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Health Canada's Proposal to Modify the Currently Permitted Uses of the Colouring Agent Amaranth in Various Foods

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0023]

January 4, 2017

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch

Canada

Summary

Food additives are regulated in Canada under Marketing Authorizations (MAs) issued by the Minister of Health and the *Food and Drug Regulations.* Approved food additives and their permitted conditions of use are set out in the Lists of Permitted Food Additives that are incorporated by reference in the MAs and published on Health Canada's website. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada has conducted a re-evaluation of the food additive uses of the colouring agent amaranth, which is currently permitted at a maximum level of use of 300 parts per million (p.p.m.), singly or in combination with other specified synthetic colours, in a range of foods including bread, jams, concentrated fruit juice, flavoured milk, ice cream and tomato catsup. The re-evaluation was conducted in support of a broader review of fifty-two azo acid dyes[1] carried out as part of the Government of Canada's Chemicals Management Plan.[2]

The results of Health Canada's re-evaluation of available data on the concentrations of amaranth actually used in foods sold in Canada reveal that exposure to amaranth is within acceptable levels from a food safety perspective. However, the existing maximum levels of use for amaranth that appear in the *List of Permitted Colouring Agents* are generally higher than actual use levels and would allow for elevated exposures if actual use levels ever increased. In order to ensure that potential exposure to the food colouring agent amaranth remains within acceptable levels, it is the intention of Health Canada to modify the *List of Permitted Colouring Agents* by creating a unique listing for "Amaranth" (it is currently grouped in the List with five other synthetic colours) and by identifying areas of use and maximum levels of use that align with actual current uses, as shown below. No changes to the singly or in combination maximum use levels for the other synthetic colours (i.e., Allura Red, Erythrosine, Indigotine, Sunset Yellow FCF and Tartrazine) are being proposed.

1 Of the fifty-two substances covered in the azo acid dye re-evaluation under the Chemicals Management Plan, only two, amaranth and tartrazine, have food additive uses.
http://www.chemicalsubstanceschimiques.gc.ca/group/azo_benzidine/dyes-colorants-eng.php
2 Additional details about the Chemicals Management Plan are available at:
http://www.chemicalsubstanceschimiques.gc.ca/plan/index-eng.php

Proposed Modifications to the *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
3.2.1	Amaranth	(1) Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; (naming the fruit) Jam with pectin; (naming the fruit) Jelly with pectin; Pineapple marmalade with pectin	(1) 100 p.p.m. singly or in combination. If used in combination with one or more of the colouring agents listed in column 1 of item 3 of this list, the combined maximum level of use not to exceed 300 p.p.m.
		(2) Liqueur; Unstandardized alcoholic beverages	(2) 300 p.p.m. singly or in combination. If used in combination with one or more of the colouring agents listed in column 1 of item 3 of this list, the combined maximum level of use not to exceed 300 p.p.m.
		(3) Hard candies; (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; Unstandardized dairy beverages, except eggnog	(3) 50 p.p.m. singly or in combination. If used in combination with one or more of the colouring agents listed in column 1 of item 3 of this list, the combined maximum level of use not to exceed 300 p.p.m.
		(4) Cream soda; Grape soda; Unstandardized non-carbonated fruit-flavoured beverages, concentrates and mixes	(4) 90 p.p.m. singly or in combination as consumed. If used in combination with one or more of the colouring agents listed in column 1 of item 3 of this list, the combined maximum level of use not to exceed 300 p.p.m., as consumed.
		(5) Unstandardized frozen desserts	(5) 55 p.p.m. singly or in combination. If used in combination with one or more of the colouring agents listed in column 1 of item 3 of this list, the combined maximum level of use not to exceed 300 p.p.m.
		(6) Eggnog; Unstandardized dressings; Vinaigrettes; Yogurt	(6) 15 p.p.m. singly or in combination. If used in combination with one or more of the colouring agents listed

Item No.	Column 1 Additive	Column 2 Permitted In or Upon	Column 3 Maximum Level of Use and Other Conditions
			in column 1 of item 3 of this list, the combined total not to exceed 300 p.p.m.
		(7) Pancake mixes; Unstandardized bakery products; Waffle mixes	(7) 40 p.p.m. singly or in combination as consumed. If used in combination with one or more of the colouring agents listed in column 1 of item 3 of this list, the combined maximum level of use not to exceed 300 p.p.m., as consumed.
		(8) Potato chips; Unstandardized desserts, except unstandardized frozen desserts; Unstandardized dessert toppings	(8) 100 p.p.m. singly or in combination. If used in combination with one or more of the colouring agents listed in column 1 of item 3 of this list, the combined maximum level of use not to exceed 300 p.p.m.

Consequential changes will also be required to item 3 of the *List of Permitted Colouring Agents* to remove "Amaranth" from column 1; to regroup some of the foods shown in column 2; and to remove reference to section B.06.002, which sets out "in combination" rules, and replace that reference with text describing the "in combination" rules in column 3, as shown below. For column 2, the food categories shown below are the same as currently listed but foods that are currently grouped as sub-item (1) would be separated into two groups. Sub-items (1) and (2) shown below are those foods in which amaranth may also be used and for which the maximum level of use also reflects the possible use of amaranth. Sub-items (3) and (4) shown below are those foods in which amaranth is not reported to be used and for which the maximum level of use does not need to reflect the possible use of amaranth.

Consequential Changes to the *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
3	Allura Red; Erythrosine; Indigotine; Sunset Yellow FCF; Tartrazine	(1) Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; (naming the fruit) Jam with pectin; (naming the fruit) Jelly with pectin; Liqueur; (naming the flavour) Milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk	(1) 300 p.p.m. singly or in combination with one or more of the colouring agents listed in column 1 of item 3 of this list and amaranth, provided the conditions of use of amaranth are respected.

