

# CODEX ALIMENTARIUS COMMISSION



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Agenda Items 5 and 6

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**CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

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**MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES AND CERTAIN COCOA-DERIVED PRODUCTS**

**Comments in reply to CL 2020/50/OCS-CF:**

**Request for comments on MLs for chocolates and certain cocoa-derived products**

Australia, Canada, Brazil, Chile, Colombia, Cuba, Ecuador, Egypt, El Salvador, European Union (EU),

Malaysia, Peru, Uganda, United States of America (USA),

European Cocoa Association (ECA) and the International Cocoa Association (ICA)

## GENERAL AND SPECIFIC COMMENTS

Member / Observer	Comments
Australia	<p>Australia is grateful for the opportunity to provide comments on this circular letter, proposing an approach to the consideration of MLs for cadmium for: (i) chocolate containing or declaring &lt;30% total cocoa solids on a dry matter basis; (ii) chocolate containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis; and (iii) cocoa powder with 100% total cocoa solids on a dry matter basis.</p> <p><b>General</b></p> <p>Australia notes that JECFA77 (2013) concluded that cadmium exposure including for high consumers of cocoa and cocoa products is not a public health and safety concern and these products are not major contributors to total dietary exposure to cadmium. Therefore, Australia maintains the view that 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 for establishing MLs for different categories of chocolate should be sufficiently flexible to ensure that high rejection rates are avoided and that there are no negative impacts on trade.</p> <p><b>ML for chocolate containing or declaring &lt;30% total cocoa solids on a dry matter basis</b></p> <p>Australia has not previously expressed any reservations and continues to support the ML of 0.3 mg/kg on the basis of the following considerations:</p> <ul style="list-style-type: none"> <li>• CCCF13 agreed on the draft ML. It was established in line with the proportionality concept, with 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, adopted by CAC41 (2018).</li> <li>• With the exception of Latin America and the Caribbean (LAC), the rejection rate is below the 5% threshold for all regions and on a worldwide basis (3.2%); the higher rejection rate for LAC (12%) is a reasonable global compromise.</li> <li>• Whilst there are regions which may achieve lower levels of cadmium in cocoa due to the nature of their soils and production methods, the draft ML will ensure a balance between globally acceptable safe levels whilst still promoting fair trade and helping to prevent competitive advantages.</li> <li>• The draft ML corresponds to an estimated cadmium intake of 0.6% of the PTMI (see CX/CF 19/13/6 – Agenda Item 6, CCCF13 (2019)).</li> <li>• The draft ML was adopted at CAC42 (2019) at Step 5, where it was determined that if new additional information provided did not justify a change to the ML, CCCF14 would recommend the adoption of the ML of 0.3 mg/kg by CAC at its next session. Upon such recommendation by CCCF14, CAC43 would adopt the ML without further discussion. As previously noted, the Australian industry has indicated it is unlikely to have additional analytical data to help refine the ML.</li> </ul> <p><b>MLs for chocolate containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and for cocoa powder with 100% total cocoa solids on a dry matter basis</b></p> <p>Australia notes proposed MLs of 0.6-0.7 mg/kg for chocolate containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis, whereby an ML of 0.6 mg/kg would see 12.6% of worldwide samples rejected (15.8% LAC samples rejected); an ML of 0.7 mg/kg would see 6.8% of worldwide samples rejected (8.9% LAC samples rejected). Even with an ML of 0.7 mg/kg, which is at the higher end of the range, the 5% threshold of rejection is exceeded.</p> <p>For cocoa powder with 100% total cocoa solids on a dry matter basis, Australia notes proposed MLs of 2.0-3.0 mg/kg, whereby a proposed ML of 2.0 mg/kg would see 5.5% of worldwide samples rejected (17.8% of LAC samples rejected); the proposed ML of 3.0 mg/kg would see 3.65% of worldwide samples rejected (12.2% of LAC samples rejected). The regions of Europe, Africa, Asia and NASWP would have 0% rejections. Australia is of the view that the dataset (n=4245) is adequate for establishing MLs for this category.</p> <p>Australia has previously advised that for both chocolates with ≥30% to &lt;50% total cocoa solids, and cocoa powder, 100% cocoa solids, we would support MLs at the higher end of the proposed ranges, as these would be valid from a proportionality perspective, as well as still being a reasonable global compromise from the perspective of practical achievability. At the proposed MLs, worldwide exposures have been calculated to be approximately 3% of the PTMI and 2% of the PTMI, respectively (see CX/CF 20/14/6 – Agenda Item 6 (CCCF14, 2020)).</p>

### **Preliminary evaluation undertaken by JECFA**

Australia notes that a preliminary evaluation undertaken by JECFA (CX/CF 20/14/3-Add.1 July 2020 – Agenda Item 3 (CCCF14, 2021)) indicates that new submitted data suggests that the consumption of cocoa products might contribute more to total cadmium exposure than the data available to JECFA77 indicated. In light of the new data, the JECFA Secretariat intends to update the dietary exposure assessment of cadmium from all food sources, available 2021. Australia has reviewed the preliminary analysis and has the following comments:

#### **Generally**

Australia is confident in the dataset that has been used to estimate MLs for the various categories of chocolate and cocoa powder. As is the case for any Codex ML, we are supportive of efforts to collect additional occurrence data where that data reflects contemporary agricultural, production and trade practices. Such data may assist in achieving a better estimate of cadmium in products that are currently traded to inform the refinement of MLs based on globally accepted safe levels and practical achievability.

