CODEX ALIMENTARIUS COMMISSION E

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

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# DISCUSSION PAPER ON THE ESTABLISHMENT OF A MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN

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

## BACKGROUND

1. A New Work Proposal was presented by India on establishing maximum levels (MLs) of total aflatoxins (AFs) in ready-to-eat (RTE) peanuts and methods of sampling & analysis at the 7th session of the Committee on Contaminants in Foods (CCCF) (April 2013). Many delegations supported the proposal and indicated that they would provide data to support the work. Some other delegations, while not opposed to the establishment of MLs in principle, proposed that a discussion paper be developed to provide an overview of the concern with RTE peanuts and to assemble data on consumption and aflatoxin levels in RTE peanuts in international trade, to allow the Committee to make a more informed decision on new work. Such data would be useful for JECFA should they conduct a risk assessment. It was noted that some of the information on MLs from different countries needed to be corrected, and countries should provide correct information on their MLs. Further proposals were made to consider Aflatoxin $B_1$ ($AFB_1$) rather than total aflatoxins as this aflatoxin was considered the most widespread and toxic compound among aflatoxins.

2. The Committee agreed to establish an electronic Working Group (EWG) Chaired by India to prepare a discussion paper for consideration at the next session of the CCCF that defines the issue, identifies the available data and specifies data requirements for establishing MLs of AFs in RTE peanuts.[1] The list of participants is provided in Appendix III.

3. It is to acknowledge the efforts of the EWG members for confirmation and providing available data/information for preparing comprehensive discussion paper on the establishment of MLs of AFB1 & total aflatoxins, methods of analysis and sampling in RTE peanuts.

4. The Committee is invited to consider the conclusions and recommendations in relation to the establishment of maximum levels for total aflatoxins in ready-to-eat peanuts and associated sampling plan (Appendix I) based on the considerations put forward in Appendix II.

1 RE13/CF, paras. 149-151.

**APPENDIX I**

**ESTABLISHMENT OF A MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN**

## CONCLUSION

1. This initiative will help to provide direct health protection to consumers, ensure fair practices in trade of RTE peanuts and help developing countries at large as peanuts are generally produced in these countries. Consumer protection from the point of view of health, food safety and ensuring fair practices in food trade taking into account the identified needs of developing countries. Relevance to Codex Strategic Goals (Codex Strategic Plan 2014-2019) would be as follows:

**Goal -1: Promoting sound regulatory frameworks**

Harmonized Codex MLs of AFs of RTE peanuts for developed and developing countries, leading to enhanced fair practices.

**Goal -2: Promoting consistent application of scientific principles and risk analysis**

Help establishment of MLs of AFs of RTE peanuts based on risk assessment.

**Goal -3: Promoting maximum application of Codex Standard**

Harmonization of MLs of AFs of RTE peanuts is an international nature of problem as recognized by the 7th CCCF; this initiative will embrace all negative aspects of both importing and exporting countries to adopt an application of uniform Codex Standard.

## RECOMMENDATIONS

2. Countries/members who participated in the EWG submitted data on MLs of AFs, however, limited data on occurrence of AFs to enable JECFA to carry out risk assessment of $AFB_1$ & total aflatoxins in RTE peanuts. Hence draft MLs of total AFs 10 µg/kg in RTE peanuts in line with tree nuts may be recommended by the EWG to the next CCCF. Existing Codex methods of sampling & analysis currently being practiced may continue for the time being even for RTE peanuts, however, there would be a need to review the method of sampling and analysis of RTE peanuts traded in all packs. With regards to identification of requirement for expert scientific advice and risk assessment by JECFA, CCCF should consider requesting JECFA to perform an exposure assessment for health impact assessment based on proposed MLs for $AFB_1$ & total aflatoxins in RTE peanuts.

