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CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 6 **CX/CF 11/5/6-Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

5th Session
The Hague, The Netherlands, 21 – 25 March 2011

PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) AND ITS ACETYLATED DERIVATIVES IN CEREALS AND CEREAL-BASED PRODUCTS (N10-2010)

(Comments at Step 3 submitted by Chile, Costa Rica, Japan and Kenya)

CHILE

Chile agrees with the document and considers very useful the information submitted, but thinks that no more maximum levels should be proposed until more data is collected, since the data submitted till now includes few developing countries, and specially very little information from South America.

Furthermore, we support asking JECFA to assess the impact of the different ML en dietary exposure.

COSTA RICA

Costa Rica appreciates the opportunity to be able to express its comments on the establishment of maximum levels (ML) for DON and its acetylated derivatives in cereals and cereal-based products:

In the document it is explained that the participants of the Electronic Working Group did not reach consensus for the appropriate establishment of maximum levels for DON and its acetylated derivates in cereals and cereal-based products. It is pointed out that they made a proposal for MLs based on occurrence levels, as follows:

- 2 mg/kg in raw wheat, maize (US: corn) and barley, to be subjected to sorting or physical treatment prior to human consumption or used as ingredients in foodstuffs.
- 1 mg/kg for foods derived from wheat, barley and maize (US: corn), including those intended for direct human consumption, except cereal-based foods for infants and young children.
- 0.5 mg/kg for cereal-based foods for infants (up to 12 months) and young children (12 to 36 months).

CR is a country with a high consumption of products derived from wheat and maize (US: corn), such as nutritious pastas, bread and wraps. However, we do not have any data available relating to the occurrence of DON in foods and we consider the establishment of an ML for this type of contaminant important, and therefore suggest that these levels be established as first international reference. We recommend keeping the Electronic Working Group, in order that it will continue to collect data and in the light of new information re-evaluate the MLs here defined, and likewise will continue with the development of analysis and sampling methods.

JAPAN

General comments

1. Data collected by the Electronic Working Group are insufficient to elaborate the MLs for DON in following the Codex principle and policy. Therefore, Japan supports the recommendation in paragraph 81 that at this stage, rather than considering MLs, the CCCF should encourage members to submit complete data set including individual food consumption data.

2. Given that there are relevant principles and policy (see note below) , Japan suggests that the Committee should consider the following points:

   - Draft MLs for raw barley, wheat and maize should be proposed by applying the ALARA principle to available occurrence data of DON from various countries and sources;
   - Draft MLs for processed products derived from barley, wheat and maize should be proposed by multiplying the draft MLs in raw commodities by respective processing factors calculated from DON concentrations in processed commodities and in raw commodities from appropriate processing studies; and
   - The 97.5th percentile of cereal and cereal based food consumption should be collected from Codex members or the GEMS/Food database to compare short-term dietary intake with the ARfD of 8 µg/kg-bw for DON.

   Note: The Guidelines and principles applied in the elaboration of MLs:

   - The third and forth indents of *the establishment of Maximum Levels* in Annex I (page 5) and *Toxicological information* in Annex I (page 4) of the *Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF)*

     (http://www.codexalimentarius.net/download/standards/17/CXS_193e.pdf)

   - Para. 12 of the *Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (in Page 100 of the Codex Procedural Manual 19th Edition)*

     (ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_19e.pdf)

   - Page 17 in the *Guidelines for predicting dietary intake of pesticide residue*

     (http://www.who.int/entity/foodsafety/publications/chem/en/pesticide_en.pdf)

   - Page *127* in the *7.3 Short-term Dietary Intake* in the *Submission and Evaluation of Pesticide Residues data for the Estimation of Maximum Residue Level in Food and Feed* (http://www.fao.org/docrep/012/i1216e/i1216e07.pdf)

Specific comments

3. Table 4 in paragraph 48, page 11 needs to be amended as follows:

Table 4.

National Assessment	Commodities Assessed	Age Gro^{up}	Est. DON Exp. (µg/kg bw/day)		Reference
			Mean	High	
Japan	Wheat	1-6	~~0.69~~	**0.69**	~~Watari~~ **Nakatani et al. 2011**
Japan	Wheat	7-14	~~0.49~~	**0.49**	~~Watari~~ **Nakatani et al. 2011**
Japan	Wheat	Adults	~~0.24~~	**0.24**	~~Watari~~ **Nakatani et al. 2011**

In addition, the corresponding reference in page 24 should be changed to:

~~Watari M. 2011. Personal communication.~~

Nakatani Y, Satoh T, Saito S, Watanabe M, Yoshiike N, Kumagai S and Sugita-Konishi Y. 2011. Simulation of deoxynivalenol intake from wheat consumption in Japan using the Monte Carlo method. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess.* 16:1-6.

4. Paragraph 52 should be changed as follows, in order to reflect additional knowledge on pre-harvest control:

   The use of microorganisms **or natural compounds** to control the growth of *Fusarium* species and the levels of DON has shown promising results. For instance, several bacterial strains, under greenhouse conditions, were able to reduce the growth of *F. graminearum* and the production of DON on irradiated wheat grains by 60-100%, whereas the disease severity was reduced by 49-71%. Two bacterial strains of the *Brevibacillus* sp. and *Streptomyces* sp. were selected as biocontrol agents for further greenhouse and field studies (Palazzini *et al*., 2007). **Precocene II, a constituent of German chamomile essential oil was able to inhibit DON production of *F. graminearum* on the rice medium with the IC_{50} value of 2 ppm (Yaguchi *et al*., 2009).**

KENYA

Specific Comment

We support the proposed **MLs of 2 mg/kg** in raw wheat, maize and barley, destined to human consumption after sorting or other physical treatment or for use as an ingredient in foodstuffs.

Justification

Our experience and available literature show that it is practically difficult to reduce the contamination in raw maize or wheat to a level lower than 2mg/kg. The ML can be achieved with application of Good Agricultural Practices (GAP).

Specific Comment

We also support the 1mg/kg for all products derived from wheat, barley and/or corn, including those intended for direct human consumption, except infant food.

Justification

This limit of 1mg/kg is achievable because, Good Manufacturing Practices (GMP) eg sorting and milling can further reduce the contamination in ingredients of these products. It should be noted that we cannot suggest a lower ML which would be more protective to the consumers because such a limit is not practically possible to achieve. Based on maize consumption patterns in Africa (up to 500g/person/day) a simple deterministic exposure assessment shows that the ML that would be protective to consumers should be set below 0.12mg/kg. Since the contamination in wheat is similar to that of maize, a more protective limit for countries including Canada where wheat is the main source of DON is also below 0,12mg. However considering the limitations of achieving the lower limit, Canada proposed an ML of 1mg/kg. Additionally, most countries that have set limits for DON in wheat, maize or cereals in general are enforcing an ML of 1mg/kg.

Specific comments

But we do not support the ML of 0.5mg/kg proposed for cereal-based infant food. Instead we recommend an ML of 0.3mg/kg.

Justification

A more stringent ML is required for infants because their body weight is low and immune system is at developmental stages. If manufacturers use cereals such rice, barley, finger millet in the manufacture of infant formula, the level of 0.3mg/kg should be achievable. Other countries such as EU and the Ukraine have established and are enforcing an ML of 0.2 mg/kg for processed cereal-based foods and baby foods for infants and young children.