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Policy for Issuing an Interim Letter of No Objection (iLONO) for a Food Processing Aid

July 31, 2015

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch





Canada

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Preamble

This document outlines Health Canada's Policy for Issuing an Interim Letter of No Objection (iLONO) for a Food Processing Aid and replaces the interim policy as described in the document entitled *Technical Consultation - Policy Intent for Issuing an Interim Letter of No Objection (iLONO) for Processing Aids (October 2013)*. While the purpose of the Policy remains the same, the current document has been modified in response to stakeholder comments received during the technical consultation and in response to the experiences of Health Canada's Food Directorate to date with iLONO submissions.

The following revisions and additions in particular were made:

(1) the policy scope was refined to apply to processing aids that are required by a federal government policy or regulation to be the subject of a LONO before they may be used in food processing (which, as of the date of publication, means antimicrobial processing aids for use in federally registered meat establishments);

(2) the iLONO review period was revised to 60 calendar days;

(3) the criterion respecting the need to demonstrate acceptance by a recognized like-minded agency no longer requires provision of a copy of the submission that led to the product's acceptance in that jurisdiction;

(4) detailed guidance is provided on what information is required in a complete iLONO submission package (Appendix A);

(5) an example of a hypothetical iLONO submission meeting the eligibility criteria is included (Appendix B); and

Purpose

The purpose of this document is to describe Health Canada's policy for issuing interim letters of no objection (iLONO) for a substance or product that:

(1) meets the administrative definition of a food processing aid set out in Health Canada's *Policy for Differentiating Food Additives and Processing Aids*, and

(2) is identical in composition and use to a substance or product that has already been assessed for safety and accepted by a recognized "like-minded" food regulatory agency or food safety assessment body. For the purposes of this iLONO policy, a recognized like-minded food regulatory agency or food safety assessment body

(hereafter referred to as a "like-minded agency") is one that meets the criteria set out on page 5 of the present document.

Scope

This policy applies only to those food processing aids for which a federal government body, namely the Canadian Food Inspection Agency (CFIA), requires a letter of no objection (LONO) from Health Canada. Currently, the CFIA only requires LONOs for those food processing aids that are intended to be used as antimicrobial agents applied directly on foods processed in federally registered meat establishments. For all other types of food processing aids Health Canada's Food Directorate will consider requests for a LONO through the usual non-mandatory review process for food processing aids.[1]

Background

In Canada, the *Food and Drug Regulations* define a "food additive" but do not define a "food processing aid". Consequently, the regulatory definition of a food additive provides the context within which the use of chemicals and other substances in food manufacture and processing is considered. To be eligible for consideration as a processing aid, a substance must be used in food manufacture or processing in a manner that causes it to fall outside the scope of the definition of a food additive. It is important to note that a substance that is regulated as a processing aid in another jurisdiction may not necessarily be considered a processing aid in Canada.

The distinction between a food additive and a food processing aid is described in Health Canada's *Policy for Differentiating Food Additives and Processing Aids*. That policy sets out an administrative definition of a food processing aid as follows:

> "A food processing aid is a substance that is used for a technical effect in food processing or manufacture, the use of which does not affect the intrinsic characteristics of the food and results in no or negligible residues of the substance or its by-products in or on the finished food."

In most cases, there has never been a regulatory requirement under the *Food and Drug Regulations* for food processing aids to undergo premarket review by Health Canada. However, the use of food processing aids, like any other substance used in processing or manufacturing of food, must not lead to a violation of section 4(1) of the *Food and Drugs Act*. While there is no mandatory pre-market review of food processing aids, under the Department's broader mandate for food safety, Health Canada's Food Directorate has for many years conducted pre-market assessments of food processing aids, upon voluntary request by industry, to determine the acceptability of proposed uses from a food safety perspective. When the outcome of an evaluation is favourable, the Food Directorate issues a

[1] http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/guide-fpa-ata-eng.php

LONO to the petitioner. In recent decades, the Food Directorate has also conducted evaluations and issued LONOs for processing aids as part of the CFIA requirements for federally registered establishments.