It is important to note that in response to a request for a new evaluation by JECFA as one alternative to the establishment of MLs (at CCCF13 (2019)), the JECFA Secretariat advised that they were unaware of sufficient new data regarding the toxicological effects to warrant a new risk assessment for cadmium. The results of such an assessment was unlikely to help CCCF in its decision-making progress any more than the existing JECFA risk assessment had helped CCCF to come to a consensus to date.

In noting the above, Australia questions the overall value of suspending work to await the results of an updated dietary exposure assessment by JECFA for all foods, as it is unlikely to change our current understanding of cocoa and cocoa products' contribution to cadmium exposure through the diet. Specifically, it is reasonable to assume that the consumption of these products remains relatively constant over time and their contribution to overall exposure will remain relatively minor. This is supported by the eWG's calculations using the contemporary dataset also used by JECFA to do its preliminary evaluation that, based on the draft MLs, exposures might be in the range of approximately 3% of the PTMI (see CX/CF 20/14/6 – Agenda Item 6 (CCCF14, 2020)).

In addition, it has already been established that MLs for cadmium present in cocoa and cocoa products 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 establishment of MLs are unlikely to serve an important role from a public health perspective and, as such, the outcomes of an updated dietary exposure assessment may be of limited use to the eWG's deliberations.

#### **Other general comments**

- Consideration needs to be given to the age of the data that has been submitted as a result of the recent calls for data, used in the preliminary evaluation. It cannot simply be assumed that because the data has only now been submitted, that it is contemporary and, as such, representative of the current global situation. Further, it is important to bear in mind that, with the finalisation and implementation of a Codex Code of Practice, cadmium concentrations in cocoa are likely to decrease over time.
- Australia notes the JECFA Secretariat's intention to update the dietary exposure assessment for cadmium appears to be a shift from the position taken at CCCF13. Australia is interested to understand how and on what basis this decision was made without the opportunity for CCCF to discuss it more fully, particularly in the context of other higher priority work and available resources.

#### **Cocoa powder**

The paper states that a comparative analysis shows that the mean cadmium concentration for cocoa powder has increased (560 µg/kg vs 130 µg/kg). The paper suggests that this might be because the highest observed concentrations in the latest submission were from the Codex regions of LAC, ASIA and NASWP, for which no data were available at the time of the evaluation made by JECFA77. However, it is important to note that the reliability of the cocoa powder data, both in terms of the original dataset and the latest submission, may be influenced by the level of detail that has been provided regarding the proportion of total cocoa solids and the intended use of the cocoa powder (i.e. whether or not the cocoa is 'ready for consumption').

#### **Cocoa beverage**

The mean and P97.5 or P95 concentrations for cocoa beverage appear to have decreased, not increased, calling into question the suggestion that the additional data indicate a higher mean occurrence concentration for cadmium in cocoa products than previously observed by JECFA, and therefore the need for an updated exposure assessment. In addition, Australia questions the relevance of providing data for this category given that MLs for cocoa beverage are not being considered.

	<p><b>Other cocoa products</b></p> <p>Australia notes that 2020 data on other cocoa products (including chocolate) has not been provided and, as such, it is not possible to comment on the direction and size of any changes to the mean cadmium content of chocolate (particularly chocolate with &lt;30% total cocoa solids on a dry matter basis) as a result of the submission of new data and the potential impact of any changes on estimated exposures.</p> <p><b><u>Australian position</u></b></p> <p>Overall, Australia considers there are adequate data to advance the development of these MLs and encourages a more practical and agile approach to reaching resolution on these matters, which does not involve delaying a decision based on the generation of additional data or a complete re-evaluation by JECFA – neither of these actions are guaranteed to bring about any greater clarity.</p> <p><b><i>Chocolate containing or declaring &lt;30% total cocoa solids on a dry matter basis</i></b></p> <p>Australia proposes that the ML of 0.3 mg/kg be considered at Step 7 at CCCF14, as recommended at CAC42, and that it not await the outcome of the JECFA evaluation on cadmium. This aligns with CCCF13 agreement to advance the ML for adoption at step 5/8 by CAC42, and CAC42's subsequent recommendations.</p> <p><b><i>Chocolate containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis</i></b></p> <p>Australia does not object to the proposal that the consideration of MLs for the above two categories be suspended awaiting the outcome of the JECFA evaluation. This option is preferable to discontinuing work on these categories of chocolate altogether. However, as detailed above, Australia questions the overall value of suspending this work pending an updated dietary exposure assessment.</p> <p>We trust that this information is useful and we wish you all the best in your further consideration of this issue.</p>
Canada	<p><b>Analysis of the data submitted in response to the 2019 call for data on cadmium in chocolate and cocoa powder (CX/CF 20/14/3-Add.1 July 2020)</b></p> <p>This analysis indicates a wider global distribution of concentrations of cadmium in cocoa powder compared to those employed in the JECFA77 (2013) total dietary exposure assessment for cadmium.</p> <p><b>Updating the total dietary exposure assessment for cadmium</b></p> <p>Considering the new data submitted in response to the 2019 call for data, the JECFA Secretariat considers it important to update the dietary exposure assessment of cadmium from all food sources. The JECFA Secretariat has issued a call for data for cadmium in all foods (closes December 1, 2020) and has included the updated total dietary exposure assessment for cadmium in the agenda of the 91st meeting of JECFA scheduled for early 2021.</p> <p>Canada is of the opinion that the need for an updated dietary exposure assessment for cadmium requires further discussion. JECFA77 demonstrated that chocolate and cocoa powder contribute minimally to dietary cadmium exposure and the provisional tolerable monthly intake (pTMI) for cadmium. Further, the maximum levels (MLs) for cadmium in chocolates and cocoa powder are being established for the purpose of trade harmonization. As it is unlikely that the consumption patterns of chocolate have changed notably since the JECFA77 (2013) assessment, estimates of the relative change in cadmium concentrations could therefore potentially be used to estimate any relative changes in exposure and the contribution of these products to the pTMI of cadmium. Finally, any updated dietary exposure assessment aimed at accurately characterizing exposure to cadmium from chocolate and cocoa products should consider the specific consumption rates of products of different cocoa solid contents by different age groups. Canada questions if the consumption data in the GEMS database would allow for this type of precision in an updated exposure assessment.</p> <p>Based on the above, Canada respectfully requests that the 14th meeting of the Codex Committed on Contaminants in Food (CCCF14) (2021) be given an opportunity to: discuss the data submitted in response to the 2019 call for data; make recommendations concerning the timing, terms, and scope of an updated JECFA assessment for cadmium; discuss the impact of the top priorities that were identified for future evaluation by JECFA at CCCF13; and ultimately determine if an updated total dietary exposure assessment for cadmium is required in order to move forward with finalizing (MLs) for the final category of chocolates (≥30% to &lt;50% cocoa solids) and cocoa powder (100% cocoa solids).</p> <p>If a total dietary exposure assessment for cadmium in all foods is conducted by JECFA, Canada suggests that the call for data be extended past December 1, 2020 to allow for the most fulsome dataset as possible to be submitted. In light of the global pandemic and the impact it has had on regulatory authorities, allowing more time for data collection, as well as preparing and uploading large datasets to the GEMS database, is recommended. Canada notes that there are also other concurrent calls for data in support of agenda items that are under consideration by CCCF14.</p>