3. Identification of any need for technical input from external bodies are anticipated none at this stage. Proposed timeline, including the starting date, proposed date for adoption at Step 5 and proposed date for adoption by the Commission are as follows:

i) Consensus at the 8th CCCF in 2014 for submitting new work proposal to CAC for setting up MLs of AFs in ready to eat peanuts

ii) New work proposal for setting up MLs of AFs in ready to eat peanuts approval by CAC in 2014

iii) Circulation of proposed draft MLs for comments at Step 3 and consideration by the 9th Session of CCCF at Step 4 in 2015.

iv) Risk assessment by JECFA in 2015, if sufficient data available.

v) Subject to availability of JECFA recommendations on draft MLs of total aflatoxins & $AFB_1$ and methods of sampling & analysis in RTE peanuts. Adoption at Step 5 by the CAC is planned for 2015 and adoption at Step 8 by the CAC in 2016.

**APPENDIX II**

## ESTABLISHMENT OF A MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN

### INTRODUCTION

1. The scope of RTE peanuts includes raw shelled peanuts, raw in-shell peanuts, roasted in-shell peanuts, roasted/blanched shelled peanuts, fried shelled peanuts with or without skin, coated peanuts in all types of packaging (consumer or bulk) and any other products having preparation of more than 20% of peanuts.

2. Global trade in peanuts with a specific reference to RTE peanuts is increasing. According to International Nut & Dried Fruit Council (INC) world peanut production reached 36,523,000 metric tons in 2012 out of which 1,620,340 metric tons were exports/imports (the data does not differentiate between the intended uses). Trade statistical data from FAOSTAT do not differentiate between peanuts for further processing and RTE. International trade of RTE peanuts is facing difficulties due to different MLs of AFs fixed by various countries which results in trade barrier. Trade in peanuts and rejections have continuously increased during the past years.

3. Presently MLs of AFs established by Codex are only for further processing category of peanuts. Thus, there is a need to establish MLs of AFs in RTE peanuts and method of sampling & analysis. Establishment of Codex MLs of AFs in RTE peanuts will provide an internationally harmonized standard and will help to address the potential impediments to international trade of RTE peanuts as well as ensure fair practices in trade of this product.

4. AFs are considered the most important group of mycotoxins in the world's food supply and are now known to be produced by at least 10 *Aspergillus* species. However, most are rare or rarely found in foods, the main fungi producing AFs remains *Aspergillus flavus* and *Aspergillus parasiticus*. Of some importance is a new species found in peanuts in the southern hemisphere, called *Aspergillus minisclerotigenes* (Pitt et al., 2012). AFs $B_1$, $B_2$, $G_1$ and $G_2$ are the four major naturally produced AFs, B and G referring to the blue and green fluorescence colours produced under UV light (Pitt and Hocking, 2009). *A. flavus*is often found in most food produced in tropical countries, having special affinity with maize, peanuts and cottonseed. Usually, *A. flavus* produces only B aflatoxins and about 40% of the isolates are toxigenic, though percentages of toxin producing isolates may vary with land use (Taniwaki and Pitt, 2012), yet is considered the main source of AFs. *A. parasiticus*produces both B and G aflatoxins and almost all isolates are toxigenic, is commonly isolated from peanuts, being quite rare to find it in other foods (Frisvad et al., 2006). Optimum conditions for AFs production by these two species is 33°C and 0.99 aw (Sanchis and Magan, 2004). AFs could be produced by fungi either before and/or after harvesting of cereals, being influenced by several environmental factors such as temperature, relative humidity, insect damage, drought and stress condition of the plants (Miraglia et al., 2006).

### CODEX MLs OF AFs IN PEANUTS

5. The General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) contains MLs of AFs for six commodities: peanuts, almonds, Brazil nuts, dried figs, hazelnuts and pistachios. For the four tree nuts separate MLs for the commodity intended for further processing (15 µg/kg) and as ready-to-eat (10 µg/kg) have been adopted.