The approach to handling food processing aid submissions has worked effectively for many years. However, the number of requests for this voluntary service has gradually increased, accompanied by a demand for expedited issuance of LONOs, in particular when LONOs are a specific requirement under programs administered by the CFIA.

To help meet this demand within the Food Directorate's existing resources, and to respond to the *Government of Canada's Red Tape Reduction Action Plan*, the Directorate is accepting submissions for interim letters of no objection (iLONO) for food processing aids used directly on foods processed in federally registered meat establishments. The CFIA will accept iLONOs as equivalent to LONOs for the purposes of programs administered by the CFIA.

Eligibility criteria for requesting an iLONO

A processing aid will be considered for an iLONO if all of the following eligibility criteria are met:

1. The iLONO submission is made as part of a processing aid submission prepared in accordance with Health Canada' Food Directorate's *A Guide for Preparing Food Processing Aid Submissions*. Petitioners should consult section 3.3.4 (Microbiological Data) of the Guide for data requirements to substantiate specific antimicrobial claims (i.e., specific pathogen reduction claims), if any, that are to be associated with the processing aid. Toxicological Data (Section 3.3.3 of the Guide) are not mandatory as part of the initial iLONO submission, however, petitioners are free to submit any and all available toxicological data considered pertinent to their submission. If additional data are required, such data may be requested after the iLONO is issued if considered necessary to support the subsequent issuance of a LONO;

2. The petitioner satisfactorily demonstrates that the substance or product meets the Canadian definition of a processing aid set out in Health Canada's *Policy for Differentiating Food Additives and Processing Aids*. Petitioners should be aware that a substance or product classified as a processing aid in one jurisdiction is not necessarily considered a processing aid in Canada;

3. The petitioner provides satisfactory evidence that the processing aid is accepted for identical conditions of use by a recognized like-minded agency; and

4. The petitioner satisfactorily demonstrates, by signed attestation or other suitable means, that the processing aid is identical in composition and quality to the processing aid accepted by the recognized like-minded agency.

Criteria used by Health Canada to recognize a like-minded agency for the purpose of this iLONO policy

Health Canada and certain other food safety agencies have similar rigorous science-based safety evaluation processes for food additives and processing aids, and the Department has information sharing arrangements with some of these agencies. Health Canada recognizes the evaluation and acceptance of a processing aid from these like-minded agencies as a basis for issuing an iLONO for an identical product provided that its use under the same conditions on foods in Canada would indeed be classified as a processing aid in Canada.

For the purpose of this policy, a recognized like-minded agency is one which:

1. Has a history of scientific rigour and applies an evidence-based approach to evaluate chemicals and other substances used in manufacturing or processing human food from a food safety perspective and has an established science-based review process for substances that would be classified food additives and/or processing aids in Canada. Health Canada's Food Directorate will rely on its experience from participating in international fora and collaborating with regulatory agencies in other jurisdictions to assess whether this criterion is met.

2. Has a memorandum of understanding (MOU) with Health Canada that includes an information exchange component, or is a government agency working on food safety programs in conjunction with an agency that has an MOU with Health Canada.

At the time of publication of this document, the following agencies met the above criteria:

- The U.S. Food and Drug Administration (FDA) [2]
- Food Standards Australia New Zealand (FSANZ)
- The European Food Safety Authority (EFSA)

This list will be updated as necessary.

[2] The U.S. FDA shares the approval process for antimicrobials used in meat and poultry processing operations with the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS). The FDA determines the safety of substances and sets safe conditions for their use, and FSIS determines their efficacy and suitability for use in meat and poultry products. Substances that have been accepted by both agencies are added to FSIS Directive 7120.1 - Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products. Consequently, a listing for an antimicrobial in Directive 7120.1 is evidence that the US FDA has determined that the antimicrobial is considered safe when used under the conditions prescribed in the listing. (Reference: *Related Documents for FSIS Directive 7120.1 – Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products*).

The iLONO process

Health Canada's Food Directorate will acknowledge receipt of an iLONO submission, by email, within seven (7) calendar days of receipt. The acknowledgement email will not indicate whether the substance or product is eligible for an iLONO.

