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Information Document on Health Canada's Proposed Maximum Limits (Standards) for the Presence of the Mycotoxin Ochratoxin A in Foods

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch

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PURPOSE

Health Canada's Bureau of Chemical Safety has recently completed a risk assessment of ochratoxin A, a potent renal carcinogen and nephrotoxic agent that is sometimes present at low concentrations in staple foods, such as cereal-derived foods, and a variety of other foods. As a result of this assessment, Health Canada scientists have concluded that risk reduction, through several options, is the preferred risk management strategy to protect the health of Canadian consumers from exposure to ochratoxin A. The purpose of this document is to provide background information and a summary of the evidence used by Health Canada scientists in support of the Department's proposed maximum limits for ochratoxin A in various food commodities.

BACKGROUND

Toxicology

Ochratoxin A is a toxic fungal metabolite that may cause nephrotoxic, teratogenic, immunosuppressive and carcinogenic effects in many species. It also causes porcine nephropathy and has been implicated in the etiology of Balkan endemic nephropathy (BEN), a chronic degenerative kidney disease associated with a high incidence of urinary tract tumours in humans. Ochratoxin A is one of the most potent renal carcinogens, inducing cancer in rats at very low doses. Consequently, ochratoxin A has been classified by the International Agency for Research on Cancer (IARC) as a *possible* human carcinogen (Group 2B), based on sufficient evidence for carcinogenicity in experimental animal studies and inadequate evidence in humans.

Exposure

The main route of human exposure to ochratoxin A is through the consumption of cereal-derived staple foods, as well as other foods such as coffee, grapes, raisins, wine, beer and soy infant formula. Many of these foods have been analysed for the presence of ochratoxin A by Health Canada's food laboratory network. In addition, the Canadian Grain Commission has been monitoring for ochratoxin A in grains for at least ten (10) years. There are currently no Canadian guidelines for managing the presence of ochratoxin A in foods.

Health Canada scientists have conducted a probabilistic exposure and human health risk assessment for ochratoxin A for all age-sex strata. It was found that

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ochratoxin A is ubiquitous and consumed at very low levels on a daily basis by most Canadians, confirming earlier findings by Health Canada that this toxin is present at low levels in 100 % of Canadian human sera. Because of their lower body weight, young children are the age group with the highest exposure to ochratoxin A.

Proposed Risk Management Strategy

While the risk of adverse health effects is low, Health Canada has identified the need to reduce exposure to ochratoxin A. To best achieve this, Health Canada proposes a combined approach of *a*) maximum limits for the presence of ochratoxin A in various food commodities; and *b*) guidelines based on Hazard Analysis of Critical Control Points (HACCP) in food production, to reduce the levels of ochratoxin A in final foods:

a) Proposed Health Canada maximum limits (MLs):

raw cereal grains*	5 ng OA/g;
directly consumer grains (i.e. rice, oats, pearled barley):	3 ng OA/g;
derived cereal products (flour**):	3 ng OA/g;
derived cereal products (wheat bran) :	7 ng OA/g;
breakfast cereals :	3 ng OA/g;
grape juice (and as ingredients in other beverages) and related products:	2 ng OA/g;
dried vine fruit (currants, raisins, sultanas):	10 ng OA/g;
baby foods and processed cereal-based foods for infants and young children :	0.5 ng OA/g
dietary foods for special medicinal purposes intended for infants:	0.5 ng OA/g

*These levels have been established taking into consideration the reducing effect of processing or redistribution.

**For bread, pastries and other flour-based foods, Health Canada considers these guidelines to pertain to the flour portion. In the future, based on further monitoring data (ongoing HC studies), the Department may consider modifying these MLs, or introduce MLs for products not yet covered, if necessary.

b) In consultation with Agriculture and Agri-food Canada and the Canadian Food Inspection Agency, introduce a Code of Practice (HACCP guidelines) pertaining to the growing and storage of food and aimed at preventing the formation of ochratoxin A in food commodities. Although a Maximum Level (ML) for raw cereal grains is considered under *a*), this ML, as well as MLs for flour and bran, could alternatively be considered as being part of HACCP guidelines for industry to follow throughout the food manufacturing process.

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Similar maximum limits for the presence of ochratoxin A in foods have already been introduced in Europe (Commission Regulation (EC) No 1881/2006) and are under consideration by the Codex Alimentarius Commission.

Comments on this proposal may be submitted in writing, by regular mail or electronically at the address indicated below. If you are submitting your comments electronically, please use the word "ochratoxin A" in the subject box of your e-mail. **Submissions must be received by 12:00 a.m. EDT on Monday, June 1, 2009.**

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