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# Notice of Modification to the *List of Contaminants and Other Adulterating Substances in Foods* to Update the Maximum Levels for Lead in Fruit Juice, Fruit Nectar and Water in Sealed Containers

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

Reference Number: [NOM/ADM-C-2017-02]

July 20, 2017

Bureau of Chemical Safety  
Food Directorate  
Health Products and Food Branch



Canada

## Notice of Modification to the *List of Contaminants and Other Adulterating Substances in Foods* to Update the Maximum Levels for Lead in Fruit Juice, Fruit Nectar and Water in Sealed Containers

### 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*. All MLs for contaminants in food are established by Health Canada and are enforceable by the Canadian Food Inspection Agency.

The *List of Contaminants and Other Adulterating Substances in Foods* specifies an ML of 0.2 parts per million (p.p.m.) for lead 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.

Health Canada conducted a scientific assessment that supports establishing a lower ML for lead in fruit juice and fruit nectar of 0.05 ppm and a lower ML for lead in water in sealed containers of 0.01 ppm, extended 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\*](#).

Consequently, Health Canada published a [\*Proposal to Update the Maximum Levels for Lead in Fruit Juice, Fruit Nectar and Water in Sealed Containers in the List of Contaminants and Other Adulterating Substances in Foods – Reference number: \[NOP/ADP C-2017-2\]\*](#). The proposal was published on March 1, 2017 and was open to the public for comments for 75 days. Although comments were provided during the comment period in response to this Notice of Proposal, as further described below in the section “Notification – Summary of Comments”, no new scientific information was submitted to the Department.

Since the conclusions of the assessment remain as described in the Notice of Proposal, Health Canada will modify sub-item 3(4) and add sub-items 3(7) and 3(8) to Part 2 of the *List of Contaminants and Other Adulterating Substances in Foods* to reflect the lower MLs for lead in fruit juice, fruit nectar and water in sealed containers, as shown in the table below. Two footnotes, shown below, will also be added to Part 2 of the List. The existing MLs for these commodities will remain in force until these modifications are made on **May 14, 2018**.

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### Modification to Part 2 of the *List of Contaminants and Other Adulterating Substances in Foods*

| Item No. | Column 1 Substance | Column 2 Food <sup>1</sup>     | Column 3 Maximum Level <sup>2</sup> |
|----------|--------------------|--------------------------------|-------------------------------------|
| 3        | Lead               | (4) Beverages                  | (4) 0.2 p.p.m.                      |
|          |                    | (7) Fruit juice; Fruit nectar  | (7) 0.05 p.p.m.                     |
|          |                    | (8) Water in sealed containers | (8) 0.01 p.p.m.                     |

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

<sup>2</sup> Maximum 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.

The existing ML of 0.2 p.p.m. for lead in “beverages” will remain unchanged in the *List of Contaminants and Other Adulterating Substances in Foods*. This ML is however scheduled for further review at a later date.

The wording “when ready-to-serve” will be removed from the “Beverages when ready-to-serve” listing to avoid redundancy with footnote 2 in the *List of Contaminants and Other Adulterating Substances in Foods*.

### Corrective Modifications

Column number identifiers (e.g., “Column 1”) have been added to the column headings of Part 1 and Part 2 of the *List of Contaminants and Other Adulterating Substances in Foods*, as illustrated in the table above, for consistency with the language used in Division 15 of the *Food and Drug Regulations* to describe the List.

### Rationale

As described in the Notice of Proposal, MLs for lead were originally established when there were sources of lead contamination in foods that are no longer relevant in Canada. Today, lead is still present in the environment but at lower 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 review of the previous MLs supports a lower ML for lead in fruit juice, fruit nectar and water in sealed containers. Canadian data demonstrate that the lower MLs for lead in fruit juice and fruit nectar as well as all types of water in sealed containers are readily achievable.

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The updated MLs are more protective of human health relative to the former MLs and align with the [Food Directorate of Health Canada's approach to managing dietary exposure to lead](#), which aims to reduce dietary exposure to levels that are as low as reasonably achievable (ALARA principle), as well as Health Canada's [Risk Management Strategy for Lead](#) that recommends reducing exposure to lead from all sources.

### Other Relevant Information

As described in the Notice of Proposal, the proposed MLs took into consideration the comments that were submitted in response to a technical consultation that was conducted by Health Canada in 2014. 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 to Health Canada's website in January 2016.

The lower ML for lead fruit juice and fruit nectar aligns with the ML established by the European Union ([EC No. 1881/2006](#)) and with guidance published by the United States Food and Drug Administration ([Juice HACCP Hazards and Controls Guidance](#)).

In 2015, the Codex Alimentarius Commission lowered its ML for lead in fruit juices and fruit nectars when ready-to-drink, except those from berries and other small fruits, from 0.05 ppm to 0.03 ppm ([CODEX STAN 193-1995](#)). While the updated Canadian ML for lead in fruit juice and fruit nectar aligns with the former Codex ML, Health Canada will consider aligning with the Codex ML once the Codex Committee on Contaminants in Food finalizes its review of the ML for fruit juice from berries and other small fruits.

The lower ML for lead in water in sealed containers aligns with the maximum acceptable concentration for lead set out in the [Guideline for Canadian Drinking Water Quality](#), the Codex ML for lead in natural mineral water ([CODEX STAN 108-1981](#)), the European Union ML for lead in bottled water ([Directive 2003/40/EC](#)) and the [World Health Organization drinking water quality guideline for lead](#), which was also adopted by the [Food Standards Australia New Zealand for lead in packaged water](#). The United States Food and Drug Administration's allowable level for lead in bottled water is 0.005 ppm ([21 CFR §165.110](#)).

### Notification – Summary of Comments

In response to Health Canada's [Proposal to Update the Maximum Levels for Lead in Fruit Juice, Fruit Nectar and Water in Sealed Containers in the List of Contaminants and Other Adulterating Substances in Foods \(NOP/ADP-C-2017-2\)](#), published on March 1, 2017, Health Canada received comments from two organizations. One organization supported the proposal and the

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other requested an explanation regarding the products to which the ML for lead in fruit juice would apply; Health Canada provided written clarification to this question.

### **Implementation and Enforcement**

The above modification will come into force **May 14, 2018**, the day it is published in the [\*List of Contaminants and Other Adulterating Substances in Foods\*](#); this date is twelve months following the close of the Notice of Proposal comment period.

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 any new scientific information on the chemical safety of foods. Anyone wishing to submit new scientific information relating to lead in fruit juice, fruit nectar and/or water in sealed containers may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words “**lead MLs for fruit juice and bottled water**” in the subject line of your e-mail.

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