

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
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Agenda Item 5

CX/CF 20/14/5-Add.1

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

14<sup>th</sup> Session

### DRAFT ML FOR CADMIUM FOR CHOCOLATES CONTAINING OR DECLARING, <30% TOTAL COCOA SOLIDS ON A DRY MATTER BASIS

#### Comments at Step 6 (Replies to CL 2019/81-CF)

*Comments of Australia, Canada, Colombia, European Union (EU), Kazakhstan, Morocco,  
Saint Kitts and Nevis, Switzerland, United States of America (USA),  
European Cocoa Association and Food Industry Asia*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/81-CF. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

#### Explanatory notes on the appendix

2. The comments submitted through the OCS are contained in the **Annex** and presented in table format.

**Comments on the draft Maximum Level for cadmium for chocolates containing or declaring, <30% total cocoa solids on a dry matter basis**

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Protecting consumers' health</p> <p>JECFA has concluded that Cd exposure due to consumption of cocoa and cocoa-derived products is not considered a concern. The tables provided in Agenda Item 6, which show %PTMI to be very low for the worldwide scenarios, tend to support JECFA's conclusions. Australia suggests further evaluation by JECFA for cadmium exposure is not needed and would further delay the establishment of MLs.</p> <p>Fair practice in trade</p> <p>Australia notes member comments made at CAC41 that proposed MLs were restrictive and could have negative socioeconomic implications for cocoa growers, especially smallholder farmers.</p> <p>Australia holds the view that MLs should be derived based on practical achievability (ALARA principle) and that the adoption of new MLs should not negatively impact trade.</p> <p>Proportionality concept for deriving MLs</p> <p>Australia notes that:</p> <ul style="list-style-type: none"> <li>• There was general agreement to consider the MLs on a proportional basis to the existing MLs (adopted at CAC41) while recognising the need for some flexibility in the proportionality between the MLs for the different categories, to avoid very high rejection rates.</li> <li>• For chocolates with ≥30% to &lt;50% TCS, the CCCF chair proposed an ML on a proportional basis of 0.5 mg/kg (rather than what was proposed by the eWG – 0.9 mg/kg). An ML of 0.5 mg/kg would generate a rejection rate of over 20% for LAC and worldwide samples. Australian response:</li> <li>• On the basis of the above, Australia supports the proportionality concept where practical achievability could be demonstrated and where rejection rates would not be unacceptably high.</li> <li>• In addition, Australia notes that, for chocolates with &lt;50% total cocoa solids, CCCF12 agreed to assess if it would be feasible to merge the two remaining chocolate categories to derive one ML. This does not appear to have been done; the CCCF agenda paper included separate analyses for the two categories. We would be interested in the impact of merging these two datasets on deriving an ML for Cd that might be more acceptable on a proportional basis to existing MLs for chocolates with higher levels of cocoa solids, whilst still being practically achievable. The expectation is that chocolate with lower percentages of total cocoa solids should also have lower levels of Cd (and thus lower MLs).</li> <li>• When considering the proportionality concept across different food categories, e.g. chocolate versus cocoa powder, it is also helpful to remember that these products are consumed in different ways. As a concentrated source of cocoa solids, cocoa powder is likely to be diluted in water/milk or added as an ingredient in recipes in small amounts, rather than eaten as is. The proportionality concept may not be as applicable in this situation.</li> </ul> <p>Conclusion</p> <p>JECFA has concluded that Cd exposure due to consumption of cocoa and cocoa-derived products is not considered a concern. Therefore, proposed MLs should be based on practical achievability i.e. ALARA, for facilitation of trade and not on the basis of public health and safety concerns. The proportionality concept should be sufficiently flexible to ensure that high rejection rates are avoided and that there are no negative impacts on trade.</p> <p>Australia notes that the proposed ML of 0.3 mg/kg for Cd in chocolates containing or declaring &lt;30% total cocoa solids, would result in a 12.7% rejection level for both LAC and worldwide - this would be inconsistent with the generally accepted 5% rejection threshold applied by Codex.