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Summary of Comments and Responses to Health Canada's Proposed Amendments to the Regulatory Tolerances for Arsenic and Lead in a Variety of Beverages

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Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch





Canada

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Background

Health Canada's Bureau of Chemical Safety, Food Directorate is proposing to update the regulatory tolerances for arsenic and lead in a variety of beverages, including bottled water, that are listed in Division 15, Table 1 of the Food and Drug Regulations (FDR).

The detailed rationale for the proposed changes can be found in the following consultation document, *Proposed Changes to the Tolerances for Arsenic and Lead in Fruit Juice, Fruit Nectar, Beverages when Ready-to-Serve, and Water in Sealed Containers*, which was posted on Health Canada's website on June 19, 2014. The consultation officially closed at 11:59 PM on September 1, 2014, although some comments were submitted on September 26, 2014 and these were also accepted.

In the above-noted document, Health Canada proposed the following:

1. Exclude apple juice from the existing tolerance of 0.1 ppm for arsenic in fruit juice, fruit nectar, and beverages when ready-to-serve, and create a separate tolerance of 0.01 ppm for total arsenic in apple juice.
2. Lower the existing tolerance for lead in fruit juice, fruit nectar, and beverages when ready-to-serve from 0.2 ppm to 0.05 ppm.
3. Lower the existing tolerances for both arsenic and lead in water in sealed containers from 0.1 and 0.2 ppm, respectively, to 0.01 ppm for both arsenic and lead and extend the tolerances to include all types of bottled water, including mineral and spring water.

Summary of Comments

Health Canada received comments from the following stakeholders representing the food industry and professional organizations:

- Canadian Beverage Association
- Canadian Bottled Water Association
- Food Processors of Canada
- Heinz Canada
- Manitoba Liquor and Lotteries
- Juice Products Association (American)
- Société des alcools du Québec
- SunRype Products Ltd.

A summary of the key questions and comments received as well as Health Canada's responses are presented below.

1) Proposal 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 juice.

Q1(i). Health Canada's scientific assessment to support the proposed lower tolerance for arsenic in apple juice should be made available.

A1(i). Health Canada's scientific assessment in support of a lower tolerance for arsenic in apple juice has been made available through the Department's website.

Q1(ii). Health Canada should consider international standards for arsenic in apple juice and how Canadian regulations would impact the import of apple juice to Canada. Segregation of apple juice products destined for the U.S. and Canada would be required as a product meeting the U.S. FDA action level of 0.01 ppm inorganic arsenic may not meet the proposed Canadian tolerance of 0.01 ppm total arsenic.

A1(ii). In consideration of the comments received during the preliminary consultation, as well as the results of its scientific assessment in support of a lower tolerance for arsenic in apple juice, Health Canada has reviewed its originally proposed risk management strategy and is now considering recommending a total arsenic tolerance in apple juice of 0.015 ppm, which closely aligns with the U.S. FDA's action level for inorganic arsenic in apple juice (see previous Response).

Q1(iii). Aligning with the U.S. FDA's action limit for inorganic arsenic in apple juice is of concern because it is not a regulatory level, the FDA has not provided a valid scientific basis for the value, and it does not provide additional public health protection.

A1(iii). Health Canada is proposing to amend an existing, but outdated, Canadian tolerance which was no longer considered to be health protective. The Department conducted a scientific assessment in support of a lower tolerance for arsenic in apple juice, which considered several criteria, not only the action level proposed by the U.S. FDA for inorganic arsenic in apple juice (see previous Response).

Q1(iv). Health Canada's proposed tolerance for total arsenic in apple juice is more stringent, not in "general agreement", with the United States Food and Drug Administration's (U.S. FDA) proposed action level for inorganic arsenic in apple juice.

