

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 6

CX/CF 21/14/6-Add.1

April 2021

ORIGINAL LANGUAGE ONLY

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

**14<sup>th</sup> Session**

**(virtual)**

**3-7 and 13 May 2020**

**Maximum levels for cadmium in  
chocolates containing or declaring  $\geq 30\%$  to  $< 50\%$  total cocoa solids on a dry matter basis  
and  
cocoa powder (100% total cocoa solids on a dry matter basis)  
(at Step 4)**

Comments at Step 3 submitted by Australia, Canada, Chile, Cuba, Ecuador, Egypt, El Salvador, European Union (EU), Iraq, United States of America (USA), FoodDrinkEurope, IAEA (International Atomic Energy Agency) and International Confectionery Association (ICA)

**Background**

1. This document compiles comments received in response to CL 2021/11/OCS-CF issued in March 2021.

**Explanatory notes on the Annex**

2. The comments are hereby compiled in the **Annex** and are presented in table format.

**COMMENTS ON MAXIMUM LEVELS FOR CADMIUM IN  
CHOCOLATES 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)**

**GENERAL AND SPECIFIC COMMENTS**

COMMENTS	MEMBER/OBSERVER
<p>Australia is grateful for the opportunity to provide comments as requested in CX/CF 21/14/6, paragraph 17, in relation to:</p> <ul style="list-style-type: none"> <li>(i) chocolates containing or declaring ≥30% to &lt;50% (total cocoa solids on a dry matter basis)</li> <li>(ii) cocoa powder (100% total cocoa solids on a dry matter basis)</li> <li>(iii) the possibility of including all available data on powdered products for the establishment of cadmium (Cd) maximum levels (MLs) for cocoa powder since data available on GEMS/Food do not have the declared percentage of cocoa content in the samples analysed.</li> </ul> <p>Specifically, as more than 80% of the data available in GEMS/Food does not show the declared percentage of cocoa content in the analysed samples, nor is it detailed if they are intermediate or final products, the eWG is recommending to change the name of the category so that all available data can be used to establish an ML.</p> <p>In providing comments, Australia has taken into account the points raised in CX/CF 21/14/6, paragraph 18, as requested. These are summarised as follows:</p> <ul style="list-style-type: none"> <li>• The recommendation of CCCF13 on the use of the proportional approach.</li> <li>• The background information presented in CX/CF 21/14/6.</li> <li>• The conclusions presented in CX/CF 21/14/6.</li> <li>• The analysis of data presented in Appendix II to CX/CF 21/14/6.</li> </ul>	<p><b>Australia</b></p>
<p>Cuba agradece el trabajo realizado por Ecuador y Ghana. En su Norma Nacional 493: 2015 sobre Contaminantes metálicos en los Alimentos, Regulaciones Sanitarias no cuenta con dicha clasificación, pero si, en el Cacao en polvo el NM permitido es de 0.8mg/kg. Por lo que nos inclinamos por el escenario 2 (enfoque de proporcionalidad): Cacao en polvo (100 % del totalde sólidos de cacao sobre la base de la materia seca) listo para el consumo para un NM de 1,3 - 1,5, a pesar que represente un por ciento por encima 8% de posibles muestras rechazadas.</p>	<p><b>Cuba</b></p>
<p>Egypt appreciates the work and efforts done by the EWG in drafting of this circulated document; and in this regard, Egypt adopts the following limits:</p> <ul style="list-style-type: none"> <li>• Chocolate with &lt; 50 % total dry cocoa solids;</li> <li>• Milk chocolate with ≥ 30 % total dry cocoa solids 0,30</li> <li>• Cocoa powder sold to the final consumer or as an ingredient in sweetened cocoa powder sold to the final consumer (drinking chocolate) 0,60</li> </ul>	<p><b>Egypt</b></p>
<p>El Salvador agradece el documento remitido por la Secretaría del Codex Alimentarius, preparado por el Grupo de Trabajo Electrónico presidido por Ecuador y copresidido por Ghana.</p> <p>El Salvador ha analizado el tema en cuestión en el subcomité técnico nacional y presenta los siguientes comentarios:</p> <p>Se agradece la extensa labor del presidente y copresidentes del GTe a fin de establecer NM de cadmio y se reconoce la importancia de velar por la inocuidad de los alimentos y la salud de los consumidores de productos derivados de cacao</p>	<p><b>El Salvador</b></p>

