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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



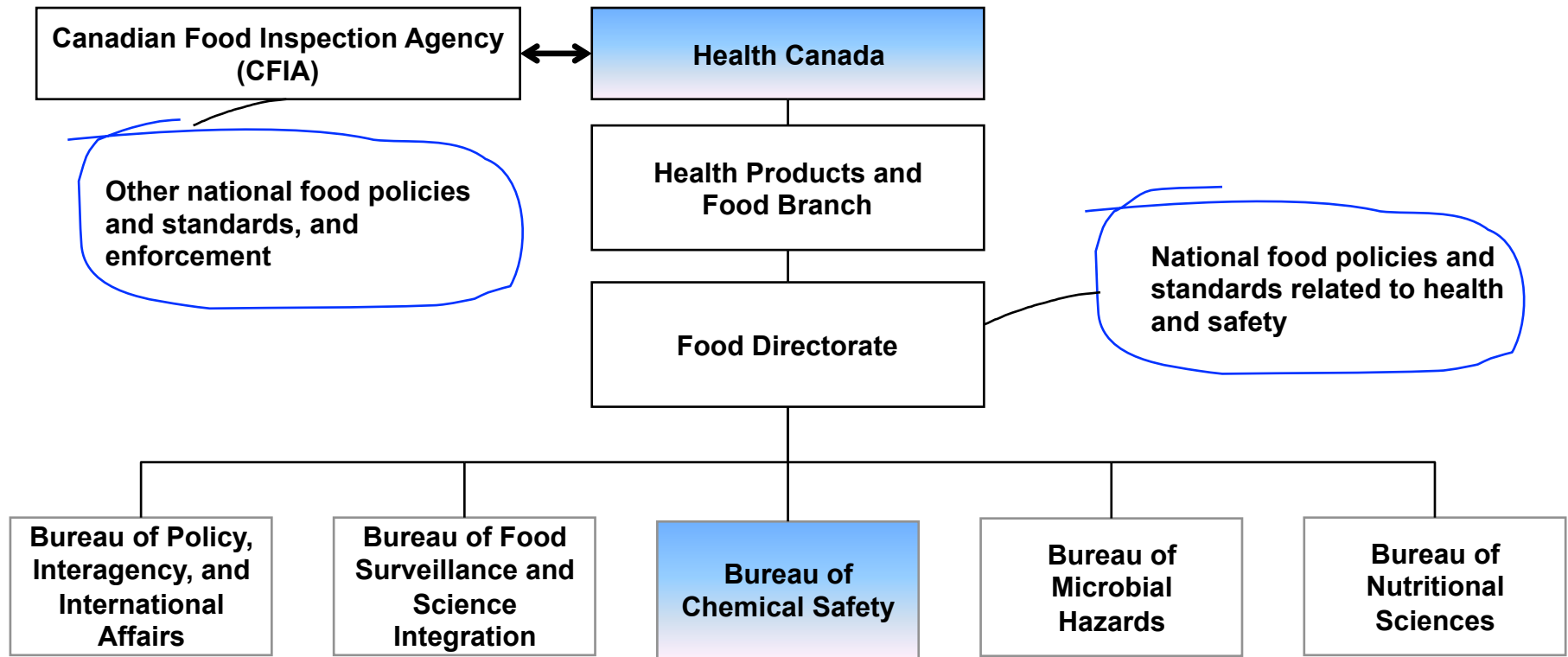
Canada 

Questions to be answered

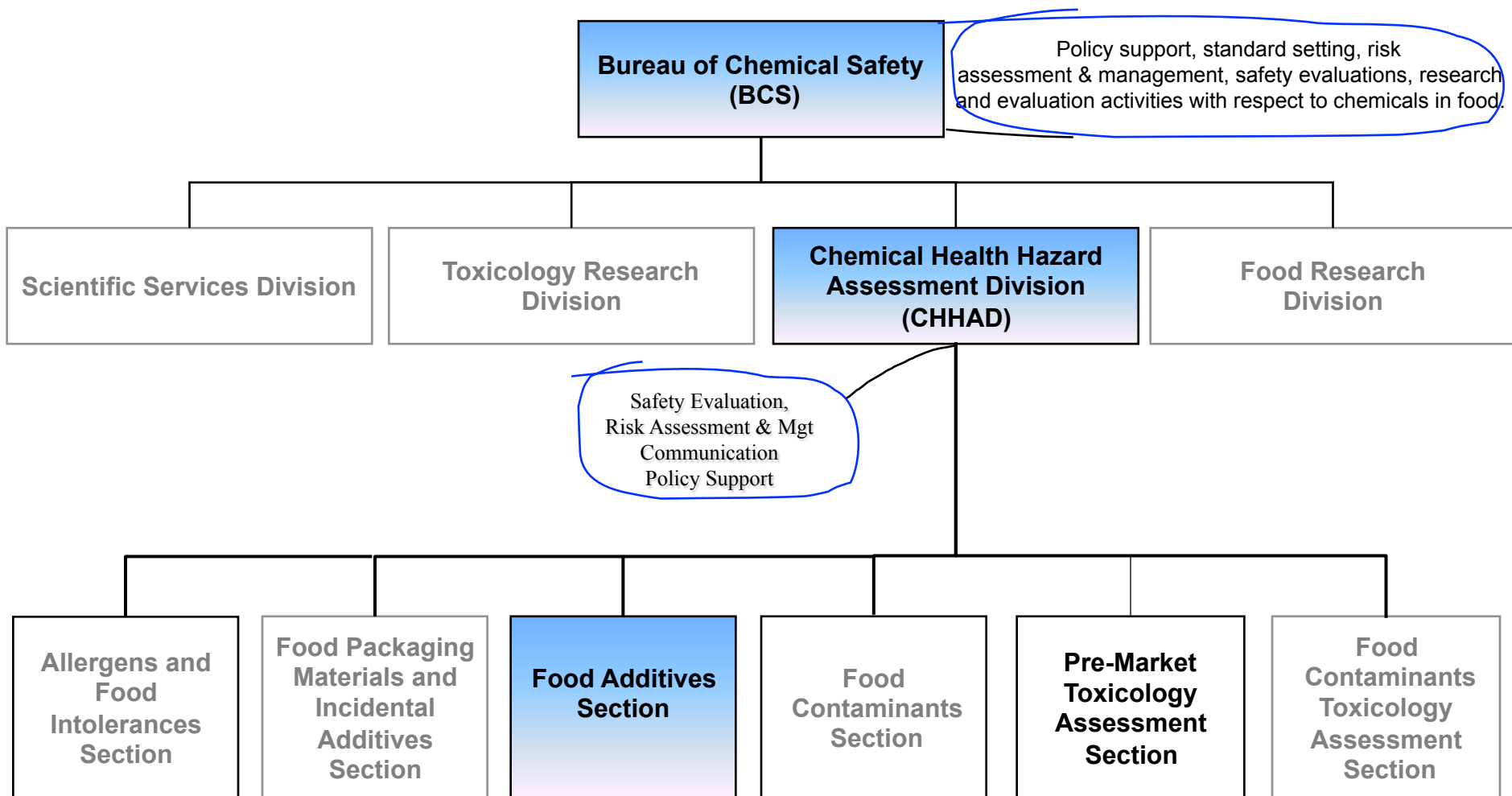
- Who are the food safety regulators in Canada?
- What are the rules for food additives?
- How does an additive get approved?
- What are the proposed changes for colours?
- What about concentrates and extracts used for colouring?



Who are Canada's food safety regulators?



Who are Canada's food safety regulators?



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 and Drug Regulations

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

B.08.061 [S]. Ice Cream Mix

(a) shall be the unfrozen, pasteurized combination of cream, milk or other milk products, sweetened with sugar, liquid sugar, invert sugar, honey, dextrose, glucose, corn syrup, corn syrup solids or any combination of such sweeteners;

(b) may contain

(i) egg,

(ii) a flavouring preparation,

(iii) cocoa or chocolate syrup,

(iv) a food colour,

(v) pH adjusting agents,

(vi) microcrystalline cellulose or a stabilizing agent or both in an amount that will not exceed 0.5 per cent of the ice cream made from the mix,

(vii) a sequestering agent,

(viii) salt,

(ix) not more than one per cent added edible casein or edible caseinates; and

(x) propylene glycol mono fatty acid esters in an amount that will not exceed 0.35 per cent of the ice cream made from the mix and sorbitan tristearate in an amount that will not exceed 0.035 per cent of the ice cream made from the mix; and

(c) shall contain not less than

(i) 36 per cent solids, and

(ii) 10 per cent milk fat or, where cocoa or chocolate syrup has been added, eight per cent milk fat.

SOR/92-400, s. 11; SOR/97-543, s. 2(F); SOR/2007-75, s. 2; SOR/2007-302, s. 4(F); SOR/2010-142, s. 6(F).