	<p><b>Suspending the MLs for chocolates containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis at Step 4 awaiting the outcome of the JECFA assessment on cadmium</b></p> <p>As noted above, Canada is of the opinion that CCCF14 (2021) should be given the opportunity to discuss the data submitted in response to the 2019 call for data for cadmium in chocolate and cocoa products and consider if an updated JECFA assessment is required in order to move forward with finalizing the MLs for chocolates containing or declaring ≥30% to &lt;50% cocoa solids and cocoa powder with 100% cocoa solids. Depending on the outcomes of the discussions on these two matters, CCCF14 could then decide if work on these two MLs should be suspended or continue.</p> <p><b>Retaining the ML of 0.3 mg/kg for chocolates containing or declaring &lt;30% cocoa solids on a dry matter basis at Step 7 awaiting the outcome of the JECFA evaluation on cadmium</b></p> <p>Canada notes that the JECFA Secretariat's summary of the data submitted in response to the 2019 call for data on cadmium in chocolate and cocoa powder (CX/CF 20/14/3 Add.1, July 2020) does not present data for chocolates containing &lt;30% cocoa solids. CAC42 advanced this ML for comments and consideration by CCCF14 (2021) at Step 7, on the understanding that unless new additional information is provided justifying a change to the ML, CCCF14 (2021) will recommend the adoption of the ML of 0.3 mg/kg by CAC. In the absence of new information, Canada sees no reason why CCCF14 would not consider recommending this ML for adoption and according to the process laid out by CAC42.</p> <p>Canada agrees with maintaining the concept of proportionality between the MLs for chocolates with different cocoa solid contents. Proportionality is supported by the proposed value of 0.3 mg/kg for chocolates containing or declaring &lt;30% cocoa solids relative to the MLs already established in the General Standard for Contaminants and Toxins in Food and Feed (GSTCFF) for two categories chocolate with higher cocoa solid contents (≥50 to &lt;70% and ≥70%).</p> <p><b>Review of established Codex Standards</b></p> <p>Canada notes that determining if a structured approach is needed in order to update existing Codex standards developed by the CCCF is currently the subject of a discussion paper. Canada is chair of this electronic working group and anticipates that a process for such reviews will be proposed by CCCF14 (2021). This process could therefore be applied to future updates of any established MLs for cadmium in chocolate or cocoa products, such as that for chocolates containing or declaring &lt;30% cocoa solids on a dry matter basis if this ML is recommended for adoption.</p>
<b>Brazil</b>	<p>Brazil considers that it is important to develop ML for these food categories, especially cocoa powder with 100% total cocoa solids on a dry matter basis. Considering the MLs established for chocolate with high cocoa content, Brazil is in favor to establish the following MLs: 0,3 mg/kg for chocolate with less than 30% cocoa solids; 0,5 mg/kg for chocolate containing between 30 and 50% cocoa solids and 1,3mg/kg for cocoa powder (100%).</p>
<b>Chile</b>	<p>Chile appreciates the opportunity to provide comments on the work in relation to maximum limits for cadmium in certain categories of chocolate and cocoa-derived products.</p> <p>Chile has reviewed the recommendations made in this circular letter and its comments are as follows:</p> <ul style="list-style-type: none"> <li>• Chile supports retaining the maximum level (ML) of 0.3 mg/kg for chocolate containing or declaring &lt;30% total cocoa solids on a dry matter basis at Step 7, and supports the continuation of work on the proposed maximum level for chocolate containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis. The justification for this is the need to ensure consumer protection across the full range of chocolate products available on the market according to cocoa content, taking into account that there are already maximum levels for chocolate containing ≥50% total cocoa solids on a dry matter basis, and that the pending levels maintain the proportionality approach already used for the maximum levels adopted at CAC41-2018 for chocolate with a higher total cocoa solids content. If the new JECFA evaluation ultimately indicates that chocolate can be a major source of cadmium exposure in consumers, the levels would need to be reviewed in due course. To address this potential risk, Chile considers that the best way to protect consumers would be to adopt a maximum level instead of suspending work awaiting the outcome of a new assessment.</li> <li>• Chile agrees to suspending the consideration of the maximum level for cocoa powder with 100% total cocoa solids on a dry matter basis, pending the outcome of the JECFA evaluation on cadmium. The justification for this is that Chile would support a maximum level close to the maximum levels already established for chocolates adopted at CAC41-2018, while maintaining the proportionality approach. With this in mind, Chile deems it prudent to suspend the work for this particular matrix.</li> </ul>
<b>Colombia</b>	<p><b>9.1 ML for chocolate containing or declaring &lt;30% total cocoa solids on a dry matter basis: for consideration at CCCF14 at Step 7</b></p>

