

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



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Organization

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Agenda Item 10

CX/CF 18/12/10

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

Twelfth Session  
Utrecht, The Netherlands, 12 - 16 March 2018

### PROPOSED DRAFT MAXIMUM LEVEL FOR AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLANS

*(Prepared by the Electronic Working Group led by India)*

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2018/6-CF available on the Codex webpage/Circular Letters:  
<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.

#### I. BACKGROUND

1. India presented a new work proposal for establishing a Maximum Level (ML) for total aflatoxins (AFT) in Ready-to-Eat (RTE) Peanuts at the 7<sup>th</sup> Session of the Committee on Contaminants in Foods (CCCF). The Committee established an Electronic Working Group (EWG) led by India to prepare a discussion paper for consideration at CCCF8 defining the issue, identifying available data and specifying data requirements for establishing an ML for AFT in RTE peanuts. CCCF8 considered the discussion paper and agreed to initiate new work, re-establishing the EWG led by India to prepare a proposal for comments and considerations at CCCF9. The 37<sup>th</sup> Session of the Codex Alimentarius Commission (CAC) approved this new work. (REP14/CF, paras 119-120, Appendix X; REP14/CAC, para. 96, Appendix VI)
2. The EWG members and observers submitted data and comments to support the consideration of possible MLs for AFT in RTE Peanuts. The EWG summarized the discussion and recommended a concentration of 10 µg/kg for the ML, in line with comparable MLs in tree nuts ("ready-to-eat"), for consideration by the CCCF9. This ML was to use existing Codex methods of sampling as given in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) currently being practiced. It was suggested that the CCCF should consider requesting that JECFA perform an exposure assessment to determine the health impact of proposed MLs for AFT in RTE Peanuts.
3. CCCF9 agreed to request that the Joint FAO/WHO Committee on Food Additives (JECFA) conduct an exposure assessment to determine the health impact and to calculate potential violation rates based on hypothetical MLs of 4, 8, 10 and 15µg/kg AFT in RTE Peanuts. It was further agreed that work on the ML for AFT in RTE Peanuts would resume once the JECFA assessment became available. (REP15/CF, paras 98-100)
4. CCCF10 recalled the decision and held the proposal pending the outcome of the JECFA assessment. Noting that this would be addressed at the 83<sup>rd</sup> JECFA Meeting, the Committee agreed that India, being the EWG leader, would prepare a proposal to establishing an ML for AFT in RTE Peanuts taking into account the outcome of the assessment from JECFA83 for consideration by CCCF11. (REP16/CF, para. 170)
5. JECFA83 performed an assessment of hypothetical MLs 4, 8, 10 and 15µg/kg of AFT in RTE Peanuts and concluded that enforcing an ML of 10, 8 or 4µg/kg in RTE peanuts would have little further impact on reducing dietary exposure to aflatoxins for the general population, compared with setting an ML of 15µg/kg. At an ML of 4µg/kg, the proportion of the world market of RTE peanuts rejected would be approximately double the proportion rejected at an ML of 15µg/kg (about 20% versus 10%).
6. Based on the JECFA83 outcome, the EWG proposed an ML of 15µg/kg of AFT in RTE Peanuts be considered by CCCF11. The Committee did not reach a consensus, however, agreed to request comments from members and observers in support of an ML of AFT in RTE Peanuts of either 15 µg/kg or 10 µg/kg.
7. CCCF11 kept [10 µg/kg or 15 µg/kg] in square brackets and sought comments of members and observers accompanied by rationale for the ML and any additional information to support the proposed ML. The EWG led by India was re-established to prepare a revised proposal for further comments and consideration by CCCF12. (REP17/CF, para. 108, Appendix IV).