6. For peanuts the MLs of 15 µg/kg applies only to peanuts intended for further processing, there is no Codex standard for RTE peanuts. The current MLs of AFs for peanuts intended for further processing has been adopted at the 23rd session of the Codex Alimentarius Commission in 1999 (ALINORM 99/37, para 102). There is also a sampling plan for total aflatoxins in peanuts intended for further processing that does not address RTE peanuts (Annex 1 to the aflatoxins entry of the GSCTFF).

7. As decided by the 7th Session of the Committee on Cereals, Pulses and Legumes (CCCPL) held in 1990, "*A corresponding guideline level for total aflatoxins in peanuts for human consumption was also agreed upon at a level of 15 µg/kg (raw) and 10 µg/kg (processed). The Committee noted that the data indicated that 15 µg/kg was a practical limit for raw peanuts, which was the product in trade. Data also indicated that normal processing would be expected to result in MLs of AFs in processed peanuts within 10 µg/kg.*" (ALINORM 91/29, para 30). This proposal was circulated at Step 3 for government comments and for consideration by the Committee on Food Additives and Contaminants (CCFAC) and the Commission.

8. At the 23rd session of the CCFAC in 1991 some delegations supported levels of 4 µg/kg for ready-to-eat peanuts and agreed to ask the CCCPL about the stage at which peanuts would be considered as processed.

9. The 8th session of the CCCPL in 1992 decided "*in the interest of enabling a proposed Consultation to arrive at a decision concerning a sampling plan linked to a specific level … to forward the levels (i.e., 10 µg/kg processed; 15 µg/kg raw) and sampling plans previously discussed*" at Step 5 which was returned to Step 3 by the 20th session of the Commission in 1993.

10. At its 9th and last session in 1994 before its adjournment *sine die*, the CCCPL discussed again guideline levels and sampling plans. It was decided not to proceed further with the level for processed peanuts and agreed to advance to Step 5 a guideline level of 15 µg/kg of total aflatoxins for peanuts intended for further processing. Some delegations agreed to this since unprocessed peanuts represented the largest part of international trade such an approach would leave the possibility for individual countries to apply a lower limit for peanuts intended for direct consumption. Other delegations objected as it did not give adequate protection to the consumer.

11. The CCFAC continued the discussion of a guideline level of 15 µg/kg during the following years taking into consideration advice from an expert consultation in 1993 and the risk assessment by the 49th JECFA Meeting (TRS 1999). Some delegations continued to argue that this level was too high and suggested 10 µg/kg for peanuts intended for further processing. At its 30th session (1998), the Committee agreed to forward MLs of 15 µg/kg AFs in peanuts intended for further processing, based on a sample size of 20 kg, at Step 8 of the procedure.

12. Significant discussions about separate MLs for tree nuts intended for further processing and RTE took place at the CCFAC and the CCCF during the next decade and, considering also further assessments by JECFA, resulted in the adoption of standards for both commodity categories.

**OCCURRENCE DATA**

13. Iran has reported 3 incidences of exceeding Iranian MLs of total aflatoxins 15 µg/kg and 9 incidences exceeding Iranian MLs of aflatoxin $B_1$ 5 µg/kg out of 70 consignments analyzed during April 2010 to August 2012 imported from China and India. Similarly, Japan has reported exceeding MLs of 10 µg/kg of total aflatoxins in peanuts exported from India: 13 consignments in 2011, 6 consignments in 2012 and 4 consignments in 2013. Malaysia has also reported exceeding MLs 15 µg/kg of total aflatoxins in peanuts exported from India: 15 consignments in 2013. However, the EWG members are yet to share occurrence data. The producing countries, exporting and importing countries do not specify RTE peanut rejection data vis-à-vis peanuts meant for other intended uses.

14. Presently, the official rejections reported due to exceeding MLs of AFs in peanuts traded under various categories including RTE peanuts are being conveyed to the producing and exporting countries by the importing countries. For example, the extracted rejection data due to exceeding MLs of AFs in various categories of peanut consignments reported by EU to the exporting countries is given in Table-1.

