



**Food and Agriculture
Organization of
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**World Health
Organization**

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Agenda Item 7

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

**Seventh Session
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**PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL IN CEREALS AND CEREAL-BASED PRODUCTS
AND ASSOCIATED SAMPLING PLANS**

*Comments at Step 3 submitted by Argentina, Costa Rica, European Union, Ghana, India, Iran, Kenya, Philippines,
Republic of Korea, Russian Federation, African Union and FoodDrinkEurope*

ARGENTINA

Argentina proposes a revision of the Spanish translation and supports the proposed limits:

Product	Description	Maximum Level
Raw cereal grains (wheat, maize and barley)	Raw Wheat, Maize and Barley after removal of damaged kernels	2 mg/kg
Flour, semolina, corn flour, flakes (and possibly grits and starch) derived from wheat, maize or barley		1 mg/kg
Cereal-based foods for infants and young children	All cereal based foods for infants (up to 12 months) and young children (12 - 36 months)	0.5 mg/kg

There are no objections concerning the sampling plans

COSTA RICA

Costa Rica welcomes the opportunity to provide comments on document CX/CF 13/7/7 Proposed Draft Maximum Levels for Deoxynivalenol in Cereals and Cereal-based Products and Associated Sampling Plans

Comment

Although Costa Rica does not have data to submit, we support the proposed levels by the working group for the following groups:

Commodities	Description	Maximum Level
Raw cereal grains (wheat, maize and barley)	Raw wheat, maize and barley after the removal of damaged kernels	2 mg/kg
Flour, semolina, meal, flakes (and possibly grits and starch) derived from wheat, maize or barley		1 mg/kg
Cereal-based foods for infants and young children	All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months)	0.5 mg/kg

Justification:

Costa Rica is a country with a diet in which high amounts of cereal-based commodities, such as wheat and maize, are consumed and this is a concern for the protection of public health. With regard to the ML for cereal-based foods intended for infants and young children, we agree to have a different value because of the vulnerability of this population.

EUROPEAN UNION

The European Union (EU) welcomes and appreciates the good work performed by the electronic Working Group under the lead of Canada on the document with proposed draft Maximum levels (MLs) for Deoxynivalenol (DON) in Cereals and Cereal-based Products and associated sampling plans.

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 after removal of damaged kernels. It is known that cleaning and sorting processes on raw cereal grains can significantly reduce the contamination level of DON in cereals. The description "after removal of damaged kernels" indicates that the maximum level applies to raw wheat, raw maize and raw barley after having undergone cleaning and sorting processes. If this is the case, the EU cannot agree with the proposed maximum level of 2 mg/kg for common wheat and barley and proposes a maximum level of 1.25 mg/kg for raw common wheat and raw barley.

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 does not contain or contains only a very low level of DON.

- 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 flour, semolina, meal, flakes (and possibly grits and starch). The EU questions the need to establish a maximum level of DON for these processed cereal products. For ochratoxin A, Codex maximum levels have only been established for raw wheat, barley and rye and not for the processed products thereof. Therefore in line with the CODEX approach as regards ochratoxin A in cereals and the fact that raw cereals are from an international trade point of view, most relevant, the EU proposes to limit the scope of maximum level setting also for DON to raw cereals.

- 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 continue to question 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 to the proposed maximum level as the level is too high. Experience in the EU has shown that significantly lower levels are achievable with reasonable effort. In the European Food Safety (EFSA) database on the occurrence of contaminants in feed and food, there are 622 data on the presence of DON in food for infants and young children. The 99 percentile of these data is 205 µg/kg, providing evidence that a possible maximum level of 0.2 mg/kg is achievable. 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 in Codex for these foods.

- Although the EU is of the opinion that an aggregate sample size of 10 kg is appropriate, the EU can agree on the proposed sampling provisions with the understanding that the EU is in favour of a sample size of 5 kg (table 1a in the proposed sampling plan).

GHANA

Comments 1: Ghana is of the view that separate limits should be set for raw cereals, semi-processed cereals and cereal-based foods intended for consumption by infants and children.

Rationale: In most developing countries, especially in Africa, the milling technology used does not necessarily result in the separation of the various kernel components, the process by which the mycotoxin levels are reduced substantially in milling fractions. Therefore it is important that an ML for raw cereal is set.