	<ul style="list-style-type: none"> <li>Advance and adopt the ML of 0.3 mg/kg for chocolate containing or declaring &lt;30 % total cocoa solids on a dry matter basis at Step 7.</li> </ul> <p><b>9.2 ML for the remaining categories of chocolate and cocoa-derived products: for consideration by the Electronic Working Group (EWG) and at CCCF14 at Step 4</b></p> <ul style="list-style-type: none"> <li>Continue the review and discussion process in the scenarios proposed by the Codex of the evaluation documents for MLs for chocolate containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis, and provide new information on cadmium in cocoa for these categories with a view to reviewing the outcome of the JECFA evaluation on cadmium.</li> </ul>
<b>Cuba</b>	Cuba appreciates the opportunity to provide comments and supports the retention of the ML of 0.3 mg/kg for chocolate containing or declaring <30% total cocoa solids on a dry matter basis at Step 7, pending the outcome of the JECFA evaluation on cadmium.
<b>Ecuador</b>	<p>Ecuador thanks the Codex Secretariat for the opportunity to submit its comments on Circular Letter CL 2020/50/OCS-CF.</p> <p>Given the statement made by JECFA (REP19/CF, paragraph 48): 'In response to one of the alternative options to the establishment of MLs presented by the EWG, which was to request a new evaluation by JECFA, the JECFA Secretariat clarified that while it stood ready to serve CCCF's need for scientific advice, it was not aware of sufficient new data regarding the toxicological effects to warrant a new risk assessment for cadmium. The results of such an assessment was unlikely to help CCCF in its decision-making progress any more than the existing JECFA risk assessment had helped CCCF to come to a consensus to date', we would like to raise the following concerns:</p> <ul style="list-style-type: none"> <li>Does JECFA require a mandate from the CCCF Priority Group to initiate a new evaluation?</li> <li>Does JECFA have the power to initiate a new evaluation on cadmium without a request from the respective committee?</li> </ul> <p>If JECFA has the power to initiate a new evaluation:</p> <ul style="list-style-type: none"> <li>When will this evaluation be carried out?</li> <li>When will the report and conclusions of this report be available to the Member States?</li> </ul> <p>In accordance with the Procedural Manual and the current mandate granted by the CCCF to the EWG chaired by Ecuador, we believe it is important for work to continue within the Codex Committee on Contaminants in Food (CCCF), whilst work is also carried out in parallel on the Risk Assessment to be performed by JECFA. Our proposed approach is therefore as follows:</p> <p>ML for chocolate containing or declaring &lt;30% total cocoa solids on a dry matter basis: for consideration at CCCF14 at Step 7 Advance and adopt the ML of 0.3 mg/kg proposed for Step 5 (chocolate containing or declaring &lt;30% total cocoa solids on a dry matter basis), as mandated at CAC42.</p> <p>ML for the remaining categories of chocolate and cocoa-derived products: for consideration by the Electronic Working Group (EWG) and at CCCF14 at Step 4</p> <p>As there is no new mandate that changes the one granted by CCCF13 with regard to the current status of work on cocoa-derived products, the work of the EWG should be continued in order to advance the proposed ML for the categories of chocolate and chocolate products, adopting a proportional approach, at CCCF14.</p>
<b>Egypt</b>	Egypt would like to thank you for the great work, and express that we cannot support the proposed maximum level (ML), as Egypt adopts stricter ML of 0.10 mg/kg to ensure sufficient level of protection for all consumers, in particular children.
<b>El Salvador</b>	<p>The CCCF has undertaken hard work in establishing MLs for cadmium in cocoa-derived products and the decision at CAC42 to maintain the proportionality approach for MLs pending their adoption for the remaining categories of chocolate.</p> <p>El Salvador does not agree with the comments made in CL 2020/50/OCS-CF and wishes to reiterate, as stated in its response to CL 2020/19/OCS-CF, that:</p> <p>It agrees that the CCCF should submit to the Codex Alimentarius Committee the proposed MLs for this category of chocolate as proposed in CX/CF 20/14/6 for approval by the CAC.</p> <p>El Salvador is prepared to offer cocoa and cocoa-derived products with lower cadmium concentrations in accordance with the results of a nationwide study which found that, at national level, cadmium concentrations in cocoa fluctuate below the ML proposed by the EWG.</p>