**Table 1: Shows some examples of rejection due to exceeding MLs of AFs in peanuts**

| Country Year | 2010 | 2011 | 2012 | 2013 (up to Nov.) |
|---|---|---|---|---|
| Argentina | 93 | 37 | 8 | 6 |
| China | 78 | 60 | 4 | 48 |
| India | 8 | 136 | 63 | 12 |
| South Africa | 23 | 12 | 2 | 2 |

Source: EU RASFF portal

15. Out of 24 EWG members, who have confirmed their participation, 14 EWG members shared their data on aflatoxin levels, consumption pattern, production/import/export on the basis of which 1st draft was prepared and 8 EWG members submitted their comments/revised data after circulation of 1st draft. Revised data/information submitted by the EWG members and available Indian data is given in Table-2.

**Table 2: Maximum levels (MLs) of aflatoxins (µg/Kg) in ready to eat (RTE) peanuts, consumption pattern, production/import/export data**

| EWG participating Country | MLs of aflatoxins (µg/kg) | | Legislation Reference No. | Methods of sampling & analysis | Consumption pattern | Production/ import/export data (MT) |
|---|---|---|---|---|---|---|
| | $B_1$ | Total (Sum of $B_1$+$B_2$+$G_1$+$G_2$) | | | | |
| 1. Africa | Not given | Not given | Not given | Not given | Not given | Not given |
| 2. Argentina | Not given | 20 | Argentine Legislation | FAO Food and Nutrition Paper 55, 1993 | Below 200 grams per person per year | Argentine population consumes neither peanut butter nor peanut oil; therefore, 100% of the production of these foods is intended for foreign markets |

| EWG participating Country | MLs of aflatoxins (µg/kg) | | Legislation Reference No. | Methods of sampling & analysis | Consumption pattern | Production/ import/export data (MT) |
|---|---|---|---|---|---|---|
| | $B_1$ | Total (Sum of $B_1+B_2+G_1+G_2$) | | | | |
| 3. Austria (Revised) | 2 | 4 | EC Regulation 1881/2006, EC Regulation 165/2010 | EC Regulation 401/2006, EC Regulation 178/2010 | School children (6 to 15 years):9.7 g/d; Women (19 to 65 years): 52.6 g/d; Men (19 to 65 years): 92.2 g/d. | Not given |
| 4. China (Revised) | 20 | Not given | Chinese National Standard, GB 2761-2011 | Sampling, not given yet, Analysis, Chinese National Standard, GB/T 18979 | 7g/person/day (not confirmed) | Annual production about 15<br>Import: none; export data about 0.7 |
| 5. Cuba | Not given | 15 | Cuba national legislation | Not given | Not confirmed the national consumption data but part of foods that are marketed in the ambulatory sale | Not given |
| 6. Iran (Revised) | 5 | 15 | ISIRI 5925, Iranian National Standard, 2002 | AOAC 999.07 (As ISIRI 6872, Iranian National Standard, 2004) | Not given | Production: 2000 tons/year<br>Import from India & China |
| 7. Japan (Revised) | Not given | 10 | Japanese legislation | Not given | 2 g/capita/day (estimated value from import and domestic production volume of peanuts) | Domestic Production (ton/year, 2012)<br>Shelled raw peanuts: 10895<br>Import (ton/year, 2012)<br>Shelled raw peanuts: 26235<br>Roasted in-shell peanuts: 6348<br>Roasted shelled peanuts: 1933<br>Fried shelled peanuts: 42676<br>Peanut butter: 4887<br>RTE peanuts containing added sugar (ex. Peanut butter): 2248 |