</p> <p>New call for data to evaluate ML</p> <p>Australia is hopeful that additional data will help in deriving an appropriate ML for chocolate with &lt;30% total cocoa solids, which also helps resolve incongruences observed between the proposed MLs for the different categories of chocolate. Unfortunately, the Australian industry has indicated that it's unlikely they have any relevant, new analytical data.</p>	<p><b>Australia</b></p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>We trust that this information is useful and we wish you all the best in your further consideration of this issue.</p> <p>At CCCF13 (2019), maximum levels (ML) of 0.3 mg/kg or 0.4 mg/kg for cadmium in chocolates containing or declaring &lt; 30% total cocoa solids on a dry matter basis were proposed for discussion. CCCF13 agreed to advance the ML of 0.3 mg/kg for adoption at Step 5/8 by the Codex Alimentarius Commission (CAC). It was acknowledged that the ML would result in a relatively low rejection rate on a worldwide basis (3.2%) but a higher rejection rate for products originating from Latin American and Caribbean regions (12%).</p> <p>The available dataset for this category was noted by CCCF13 to include a suitable number of samples from all geographic regions. Both of the MLs proposed for discussion at CCCF13, 0.3 mg/kg and 0.4 mg/kg, reflect the proportional decrease in cadmium concentration in chocolates of lower cocoa solid content as compared to the MLs already established for chocolates with greater cocoa solid contents. Given that the JECFA did not identify any health concerns associated with dietary cadmium exposure from chocolate or other foods, and that the discussion document supporting this work (CX/CF 19/13/6) demonstrated a negligible difference in cadmium exposure between the two proposed ML values, a higher ML of 0.4 mg/kg for cadmium in chocolates containing or declaring &lt; 30% total cocoa solids could be reconsidered. This higher ML may better facilitate trade as it would result in a 1.4% worldwide rejection rate and 4.7% rejection rate for chocolate products containing &lt; 30% cocoa solids from Latin American and the Caribbean regions.</p> <p>Canada has submitted additional data on cadmium in chocolates, including those containing or declaring &lt; 30% total cocoa solids, in response to the JECFA Call for Data (deadline 10 November 2019) for consideration by CCCF14 (2020).</p> <p>Canadian data indicate that ML values of both 0.3 mg/kg and 0.4 mg/kg cadmium in chocolates containing &lt; 30% total cocoa solids are readily achievable for products with similar cocoa solid content that are sold in Canada.</p>	<p><b>Canada</b></p>
<p>Colombia supports the proposal for a maximum limit of 0.3 mg/kg for cadmium in chocolates containing or declaring &lt; 30% total cocoa solids on a solid matter basis.</p> <p>Considering the results of cadmium evaluations JECFA73 and JECFA77, the concept of proportionality between ML values for the different categories of chocolate and cocoa derivatives agreed at CCCF13, the continuing discussions and the decisions made on this ML in CCCF13 (2019) and CAC42 (2019), as well as the percentages of cadmium found in Colombian chocolates, Colombia supports the level of 0.3 mg/kg. In view of our national production of this product category, Colombia believes reducing this level further could prove restrictive for our national production. It is worth pointing out that, based on our national consumption according to the Colombian National Nutrition Survey (Encuesta Nacional de Situación Nutricional - ENSIN), which includes a quantification of national consumption, cadmium in chocolate products does not represent a significant portion of total tolerable intake. This is in line with the JECFA evaluation.</p>	<p><b>Colombia</b></p>
<p>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 &lt;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.</p> <p>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.</p> <p>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 &gt;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 to 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.</p> <p>Technical justification from the point of view of protecting consumers' health</p> <p>A. The EFSA risk assessment on cadmium in food (EFSA, 2009a)</p>	<p><b>European Union</b></p>

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<p>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.</p> <p>Data selection:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul> <p>Dose-response analysis:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul> <p>Adjustment for variability and TWI derivation:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• Therefore 2.5 µg/kg bw per week was selected as the TWI for Cd.</li> <li>• 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).</li> </ul> <p>B. Differences between the EFSA and JECFA assessment</p> <p>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.</p> <p>C. Update dietary exposure assessment (EFSA, 2012)</p>	

