

CODEX COMMITTEE CONTAMINANTS IN FOOD

14th Session – 20 – 24 April 2020

European Union comments on

Codex Circular Letter CL 2019/81 OCS/CF :

Request for comments at Step 6 on the draft maximum level for cadmium in chocolates containing or declaring <30% total cocoa solids on a dry matter basis.

European Union Competence

European Union Vote

The European Union (EU) would like to reiterate its reservation against the proposed draft ML of 0.3 mg/kg for cadmium in chocolate containing or declaring <30% total cocoa solids on a dry matter basis. The EU cannot support the proposed maximum level (ML), as the EU argues for a stricter ML of 0.10 mg/kg to ensure sufficient protection of all consumers, in particular children.

The EU risk assessment shows that children at the mean dietary exposure could exceed the tolerable weekly intake (TWI) about 2-fold. The EU dietary exposure assessment clearly substantiates the need for strict cadmium ML in chocolate as for the group 'other children', 'chocolate (cocoa) products' contribute for 6.4% to the dietary cadmium exposure and it is the 3rd highest contributor after 'potatoes and potato products' (13.6%) and 'bread and rolls' (9.9%). In toddlers, 'chocolate (cocoa) products' contribute for 3.7% to the dietary Cd exposure. A summary of the EU risk assessment and exposure assessment on cadmium can be found below.

The EU would also like to comment on the fact that the Codex Alimentarius Commission stated that the concept of proportionality (with Codex MLs of 0.8 mg/kg for 50-70% chocolate and 0.9 for >70% chocolate) agreed by CCCF should be respected. The EU believes that applying the concept of proportionality is not justified because milk chocolate is consumed by children, while dark chocolate usually isn't. In order the adequately protect

children against the harmful effects from cadmium, an ML of 0,10 mg/kg would be appropriate for chocolate containing less than 30% of cocoa solids, even if this ML is not proportionate to the previously agreed MLs for dark chocolates.

Technical justification from the point of view of protecting consumers' health

A. The EFSA risk assessment on cadmium in food (EFSA, 2009a)

The risks to human health related to the presence of cadmium (Cd) in food were assessed by the CONTAM Panel in 2009 (EFSA, 2009a). The CONTAM Panel derived a Tolerable Weekly Intake (TWI) of 2.5 µg/kg body weight (bw) per week. The approach for the derivation of the TWI is detailed here below.

Data selection:

- EFSA performed a meta-analysis of human epidemiological studies selected through an extensive literature search (EFSA, 2009b). The literature search was aimed to identify published studies where urinary Cd levels were measured together with biomarkers of renal and/or bone effects.
- Out of more than 5000 abstracts, eventually 34 studies were selected where urinary levels of Beta-2-microglobulin (B2M) were measured as an early biomarker of kidney tubule damage.
- Since individual values were not available, summary statistics (geometric means of urinary Cd versus B2M levels) were considered, resulting in 165 data points covering about 30,000 individuals from the selected studies.

Dose-response analysis:

- Benchmark dose (BMD) analysis was performed for the whole population and for subject over 50 years of age, excluding subgroups exclusively composed of workers. Adjustment for ethnicity (Asian versus Caucasian) was included to account for differences in background B2M excretion levels.
- All analyses were performed considering a benchmark response (BMR) of 5%, related to an increase of urinary B2M levels over a cut-off of 300 µg B2M/g creatinine. Excretion levels above this cut-off are considered as adverse.
- The CONTAM Panel selected a rounded BMDL5 of 4 µg/g creatinine (i.e. a urinary Cd level) as reference point or point of departure for the risk assessment.

Adjustment for variability and TWI derivation:

- The BMDL of 4 µg/g creatinine was corrected considering the possible uncertainties, in particular in relation to the use of group means instead of individual values of urinary Cd levels in the dose-response analysis. This resulted in a chemical specific adjustment factor of 3.9, which was considered to cover 95% of the population variability.
- Adjustment of the BMDL5 by this factor led to an internal reference level of 1 µg/g creatinine for urinary Cd, that would indicate that 95% of the population would not exceed the cut-off level of 300 µg B2M/g creatinine.

