Regulation of Food Colours in Canada

IACM Global Color Conference
“Navigating the Evolving Landscape for Food Colors”
November 15-17, 2016
Arlington, VA

Carl Strowbridge
Questions to be answered

• Who are the food safety regulators in Canada?

• What are the rules for food additives?

• How does an additive get approved?

• What are the proposed changes for colours?

• What about concentrates and extracts used for colouring?
Who are Canada’s food safety regulators?

Canadian Food Inspection Agency (CFIA)

- Other national food policies and standards, and enforcement

Health Canada

- Health Products and Food Branch

Food Directorate

- Bureau of Policy, Interagency, and International Affairs
- Bureau of Food Surveillance and Science Integration
- Bureau of Chemical Safety
- Bureau of Microbial Hazards
- Bureau of Nutritional Sciences

National food policies and standards related to health and safety
Who are Canada’s food safety regulators?

Bureau of Chemical Safety (BCS)

- **Scientific Services Division**
- **Toxicology Research Division**
- **Chemical Health Hazard Assessment Division (CHHAD)**
- **Food Research Division**

**Key Responsibilities:**
- Policy support, standard setting, risk assessment & management, safety evaluations, research and evaluation activities with respect to chemicals in food.
- Safety Evaluation, Risk Assessment & Mgt
- Communication
- Policy Support

**Sections:**
- **Food Additives Section**
- **Food Contaminants Section**
- **Pre-Market Toxicology Assessment Section**
- **Food Contaminants Toxicology Assessment Section**
- **Allergens and Food Intolerances Section**
- **Food Packaging Materials and Incidental Additives Section**
Food Additives Section

• Coordinates premarket evaluation of food additives

• Letters of Opinion on other ingredients added to foods (e.g. flavourings, fruit and vegetable coatings, non-additive colour ingredients) and on food processing aids

• Information to other government groups, industry and the public

• International standards through Codex Committee on Food Additives

• Health risk assessment in support of CFIA (e.g. food containing non-permitted additive)
Legislation and regulations

**Food and Drugs Act**
Applies to the sale in Canada of all food, drugs, natural health products, cosmetics and medical devices, whether manufactured in Canada or imported

**Food and Drug Regulations**

**Ministerial Regulations**
(Marketing Authorizations)
Food and Drugs Act

• Defines “food”

• No person shall sell an article of food that
  (a) has in or on it any poisonous or harmful substance
  (d) is adulterated

• No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety
Food regulations in Part B

• Labelling requirements for prepackaged foods
• Compositional standards for foods
• Definition of “food additive”
• General rules for food additives
28 Divisions in Part B

1. General

2. Alcoholic Beverages

4. Cocoa and Chocolate Products

6. Food Colours

8. Dairy Products

11. Fruits, Vegetables, Their Products And Substitutes

13. Grain And Bakery Products

14. Meat, Its Preparations And Products

16. Food Additives

23. Food Packaging Materials

28. Novel Foods
Compositional standards

Prescribe the standard of composition, strength, potency, purity, quality or other property of the food

Specific or general
• wine, flour, butter, orange juice, cheddar cheese
• prepared meat, (naming the flavour) flavour

Standards for colouring agents contain specifications
• Allura Red (FD&C Red No. 40), β-Carotene
**Definition of food additive**

*food additive* means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include

(a) any nutritive material that is used, recognized or commonly sold as an article or ingredient of food;
(b) vitamins, mineral nutrients and amino acids, other than those listed in the tables to Division 16;
(c) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives;
(d) agricultural chemicals, other than those listed in the tables to Division 16;
(e) food packaging materials and components thereof; and
(f) drugs recommended for administration to animals that may be consumed as food.

Note: Reference to Division 16 should be taken as a reference to the Lists of Permitted Food Additives.
General rules for food additives

• Only permitted additives may be sold as additives

• Substance or mixture sold for use as an additive must include amount of each additive present or directions for use

• Must meet its food grade specifications
Prohibited to sell a food that contains an additive unless the additive is:

- Permitted in the food for the purpose for which it has been added
- Added in an amount within any set limit
General rules for food additives

• An additive must be declared in list of ingredients

• Must be declared by common name. Usually this is the name in the food additive list(s).
  • “colour” permitted for use as common name for colouring agents
Where are the permitted food additives listed?

