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# Transition Guide: Understanding and Using the Lists of Permitted Food Additives

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Food Directorate

Health Products and Food Branch

Canada

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# 1.0 Introduction

The way in which Health Canada formally approves food additives once a scientific assessment has determined that a food is safe is changing. On April 26, 2012, as part of Bill C-38 - the *Jobs, Growth and Long-term Prosperity Act* - the Government of Canada introduced amendments to the *Food and Drugs Act* that will enable Health Canada to streamline and accelerate the process by which it enables the use of food additives that have been evaluated as safe for use in Canada. The amendments received Royal Assent on June 29, 2012, and have since come into force.

The amendments provide the Minister of Health with the authority to implement certain food decisions through ministerial regulations called Marketing Authorizations (MAs) as well as a more flexible authority to incorporate documents by reference into the *Food and Drug Regulations* and food MAs. These tools will enable Health Canada to more efficiently provide Canadians with access to safe food products and improve Health Canada's responsiveness to emerging science, food innovation, and/or health and safety risks. These improvements are made without changing the nature or rigour of the Department's scientific safety evaluations.

Health Canada is using these new tools to strengthen the responsiveness, sustainability and efficiency of its food additives regulatory system.

# 2.0 New Regulatory Tools for Foods

## 2.1 Marketing Authorizations (MA)

MAs are ministerial regulations that enable the Minister of Health to:

1. Exempt foods from certain prohibitions found in the *Food and Drug Act* and/or *Food and Drug Regulations*, such as those pertaining to substances found in or on foods or regarding claims on foods;
2. Set classes;
3. Set conditions; and
4. Incorporate documents by reference.

As regulations, MAs are subject to the requirements of the *Statutory Instruments Act*(SIA) and the *Cabinet Directive on Regulatory Management* (CDRM). This means that the principles of good regulation making, such as public consultation and review by Justice Canada, must be met and followed, and final publication of MAs takes place in the *Canada Gazette, Part II*. However, as MAs are ministerial regulations and not Governor in Council (GIC) regulations, the entire regulatory development, consultative and approval process is managed by Health Canada, providing greater control over prioritization and approval timelines. Additionally, final approval rests with the Minister of Health.

## 2.2 Incorporation by Reference

Pursuant to section 30.5 of the *Food and Drugs Act*, the Minister of Health now has the explicit authority to incorporate documents by reference into a food Marketing Authorization or to seek the incorporation of a document into the *Food and Drug Regulations* via a GIC regulation. Incorporated documents may be Government of Canada documents (e.g. a specific Health Canada guideline, list or method) and/or third party documents (e.g. Codex standard). Additionally, the incorporation may be "static" (e.g. incorporating a specific version of a guideline) or may be "ambulatory" (e.g. incorporating a guideline with the knowledge that it is amended from time to time).

**Documents incorporated by reference have the force of law**

Modifications to ambulatory incorporated Government of Canada documents can be made administratively as opposed to requiring regulatory amendments, while maintaining due process, including thorough safety assessments and public and stakeholder engagement. This means that changes that have been thoroughly scientifically reviewed may be implemented in a much timelier and more efficient manner.

# 3.0 Food Additive Marketing Authorizations and the Lists of Permitted Food Additives

Historically, permitted food additives have been listed in 15 tables housed under Part B, Division 16 of the *Food and Drug Regulations*. Section B.16.100 of the Regulations prohibits the sale of a substance as an additive unless it is found on one of the 15 tables. In addition to this, section B.16.007 further prohibits the sale of a food containing a food additive other than a food additive provided for in sections B.01.042 (Standardized foods), B.01.043 (Unstandardized foods) and B.25.062 (Foods for infants). These latter three sections ultimately point back to the tables of Division 16 for the list of permitted food additives and the foods to which they may be added.

## 3.1 New Approach

Pursuant to the new MA and Incorporation by Reference authorities provided under the *Food and Drugs Act*, the Minister of Health has enacted 15 MAs which mirror the 15 classes of food additives found under Division 16 of the *Food and Drug Regulations* (e.g. MA for permitted anticaking agents, MA for permitted colouring agents).

Each MA defines the additive function ("class"), sets out the specific regulatory exemptions for that class of additives, and incorporates by reference an administrative list of the permitted food additives found within that class. The lists are all housed on the Health Canada website (see section 3.3 of this guide) and consist of the approved additives found in Part B, Division 16 of the *Food and Drug Regulations* as well as a number of additives for which Interim Marketing

Authorizations (IMAs) had been issued. The official titles of the 15 lists of permitted food additives are provided in Appendix A of this transition guide.