- The TWI of 2.5 µg/kg bw per week was derived by applying a one-compartment toxicokinetic model, based on a cohort of 680 women who were randomly selected for urine sampling during 2004 – 2007 and in parallel assessed for food intake on three different occasions during the same period using a food frequency questionnaire.
- The toxicokinetic model indicated that a daily exposure lower than 0.36 µg/kg bw (corresponding to a weekly exposure of 2.52 µg/kg bw) would allow 95% of the population to remain below the internal reference level of 1 µg/g creatinine for urinary Cd.
- Therefore 2.5 µg/kg bw per week was selected as the TWI for Cd.

The CONTAM Panel concluded in 2009 that “the mean exposure for adults across Europe is close to, or slightly exceeding, the TWI of 2.5 µg/kg bw. Subgroups such as vegetarians, children, smokers and people living in highly contaminated areas may exceed the TWI by about 2-fold. Although the risk for adverse effects on kidney function at an individual level at dietary exposures across Europe is very low, the current exposure to Cd at the population level should be reduced” (EFSA 2009a).

B. Differences between the EFSA and JECFA assessment

In 2010, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) reviewed its previous assessment on Cd in food (FAO/WHO, 2010) and established a Provisional Tolerable Monthly Intake of 25 µg/kg bw, corresponding to a weekly intake of 5.28 µg/kg bw. The EFSA CONTAM Panel published a statement in 2011 summarising the main differences between the EFSA and JECFA assessments (EFSA, 2011) and concluded that the TWI of 2.5 µg/kg bw per week had to be maintained in order to ensure a high level of protection of consumers.

C. Update dietary exposure assessment (EFSA, 2012)

In 2012, EFSA updated its dietary exposure assessment by using a larger dataset on consumption data (the EFSA comprehensive food consumption database) and new occurrence data compared to the assessment in 2009. The highest dietary exposures were calculated for toddlers (1 - <3 years) and other children (3 - <10 years). For toddlers, the middle bound (MB) mean Cd exposure varied between 3.8 and 6.8 µg/kg bw per week and the MB 95th percentile exposure ranged from 5.3 to 10.1 µg/kg bw per week. For other children, the MB mean Cd exposure varied between 3.1 and 5.0 µg/kg bw per week and the MB 95th percentile exposure ranged from 4.6 to 10.2 µg/kg bw per week. In other children, ‘chocolate (cocoa) products’ contributed for 6.4% to the dietary Cd exposure and was the 3rd highest contributor after ‘potatoes and potato products’ (13.6%) and ‘bread and rolls’ (9.9%); 2 food groups for which the contribution was driven by the high consumption. In toddlers, ‘chocolate (cocoa) products’ contributed for 3.7% to the dietary Cd exposure. Adolescents had a lower dietary exposure to Cd compared to toddlers and other children, but ‘chocolate (cocoa) products’ was still an important contributor (5.9%). In addition, it was noted that there were differences between countries regarding the contribution of ‘chocolate (cocoa) products’, showing that in some countries (like the Netherlands and Belgium) the contribution was substantially higher.

This dietary exposure assessment confirmed that children at the mean and 95th percentile dietary exposure could exceed the TWI. In general, the adult age groups had a lower exposure, but the 95th percentile dietary exposures are close to or above the TWI (EFSA, 2012).

D. References

EFSA (European Food Safety Authority), 2009a. Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on cadmium in food. *The EFSA Journal*, 980, 1-139.

EFSA (European Food Safety Authority), 2009b. Technical report of EFSA prepared by the Assessment Methodology Unit on Meta-analysis of dose-effect relationship of cadmium for benchmark dose evaluation. *EFSA Scientific Report*, 254, 2-62.

EFSA (European Food Safety Authority), 2011a. Statement on tolerable weekly intake for cadmium. *The EFSA Journal*, 9(2):1975, [19pp.].

EFSA (European Food Safety Authority), 2012. Cadmium dietary exposure in the European population. *EFSA Journal* 2012;10(1):2551. [37 pp.]

FAO/WHO (Food and Agriculture Organization/World Health Organization), 2010. Joint FAO/WHO Expert Committee on Food Additives. Seventy-third meeting, Geneva, 8–17 June 2010. Summary and Conclusions. Issued 24 June 2010.