Comment 2: Ghana supports the proposed ML of 2 mg/kg in raw wheat (common and durum), maize and barley. However these cereals should be subject to sorting, to remove damaged kernels and other foreign materials after which the proposed ML for DON in raw cereals should be applied.

Rationale: Many African communities consume maize without further processing therefore a lower ML would be preferable to ensure adequate protection of human health, though not practically achievable; considering that from the GEMS/Food Consumption Cluster Diet Group 1, Ghana, South and East Africa consume 248g/day maize.

The data for DON submitted by the various electronic working group members indicates that the ML of 2 mg/kg for raw wheat, maize and barley would in general involve rejection of less than 10% of samples, except in years of high DON contamination.

Comment 3: We support the proposed single ML of 1 mg/kg for semi-processed products (flour, semolina, meal, grits, flakes and starch) derived from wheat, maize and barley for direct human consumption (other than infant food).

Rationale: Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) can reduce the DON levels as low as reasonably achievable. A single ML would be easier to implement for these category of products. There are certain terms used to describe processed grain products which are not universal. The same term may actually represent products processed differently in different parts of the world. A single ML for all specified semi-processed commodities would minimize potential confusion from different terminologies.

Comment 4: We do not support the proposed ML of 0.4mg/kg for cereal-based foods for infants and young children. We recommend an ML of 0.3mg/kg.

Rationale: Infants (up to 12months) and young children (12 to 23 months) are considered the most vulnerable sub-group to the critical chronic toxicological effect of DON exposure of reduced/retarded growth. A more stringent ML is therefore required because they have low body weights and their immune system is at the vulnerable developmental stage. These lower levels are achievable with GAPs and GMPs.

Comment 5: We propose that different sampling plan design should be used for the different raw cereals. We therefore support the proposed sample size for smaller grains (wheat and barley; 1.0kg) and sample size of 10 kg for maize.

Rationale: The sampling variance for shelled maize is larger than that of wheat and barley. Therefore the smaller the kernel size, the lower the sampling variability. Both wheat and barley have a larger number of kernels per unit mass (approx. 30,000 kernels/kg) than shelled maize (approx. 3000kernels/kg).

INDIA

We support to consider a single ML of 1 mg/kg for semi-processed foods derived from wheat, maize and/or barley and also favor to include 'grits' under the category of semi-processed foods. Hence, 'grits' should be mentioned in paragraph 5 table under commodities at ML of 1 mg/kg.

Rationale: All semi processed foods like flour, semolina, meal, grits and flakes undergo similar Milling techniques. Hence single level of ML should be applicable to all the products.

IRAN

Iran appreciates the electronic Working group under leadership of Canada and co-chaired by the European Union for preparing Proposed Draft Maximum Levels for deoxynivalenol (DON) in cereals and cereal-based products.

The e-WG considers MLs for individual semi-processed wheat, maize/corn and barley grain products and rice is not in the list of cereals.

There are some evidence about occurrence of DON in rice (Report TRS 906-JECFA 56/35, JECFA47, 2001, Pavlina Sobrova and etal. Deoxynivalenol and its toxicity, Interdiscip Toxicol. 2010 September; 3(3): 94–99).

The main contributor to DON in the diet in Europe is wheat (~80%), whereas in the Far East, rice is equally important.

Iranian delegations propose to include the ML of DON for rice and it's product too.

KENYA

GENERAL COMMENT:

Kenya would like to appreciate the work done by re-established electronic working group (e-WG), led by Canada and co-chaired by the European Union to consider MLs for individual semi-processed wheat, maize/corn and barley grain products, lower ML values for infant cereals than the one previously proposed, and the development of operational characteristic curves for the sampling plan.

We also take in consideration DON concentration required in wheat bran for exposure to reach the PMTDI of 1 µg/kg bw/day and the ARfD of 8 µg/kg bw/day and Calculations based on an average body weight of 60 kg.

COMMENTS:

Kenya supports the setting of the MRLs of Deoxynivalenol for the raw cereals and semi-processed products. By implementing GAP and GMP, countries will be able to achieve the levels of DON proposed in this document.

We therefore recommend that the Committee consider maintaining the proposed ML of 0.5 mg/kg for DON in cereal-based foods intended for infants and young children as this value remains protective of human health and is readily achievable as mentioned in the report of e-WG.