	<p>Furthermore, with regard to JECFA's call for data on cadmium in all food sources, and specifically chocolate and cocoa products, we propose that each of the ML projects for the various food categories are finalised and that once the outcome of the risk assessment is known, should these MLs need to be changed, action is taken in accordance with the Codex Procedural Manual.</p>
<b>EU</b>	<p>European Union Competence European Union Vote</p> <p><b><u>COMMENTS ON THE CONSIDERATIONS OUTLINED IN § 9 OF THE DOCUMENT</u></b></p> <p>The European Union (EU) can accept the retention of the ML of 0.3 mg/kg for chocolates containing or declaring &lt;30% total cocoa solids on a dry matter basis at Step 7 awaiting the outcome of the JECFA evaluation on cadmium. The EU wishes however to remind and to reiterate its current reservation to the adoption of 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 the EU is of the opinion of the need for a stricter ML to ensure sufficient protection of all consumers, in particular children.</p> <p>The EU can agree to suspending the consideration of MLs for chocolates containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis awaiting the outcome of the JECFA evaluation on cadmium.</p> <p>The EU wishes furthermore to highlight the importance of finalising as soon as possible the draft Code of practice for the prevention and reduction of cadmium contamination in cocoa beans, currently under discussion, in order to enable its implementation without any further delay. The implementation of good practices will lead to the reduction of cadmium contamination in cocoa beans and their products and will help achieve levels that ensure a high level of human health protection, in particular of children, a vulnerable group of the population.</p>
<b>Malaysia</b>	<p>Awaiting the outcome of the JECFA evaluation on cadmium from all food sources (particularly in chocolates and cocoa products) that will be available in 2021, Malaysia supports to:</p> <ol style="list-style-type: none"> <li>i. retain the ML of 0.3 mg/kg for chocolates containing or declaring &lt;30% total cocoa solids on a dry matter basis at Step 7</li> <li>ii. suspend the consideration of MLs for chocolates containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis.</li> </ol>
<b>Peru</b>	<p>We would be grateful if the Secretariat could clarify the following queries regarding CL 2020/50/OCS-CF:</p> <ul style="list-style-type: none"> <li>• Does JECFA require a mandate from the CCCF Priority Group to initiate a new evaluation?</li> <li>• Does JECFA have the power to initiate a new evaluation on cadmium without a request from the respective committee?</li> <li>• If JECFA has the power to initiate a new evaluation:</li> <li>• When will this evaluation be carried out, what will be its scope, and how long will it last?</li> <li>• When will the report and conclusions of this report be available to the Member States?</li> </ul> <p>Furthermore, Peru responds as follows to the questions posed in CL 2020/50/OCS-CF:</p> <ul style="list-style-type: none"> <li>• Advance and adopt the ML of 0.3 mg/kg proposed for Step 7 (chocolate containing or declaring &lt;30% total cocoa solids on a dry matter basis), as agreed.</li> </ul> <p>There is no new mandate that changes the one granted by CCCF13 with regard to the current status of work on cocoa-derived products. We therefore support:</p> <ul style="list-style-type: none"> <li>• The continuation of the work being undertaken by the EWG to advance the proposed ML for the categories of chocolate and chocolate products (chocolate containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis), adopting a proportional approach, at CCCF14; see link*.</li> </ul> <p>(*) link: <a href="http://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?lnk=1&amp;url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-13%252FREPORT%252FFinal%252520Report%252FREP19_CFs.pdf">http://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?lnk=1&amp;url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-13%252FREPORT%252FFinal%252520Report%252FREP19_CFs.pdf</a></p>