A1(iv). All available Canadian and U.S. data on the contribution of inorganic arsenic (sum of arsenite and arsenate) to total arsenic in apple juice was reviewed as part of Health Canada's scientific assessment in support of a lower tolerance for arsenic in apple juice. Using the mean value of the proportion of total arsenic that is present as inorganic arsenic in apple juice from a combined Canadian and U.S. dataset, total arsenic concentrations of 0.01 ppm and 0.015 ppm were determined to correspond to inorganic arsenic concentrations of approximately 0.0074 ppm and 0.011 ppm, respectively. As such, a Canadian total arsenic tolerance of 0.01 ppm would be somewhat more stringent than the U.S. FDA's proposed action level for inorganic arsenic in apple juice and a total arsenic tolerance of 0.015 ppm would be equivalent to the FDA's proposed action level.

The difference between the mean inorganic arsenic concentrations when a total arsenic tolerance of 0.015 ppm is applied to the combined Canadian and U.S. data set and when the FDA's inorganic arsenic action level of 0.01 ppm is applied to the same data set, is 0.0011 ppm (or 1.1 ppb) inorganic arsenic, which is considered to be insignificant.

Q1(v). Establishing a tolerance for arsenic in apple juice that is the same as the Maximum Acceptable Concentration (MAC) of arsenic in the Canadian Guidelines for Canadian Drinking Water Quality is not good science. Apple juice should have a higher arsenic tolerance than municipal drinking water because it is consumed in smaller relative quantity.

A1(v). As outlined in the scientific assessment in support of a lower tolerance for arsenic in apple juice, Health Canada considered the following criteria in the development of an updated tolerance for arsenic in apple juice: impact on exposure and related health risks; achievability in consideration of an arsenic concentration that is As Low as Reasonably Achievable (ALARA principle); and existing domestic and international arsenic guidelines for similar food products. Health Canada is of the opinion that it is reasonable to consider the MAC for arsenic in drinking water in the development of an updated tolerance for arsenic in apple juice because apple juice is primarily a water-based beverage that is commonly manufactured from concentrate and because inorganic arsenic is the predominant form of arsenic in both drinking water and apple juice.

Q1(vi). Water is a potential source of arsenic in apple juice made from concentrate. In practice, the tolerance for single-strength apple juice that is used to make apple juice concentrate should be less than 0.01 ppm to ensure that the final reconstituted product meets the proposed 0.01 ppm tolerance.

A1(vi). Health Canada is proposing an updated tolerance for arsenic in apple juice that would apply to the product as consumed, and is not proposing guidance for ingredients used to produce finished apple juice products offered for sale in Canada.

Q1(vii). Why is Health Canada focusing its risk management actions on arsenic in apple juice? Other products, such as rice, have been recognized by the European Food Safety Authority and the Codex Alimentarius Commission as being more significant contributors to dietary arsenic exposure and thus a greater potential public health concern.

A1(vii). As stated in the consultation document, the regulatory tolerances for arsenic (and lead) in Division 15, Table 1 of the *FDR* are considered to be outdated and were established when there were sources of contamination that are no longer relevant in Canada. A lower tolerance for arsenic in apple juice is readily achievable and would be more protective of human health. 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 1 to 4 year-olds in Canada and continues to be one of the most commonly consumed juice types in older age groups of children. Health Canada may be proposing updates to the existing arsenic tolerance for other fruit juices and fruit nectars in the future and may also consider whether risk management strategies for other food commodities that can make relatively high contributions to overall dietary arsenic exposure are necessary. Additionally, Health Canada is an active member of the Codex Committee on Contaminants in Food, which recently established a Maximum Levels (ML) for inorganic arsenic in polished rice and has proposed an ML for inorganic arsenic in husked rice.

Q1(viii). Health Canada's Food and Nutrition webpage on arsenic states that the "levels of arsenic found in food sold in Canada are generally very low and there is no need to change dietary habits to reduce exposure to arsenic."

A1(viii). Health Canada is not suggesting any changes to the dietary habits of Canadians in order to reduce exposure to arsenic. Health Canada continues to recommend that Canadians eat a balanced diet by following the guidance provided in *Eating Well with Canada's Food Guide*.

The Department is proposing to *replace the existing, outdated tolerance* for arsenic in apple juice with a separate, lower tolerance *that available Canadian data shows is readily achievable.*

Q1(ix). No information is presented that demonstrates that lowering the tolerance for total arsenic in apple juice will have a significant positive impact on human health.

