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Health Canada's Proposal to Remove Epichlorohydrin From the *List of Permitted Starch-Modifying Agents* and 2- Nitropropane From the *List of Permitted Carrier or Extraction Solvents*

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0015]

March 31, 2016

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 pre-market approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

In 2006, the Government of Canada announced the launch of the first phase of the Chemicals Management Plan (CMP)¹ which identified approximately 200 chemical substances, based on their properties and uses in Canada, as high priorities for assessment. Epichlorohydrin and 2-nitropropane (2-NP) were among this first group of substances to be assessed under CMP.

The final CMP screening assessment reports concluded that epichlorohydrin and 2-nitropropane (2-NP) may be harmful to human health. Although Canadians' exposure to these two chemicals from all possible uses is considered to be low or very low, the Government of Canada is taking action so that exposure remains low. Presently, these two substances have very restricted food uses that are controlled through Canada's food additive regulations. Epichlorohydrin is permitted for use in the manufacture of modified food starch and 2-NP is permitted for use in the fractionation of vegetable oils.²

Epichlorohydrin appeared in the first iteration of the food additive tables (SOR/64-366) in September 1964, while 2-NP appeared in the first iteration of Table XV (SOR/75-49) in January 1975. Although provisions for the use of both epichlorohydrin and 2-NP have long been in place, consultation with the food industry and other sources of available information indicate that there is minimal, if any, use of either of these two substances by the food industry in Canada and in the United States for purposes described in the [List of Permitted Starch-Modifying Agents](#) and in the [List of Permitted Carrier or Extraction Solvents](#).

Nevertheless, as the current scientific information does not support the safety in use of either of these two additives, Health Canada intends to remove epichlorohydrin from the *List of Permitted Starch-Modifying Agents* and 2-NP from the *List of Permitted Carrier or Extraction Solvents*.

1 For additional details, please see the Chemicals Management Plan website at <http://www.chemicalsubstanceschimiques.gc.ca/plan/index-eng.php>

2 See Item E.1 of the *List of Permitted Starch Modifying Agents* and Item 18 of the *List of Permitted Carrier or Extraction Solvents*, which can be accessed from Health Canada's website: <http://www.hc-sc.gc.ca/fn-an/securit/addit/list/index-eng.php>

Rationale

The final CMP screening assessment reports for epichlorohydrin and 2-NP concluded that, on the basis of carcinogenicity observed in experimental animal studies, these two substances may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.^{3,4} With respect to food additive uses of these substances, it is unlikely that epichlorohydrin is used today by North American starch manufacturers and, if it were used, the residual levels of epichlorohydrin in the modified starch would be negligible. 2-NP is no longer used in vegetable oil processing in North America and its use as a food processing solvent is discouraged internationally. Although there is a low probability of exposure in Canada to these two substances through possible food additive uses, the Government of Canada's proposed risk management approach for each substance, posted online on January 31, 2009 and July 31, 2010, respectively, included that consideration would be given to delisting epichlorohydrin and 2-NP from the Lists of Permitted Food Additives.^{5,6}

As the current scientific information does not support the use in food processing of either epichlorohydrin or 2-NP, Health Canada is proposing to remove the entry for epichlorohydrin from the *List of Permitted Starch-Modifying Agents* and to remove the entry for 2-NP from the *List of Permitted Carrier or Extraction Solvents*.

Other Relevant Information

There are no food additive uses for either epichlorohydrin or 2-NP reflected in the Codex General Standard for Food Additives.

There are no food-grade specifications for epichlorohydrin established by the international Joint FAO/WHO Expert Committee on Food Additives (JECFA). With respect to 2-NP, in 1989, JECFA considered newer toxicological studies on 2-NP and decided not to extend the temporary acceptance of 2-NP as a fractionating solvent for use in producing fats and oils.⁷ JECFA subsequently withdrew the food-grade specifications for 2-NP in 2000 as no information on the technical justification for this use of 2-NP was provided nor was information submitted that would allow for the establishment of a safe level of intake of 2-NP.⁸

3 "Screening Assessment for the Challenge, Oxirane, (chloromethyl)-, (Epichlorohydrin)", November 2008 (<http://www.ec.gc.ca/es-ees/default.asp?lang=En&n=BA416AA1-1#a6>)

4 "Screening Assessment for the Challenge, Propane, 2-nitro-, (2-Nitropropane)" July 2010 (https://www.ec.gc.ca/es-ees/3FDF4576-A2A4-4791-816B-A763D8CF6BF6/batch8_79-46-9_en.pdf)

5 "Proposed Risk Management Approach for Oxirane, (chloromethyl)-, (Epichlorohydrin)", January 2009 (<http://www.ec.gc.ca/es-ees/default.asp?lang=En&n=DB6AE919-1#top>)

6 "Proposed Risk Management Approach for Propane, 2-nitro-, (2-Nitropropane)", July 2010 (<http://www.ec.gc.ca/es-ees/default.asp?lang=En&n=52DBA444-1>)

7 Evaluation of certain food additives and contaminants. Thirty-fifth Report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organization Technical Report Series 789. Geneva, 1990.

8 Evaluation of certain food additives and contaminants. Fifty-fifth Report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organization Technical Report Series 901. Geneva, 2001.

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In the United States, starch modifying agents such as epichlorohydrin are not regulated as food additives. Rather, the modified food starches themselves are regulated and there are specific provisions pertaining to the starch modifying agents that may be used. The U.S. Code of Federal Regulations (CFR) currently permit modified starch made with epichlorohydrin to be used as a direct food additive (21 CFR 172.892).

As noted previously, available information indicates that epichlorohydrin is no longer used in either Canada or the United States as a starch modifying agent. This is reflected in the food-grade specifications for modified food starch set out in the Food Chemicals Codex (FCC). Although the third edition of the FCC, published in 1981, recognised the possible use of epichlorohydrin as a starch modifying agent, more recent editions (dating back to 1996) do not.

Europe, Australia and New Zealand do not permit the use of starch modified with epichlorohydrin in food, nor do they identify 2-NP as having any acceptable food additive uses.⁹

In view of the above, there are no expected implications for international trade as a result of revoking the food additive provisions for epichlorohydrin and 2-NP.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the [List of Permitted Starch-Modifying Agents](#) and in the [List of Permitted Carrier or Extraction Solvents](#). This will be announced via a Notice of Modification which will be published on [Health Canada's Website](#).

As no trade implications are expected and as the proposed changes are a response to the conclusion that the safety in use of these additives is not supported, Health Canada plans to implement the changes to the Lists immediately following the close of the comment period.

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:

[Bureau of Chemical Safety, Food Directorate](#)
251 Sir Frederick Banting Driveway
Tunney's Pasture, PL: 2202C

⁹ Table to clause 13 of the Standard 1.3.3 of the *Australia New Zealand Food Standards Code* and the EU's Food Additive Database (https://webgate.ec.europa.eu/sanco_foods/main/?sector=FAD).

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If communicating by e-mail, please use the words “**Epichlorohydrin and 2-NP**” in the subject line of your e-mail. Health Canada is able to consider information received by **June 13, 2016**, 75 days from the date of this posting.