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Proposed Changes to the Tolerances for Arsenic and Lead in Fruit Juice, Fruit Nectar, Beverages when Ready-to-Serve, and Water in Sealed Containers

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Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

Proposed Changes to the Tolerances for Arsenic and Lead in Fruit Juice, Fruit Nectar, Beverages when Ready-to-Serve, and Water in Sealed Containers

Purpose

The Food Directorate's Bureau of Chemical Safety is proposing to update certain regulatory tolerances within Division 15 of the *Food and Drugs Regulations*, specifically those for arsenic and lead in a variety of beverages, including bottled water. The purpose of this document is to provide background information and a summary of the evidence used by Health Canada in support of the recommended updates.

Summary

Currently, Table 1 of Division 15 of the *Food and Drug Regulations*¹ specifies tolerances of 0.1 parts per million (ppm) of arsenic and 0.2 ppm of lead in fruit juice, fruit nectar, beverages when ready-to-serve², and water in sealed containers other than mineral or spring water. Should these foods contain arsenic or lead at concentrations above these tolerances, they are considered to be adulterated and therefore may not be sold in Canada.

Fruit juice makes a significant contribution to dietary lead and arsenic exposure, particularly in infants and young children. Therefore, this commodity group was identified as a priority for setting updated lead and arsenic tolerances. Health Canada is proposing to exclude apple juice from the existing tolerance for arsenic in fruit juice, fruit nectar, and beverages when ready-to-serve and create a lower tolerance of 0.01 ppm for total arsenic in apple juice³. Health Canada is also proposing to lower the existing tolerance for lead in fruit juice, fruit nectar, and beverages when ready-to-serve to 0.05 ppm.

Furthermore, Health Canada is recommending that the existing tolerances for both arsenic and lead in water in sealed containers be lowered to 0.01 ppm and extended to include all types of bottled water, including mineral and spring water, which have a standard of identity under Part B, Division 12 of the *Food and Drug Regulations*. This update will bring the safety-based standards for lead and arsenic in bottled water in-line with the maximum acceptable concentrations (MACs) for these trace elements as set out in the [*Guidelines for Canadian Drinking Water Quality*](#).

1 Division 15 (Adulteration of Food) of the *Food and Drug Regulations*:
http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-158.html#h-109

2 For the purposes of the proposed tolerances, "ready-to-serve" means ready to consume, whether purchased as such or prepared from a concentrated product as per the package directions.

3 Health Canada's proposed tolerance of 0.01 ppm arsenic in apple juice will apply to this beverage on a ready-to-serve basis, as well as the apple juice portion of any juice blends or drinks.

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Health Effects of Arsenic and Lead

Arsenic is a naturally occurring element that can exist in various organic and inorganic forms; the sum of all arsenic species represents the total arsenic concentration. Both organic and inorganic forms of arsenic can be found in food, although the proportion of each type can vary significantly from one food to another. In both apple juice and bottled water, inorganic arsenic is the predominant arsenic species although a low percentage of organic species can sometimes be detected.

Inorganic forms of arsenic are considered to be of greatest significance from a human health perspective. Epidemiological studies of populations in Asia have associated the development of skin lesions, various cancers, developmental toxicity, neurotoxicity, cardiovascular disease, and diabetes with chronic ingestion of drinking water containing elevated concentrations of inorganic arsenic (ranging from 10 to 100 times greater than the current *Canadian Drinking Water Quality Guideline* for arsenic). Methylated (monomethylarsonic acid and dimethylarsinic acid) or organic species of arsenic do not appear to be as toxic as inorganic forms of arsenic.

The majority of lead in the environment occurs as the result of human industrial activities such as mining, smelting and ore processing. Lead can exist in both organic and inorganic forms however the inorganic forms are usually predominate in food and water. Analysis of lead typically involves the total determination of all forms.

Long-term exposure to lead can cause neurodevelopmental, neurodegenerative, cardiovascular, renal and reproductive effects. Developing infants and young children are most sensitive to the toxic effects of lead as they absorb lead more easily than adults and their nervous systems are particularly susceptible. For children, depending on the extent and duration of exposure, lead may have subtle effects on neurodevelopmental outcomes, the most sensitive endpoint being a reduction of intelligence quotient (IQ). For adults, the most sensitive adverse effect associated with chronic lead exposure is considered to be an increase in systolic blood pressure.

Rationale for Lowering the Tolerances for Arsenic in Apple Juice and Lead in Fruit Juice, Fruit Nectar, and Beverages when Read-to-Serve

The existing regulatory tolerances for arsenic and lead in fruit juice, fruit nectar, and beverages when ready-to-serve were established several years ago when there were greater sources of arsenic and lead contamination to foods that are no longer relevant in Canada, such as the use of arsenical pesticides as well as leaded gasoline, paint, and soldering material used for food cans.