Prior to October 25, 2012
• 15 tables of Division 16 (FDR) and in food standards

Today
• 15 Lists on Health Canada’s website

Still organized by functional class
The Lists of Permitted Food Additives

### List of Permitted Colouring Agents

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Column 1 Additive</th>
<th>Column 2 Permitted in or Upon</th>
<th>Column 3 Maximum Level of Use and Other Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>(1) Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated (naming the fruit) juice except frozen concentrated orange juice; Fig marmalade with pectin; Fish roe (caviar); Ice cream mix; Ice milk mix; Icing sugar; Liqueur; Lobster paste; (naming the flavour) Milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk solids; (naming the flavour) Skim milk; (naming the flavour) Skim milk with added milk solids; (naming the fruit) Jam with pectin; (naming the fruit) Jelly with pectin; Pickles; Pineapple marmalade with pectin; Relishes; Sherbet; Smoked fish; Tomato catsup</td>
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<td>(2) Unstandardized foods</td>
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<td>(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)</td>
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<td>1.1</td>
<td>Annatto</td>
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<td>(2) 1.0% (Residues of annatto in sausage prepared with such casings not to exceed 100 p.p.m.)</td>
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Interaction of the Lists and Standards

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**Standards in the FDR**

B.14.032(d)(xvi). In the case of longaniza, (A) annatto in such amount as will result in the finished product containing not more than 1000 ppm, if annatto is shown, by the word “annatto”, in the list of ingredients on the label

B.14.004. Meat, meat by-products or preparations thereof are adulterated if any of the following substances or class of substances are present therein or have been added thereto:

c) colour other than annatto, allura red and sunset yellow FCF where provided for in this Division, and caramel

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<td>1A.</td>
<td>β-apo-8′-carotenal</td>
<td>(3) Cream cheese spread</td>
<td>(3) 35 ppm, in accordance with the requirements of section B.08.038</td>
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B.08.038(1)(b)(iv) one or more of the following colouring agents:

(B) in an amount not exceeding 35 ppm, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate
Example of Colour Standard

**B.06.043 [S]. Ponceau SX** shall be the disodium salt of 2-(5-sulpho-2,4-xylylazo)-1-naphthol-4-sulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

**(a)** 0.2 per cent water insoluble matter, as determined by official method FO-8;

**(b)** 0.2 per cent combined ether extracts, as determined by official method FO-9;

**(c)** 1.0 per cent subsidiary dyes, as determined by official method FO-10; and

**(d)** 0.5 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 9; SOR/84-440, s. 3.
How do the lists work from a legal perspective?

• Each list is incorporated by reference into a Marketing Authorization (MA)

• Each MA is a Ministerial Regulation. Legal provisions are in the MA

• The MA exempts from prohibitions if conditions are met

• Conditions can be set out in the Lists (e.g. food, level of use)

• Each list is an administrative document that the Food Directorate can amend as needed (in most cases)
How do the lists work from a legal perspective?

Food

2 (1) When a colouring agent that is set out in column 1 of the List is added to a food that is set out in column 2, the food is exempt from the application of paragraphs 4(1)(a) and (d) and sections 6 and 6.1 of the Food and Drugs Act and sections B.01.042, B.01.043, B.06.002 and B.16.007, as applicable, of the Food and Drug Regulations, in respect of the use or presence of the agent only, if the amount of the agent does not exceed the maximum level of use for that food that is set out in column 3 and if any other conditions that is set out in that column is met.

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(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)

(2) Good Manufacturing Practice

(3) Good Manufacturing Practice
How can I request a change to a List?

