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Health Canada's Proposal to Update the Maximum Levels for Arsenic in Apple Juice and Water in Sealed Containers in the *List of Contaminants and Other Adulterating Substances in Foods*

Notice of Proposal – *List of Contaminants and Other Adulterating Substances in Foods*

Reference Number: [NOP/AVP C-2017-1]

March 1, 2017

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

Summary

Food contaminants and other adulterating substances are chemicals that may be present in foods at levels that could impact the overall safety and/or quality of foods. These substances can either be inadvertently present in foods or in some cases intentionally added for fraudulent purposes. Establishing maximum levels (MLs) is a form of risk management that may be employed to reduce exposure to a particular chemical contaminant in food sold in Canada. Canadian MLs for chemical contaminants in food are set out in the [*List of Contaminants and Other Adulterating Substances in Foods*](#), which is incorporated by reference into section B.15.001 of Division 15 of the *Food and Drug Regulations*, and in the [*List of Maximum Levels for Various Chemical Contaminants in Foods*](#), which has a history of being maintained on Health Canada's website outside of the *Food and Drug Regulations*. Health Canada is working towards the consolidation of all MLs into the single regulatory *List of Contaminants and Other Adulterating Substances in Foods* and is also systematically reviewing and updating, as appropriate, existing MLs in both of these lists. All MLs for contaminants in food are established by Health Canada and are enforceable by the Canadian Food Inspection Agency (CFIA).

The *List of Contaminants and Other Adulterating Substances in Foods* specifies an ML of 0.1 parts per million (ppm) for arsenic in fruit juice, fruit nectar, beverages when ready-to-serve, and water in sealed containers (commonly referred to as bottled or prepackaged water) other than mineral or spring water. If these foods contain arsenic at concentrations above 0.1 ppm, they are considered adulterated and in violation of the *Food and Drugs Act* and *Regulations*. All existing MLs for arsenic in the *List of Contaminants and Other Adulterating Substances in Foods* were developed on a total arsenic basis.

Health Canada is proposing to exclude apple juice from the existing ML for arsenic in fruit juice and establish a separate, lower ML of 0.015 ppm for total arsenic in apple juice. This ML would also apply to apple juice when used as an ingredient in other foods and to apple juice concentrate when reconstituted to its ready-to-serve form. Furthermore, Health Canada is proposing to lower the existing ML for arsenic in water in sealed containers to 0.01 ppm and extend the ML to apply to all types of bottled water, including mineral and spring water, which have a standard of identity under [*Division 12*](#) of the *Food and Drug Regulations*.

The existing ML for arsenic in these beverages was established when there were sources of arsenic contamination to foods that are no longer relevant in Canada. Therefore, the existing MLs do not reflect concentrations of arsenic typically found in these types of beverages today and are no longer considered to be health protective.

It is the intention of Health Canada to modify Part 2 of the [*List of Contaminants and Other Adulterating Substances in Foods*](#) as outlined below.

Proposed Modifications to Part 2 of the *List of Contaminants and Other Adulterating Substances in Foods*

Item No.	Substance	Food ¹	Maximum Level ²
1	Arsenic	(3) Fruit juice except apple juice ; Fruit nectar; Beverages	(3) 0.1 ppm
		(4) Apple juice	(4) 0.015 ppm
		(5) Water in sealed containers	(5) 0.01 ppm

¹Maximum levels also apply to the food when it is used as an ingredient in other foods.

²Maximum levels apply to foods on a fresh weight basis. For foods that are dehydrated or concentrated, the maximum level applies to the food that is rehydrated or reconstituted to its original form or concentration, unless otherwise specified.

At this time, the existing ML of 0.1 ppm for arsenic in 'fruit juice except apple juice; fruit nectar; beverages' will remain in the *List of Contaminants and Other Adulterating Substances in Foods*. Health Canada intends to review and update, as appropriate, these and all other MLs for arsenic in Part 2 of the List.

Corrective modification

To avoid redundancy with proposed footnote 2 to the *List of Contaminants and Other Adulterating Substances in Foods*, which indicates that the MLs apply to foods on a fresh weight basis that are in their original form or concentration, the wording 'when ready-to-serve' is proposed to be removed from the 'beverages' listing.

