Notice of Proposal – List of Contaminants and Other Adulterating Substances in Foods

Reference Number: [NOP/ADP C-2018-1]

Santé

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) are forms 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.

New information regarding how raw apricot kernels are being sold in Canada is available. There are also indications that consumers may not be aware of or follow Health Canada's existing consumption advisory for adults to consume no more than three bitter apricot kernels a day and that they should not be consumed by children. This suggests that further risk management actions are required to address any potential health risks associated with acute cyanide poisoning from the consumption of raw apricot kernels, which can lead to serious adverse health effects.

The purpose of this notice is to seek feedback on three risk management options to protect Canadians from the risk of cyanide exposure due to the consumption of apricot kernels. The risk management options are described below.

Option A

Prohibit the sale of apricot kernels for human consumption, including if intended for further processing, if they contain extractable cyanide, by adding extractable cyanide in apricot kernels to Part 1 of the List of Contaminants and Other Adulterating Substances in Foods. The prohibition would also apply to apricot kernels used as an ingredient in other foods. OR

Option B

Establish an ML of 20 parts per million (ppm) for total extractable cyanide in apricot kernels sold for human consumption, including if intended for further processing, by adding this ML to Part 2 of the List of Contaminants and Other Adulterating Substances in Foods. The ML would also apply to apricot kernels used as an ingredient in other foods. OR

Option C

Prohibit the sale of apricot kernels for human consumption if they contain extractable cyanide, with the exception of processed apricot kernels with total extractable cyanide concentrations of 20 ppm or lower. This would entail adding extractable cyanide in apricot kernels to Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods* (i.e., Option A) and an ML of 20 ppm total extractable cyanide in processed apricot kernels to Part 2 of the *List of Contaminants and Other Adulterating Substances in Foods*.

In Option A, apricot kernels sold for human consumption as foods, including if intended for further processing or used as an ingredient in other foods, would be declared adulterated if they contained any extractable cyanide and their sale in Canada prohibited in accordance with Part I, Section 4 of the *Food and Drugs Act* (the *Act*).

In Option B, apricot kernels sold for human consumption, including if intended for further processing or used as an ingredient in other foods, would be subject to a maximum level of 20 ppm total extractable cyanide. Apricot kernels exceeding the ML would be in violation of Part I, Section 4 of the *Act*.

In Option C, Option A would still apply, but processed apricot kernels with total extractable cyanide concentrations of 20 ppm or less would be exempt from the prohibition of the sale of apricot kernels outlined in Option A.

All options are considered to be equally health protective as the establishment of an ML value is expected to keep exposures to cyanide from consuming apricot kernels below levels that have been associated with adverse effects.

It is the intention of Health Canada to modify the *List of Contaminants and Other Adulterating Substances in Foods* as described in Option A, or Option B, or Option C, and as outlined in bold text below.

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

Option A – Part 1 only

Part 1			
Item	Column 1	Column 2	
No.	Substance	Food	
19	Extractable cyanide		

<u>OR</u>

Option B – Part 2 only

Part 2			
Item	Column 1	Column 2	Column 3
No.	Substance	Food ¹	Maximum Level
(TBD)	Total extractable cyanide	Apricot kernels sold for consumption	20 p.p.m.

OR

Option C - Part 1 and Part 2

¹ See Part 2					
19	Extractable cyanide	Apricot kernels sold for consumption ¹			
No.	Substance	Food			
Item	Column 1	Column 2			
Part 1					

(TBD)	Total extractable cyanide	Processed apricot kernels	20 p.p.m.
(TDD)		D 1 . (1 1	
No.	Substance	Food ¹	Maximum Level
Item	Column 1	Column 2	Column 3
Part 2			

Rationale

Apricot kernels are the seeds found inside the pits or stones of apricots. These kernels resemble small almonds. There are two general types of apricot kernels based on taste; sweet and bitter. Both types naturally contain cyanogenic glycosides, primarily amygdalin, which has the potential to release cyanide when ingested. The sweet varieties of apricot kernels generally contain lower concentrations of amygdalin, thus would release less cyanide than the bitter varieties. However, the reported amygdalin concentrations within each type of apricot kernel can vary significantly and are expected to overlap. As such, the level of amygdalin or the potential amount of cyanide that could be released following ingestion cannot be used to differentiate between the sweet and bitter varieties of apricot kernels.