File a food additive submission with Health Canada’s Food Directorate

Request:

- New food additive be permitted for use
- New use of an already-permitted food additive (“extension of use”)
  - Change the maximum level of use
  - Use the additive in another food
  - Add a new permitted source for a food enzyme
Submission must be “in a form, manner and content satisfactory to” the Minister, and shall include (B.16.002 of the FDR):

a) Description, chemical name, method of manufacture, and specifications
b) Purpose of use, directions for use
c) Method of analysis (where necessary)
d) Efficacy data
e) Safety information
f) Residue data for use in accordance with GMP
g) Proposed maximum limit for residues
h) Specimens of the labelling proposed for the additive
i) Samples (additive, active ingredient, food containing additive)

Additional guidance available on website and by contacting CHHAD.
Submission evaluation and decision

Safety (and Efficacy)

- Chemistry
- Technological function, proposed conditions of use
- Exposure
- Toxicology
- Microbiology (and Molecular biology, as appropriate)
- Nutrition

Comments

Decision

CFIA & Stakeholders

Recommendation to a senior management committee in Food Directorate

Target = 410 days
Implementing the decision

Committee recommends modification of the list(s)

“Notice of Proposal” to modify list published on Health Canada’s website

comment period

Comments addressed and modification(s) revised (if applicable)

List modified and “Notice of Modification” published on Health Canada’s website

List modified and “Notice of Proposal” to modify list published on Health Canada’s website

Comments addressed and modification(s) revised (if applicable)

List modified and “Notice of Modification” published on Health Canada’s website
NOP’S and NOM’s

Health Canada
www.hc-sc.gc.ca

We’re revising Canada’s food guide. Participate in the consultation process to help revise Canada’s food guide.

Home > Food & Nutrition > Legislation & Guidelines > Acts & Regulations

Acts & Regulations
Regulatory Proposals recently prepublished in the Canada Gazette, Part I
Regulatory Amendments recently published in the Canada Gazette, Part II

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Healthy Canadians
Media Room
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Transparency
Regulatory Transparency and Openness
Completed Access to Information Requests
Proactive Disclosure

Food and Nutrition

Notices of Proposal and Notices of Modification

Notices of Proposal
Notices of Proposal (NOP) are the means by which Health Canada notifies the Canadian public of its intent to amend a departmental document that is incorporated by reference into a Marketing Authorization or the Food and Drug Regulations.

Each NOP provides a summary and rationale for the proposal and is published online for public consideration. Each notice will specify a comment period during which interested parties may provide their input on the proposal. Comments are to be sent to the contact identified in the NOP.

List of Notices of Proposal

- Notice of Health Canada’s Proposal to Enable the use of a New Food Additive, Decitabane as a Sweetener in Certain Unstandardized Foods Including Certain Beverages - Reference Number: NOP/AVP-0022 [2016-10-27]
- Notice of Health Canada’s Proposal to Enable the Use of Lactobacillus lactis DSM 11037 as an Oxygen Scavenger in Certain Modified Atmosphere-Packaged (MAP) and Vacuum-Packaged Preserved Meat Products - Reference Number: NOP/AVP-0021 [2016-09-20]
What about the Division 16 Tables?

- Tables still in Division 16 but generally not being updated
- Standards not being updated with respect to additives
- Refer to the Lists of Permitted Food Additives on website
- Use Lists together with standards
- Regulatory “clean-up” planned to revoke Tables and to address how permitted additive uses are reflected in standards
Proposed Changes to Colour Labelling, Food Additive Specifications & Synthetic Colour Certification Requirements
Proposed Regulatory Amendments

- 75-day public consultation period closed August 27, 2015
- Comments have been reviewed with no expected changes to the proposal
- Register and publish final regulations in Part II of the Canada Gazette
Colour Labelling – current situation

- Colouring agents and other additives must be declared by common name
  - Name set out in *List of Permitted Colouring Agents*
  - FDR identifies “colour” as a common name
Proposed change for colour labelling

• Revoke “colour” as a common name

• Consequence: Declare by name set out in *List of Permitted Colouring Agents*

• For some food additives, CFIA recognizes certain names as acceptable synonyms
• If specs are in Part B, the additive must meet those specs

• If no specs in Part B, but there are in the Food Chemicals Codex (FCC), additive must meet specs in the FCC

• About half of the permitted colouring agents have standards in Division 6. The standards contain some specs