COMMENTS	MEMBER/OBSERVER
<p>En ese sentido se expresa que:</p> <ul style="list-style-type: none"> <li>(i) A la luz de las recomendaciones y conclusiones que figuran en el documento CX/CF 21/14/6 respecto a la tasa de rechazo para los NM de cadmio en chocolates que contienen o declaran entre <math>\geq 30\%</math> y <math>&lt; 50\%</math> de STC propuestos;</li> <li>(ii) Reconociendo los resultados de la evaluación de la exposición alimentaria al Cadmio de todas las fuentes de alimentos, los productos derivados del cacao representan entre el 0,2% y el 9% según informe del JECFA, la cual puede considerarse mínima respecto a otros alimentos; y</li> <li>(iii) Tomando en cuenta los resultados del estudio “Determinación de niveles de cadmio en almendras de cacao (<i>Theobroma cacao</i>), en Centro América y República Dominicana” llevado a cabo por el Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA), donde se estima que la media de concentración de Cd en cacao Salvadoreño es de 0.01mg/kg y que en el 75% de las muestras no se determinó presencia de dicho contaminante.</li> </ul> <p>El Salvador apoya el NM de 0,5 - 0,6 mg/kg para Chocolate que contiene o declara entre <math>\geq 30\%</math> y <math>&lt; 50\%</math> del total de sólidos de cacao sobre la base de materia seca y el NM de 1,3 - 1,5 mg/kg para el cacao en polvo (100% de sólidos totales de cacao sobre la base de materia seca) en concordancia con lo dictaminado por el CCCF13 de aplicar un enfoque de proporcionalidad respecto de los NM ya establecidos.</p>	
<p>European Union comments for the CODEX COMMITTEE ON CONTAMINANTS IN FOOD 14th Session Virtual session, 3-7 and 13 May 2021 Agenda Item 6: Maximum levels for cadmium in chocolates containing or declaring <math>\geq 30\%</math> to <math>&lt; 50\%</math> total cocoa solids on a dry matter basis and cocoa powder (100% total cocoa solids on a dry matter basis) (at Step 4) (Codex Circular Letter CL 2021/11-CF) European Union Competence European Union Vote</p> <p>The European Union (EU) welcomes the work on the development of maximum levels (MLs) for cadmium in chocolates and cocoa-derived products by the electronic Working Group chaired by Ecuador and co-chaired by Ghana.</p> <p>The EU appreciates the 2021 JECFA exposure assessment of cadmium from all sources, which facilitates a science-based continuation of the discussion.</p> <p>JECFA confirmed that children are the consumer groups, which undergo the highest exposure to cadmium. Even though JECFA concludes that for most consumers the exposure remains below the PTMI, the EFSA risk assessment (1) concludes differently, because in the EU a TWI is established, which is 50% lower than the toxicological reference value established by JECFA (2). JECFA now concluded that cocoa products with high cadmium concentrations can contribute up to 9.4% of the exposure of European children of 3-9 years old and for Europeans consuming only cocoa products from the LAC region, cocoa products can even be the main contributors to the cadmium exposure (39.4% of the cadmium exposure). This justifies the need to restrict the exposure of consumers to cadmium from chocolate and cocoa products.</p> <p>In view of the fact that in the EU for many consumers the TWI is already exceeded and that cocoa products are an important contributor to the exposure, the EU considers it important to establish strict MLs for these products, in order to ensure a high level of human health protection for all consumer groups and especially for the more vulnerable young consumers.</p>	EU

COMMENTS	MEMBER/OBSERVER
<p>As already commented by the EU at CCCF13, the EU does not agree to apply the proportional approach for the MLs for cocoa powder and chocolate containing less than 50% of cocoa solids, as these products are regularly consumed by children, while the darker chocolates are not, due to their bitter taste. Furthermore, the EU notes that the conclusions taken for the world wide data are driven by a large proportion of data from the LAC region and that data from other cocoa producing regions such as Africa and Asia are much underrepresented. It is also not clear whether the data originate from recent years and whether mitigation practices were applied to limit the cadmium concentrations in the crops.</p> <p><u>Chocolates</u>: For the reasons explained above the EU wishes to express its reservation as regards the proposed MLs of 0.5-0.7 mg/kg for chocolate and chocolate products containing or declaring <math>\geq 30\%</math> to <math>&lt; 50\%</math> total cocoa solids on a dry matter basis. The EU is of the opinion that a stricter ML of 0.30 mg/kg is needed to ensure a sufficient protection of all consumers, in particular children.</p> <p><u>Cocoa powder</u>: The EU would also like to express its reservation as regards the proposed MLs of 1.3-3.0 mg/kg for cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption. The EU is of the opinion that a stricter ML of 0.60 mg/kg is needed, to ensure a sufficient protection of all consumers, in particular children. As an alternative, as cocoa powder is a commodity, which is of less significance for international trade, the EU could agree not to set a Codex ML for cocoa powder. The EU does not agree with the proposed option of considering all data for powdered products for the establishment of an ML for cocoa powder, as the cadmium concentrations in mixtures of cocoa powder and sugar depend on the amount of pure cocoa powder in the product.</p> <p>The EU is of the opinion that the ALARA principle should be applied on data, which were obtained from crops on which good practices were applied. Therefore, the EU wishes 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 focus needs to be on the implementation of good practices, which 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> <p>-----</p> <p>(1) In 2009 the EFSA CONTAM Panel derived a Tolerable Weekly Intake (TWI) of 2.5 <math>\mu\text{g}/\text{kg}</math> body weight (bw) per week and concluded that the mean exposure for adults across Europe is close to, or slightly exceeding, the TWI of 2.5 <math>\mu\text{g}/\text{kg}</math> bw. Subgroups such as vegetarians, children, smokers and people living in highly contaminated areas may exceed the TWI by about 2-fold. 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>(2) In 2011 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 <math>\mu\text{g}/\text{kg}</math> bw per week had to be maintained in order to ensure a high level of protection of consumers. Statement on tolerable weekly intake for cadmium. The EFSA Journal, 9(2):1975, [19pp.].</p>	
<p>We support measures that respond to science-based risk, following the scientific risk assessment by JECFA, and the risk management principle that maximum levels, when necessary, should be globally reasonably achievable, following the principle of ALARA and based on sufficient global data. Measures need to carefully balance the practicalities and implications, to provide common standards that are globally achievable and will help fairness in international trade.</p>	<p><b>FoodDrinkEurope</b></p>

