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# Health Canada's proposal to transfer the maximum level for patulin in apple juice and unfermented apple cider from the *List of Maximum Levels for Various Chemical Contaminants in Foods* to the regulatory *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-2017-4]

August 4, 2017

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 sold in Canada. Canadian MLs are set out in the [\*List of Contaminants and Other Adulterating Substances in Food\*](#), 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*. Health Canada is working towards the consolidation of all MLs into the single regulatory *List of Contaminants and Other Adulterating Substances in Foods* and is also systematically reviewing and updating, as appropriate, existing MLs in both of these lists. All MLs for contaminants in food are established by Health Canada and are enforceable by the Canadian Food Inspection Agency.

The *List of Maximum Levels for Various Chemical Contaminants in Foods* specifies an ML of 50 parts per billion (p.p.b.) (expressed in the list as 50 µg/kg or micrograms per kilogram) for patulin in apple juice, including the apple juice portion of any juice blends or drinks, and unfermented apple cider. If these foods contain patulin at concentrations above 50 p.p.b., they would be considered in violation of section 4(1) of the [\*Food and Drugs Act\*](#).

The existing ML for patulin in apple juice was established by Health Canada in 2011. The Department has confirmed that this ML continues to be health protective and relevant in the Canadian context.

Health Canada is proposing to transfer the existing ML for patulin in apple juice, including the apple juice portion of any juice blends or drinks, and unfermented apple cider from the *List of Maximum Levels for Various Chemical Contaminants in Foods* to the regulatory *List of Contaminants and Other Adulterating Substances in Foods*, thereby removing this ML from the first list. It is the intention of Health Canada to modify Part 2 of the *List of Contaminants and Other Adulterating Substances in Food* as outlined below. Footnote 1, which explains that MLs also apply to the food when it is present as an ingredient in another food, would make the qualifying text that follows the current listing of "apple juice" redundant. Therefore, the text "including the apple juice portion of any juice blends or drinks" will not appear after apple juice in the proposed listing.

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

<b>Item No.</b>	<b>Column 1 Substance</b>	<b>Column 2 Food<sup>1</sup></b>	<b>Column 3 Maximum Level<sup>2</sup></b>
(TBD)	Patulin	Apple juice; Unfermented apple cider	50 p.p.b. (parts per billion)

<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.

**Rationale**

Patulin is a secondary fungal metabolite (i.e., a mycotoxin) that can be found in rotting fruit, particularly apples. Human exposure to patulin can occur, usually at very low levels, through the consumption of apple-derived products such as apple juice and unfermented apple cider. Exposure to patulin can cause gastrointestinal irritation and kidney dysfunction, as well as immunotoxic, genotoxic and clastogenic effects in many animal species at sufficiently high doses. Most of the information on the potential toxicity of patulin is derived from experimental animal studies and there is limited to no data from epidemiological studies which have shown adverse effects in humans related to patulin exposure from the consumption of food.

The risk assessment conducted by Health Canada's Food Directorate, in support of the establishment of the ML for patulin in apple juice and unfermented apple cider in 2011, identified young children as the age group with the highest potential exposure to patulin due to their low body weights and high consumption of apple juice. Therefore, the ML was established to help minimise exposure to patulin in this population sub-group while also being protective for the general Canadian population.

Health Canada's Food Directorate has recently reviewed the existing Canadian ML for patulin in apple juice and unfermented apple cider and considers that the scientific basis upon which it was established continues to support the ML. The Department is of the opinion that an ML of 50 p.p.b. patulin in apple juice and unfermented apple cider is health protective of the general Canadian population as well as young children based on both acute and chronic exposure

scenarios. Furthermore, a review of contemporary occurrence data for patulin in apple juice and unfermented apple cider sold in Canada support that an ML of 50 p.p.b. in both of these commodities is readily achievable when good agricultural, manufacturing and storage practices are followed.

## Other Relevant Information

The Canadian ML for patulin in apple juice, when reconstituted to its ready-to-serve form and therefore in its original juice concentration, and unfermented apple cider, aligns with the ML established by the Codex Alimentarius Commission (Codex; [CODEX STAN 193-1995](#)) and the action level of the United States Food and Drug Administration ([Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice Products](#)). The European Commission has established a 50 p.p.b. ML for patulin in fruit juices, fruit nectars, spirit drinks, cider and other fermented drinks derived from apples or containing apple juice ([EC No. 1881/2006](#)), as well as a lower ML of 10 p.p.b. patulin in apple juice labelled and sold for consumption by infants and young children.

Codes of Practice are available to producers seeking information on preventing patulin contamination. For example, the [Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages](#) was adopted by the Codex Alimentarius Commission in 2003. As well, in 2001 Health Canada and the Canadian Food Inspection Agency, in consultation with stakeholders, developed a [Code of Practice for the Production and Distribution of Unpasteurized Apple and Other Fruit Juice/Cider in Canada](#).

## Implementation and Enforcement

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 Food](#). 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:

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If communicating by e-mail, please use the words **Patulin Maximum Level for Apple Juice and Unfermented Apple Cider** in the subject line of your e-mail. Health Canada is able to consider information received by **October 17, 2017**, 75 days from the date of this posting.