The iLONO submission package will be assessed within sixty (60) calendar days of the date of the acknowledgement email. If there are major deficiencies, for example material is missing that should have been included based on the eligibility criteria provided in this iLONO policy, the petitioner will be advised by email that the submission is ineligible for further consideration and that the file has been closed. Minor clarifications must be addressed by the petitioner in a timely manner during this 60-day period. Failure to acknowledge and respond to the requested clarification(s) within 14 calendar days will result in the file being closed.

If an iLONO submission is determined to be ineligible, the Directorate will inform the petitioner whether the submission can still be considered for a LONO and entered into queue for the usual food processing aid evaluation process.[3] The petitioner must advise the Directorate, in writing, within seven (7) calendar days of the date of the notification email that the petitioner wishes to have the submission placed in queue for the LONO process. If the Directorate does not receive the petitioner's response within seven (7) calendar days, the file will be closed and the petitioner will be informed by email accordingly.[4] A petitioner can refile an iLONO submission at any time accompanied by the material needed to support the submission as set out in this policy. However, the submission will be placed in the iLONO queue and the timelines will start again.

If the iLONO processing aid submission package is satisfactory and no concerns are identified, Health Canada's Food Directorate will issue an iLONO to the petitioner within the aforementioned 60-day period. The iLONO will be valid so long as the following conditions continue to be met:

- The composition and use of the substance or product remains the same as stated in the original submission;
- The recognized like-minded agency does not change its position regarding the status of the substance or product; and
- The Food Directorate does not issue correspondence to the petitioner indicating otherwise

[3] This could occur, for example, if the petitioner filed a complete processing aid submission with the iLONO submission package but did not adequately demonstrate that the substance or product was evaluated for safety and accepted by a recognized like-minded agency.
[4] An email response indicating whether the petitioner would like to pursue a LONO is sufficient.

Currently, there is no timeline for the Food Directorate to issue a LONO that would supersede the iLONO. However, the Directorate retains the option of conducting a full assessment of the processing aid submission (filed by the petitioner as part of the iLONO submission package) at any time. The Food Directorate may revoke the iLONO based on the outcome of that assessment or based on failure to satisfactorily respond to any deficiencies identified during the assessment. The Food Directorate can also revoke the iLONO if the like-minded agency changes its position regarding the status of the substance or product.

Filing an iLONO submission

iLONO submissions should be accompanied by a cover letter requesting an iLONO, a completed food processing aid submission checklist, and all supporting information. Please refer to Appendices A andB of this policy for submission guidance. The package should be sent to the Chief of the Food Directorate's Chemical Health Hazard Assessment Division at the following address:

Chief
Chemical Health Hazard Assessment Division
Bureau of Chemical Safety, Food Directorate
Health Products and Food Branch, Health Canada
251 Sir Frederick Banting Driveway
Postal Locator 2201C
Ottawa, ON
K1A 0K9

Submissions that are 20 pages or less may be sent to the email address shown below. The words "**iLONO processing aid submission**" should appear in the subject line of your email.

E-mail: CHHAD.Inquiries_Requetes.DEDPCS@hc-sc.gc.ca

Inquiries about this policy

Comments or questions about this policy can be submitted to the Chemical Health Hazard Assessment Division at the same coordinates identified above. If you are submitting feedback on the policy electronically, please use the words "**Policy for issuing an iLONO**" in the subject line of your email.

References

CFIA (Canadian Food Inspection Agency). (2014). *Questions and Answers: Repealing requirements for pre-market registration of construction materials, packaging materials and non-food chemicals used in federally registered meat establishments*

CFIA (Canadian Food Inspection Agency). (2010). *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products.*

Government of Canada. (2014). Regulations Amending the *Meat Inspection Regulations, 1990*.

Health Canada. (2015). *A Guide for Preparing Food Processing Aid Submissions*.

Health Canada. (2015). *The Food and Drug Regulations*.

Health Canada. (2011). *Priority Scheduling and Expedited Handling of Submissions that have the Capacity to Enhance Food Safety*.

Health Canada. (2008*). Policy for differentiating food additives and processing aids*.