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



General rules for food additives

- 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



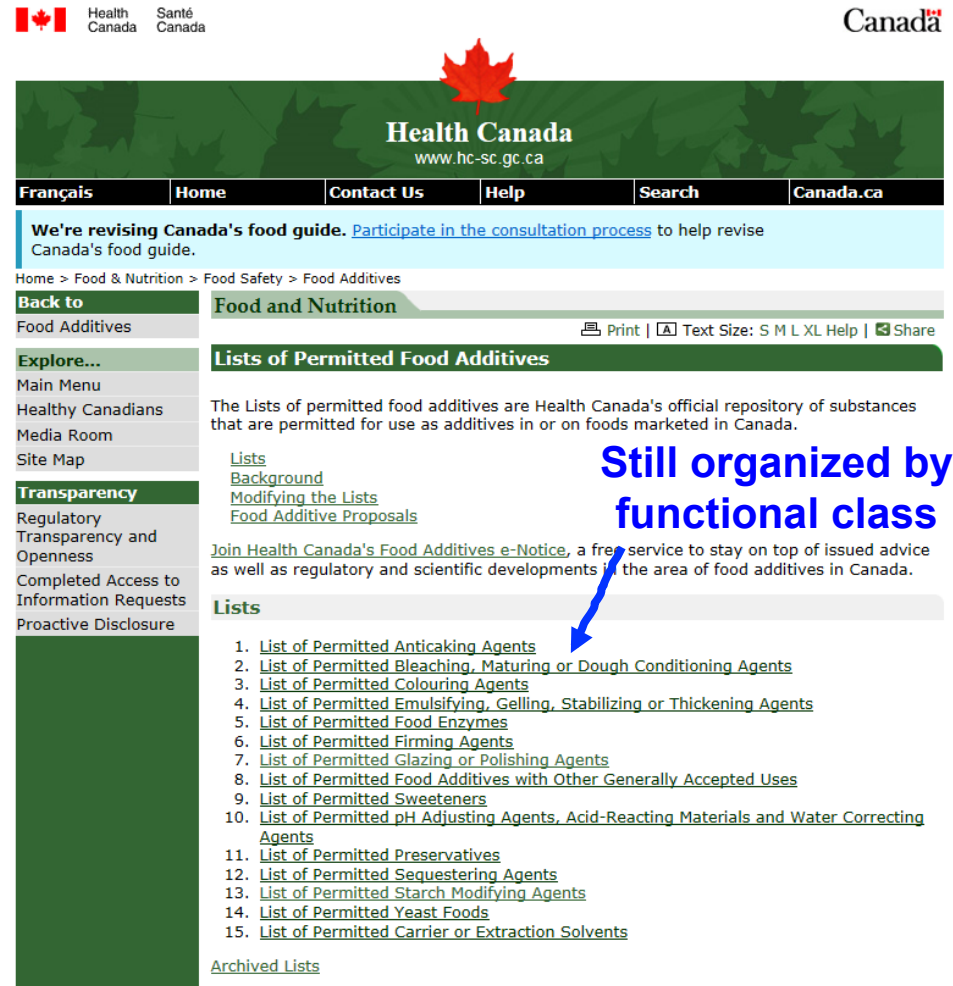
Where are the permitted food additives listed?

Prior to October 25, 2012

- 15 tables of Division 16 (FDR) and in food standards

Today

- 15 Lists on Health Canada's website



Health Canada
www.hc-sc.gc.ca

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We're revising Canada's food guide. [Participate in the consultation process](#) to help revise Canada's food guide.

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Lists of Permitted Food Additives

The Lists of permitted food additives are Health Canada's official repository of substances that are permitted for use as additives in or on foods marketed in Canada.

[Lists](#)
[Background](#)
[Modifying the Lists](#)
[Food Additive Proposals](#)

[Join Health Canada's Food Additives e-Notice](#), a free service to stay on top of issued advice as well as regulatory and scientific developments in the area of food additives in Canada.

Lists

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 and 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](#)

[Archived Lists](#)

Still organized by functional class



The Lists of Permitted Food Additives

List of Permitted Colouring Agents

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
1.	Alkanet; Aluminum Metal; Annatto; Anthocyanins; Beet Red; Canthaxanthin; Carbon Black; Carotene; Charcoal; Chlorophyll; Cochineal; Iron Oxide; Orchil; Paprika; Riboflavin; Saffron; Saunderswood; Silver Metal; Titanium Dioxide; Turmeric; Xanthophyll	(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	(1) Good Manufacturing Practice
		(2) Unstandardized foods	(2) Good Manufacturing Practice
		(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(3) Good Manufacturing Practice
1.1	Annatto	(1) Longaniza; Tocino	(1) 0.1% in accordance with the requirements of paragraph B.14.031(i) or subparagraph B.14.032(d)(xvi)
		(2) Sausage casings	(2) 1.0% (Residues of annatto in sausage prepared with such casings not to exceed 100 p.p.m.)
1.2	Annatto; Canthaxanthin;	Margarine	Good Manufacturing Practice

