European Union comments for the

CODEX COMMITTEE ON CONTAMINANTS IN FOOD 9th Session

New Delhi, India, 16 – 20 March 2015

Agenda Item 9

Draft maximum levels for deoxynivalenol (DON) in cereal-based foods for infants and young children; in flour, meal, semolina and flakes derived from wheat, maize or barley; and in raw cereal grains (wheat, maize and barley) and including sampling plans for raw cereal grains (retained at Step 7)

(REP14/CF Appendix XII)

European Union Competence European Union Vote

The EU would like to provide the following comments:

The proposed ML for cereal based foods for infants and young children

The EU cannot agree to the proposed ML of 0.2 mg/kg for cereal based foods for infants and young children in case the ML applies to the commodity as consumed. A maximum level on the commodity as consumed would make the level for the traded products, such as powdered cereal based foods for infants and young children, very difficult as no precise instructions are provided for making these products ready for consumption. Furthermore a maximum level of 0.2 mg/kg for cereal based foods for infants and young children as consumed would result in a maximum level in the powdered cereal based foods for infants and young children higher than the proposed maximum level of 1 mg/kg for flour, semolina, meal and flakes derived from wheat, maize and barley. This is unacceptable as the group PMTDI for DON and its acetyl-derivatives is based on a no-observed-effect level for decreased body weight gain in a long term feeding study in mice. This endpoint is of particular relevance for infants, toddlers, children and adolescents, since they are in growing life stages. Exposure above the group PMTDI for these age groups is therefore of concern.

The EU is of therefore of the opinion that the ML of 0.2 ppm should apply to the commodity on a dry matter basis.

The proposed maximum level (ML) for raw cereal grains (wheat, maize and barley)

The EU can agree with the proposed maximum level of 2 mg/kg for deoxynivalenol (DON) in raw cereal grains (wheat, maize and barley), with the description that it relates to raw wheat, maize and barley grain prior to sorting and 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. Therefore, the EU is of the opinion that acceptance of a level for DON in 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.

The EU wishes further to indicate that 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 proposed ML for flour, semolina, meal and flakes derived from wheat, maize or barley

As regards the proposed maximum level of 1 mg/kg for flour, semolina, meal and flakes derived from wheat, maize or barley, the EU has consulted with their risk assessment body (European Food Safety Authority – EFSA).

EFSA has adopted on 28 November 2013 a "Statement on the risks for public health related to a possible increase of the maximum level of deoxynivalenol for certain semi-processed cereal products" ¹

The overall conclusion of the risk assessment is that "The exposure estimations in this statement indicate that the group Health Based Guidance Values (HBGVs) are already exceeded by the parent compound DON in a number of cases. An increase of the DON ML can be expected to be associated with an increase of the levels of DON and Ac-DONs in barley flour, wheat flour and semolina, and can therefore increase the exposure and consequently the exceedances of the group HBGVs."

Given this conclusion, the EU cannot agree on the proposed maximum level of 1 mg/kg for flour, semolina, meal and flakes derived from wheat, maize or barley.

The proposed sampling procedure

As regards the sampling procedure, the EU maintains its reservation with the proposed aggregate sample weight of 1 kg for raw wheat and barley. The EU is of the opinion that an aggregate sample weight of 10 kg is preferable, but can accept 5 kg. Also for raw maize, 10 kg sample size is preferable, but 5 kg is acceptable by way of compromise.

The EU proposes to consider an aggregate sample weight of 10 kg, which might be reduced to a laboratory sample of 1 kg by making use of a mechanical or automatic divider.

¹ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2013. Statement on the risks for public health related to a possible increase of the maximum level of deoxynivalenol for certain semi-processed cereal products. EFSA Journal 2013;11(12):3490, 56 pp. doi:10.2903/j.efsa.2013.3490 Available online: www.efsa.europa.eu/efsajournal