| EWG participating Country | MLs of aflatoxins (µg/kg) | | Legislation Reference No. | Methods of sampling & analysis | Consumption pattern | Production/ import/export data (MT) |
|---|---|---|---|---|---|---|
| | $B_1$ | Total (Sum of $B_1+B_2+G_1+G_2$) | | | | |
| 8. Russia (Revised) | 5 | Not given | Russian national legislation | Tutelyan V.A., Eller K.I., Sobolev V.S. A survey using normal-phase HPLC of aflatoxins in domestic and imported foods in the USSR Food Additives and Contaminants, 1989, Vol. 6, No. 4, p. 459-465 (LOD of aflatoxin $B_1$ 0.1 ppb) | 1.6 g/day '9<br>3.06 g/day '12<br>average intake according to the 5-years statistics is at 2.06 g/day | Import<br>2012: 159655<br>2011: 106391.1<br>2010: 94780.6<br>Export<br>2012: 180<br>2011: 204<br>2010: 172 |
| 9. Sudan | Not given | 10 | Sudanese Standards and Measurements Organization No 2839 /2004 | Not given | 30-40% of production | Production: 800000 |
| 10. Thailand | Not given | 20 | Notifications of the Ministry of Public Health No. 98/2529 (1986) (mandatory regulation) | Not given | 0.83 g/person/ day for Thai age >3 years | Not given |
| 11. Uganda | Not given | 10 | Not given | Not given | Scarce data | Not given |
| 12. UK (Revised) | 2 | 4 | EC Regulation 1881/2006, EC Regulation 165/2010 | Commission Regulation (EC) No 401/2006 as amended by Commission Regulation (EU) No 178/2010 | Chronic consumption: 0.101 g/kg bw/d<br>Acute consumption: 0.414 g/kg bw/d | Not given |
| 13. USA (Revised) | Not given | 20 | U.S. Federal Food, Drug, and Cosmetic Act | Not given | Gathering data on the consumption | Not given |
| 14. ICMSF (New comments) | Not given | Not given | Not given | Not given | Not given | Not given |
| **Available Indian data and MLs in peanuts:** | | | | | | |
| 1. India | Not availa ble | 30 | Food Safety and Standards (contaminants, toxins and residues) Regulations, 2011 | For exports country specific or CODEX STAN 193-1995 Annex-I General Standard for Contaminants and Toxins in Food and Feed | Not available | Production: million MT<br>2009-10: 5.43<br>2010-11: 8.26<br>2011-12: 6.96<br><br>Export s: MT<br><br>2010-11: 4,33,753<br>2011-12: 8,32,617<br>2012-13: 5,35,661 |

16. The above data shows that there is no uniformity across the countries on MLs of AFs in RTE peanuts. It is observed from the data/information provided by the EWG members that producing, exporting and importing countries have established MLs of $AFB_1$ and total aflatoxins in peanuts which also applies to RTE peanuts. As a result of which the peanut producing and exporting countries are facing rejections due to exceeding MLs of AFs.

**CONSUMPTION DATA**

17. Information on consumption data submitted by the EWG members is given above. The world peanut production reached 36,523,000 MT in 2012 of which 1,620,340 MT were exports/imports. As can be observed from the above data, peanuts are widely consumed in various countries and the international market potential has been increasing. The peanut producing countries have established MLs of AFs between 10 μg/kg to 30 μg/kg which applies to all categories of peanuts. As concluded in 49th JECFA meeting, "roasting of groundnuts reduces aflatoxin levels by 50-80% "and peanuts are roasted for RTE purposes. However, the importing countries have set up these limits as low as 2 μg/kg to 5 μg/kg for AFB1 and 10-15 μg/kg for total AFs.

18. Distribution of aflatoxins across a consignment/lot of peanut kernels and dietary exposure to peanuts**, s**ince aflatoxin is a fungal metabolite and not an innate constituent of peanut kernels, in any given lot, the distribution of contaminated kernel are likely to be extremely heterogeneous. It has been observed that in visually selected (suspected) peanuts from two lots, aflatoxin was found in about half the nuts (trace to 1,100,000 μg/kg) with an average of 112,000 μg/kg. Thus one highly contaminated kernel among 10,000 kernels could result in an average concentration of 50 μg/kg. The skewed distribution of aflatoxin in and across the kernels obstructs determination of representative value of a given consignment/lot.