**Defined
in B.
01.044**

**The condition
of use refers
back to the
food standard
for more detail.**

The list of permitted foods includes named foods as well as “unstandardized foods” (named foods can be standardized or unstandardized)



Interaction of the Lists and Standards

List of Permitted Colouring Agents

Item No.	Additive	Permitted in or Upon	Maximum Level of Use and Other Conditions
1.	Annatto	Longaniza; Tocino	1.0% in accordance with the requirements of paragraph B.14.031(i) or subparagraph B.14.032(d)(xvi)

Item No.	Column 1 Additive	Permitted in or Upon	Maximum Level of Use and Other Conditions
1A.	β -apo-8'-carotenal	(3) Cream cheese spread	(3) 35 ppm, in accordance with the requirements of section B.08.038

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

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.

List of Permitted Colouring Agents

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
1.	Alkanet; Aluminum Metal; Annatto; Anthocyanins; Beet Red; Canthaxanthin; Carbon Black; Carotene; Charcoal; Chlorophyll; Cochineal; Iron Oxide; Orchil; Paprika; Riboflavin; Saffron; Saunderswood; Silver Metal; Titanium Dioxide; Turmeric; Xanthophyll	(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	(1) Good Manufacturing Practice
		(2) Unstandardized foods	(2) Good Manufacturing Practice
		(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(3) Good Manufacturing Practice
1.1	Annatto	(1) Longaniza; Tocino	(1) 0.1% in accordance with the requirements of paragraph B.14.031(i) or subparagraph B.14.032(d)(xvi)
		(2) Sausage casings	(2) 1.0% (Residues of annatto in sausage prepared with such casings not to exceed 100 p.p.m.)
1.2	Annatto; Canthaxanthin;	Margarine	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