Health Canada. (2015). *The Food and Drugs Act*.

Appendix A: Detailed guidance for preparing an iLONO submission that meets the eligibility criteria

A complete iLONO submission package will include:

- A cover letter from the petitioner, or agent acting on behalf of the petitioner, that specifically requests an iLONO and identifies the processing aid, its purpose of use, and the foods that are to be manufactured with the processing aid, and that summarizes the conditions of use for the processing aid;
- A completed food processing aid submission checklist from Annex A of Health Canada's *A Guide for Preparing Food Processing Aid Submissions*, which is a tool to assist in the preparation of the iLONO submission. If a checklist item is marked "N/A", then a rationale must be provided for not including the itemized information. However, the Food Directorate reserves the right to request any such information.

A complete iLONO submission package will also include the following supporting documentation satisfying each of the four eligibility criteria as set out by the *Policy for Issuing an Interim Letter of No Objection (iLONO) for a Food Processing Aid:*

- A processing aid submission, prepared in accordance with Health Canada's *A Guide for Preparing Food Processing Aid Submissions*. If specific antimicrobial claims are associated with the use of the processing aid, such as a claim about reduction of a particular pathogenic microorganism the submission must include data demonstrating the microbiological efficacy of the processing aid. Care must be taken to provide efficacy data that are relevant to the foods to be treated with the processing aid and the conditions under which the processing aid is to be used. If a food category is to be treated with the processing aid (for example, "prepared poultry meat"), then the results of tests done with at least three (3) representative foods of the category must be provided.

  When specific antimicrobial claims (i.e., pathogen reduction claims) are associated with the processing aid, the iLONO will only apply to those foods and uses for which supporting efficacy data has been provided.

  If the original data package that supported the product's acceptance by a recognized like-minded agency is submitted as part of the iLONO submission package, and if the petitioner wishes certain elements of that original data package to be considered to support the iLONO submission, then the cover letter for the iLONO processing aid submission or the food processing aid submission checklist should clearly state this and identify the location of this information.

- Information demonstrating that the substance or product meets the definition of a processing aid as set out in Health Canada's *Policy for Differentiating Food Additives and Processing Aids*. To meet this criterion, the iLONO request package must include:

  - The petitioner's written evaluation of the product through each question in the decision tree in the *Policy for Differentiating Food Additives and Processing Aids*;

  - Residue data or "worst-case" calculations[5] that demonstrate that no or negligible residues will result in or on foods treated with the processing aid when it is used as requested; and

  - Satisfactory demonstration that the use of the substance or product does not affect the characteristics of the food.

- Satisfactory demonstration that the substance or product is identical in composition and quality to one previously accepted as safe for human food use by a recognized like-minded agency, and the intended use is accepted as safe for human food use by that like-minded agency.

[5] "Worst-case" calculations are acceptable to meet this criterion when filing the iLONO submission, but the Food Directorate reserves the right to request analytical data should they be needed for the evaluation.

- The complete chemical composition of the substance or product must be provided. A written and signed attestation is an acceptable means to demonstrate that the substance or product is identical in composition and quality to one previously accepted as safe for human food use by a like-minded agency, and that the intended conditions of use fall within the range of conditions previously accepted as safe for human food use for that product by that like-minded agency.

- Supporting documentation that satisfactorily demonstrates that the use of the substance or product has been accepted by a recognized like-minded agency. For example, the petitioner can provide a letter from that agency indicating such acceptance, or the petitioner can identify the specific regulatory provision that permits such use and attest that the substance or product and its use conforms to that regulatory provision.

Appendix B: Example of an iLONO submission that meets the eligibility criteria

Note: The company name, the product name, and the submission described do not exist; are not intended to be similar to any actual company, product, or submission; and appear below for demonstration purposes only.

