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# Health Canada's Proposal to Transfer the Maximum Level for total glycoalkaloids (TGA) in potato tubers (fresh weight) 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-2017-5]

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. Canadian MLs for chemical contaminants in food 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's Food Directorate and are enforceable by the Canadian Food Inspection Agency.

The *List of Maximum Levels for Various Chemical Contaminants in Foods* specifies an ML of 200 parts per million (ppm) total glycoalkaloids in potato tubers (fresh weight), with total glycoalkaloids specified as being the sum of alpha-solanine and alpha-chaconine. These two glycoalkaloids are estimated to comprise approximately 95% of the total glycoalkaloid (TGA) content of potatoes. If potato tubers are found to contain TGA concentrations above 200 ppm, they would be considered in violation of section 4(1) of the [Food and Drugs Act](#).

Based on the weight of evidence from case studies on human exposure to glycoalkaloids from potato tubers, a TGA concentration of 200 ppm or less is still considered to be protective of the health of Canadians.

Health Canada is proposing to transfer the existing ML for TGA in potato tubers from the *List of Maximum Levels for Various Chemical Contaminants in Foods* to the regulatory *List of Contaminants and Other Adulterating Substances in Foods*. 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. Note that the term 'fresh weight' will no longer need to be specified after 'potato tubers' as footnote 2 states that all MLs apply to foods on a fresh weight basis.

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

Item No.	Column 1 Substance	Column 2 Food <sup>1</sup>	Column 3 Maximum Level <sup>2</sup>
(TBD)	Glycoalkaloids, total (sum of alpha-solanine and alpha-chaconine)	Potato tubers	200 p.p.m.

<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**

Glycoalkaloids are a group of nitrogen-containing compounds that are naturally produced in various cultivated and ornamental plant species of the Solanaceae family, which includes vegetables such as potatoes, tomatoes, eggplants and peppers. There are numerous types of glycoalkaloids that vary in their potential toxicities to humans. Humans regularly consume low levels of a variety of glycoalkaloids through their diet without experiencing adverse health effects. The majority of past reports of adverse effects in humans related to glycoalkaloids have involved exposure from consumption of potatoes.

Symptoms associated with elevated exposure to glycoalkaloids from the consumption of potatoes include a bitter or burning sensation in the mouth and gastrointestinal disturbances such as nausea, vomiting, stomach and abdominal cramps and diarrhea. More severe cases of glycoalkaloid poisoning may be accompanied by a variety of neurological effects such as drowsiness, apathy, restlessness, shaking, confusion, weakness and disturbed vision.

Two types of glycoalkaloids that have the potential to produce adverse effects in humans, alpha-solanine and alpha-chaconine, represent approximately 95% of the total glycoalkaloid content of potatoes. The majority of glycoalkaloids in potato tubers are present in the skin and higher concentrations are generally found in potatoes that show signs of physical change or damage.

Glycoalkaloids are heat stable and therefore cooking practices such as baking, boiling, frying and microwaving have not been shown to significantly reduce their concentrations in potatoes. However, it has been demonstrated that the occurrence of glycoalkaloids in fresh potatoes can vary between potato cultivars and be affected by climatic and storage conditions such as temperature and light exposure.

The existing ML of 200 ppm for TGA in fresh potato tubers was developed by Health Canada over three decades ago in conjunction with public guidance provided by Agriculture Canada. The 200 ppm value is generally recognized as a safe concentration in potato tubers as most reported cases of adverse effects associated with glycoalkaloid exposure have occurred at concentrations above this value.

In 2014 Health Canada's Food Directorate conducted a comprehensive review of the most up-to-date toxicological information on alpha-solanine and alpha-chaconine. The review concluded that consumption of potatoes with a total combined alpha-solanine and alpha-chaconine concentration of 200 ppm or less continues to protect consumers from adverse health effects associated with glycoalkaloids in potatoes. Therefore, Health Canada is of the opinion that the ML of 200 ppm total glycoalkaloids in potato tubers continues to be protective of the health of the Canadians. This risk management approach is supplemented by [Health Canada's guidance on minimising exposure to glycoalkaloids from potatoes](#). Canadian monitoring data demonstrates that the existing ML of 200 ppm total glycoalkaloids in potato tubers is achievable when good agricultural, manufacturing and storage practices are followed.

## Other Relevant Information

An upper limit of 200 ppm TGA is generally recognized as a safe concentration in potato tubers, as reported in various publications including the Organisation for Economic Co-operation and Development's 2002 [Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants](#).

The U.S. Department of Agriculture (USDA) has historically accepted a non-regulatory guideline, or upper level, for the TGA content of potato tubers of 20 milligrams of glycoalkaloids for each 100 grams of fresh potato (equivalent to 200 ppm).

The [Swedish National Food Administration has established a maximum level of 200 ppm TGA in potato tubers](#).

## 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 **Glycoalkaloids Maximum Level for Potato Tubers** 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.