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Health Canada's Notice of Modification to Update the Maximum Level for Total Arsenic in Fruit Juice and Fruit Nectar in Part 2 of the *List of Contaminants and Other Adulterating Substances in Foods*

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

Reference Number: NOM/ADM C-2022-3

August 17, 2022



Canada

Summary

Food contaminants and other adulterating substances are chemicals that should not 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 a prohibition or a maximum level (ML) are forms of risk management that may be employed to eliminate or reduce exposure to a particular chemical contaminant in food sold in Canada. Prohibitions and MLs for chemical contaminants in food are set out in Part 1 and Part 2, respectively, of 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](#) (the Regulations). Maximum levels are also set out in the [List of Maximum Levels for Various Chemical Contaminants in Foods](#), which is maintained on Health Canada’s website. All prohibitions and MLs for contaminants in food are established by Health Canada’s Food Directorate based on scientific evidence and in consultation with stakeholders and are enforceable by the Canadian Food Inspection Agency.

On April 9, 2021, Health Canada published a [Proposal to Update the Maximum Level for Total Arsenic in Fruit Juice and Fruit Nectar in the List of Contaminants and Other Adulterating Substances in Foods \(NOP/ADP C-2021-2\)](#). The proposal was open for public comment for 75 days and closed on June 22, 2021. Responses to submitted comments are summarized in the “Notification – Summary of Comments and Health Canada’s Responses” section, below.

As no new scientific information was received that would alter the approach described in the Notice of Proposal, Health Canada established new MLs of 0.01 ppm inorganic arsenic in fruit juice and fruit nectar, except grape juice and grape nectar, and 0.03 ppm inorganic arsenic in grape juice and grape nectar, as set out in new sub-item 1.2(4) and sub-item 1.2(5), respectively, to Part 2 of the [List of Contaminants and Other Adulterating Substances in Foods](#), as shown in bold in the table below. These MLs apply to products in their ‘as consumed’ form. In addition, sub-item 1.1(3) of Part 2 of the [List of Contaminants and Other Adulterating Substances in Foods](#) was modified by removing the food categories ‘Fruit juice; Fruit nectar’, and replacing with “except fruit juice, fruit nectar, grape juice and grape nectar”, as shown in bold in the table below.

Modification to Part 2 of the [List of Contaminants and Other Adulterating Substances in Foods](#)

Item No.	Column 1 Substance	Column 2 Food ¹	Column 3 Maximum Level
1.1	Arsenic, total	(3) Beverages, except fruit juice, fruit nectar, grape juice and grape nectar	(3) 0.1 p.p.m. applied to products as consumed
1.2	Arsenic, inorganic (sum of arsenite (As III) and arsenate (As V))	(4) Fruit juice, except grape juice; Fruit nectar, except grape nectar	(4) 0.01 p.p.m. applied to products as consumed
		(5) Grape juice; Grape nectar	(5) 0.03 p.p.m. applied to products as consumed

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

Rationale

Health Canada is committed to minimizing dietary exposure to inorganic arsenic in food to as low as reasonably achievable. Long-term exposure to elevated levels of inorganic arsenic can contribute to a possible increased risk of certain cancers and other health effects such as neurotoxicity, skin lesions and diseases of the circulatory system. Elevated exposure during early stages of life may also increase the risk of adverse effects experienced later in life.

Fruit juices can represent a significant source of exposure to inorganic arsenic in the diet of Canadian children. The previous ML of 0.1 ppm for arsenic in fruit juice and fruit nectar was established many decades ago. Since that time, activities that contribute to the presence of arsenic in the environment have decreased and arsenic concentrations in fruit juices are much lower. As such, the previous ML does not reflect the concentrations of arsenic typically found in fruit juices today. Surveillance data available to Health Canada indicate that the new MLs are readily achievable for fruit juice and fruit nectar products available for sale in Canada.

The MLs of 0.01 ppm for fruit juices and fruit nectar (except grape juice and grape nectar) and 0.03 ppm for grape juice and grape nectar, will help minimize dietary exposure to inorganic arsenic by requiring that levels in such products sold in Canada remain as low as possible.

Other Relevant Information

Health Canada's ML of 0.01 ppm for inorganic arsenic in fruit juice and fruit nectar (except grape juice and grape nectar) aligns with the United States Food and Drug Administration's (U.S. FDA) [action level](#) of 0.01 ppm inorganic arsenic in apple juice.

Notification – Summary of Comments and Health Canada's Responses

Health Canada received comments from the Canadian Beverage Association (CBA) and the Juice Products Association (JPA), following the publication of the Department's *Proposal to Update the Maximum Level for Total Arsenic in Fruit Juice and Fruit Nectar in the List of Contaminants and Other Adulterating Substances in Foods* ([NOP/ADP C-2021-2](#)) on April 9, 2021. Several comments from the CBA and the JPA were similar. Unless specifically indicated, comments were from both organizations and cover the main topic of the comment. These comments and Health Canada's responses are summarized below.

It is also noted that the Ontario Dietitians in Public Health (ODPH), the Dietitians of Canada (DC), and the Canadian Paediatric Society (CPS) previously submitted comments as part the Department's proposal in 2019 to establish MLs for inorganic arsenic in polished and husked rice ([NOP/ADP C-2019-2](#)). Comments provided by ODPH, DC and CPS on that proposal indicated support to lower MLs for arsenic in fruit juices.

