key priority, which will assist timelier web posting of decisions.

Comment Group 9: Filing e-submissions with the Food Directorate

9A: Request to submit submissions electronically rather than paper copies

The Food Directorate is continually seeking out and evaluating opportunities for process improvements that will aid its petitioners and stakeholders. These comments will continue to be a part of future discussions at the Food Directorate concerning operational and IM/IT system assessments. The Food Directorate will remain in consultation with broader Health Products and Food Branch IM/IT initiatives, and align itself with those initiatives.

Guidance documents for some submission types already indicate conditions under which submissions may be sent by e-mail. If a petitioner wishes to send submissions or deficiency responses in an electronic format, the Submission Management Information Unit can assist, on a case-by-case basis.

Annex 1: Changes to the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods

The following updates have been made to the *Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods*:

- Section 3.1.1 – Unacceptable Submissions: when an applicant is notified that their submission has not been accepted for review, a list of the missing and necessary information required to pass the screening phase will be included in the letter.

- Section 3.2 – Scientific Review: the text has been edited to reflect that the Food Directorate will notify petitioners within this phase of the submission management process if a submission will not be completed within 410 days.

- Section 3.2 – Scientific Review: For novel foods submissions, Scientific Screening is completed within the first 30 days of the process to identify deficiencies or safety concerns. If deficiencies are communicated, any time with the petitioner will not be counted within the timeframe for scientific review. Upon passing the screening phase, the petitioner will be notified that the submission's review will continue within the Scientific Review phase. Currently, the Food Directorate is running a pilot with a screening step as part of the infant formula submission evaluation process.