Company A23 is requesting an iLONO for the antimicrobial product "BacBeGone", for treatment of red meat parts and poultry meat parts in federally-registered meat establishments in Canada, and for use in processing fresh fruits and vegetables in Canada. The product is already marketed by A23 in the United States of America (under another brand name, BacBeWare) which the company claims is chemically identical to the proposed Canadian product BacBeGone. Health Canada's Food Directorate indicated to Company A23 that the proposed fruit and vegetable uses, which are not eligible for consideration for an iLONO, can be considered under the existing voluntary LONO process if they still wished to pursue these uses. Accordingly, A23 was advised that if specific antimicrobial claims are being made for fruits and vegetables, efficacy data for at least 3 representative fruits and 3 representative vegetables will be required, in addition to chemical residue data post-treatment for representative foods.

Company A23 provided the following information in the iLONO submission to Health Canada's Food Directorate:

1. US FDA GRAS Notification for BacBeWare: GRAS Notification No. GRN 000, an e-copy of the GRAS Notification submission package, and a copy of the US FDA response letter to A23 regarding GRAS No. GRN 000.

2. Detailed conditions of use for BacBeGone, including the directions for use that will be provided on the product label to the users of BacBeGone.

3. The proposed label including a statement that "BacBeGone" is an antimicrobial agent to be used in processing red meat parts and poultry meat parts, for the reduction of *Listeria monocytogenes*.

4. Efficacy data was provided as part of the processing aid submission in support of the claim that BacBeGone, when used as proposed, led to a microbial reduction on red meat parts and poultry meat parts. The efficacy data was provided for three (3) representative meat parts and three (3) representative poultry parts intended to be treated with BacBeGone. The data also indicate the minimum levels of use that are needed for the claimed microbial reduction under various intended conditions of use for these foods. NB: The data were, in fact, for the product marketed in the United States (BacBeWare), but the petitioner showed that BacBeGone is identical in composition to BacBeWare (see point 6 below).

5. US FDA Food Contact Notification for the BacBeWare formulation: FCN No. 000; an e-copy of the FCN submission package; reference to the corresponding listing in the *Inventory of Effective Food Contact Substance (FCS) Notifications*; reference to the corresponding listing in the USDA Food Safety Inspection Service (FSIS) Directive 7120.1 (*Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products*); and a copy of the USDA FSIS response letter to Company A23 regarding FCN No. 000.

6. A table comparing the chemical composition of BacBeGone to the product marketed in the United States (BacBeWare), and written, signed attestation from A23 that the quantitative composition of the two products are identical and that the ingredients and components are of food-grade quality.

The Food Directorate reviewed the submitted information and confirmed that the US FDA and FSIS had not objected to the use of BacBeGone (under the brand name BacBeWare used in the United States), with conditions of use identical to those being proposed for BacBeGone in Canada, as an antimicrobial treatment for red meat parts and poultry parts only for the reduction of *L. monocytogenes*.

Company A23 provided all the information required to allow Health Canada's Food Directorate to consider an iLONO under the policy:

- The company provided a complete processing aid submission, including efficacy data, for the proposed uses on red meat and poultry;

- The company provided a decision tree for classifying BacBeGone as a processing aid;

- The company satisfactorily demonstrated, in this case by written signed attestation as well as supporting information, that the product is identical in composition, quality and intended use to a product previously accepted as safe for human food use by a recognized like-minded agency;
- The company provided evidence that the formulation to be sold as BacBeGone in Canada is accepted for identical conditions of use by a recognized like-minded agency, in this case, the US FDA and the USDA FSIS. The company also provided the complete submission packages for both the FDA GRAS Notification and the FCN.
- The Food Directorate considered the following as sufficient to support the criteria of acceptance by a recognized like-minded agency: USDA FSIS response letter to the FCN; reference to the specific listing in FSIS Directive 7120.1 of the active ingredients that are in the BacBeGone formulation and conditions of use; and reference to the listing in the US FDA's Inventory of Effective Food Contact Substance (FCS) Notifications. The GRAS Notification and the original complete FCN submissions themselves, while helpful, were not required to satisfy the eligibility criteria respecting acceptance by a recognized like-minded agency, and were considered supplementary supporting information.

On the basis that all eligibility criteria were respected, as described above, Health Canada's Food Directorate issued an iLONO for the use of BacBeGone as an antimicrobial treatment on red meat parts and poultry parts.