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		solids; Pineapple marmalade with pectin; (naming the flavour) Skim milk; (naming the flavour) Skim milk with added milk solids	
		(2) Unstandardized foods	(2) 300 p.p.m. singly or in combination with one or more of the colouring agents in column 1 of item 3 of this list and amaranth, provided the conditions of use of amaranth are respected.
		(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*)	(3) 300 p.p.m. singly or in combination with one or more of the colouring agents in column 1 of item 3.
		(4) Bread; Butter; Concentrated (naming the fruit) juice except frozen concentrated orange juice; Fish roe (caviar); Ice cream mix; Ice milk mix; Icing sugar; Lobster paste; Pickles; Relishes; Sherbet; Smoked fish; Tomato catsup	(4) 300 p.p.m. singly or in combination with one or more of the colouring agents in column 1 of item 3 of this list.

This proposal is expected to have no impact on the food industry given that the food categories, as shown in the first table, were developed based on the following two sources of information: (1) feedback from the food industry which had identified the foods in which amaranth is currently used and at what levels; and (2) the results of targeted surveys of amaranth in food that were conducted by the Canadian Food Inspection Agency. For some food categories in which amaranth may currently be legally used, there was either no reports received of actual use of amaranth or there was clear indication from the industry that amaranth is not used. These food categories have not been included among the proposed list of foods in which amaranth may be used.

Rationale

In 2014, Health Canada's Food Directorate completed a re-evaluation of the potential exposure to amaranth from its use as a food colouring agent. The re-evaluation was conducted in support of the Government of Canada's Chemicals Management Plan Groupings Initiative, in which fifty-two azo acid dyes, including amaranth, were assessed. As part of the evaluation, the actual concentrations of amaranth presently added to food were obtained from the food industry through a Call for Data. The feedback received was used to estimate potential exposure to amaranth

among the population in Canada. The conclusion that there is not expected to be a health risk is based on the present use patterns among the food industry.

For a majority of the foods in which amaranth was reported to be used, the actual concentrations of amaranth in the food were below the maximum permitted level of use. The current regulatory conditions of use for amaranth, some of which are based on usage data from the 1970's and which were based on the body of scientific evidence available at that time, evidently no longer reflect current use patterns and generally permit the use of amaranth at higher use levels and in more food categories than necessary. An exposure assessment demonstrated that if amaranth were used at its current maximum permitted level in all permitted foods, it would result in an unacceptably elevated exposure to amaranth. Therefore, updated conditions of use for amaranth are being proposed to ensure that exposures remain within acceptable levels and to reflect current use patterns of amaranth in foods.

In order to develop a proposal on revised conditions of use for amaranth, the assessment of potential exposure to amaranth from its food additive uses in foods for which there was evidence of its use was conducted again, this time using the actual concentrations of amaranth in foods sold in Canada, as reported in 2013 and 2014 by the food industry and as well as the concentrations measured in targeted surveys by the Canadian Food Inspection Agency.

The updated exposure assessment employed single-day (24-hr recall) data on the consumption of foods[3]; it assumed a daily frequency of consumption of foods; it assumed that all of the foods included in the assessment always contain added amaranth and that the concentration was at the upper range of reported levels; and it sometimes assumed that amaranth was present in all foods within a particular food category when it could actually only be present in a sub-set of foods within that category. The exposure assessment can therefore be described as conservative.

The conservatively estimated mean intakes of amaranth among the various age groups were either below or approximated the Acceptable Daily Intake (ADI) of 0.5 mg/kg bw/day which was established by the Joint Expert Committee on Food Additives (JECFA). The intakes were also similar to or lower than the estimates that were published in the Chemicals Management Plan Screening Assessment Report which had concluded that reported food additive use levels of amaranth do not pose an unacceptable health risk. The ADI is the dose of a substance that an individual can ingest daily over a lifetime without an appreciable health risk. The ADI for amaranth incorporates an uncertainty value of 100, meaning that the ADI is 100 times less than the minimum dose at which no adverse effects were seen in experimental animals.

Based on the results of the exposure assessment, the Food Directorate considers that the proposed new conditions of use for amaranth will ensure that total dietary exposure to amaranth will remain within acceptable levels. As such, the Directorate is proposing to amend the *List of*

3 Canadian Community Health Survey Cycle 2.2 (Statistics Canada 2004)

Permitted Colouring Agents by adjusting the food categories and the majority of the corresponding maximum levels of use to better reflect actual areas and levels of use of amaranth.

As noted, this proposal is expected to have no impact on the food industry because the food categories as shown in the first table were developed based on feedback from the food industry, which identified the foods in which amaranth is currently used and at what levels, and based on targeted surveys conducted by the Canadian Food Inspection Agency.

Other Relevant Information

Amaranth has permitted food additive uses in other jurisdictions, including Europe, Australia and New Zealand. Based on studies conducted internally by the United States *Food and Drug Administration* (U.S. FDA), it was delisted for use in food in the United States in 1976. Canada and other international regulatory agencies consider that the earlier studies upon which the U.S. FDA based its decision had significant limitations and that the current body of scientific evidence supports the safety in use of amaranth as a food additive within specific conditions.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the *List of Permitted Colouring Agents*. This will be announced via a Notice of Modification which will be published on Health Canada's Website.

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

Contact Information

For additional information or to submit comments related to this proposal, please contact:

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If communicating by e-mail, please use the word "**Amaranth**" in the subject line of your e-mail. Health Canada is able to consider information received by **March 18, 2017**, 75 days from the date of this posting.