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Summary of Comments from Health Canada's Consultation on its Proposal to Introduce a Maximum Level for the Presence of Patulin in Apple Juice and Unfermented Apple Cider Sold in Canada

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Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

Health Canada's Bureau of Chemical Safety, Food Directorate recently completed a consultation on its proposal to introduce a 50 ng/g (ppb) standard (maximum level) for the presence of the mycotoxin patulin in apple juice, including the apple juice portion of any juice blends or drinks, and unfermented apple cider sold in Canada.

Patulin is a naturally occurring toxic fungal metabolite (mycotoxin) that may cause gastrointestinal irritation and kidney dysfunction, as well as immunotoxic, genotoxic and clastogenic effects in many animal species when ingested at sufficiently high doses.

The main route of human exposure to patulin is through the consumption of apple juice and related products. Due to their low body weight and higher consumption of the affected products, young children comprise the age group with the highest potential exposure to patulin.

A [consultation on this proposal](#) was made publicly available for comment on Health Canada's Food and Nutrition website comments for a 75 day period between July 21, 2011 and October 04, 2011.

Several comments were received during the course of this consultation:

1. One industry association expressed opposition to the patulin maximum level (ML) with the opinion that it would be detrimental to the growers who supply the raw products to processors. This industry association also stated that apple growers and juice and cider makers do take precautions to reduce patulin levels. Although this association is confident that Health Canada's proposed ML is achievable, and would be meaningful from a public health perspective, they believe this will be a burden to apple growers. Health Canada responded to this association and acknowledged that the industry's efforts are reflected in the monitoring data which demonstrate very low levels of patulin in these products and that the proposed ML is readily achievable. As such, Health Canada is confident that the ML for patulin will not be detrimental to apple growers, nor juice or cider makers. Health Canada also clarified that the analyses of samples by the Canadian Food Inspection Agency (CFIA) for compliance with the proposed ML for patulin will be conducted on the final juice or cider product.
2. A second industry association provided a letter citing general support of the proposed ML, provided it is applied only to products for sale to consumers.
3. A third industry association expressed general support for the proposed ML to manage any potential risk to very high consumers of apple juice. This association also recommended that any guidance documentation regarding the maximum level for patulin clearly indicate that in juice blends containing apple juice, the ML applies only to the apple juice portion of the blend, and that the potential risk from exposure to patulin is only for young children who consume large quantities of apple juice. Health Canada responded with an acknowledgement of this association's general support and recommendation.
4. One comment was received from the general public regarding the applicability of the ML to pear puree and pear juice. Health Canada clarified that the proposed patulin ML would apply exclusively to apple juice (and the apple juice portion of any juice blends) and unfermented apple cider, and would therefore not be applicable to pear puree or pear juice.

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In addition to these comments, Health Canada consulted with the CFIA before and during the consultation on the proposed ML for patulin, and no objections were brought forward. Furthermore, a ML for patulin of 50 ng/g in apple juice, and apple juice as an ingredient in other beverages has been adopted by the Codex Alimentarius Commission. The United States Food and Drug Administration has set an action level of 50 ng/g of patulin in apple juice, apple juice concentrates and other apple juice products. The European Commission has also adopted a patulin ML of 50 ng/g in fruit juices, concentrated fruit juices and fruit nectars.

After reviewing all comments received on the current consultation, and considering the inherent potential health risk to young children who may be heavy consumers of these products, it remains the opinion of the department that the risk of adverse health effects is negligible if patulin concentrations in apple juice and unfermented apple cider are maintained at 50 ng/g or below.

Therefore, the adoption of a 50 ng/g (ppb) standard (maximum level) for the presence of the mycotoxin patulin in apple juice, including the apple juice portion of any juice blends or drinks, and unfermented apple cider sold in Canada is now considered effective by the department.

The [maximum level for patulin](#) will be referred to as a standard and will be listed on the Health Canada website.

For more information on this initiative, please contact the [Chemical Health Hazard Assessment Division](#) at bc-s-bipc@hc-sc.gc.ca.