GENERAL COMMENTS	MEMBER/OBSERVER
<p>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 - &lt;3 years) and other children (3 - &lt;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).</p> <p>D. References</p> <p>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.</p> <p>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.</p> <p>EFSA (European Food Safety Authority), 2011a. Statement on tolerable weekly intake for cadmium. The EFSA Journal, 9(2):1975, [19pp.].</p> <p>EFSA (European Food Safety Authority), 2012. Cadmium dietary exposure in the European population. EFSA Journal 2012;10(1):2551. [37 pp.]</p> <p>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.</p>	
Kazakhstan supports proposed ML for cadmium in chocolates containing or declaring <30% total cocoa solid on a dry matter basis.	<b>Kazakhstan</b>
Morocco is not in favour of setting a maximum limit of 0.3 mg/kg, because the exporter countries Cameroon, Côte d'Ivoire, Ghana and Nigeria, which account for 75% of world cocoa production, are able to supply cocoa with a limit of less than 0.3 mg/kg, which protects consumer health better.	<b>Morocco</b>
Would this include unprocessed chocolates?	<b>Saint Kitts and Nevis</b>
<p>Switzerland's comments to CL 2019/81 OCS/CF</p> <p>Switzerland would like to express its reservation against the proposed draft ML of 0.3 mg/kg for cadmium in chocolate containing or declaring &lt; 30 % total cocoa solids on a dry matter basis as Switzerland will set a lower ML of 0.1 mg/kg for this category in order to protect consumers, especially children.</p> <p>The risk assessment for Swiss consumers is based on the EFSA risk assessment in cadmium in food (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 209, 980, 1-139) and its update (Cadmium dietary exposure in the European population. EFSA Journal 2012; 10(1):2551). These evaluations indicated that especially for toddlers and children chocolate and cocoa products are an important contributor to the cadmium exposure, especially for Countries with a high consumption.</p>	<b>Switzerland</b>
<p>The United States (U.S.) appreciates the opportunity to provide comments at Step 6 on the draft maximum level (ML) of 0.3 mg/kg for chocolates containing or declaring &lt; 30% total cocoa solids on a dry matter basis (CL 2019/81/OCS-CF, APPENDIX).</p> <p>The U.S. supports the draft ML of 0.3 mg/kg for chocolates containing or declaring &lt; 30% total cocoa solids on a dry matter basis for the following reasons:</p> <ul style="list-style-type: none"> <li>The draft ML is based on the proportionality of cocoa solids, agreed to by CCCF, in relation to the MLs of 0.8 mg/kg and 0.9 mg/kg for chocolates containing or declaring ≥ 50% to &lt; 70% and ≥ 70% total cocoa solids on a dry matter basis, respectively, that were adopted by the 41st Session of the Codex Alimentarius Commission (CAC41, 2018).</li> </ul>	<b>USA</b>

GENERAL COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li>• The draft ML is based on data with good geographical distribution obtained from several rounds of data calls, with a relatively low rejection rate on a worldwide basis.</li> <li>• Although the draft ML would result in a higher rejection rate for some Latin American and Caribbean countries, it represents a compromise.</li> <li>• As noted by the FAO representative at CAC42 (2019), the draft ML does not pose a food safety concern based on the JECFA77 (2013) review, which also concluded that cadmium intake from consumption of chocolate and cocoa-derived products was insignificant compared to other sources of dietary exposure to cadmium.</li> </ul> <p>The U.S. also agrees with CAC42 conclusion that if there is no new additional information to justify a change to the draft ML, CCCF14 (2020) will recommend the adoption of the draft ML of 0.3 mg/kg by CAC43 (2020). In the absence of food safety concerns related to the draft ML of 0.3 mg/kg, the U.S. considers the draft ML to be an appropriate compromise.</p>	
<p>The European Cocoa Association (ECA) would like to thank the chairs and members of the electronic Working Group on Maximum Levels for Cadmium in Chocolate and Cocoa Derived Products for their work.</p> <p>ECA agrees with the suggested Maximum level for Cadmium in chocolates containing or declaring &lt;30% total cocoa solids on a dry matter basis at 0.3 mg/kg and has no further comments at this stage.</p>	<b>European Cocoa Association</b>
<p>FIA continues to support the recommended ML of 0.3 mg/kg for Chocolates containing or declaring &lt;30% total cocoa solids on a dry matter basis.</p>	<b>Food Industry Asia</b>