Food Additive Submission Requirements

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

CFIA &
Stakeholders

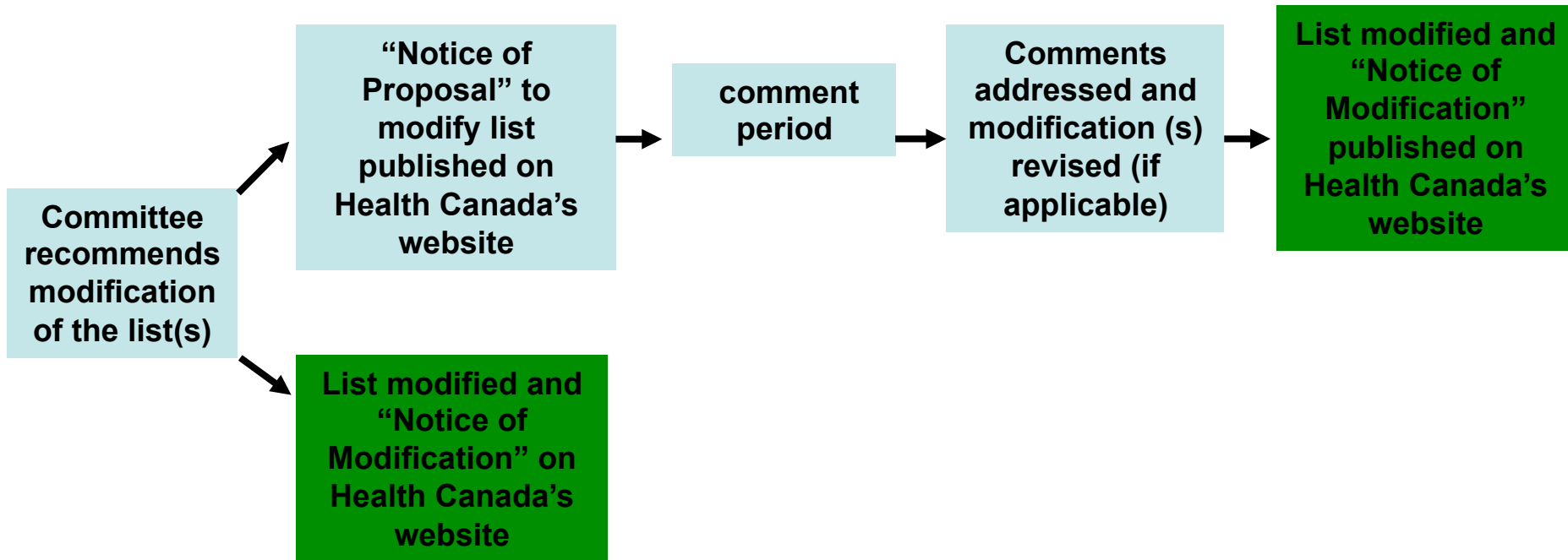
Decision

Recommendation
to a senior
management
committee in
Food Directorate

Target = 410 days



Implementing the decision



NOP'S and NOM's



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Acts & Regulations

Regulatory Proposals recently published in the *Canada Gazette*, Part I

Regulatory Amendments recently published in the *Canada Gazette*, Part II

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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, Advantame, as a Sweetener in Certain Unstandardized Foods Including Certain Beverages - Reference Number: NOP/AVP-0022](#) [2016-10-27]
- [Notice of Modification to the List of Permitted Preservatives to Enable the Use of Potassium Acetate and Potassium Diacetate in Certain Meat and Poultry Products - Document Reference Number: NOM/ADM-0080](#) [2016-10-21]
- [Notice of Health Canada's Proposal to Enable the Use of *Lactococcus 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*

June 13, 2015
Vol. 149, No. 24
www.gazette.gc.ca



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



Specifications – current situation

- 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 colour certification – current situation

- 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 CGI

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

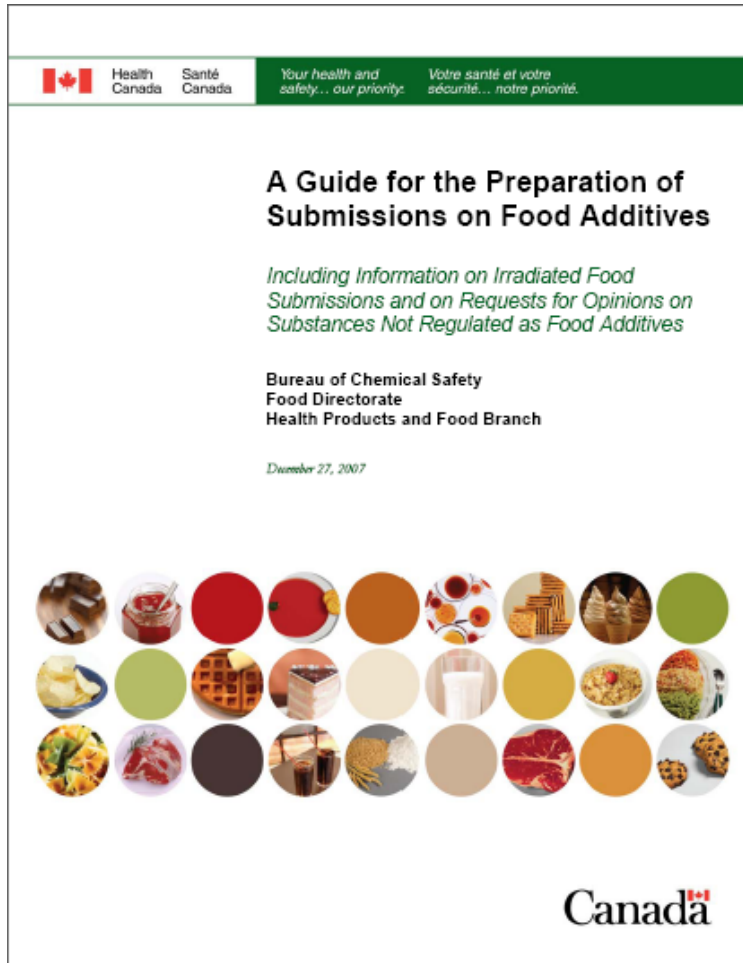
- **Highly purified extract**
 - Selective extraction, filtration and/or concentration of colouring principle(s)
 - Regulated as colouring agents (mandatory premarket review)

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)



Detailed and Abridged Submission Guidance



Abridged guidance: “Food Additives - Submission Preparation”

[http://www.hc-sc.gc.ca/fn-an/securit/addit/
sub_prep_demande-eng.php](http://www.hc-sc.gc.ca/fn-an/securit/addit/sub_prep_demande-eng.php)

<http://www.hc-sc.gc.ca/fn-an/pubs/guide-eng.php>



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

<http://www.hc-sc.gc.ca/fn-an/securit/addit/list/index-eng.php>

- 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>





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