



PROVISION COALITION

PROCESSING FOOD SUSTAINABLY

100 Stone Road West, Suite 205
Guelph, Ontario N1G 5L3
P. 519-822-2042
info@provisioncoalition.com
www.provisioncoalition.com

Reversal of CEPA Toxic Decision for Amaranth

The Importance of Responding to Health Canada and Environment Canada Requests for Data

Date: July 31, 2015

Prepared by: Keith Mussar

Keith Mussar & Associates
Agri-FOOD CONSULTANTS

Relevance to Provision Members

Data provided by Provision members to Health Canada in 2014 directly contributed to the reversal of Health Canada's decision to declare amaranth, a CEPA toxic substance. Had Provision members not responded to the Health Canada request for data (see [Provision Brief #4](#), "Risk Assessment of Food Related Substances by Health Canada and CEPA", March 2014), the use of amaranth in food would have been prohibited or substantially reduced.

Health Canada will be re-engaging stakeholders in consultation in 2015 to determine actions that will ensure that the exposure of consumers to amaranth does not increase through the use of amaranth as a food colour.

Background

Amaranth (also known as FD&C Red No. 2 and E123 in the UE) is a red food colour used in the manufacture of a wide variety of foods including:

- Non-alcoholic beverages and beverages from mixes and concentrates
- Condiments, dressings, sauces and gravies
- Snack foods (some chips and other snacks)
- Candy, cake decorations and icing
- Breakfast cereals
- Jam and jelly products
- Flavoured milk and milk products
- Rice products and pastas
- Baked goods and bakery mixes
- Desserts, dessert mixes, toppings and fillings

Amaranth is permitted for use in food in Canada to a maximum level of 300 parts per million. Food is the main source of exposure for Canadian consumers to amaranth. Amaranth is included in the Aromatic Azo-and Benzidine-based Substances Group that is undergoing environmental and human health risk assessment under the Chemicals Management Plan.

When a risk assessment results in a substance being determined CEPA Toxic, Environment Canada and Health Canada are obligated to implement risk management activities to limit the exposure of the substance to the environment and Canadian consumers. When limiting the current use of a substance, pre-approval of the substance for new applications or prohibition of use are actions that can be undertaken by Health Canada and Environment Canada Officials.

Amaranth CEPA Toxic Decision

Events Leading to Amaranth CEPA Toxic Decision

Industry response was limited to Environment Canada's Section 71 notice (<http://gazette.gc.ca/rp-pr/p1/2011/2011-12-17/html/sup-eng.html>) in December 2011 to collect data on the use of Aromatic Azo and Benzidine-base substances, which included amaranth.

Health Canada based the human health risk assessment for amaranth on the maximum level of amaranth approved for use under the Food and Drug Regulations, as data regarding the actual use was not reported by the food sector. Health Canada declared amaranth to be a CEPA Toxic substance. Using the maximum level of amaranth approved for use under the Food and Drug Regulations, Health Canada calculated that the dietary exposure of toddlers, children and teenagers exceeded the Acceptable Daily Intake (0.5 mg/kg-body weight per day).

Events Leading to the Reversal of the Amaranth CEPA Toxic Decision

Health Canada issued a targeted request for data on the use of amaranth in food products produced in Canada and imported into Canada (March 2014). Provision members sent data to Health Canada in response to Health Canada's request for information published in Provision Brief #4 March 2014.

Based on data provided by Provision members and others, Health Canada published "*Proposed Findings in the Certain Azo Acid Dyes (Azo Package 3) Draft Screening Assessment Report as part of the Aromatic Azo and Benzidine-based Substance Grouping*" (see [attached](#)) designating amaranth as a non CEPA Toxic substance (October 2014).

Health Canada and Environment Canada published the *Draft Screening Assessment for Certain Azo Acid Dyes in the Aromatic Azo and Benzidine-based Substance Grouping* designating amaranth as not CEPA Toxic, October 2014 <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=05BF983D-1>.

Amaranth - Next Steps

To ensure that the exposure of consumers to amaranth does not increase through the use of amaranth as a food colour, Health Canada has signaled that it will undertake the following actions in 2015:

- Amend the *List of Permitted Colouring Agents* to limit the food categories to which amaranth may be added
- Lower some or all of the maximum levels of use of amaranth in specific food categories
- Introduce regulations that would require the labelling of colours by their common name(s)

It is expected that Health Canada will engage stakeholders in consultation in 2015 to determine which of the above actions would be appropriate.

Other Food Colours from the Aromatic Azo and Benzidine-based Substance Grouping

Tartrazine

Tartrazine was determined to not be CEPA Toxic by Health Canada and Environment Canada (<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=05BF983D-1>). The report identified “Tartrazine is not proposed to be harmful to human health or the environment based on current levels of exposure.” Tartrazine is a food colour that is approved for use in Canada at a level of 300 parts per million in foods and beverages.

Orange II

Orange II is not approved for use as a colour in food or beverages in Canada. It is known however, that Orange II is a subsidiary colour or component colour of the food colour sunset yellow, which is approved for use in Canada.

Health Canada determined that exposure to Orange II “via food additive uses is expected to be negligible.”