A1(ix). There are numerous health effects known to be associated with elevated exposure to inorganic arsenic. As such, preventing exposure to elevated levels of arsenic would have a positive impact on human health. An updated tolerance for arsenic would help to prevent the sale of any apple juice that contains unnecessarily high concentrations of arsenic. By proposing a lower tolerance, the Food Directorate's Bureau of Chemical Safety is fulfilling its mandate to manage the levels of hazardous chemicals in the Canadian food supply and ensure that dietary exposure to such chemicals remains as low as possible.

Q1(x). Health Canada's Food and Nutrition webpage on arsenic states that "current scientific evidence does not clearly indicate that infants and children are more susceptible than adults to the toxic effects of arsenic." Therefore, what is the rationale for focusing on reducing children's exposure to arsenic in apple juice?

A1(x). Since the time that the information on the cited Health Canada webpage was developed, scientific evidence has become available that suggests that exposure to inorganic arsenic during childhood could be a risk factor for increased cancer rates during the adult years[1]. Furthermore, exposure to contaminants on a body weight basis is greatest in infants and children. Health Canada's webpage will be updated to reflect the most up-to-date information on the potential hazards posed by inorganic arsenic.

Q1(xi). According to Health Canada's Food and Nutrition website on arsenic, "inorganic arsenic is considered to be the most toxic to human health, while organic arsenic is considered to be non-toxic"…not of concern to human health. Therefore, proposing a tolerance for total arsenic is not reflective of the true risks, if any, associated with arsenic in apple juice.

A1(xi). The majority of arsenic in fruit juice is present as inorganic arsenic species (arsenite and arsenate) and these are considered to be of greatest concern to human health. However, most fruit juices also contain methylated arsenic species (i.e. monomethylarsonic acid (MMA) and dimethylarsinic acid (DMA)). The toxicological database for MMA and DMA is increasing and information has become available to suggest that, unlike other non-toxic forms of organic arsenic such as arsenobetaine and arsenocholine, MMA and DMA may have some toxic potential.

Q1(xii). Establishing a tolerance for total arsenic in apple juice would raise issues regarding testing and compliance.

A1(xii). The existing tolerances in Division 15, Table 1 of the *FDR* are for total arsenic in certain foods; these tolerances have been in place for many years. The analysis of individual

[1] References provided at the end of this document

arsenic species is more time consuming and expensive than that of total arsenic, which makes it advantageous to establish a tolerance based on total arsenic.
Comments and questions concerning compliance monitoring and enforcement of tolerances should be forwarded to the Canadian Food Inspection Agency (CFIA).

Q1(xiii). Establishing a tolerance for total arsenic in apple juice would result in consumer confusion and foster a belief that all forms of arsenic are a concern to human health.

A1(xiii). Health Canada has not received questions or feedback from the public that suggest that there is consumer confusion regarding the existing tolerance for arsenic in fruit juice, fruit nectar, and ready-to-serve beverages, which is based on a total arsenic concentration. Health Canada regularly responds to public inquires pertaining to contaminants in the Canadian food supply and will continue to answer any questions regarding the tolerance for arsenic in apple juice.

Q1(xiv). Health Canada has not recommended any control or removal measures for arsenic in apple juice and industry is unaware of any such treatment methodologies. A review of known technologies should be conducted and a tolerance for arsenic in apple juice that is achievable when those technologies are employed should be considered.

A1(xiv). Data on the total arsenic concentrations in apple juice sold in Canada demonstrate that 93% of samples tested can meet a hypothetical tolerance of 0.01 ppm total arsenic and 97% of samples tested can meet a hypothetical tolerance of 0.015 ppm total arsenic. These data suggest that the amount of arsenic in the majority of apple juice available in Canada is already very low and that the agricultural and manufacturing practices that are currently employed are generally sufficient to meet the lower proposed tolerance.

Q1(xv). Is there a health-based reason to restrict the arsenic concentration in the apple juice portion of a juice blend to 0.01 ppm if the total arsenic concentration in the finished juice blend product does not exceed the existing 0.1 ppm arsenic tolerance for all other (i.e. non-apple) types of fruit juices and nectars?