COMMENTS	MEMBER/OBSERVER
<p><u>SUBJECT: CCCF ITEM 6. MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES AND COCOA-DERIVED PRODUCTS – RESPONSE TO CL2021/11/OCS-CF</u></p> <p>The International Confectionery Association thanks the electronic working group (EWG) Chair, Ecuador, the co-chair Ghana, and the working group members for preparing and distributing the document CX/CF 21/14/6. We appreciate the opportunity to comment on this document and support the further discussions at the Codex Committee on Contaminants in Food (CCCF) 14th session, May 3-7, and 13, 2021.</p> <p>Our position is to support measures that respond to science-based risk, following the scientific risk assessment by JECFA, and the risk management principle that maximum levels, when necessary, should be globally reasonably achievable, following the principle of ALARA and based on sufficient global data.</p> <p>Regarding the analysis of data, besides the work of the EWG, we welcome the outcome of the recent JECFA91 summary report. We were initially unclear why JECFA was tasked to review further data when the EWG was already developing risk management proposals based on achievability data and the past JECFA77 risk assessment. But nevertheless, the JECFA91 report has been helpful in consolidating recent information on the dietary exposure aspects of the risk assessment. The findings of the JECFA91 report were helpfully summed-up during the webinar hosted by the Codex and JECFA secretariats on March 17, 2021. We appreciate that during the webinar the JECFA secretariat apologized for the confusion caused to the EWG, highlighting that JECFA has the responsibility to ensure the scientific integrity of its assessment, and felt it was important to review the significant new data for best science-based conclusions on dietary exposure from cadmium.</p> <p>Further building on the JECFA77 findings, JECFA91 concluded on low risk from dietary exposure from cocoa and cocoa products, reportedly based on data collected since 2011, from national studies and GEMS/ Food cluster diets, including 277,292 data points.</p> <p><u>Overall Dietary Exposure</u></p> <p>Main contributors to exposure from cadmium in the diet include: cereals, cereal-based products, vegetables, fish and seafood. JECFA noted the current Provisional Tolerable Monthly Intake recommendation (25ug/kg.bw) is based on chronic long-term bioaccumulation from exposure over 45-60 years. The Committee noted that dietary exposure above the PTMI for limited periods may be of lesser concern in younger age groups. However, there would be potential concern for regular exposure above the PTMI throughout adulthood.</p> <p><u>Cocoa Products</u></p> <p>Dietary exposure to cadmium from cocoa products in national estimates is low, the total mean dietary exposure ranging from 0.2 to 9.4%. Using global regional cluster diets based on data collected under the GEMS food program, JECFA determined cadmium from cocoa products to contribute 0.1 to 5.9% of total dietary exposure. The highest of these clusters were in westernized regions, in Europe and North America. Overall, the contribution to cadmium exposure from cocoa products ranging from 0.1-9.4% was considered to be low, including countries with high consumption.</p> <p>Using the collected GEMS data from all region clusters, the mean contribution of cocoa products to total dietary cadmium exposure was estimated at 2.2% without applying the proposed and established Maximum Levels (MLs) to restrict cadmium, and 1.5% if the MLs were applied. A low mean reduction to dietary cadmium exposure of 0.7% across clusters, ranging from 0% to 2.4% reduction in individual clusters. Codex MLs are generally only determined to be necessary for foods contributing 5% or more to total dietary exposure.</p> <p>If applying MLs to the GEMS data, rejections of 2.1-10.7% were estimated for chocolate samples, and 16.3% rejection for 100% cocoa powder samples, with substantial cocoa powder rejection rates, up to 30% in some regions. These estimates assumed a proposed ML of 1.5 mg/kg for cocoa powder.</p>	<p>ICA</p>