<p><b>Trinidad and Tobago</b></p>	<p><b>1: Retaining the ML of 0.3 mg/kg for chocolates containing or declaring &lt;30% total cocoa solids on a dry matter basis at Step 7 while awaiting the outcome of JECFA evaluation on cadmium</b></p> <p>We would like to express our reservation with regards to the present ML or a proposed modified ML being adopted without further discussion, following the report of the JECFA. The rationale for this is that we cannot prejudge the outcome of the new data and the analysis and recommendations of the JECFA.</p> <p><b>2: Suspend the consideration of MLs for chocolates containing or declaring &gt;30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis awaiting the outcome of the JECFA evaluation</b></p> <p>Also support the decision at the CCCF13, that if consensus is not reached at CCCF14 for the remaining categories, work should be discontinued until the Code of Practice for the prevention and reduction of cadmium contamination in cocoa beans is finalized and implemented.</p> <p>Also query the rationale behind only setting MLs for chocolates containing or declaring &gt;30% to &lt;50% and not for a category of chocolates containing or declaring &gt;50% to &lt;100%.</p> <p>Query the rationale for applying the concept of proportionality to determine MLs for categories &gt;30% to &lt;50 and others without considering data on consumption patterns for the various categories by vulnerable groups and age-related cohorts.</p>
<p><b>Uganda</b></p>	<p>9.1) Uganda agrees to retain the ML of 0.3 mg/kg for chocolates containing or declaring &lt;30% total cocoa solids on a dry matter basis at Step 7 as awaiting the outcome of the JECFA evaluation on cadmium.</p> <p>9.2) Uganda also supports suspending of the consideration of MLs for chocolates containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis as awaiting the outcome of the JECFA evaluation on cadmium.</p> <p><b>Justification:</b> Basing on Uganda’s laboratory data on presence of Cd in Cocoa, ML of 0.3 mg/kg is a benchmark for most of the samples obtained from different regions of the country. However, Uganda calls for JECFA’s toxicological evaluation on the maximum limit of cadmium contaminant.</p>
<p><b>USA</b></p>	<p>The United States appreciates the opportunity to provide comments in response to CL 2020/50/OCS-CF, which requests input on (a) how to facilitate consideration of the ML for chocolate containing or declaring &lt;30% total cocoa solids (TCS) on a dry matter basis and (b) how to provide guidance to the EWG on their work on the MLs for chocolates containing or declaring ≥30 % to &lt;50% TCS on a dry matter basis and cocoa powder with 100% TCS on a dry matter basis, considering the conclusions of the July 2020 FAO/WHO JECFA Secretariat report (CX/CF 20/14/3-Add. 1).</p> <ul style="list-style-type: none"> <li>• The United States does not support the proposal by the Codex Secretariat to retain the ML of 0.3 mg/kg for chocolates containing or declaring &lt;30% TCS on a dry matter basis at Step 7. <ul style="list-style-type: none"> <li>○ The United States supports the committee recommending adoption of the draft ML of 0.3 mg/kg at Step 8 at CCCF14 (see U.S. comments in CX/CF 20/14/5 Add. 1).</li> <li>○ CAC42 concluded 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.”</li> <li>○ No new information has been provided to justify a change to the draft ML of 0.3 mg/kg. The draft ML is based on occurrence data for cadmium in chocolates containing &lt;30% TCS, which is distinct from the cocoa powder data that prompted the Secretariat’s proposal for a new JECFA cadmium assessment. A new JECFA exposure assessment based on the 97.5th percentile for cocoa powder would not affect the calculated exposure from chocolates containing &lt;30% TCS.</li> </ul> </li> <li>• The United States does not believe that a JECFA re-evaluation should be held before CCCF14 in order to provide guidance to the EWG. Instead, CCCF should consider JECFA’s proposal for a new cadmium assessment at the next CCCF session. The reasons for this approach are as follows: <ul style="list-style-type: none"> <li>○ CCCF has not had the opportunity to weigh in on the scope, objectives, or terms of reference of an exposure assessment for all cadmium products or to consider the possible work projects that might result from such an assessment. It is unusual for JECFA to plan assessments for CCCF that address CCCF-related work without CCCF input and discussion. Discussion and planning at CCCF14 will ensure that the assessment addresses the needs of the Committee. This is particularly important given the scope of products that might be affected by a broad new exposure assessment. CCCF already has a full agenda, and the need for new work on cadmium MLs should be considered in light of the committee’s overall priorities.</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ If CCCF proceeds with a new cadmium exposure assessment, member countries will need time to plan new sampling assignments and gather new data. JECFA issued a new call for data on August 13, 2020, for cadmium data from all food sources, food consumption patterns, and biomarkers of exposure, with information to be submitted before December 1, 2020. Given the Covid-19 pandemic, our ability to conduct sampling and provide relevant and up to date occurrence data has been greatly reduced, and we may not be able to provide sufficient data by the requested deadline or even through early 2021. Also, it is unclear if international experts would be able to participate in any physical session conducted by JECFA.</li> <li>○ Finally, there is no pressing need for an evaluation of cadmium to address chocolate and cocoa MLs before CCCF14, because CCCF13 and CAC42 have already recommended paths of action for resolving ongoing cadmium in chocolate issues. For chocolate containing &lt;30% TCS, CAC42 recommended 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.” For chocolate containing &gt;=30% to &lt;50% TCS on a dry matter basis and for cocoa powder with 100% TCS on a dry matter basis, CCCF13 recommended that if consensus could not be reached at CCCF14, work would be discontinued until the “Code of practice for the prevention and reduction of cadmium contamination in cocoa beans” was finalized and implemented.</li> <li>• In February 2020, in response to CL 2020/19/OCS-CF, the United States commented that we did not object to an ML in the range of 0.6-0.7 mg/kg for chocolates containing &gt;=30% to &lt;50% TCS; that the proposed MLs aligned with the proportionality approach; and that the proposed MLs are based on data from several data calls and represent a global compromise. We also commented that we could agree to an ML of 0.5 mg/kg, based on previous proposals. Further, for cocoa powder containing 100% TCS, we commented that we did not object to the ML of 1.5 mg/kg proposed in 2018 (CCCF12) and 2019 (CCCF13). The United States still supports these positions based on the data reviewed by the EWG. However, if the Committee concurs with the proposed new exposure assessment for cadmium, the United States can agree with suspending work on the MLs for chocolate containing &gt;=30% to &lt;50% TCS on a dry matter basis and cocoa powder with 100% TCS. This aligns with the recommendation by CCCF13 (REP19/CF) that if consensus could not be reached at CCCF14 on these categories, work would be discontinued until the Code of Practice was finalized and implemented.</li> </ul> <p>In summary, the United States does not concur with the Secretariat proposal to retain the draft ML of 0.3 mg/kg (&lt;30% TCS) at Step 7; further, the U.S. requests that JECFA’s proposed cadmium assessment be considered at the next CCCF meeting to discuss its scope, objectives, and terms of reference, and to provide ample time to ensure that the assessment has the requisite data and experts to respond fully to the needs of CCCF.</p>
<b>ECA</b>	<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. We agree with the options suggested in the Circular letter CL2020/50-CF and have no further comments at this stage:</p> <p>For chocolates containing or declaring &lt;30% total cocoa solids on a dry matter basis: Retain the ML of 0.3 mg/kg awaiting the outcome of the JECFA evaluation on cadmium.  For chocolates containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis: Suspend the consideration of MLs for both categories awaiting the outcome of the JECFA evaluation on cadmium.</p>
<b>ICA</b>	<p>We, the International Confectionery Association, wish to extend our continued thanks for the perseverance of Codex on these important items of the contaminants agenda, particularly in view of the added complexity of the pandemic situation. We thank the Codex Secretariat, JECFA for its support on data collection, and the electronic Working Group chaired by Ecuador co-chaired by Ghana.</p> <p>In April this year, we shared our positions on the cadmium in cocoa items with the Codex Secretariat for the CCCF14 meeting. However, as this meeting could not be held in 2020, we appreciate the updated considerations being shared in the circular letter. This includes developments from the JECFA assessment of new data, further outlined in document CX/CF 20/14/3-Add.1, July 2020, as well as a wider call for additional data on cadmium. We welcome this opportunity to comment further on the considerations described in the circular letter.</p> <p>As an overarching comment, we fully support the proportional, science-based approach to standard-setting on chemicals in food, following the established Codex principles. Common, achievable standards, based on science, add credibility, are defensible, and explainable to producers, manufacturers, governments, the public, and other stakeholders. We wish to underscore the importance of maintaining a consistent scientific basis and support for global achievability of common standards, protecting</p>