A1(xv). Health Canada is proposing to apply a lower tolerance for arsenic in apple juice to the apple juice portion of juice blends or drinks as apple juice is a common component of juice blends. Apple juice can readily achieve the proposed lower arsenic tolerance and it would not generally be considered acceptable to use apple juice containing elevated levels of arsenic as an ingredient in other foods. Health Canada is reviewing data for arsenic species in other types of fruit juices and may be proposing updates to the tolerance for arsenic in additional fruit juices and nectars in the future, which will also take into consideration achievability (i.e. ALARA levels).

2) Proposal to lower the existing tolerance for lead in fruit juice, fruit nectar, and beverages when ready-to-serve to 0.05 ppm.

Q2(i). What types of products are included in the "beverages when ready-to-serve" category (e.g. fruit and vegetable smoothies, alcoholic beverages)?

A2(i). In consideration of feedback provided as part of the preliminary consultation, Health Canada proposes to further focus the present updates on the lead tolerance in fruit juice and nectar only. Health Canada will be reviewing the other lead tolerances in Division 15, Table 1 in the future. As part of this work, the food category descriptions associated with each tolerance will be reviewed and updated, as appropriate, with a view to address any ambiguity as to the types of food that are included in the existing categories, such as "beverages when ready-to-serve". Any proposed changes to the existing lead tolerances will be developed in consultation with stakeholders.

Q2(ii). The proposed lower tolerance for lead in fruit juice, fruit nectar, and beverages when ready-to-serve is supported by Canadian stakeholders and is consistent with the ML established by the Codex Alimentarius Commission for lead in fruit juices and nectars.

A2(ii). Health Canada is an active participant in the Codex Committee on Contaminants in Food, which is currently reviewing the existing MLs for lead in a variety of food commodities. Health Canada aims to align its food contaminant standards with Codex MLs if it is determined that the Codex ML in question is appropriate to the Canadian context.

3) Proposal to lower the existing tolerances for both arsenic and lead in all types of water in sealed containers to 0.01 ppm.

Q3(i). The proposed lower tolerances for arsenic and lead in bottled water, including mineral and spring water, are supported by Canadian industry as they align with the arsenic and lead MACs in the Guidelines for Canadian Drinking Water Quality as well as the standards of the Canadian Bottled Water Association (CBWA), and the Codex Alimentarius Commission (CAC).

A3(i). Health Canada's objective has been to bring the chemical and radiological standards for bottled water in-line with those of the MACs set out in the *Guidelines for Canadian Drinking Water Quality and in consideration of the chemical standards of the CBWA and the CAC.*

Summary of Tolerance Updates Being Proposed by Health Canada

1. In consideration of the comments received during the preliminary consultation, as well as the results of its scientific assessment in support of a lower tolerance for arsenic in apple juice, Health Canada has reviewed its proposed risk management strategy and is recommending to exclude apple juice from the existing tolerance of 0.1 ppm total arsenic in fruit juice, fruit nectar, and beverages when ready-to-serve, and is now proposing to create a separate tolerance of 0.015 ppm for total arsenic in apple juice.

2. In consideration of feedback provided as part of the preliminary consultation, Health Canada proposes only to update the lead tolerance in fruit juice and fruit nectar only, which will not include ready-to-serve beverages. As such, Health Canada proposes to lower the existing tolerance for lead in fruit juice and fruit nectar from 0.2 ppm to 0.05 ppm.

3. Health Canada is also proposing to lower the existing tolerances for both total arsenic and lead in water in sealed containers from 0.1 and 0.2 ppm, respectively, to 0.01 ppm for both arsenic and lead and extend the tolerances to include all types of bottled water, including mineral and spring water.

Next Steps

Health Canada is continuing to update its overall dietary exposure assessments for lead and arsenic, and examine how the various types of foods in the Canadian diet contribute to exposure to these trace elements.

Prior to proceeding with any regulatory change to the existing tolerances for lead and arsenic in any food commodity, there will be an additional opportunity for stakeholders to provide comments/feedback to Health Canada.

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