Rationale

Arsenic is naturally occurring in the environment and can exist in various organic and inorganic forms. Both organic and inorganic forms of arsenic can be found in foods at very low levels, although the relative proportion of each depends on the type of food. Long-term exposure to elevated levels of inorganic arsenic can contribute to a possible increased risk of certain cancers and can affect the gastrointestinal tract, kidneys, liver, lungs and epidermis. There is also some evidence to indicate that the developing fetus and young children are more sensitive to inorganic arsenic relative to older population subgroups. As apple juice is frequently consumed by infants and young children and can represent a significant potential dietary source of arsenic, this commodity group was identified as a priority for setting an updated arsenic ML.

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The existing MLs for arsenic were established when there were sources of arsenic contamination in foods that are no longer relevant in Canada, such as the use of arsenical pesticides. Today, arsenic is present in the environment at low levels as a result of its natural occurrence in rock and soil and release from industrial activities such as mining, smelting and ore processing.

Health Canada's scientific assessment supported the development of a separate and lower ML for total arsenic in apple juice. Expressing the ML on a total arsenic basis enables the inclusion of all arsenic species of potential relevance to human health and allows for the comparison to analytical data that are most commonly collected for arsenic. Canadian monitoring data demonstrates that the proposed lower MLs for total arsenic in apple juice and all types of water in sealed containers are readily achievable when good agricultural and manufacturing practices are followed. The proposed MLs are more protective of human health relative to existing MLs and align with Health Canada's commitment to reduce dietary exposure to chemical contaminants in food to levels that are as low as reasonably achievable (ALARA principle).

Other Relevant Information

In 2014, Health Canada's Food Directorate conducted a technical consultation proposing to lower the MLs for arsenic in apple juice and all types of water in sealed containers. Stakeholders representing the food industry and professional organisations expressed concern regarding the achievability of the then proposed ML of 0.01 ppm total arsenic in ready-to-drink apple juice. The current proposed ML of 0.015 ppm total arsenic in apple juice takes into consideration the submitted comments and Health Canada's scientific assessment in support of a lower ML for arsenic in apple juice. Stakeholders were supportive of the proposed lower ML for arsenic in all types of water in sealed containers which would align the Canadian ML with international standards and those of other national food regulatory agencies. The [*Summary of Comments and Responses to Health Canada's Proposed Amendments to the Regulatory Tolerances for Arsenic and Lead in a Variety of Beverages*](#) was posted on Health Canada's website on January 28, 2016.

The proposed ML for total arsenic in apple juice is in general alignment with the United States Food and Drug Administration (US FDA) [proposed action level of 0.01 ppm inorganic arsenic in apple juice](#). The Codex Alimentarius Commission (Codex), European Union (EU) and Food Standards Australia New Zealand (FSANZ) have not established MLs for arsenic in apple juice or any type of fruit juice.

Lowering the ML for total arsenic in all types of water in sealed containers, including those with a standard of identity in Division 12 of the *Food and Drug Regulations* (i.e., mineral and spring water), aligns with the maximum acceptable concentration for arsenic set out in the [*Guideline for Canadian Drinking Water Quality*](#). The proposed lower ML for total arsenic also aligns with the Codex ML for total arsenic in natural mineral water ([CODEX STAN 108-1981](#)), the EU ML for total arsenic in bottled water ([Directive 2003/40/EC](#)), the [World Health Organization drinking water quality guideline for arsenic](#), which was also adopted by [Food Standards Australia New](#)

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[Zealand for arsenic in packaged water](#), and the US FDA allowable level for arsenic in bottled water ([21 CFR §165.110](#)).

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in Part 2 of the [List of Contaminants and Other Adulterating Substances in Foods](#). Health Canada proposes to publish the changes to the List 12 months following the close of the 75-day comment period, provided that no data or information regarding the proposed changes are submitted that would potentially alter the proposal. Changes to the *List of Contaminants and Other Adulterating Substances in Foods* 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 or information related to this proposal, please contact:

[Bureau of Chemical Safety, Food Directorate](#)

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If communicating by e-mail, please use the words “**Arsenic MLs for Apple Juice and Bottled Water**” in the subject line of your e-mail. Health Canada is able to consider information received by **May 14, 2017**, 75 days from the date of this posting.