The 15 MAs work by exempting the food additives that appear on the corresponding incorporated lists from the prohibition found under section B.16.100, if at the time of sale, all other requirements of the *Food and Drug Regulations* are met. In addition, the MA exempts foods that contain a food additive from the application of paragraphs (4)(1)(a) and (d) and section 6 and 6.1 of the *Food and Drugs Act* and sections B.01.042, B.01.043 and B.16.007, as applicable, of the *Food and Drug Regulations* only in respect of the use or presence of the additive provided that the additive used is found on the corresponding incorporated list and all conditions indicated in the list are met.

The 15 lists are incorporated in the MAs on an ambulatory basis. This means that as the lists are updated from time to time, the changes are automatically and immediately in force. Future amendments to any of these lists, such as the addition or delisting of an additive or the extension of the use of an additive, may be done administratively following the completion of the scientific assessment and with an appropriate public and international notification and comment period. Further information on changing the lists of permitted food additives is provided under Section 4.0 of this guide.

## 3.2 Interpreting and Using the Lists of Permitted Food Additives Tables

The Government of Canada has yet to repeal the additive tables found in Division 16 of the *Food and Drug Regulations* but intends to do so. This will require a GIC regulatory process which will be pursued in a timely manner.

Until the tables are repealed, there will temporarily exist two sets of additive lists: the tables found in Division 16 of the Regulations and the new incorporated lists housed on Health Canada's website (see section 3.3 of this document).

**Stakeholders are advised to refer to the new administrative Lists of Permitted Food Additives when seeking information on authorized additives and authorized additive uses,** as these are the most up-to-date and will be considered authoritative by Health Canada and the Government of Canada more broadly. From now on, newly enabled additives, extensions of use and additive de-listings will only be reflected on the new lists. The Canadian Food Inspection Agency (CFIA) will reference the new lists.

## 3.3 Accessing the Lists of Permitted Food Additives

The new Lists of Permitted Food Additives as well as the Food Additive MAs are available through the Health Canada website:

- Access the Lists of Permitted Food Additives
- Access the Food Additive MAs

## 3.4 Food Standards of Composition and Identity

The provisions within the food standards that are specific to food additives will no longer be updated to reflect new or adjusted food additive uses. As such, stakeholders must look to the Lists of Permitted Food Additives for accurate information on which food additives are permitted in particular standardized foods. Stakeholders wishing to market a standardized food in Canada are reminded to continue to read the standards in conjunction with the Lists of Permitted Food Additives to ensure that all requirements for that standardized food are met.

In order to move forward with the new system for food additives, the MAs needed to exempt foods from the standard-specific prohibitions of the *Food and Drugs Act* (FDA) and the *Food and Drug Regulations* (FDR) (sections 6 and 6.1 of the FDA and section B.01.042 of the FDR). It is important to note that this exemption applies **only** to the use and presence of food additives in standardized foods. Lifting these prohibitions was necessary, as otherwise most changes to food additive use for standardized foods would still have required a regulatory amendment (to the food standard) in addition to the administrative change to the relevant food additive list, negating any efficiency gains under the new system.

It is important to note, however, that there are certain instances where the standards contain specific conditions of use for a food additive but these conditions have not appeared in the tables to Division 16. To ensure that these conditions and specifications continue to apply to their respective standardized foods, the column titled "maximum level of use and other conditions" of each incorporated list will, where relevant, refer the reader back to the applicable standard to ensure that the use of any additive or combination of additives in a standardized food meets the specifications of the standard.

**Example:**

Under Division 16 of the Regulations, Table IV (*Food Additives that may be used as Emulsifying, Gelling, Stabilizing or Thickening Agents*), Item L.2, which pertains to the use of lecithin in chocolate and cocoa products, specifies in column 3 that the maximum level of use for this additive is "1.0%". In addition to this, the standards for chocolate and cocoa products subparagraphs B.04.006 (*c*)(v), B.04.007(*c*)(v) , B.04.008(*c*)(v), B.04.009 (*b*)(v), B.04.010 (*b*)(v), and B.04.011(*b*)(v), of the Regulations) provide additional conditions regarding the maximum level of use for this additive when used in combination with other permitted emulsifiers when used in these standardized foods.

To ensure that these additional conditions on the use of the additive are maintained, the maximum level of use for lecithin when used in chocolate and cocoa products has been reworded under the new *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* to "1.0% **in accordance with the requirements of sections B.04.006. B.04.007, B.04.008, B.04.009, B.04.010 and B.04.011.**"

### 3.5 Note on Additives with Other Generally Accepted Uses

The *MA for Food Additives with Other Generally Accepted Uses* and its incorporated list pertain to additives with uses that do not fall within one of the other 14 classes. This MA specifies that the "purposes of use" of the additives found on this list are limited to those that were indicated in Table VIII "Miscellaneous Food Additives" of Division 16 at the time of the coming into force of the MA. This means that:

- Additive submissions pertaining to uses that are currently listed in the *MA for Food Additives with Other Generally Accepted Uses* may be incorporated into the corresponding list administratively, following a satisfactory safety assessment.
- However, new purposes of use (i.e. those not previously described in this list or captured by one of the other 14 classes/MAs) that are assessed and deemed safe will require the creation of either a new MA or an amendment to the *MA for Food Additives with Other Generally Accepted Uses*.

