



JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS  
AND ASSOCIATED SAMPLING PLANS

(AT STEP 3)

INCLUDING THE POSSIBLE REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF  
MYCOTOXIN CONTAMINATION IN CEREALS (CAC/RECP 51-2003)

*Comments at Step 3 submitted by Costa Rica, European Union, Japan, Kenya and USA*

**COSTA RICA**

Costa Rica appreciates the opportunity to submit its comments on document CX/CF12/6/9 Proposed draft Maximum Levels for Deoxynivalenol (DON) in Cereals and Cereal-based Products and Associated Sampling Plans.

Costa Rica does not have data on the levels of DON in cereals and cereal-based products for human consumption; however, we agree about the importance of establishing ML for this contaminant. In view of the world differences in the intake of the different cereals, and the degree of contamination among regions and seasons, we support the option of setting ML for raw cereals and semi-processed products, like flour, instead of for finished cereal-based products, such as bread and breakfast cereals, excepting for cereal-based foods for infants and young children.

Concerning the sampling plans, though it is appropriate setting ML and then developing the sampling plans, we find adequate the proposal presented as a Codex plan.

**Justification:**

Since DON occurs in raw cereals, controlling the levels in raw matters and semi-processed products would ensure reducing the levels of DON in finished products. Besides, it is key setting a ML in cereals-based foods for infants and young children because this is the most vulnerable group due to the critical chronic toxicity effects on stunting and reduced growth.

**EUROPEAN UNION**

The EU would like to provide the following comments:

- A maximum level of 2 mg/kg for DON is proposed in raw cereal grains (wheat, maize and barley), with the description that it relates to raw wheat, maize and barley grain to be subject to sorting or other physical treatment before human consumption or before use as an ingredient in other foods.

It is known that cleaning and sorting processes on raw cereal grains can significantly reduce the contamination level of DON in cereals. Therefore, the EU requests clarification that acceptance of a level for raw cereal grains at Codex level is not in contradiction with the setting of stricter levels by member countries for cereal grains marketed for first-stage processing after eventually cleaning and sorting processes on the raw cereal grains have been applied. In case this is confirmed, the EU could agree on the proposed levels. In case this is not confirmed, the EU cannot agree on the proposed maximum level as it is considered too high, in particular for common wheat and barley, as processes other than cleaning and sorting, applied in food manufacturing do not remove DON from the food chain.

In the EU, the maximum level for unprocessed maize is not applicable in case the maize is intended for wet milling as the produced starch do not or only a very low level of deoxynivalenol.

- The EU is of the opinion that it should be clarified if wheat includes common and durum wheat or only common wheat.

- A maximum level of 1.0 mg/kg is proposed for semi-processed products derived from wheat, maize and barley with the description that it relates to flour, semolina, meal, grits, flakes and starch. The EU notes that there are significant differences as regards the presence of DON in the different semi-processed products such as the DON levels between starch and wholemeal flour. Furthermore the EU notes that there is also a significant difference in DON level between the different milling fractions of maize depending on the particle size. While the proposed can be considered strict or even too low for certain semi-processed products, the EU considers the maximum level to be too high for other semi-processed products. Therefore it might be appropriate to compile and to consider the occurrence data of DON in the different semi-processed products under consideration individually. This would enable to consider the appropriateness of establishing one single maximum level for the semi-processed products or if it would be more appropriate to group the semi-processed products according to their level of deoxynivalenol and to establish a different maximum level for the different groups of semi-processed products.

- A maximum level for cereal based foods for infants and young children of 0.5 mg/kg is proposed. The EU agrees that infants and young children should be considered as the most vulnerable group of the population to DON exposure in terms of the critical chronic toxicological effect of reduced growth/growth retardation. However, the EU questions the need to establish a maximum level at Codex for cereal based foods for infants and young children given that the international trade in these foods is very limited. In case the CCCF decides that it is appropriate to establish a maximum level at Codex level for cereal based foods for infants and young children, the EU cannot agree on the proposed maximum level as the level is too high. Experience in the EU has shown that significantly lower levels are achievable with reasonable efforts. The EU therefore proposes a maximum level of 0.2 mg/kg for cereal based foods for infants and young children in case the CCCF decides that it is appropriate and needed to establish a maximum level at Codex level for these foods.

