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Health Canada's Proposal to Add Maximum Levels for Inorganic Arsenic in Polished (White) and Husked (Brown) Rice to 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-2019-2

June 14, 2019

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 foods. 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](#). 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 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 (CFIA).

Health Canada is proposing to establish new MLs for inorganic arsenic in polished (white) and husked (brown) rice of 0.2 and 0.35 parts per million (ppm), respectively. These MLs would also apply to white and brown rice when used as an ingredient in other foods.

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

Part 2			
Item No.	Column 1 Substance	Column 2 Food ¹	Column 3 Maximum Level
(TBD)	Inorganic arsenic	(1) Polished (White) rice	0.2 p.p.m.
		(2) Husked (Brown) rice	0.35 p.p.m.

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

Rationale

Arsenic is naturally occurring in the environment, therefore, very low levels are present in various foods. Long-term exposure to elevated levels of inorganic arsenic can contribute to a possible increased risk of certain cancers and other non-cancer effects.

Health Canada's Proposal to add maximum levels for inorganic arsenic in white and brown rice to the *List of Contaminants and Other Adulterating Substances in Foods*

Health Canada is committed to ensuring that dietary exposure to food contaminants is as low as reasonably achievable. Rice represents a significant source of exposure to inorganic arsenic in the diet of Canadians. To minimize dietary exposure to inorganic arsenic, Health Canada is proposing to establish MLs of 0.2 ppm and 0.35 ppm for inorganic arsenic in polished (white) and husked (brown) rice, respectively. The MLs would also apply to the rice portion of rice-containing products.

Canadian surveillance data demonstrate that these MLs are readily achievable for rice and rice products available for sale in Canada.

Other Relevant Information

International Regulatory Actions

In 2014 and 2016, the Codex Alimentarius Commission established MLs of 0.2 ppm and 0.35 ppm for inorganic arsenic in polished (white) and husked (brown) rice, respectively ([CODEX STAN 193-1995](#)). The proposed MLs by Health Canada align with those established by the Codex Alimentarius.

The European Commission has established MLs for inorganic arsenic of 0.2 ppm in non-parboiled milled rice (polished or white rice); 0.25 ppm in parboiled rice and husked rice; 0.3 ppm in rice waffles, rice wafers, rice crackers and rice cakes; 0.1 ppm in rice destined for the production of food for infants and young children ([Commission Regulation 2015/1006](#)).

The United States Food and Drug Administration (U.S. FDA) has not established regulatory MLs for inorganic arsenic in rice although, in 2016, they issued a proposed [action level of 0.1 ppm for inorganic arsenic in infant rice cereals](#). As of April 2019, this action level has not been adopted as a regulatory ML and thus remains at the proposal stage.

Food Standards Australia New Zealand has not established MLs specifically for inorganic arsenic in rice, although they have set an ML of 1 ppm for total arsenic in cereals grains and milled cereal products ([Australia and New Zealand Food Standards Code – Schedule 19](#)). As per [Schedule 22](#) of the Australia and New Zealand Food Standards Code, grains include rice in husk.

Additional Information Request – Rice-Based Foods Intended for Infants and Young Children

Health Canada is considering additional, more protective, risk management measures for rice-containing foods intended specifically for infants and young children. There is evidence that exposure to high levels of inorganic arsenic during critical windows of early development may represent a risk for infants and young children.

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To inform possible future risk management measures for rice-containing foods intended for infants and young children, the Canadian Food Inspection Agency will be conducting a targeted survey specifically for these foods in 2019-2020.

Interested stakeholders from the food industry and the public are invited to submit any comments on the proposed rice MLs and data or information on arsenic levels, reduction strategies, or other relevant information pertinent to arsenic in rice-based foods for infants and young children that would inform this work. As noted above, the EC has set an ML of 0.1 ppm inorganic arsenic in rice destined for the production of food for infants and young children and the U.S. FDA has proposed an action level of 0.1 ppm inorganic arsenic in infant rice cereals.

If it is determined that additional MLs for other rice-based foods are warranted then Health Canada will announce its intention to establish these MLs via a Notice of Proposal published on [Health Canada's Website](#).

Implementation and Enforcement - Maximum Levels for Inorganic Arsenic in White and Brown Rice

The proposed current changes to add MLs of 0.2 ppm and 0.35 ppm for inorganic arsenic in polished (white) and husked (brown) rice, respectively, to the [List of Contaminants and Other Adulterating Substances in Food](#) will be effective the day on which they are published in Part 2 of the list. Health Canada proposes to publish the changes to the list 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 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 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 Rice**” in the subject line of your e-mail. Health Canada is able to consider information received by **August 27, 2019**, 75 days from the date of this posting.