PHILIPPINES

Using 97.5 percentile consumption values to estimate acute risks of exposure to DON-contaminated maize in the Philippines, the risk to public health and safety for consumers is considered low. We agree with the current proposed MLs of 2mg/kg for raw cereal grains (maize) and 1 mg/kg for flour, semolina meal, flakes (and possibly grits and starch) derived from wheat, maize or barley as recommended by the Electronic Working Group.

REPUBLIC OF KOREA

General comments

The Republic of Korea supports the proposed draft maximum levels and sampling plans.

The Republic of Korea proposes that maximum level for cereal based infant formula may be altered from 0.5 mg/kg to 0.2 mg/kg.

Rationale: The monitoring data shows the contents of DON in cereal-based foods for infants and young children being under 0.2mg/kg and the monitoring data had been submitted last year by Republic of Korea.

RUSSIAN FEDERATION

We do not support the proposed maximum levels of DON in wheat and wheat semi-products, and consider setting the stricter regulations: 700 µg/kg of DON in wheat and major refined products (wheat, barley) and 1000 µg/kg in raw barley after damaged grains removal – as the most reasonable measure.

Also we do not support the proposed MLs of DON in cereal-based foods for infant and young children as 500 µg/kg and we suggest the more strict MLs of DON for cereal-based foods for infants and young children and believe that the most optimal value of DON MLs in baby food should be established at level 100 µg/kg.

Rational:

High consumption of bread and wheat-products (from 220 to 300 g/day), along with other grain products, including barley and corn, is one of the dietary habits of Russian population.

In this regard, it should be noted that the consumption of wheat products contaminated at the proposed ML (1000 µg/kg) will lead to the possible intake of DON exceeding the value of the PMTDI more than 3,7 - 5 times.

Taking into account the possible additional DON intake from other cereal products the total DON intake will be pretty close to the value of the acute reference dose (ARfD = 8 µg/kg pw/day), and will exceed the PMTDI of DON more than 4,4-6 times.

Thus, taking into account the high levels of bread wheat consumption in Russia, the value of PMTDI of DON, toxicological data and the actual levels of DON contamination of grain, ML of DON in wheat and major wheat based products in our country was established at 700 µg/kg.

Regarding the recommended MLs of DON in cereal-based foods for infant and young children as 500 µg/kg, we believe this amount is overrated. Taking into consideration traditionally high levels of baby foods consumption by children, particularly infants – 30 - 45 grams per day – the daily intake of DON may exceed by more than 3 times the value of PMTDI of DON (1 µg/kg pw/day). Thus, we suggest more strict MLs of DON for cereal-based foods for infants and young children and believe that the most optimal value of DON MLs in baby food should be established at level 100 µg/kg.

AFRICAN UNION

<p>African Union supports the setting of limits only for raw cereals, semi-processed cereals and cereal-based foods intended for consumption by infants and children</p> <p>African Union supports the proposed ML of 2 mg/kg in raw wheat (common and durum), maize and barley to be subject to sorting or other physical treatment before human consumption or before use as an ingredient in other foods.</p>	<p>A ML for raw cereal is required due to the fact that in many developing countries, especially in Africa, milling is not necessarily the sophisticated operation prevalent in developed countries but can frequently be performed in small-scale local operations, which do not entail separation of various kernel components, the process by which mycotoxin contamination is reduced in milling fractions intended for human consumption.</p> <p>The data provided by the working group indicate that this level can mostly be achieved by Good Agricultural Practice (except in certain years of high contamination levels). This level is commensurate with levels applied by various national agencies, especially major producer countries such as Canada and Argentina. Data provided by the electronic working group indicate that the ML of 2 mg/kg for raw wheat, maize and barley would in general involve rejection of less than 10% of samples, except in years of high DON contamination. However, many African communities consume maize without further processing. For this population, a lower limit would be desirable from a health protective view, but is not practically achievable. For example, WHO GEMS/Food Consumption Cluster Diet Group I (South and East Africa and Ghana) consume 248 g/day maize requiring a ML of 0.24 mg/kg to prevent the population exceeding the provisional maximum tolerable daily intake (PMTDI) for DON set by JECFA at 1 µg/kg body weight/day (Table 1 in CX/CF12/6/9).</p>
<p>African Union supports the ML of 1 mg/kg for semi-processed products (flour, semolina, meal, grits, flakes and starch) derived from wheat, maize and barley for direct human consumption (other than infant food).</p> <p>We also support the recommendation that no distinction be made between these semi-processed products as regards the setting of a ML.</p>	<p>The ML of 1 mg/kg for semi-processed foods is achievable because Good Manufacturing Practices (e.g. sorting and milling) can reduce contamination levels present in raw grains. The ML is consistent with levels currently enforced in a number of countries.</p> <p>A single ML for all these semi-processed products will be easier to administer, especially given the different terminology for these products employed by various stake holders.</p>