health, and promoting fairness for international trade. We are also sensitive to the increasing importance of sustainability, reducing adverse environmental impact, enhancing food supply and minimizing food waste. Unduly-strict standards that lead to crop rejection without tangible health benefit, that adversely affect food production, food supply, farming communities, and create food waste, are not in the public interest for global sustainability.

We support the principles of proportionality and ALARA, based on the data shared at Codex on this issue. Setting Maximum Levels (MLs) without unnecessary delay makes sense, to establish global standards and avoid the confusion where differences exist in some regions, and which are cause for considerable concern. Holding-off setting MLs, as suggested in the circular letter, will only serve to further complicate the landscape and lead to countries defaulting to standards already set in some regions which are unachievable, not based on global ALARA, and not based on the proportional scientific approach that CCCF has aligned upon. The Code of Practice for reducing cadmium in cocoa, being established under the separate agenda item, will help determine best practices and further scope on mitigation developments, for review of achievable MLs in the future. However, for now, we need to ensure Codex provides a realistic reference point for global standards based on available data and achievability.

The updated view from JECFA, shared in document CX/CF 20/14/3, submitted July 2020 for CCCF14, concludes that:

“The new data submitted to the GEMS/Food reflect a wider global distribution of occurrence data of cadmium in cocoa products compared to 2013 when JECFA77 evaluated the same products. The additional data seem to indicate a higher mean occurrence concentration for cadmium in cocoa products than previously observed by JECFA.”

This is clearly supported in the data shared with CCCF, showing that data globally needs to be fully taken into account when determining what is achievable. Despite JECFA 77 in 2013 concluding no health concern from cadmium in cocoa and chocolate products, we pursued setting MLs to take into account global data, in view of unachievable precedents for MLs being set in some regions. Therefore, we already have taken into account the data and justification for MLs for cadmium in cocoa and chocolate products based on global achievability.

We are concerned that without discussion at CCCF, procedurally this should not have gone forward to JECFA for another risk assessment, and this has created delays. While JECFA continues its assessment on cadmium in cocoa and chocolate products, as well as in other foods, it makes no sense to put the alignment on globally-ALARA MLs on hold, pending an outcome that will likely suggest ALARA MLs are needed. The circular letter, in paras 7 and 9 (see Annex), suggests holding and suspending ML proposals pending the JECFA outcome, but we already have the data on achievability and proportionality. It makes sense to move forward following the correct procedure, with MLs as previously proposed.

We reiterate our positions on achievable MLs, submitted earlier for CCCF14, already anticipating the JECFA update on data. We would appreciate these positions being taken into account, to make progress in setting the anticipated proportional, ALARA-based MLs:

#### **REGARDING DRAFT MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES AND COCOA-DERIVED PRODUCTS**

##### **CCCF14 - ITEM 5. Draft ML for cadmium for chocolates containing or declaring <30% total cocoa solids on a dry matter basis (at Step 7)**

###### **Category <30% cocoa solids on a dry matter basis**

An outcome from the Codex Committee on Contaminants in Food (CCCF13), April 29 – May 3, 2019, was a proposal put forward for adoption by the Codex Alimentarius Commission (CAC), a global ALARA-based maximum level (ML) of 0.3 mg/kg for cadmium in products with < 30% dried cocoa solids. This ML was proposed by the EWG, chaired by Ecuador and co-chaired by Ghana, and gained support at CCCF13 to go forward for adoption by CAC. The proposed ML allows necessary flexibility for cocoa supply, particularly in geographical regions with volcanic soils that can lead to greater uptake of naturally-occurring cadmium, such as in Latin America. Even at the proposed level of 0.3 mg/kg, the EWG data indicated as much as 12% of cocoa would exceed the level. With 12% rejection rate we could also support levels greater than 0.3 mg/kg for this category.