19. According to the WHO Global Environment Monitoring System **(**GEMS) program, average daily per capita consumption of shelled peanuts varied from 0.7gm to 21.8gm. The extent of aflatoxin exposure from peanuts is observed to be relatively less when compared to cereals as the consumption of peanuts is lower. For example, average daily consumption of shelled peanuts and maize in EU countries is 4.0g & 33.3g, respectively. Amounts of maize, peanuts and other nuts consumed in each GEMS/Food Consumption Cluster Diet is given in Table-3.

**Table 3: Consumption (g/day) of maize, peanuts and other nuts in each GEMS/Food Cluster Diet**

| Cluster / Diet (g/day) | A | B | C | D | E (EU) | F | G | H | I | J | K | L | M (USA) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Tree nuts | 4.2 | 21.5 | 3.9 | 3 | 5.5 | 10.2 | 16.3 | 15.7 | 9.7 | 1.9 | 19.1 | 29 | 5.6 |
| Almonds | 0 | 1.9 | 1 | 0 | 1 | 0.8 | 0 | 0.1 | 0 | 0 | 0 | 0.3 | 0.3 |
| Brazil nuts | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.1 |
| Hazelnuts | 0.0 | 2.1 | 0.0 | 0.1 | 1.3 | 0.3 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 |
| Pistachios | 0.0 | 0.7 | 0.5 | 0.9 | 0.3 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 |
| Walnuts | 0.0 | 1.3 | 0.0 | 0.1 | 0.3 | 0.1 | 0.2 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.4 |
| Peanuts in shell | 7.6 | 4.3 | 3 | 1 | 5.6 | 2 | 10.6 | 2.9 | 6.6 | 30.5 | 1.3 | 1 | 9.7 |
| Peanuts shelled | 5.2 | 3.1 | 2.1 | 0.7 | 4 | 1.4 | 7.6 | 2.1 | 4.7 | 21.8 | 0.9 | 0.7 | 6.9 |
| Maize | 82.7 | 148.4 | 135.9 | 31.8 | 33.3 | 7.5 | 35.2 | 298.6 | 248.1 | 57.4 | 63.1 | 58.6 | 85.5 |

Source: GEMS/Food Consumption Cluster Diet WHO 2006

**A** = Mauritius; **B** = Cyprus, Greece, Israel, Italy, Portugal, Spain, Turkey; **C** = Algeria, Egypt, Jordan, Morocco, Syrian Arab Republic, Tunisia; **D** = Armenia, Belarus, Bosnia and Herzegovina, Bulgaria, Iran, Macedonia, Moldova, Romania, Russian Federation, Serbia and Montenegro, Ukraine; **E** = Austria, Belgium, Croatia, Czech Republic, Denmark, France, Germany, Hungry, Ireland, Luxembourg, Malta, The Netherland, Poland, Slovakia, Slovenia, Switzerland, United Kingdom; **F** = Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Sweden; **G** = China, India, Indonesia, Malaysia, Nepal, Sri Lanka, Thailand, Viet Nam; **H** = Guatemala, Honduras, Mexico, Paraguay, Peru, El Salvador; **I** = Kenya, Malawi, Mozambique, South Africa, Tanzania, United Republic of Zimbabwe; **J** = Nigeria, Sudan; **K** = Barbados, Belize, Brazil, Colombia, Costa Rica, Cuba, Dominican Republic, Jamaica, Surinam, Venezuela; **L** = Japan, Republic Korea, The Philippines; **M** = Argentina, Australia, Canada, Chile, New Zealand, United States of America, Uruguay.

**TOXICOLOGICAL ASPECTS**

20. Aflatoxins were evaluated by JECFA at several meetings. The 49th meeting in 1998 performed a comprehensive risk assessment including an exposure assessment that applied different hypothetical maximum levels to existing contamination patterns of food commodities (WHO TRS 884; pp. 69 – 77). The meeting agreed that aflatoxins are considered to be human liver carcinogens, $AFB_1$ being the most potent one. Maize and groundnuts were identified as main contributors of dietary intake of aflatoxins. According to JECFA the roasting of groundnuts reduces aflatoxin levels by 50-80% (49th meeting).