<p>African Union DOES NOT support the ML of 0.4 mg/kg proposed for cereal-based infant food. Instead we recommend an ML of 0.3 mg/kg. For infants and toddlers, greater protection is required than avoidance of a dose that might induce acute health symptoms (ARfD 8 µg/kg bw), rather protection should be aimed at chronic exposure by considering the PMTDI (1 µg/kg bw) instead.</p>	<p>A more stringent ML is required for infants because their body weight is low and immune system is at developmental stage. This level is achievable by Good Manufacturing Practices. Manufacturers in the EU meet a stricter ML of 0.2 mg/kg for processed cereal-based foods for infants and young children.</p> <p>Unpublished data from an African study indicate that at about 17 months (about 10 kg body weight), toddlers were consuming 80 g maize per day. At a contamination level of 0.4 mg/kg, this equates to an exposure of approximately 3.2 µg/kg bw/day, well below the ARfD, but still well above the PMTDI.</p> <p>Although contamination data on infant foods are limited, we suggest a limit lower than 0.4 mg/kg because of the above reason.</p>
<p>African Union supports the proposed sampling plan as regards the 10 kg sample size for maize, but a 1 kg sample size for wheat and barley.</p> <p>How to deal with analytical recovery and uncertainty should be made part of the decision rule for enforcement.</p>	<p>As discussed in paragraph 48, the larger kernel size of maize means a larger sample size is needed. However, for small grain cereals, this sample size can be reduced (and achieve the same uncertainties). The smaller sample sizes would be easier to handle in laboratories.</p> <p>Confusion over differing treatment of recoveries and of uncertainty in the accept / reject decision needs to be avoided.</p>

FOODDRINKEUROPE

Agreed:

- **CONCLUSIONS AND RECOMMENDATIONS**

§ 6, page 3 - We 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.

§ 6, page 3 –Agree that Milling of raw cereal grains can substantially reduce DON levels

- **Consideration of separate MLs for semi-processed foods from wheat, maize or barley**

§9, page 10 (previously §13). Agreed. The ML of 1 mg/kg for semi processed foods is not expected to result in trade barriers based on current data. **The proposed ML can be supported** as considered achievable based on current knowledge despite data remains still limited to date. Moreover, we support the implementation of GAP and GMP described in “Code of Practice for the Prevention and Reduction of Mycotoxin contamination in Cereals CAC/RCP 51-2003” to reduce Don levels as low as reasonably achievable.

- **Consideration of establishing an ML for bran from wheat or maize/corn**

§13, page 11, (previously §17) Due to the fact that the knowledge on DON occurrence in bran products remains limited at this time, we believe a global representation of consumption data for wheat and corn bran should be considered before developing an ML for DON.

- **Consideration of an ML lower than 0.5 mg/kg for DON in cereal-based foods intended for infants and young children**

§19, page 12 (previously §23): Agreed. Recommended ML for cereal-based foods intended for infants and young children of 0.5 mg/kg is in-line with FoodDrinkEurope comment.

Not Agreed/ Taken:

It should be made note that some areas of the world (such as the US and Canada) will struggle to meet requirements set out by this paper.

§2, Page 8 -No explicit mention of DON being water soluble was made. Since DON is water soluble, wet milling of corn will substantially reduce DON in starch used for food products. Furthermore, as with EU regulation (1126/2007) an exemption for unprocessed Maize used for starch production (wet milling) is appropriate.

- **Original studies conducted by Whitaker and colleagues, and Freese and colleagues for raw wheat, barley and shelled maize**

§28, page 14 (previously §33): The following was not noted in the new draft: Testing - the measure of testing cannot be HPLC based in the field, it has to be user friendly, and reproducible, nowadays the LF strip test and the ELISA kits are available, which are reasonably fast; we recognize that more work is needed in this field.