COMMENTS	MEMBER/OBSERVER
<p>To set MLs for a low-risk item, without tangible health benefit, and with such high rejection rate would be unacceptable. It would conflict with the United Nations Sustainable Development Goals, where avoiding unnecessary food waste is a top priority. It would be out of line to set such a ML, that would result in high food waste, causing significant economic burden to regional farmers and producers.</p> <p>During the JECFA webinar, questions were raised asking to clarify whether there is any need to set MLs in cocoa, with such low risk and low presence of cadmium in cocoa and chocolate products. The JECFA secretariat clarified that JECFA assesses the risk, but then it is for the CCCF to determine the risk management measures necessary, including wider political considerations. On this point we have concerns. Political considerations often create non-science barriers to securing truly harmonized, globally achievable risk management measures. CCCF MLs are based on scientific risk, global data and reasonable achievability. Political preferences should not be the basis for global harmonized standards.</p> <p><u>Proportionality &amp; Non-Fat Solids</u></p> <p>The scenario of a proportional approach shown in Appendix II, Table 7. and Figure 3. demonstrates that the existing MLs are only roughly proportional, and different categories of products have different considerations. Cocoa solids include varying levels of cocoa butter, which does not accumulate cadmium. In chocolate bars and chocolates, the cocoa butter is proportionally much higher than in cocoa powder. For example, for chocolate products with <math>\geq 70\%</math> cocoa solids, the ML 0.9 mg/kg was set, based on submitted occurrence data for achievability in chocolate products. For chocolate bars, the cocoa butter content of the cocoa solids is generally around 54.5%. In this case, 45.5% of the solids are non-fat and could contribute up to the ML of 0.9 mg/kg. Whereas for 100% cocoa powder, the cocoa butter content is generally 10-12%, or <math>&lt; 0.5\%</math> in defatted cocoa powder. Therefore, 88-90% or for defatted over 99.5% of the non-fat solids can contribute to the cadmium. Proportionally, this is twice the amount of non-fat solids compared with chocolate bars. In Appendix I, the proportionality-based Scenario 2 proposes 1.3 – 1.5 mg/kg for 100% cocoa powder, although it conflicts with the achievability data submitted to GEMS. This is understandable, as it does not take into account the low proportion of cocoa butter. The truly proportional ML would be double this value, as double the non-fat cocoa solids are present, requiring a ML of 2.6 – 3.0 mg/kg for 100% cocoa powder. This ML range aligns with the ALARA-based GEMS data proposal in Scenario 1. Proportionality makes good sense, although products need to be equivalent and cocoa powder considerations need to be adjusted for cocoa fat solids.</p> <p><u>Proposed MLs for cadmium in chocolate and chocolate products containing or declaring <math>\geq 30\%</math> to <math>&lt; 50\%</math> total cocoa solids on a dry matter basis; and cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption, document CX/CF 21/14/6, Appendix 1.</u></p> <p>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.</p> <p><u>Category <math>\geq 30 - &lt; 50\%</math> cocoa solids on a dry matter basis</u></p> <p>Based on discussions at past CCCF sessions, a roughly proportional approach was determined to be appropriate for setting these MLs, based on percentage of total cocoa solids on a dry matter basis. This also needs to match the global achievability data for the product category. Based on the further data shared with GEMS food, and in the new discussion document, we can support the Scenario 1 proposed ML range of 0.6-0.7 mg/kg as being globally reasonably achievable. In view of projected rejections, our preference to protect supply and avoid unnecessary crop rejection is 0.7 mg/kg.</p>	

COMMENTS	MEMBER/OBSERVER
<p><u>Category 100% cocoa powder</u></p> <p>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.</p> <p>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 with the new data on global occurrence and exposure JECFA91 again concludes that cocoa and cocoa products present low exposure risk.</p> <p>We believe the establishment of a ML for 100% cocoa powder based on global achievability data is technically appropriate, and in line with proportionality when taking account of non-fat solids. This would have no significant effect on dietary exposure concerns, 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.</p> <p>Based on the data assessed and provided in the new document, in view of achievability challenges identified by the EWG, we can support the range listed in the Scenario 1 option, for achievability across the regions, 2.0 mg/kg - 3.0 mg/kg for the category 'cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption'. Importantly, the Scenario 2 proposing 1.3 - 1.5 mg/kg for this same category is clearly unachievable based on the data and unacceptable rejection rates, much higher than the 5% guideline used by Codex. The proportionality basis is mis-informed, as explained above, as it does not take into account the low proportion of cocoa butter in 100% cocoa powder, compared with chocolate, such as in chocolate bars. The proportionality-based range for non-fat cocoa solids in cocoa powder would be 2.6 – 3.0 mg/kg. There is no health reason in this case to set a ML that is disproportionate to the occurrence data or the science-based low risk.</p> <p>We thank the Committee for taking into account these considered points and look forward to further discussion at the CCCF14 session</p>	

**SPECIFIC COMMENTS**

**MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES AND COCOA POWDER**

**1. Chocolates containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis**

COMMENTS	MEMBER/OBSERVER
<p>Australia notes that the eWG has analysed a total of 924 samples in this category of chocolates, with an additional 161 samples obtained from the 2020 data call. Australia has considered the new dataset and scenarios, and has conducted a comparative analysis with the results from 2020 to determine the continued validity of the proposed MLs.</p> <p>Australia notes that despite the additional data, a comparison with Table 2 from CX/CF 20/14/6 (February 2020) indicates that the maximum Cd value for each region is unchanged. In addition:</p> <ul style="list-style-type: none"> <li>• Both the Worldwide and LAC Cd averages have decreased from 0.28 to 0.26 mg/kg and from 0.34 to 0.31 mg/kg, respectively.</li> <li>• Likewise, both the Worldwide and LAC P95 values have decreased from 0.84 to 0.80 and 0.92 to 0.85 respectively.</li> </ul> <p><u>Scenario 1</u>: Determination of ML by analysis of the GEMS/Food data</p> <p>A comparison of the ML scenarios presented in Table 3 with data from 2020 indicates that rejection levels at various MLs have decreased. This is to be expected given the reductions noted in the average Cd concentrations (Table 2). Specifically:</p> <ul style="list-style-type: none"> <li>• A proposed ML of 0.6 mg/kg would now see:             <ul style="list-style-type: none"> <li>o 10.39% of Worldwide samples rejected, vs 12.6% rejected based on the 2020 projections.</li> <li>o 13.16% of LAC samples rejected, vs 15.83% based on 2020 data.</li> </ul> </li> <li>• A proposed ML of 0.7 mg/kg would now see:             <ul style="list-style-type: none"> <li>o 5.74% of Worldwide samples rejected, vs 6.82% rejected based on the 2020 data.</li> <li>o 7.33% of LAC samples rejected, vs 8.95% based on 2020 data.</li> </ul> </li> </ul> <p>At the proposed MLs, Worldwide exposures have been calculated to be approximately 3% of the PTMI.</p> <p><u>Scenario 2</u>: Determination of ML by proportionality approach</p> <p>Australia notes that this section includes details on the determination of an ML for chocolate ≥30% to &lt;50% tcs using a proportionality approach. This approach takes into account MLs that have already been set (≥50% to &lt;70% tcs and ≥70% tcs), as well as proposed MLs (&lt;30% tcs and 100% tcs) to derive a proposed ML of 0.5 mg/kg.</p> <p>Australia has reviewed the information provided in this section, including Figure 2, but would welcome further details/calculations describing how this proposed ML was derived using the proportionality method. In particular, it is not clear if the proposed ML(s) are 0.48 mg/kg, 0.5 mg/kg and/or 0.6 mg/kg.</p> <p>Proposed MLs for 0.6 mg/kg have already been considered in Scenario 1 above. A proposed ML of 0.5 mg/kg was last considered in 2019. With the latest data a proposed ML of 0.5 mg/kg would see 16.3% of Worldwide samples rejected and 20.53% of LAC samples rejected. Worldwide exposures have been calculated to be approximately 2.6% of the PTMI (vs 3% for Scenario 1 above).</p>	<p><b>Australia</b></p>