- On the recommendation that the Committee should consider how to address the enforcement of MLs during periods of increased DON contamination and when higher levels of DON are generally encountered, the EU is of the position that such a consideration could be appropriate at country/regional level, but is of the opinion that such a discussion at worldwide level is not really relevant. Indeed, the levels of DON are related to regional climate conditions and therefore the higher levels of DON will be encountered on a regional level but not on a worldwide level.

- The EU can agree on the proposed sampling provisions.

## JAPAN

### General Comment

1. For the reasons below, CCCF should elaborate an ML based on sound science and in accordance with the Codex principles and policies.

- *The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)* stipulates as follows:
  - "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence";
  - "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist"; and
  - "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations".
- *The Risk Analysis Principle Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods* in the *Procedural Manual* stipulates as follows:
  - "CCCF's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food";
  - "CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise";
  - "CCFA/CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food"; and
  - "Before finalizing proposals for maximum levels for contaminants and naturally occurring toxicants, CCCF shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCCF".

- The *establishment of Maximum Levels* in Annex I of the *General Standard for Contaminants and Toxins in Food and Feed (GSCTFF)* stipulates as follows:
  - "MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade";
  - "Proposals for MLs in products should be based on data from various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade";
  - "In all cases, a validated method of analysis should be available with which a ML can be controlled";
  - "The contaminant as it should be analyzed and to which the ML applies should be clearly defined"; and
  - "The product as it should be analyzed and to which the ML applies, should be clearly defined".
- 2. Based on above, Japan provides the following comments on the proposed draft MLs for DON in cereals and cereal-based products from multiple viewpoints as below.

#### Need for distribution curves

3. Japan believes that the Committee should elaborate MLs for DON in foods applying the ALARA principle to the distribution curves of concentration of DON. Since the *Code of Practice for the prevention and reduction of mycotoxin contamination in cereals* (CAC/RCP 51-2003) was adopted in 2003, member countries are supposed to have implemented the practice around 2005. Therefore, the Committee should prepare the distribution curves of concentration of DON in cereals and cereal-based products based on the occurrence data from 2005 to 2011.

#### Criteria of analytical methods

4. Japan believes that the Committee should establish criteria of analytical methods for DON in foods clearly in accordance with the *GSCTFF*. Considering the *Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance Thereof* in the *Procedural Manual*, the numeric values of the analyte, matrix, ML, lower level of minimum, limit of detection, limit of quantification, precision, recovery and trueness should be clearly defined.

#### **KENYA**

1. Raw cereal grains (wheat, maize and barley)-2Mg/kg
2. Semi-processed products derived from wheat, maize and barley- 1mg/kg
3. Cereal-based foods for infants (up to 12 months) and young children (12 to 36 months)-0.5mg/kg

Kenya would like the committee to consider setting MLs only for those for all commodities that are both for domestic consumption and for international trade as the code of Ethic emphasized without discrimination.

Since DON occurs at the raw grain level, controlling levels in the raw and semi-processed products would ensure that the levels in processed products are reduced for both domestic consumption and as well as for traded products.

#### **USA**

- The U.S. would not object to the proposed ML of 1 mg/kg for DON in milled products and foods derived from wheat, maize, and barley being advanced to the next Step.
- The U.S., however, questions the need to establish an ML for DON in raw wheat, maize, and barley with the establishment of ML for DON in milled products and in foods derived from wheat, maize and barley.
  - Milling of raw cereal grains can substantially reduce DON levels.
  - Since DON is water soluble, it is partitioned into the aqueous phase during wet milling of corn to substantially reduce DON in the solid corn starch fraction used for food products.
  - Setting an ML for DON in raw cereal grains may restrict trade unnecessarily.
- The U.S. supports the following recommendations of the electronic Working Group:
  - Codex member countries should continue to monitor or implement monitoring programs for the occurrence of DON and DON derivatives in wheat, maize and other cereals.
  - When there is a call for data, members should be encouraged to submit complete data sets to JECFA that include individual samples, and that take geographical locations and regional differences into consideration.

- Members, especially those who are primary producers and exporters of cereal grains, should be encouraged to provide information on whether or not they have implemented the Code of Practice (CAC/RCP 51-2003) or other Code of Practices and whether or not they succeeded in reducing contamination of cereals with DON. The availability of this information would enable the Committee to obtain a better global perspective of DON occurrence, exposure levels and variations associated with different environmental conditions and agronomic practices. An evaluation of the responses received could be helpful in determining whether the existing Code of Practice should be revised and/or updated.
- The inclusion of the Proposed Draft Sampling Plan provides information that the Committee may consider after the elaboration of MLs has been finalized.