

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

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TO Codex Contact Points
Contact Points of international organizations having observer status with Codex

FROM Secretariat,
Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Program

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

DEADLINE **10 November 2019**

BACKGROUND

1. The 73rd Meeting of the Joint FAO/WHO Committee on Food Additives (JECFA73, 2010) re-evaluated cadmium in foods at the request¹ of 3rd Session of the Codex Committee on Contaminants in Foods (CCCF03, 2009). The outcome² of the evaluation indicated that exposure estimates considering different age groups and dietary habits resulted in no exceedance of the new provisional tolerable monthly intake (PTMI) of 25 µg/kg bw established by JECFA at this Meeting. Consequently, CCCF05 (2011) agreed³ that no follow-up action was necessary in relation to the maximum levels (MLs) for cadmium in various foods in the Codex General Standards for Contaminants and Toxins in Food and Feed (GSCTFF) (CXS 193-1995).
2. Following a further request⁴ from CCCF06 (2012) for an exposure assessment to cadmium from cocoa and cocoa products, the JECFA Secretariat informed CCCF08 (2014) that JECFA77 (2013) concluded⁵ that total cadmium exposure including for high consumers of cocoa and cocoa products was not considered to be of concern.
3. Following the outcome of the JECFA77 evaluation, CCCF08 considered a proposal from Ecuador to establish MLs for cadmium in chocolates and cocoa-derived products. Ecuador indicated⁶ that while the evaluation of JECFA77 had noted that the intake of cadmium from the consumption of chocolate and cocoa-derived products was not a health concern, the lack of an ML for cadmium in cocoa and its derived products could threaten exports from some Member Countries, especially developing countries who were the major exporters of cocoa. Ecuador further explained that following the JECFA advice, proposals for MLs for cadmium in chocolates and cocoa-derived products for consideration by CCCF would be derived based on achievability with minimum negative impact on trade.
4. CCCF08 agreed⁷ to initiate new work on MLs on cadmium in chocolates and cocoa-derived products. The 37th Session of the Codex Alimentarius Commission (CAC37, 2014) approved⁸ the new work.
5. CCCF considered the product categories for which MLs should be established at its 9th (2015)⁹, 10th (2016)¹⁰, 11th (2017)¹¹, 12th (2018)¹² and 13th (2019)¹³ sessions.

¹ REP09/CF, paras. 119-120, Appendix XI;
REP10/CF, para. 100, Appendix VIII

² REP11/CF, para. 14; CX/CF 11/5/3

³ REP11/CF, para. 95

⁴ REP12/CF, paras. 159, 161-163, Appendix XI;
REP13/CF, paras. 13, 142, 144-146

⁵ REP14/CF, paras. 6-7; CX/CF 14/8/3

⁶ REP14/CF, para. 141

⁷ REP14/CF, paras. 141-142, Appendix XI

⁸ REP14/CAC, Appendix VI

⁹ REP15/CF, paras. 52-55;

¹⁰ REP16/CF, paras. 101-119

¹¹ REP17/CF, paras. 90-99

¹² REP18/CF, paras. 47-68

¹³ REP19/CF, paras. 45-56

6. CCCF11 (2017) agreed¹⁴ on the categories of chocolates for which MLs would be established. CCCF12 (2018) further agreed¹⁵ on the cocoa-derived products for which MLs would be established and forwarded¹⁶ the following MLs for certain categories of chocolates for adoption by CAC41 (2018).

- ML of 0.9 mg/kg for chocolates containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis
- ML of 0.8 mg/kg for chocolates containing or declaring $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis

7. CAC41 adopted¹⁷ the above MLs as proposed by CCCF12.

8. CAC41 further noted¹⁷ the reservation of Peru as the MLs were too restrictive and would have negative socioeconomic implications for cocoa growers, especially smallholder farmers. Peru enquired¹⁷ whether JECFA could re-evaluate the PTMI due to its provisional nature and in the light of new scientific evidence and noted that the application of a COP could assist countries in reducing cadmium contamination in cocoa beans.

9. The JECFA Secretariat explained¹⁷ that “provisional” was standard terminology and did not imply the value had temporary status, and noted that the PTMI, since it had been recently reviewed, based on a large, worldwide dataset covering several years, was unlikely to be influenced by any new data that may have become available since the last evaluation.

10. CCCF13 (2019) considered MLs for remaining categories of chocolates and cocoa-derived products. In response to a request for a new evaluation by JECFA as one alternative to the establishment of MLs, the JECFA Secretariat clarified that he 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.

11. There was general agreement to consider the MLs on a proportional basis to the existing MLs (adopted at CAC41) while recognizing the need for some flexibility in the proportionality between the MLs for the different chocolate categories to avoid very high rejection rates.

12. When considering MLs for the category of chocolate containing or declaring $<30\%$ total cocoa solids on a dry matter basis, there was general support for the proposed ML of 0.3 mg/kg recognizing that there was a good proportional distribution of geographic data with a relatively low rejection rate on a worldwide basis (3.2%) although it was noted that this would result in higher rejection rates of 12% in particularly the Latin American and Caribbean region.