21. Based on the comparison of two hypothetical standards of aflatoxin contamination in food (10 µg/kg or 20 µg/kg) the Committee concluded that their impact on public health depends on the fraction of samples to be rejected for human consumption. If the fraction of samples to be excluded under the two standards is similar, the higher standard would yield essentially the same risk of liver cancer as the lower standard.

22. For groundnuts JECFA verified this result using limited available data (Europe, US): if "all groundnuts are included, the average aflatoxin concentration would be 15 µg/kg. The average aflatoxin concentration would be 0.6 µg/kg if all samples with levels above 20 µg/kg were excluded and 0.5 and 0.4 µg/kg if all samples with levels above 15 and 10 µg/kg, respectively, were excluded." (WHO FAS 40). More detailed assessment using monitoring data from Europe and the US and applying those to five regional diets confirmed that the main impact on aflatoxins intake from groundnuts was whether a maximum level, was applied rather than whether the maximum levels was 10 µg/kg, 15 µg/kg, or 20 µg/kg.

23. JECFA at the 68th meeting of the Committee confirmed the hazard characterization of aflatoxins as genotoxic carcinogens that induce tumours in the liver of animals and humans and for which no tolerable levels can be established (WHO TRS 947, pp. 159-169; WHO FAS 59, pp. 305-356).

24. In response to a request from CCCF, the Committee assessed the impact of different MLs of AFs exposure on data provided by producing countries, noting that these better represent the materials in commerce and result in a robust estimate of aflatoxins dietary exposure from the tree nuts. Consumption of almonds, Brazil nuts, hazelnuts, pistachios, and dried figs contributed greater than 5% of the total aflatoxin dietary exposure in only five of the 13 GEMS/Food cluster diets. If fully enforced, an ML at 20 µg/kg in hazelnuts, almonds, pistachios, Brazil nuts, and dried figs would only have an impact on the relative contribution to AFs dietary exposure in these clusters, including high-level consumers of tree nuts (due solely to high level contamination reported for pistachios). For tree nuts other than pistachios, the presence of an ML has no effect on AFs dietary exposure. Moreover, the Committee concluded that enforcing an ML of 15, 10, 8, or 4 µg/kg, would have little further impact on the overall dietary exposure to AFs in all five of the highest exposed population groups compared to setting an ML of 20 µg/kg.

25. As part of its reply to the specific request from CCCF on tree nuts JECFA did also assess the contribution of various commodities including groundnuts to overall aflatoxin intake. The JECFA noted at several occasions that the reduction of AFs in dietary exposure is an important public health goal; particularly in populations who consume high levels of any potentially AFs contaminated food.

26. The risks arising from the exposure to AFs were evaluated through potency estimates for human liver cancer derived from epidemiological and toxicological studies. The potency of AFs was defined by the JECFA to be 30 times higher in carriers of hepatitis B virus (HBsAg+; about 0.3 cancers/year/100000 individuals) than in non-carries of hepatitis B virus (HBsAg-; about 0.01 cancers/year/100000 individuals). Thus, reduction of AFs intake in populations with a high prevalence of hepatitis B carriers will have a greater impact on reducing liver cancer rates than in populations with a low prevalence of carriers.

27. At its 64th meeting, the JECFA (FAO/WHO, 2005) decided that evaluations on compounds that are both genotoxic and carcinogenic, such as AFs, should be based on the estimation of Margins of Exposure (MOE). The MOE is defined as the ratio between a toxicological threshold (such as the BMDL3) and the intake. MOE lower than 10000 may indicate a public health concern (EFSA, 2005).

**METHODS OF SAMPLING & ANALYSIS**

28. Currently, the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995) and Code of practice for the prevention and reduction of aflatoxin contamination in peanuts (CAC/RCP 55-2004) are available.