• Specs for arsenic, lead and heavy metals in B.06.003 apply to Division 6 colouring agents
Proposed changes for specifications

• Additives, including colouring agents, must meet either FCC or JECFA specs

• Remove standards for food colouring agents in Division 6

   Exceptions (no FCC or JECFA specs):  Ponceau SX
                                        Citrus Red No. 2

• Remove spec for heavy metals (B.06.003(c)). Spec for arsenic and for lead to be retained for colouring agents without FCC or JECFA specs (but moved from B.06.003 to B.01.045).
• Synthetic colours must be certified by HC (or acceptable agency) that they meet their respective FDR standards and B.06.003

• The U.S. requires certification of synthetic color additives

• Australia and New Zealand, and the EU, require that synthetic food colours meet certain specifications, but they do not have a certification requirement.
Proposed changes for colour certification

- Remove the requirement for synthetic colours to be certified by Health Canada

- Onus will be on food seller to ensure that synthetic colours, like all other food additives, meet required food-grade specifications

- Verification that synthetic colours meet required food-grade specifications will be under CFIA’s oversight, as with other food additives
Proposed Coming into force

Proposed Change:
Delete FDR specifications for most food colouring agents, add reference to JECFA specs, and eliminate certification requirement for synthetic colours

In force:
Date of publication of regulatory amendments in CGII

Proposed Change:
Remove the option of using “colour” as a common name

In force:
Five year transition period is proposed to bring products into compliance with new labelling requirements (grouped with changes to nutrition labelling)
Summary of Proposed Changes for Colouring Agents

Current requirements

- Declare by individual common name or by “colour”
- If specs are in Part B, the additive must meet those specs. If no specs in Part B, but there are in the FCC, additive must meet specs in the FCC
- Specs for arsenic, lead and heavy metals in B.06.003 apply to Div. 6 colouring agents.
- Certification requirement for synthetic colours

Proposed New requirements

- Declare by individual common name (5 year transition period)
- Meet FCC or JECFA specs. Exceptions Ponceau SX and Citrus Red No. 2
- Spec for arsenic and for lead to be retained for colouring agents without FCC or JECFA specs (but moved from B.06.003 to B.01.045).
- Elimination of certification requirement
What about Concentrates and extracts used for colouring?

Concentrate or crude extract

• Non-selective concentration, extraction and/or filtration

• Ratio of colouring principle(s) to other constituents not substantially different than for source material

• Extraction solvents and other additives used in manufacture must be permitted

• Use in food subject to section 4 of the *Food and Drugs Act*

• Letter of opinion upon request (non-mandatory premarket review)

Examples: Concentrated juices, crude *Spirulina* extract
Concentrates and extracts used for colouring

• Highly purified extract

  • Selective extraction, filtration and/or concentration of colouring principle(s)

  • Regulated as colouring agents (mandatory premarket review)

Examples: Chlorophyll, Grape skin extract, Beet red, Annatto

Can request an opinion on whether a concentrate or extract would be considered a colouring agent or non-additive colouring ingredient (submit info for consideration)
A Guide for the Preparation of Submissions on Food Additives

Including Information on Irradiated Food Submissions and on Requests for Opinions on Substances Not Regulated as Food Additives

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch

December 27, 2007

Abridged guidance:
“Food Additives - Submission Preparation”


Other Relevant Documents

- **Food and Drugs Act and Regulations**
  http://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html

- **Lists of Permitted Food Additives**

- **CFIA’s Permitted Synonyms for Food Additives Table**
  http://www.inspection.gc.ca/food/labelling/food/labelling-for-industry/list-of-ingredients-and-allergens/table/eng/1369857665232/1369857767799

- **Food Directorate’s Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods**
  http://www.hc-sc.gc.ca/fn-an/consult/additives-additifs-eng.php#s1
Bureau of Chemical Safety
bcs-bipc@hc-sc.gc.ca

Carl.Strowbridge@hc-sc.gc.ca

Senior Scientific Evaluator, Food Additives Section
Chemical Health Hazard Assessment Division
Bureau of Chemical Safety, Food Directorate
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