COMMENTS	MEMBER/OBSERVER
Canada supports an ML of 0.7 mg/kg for chocolates containing or declaring $\geq 30\%$ to $< 50\%$ total cocoa solids on a dry matter basis.	Canada
Chile mantiene apoyo al nivel máximo de hasta 0,7 mg/kg para el chocolate que contiene o declara un contenido $\geq 30\%$ y $< 50\%$ del total de sólidos de cacao sobre la base de materia seca. Lo anterior se justifica en la necesidad de entregar protección al consumidor en toda la gama de tipos de chocolates disponibles en el mercado según su contenido de cacao, sumado a que los resultados de la última evaluación de exposición realizada por JECFA durante el año 2020, a la luz de una mayor cantidad de datos, confirman lo ya concluido el 2013, respecto de que la exposición a Cadmio a partir del consumo de productos derivados del cacao sería insignificante. Chile considera que este nivel mantiene el enfoque de proporcionalidad ya utilizado para los niveles máximos adoptados en la CAC41-2018 para chocolates con mayor contenido de sólidos totales de cacao [entre $\geq 50\%$ y $< 70\%$ del total de sólidos de cacao (0,8 mg/kg), y $> 70\%$ del total de sólidos de cacao (0,9 mg/kg)].	Chile
Apoyar dentro del ESCENARIO 1, el nivel de 0,7 mg/kg ya que es el que aporta menores porcentajes de rechazo comercial. Consideramos que este nivel se enmarca en el análisis de proporcionalidad y la flexibilidad permitida según el mandato del CCCF13.	Ecuador
Agree with proposed.	Iraq
<p>The United States appreciates the work that Ecuador and the electronic working group (EWG) have done in preparing the recommendations on maximum levels (MLs) for cadmium in chocolates containing or declaring <math>\geq 30\%</math> to <math>&lt; 50\%</math> total cocoa solids on a dry matter basis and cocoa powder (100% total cocoa solids on a dry matter basis).</p> <p><u>General comments</u></p> <p>The United States notes the following key results of the summary report of the JECFA91 evaluation (February 2021):</p> <ul style="list-style-type: none"> <li>• The JECFA91 evaluation concluded, consistent with previous evaluations, that the contribution of cocoa products to dietary cadmium exposure was minor in comparison to other dietary sources (0.1–9.4% for national studies and estimates based on GEMS/Food cluster diets), even in countries in which the consumption of cocoa products is relatively high.</li> <li>• JECFA91 also concluded that application of both established and proposed MLs for chocolate and cocoa powder may result in substantial rejection rates (on average, 16 %, and up to 30% in Latin America) for products from some regions, but has only a minor impact (mean decrease across clusters of 0.7%, range 0.0–2.4%) on total dietary cadmium exposure.</li> </ul> <ul style="list-style-type: none"> <li>• The United States does not object to an ML in the range of 0.5-0.7 mg/kg (Scenario 1 or Scenario 2).</li> <li>• MLs of 0.5, 0.6, and 0.7 mg/kg have worldwide rejection rates of 16.2%, 10.4% and 5.7%, and Latin American rejection rates of 20.5%, 13.2% and 7.3%, respectively. Given the lack of a food safety issue based on JECFA evaluations, the higher MLs (0.6-0.7 mg/kg) would be more appropriate, given the lower rejection rates.</li> <li>• The proposed MLs are proportional to previously adopted MLs of 0.8 mg/kg and 0.9 mg/kg for chocolates containing or declaring <math>\geq 50\%</math> to <math>&lt; 70\%</math> and <math>\geq 70\%</math> total cocoa solids on a dry matter basis.</li> <li>• Although the proposed MLs of 0.6-0.7 mg/kg would result in higher rejection rates for some Latin American and Caribbean countries, they are based on data provided from several data calls and are supported by the proportionality approach.</li> </ul>	USA
Consider Scenario 1, with 0.6 – 0.7 mg/kg ML	IAEA