While it is understandable that regions with less volcanic soils may achieve lower levels of cadmium in cocoa, it is important to maintain a consistent global approach to standards based on scientific risk and achievability in all regions. Codex standards on contaminants should not be a basis for competitive advantage on any given issue, otherwise all countries would likely routinely adopt competitive stances, compromising the collaborative approach for fairness.

At CAC, we were concerned about the extended non-science based discussions, with some delegations proposing to push the level even lower for this category, to create even higher rejections, despite the 0.3 mg/kg level being supported by the EWG data for achievability, the CCCF recommendation, the principles of global Codex standards based on science and global achievability, and exceeding the recommendations from the JECFA scientific risk assessment. In view of information shared over the past year, we could support higher levels for this category to reduce unnecessary rejections, although we can also maintain support for the minimum acceptable, science-based level

of 0.3mg/kg for this category, based on the intention of the consensus at CCCF13. Further data on the global achievability of the proposed ML of 0.3 mg/kg for products with < 30% dried cocoa solids confirm the challenge in achieving even 0.3 mg/kg. This level cannot be reduced further based on achievability, without scientific merit, and would create high rejections in some regions.

Importantly, our concern is not to compromise global cocoa supply with unduly strict standards, but to follow the principles of proportionality and ALARA. Currently, the CCCF is developing a Code of Practice on cadmium in cocoa to determine longer-term opportunities for practices and scope to further lower uptake. In the meantime, the original proposed ML or slightly higher would meet the Codex principles.

**CCCF14 - ITEM 6. Proposed draft MLs for cadmium in chocolate and chocolate products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis; and cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption (at Step 3)**

This issue impacts cocoa supply, with science-based challenges in significant producing regions of the world, in particular geological factors that contribute to natural presence of cadmium. Measures need to carefully balance the practicalities and implications, to provide common standards that are globally achievable and will help fairness in international trade.

**Category ≥30-<50% cocoa solids on a dry matter basis**

Based on discussions at past CCCF sessions, a proportional approach was determined to be appropriate for setting these MLs, based on percentage of total cocoa solids on a dry matter basis. With the further data shared in the new discussion document, we can support the proposed ML range of 0.6-0.7 mg/kg as being globally reasonably achievable, and meeting the intended proportional approach determined by CCCF. In view of projected rejections, our preference to protect supply and avoid unnecessary crop rejection is 0.7mg/kg.

**Category 100% cocoa powder**

We have a fundamental concern on this category. The reality is that some regions of the world, notably the EU, have already set an unduly-strict ML standard for this category, and other regions are using this as a default in the absence of a Codex standard. We are seeing a ML of 0.6 mg/kg for 100% cocoa powder in some regions. This is disproportionate with the science, and not achievable even for categories from 50% and 70% cocoa solids on a dry weight basis, where respective levels of 0.8 mg/kg and 0.9 mg/kg have already been adopted by Codex. The unachievable ML precedent already set in some regions causes a significant problem. In the absence of a Codex standard, this disproportionate ML is likely to be further adopted as a default reference point in other regions.

Indeed, this issue is one of the primary reasons that cadmium in cocoa came onto the CCCF agenda, to align common global standards. In 2013, JECFA77 concluded that cadmium in cocoa is not a priority concern for health, and even with the new data on global occurrence the next step would be to determine ALARA levels if exposure is a concern, and this we can already do using the new data collected under CCCF.

We believe the establishment of a proportionate ML for 100% cocoa powder is technically appropriate, and would have no significant effect on dietary exposure, particularly as cocoa powder is always used in combination with other ingredients, in low quantities, rarely above 20%, such as cocoa/ chocolate beverages, baking, cookies and biscuits, ice cream, puddings, cake preparations.

During CCCF13, a possible ML for 100% cocoa powder was briefly discussed, at a level of 1.5 mg/kg, and this looked like a possible reasonably achievable solution for this category, although in view of achievability challenges identified by the data assessed by the EWG over the past year we can support a higher ML. The ML should apply to 100% cocoa powder products sold directly to the consumer. There is no health reason in this case to set a ML that is disproportionate to the science.

**ANNEX – EXTRACTS FROM CIRCULAR LETTER CL 2020/50/OCS-CF**

Para 7. CCCF14 will be considering the ML for chocolates containing or declaring <30% total cocoa solids on a dry matter basis (at Step 7) and the proposals from the EWG for MLs for chocolates and chocolate products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis; and cocoa powder (100% total cocoa solids on a dry matter basis) using the proportional approach (at Step 4).

Para 9. Such considerations may include the following:

9.1 ML for chocolates containing or declaring <30% total cocoa solids on a dry matter basis: For consideration at CCCF14 at Step 7 • Retain the ML of 0.3 mg/kg for chocolates containing or declaring <30% total cocoa solids on a dry matter basis at Step 7 awaiting the outcome of the JECFA evaluation on cadmium.

	9.2 MLs for the remaining categories of chocolates and cocoa-derived products: For consideration in the EWG and at CCCF14 at Step 4 • Suspend5 the consideration of MLs for chocolates containing or declaring $\geq 30\%$ to $< 50\%$ total cocoa solids on a dry matter basis and cocoa powder with 100% total cocoa solids on a dry matter basis awaiting the outcome of the JECFA evaluation on cadmium.
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