8. Therefore, a circular letter, CL 2017/57-CF, was issued in May 2017 inviting comments through the Codex Online Commenting System (OCS) by 31st August, 2017 and EWG was re-established.
9. During the OCS compilation, comments were received from 16 member countries and observers. Out of these 16 respondents, 7 respondents (5 member countries and 2 observers) expressed support for the ML of 15 µg/kg for AFT in RTE Peanuts, 6 respondents (5 member countries and 1 member organization) expressed support for an ML of 10 µg/kg, and 3 member countries did not support either of the ML.
10. Those who have supported the ML of 15 µg/kg provided justification on the basis of the outcome of the JECFA83 report, which concluded that there would be minimal further reduction in dietary exposure to AFT if an ML was set at 10 µg/kg compared with 15 µg/kg, however, the rejection rate of RTE Peanuts would be higher with an ML of 10 µg/kg versus an ML of 15 µg/kg. Therefore, setting an ML of 15 µg/kg for AFT in RTE Peanuts would be of benefit to international trade without further compromising the consumer's health as compared to an ML of 10 µg/kg.
11. Those who supported the ML of 10 µg/kg were of the view that MLs should be established on the basis of the ALARA (as low as reasonably achievable) principle at levels necessary to protect the consumer as specified in the "Criteria for the Establishment of Maximum Levels in Food and Feed" in the GSCTFF (CXS 193-1995).
12. Out of the remaining 3 member countries, one expressed an opinion that the ML for AFT in RTE Peanuts should not exceed the ML set for peanuts intended for further processing, namely 15 µg/kg. Another member country was of the view that the ML of AFT in RTE Peanuts should be stricter than that of RTE Pistachios (10 µg/kg), as Aflatoxin intake from Peanuts is greater than Aflatoxins intake from Pistachios based on the consumption patterns of both commodities. And, one respondent suggested an ML of 4 µg/kg for AFT in RTE Peanuts, as the proposed ML appear to be high. However, the current circular letter specifically requested comments on the two MLs of 10 µg/kg or 15µg/kg, as agreed in the 11th Session of CCCF.

## II. FIRST ROUND OF CONSULTATION

13. Subsequently, an EWG was established. The list of participants can be found in Appendix II. A first draft proposal was prepared based on the comments received through OCS (CL 2017/57-CF) and circulated to all EWG members for first round of consultation for considering the establishment of ML of 15 µg/kg for AFT in RTE Peanuts.
14. In the first draft proposal, the EWG members were requested to consider the following paragraph from CXS 193-1995-Annex I, third point of the second paragraph under the heading "Establishment of MLs":

*"MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade. Where possible, MLs should be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable and necessary to protect the consumer. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and significant economic aspects are at stake"*
15. It was also mentioned that JECFA83 concluded that enforcing an ML of 10, 8 or 4 µg/kg for RTE Peanuts would have little further impact on dietary exposure to AFT for the general population, compared with setting an ML of 15 µg/kg, however, the rejection rate of 9.7% at an ML of 15 µg/kg increased to 12.6% at an ML of 10 µg/kg (JECFA83 report).
16. In the first round of consultation, comments were received from 10 member countries and 2 observer organizations. Out of 12 respondents, 4 member countries and 2 observer organizations supported setting an ML of 15 µg/kg for AFT in RTE Peanuts whereas 6 member countries were not supporting setting an ML of 15 µg/kg for AFT in RTE Peanuts.

## III. ANALYSIS OF COMMENTS RECEIVED FROM EWG MEMBERS AFTER FIRST ROUND OF CONSULTATION

17. The following justifications are provided by those member countries who are supportive of setting an ML of 15 µg/kg AFT in RTE Peanuts:

- As concluded in the JECFA83 assessment, there would be minimal further reduction in dietary exposure to AFT if an ML was set at 10 µg/kg compared with 15 µg/kg, however, the rejection rate of RTE Peanuts would be higher with an ML of 10 µg/kg versus an ML of 15 µg/kg.
  - An ML of 15 µg/kg lowered the rejection rate, as compared with 10 µg/kg by nearly 3%. One country informed that a 3% increase in the rejection rate would result in loss from international trade of about 100,000 metric tons of RTE Peanuts, with a trade value of about US\$ 140 million (Global Trade Information Services for Calendar Year 2016, paid subscription).
  - A lower rejection rate increases supply in order to meet the rising demand for RTE peanuts and is expected to lower prices in favour of the consumer.
  - A higher rejection rate would in turn contribute to food waste and have a negative impact on trade without a corresponding public health benefit.
18. The following justifications are provided by those member countries who are supportive of setting an ML of 10 µg/kg AFT in RTE Peanuts:
- An ML for RTE Peanuts should be set lower than the ML for AFT in Peanuts destined for further processing which was already established as 15µg/kg and mitigation measures of Aflatoxins level in Peanuts destined for further processing could be adopted as per *Code of Practice for the Prevention and Reduction of Aflatoxins Contamination in Peanuts* (CXC 55-2004).
  - The approach of setting MLs for AFT in Peanuts (destined for further processing) and RTE Peanuts should be consistent with the approach already taken for setting Codex MLs for Almonds, Brazil nuts, Hazelnuts and Pistachios. All existing Codex MLs for AFT in RTE Tree nuts are set lower than MLs for that intended for further processing.
  - An ML of Aflatoxin in Peanuts should be set as low as possible taking into account genotoxicity (carcinogens) of Aflatoxins and the fact that Peanuts can be one of the main contributors to total exposure to AFT in certain parts of the world.
  - The establishment of MLs is not only to be based on exposure assessment by JECFA but has to take into account all the criteria for the establishment of ML in food and feed mentioned in point 1.3.3 and elaborated in more detail in the Annex I of CXS 193-1995. In this case it is especially important to consider impact on any population groups which are especially vulnerable, risk management options and considerations including consideration of alternative solutions.
  - GEMS/Food did not differentiate between RTE Peanuts and Peanuts for further processing. In addition, the data may be biased due to the prevalence of occurrence data collected from developed countries on Peanuts from different parts of the world. While the general bias and uncertainty that ensues, there is still an underestimation of the potential in public health protection that could be part of the introduction of lower MLs.

#### IV. SECOND ROUND OF CONSULTATION

19. In the second draft proposal, EWG members were requested to consider an ML of 10µg/kg for AFT in RTE Peanuts keeping in view maintaining consistency with the past approach taken by Codex for other Tree nuts. Comments were received from 9 member countries and 2 observer organizations during second round of consultation.
20. There is general support to the proposal of establishing an ML of 10µg/kg for AFT in RTE Peanuts.
21. Two member countries and two member organizations are in support of establishing an ML of 15 µg/kg AFT in RTE Peanuts referring JECFA83 assessment. Out of two member countries who supported an ML of 15 µg/kg, one member is of the view that MLs for AFT in Peanuts intended for further processing be reviewed if an ML of 15 µg/kg for AFT in RTE Peanuts is to be established and the biases in the JECFA assessment (REP17/CF) regarding the geographic representation of the data and differentiation of peanuts intended for further processing from those that are RTE should be addressed prior to an ML being forwarded to the Commission for adoption.
22. One member country also suggested, as a consensus, a range of 10 - 15µg/kg for AFT on RTE peanuts could be considered.

**V. CONCLUSION**

23. In view of the above, it appears that there is general consensus for the ML of 10 µg/kg for AFT in RTE Peanuts considering carcinogenicity of AFT and consistency of approach already taken by Codex for establishing MLs of AFT for other Tree nuts.
24. As regards the comment mentioned in paragraph 21 above, it may be mentioned that while noting the intervention of JECFA secretariat in the CCCF11 (REP17/CF, para 107) in this context, the Committee agreed to request comments on the levels of 10 µg/kg or 15 µg/kg at step 3
25. In accordance with majority view, fixing an ML for AFT in RTE peanuts at 10 µg/kg appears to be a feasible outcome which would address the immediate trade concerns as well as safety concerns vis a vis further deferment of setting up ML for AFT in RTE peanuts.

**VI. RECOMMENDATION**

26. In light of the conclusions at paragraphs 23-25, and in accordance with the mandate of the EWG (REP17/CF, para 108), EWG proposes that CCCF12 recommends an ML of 10 µg/kg for AFT in RTE Peanuts for adoption by CAC as presented in Appendix I.

**APPENDIX I****PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS  
AFLATOXINS, TOTAL**

<b>Commodity / Product Name</b>	<b>Maximum Level (ML) µg/kg</b>	<b>Portion of the Commodity / Product to which the ML applies</b>	<b>Notes / Remarks</b>
Peanuts	10		The ML applies to peanuts "ready to eat"

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