Small amounts of cyanide can be detoxified by the human body but high exposures over a short duration can result in severe adverse health effects (i.e., cyanide poisoning). There is currently a

lack of consistent criteria to classifying an apricot kernel as either bitter or sweet and, as a result, the proposed modifications to the <u>List of Contaminants and Other Adulterating Substances in Foods</u> will apply to all apricot kernels sold for human consumption.

In 2009, Health Canada conducted a health risk assessment for cyanide in bitter apricot kernels and issued an <u>advisory</u> on the Department's website indicating that there is a concern about the potential health effects associated with large numbers of bitter apricot kernels being consumed on a regular basis, particularly by young children, and that adults should not consume more than three kernels per day, ground and mixed with other foods.

Between 2013 and 2017, 195 inquiries were received by provincial poison control centres relating to the consumption of apricot kernels (bitter or sweet not specified). While no severe effects were reported, 86% of all calls were described as 'unintentional' exposure, suggesting that the consumer was not aware that the apricot kernels contained potentially elevated levels of cyanogenic glycosides/cyanide.

In November 2017, Health Canada published a reminder of the 2009 <u>consumer advisory</u> and further recommended that bitter apricot kernels not be eaten by children. Health Canada also further assessed how these products are sold through surveys in seven major urban centers across Canada. Apricot kernels were sold in approximately 50% of the 45 stores surveyed. They are most commonly sold at health food stores and certain ethnic food stores, either pre-packaged or in bulk. Apricot kernels are typically available for sale as whole or half kernels. They may also be sold ground and used as an ingredient in other foods and beverages.

In 2018, the Department updated its health risk assessment for apricot kernels and confirmed that Health Canada's 2009 consumption advice, that adults should not consume more than three bitter apricot kernels per day, continues to be protective of human health. Health Canada is also not aware of any confirmed reports of cyanide poisoning from the consumption of bitter apricot kernels since the original advice was first issued in 2009. However, to further protect the health of Canadians, particularly those who are not aware of Health Canada's advisory and who may consume apricot kernels in a manner that could potentially put them at risk for cyanide poisoning, Health Canada is taking a precautionary approach and proposing further risk management action as described above.

Other Considerations

Amygdalin is often incorrectly referred to as "laetrile" or "vitamin B17". Laetrile, a compound manufactured from amygdalin, has historically been associated with health claims, such as the prevention and treatment of cancer. Health Canada has not approved any medicinal or natural health uses of apricot kernels, laetrile or "vitamin B17" and does not permit cancer treatment claims for natural health products.

Paragraph D.01.004 (1)(a) of the <u>Regulations</u> also prohibits making a statement or claim concerning the vitamin content of a food unless the vitamin is set out in column 1 of Part 2 of the

'Table of Daily Values'. As vitamin B17 is not listed in this table, Health Canada considers any food, including apricot kernels, making a statement or claim relating to its vitamin B17 content to be in violation of the Regulations.

Other Relevant Information

International Regulatory Actions

Other food regulatory organizations have taken similar precautionary approaches to managing the potential risk associated with the consumption of apricot kernels.

In 2017, the European Commission (EC) established an ML of 20 ppm for hydrocyanic acid (cyanide) in unprocessed, whole, ground, milled, cracked, chopped apricot kernels placed on the market for the final consumer (Commission Regulation EU 2017/1237). The EC ML applies to both the sweet and bitter varieties of apricot kernels. The United Kingdom Food Safety Authority also applies the EC ML.

In 2015, Food Standards Australia New Zealand (FSANZ) prohibited the retail sale of raw apricot kernels as a food (Food Standards Code Standard 1.1.1), with the exception of apricot kernels used as an ingredient in a food for sale if the kernels have been or will be subject to processing or a treatment that renders them safe for human consumption (Food Standards Code Standard 1.4.4).

In 2015, the German Federal Institute for Risk Assessment (BfR) issued a consumption advisory for bitter apricot kernels recommending that consumption be limited to no more than two kernels per day. The BfR also suggests that the packaging of bitter apricot kernels should carry warnings of potential health risks and state the recommended maximum daily intake.

The United States Food and Drug Administration (US FDA) has not developed any specific regulation or advice relating to apricot kernels consumed as a food.

Implementation and Enforcement

One of the three proposed options will be effective the day on which they are published in Part 1 or Part 2, or both Parts, 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 three options. 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 **Cyanide in Apricot Kernels** (NOP C-2018-1) in the subject line of your e-mail. Health Canada is able to consider information received by **March 4, 2019**, 75 days from the date of this **posting**.