Today, arsenic and lead are present in the environment at low levels as a result of their natural occurrence and release from anthropogenic sources. The levels of arsenic and lead in foods available in Canada have been stable at very low levels for many years; these trace amounts typically reflect the expected accumulation from the environment.

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Available Canadian monitoring data demonstrate that the proposed tolerances for arsenic in apple juice and lead in fruit juice, fruit nectar, and beverages when ready-to-serve are readily achievable when good agricultural and manufacturing practices are followed. Furthermore, the proposed lower tolerances are more protective of human health than those that currently exist. Lowering these tolerances aligns with Health Canada's general commitment to reduce dietary exposure to contaminants, and lead in particular, to levels that are as low as reasonably achievable (ALARA).⁴

The proposed 0.05 ppm lead tolerance in fruit juice, fruit nectar, and beverages when ready-to-serve is consistent with the Codex Alimentarius Commission's current maximum level for lead in fruit juices and nectars. The Food Directorate's Bureau of Chemical Safety will consider any revisions to existing Codex Maximum Levels (MLs) or new Codex MLs for lead in foods for applicability within the Canadian context, and will also continue to use monitoring data for lead in foods to determine the need for new or lower Canadian tolerances, as appropriate. While fruit juice as a general food category can make a significant contribution to dietary lead exposure of infants and young children, future consideration will be given to the development of separate tolerances for different types of juices.

In the fruit juice category, Health Canada has specifically identified apple juice as a priority for setting an updated arsenic tolerance. Apple juice is the most frequently consumed type of fruit juice by Canadian children and represents a significant potential dietary source of arsenic in this demographic group. As such, an important criterion for determining the need for a tolerance is met in this particular case. This approach to establishing tolerances for contaminants in food is consistent with that used internationally.⁵

Apple juice is a water-based beverage that is typically manufactured from concentrate. Health Canada is therefore proposing a tolerance for total arsenic which is consistent with the MAC of 0.01 ppm for total arsenic provided in the *Guidelines for Canadian Drinking Water Quality*. The MAC for total arsenic in drinking water was developed based on toxicological information for inorganic arsenic, which is the predominant form of arsenic in both drinking water and apple juice. Establishing a tolerance based on total arsenic is therefore considered to be a conservative approach since it applies to the sum of all arsenic species. Health Canada's proposed tolerance of 0.01 ppm total arsenic in apple juice is in general agreement with the United States Food and Drug Administration's proposed action level for inorganic arsenic in apple juice.

As more data for arsenic and its species becomes available for other types of fruit juices and food commodities, the Food Directorate's Bureau of Chemical Safety will consider developing additional tolerances, or updating existing tolerances, as required.

⁴ The Food Directorate's approach to managing dietary exposure to lead can be found at: http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/envIRON/lead_strat_plomb_strat-eng.php

⁵ Annex I of the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995). Accessed on October 23, 2013 from the website of the United Nations Food and Agriculture Organization: http://www.fao.org/fileadmin/user_upload/agns/pdf/CXS_193e.pdf

Rationale for Updating the Tolerances for Arsenic and Lead in Water in Sealed Containers

As noted above, the existing regulatory tolerances for arsenic and lead were established when there were sources of contamination to these trace elements that are no longer relevant in Canada. Available monitoring data for all types of bottled water sold in Canada demonstrate that the proposed tolerances of 0.01 ppm for arsenic and 0.01 ppm for lead are readily achievable. Lowering these tolerances is protective of human health and in accordance with the Health Canada's commitment to ensure that levels of these contaminants in food are ALARA.

The proposed tolerances for arsenic and lead in all types of bottled water, including those with a standard of identity in Division 12 of the *Food and Drug Regulations* (i.e., mineral and spring water), align with the health-based MACs of 0.01 ppm for arsenic and lead as set out in the *Guidelines for Canadian Drinking Water Quality*.

The proposed tolerances are also in-line with the MLs of 0.01 ppm established by the Codex Alimentarius Commission for both arsenic and lead in natural mineral waters.

Submitting Comments to Health Canada

Comments on this proposal may be submitted in writing by regular mail or electronically at the address indicated below. If you are submitting your comments electronically, please use the phrase "**Arsenic and Lead Tolerances**" in the subject box of your e-mail. **Submissions must be received by 11:59 p.m. EST on September 01, 2014.**

Contact Information

For additional information or to submit comments related to this proposal, please contact the Food Directorate's Bureau of Chemical Safety:

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