



PROVISION COALITION

PROCESSING FOOD SUSTAINABLY

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Brief 4: Risk Assessment of Food Related Substances by Health Canada and CEPA

Date: March 6, 2014

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Background

Recently, a board member reported to the Provision Coalition Board of Directors regarding a discussion held at a Health Canada-CFIA industry meeting in Ottawa on January 27, 2014.

Keith Mussar & Associates was asked to confirm the substance of the discussion with Health Canada regarding the Canadian Environmental Protection Act, 1999 (CEPA) and the process for review of food related substances by Health Canada under CEPA.

Health Canada Oversight of Food Substances Under CEPA

Barbara Lee, Director, Bureau of Chemical Safety for the Food Directorate at Health Canada gave the presentation on January 27, 2014, which initiated the discussion.

Health Canada and Environment Canada both contribute to the oversight and determination of the environmental safety of a food substance under the Canadian Environmental Protection Act. Specifically, Health Canada determines the human health risk from direct exposure [consumption] and indirect exposure [environmental contact] to a substance. Environment Canada determines the risk to the environment due to release of the substance into the environment.

The final determination of the environmental toxicity or “CEPA toxicity” of a substance is informed by the human health risk assessment and the environmental health risk assessment.

Environmental Toxicity = Human Health Risk + Environmental Health Risk

Section 71 notices are used by Environment Canada to compel industry to provide data regarding the use, import, manufacture, environmental release and disposal of a targeted substance. This data is primarily used by Environment Canada for the environmental risk assessment.

Section 71 data may not be specific enough for Health Canada’s purposes as food substances are often used for applications other than food. For instance, food grade vegetable oil is used for industrial purposes as a lubricant in drilling or as an ingredient in paint.

When data is not available from industry regarding the amount of a substance used specifically in food for the human health risk assessment, Health Canada assumes the amount used is the maximum allowable level approved for use as prescribed under the Food and Drug Regulations.

When the maximum amount allowed under the regulations for all approved uses of a food substance exceed the Acceptable Daily Intake or ADI for the substance, Health Canada deems the substance to be “CEPA toxic.”

Amaranth Designation as CEPA Toxicity

The discussion on January 27, 2014, reported on by the board member, was with regards to the food colour amaranth. Amaranth is also known as FD&C Red No. 2 and E123 in the UE.

Amaranth will be deemed “CEPA toxic” by Health Canada because the allowable level prescribed under the Food and Drug Regulations exceeds the ADI.

If deemed to be “CEPA toxic”, Health Canada will take action to manage its use. Health Canada could pursue one or more of the following:

- Reduce the amount of amaranth that can be used in approved food applications.
- Reduce the number of food applications where amaranth can be used. Health Canada could rescind the approval for use of amaranth in non-standardized food.
- Require pre-approval for the use of amaranth in new food applications.
- Prohibit the use of amaranth in food. U.S. FDA prohibits the use of amaranth for health and safety reasons.

Recommended Action for Provision Members

To reduce the risk of designation of amaranth as “CEPA toxic”, it is recommended that Provision members provide the following information to Health Canada regarding the use of amaranth in food and food ingredients which they manufacture in Canada or import into Canada.

1. Type of food and food ingredients in which amaranth is used
2. Level or amount of amaranth used in the food or food ingredients
3. Categories of food in which amaranth is **NOT** used. Reporting this is as important as responding to 1 & 2 as amaranth is allowed for use in all food that is designated as non-standardized. In the absence of data on where amaranth isn’t used, Health Canada will conclude that amaranth is used in all non-standardized foods.

Health Canada is seeking data on the use of amaranth in all foods. The following food categories are of particular interest.

- Non-alcoholic beverages
- Beverages prepared from mixes or concentrates
- Condiments, dressings, sauces and gravies
- Snack foods
- Ice cream, ice milk, sherbets and related foods
- Confectionary
- Cake decorations and icing
- Baked goods
- Breakfast cereals and breakfast foods

Data Reporting and Timeline

Provision members are asked to submit data via e-mail to Health Canada at bcsc-bipc@hc-sc.gc.ca, with a copy to Robin Churchill at robin.churchill@hc-sc.gc.ca

Robin Churchill is the Senior Scientific Evaluator, Chemical Health Hazard Assessment Division, Bureau of Chemical Safety, Food Directorate at Health Canada.

Deadline for submission is April 30th 2014.

Future Health Canada Request for Data

It is anticipated that Health Canada will be seeking data on the use of a number of other food substances in 2014-2015 which is independent of the Section 71 notices that have already been completed.

Information will be provided to Provision Coalition members as requests are made available.