29. Aflatoxins in peanuts are heterogeneously distributed, which makes representative sampling extremely difficult. Therefore, considerable care and planning are needed in sampling and sample analysis to ensure the accuracy of the estimated levels of aflatoxins. Currently non-destructive methods are not available for measuring aflatoxin contents in peanuts. A typical analytical method for the determination of aflatoxins in peanut kernels includes sampling, milling and homogenization. Therefore, for a precise determination of representative (average) value of aflatoxin load in an individual consignment/lot, the entire consignment/lot needs to be ground for analysis which is impractical. Hence, it is necessary to design methods of sampling & analysis aimed at eliminating the chances of clearing any consignment/lot which may have an average load of aflatoxin higher than the MLs rather than being aimed at determining representative (average) value of aflatoxin load of an individual consignment/lot. The existing method of sampling & analysis designed is based on probabilistic risk assessment to reduce the chances of entry of contaminated lots into food supply chain rather than their complete elimination. Existing Codex methods of sampling & analysis currently being practiced may continue for the time being even for RTE peanuts. However, there would be a need to review the method of sampling and analysis of RTE peanuts traded in all packs.

**DISCREPANCY IN EXISTING MLs**

30. Information gathered from the CRDs of agenda item 20 of 7$^{th}$ CCCF Session 8-12 April 2013 Moscow Russian Federation, the MLs of AFs in RTE peanuts/peanuts established by Thailand: 20 µg/kg total aflatoxins; Kenya: 10 µg/kg total aflatoxins; Malaysia: 10 µg/kg total aflatoxins; Russia: 5 µg/kg $AFB_1$, EU: 2 µg/kg $AFB_1$ and 4 µg/kg total aflatoxins; USA: 20 µg/kg total Aflatoxins; China: 20 µg/kg $AFB_1$. Korea has proposed 10 µg/kg $AFB_1$ and 15 µg/kg total aflatoxins, African Union and Ghana have proposed MLs between 4 µg/kg and 15 µg/kg total aflatoxins. Apparently, this shows that there is a great disparity.

31. Discrepancy in fixing MLs of same foodstuff by different countries or diet clusters, however, is often discussed on the basis of wide differences in per capita consumption of various foodstuffs in different countries/diet clusters. Even though this sounds logical, the calculations clearly indicate that the wide difference in total possible intake of aflatoxins from various sources (nuts and maize) across the countries/diet clusters. The discrepancy is that in spite of fact that per day consumption of peanuts (4 g/day) is 1/8$^{th}$ of the per day consumption of maize quantity (33.3 g/day), the MLs of aflatoxins kept 4 μg/kg for both these commodities. Thus there are a lot of inconsistencies in fixing MLs of aflatoxin in various foodstuffs by different countries which is considered to be neither logical nor scientific. Comparative data of peanuts and various foodstuffs is available for EU and USA and is given in Table-4.

**Table 4: Consumption of peanuts and various foodstuffs in EU and USA**

| Foodstuff | EU | | USA | |
|---|---|---|---|---|
| | Per capita consumption | MLs | Per capita consumption | MLs |
| | (g/day) | (ng/g) | (g/day) | (ng/g) |
| **Peanuts** | 4 | 4 | 6.9 | 20 |
| **Tree nuts** | 5.5 | 4 | 5.6 | 20 |
| **Almonds** | 1 | 10 | 0.3 | 20 |
| **Brazil nuts** | 0.1 | 10 | 0.1 | 20 |
| **Hazelnuts** | 1.3 | 10 | 0.1 | 20 |
| **Pistachios** | 0.3 | 10 | 0.2 | 20 |
| **Walnuts** | 0.3 | 4 | 0.4 | 20 |
| **Nuts (total)** | 12.5 | | 13.6 | |
| **Maize** | 33.3 | 4 | 85.5 | 20 |
| **Nuts + Maize** | 45.8 | | 99.1 | |

Source: FAO 1998 Mycotoxin Prevention and Control in Food Grain Food and Agricultural Organization of the United Nations Rome.

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**APPENDIX III**

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