



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Way Forward:

New Food Legislative Authorities and Food Regulatory Modernization

Case Study: Food Additives

CMC
Feb 22 , 2013



Canada 

Context for change

- GoC Regulatory Reform agenda
 - Red tape reduction initiatives
 - Regulatory Cooperation Council
- Health Products and Food Branch Regulatory Roadmap
<http://www.hc-sc.gc.ca/ahc-asc/activit/strateg/mod/roadmap-feuillederoute/rm-fr-eng.php>
- New legislative authorities: Marketing Authorization (MA) and (expanded) Incorporation by Reference (IbR)
 - Tabled as part of Budget Bill C-38 April 26, 2012
 - Bill C-38 received royal assent June 29, 2012
 - Officially in force as of October 25, 2012



MA fundamentals

- Enables the Minister to implement certain food safety decisions through a streamlined ministerial regulatory process
- Scope of MAs clearly defined in the *Act*:
 - MAs can exempt from the FDA and associated regulations
 - Cannot be used to set prohibitions
 - Subject matter: claims, substances
 - MAs can establish classes
 - MAs can set conditions
 - MAs can incorporate documents by reference
- Subject to provisions of the *Statutory Instruments Act (SIA)* and to principles of the *Cabinet Directive on Regulatory Management (CDRM)*



IbR fundamentals

- Enables the incorporation by reference of documents maintained by GoC or other parties
 - May include documents that are amended “from time to time”
 - Documents must be accessible
- Documents can be incorporated via an MA or GiC regulation
 - They may be amended administratively, as needed, as opposed to requiring regulatory amendments
- Incorporated documents have the force of law
- Due process remains (e.g., science, consultation/notification)



Using the new authorities – at a glance

What will change?

- Faster implementation of certain changes to food safety rules, after the safety assessment is completed
- Increased responsiveness to innovation, emerging issues, and scientific developments

What will not change?

- Scientific scrutiny and rigour of analysis
- Enforceability
- Checks and balances, principles of regulatory management
- Consultative and transparent processes
- Rules are rules (assessing regulatory burden)



CASE STUDY

Application of New Tools to Food Additives



Food Additives – Changes to System

- ❑ No changes to the submission process or the submission review process
 - *A Guide for the Preparation of Submission of Food Additives* updated to reflect new tools for enabling food additives
 - No change to the content regarding the submission process
- ❑ What has changed?
 - The process to enable food additives once the science review is complete
 - No longer require GIC regulations or Interim Marketing Authorizations (IMAs) to enable the use of food additives
 - A permitted food additive will appear in one or more of the Lists of Permitted Food Additives (15 in total) that are incorporated by reference (IbR) by an associated Marketing Authorization (MA)
 - Changes to the lists will be done by the Department following the science review and with appropriate notification



The Tools – Marketing Authorizations

Marketing Authorization (MA)

- ❑ 15 Marketing Authorizations – one for each of the existing food additive tables
- ❑ Published in *Canada Gazette*, Part II on October 24, 2012
- ❑ Accessible via a link on HC website

Each MA :

- ❑ Sets out the applicable exemptions to the FDA and FDR
- ❑ Incorporates by reference (IbR) the appropriate list of permitted food additives
 - *Marketing Authorization for Food Additives That May Be Used as Anticaking Agents* incorporates the *List of Permitted Anticaking Agents* (replaces Table 1 of Division 16)
- ❑ Defines the technical function of the corresponding additives on list
- ❑ Defines key terms used in MA



The Tools - Incorporation by Reference (IbR)

- ❑ Each IbR list (lists of permitted food additives) corresponds to a Table in Division 16
 - 15 Tables in Division 16 = 15 Lists of Permitted Food Additives (see Appendix A)
- ❑ Each list of permitted food additives is incorporated by reference by the associated MA
- ❑ Modifications to the lists will be done by the department following the scientific assessment and appropriate notification and comment period
- ❑ Revised lists and notification documents will be available on HC's website



The Tools – Incorporation by Reference

- ❑ Information is presented in the same format as the Tables to Division 16
- ❑ Some modifications made to the Maximum Level Use column
 - Has changed to “Maximum level of use and other conditions”
 - In some instances, new text has been added to capture the rule that is specified in a standard (see Appendix B)
 - No change in the content of the rule that applies to that food additive



Lists of Permitted Food Additives “trump” the additive provisions in the standards

- Reminder: Note where list explicitly references (re-applies) provisions in standards



Standards of Composition and Identity

- ❑ MA exempts the food from the provisions in the standard(s) ONLY with regard to the use or presence of the food additive
- ❑ Food additive must not exceed the maximum level of use and must meet all conditions set out in the list
- ❑ Any labelling or packaging requirements that are set out in a standard continue to apply
- ❑ Standards will no longer be updated to reflect the food additive changes



Standards must be read in conjunction with the Lists of Permitted Food Additives



IbR List of Food Additives

- ❑ Majority of outstanding IMA's have been incorporated into the lists of permitted food additives
 - IMA's for food additives that would have been listed in Table VIII and require a new purpose of use will be added following consultation on a revised *MA for Food Additives with Other Generally Accepted Uses*
- ❑ Table VIII of Division 16 “Miscellaneous Food Additives” now referred to as *List of Permitted Food Additives with Other Generally Accepted Uses*
- ❑ Table III of Division 16 “Colouring Agents” - manner in which the additives are listed in column 1 will appear different. There has been no change in the content or the rules that apply to the use of colours



