CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 10 **CX/CF 22/15/10**

March 2022

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

15th Session
Virtual
9-13 and 24 May 2022

MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN

(Prepared by the Electronic Working Group led by India)

Codex members and observers wishing to submit comments at Step 3 on this document should do so as instructed in CL 2022/19-CF available on the Codex webpage[1]

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 7th session of the Codex Committee on Contaminants in Foods (CCCF07, 2013). The Committee established an Electronic Working Group (EWG) led by India to prepare a discussion paper for consideration at CCCF08 (2014) defining the issue, identifying available data and specifying data requirements for establishing an ML for AFT in RTE peanuts.[2]

2. CCCF08 (2014) 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 CCCF09 (2015).[3] The 37th Session, the Codex Alimentarius Commission (CAC37, 2014) approved this new work.[4]

3. 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 an ML of 10 µg/kg, in line with comparable Codex MLs in tree nuts ("ready-to-eat"), for consideration by CCCF09 (2015). The existing Codex methods of sampling for peanuts for further processing detailed in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) currently being utilized would suffice for this category as well taking into account the old and new data were provided applying the same method of sampling by the members. It was suggested that the CCCF should consider requesting that JECFA perform an exposure assessment to determine the health impact of proposed ML for AFT in RTE peanuts.

4. CCCF09 (2015) agreed to request that the Joint FAO/WHO Expert Committee on Food Addirives (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.[5]

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1 Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.
Codex webpage/CCCF/Circular Letters:
http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF

2 REP13/CF07, paras. 149-151

3 REP14/CF08, paras. 115-120, Appendix X

4 REP14/CAC37, Appendix VI

5 REP15/CF09, paras. 92-100

5. CCCF10 (2016) recalled the decision to request a JECFA assessment and held the work on an ML proposal at Step 4 pending the outcome of the JECFA assessment. Noting that this would be addressed at the 83rd Meeting of JECFA (JECFA83, 2016), the Committee agreed that India, being the EWG chair, would prepare a proposal to establishing an ML for AFT in RTE Peanuts taking into account the outcome of JECFA83 assessment for consideration by CCCF11 (2017).[6]

6. 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 4 µg/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 4 µg/kg, the proportion of the world market of RTE peanuts rejected would be approximately double the proportion rejected at an ML of 15 µg/kg (about 20% versus 10%). Based on the JECFA83 outcome the EWG proposed an ML of 15 µg/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]

7. CCCF11 (2017) kept the MLs of 10 µg/kg or 15 µg/kg in square brackets and sought comments from 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 (2018).[8] A Circular Letter, CL 2017/57-CF was issued[1] and the EWG was re-established.

8. 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 organisation) expressed support for an ML of 10 µg/kg, and 3 member countries did not support either of the MLs.

9. Those who 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 (12.6%) versus an ML of 15 µg/kg (9.7%). 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. Those who supported the ML of 10 µg/kg were of the view that ML 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 *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

10. Out of the remaining 3 member countries who commented, one expressed an opinion that the ML for AFT in RTE peanuts should not be higher than 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 aflatoxin intake from pistachios based on the consumption patterns of both commodities. In addition, one respondent suggested an ML of 4 µg/kg for AFT in RTE peanuts, as the proposed ML appeared to be high. However, the circular letter specifically requested comments on the two MLs of 10 µg/kg or 15µg/kg, as agreed at CCCF11.

11. Subsequently, an EWG was established and following two rounds of consultations, the EWG recommended an ML of 10 µg/kg for AFT in RTE peanuts. The full discussion and considerations are presented in working document CX/CF 18/12/10[9].

12. CCCF12 concluded to hold the proposed ML AFT RTE Peanuts 10 µg/kg at Step 4 to ensure implementation of the *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts* (CXC 55-2004), JECFA would issue a call for data in three years' time and an EWG would be re-established, once the data were submitted to prepare a proposal for consideration by CCCF15. It was clarified that data should be specifically for RTE peanuts and as moved in trade and that the data should clearly indicate if they referred to RTE or for further processing such as oil production or for feed.[10]

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6 REP16/CF10, paras. 170 & 173

7 The summaries and full reports of JECFA meetings are available at the relevant FAO and WHO sites:
FAO: http://www.fao.org/food-safety/resources/publications/en/
WHO: www.who.int/foodsafety/publications/jecfa/en/

8 REP17/CF, para. 108, Appendix IV

9 Working papers for CCCF12 (2018), including CX/CF 18/12/10, are available from the CCCF12 website:
https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCCF&session=12

10 REP18/CF12, paras. 103-115, Appendix VII

13. CCCF14 (2021) agreed to re-establish the EWG led by India to consider new/additional GEMS/Food data only and take into account old and new data for comparison, update the working paper (CX/CF 18/12/10) that was presented at CCCF12; and prepare a revised proposal for ML for AFT in RTE peanuts and associated sampling plan for comments for consideration by CCCF15 taking into consideration the outcome of the impact assessment conducted by JECFA83 and the new and old datasets available on GEMS/Food for further consideration by the EWG.[11]

II. Process followed by EWG

14. A circular letter for nomination of EWG participants from members and observers was issued by the Codex Secretariat. Seventeen members and four observer organisations registered for teh EWG.

