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Health Canada's Proposal to Lower the Maximum Levels for Lead in Concentrated Infant Formula and Infant Formula When Ready-to-Serve 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/ADP C-2019-1

June 5, 2019

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

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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 or naturally present in foods or, in some cases, intentionally added for fraudulent purposes. Establishing a prohibition or a maximum level (ML) is a form of risk management that may be employed to eliminate or reduce exposure to a particular chemical contaminant in foods. Canadian 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.

The *List of Contaminants and Other Adulterating Substances in Foods* specifies MLs of 0.15 parts per million (ppm) for lead in concentrated infant formula and 0.08 ppm for lead in infant formula when ready-to-serve. If these foods contain lead at concentrations above these values, they are considered adulterated and in violation of the *Food and Drugs Act* and *Regulations*.

The existing MLs for lead in infant formula were established when there were sources of lead contamination to foods that are no longer relevant in Canada. These MLs do not reflect the concentrations of lead typically found in these types of foods today.

Health Canada is proposing to consolidate the two existing MLs for lead in infant formula into a single, lower ML of 0.01 ppm that would apply to all types of infant formula on an 'as consumed' basis. Therefore, only one entry for lead in infant formula will be required in Part 2 of the List and the term "applied to products as consumed" will be placed in Column 3 (Maximum Level) as a description of how to apply the ML for lead to those foods. Note that the terms 'concentrated' or 'when ready-to-serve' will also no longer need to be specified in this case.

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.

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Proposed 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
3		(5) Evaporated milk; Condensed milk	(5) 0.15 p.p.m.
		(6) Infant formula	(6) 0.01 p.p.m. applied to products as consumed
¹ The maximum level also applies to the food when it is used as an ingredient in other foods.			

Corrective Modifications

For consistency with the current proposal and to continue to ensure the clear application of the MLs, the wording 'applied to products as consumed' will replace the wording 'as consumed' in all entries in Part 2 Column 3 of the *List of Contaminants and Other Adulterating Substances in Foods* where 'as consumed' is currently specified.

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

Item No.	Column 1 Substance	Column 2 Food ¹	Column 3 Maximum Level
1	Arsenic	(3) Beverages; Fruit juice; Fruit nectar	(3) 0.1 p.p.m. applied to products as consumed
3	Lead	(4) Beverages	(4) 0.2 p.p.m. applied to products as consumed
		(7) Fruit juice; Fruit nectar	(7) 0.05 p.p.m. applied to products as consumed
10	Patulin	Apple juice; Unfermented apple cider	50 p.p.b. applied to products as consumed

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Rationale

Lead has no known function in the human body and it is internationally agreed that measures should be taken to identify methods of reducing exposure to lead. Long-term exposure to elevated levels of lead is associated with neurodevelopmental, neurodegenerative, cardiovascular, renal and reproductive effects. Infants and young children are the most sensitive to the toxic effects of lead as they absorb lead more readily than adults and their developing nervous systems are particularly susceptible.

The proposed lower ML is readily achievable based on Canadian monitoring data and more protective of human health relative to the existing MLs. This update also aligns with [Health Canada's approach to managing dietary exposure to lead](#), which aims to reduce 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.

The proposed lower ML would apply to all formats of infant formula (powdered, concentrated, and ready-to-serve) and types (dairy and soy), including those intended for special medical purposes (e.g. to address certain allergies or inborn metabolic errors), when expressed on an 'as consumed' basis.

The proposed ML will also apply to infant formula products targeted to any age group that spans, either fully or in part, 0 to 12 months of age (e.g. 0-6 months, 6-18 months, 6-24 months), which is consistent with the definition of an infant as a person under the age of one year, as per Section [B.25.001 of the Food and Drug Regulations](#). This approach would focus risk management efforts for lead on those age groups who could be consuming these types of formula as a sole, or predominantly sole, source of nutrition, and for which lead exposure would be greatest.

Other Relevant Information

The proposed, lower ML (0.01 ppm) for lead in infant formula on an 'as consumed' basis aligns with the MLs established by both the European Union (EU; [EC No. 2015/1005](#)) and the Codex Alimentarius Commission (Codex; [CODEX STAN 193-1995](#)) of 0.01 ppm lead in infant formula, formula for special medical purposes intended for infants and follow-up formula.

The proposed ML (0.01 ppm) also aligns with the maximum acceptable concentration for lead set out for municipal drinking water in the [Guideline for Canadian Drinking Water Quality](#), as well as the updated ML for lead in water in sealed containers set out in Part 2 of [The List of Contaminants and Other Adulterating Substances in Foods](#).

Implementation and Enforcement

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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 following the close of the 75-day comment period and after considering the 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-related aspects of the *Act* and its associated regulations.

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 “**Lead ML for Infant Formula**” in the subject line of your e-mail. Health Canada is able to consider information received by **August 18, 2019**, 75 days from the date of this posting.