Compliance and Enforcement

- ❑ Lists and MA's have been enabled as of end of October 2012
- ❑ Tables to Division 16 will not be revoked until later but will no longer be updated
- ❑ Stakeholders are advised to refer to the new administrative Lists of Permitted Food Additives when seeking information on authorized additives and authorized additive uses
 - Lists are considered authoritative by Health Canada and CFIA
- ❑ Newly enabled additives, extensions of use and additive de-listings will only be reflected on the new lists. Standards will no longer be updated with regard to additives.
- ❑ Stakeholders are reminded to read the standards in conjunction with the Lists of Permitted Food Additives and comply with the appropriate requirements for the standard should they wish to market a standardized food in Canada
- ❑ Transition Guide has been posted on HC's website



CAUTION



Current status

- ❑ Initial lists of permitted food additives have been posted and has been updated as the science reviews and notifications are completed
- ❑ Priority has been given to enabling those food additives that have been reviewed but not yet enabled
- ❑ Consultation of the revised *Marketing Authorization for Food Additives with Other Generally Accepted Uses*
 - To allow for select new food additive purposes of use (short-term issues)
- ❑ Process to revoke the Tables to Division 16 and the associated consequential amendments to the *Food and Drug Regulations* will commence later this fall



New Food Additive and Extension of Use

Upon completion of the scientific assessment, should the science support the submission, Health Canada will notify the public of its intent to modify the Lists of permitted food additives via:

- ❑ **New Food Additives** – Notice of Proposal
- Notice of Modification
- ❑ **Extension of Use** – Notice of Modification



List of Notices of Modification

- ❑ Propylene Glycol Mono Fatty Acid Esters as an Emulsifier and Stabilizer in Ice Milk Mix [2012-02-13]
- ❑ Use of Ascorbic Acid as a Preservative in Olives [2012-12-20]
- ❑ Use of Amylase Produced by *Bacillus licheniformis* JS1252 in Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products [2012-12-19]
- ❑ Use of Steviol Glycosides as a Table-Top Sweetener and as a Sweetener in **Certain Food Categories** [2012-11-30]
- ❑ Addition of Potassium Lactate and Sodium Lactate to Standardized Meat Products and Poultry Meat Products [2012-11-20]



Technical Consultation -

- ❑ Technical Consultation on Health Canada's Proposal to:
 - Enable the Use of the Food Additive 'Hexose Oxidase' in pizza mozzarella cheese, part-skim pizza mozzarella cheese, ultra-heat treated milk, and dough for bread, baking and pasta
 - Enable the Use of Dimethyl Dicarbonate as a Preservative in Wine and in Unstandardized Water-Based Non-alcoholic Beverages
 - Enable the use of the Food Additive 'Trisodium Pyrophosphate' in certain Standardized Meat, Poultry and Marine and Freshwater Products, and in Unstandardized Foods



Appendix A -Tables (current) vs Lists (new norm)

Table	Food additives that may be used as
I	Anticaking Agents
II	Bleaching, Maturing or Conditioning Agents
III	Colouring Agents
IV	Emulsifying, Gelling, Stabilizing or Thickening Agents
V	Food Enzymes
VI	Firming Agents
VII	Glazing or Polishing Agents
VIII	Miscellaneous Food Additives
IX	Sweeteners
X	pH Adjusting Agents, Acid-reacting Materials and Water Correcting Agents
XI	Preservatives (Class I, II, III & IV)
XII	Sequestering Agents
XIII	Starch Modifying Agents
XIV	Yeast Foods
XV	Carrier or Extraction Solvents

List of Permitted ...
Anticaking Agents
Bleaching, Maturing or Conditioning Agents
Colouring Agents
Emulsifying, Gelling, Stabilizing or Thickening Agents
Food Enzymes
Firming Agents
Glazing or Polishing Agents
Food Additives with Other Generally Accepted Uses
Sweeteners
pH Adjusting Agents, Acid-reacting Materials and Water Correcting Agents
Preservatives (Class I, II, III & IV)
Sequestering Agents
Starch-Modifying Agents
Yeast Foods
Carrier or Extraction Solvents

Appendix B -Tables (current) vs Lists (new norm)

Table IV - Food Additives that may be used as Emulsifying, Gelling, Stabilizing and Thickening Agents

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
A.1	Acacia Gum	(1) Cream; French dressing; ; (naming the flavour) Skim milk with added milk solids (2) Ice cream; Ice cream mix; Ice milk mix; Ice milk (3) Sherbet (4) Unstandardized foods (5) Calorie-reduced margarine (6) Canned Asparagus; Canned green beans; Canned Wax Beans; Canned peas	(1) Good Manufacturing Practices (2) 0.5% (3) 0.75% (4) Good Manufacturing Practices (5) 0.5% in accordance with the requirements of section B.09.017 (6) 1.0% in accordance with requirements of clause B.11.002 (d) (viii) (C)

List of Permitted Food Additives that may be used as Emulsifying, Gelling, Stabilizing or Thickening Agents

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Acacia Gum	(1) Cream; French dressing; (naming the flavour) Skim milk with added milk solids (2) Ice milk mix; Ice milk (3) Ice cream mix; Ice cream (4) Sherbet (5) Unstandardized Foods (6) Calorie-reduced margarine (7) Canned Asparagus; Canned green beans; Canned Wax Beans; Canned peas	(1) Good Manufacturing Practices (2) 0.5% in accordance with the requirements of section B.08.071 (3) 0.5% in accordance with the requirements of section B.08.061 (4) 0.75%in accordance with the requirements of section B.08.063 (5) Good Manufacturing Practices (6) 0.5% in accordance with the requirements of section B.09.017 (7) 1.0% in accordance with requirements of clause B.11.002 (d) (viii) (C)

What does GMP – in context of Food Additives

- ❑ **B.01.044.** Where the limit prescribed for a food additive in a table to section B.16.100 is stated to be “Good Manufacturing Practice”, the amount of the food additive added to a food in manufacturing and processing shall not exceed the amount required to accomplish the purpose for which that additive is permitted to be added to that food.