15. Available GEMS/Food data from the year 2011 to 2020 was shared for analysis of the EWG. It was clear to the EWG that the data from 2017 onwards submitted by members was data submitted after implementation of the CoP and as noted by CCCF12 and CCCF14, for resuming deliberations, should be based on new/additional data submitted by the members to GEMS/Food. GEMS/Food old and new data from the year 2011 to 2020 was critically reviewed taking into consideration as noted by CCCF14.

16. The first draft of the report for discussion in the EWG was prepared and circulated to members and observers l. Comments from five member organization were received. The comments were reviewed and incorporated in the EWG report for submission to the Codex Secretariat. The considerations and discussion are provided in Appendix II.

III. Conclusion

17. The EWG concludes that there is sufficient justification to recommend an ML ≥10 to < 15 µg/kg for AFT in RTE Peanuts considering the carcinogenicity of AFT and the conclusion of JECFA 83. However based on the consistency of approach already taken by Codex for establishing MLs of AFT for tree nuts (i.e. 10 µg/kg for RTE & 15 µg/kg for further processing) and considering the fact that aflatoxin in peanuts intended for further processing has already an ML of 15 µg/kg , the EWG proposes an ML of either 10 µg/kg or 12 µg/kg for the RTE Peanuts (Appendix I) with existing *sampling* plan for peanuts for further processing as given in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) to apply also for RTE Peanuts also taking into account the followings:

    i) The old and new GEMS/Food data sets for determining ML of AFT in RTE Peanuts are based on the existing method of sampling and that

    ii) CCCF may consult with the Codex Committee on Methods of Analysis and Sampling (CCMAS) to review the entire sampling plan for update after the ML for AFT in RTE peanuts and other products under consideration of CCCF are adopted.

IV. Recommendation

18. CCCF is invited to consider:

    a. an ML of AFT in RTE peanuts either 10µg/kg or 12 µg/kg (Appendix I) based on the considerations provided in paragraph 17 and the data/information provided in Appendix II;

    b. the recommendation to apply the sampling plan for AFT in peanuts intended for further processing, as described in *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), also to RTE peanuts, based on the considerations provided in paragraph 17 (i-ii); and

    c. the advancement of the ML to final adoption by CAC45 (2022).

[11] REP21/CF14, paras. 139-145

APPENDIX-I

PROPOSED MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS

(For comments)

Commodity / Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity / Product to which the ML applies	Notes / Remarks
Peanuts	either 10 or 12	Unless specified, seed or kernels with or without shell	The ML applies to peanuts labelled as "ready-to-eat"

APPENDIX II

DISCUSSION PAPER ON THE ESTABLISHMENT OF A MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS
(For information)

1. The differentiation of GEMS/Food data provided to the Electronic Working Group (EWG) was categorised in two segments one prior to the 83rd Meeting of the Joint FAO/WHO Expert Meeting on Food Additives in November 2016 assessment and 2017 onwards after implementation of *Code of Practice for the prevention and reduction of Aflatoxin contamination in peanuts* (CXC 55-2004) by the Codex members. The Electronic Working Group (EWG) analyzed GEMS/Food data for the years 2017, 2018, 2019 and 2020 taking followings into consideration:

i) The outcome of the impact assessment conducted by JECFA83-November 2016

ii) The new 65 041 analytical data from GEMS/Food for the years 2017, 2018, 2019 and 2020 after implementation of COP as per the following distribution:

Table 1: Distribution of the occurence data submitted to GEMS/Food for the years 2017, 2018, 2019 and 2020

Year of sample	Regions/countries	Number of analytical data	Sub-total
2017	Brazil	282	40629
	Canada	220	
	India	19281	
	Philippines	44	
	Singapore	160	
	Thailand	33	
	United States of America	5050	
	WHO European Region	15559	
2018	Brazil	57	16879
	Canada	120	
	India	7450	
	Philippines	43	
	Singapore	96	
	Thailand	06	
	United States of America	3814	
	WHO African Region	40	
	WHO European Region	5253	
2019	Philippines	2	4934
	Singapore	3	
	WHO European Region	3587	
	India	1342	
2020	Brazil	05	2599
	Canada	84	
	Japan	61	
	Philippines	35	
	Senegal	10	
	Singapore	216	
	Thailand	22	
	United States of America	71	
	WHO European Region	2095	
		Total	65041

2. After implementation of the COP by the countries for the years 2017, 2018, 2019 and 2020, the violation percentage as per GEMS/Food data for peanuts at ML of ≤4 to >15 is as follows:

Table 2: Analysis of the GEMS/Food data

Year	Total data sets	No. of samples detected AFT at ≤4 µg/kg	% age of samples detected AFT at ≤4 µg/kg	No. of samples detected AFT at >4 to ≤10 µg/kg	% age of samples detected AFT at >4 to ≤10 µg/kg	No. of samples detected AFT at >10 to ≤15 µg/kg	% age of samples detected AFT at >10 to ≤15 µg/kg	No. of samples detected AFT at >15 µg/kg	% age of samples detected AFT at >15 µg/kg
2017	40629	25893	63.73	10760	26.48	1619	3.98	2357	5.80
2018	16879	8280	49.05	6,965	41.26	759	4.49	875	5.18
2019	4934	3547	71.88	1,258	25.50	73	1.47	56	1.13
2020	2599	2526	97.19	32	1.23	9	0.35	2	0.07
Total	65,041	40,246	61.88	19,015	29.24	2,460	3.78	3,290	5.06

3. The GEMS/Food data set of 65 041 analytical results after implementation of the COP by the countries for the years 2017, 2018, 2019 and 2020 shows that the occurrence of total aflatoxins (AFT) in peanuts at ≤4 µg/kg are percentage of as high as 63.73, 49.05, 71.88 and 97.19. In case of AFT at >4 to ≤10 µg/kg the percentages would be 26.28, 41.26, 25.50 and 1.23 respectively for the years 2017, 2018, 2019 and 2020. In case of AFT at >10-≤15 µg/kg the percentages would be 3.98, 4.49, 1.47 and 0.35 for the years 2017, 2018, 2019 and 2020 respectively.

4. The analysis of GEMS/Food data for estimation of the percentage of rejection in trade at proposed maximum levels (MLs) of AFT at 4 µg/kg, 10 µg/kg and 15 µg/kg has been given in the following tables:

Table 3: Hypothetical ML of 4 µg/kg

Year	Total data sets	No. of samples detected AFT at ≤4 µg/kg	% age of samples detected AFT at ≤4 µg/kg	%Rejection at Hypothetical ML of AFT at 4 µg/kg
2017	40629	25893	63.73	36.27
2018	16879	8280	49.05	50.95
2019	4934	3547	71.88	28.12
2020	2599	2526	97.19	2.81
Total	65,041	40,246	61.88	38.12

Table 4: Hypothetical ML of 10 µg/kg

Year	Total data sets	No. of samples detected AFT at ≤10 µg/kg	% age of samples detected AFT at ≤10 µg/kg	%Rejection at Hypothetical ML of AFT at 10 µg/kg
2017	40629	36653	90.21389	9.79
2018	16879	15245	90.31933	9.68
2019	4934	4805	97.38549	2.61
2020	2599	2558	98.42247	1.58
Total	65,041	59261	91.1133	8.89

Table 5: Hypothetical ML of 15 µg/kg

Year	Total data sets	No. of samples detected AFT at ≤15 µg/kg	% age of samples detected AFT at ≤15 µg/kg	%Rejection at Hypothetical ML of AFT at 15 µg/kg
2017	40629	38272	94.19873	5.80
2018	16879	16004	94.81604	5.18
2019	4934	4878	98.86502	1.13
2020	2599	2567	98.76876	1.23
Total	65,041	61721	94.89553	5.10

5. The EWG has also analyzed data prior to 2017 i.e. before implementation of the COP by countries and JECFA83-2016 outcome concluding 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. It is noted that the occurrence data analysis of producing and exporting countries/regions shows a large range of AFT concentration, while the data analysis of importing countries/regions does not show AFT occurrence due to exclusion of material for shipments which does not comply with the ML of AFT enforced by these countries.

6. Based on the conclusion of the earlier deliberations in the EWG and CCCF plenary the EWG had already given its recommendations to set ML for AFT for RTE Peanuts 10 µg/kg adoption which was kept on hold at Step 4 awaiting occurrence data after implementation of COP by countries. The analysis of the GEMS/Food data after implementation of the COP by the countries for the years 2017, 2018, 2019 and 2020 support a ML of 15 µg/kg in RTE peanuts based on the rate of violation (which is approx. 5%) which will also protect the health of consumers. However, considering discussions and decision of previuos CCCF on this matter, the EWG consider to recommend any ML of AFT between ≥10 to < 15 µg/kg. The EWG further recommends the existing Codex sampling for peanuts for further processing as given in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) to apply also for RTE Peanuts also taking into account the following:

iii) The old and new GEMS/Food data sets for determining ML of AFT in RTE Peanuts are based on the existing method of sampling.

iv) CCCF may consult with the Codex Committee on Methods of Analysis and Sampling (CCMAS) to review the entire sampling plan for update after the ML for AFT in RTE peanuts and other products under consideration by CCCF are adopted.

APPENDIX III

LIST OF PARTICIPANTS

EWG Chair

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Nigeria	Mr. Umar Abdulsalam Senior Agricultural Officer (Maize Value Chain)
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United States of America	Lauren Robin Branch Chief/US Delegate FDA Anthony Adeuya Chemist/US Delegate FDA Quynh-Anh Nguyen Consumer Safety Officer/US Delegate FDA
American Peanut Council	Jim Elder Export Technical Consultant American Peanut Council United States
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Institute of Food Technologists (IFT)	James Coughlin, President Coughlin & Associates Dojin Ryu, Professor – Food Science University of Idaho, USA Martin Slayne Vice President Regulatory Affairs Ingredion
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