<b>COMMENTS</b>	<b>MEMBER/OBSERVER</b>
<p><u>Category ≥30-&lt;50% cocoa solids on a dry matter basis:</u></p> <p>Based on the further data shared with GEMS food, and in the new discussion document, we can support the Scenario 1 proposed ML range of 0.6-0.7 mg/kg as being globally reasonably achievable. In view of projected rejections, our preference to protect supply and avoid unnecessary crop rejection is 0.7 mg/kg.</p>	<b>FoodDrinkEurope</b>
<p>Based on discussions at past CCCF sessions, a roughly proportional approach was determined to be appropriate for setting these MLs, based on percentage of total cocoa solids on a dry matter basis. This also needs to match the global achievability data for the product category. Based on the further data shared with GEMS food, and in the new discussion document, we can support the Scenario 1 proposed ML range of 0.6-0.7 mg/kg as being globally reasonably achievable. In view of projected rejections, our preference to protect supply and avoid unnecessary crop rejection is 0.7 mg/kg.</p>	<b>ICA</b>

**2. Cocoa powder (100% total cocoa solids on a dry matter basis)**

COMMENTS	MEMBER/OBSERVER
<p>Australia notes that the dataset in 2021 for cocoa powder had a total of 5943 samples, with an additional 1698 samples obtained from the 2020 data call. The maximum Cd value was 9.9 mg/kg (from the LAC dataset). Due to the wide variability of the dataset, the eWG calculated the standard deviation and used this to reduce the dataset to 5781, which covered 99.7% of the data. Following this process, the maximum Cd value in the dataset is 4.2 mg/kg.</p> <p>Again, Australia has conducted a comparative analysis with the results from 2020 in order to determine the continued validity of the proposed MLs. A comparison with Table 4 from CX/CF 20/14/6 (February 2020) indicates that despite the additional data and subsequent data manipulations:</p> <ul style="list-style-type: none"> <li>• The Worldwide Cd average remains the same, at 0.56 mg/kg.</li> <li>• The maximum Cd concentration for the LAC dataset went from 9.9 to 4.2 mg/kg. However, the LAC Cd average concentration only decreased by a relatively small amount – from 1.34 to 1.095 mg/kg. This would seem to indicate that the value of 9.9 mg/kg was an outlier and, as such, lends support to the eWG’s decision to use the standard deviation to remove outliers. Therefore, Australia has no objections to using the standard deviation approach in an effort to remove outliers (which may otherwise have a negative impact on the subsequent analyses) and enhance the homogeneity of the dataset.</li> </ul> <p><u>Scenario 1:</u> Determination of ML by analysis of the GEMS/Food data</p> <p>A comparison of the ML scenarios presented in Table 6 with data from 2020 indicates that rejection levels at various MLs have again decreased. Specifically:</p> <ul style="list-style-type: none"> <li>• A proposed ML of 2.0 mg/kg would now see:             <ul style="list-style-type: none"> <li>o 5.39% of Worldwide samples rejected, vs 5.46% rejected based on the 2020 projections.</li> <li>o 13.42% of LAC samples rejected, vs 17.82% based on 2020 data.</li> </ul> </li> <li>• A proposed ML of 3.0 mg/kg would now see:             <ul style="list-style-type: none"> <li>o 2.49% of Worldwide samples rejected, vs 3.65% rejected based on the 2020 data.</li> <li>o 6.34% of LAC samples rejected, vs 12.22% based on 2020 data.</li> </ul> </li> <li>• Australia notes that to bring LAC samples under the 5% threshold of rejection, an ML of 3.4 mg/kg would need to be applied.</li> </ul> <p>At the proposed MLs, Worldwide exposures have been calculated to be approximately 2.5 – 5.5% of the PTMI.</p> <p><u>Scenario 2:</u> Determination of ML by proportionality approach</p> <p>Australia notes that this section includes details on the determination of an ML for cocoa powder with 100% tcs using a proportionality approach. This approach takes into account MLs that have already been set/proposed to derive a proposed range of MLs of 1.3 – 1.5 mg/kg. Per Figure 2, Australia would welcome further details/calculations to accompany Figure 3.</p> <p>A proposed ML of 1.5 mg/kg was last considered in 2019. With the latest data, proposed MLs between 1.3 – 1.5 mg/kg would see a considerable percentage of rejected samples i.e.:</p> <ul style="list-style-type: none"> <li>• 8.26 – 11.5% of Worldwide samples rejected and</li> <li>• 20.38 – 27.64% of LAC samples rejected.</li> </ul>	<p><b>Australia</b></p>