Summarized Comments	Health Canada Response
<p>The proposal did not provide monitoring data or other scientific references that formed the basis of Health Canada's assessment in support of the revised MLs for arsenic in fruit juice and fruit nectar.</p>	<p>Health Canada's supporting assessment is available here.</p>
<p>There is a lack of evidence linking adverse health effects from arsenic exposure with fruit juice consumption and a lack of evidence on how a lower ML will impact human health.</p>	<p>Long-term exposure to elevated levels of inorganic arsenic can contribute to a possible increased risk of certain cancers and other health effects such as neurotoxicity, skin lesions and diseases of the circulatory system. Elevated exposure during early stages of life may also increase the risk of adverse effects experienced later in life. Fruit juice consumption is a primary contributor to dietary inorganic arsenic exposure for children ages 1 to 8 years.</p> <p>The previous ML for arsenic in fruit juice and fruit nectar of 0.1 ppm greatly exceeds the arsenic concentrations that are observed today in fruit juice products sold in Canada (less than 0.01 ppm). The new, lower MLs are in-line with achievable concentrations today and will help ensure that exposures to arsenic from fruit juice consumption remain as low as reasonably possible.</p> <p>For more information, you can access Health Canada's supporting assessment here.</p>
<p>The Health Canada MLs for fruit juice and fruit nectar do not align with the U.S. FDA's action level as the latter is only proposed at this time and only applies to apple juice.</p>	<p>The U.S. FDA considers their action level of 0.01 ppm inorganic arsenic in apple juice to be achievable and protective of public health. Although this action level currently only applies to apple juice, monitoring and surveillance data available to Health Canada indicate that inorganic arsenic concentrations less than 0.01 ppm in all types of fruit juices and fruit nectar, with the exception of grape juice, are readily achievable. As such, Health Canada considers it reasonable to establish the same ML for all types of fruit juices and fruit nectars, except for grape juice and grape nectar. For grape juice and grape nectar, an inorganic arsenic concentration of 0.03 ppm is considered similarly achievable.</p> <p>Health Canada is of the opinion that the revised ML for fruit juices and fruit nectar aligns with the U.S. FDA's action level for apple juice.</p>

Summarized Comments	Health Canada Response
<p>It is not possible to know whether an ML of 0.01 ppm is achievable for all types of fruit juices, other than grape juice, and this could impact the sale of some types of juices in Canada. The JPA also points to a study where arsenic concentration in mango fruit varied based on varying soil pH, which would suggest the ML may not be achievable.</p>	<p>Health Canada’s supporting assessment considered surveillance and monitoring results for fruit juice and fruit nectar products sold in Canada collected from 2009 to 2016 by the Canadian Food Inspection Agency (CFIA) and Health Canada. This database included over 640 samples of various types of fruit juices and fruit nectars such as apple, grape, cranberry, orange, lemon, lime, grapefruit, apricot, blueberry, blackberry, cherry, guava, mango, peach, pear, pineapple, pomegranate, raspberry, watermelon, prune, and blends thereof.</p> <p>Based on this dataset, an ML of 0.01 ppm inorganic arsenic is expected to be achievable for all types of fruit juices and fruit nectars, with the exception of grape juice, for which an ML of 0.03 ppm is expected to be readily achievable.</p>
<p>Health Canada is encouraged to have an open dialogue with the U.S. FDA about their on-going <i>Closer to Zero</i> initiative to ensure a harmonized approach by both countries.</p>	<p>Health Canada is aware of the U.S. FDA’s initiative <i>Closer to Zero</i> which aims to identify actions the agency will take to reduce, as low as possible, exposure to arsenic, lead, cadmium and mercury from foods eaten by babies and young children. Health Canada has also been in discussion with the U.S. FDA on this initiative and will keep an open communication with its counterparts at the administration as this initiative advances. We note that Health Canada’s new MLs for fruit juices and fruit nectars and the U.S. FDA’s <i>Closer to Zero</i> initiative share a common goal which is to minimize exposure to arsenic from foods commonly consumed by young children.</p>
<p>In its proposal, Health Canada states that <i>“long-term exposure to very high levels of inorganic arsenic may contribute to a possible increased risk of certain cancers and other adverse health effects”</i>. The JPA notes that Health Canada does not define “high levels of inorganic arsenic” nor do they provide data to suggest that there are high levels of inorganic arsenic in fruit juices and fruit nectars.</p>	<p>Studies have shown that exposure to elevated levels of inorganic arsenic in drinking water may increase the risks of various adverse health effects. The levels of exposure to inorganic arsenic that have caused adverse health effects reported in such studies, are above exposure levels expected from the diet in Canada. However, there remains some uncertainty on quantifying the health risks at low exposures to inorganic arsenic, such as those from the diet, and therefore, Health Canada is of the opinion that the best approach to protecting the health of Canadians is to minimize dietary exposure.</p> <p>Inorganic arsenic concentrations in fruit juice and fruit nectar products sold in Canada are very low. The previous ML for arsenic in fruit juices and fruit nectars far exceeds the concentrations that are observed in these products today. As such, maintaining the previous ML would permit arsenic concentrations higher than levels that are readily achievable</p>

Summarized Comments	Health Canada Response
	and would not be consistent with Health Canada’s position to minimize dietary exposure to inorganic arsenic.

Implementation and Enforcement

The above modification came into force on **August 17, 2022**, the day it is published in Part 2 of the [List of Contaminants and Other Adulterating Substances in Foods](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the food-related aspects of the *Food and Drugs Act* and its associated regulations.

Contact Information

Health Canada's Food Directorate is committed to reviewing new scientific information on the chemical safety of foods. Anyone wishing to submit new scientific information relating to inorganic arsenic in fruit juice and fruit nectar may do so in writing, by postal mail or email. If you wish to email the Food Directorate, please use the words “**Arsenic in fruit juice and fruit nectar (NOM C-2022-3)**” in the subject line.

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