Moving forward, Health Canada intends to consult with stakeholders on options pertaining to the *MA for Food Additives with Other Generally Accepted Uses* and the authorization of new purposes of use.

## 4.0 Changing the Lists of Permitted Food Additives

### 4.1 Submission Process and Amending the Lists

The process and information requirements for making a food additive submission have not changed. Petitioners may refer to Health Canada's "*A Guide for the Preparation of Submissions on Food Additives*" for instructions on how to make a submission to modify the Lists of Permitted Food Additives, including information requirements.

Proposals to amend the Lists of Permitted Food Additives, whether initiated by the Government of Canada or at the request of a petitioner, will continue to undergo the same rigorous scientific safety assessment. Furthermore, appropriate engagement with stakeholders, including the public, will continue to be undertaken when there are proposals to modify the lists, in the form of a notification and comment period. Health Canada will also continue with parallel World Trade Organization (WTO) notification, to inform member countries of the proposal and allow for their comments as well.

#### Proposed Timelines

Amendments to the lists - such as the addition of a new additive or the extension of use of an existing additive - will no longer require lengthy regulatory amendments (as was the case when they were part of Division 16 of the *Regulations*). This means that changes may be enabled in a timelier and more efficient manner once the scientific assessment is completed. Timelines for the administrative modification of the Lists of Permitted Food Additives are described below:

- **Addition of a new food additive to an existing List**
  Following the completion of the scientific assessment and internal review and approval, notification of Health Canada's intent to amend one of the lists to include the new additive will be posted online. Interested domestic and international stakeholders will have 60 days to provide comments. If no new scientific/safety information comes to light during this period, the new additive will be enabled following the close of the notification period. Please note that should new scientific/safety information be raised at any time following the enabling of the additive, Health Canada will review its decision and adjustments to it may be made.

  Time from determination of safety and senior management approval to enabling of the new additive = no more than 6 months.

- **Extension of use of an existing food additive**
  Following the completion of the scientific assessment and internal review and approval, notification of Health Canada's amending of a list to extend the use of an additive will be posted online. The extension is enabled at the time of notification, as occurred previously through the Interim Marketing Authorization (IMA) instrument. Please note that should new scientific/safety information be raised at any time following the enabling of the extension of use, Health Canada will review its decision and adjustments to it may be made.

  Time from determination of safety and senior management approval to enabling of the extension of use = 2 to 3 months.

***Note:*** Submissions for a new additive or for an extension of use that is not within the scope of one of the 15 classes will necessitate the creation of a new MA or the amendment of an existing MA. This is a lengthier regulatory process; however, it is expected to be faster than the GIC regulatory process.

## 4.2 Discontinuation of the Interim Marketing Authorization Authority

The Interim Marketing Authorization (IMA) was a tool that allowed the sale of a food containing an additive whose extension of use had been assessed as safe but had not yet been added to the tables in Division 16 of the Regulations. The IMA has been replaced at the level of the *Food and Drugs Act* with the new MA authority. As such, Health Canada will no longer be issuing IMAs for food additives.

Regarding existing IMAs for food additives, the majority have been added to the Lists of Permitted Food Additives. The small number of outstanding food additive IMAs will be added to the Lists of Permitted Food Additives as quickly as possible. In the interim, the extensions of use covered by these few IMAs remain valid under the auspices of the transitional provisions of the new legislative measures.

## Appendix A

Titles of the 15 lists of permitted food additives that are incorporated by reference through the 15 food additive MAs:

1. List of Permitted Anticaking Agents
2. List of Permitted Bleaching, Maturing or Dough Conditioning Agents
3. List of Permitted Colouring Agents
4. List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents
5. List of Permitted Food Enzymes
6. List of Permitted Firming Agents
7. List of Permitted Glazing or Polishing Agents
8. List of Permitted Food Additives with Other Generally Accepted Uses*
9. List of Permitted Sweeteners
10. List of Permitted pH Adjusting Agents, Acid-Reacting Materials or Water Correcting Agents
11. List of Permitted Preservatives
12. List of Permitted Sequestering Agents
13. List of Permitted Starch Modifying Agents
14. List of Permitted Yeast Foods
15. List of Permitted Carrier or Extraction Solvents

* Corresponds to Table VIII "Miscellaneous Food Additives" found under Div. 16 of the Food and Drug Regulations.