COMMENTS	MEMBER/OBSERVER
<p>For proposed MLs ranging from 1.3 – 1.5 mg/kg, Worldwide exposures have been calculated to be approximately 1.7 – 2.2% of the PTMI (vs approximately 2.5 – 5.5% for Scenario 1 above).</p> <p><u>Australian comments</u></p> <p>Australia notes that the proposed MLs for chocolate ≥30% to &lt;50% tcs and cocoa powder 100% tcs (per Scenario 1), are the same as those proposed in 2020:</p> <ul style="list-style-type: none"> <li>• Chocolate containing or declaring ≥30% to &lt;50% total cocoa solids on a dry matter basis      0.6 – 0.7 mg/kg</li> <li>• Cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption      2.0 – 3.0 mg/kg</li> </ul> <p>We have previously advised that for both food categories, we would support MLs at the higher end of the proposed ranges. Based on these latest analyses (2021), our views remain unchanged for the following reasons.</p> <p><u>JECFA evaluation</u></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. However, JECFA has conducted a new evaluation of the contribution of cocoa and cocoa products to the mean dietary exposure to Cd. Analyses using these data confirm that cocoa and cocoa products are not major contributors to dietary exposure to Cd. Further, applying the established/proposed MLs compared to not applying them result in an average decrease in the contribution of cocoa products to the dietary exposure to cadmium of 0.7%. However, application of established/proposed MLs for chocolate categories and cocoa powder may result in substantial rejection rates (up to 30%) for certain products from some regions.</p> <p><u>Rejection rates</u></p> <p>In light of the latest evaluation by JECFA, 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. With the new data, the rejection rates for both categories for Scenario 1 MLs have decreased. This is encouraging from the perspective of avoiding disruption to international trade. The highest rejection rate noted for Scenario 1 MLs is 7.33% (LAC chocolate samples). Australia considers this to be a reasonable global compromise from the perspective of practical achievability.</p> <p>In contrast, the rejection rates for Scenario 2 MLs may be as high as 27%; this is considered an unreasonable level of rejection in the absence of any identified public health and safety concern.</p> <p><u>Proportionality</u></p> <p>Australia is of the view that the proportionality approach 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. For chocolates ≥30% to &lt;50% tcs, Scenario 1 MLs are considered valid from a proportionality perspective. An ML of 0.5 mg/kg derived in Scenario 2 using the proportionality approach is, however, difficult to justify in light of the high rejection rates (up to 20.53% for LAC).</p> <p>Australia notes that whilst it is important to have regard to the proportionality concept, it may not be as applicable when considering MLs for cocoa powder against those for chocolate. This is because these products are very different in their composition and are used/consumed in different ways. As a concentrated source of cocoa solids, cocoa powder may be used in a variety of food applications (e.g. baking, icing, beverage powder etc.).</p>	

COMMENTS	MEMBER/OBSERVER
<p>It is therefore not possible to determine its final destination nor the concentrations in which it is used. It is likely to be diluted in water/milk or added as an ingredient in recipes in small amounts, rather than eaten as is. For this reason, Australia is of the view that setting an ML for cocoa powder that is based on the proportionality approach designed for chocolates with varying levels of total cocoa solids is not wholly appropriate. In addition, as mentioned above, Scenario 2 MLs would see unacceptable rates of rejection for cocoa powder products in the absence of any public health and safety concern.</p>	
<p>Canada suggests suspending the work to elaborate an ML for cocoa powder and revisiting it in 3 to 5 years after the CoP for cadmium in cocoa and chocolate is finalized and implemented.</p> <p>Evaluating more recent cocoa powder data in a few years time would allow for the discrepancy in the hypothetical MLs based on the actual cocoa powder data and the MLs estimated based on proportionality to be reconciled. The lack of alignment of these MLs suggests that the data from GEMS/Food being used to propose hypothetical MLs may not be fit for purpose.</p> <p>Future calls for data should require information on the percent cocoa solid content and if the product is ready for consumption to be included, which would strengthen the dataset used to propose an ML and would help reconcile the question regarding the naming of this product category.</p>	Canada
<p>Chile está de acuerdo con un nivel máximo para cacao en polvo con 100% del total de sólidos de cacao, de 1,3 ppm, lo anterior, ya que se refleja de mejor manera el principio de proporcionalidad.</p>	Chile
<ul style="list-style-type: none"> <li>• The United States does not object to the ML range of 1.3-1.5 mg/kg (Scenario 2) that is supported by a proportionality approach, given 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.</li> <li>• The United States considers the proposed ML range of 2.0-3.0 mg/kg (Scenario 1) to be too high in comparison to established MLs.</li> </ul>	USA
<p>Consider Scenario 1, with 2 – 3 mg/kg ML</p>	IAEA
<p><u>Category 100% cocoa powder</u>: In 2013, JECFA77 concluded that cadmium in cocoa is not a priority concern for health, and with the new data on global occurrence and exposure JECFA91 again concludes that cocoa and cocoa products present low exposure risk.</p> <p>We believe the establishment of a ML for 100% cocoa powder based on global achievability data is technically appropriate. This would have no significant effect on dietary exposure concerns, 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.</p> <p>Based on the data assessed and provided in the new document, in view of achievability challenges identified by the EWG, we can support the range listed in the Scenario 1 option, for achievability across the regions, 2.0 mg/kg - 3.0 mg/kg for the category 'cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption'.</p>	FoodDrinkEurope

COMMENTS	MEMBER/OBSERVER
<p>Based on the data assessed and provided in the new document, in view of achievability challenges identified by the EWG, we can support the range listed in the Scenario 1 option, for achievability across the regions, 2.0 mg/kg - 3.0 mg/kg for the category 'cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption'. Importantly, the Scenario 2 proposing 1.3 - 1.5 mg/kg for this same category is clearly unachievable based on the data and unacceptable rejection rates, much higher than the 5% guideline used by Codex.</p> <p>The proportionality basis is mis-informed, as explained above, as it does not take into account the low proportion of cocoa butter in 100% cocoa powder, compared with chocolate, such as in chocolate bars. The proportionality-based range for non-fat cocoa solids in cocoa powder would be 2.6 – 3.0 mg/kg. There is no health reason in this case to set a ML that is disproportionate to the occurrence data or the science-based low risk.</p>	ICA

**3(a) Reconsider the name of the category "cocoa powder (100% total cocoa solids based on dry matter) ready for consumption":** Taking into account that more than 80% of the data available in GEMS / Food does not show the declared percentage of cocoa content in the analyzed samples, nor is it detailed if they are intermediate or final products, it is recommended to change the name of the category so that all available data can be used to establish an ML.