13. CCCF13 agreed to advance the ML of 0.3 mg/kg for chocolates containing or declaring $<30\%$ total cocoa solids on a dry matter basis for adoption at Step 5/8 by CAC42 and noted the reservations of the European Union (EU), Norway and Ecuador to this decision.

14. The European Union could not support the proposed ML as in the EU a more conservative HBGV was in place. For the EU risk assessment, it had been shown that for certain vulnerable groups the health-based guidance value (HBGV) could be exceeded up to six-fold; and that in terms of exposure of children to cadmium, strict levels had been set in the EU for chocolate products containing less than 50% total cocoa solids on a dry matter basis and for cocoa powder which was used as an ingredient in chocolate milks consumed by children. Ecuador also could not support this ML because of the high rejection rates for the Latin American and Caribbean region.⁻¹⁸

15. CAC42 (2019) held extensive discussions on the proposed ML of 0.3 mg/kg for chocolates containing or declaring $<30\%$ total cocoa solids on a dry matter basis. As there was no consensus on the final adoption, the proposed ML was adopted at Step 5 which would allow for further discussion at CCCF and noted the reservations of EU, Norway and Switzerland as, based on the European Food Safety Authority (EFSA) opinion, only a stricter ML of 0,1 mg/kg can ensure sufficient protection of all consumers, in particular of children. CAC42 agreed that discussion would be limited to the ML of 0.3 mg/kg for chocolates containing or declaring $<30\%$ total cocoa solids on a dry matter basis. The concept of proportionality as agreed by CCCF with respect to the adopted MLs by CAC41 should be maintained. If new additional information provided does not justify a change to the ML, CCCF14 will recommend the adoption of the ML of 0.3 mg/kg by CAC at its next session.

16. CAC42 confirmed that upon such recommendation by CCCF14, CAC43 shall adopt the ML without further discussion. Reservations were expressed to this decision.¹⁹

¹⁴ REP17/CF, para. 97, Appendix XIII

¹⁵ REP18/CF, para. 63

¹⁶ REP18/CF, para. 67, Appendix III

¹⁷ REP18/CAC, paras. 29-32, Appendix III

¹⁸ REP19/CF, paras. 45-56, Appendix III

¹⁹ REP19/CAC, paras. 52-67, Appendix III

REQUEST FOR COMMENTS

17. Codex member countries and observer organizations are kindly invited to provide their comments at Step 6 on the draft ML of 0.3 mg/kg for chocolates containing or declaring <30% total cocoa solids on a dry matter basis by providing technical justification from the point of view of protecting consumers' health and ensuring fair practices in trade (see Appendix).

18. When submitting comments on this CL, Codex members and observers are kindly invited to consider the outcomes of the JECFA73 and JECFA77 evaluations on cadmium, the proportionality concept between the MLs for the different categories of chocolates and cocoa-derived products agreed to by CCCF13, the discussions held, and decisions made on this ML at CCCF13 (2019) and CAC42 (2019).

19. In addition, Codex members and observers are kindly invited to provide further occurrence data on cadmium in chocolates containing or declaring < 30% total cocoa solids on a dry matter basis in reply to the JECFA Call for Data²⁰ (Deadline 10 November 2019) available from the FAO and WHO websites to facilitate the consideration of this ML at CCCF14 (2020).

GUIDANCE ON THE PROVISION OF COMMENTS THROUGH THE OCS

20. The draft ML of 0.3 mg/kg for chocolates containing or declaring <30% total cocoa solids on a dry matter basis is uploaded to the Codex Online Commenting System (OCS): <https://ocs.codexalimentarius.org/>, as per the guidance below.

21. Comments should be submitted through the Codex Contact Points of Codex members and observers using the OCS.

22. Contact Points of Codex members and observers may login to the OCS and access the document open for comments by selecting "Enter" in the "My reviews" page, available after login to the system.

23. Contact Points of Codex members and observer organizations are requested to provide proposed changes and relevant comments/justifications on a specific paragraph (under the categories: editorial, substantive, technical and translation) and/or at the document level (general comments or summary comments). Additional guidance on the OCS comment categories and types can be found in the OCS Frequently Asked Questions (FAQs).

24. Other OCS resources, including the user manual and short guide, can be found at the following link: <http://www.fao.org/fao-who-codexalimentarius/resources/ocs/en/>.

25. For questions on the OCS, please contact Codex-OCS@fao.org.

²⁰ FAO website: <http://www.fao.org/food/food-safety-quality/scientific-advice/calls-data-experts/en/>
WHO website: <https://www.who.int/foodsafety/call-data/en/>

APPENDIX**REQUEST FOR COMMENTS AT STEP 6
DRAFT MAXIMUM LEVEL FOR CADMIUM IN CHOCOLATES
CONTAINING OR DECLARING <30% TOTAL COCOA SOLIDS ON A DRY MATTER BASIS**

| Commodity/Product Name | ML (mg/kg) | Notes/Remarks |
|--|-----------------------|---|
| Chocolates containing or declaring <30% total cocoa solids on a dry matter basis | 0.3 | Including milk chocolate, family milk chocolate, milk chocolate couverture, Gianduja milk chocolate, table chocolate, milk chocolate Vermicelli/milk chocolate flakes |