**3(b) The possibility of including all available data on powdered products for the establishment of ML(s) for cocoa powder since data available on GEMS/Food do not have the declared percentage of cocoa content in the samples analyzed.**

COMMENTS	MEMBER/OBSERVER
<p><u>3(a) Reconsider the name of the category "cocoa powder (100% total cocoa solids based on dry matter) ready for consumption":</u> Taking into account that more than 80% of the data available in GEMS / Food does not show the declared percentage of cocoa content in the analyzed samples, nor is it detailed if they are intermediate or final products, it is recommended to change the name of the category so that all available data can be used to establish an ML.</p> <p>Australia acknowledges that the reliability of the cocoa powder data 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').</p> <p>However, Australia would be grateful for clarification of the proposal being put forward by the eWG, in particular:</p> <ul style="list-style-type: none"> <li>• Is the eWG seeking to reinstate discarded data that claimed to be mixtures of cocoa with sugars and other added ingredients (as described in paragraph 20)?</li> <li>• What is the proposed new name for this category of cocoa powder products?</li> </ul> <p>Depending on the answers to the above two questions, Australia questions the proposed course of action and is concerned that it may only further delay the establishment of an ML for this category.</p> <p>Australia queries whether a possible way forward would be to conduct an analysis of the subset of cocoa powder data available in GEMS/Food that does show the declared percentage of cocoa content in the analysed samples, as a means of validating the analyses conducted on the full data set of 5781.</p>	Australia
<p><u>3(b) The possibility of including all available data on powdered products for the establishment of ML(s) for cocoa powder since data available on GEMS/Food do not have the declared percentage of cocoa content in the samples analyzed.</u></p> <ul style="list-style-type: none"> <li>• Overall (and notwithstanding the comments regarding cocoa powder), Australia considers there are adequate data to advance the establishment of MLs for these remaining categories.</li> <li>• Australia has no objections to using the standard deviation approach in an effort to remove outliers and enhance the homogeneity of the cocoa powder dataset.</li> <li>• Australia would welcome more details on the determination of MLs by the proportionality approach.</li> <li>• Australia notes that a new evaluation by JECFA (2021) has concluded that cadmium exposure 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.</li> <li>• On the basis of the above, Australia supports MLs at the higher end of the proposed ranges for Scenario 1. These are a reasonable global compromise from the perspective of practical achievability and, in the case of chocolates with ≥30% to &lt;50% tcs, are still valid from a proportionality perspective. The proposed MLs offer a degree of flexibility when compared with that set in the Australia New Zealand Food Standards Code.</li> </ul> <p>We trust that this information is useful and we wish you all the best in your further consideration of this issue.</p>	

COMMENTS	MEMBER/OBSERVER
<p><u>Editorial revisions</u></p> <p><u>Table 1:</u> The second and third column headings should be revised to indicate that the numbers presented in these columns represent the number of samples that were present in GEMS/Food before and after the latest (2020) call for data.</p> <p><u>Figure 1:</u> The figure and associated text (i.e. paragraph 14) should be revised to indicate the correct chocolate categories i.e. &lt;30% tcs, ≥30 to &lt;50% tcs etc.</p> <p>Certain variables appear to be missing or else out of alignment including:</p> <p>ML for chocolate &lt;30% tcs should be at 0.3 mg/kg  ML for chocolate ≥70% tcs is missing  ML for chocolate ≥50 - &lt;70% tcs should be at 0.8 mg/kg</p> <p>For the ML of 0.6 mg/kg, the black line appears to sit at around 14% rather than the calculated level of 10.39%</p> <p><u>Table 4:</u> Australia queries the need to present Table 4 as it appears to replicate all of the information already provided in Table 3 with the exception of the blue banding.</p> <p>Paragraph 19    Second line, 10.23 should read 10.39%.  Paragraph 22    The reference to Table 1 should be revised to refer to Table 1 of CX/CF 20/14/6.  Paragraph 30    The reference to Table 6 should be revised to refer to Table 7.</p> <p><u>Table 6 and Table 8:</u> With regards to Asia, possible rejected samples (%) for the ML Scenario of 1.6 mg/kg are different. In Table 6, the value given is 0.891%, whilst in Table 8, the value is 0.223%. It would appear that the Table 6 value is incorrect.</p>	<p><b>Australia</b></p>
<ul style="list-style-type: none"> <li>• The United States does not recommend renaming the category, which was agreed to after much consideration at previous sessions.</li> <li>• The United States agrees with the EWG that it was appropriate, in developing the ML, to consider all data for cocoa powder samples that did not list other ingredients in the GEMS/Food database.</li> <li>• Member countries can determine how to apply any established ML to products where 100% cocoa powder is diluted with other ingredients.</li> </ul>	<p><b>USA</b></p>
<p>Renaming the category would be a temporary measure; assumes that new data including declarations is not possible</p>	<p><b>IAEA</b></p>