CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5

CX/CF 12/6/8
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Sixth Session
Maastricht, The Netherlands, 26 – 30 March 2012

# PROPOSED DRAFT MAXIMUM LEVELS FOR ARSENIC IN RICE

(AT STEP 3)

Codex Members and Observers wishing to submit comments at Step 3 on the proposed draft maximum levels for Arsenic in Rice, including possible implications for their economic interests, should do so in conformity with the *Uniform Procedure for the Elaboration of Codex Standards and Related Texts* (Codex Alimentarius Commission Procedural Manual) before 24 February 2012. Comments should be directed:

| to: | with a copy to: |
|---|---|
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## BACKGROUND

1. The 5th Session of the Codex Committee on Contaminants in Foods (CCCF) agreed to initiate new work on maximum levels for arsenic in rice subject to approval by the 34th Session of the Commission based on the information and recommendations provided in working document CX/CF 11/5/10 presented for consideration at that session. The Committee also agreed to re-convene the electronic Working Group, led by China, working in English only and open to all Codex members and observers, who would prepare a working paper considering MLs for arsenic in rice based on the considerations made at plenary for deliberation at the next session of the Committee. The electronic Working Group should specify in the paper whether the MLs apply to total and/or inorganic arsenic in rice.[1]

2. The Commission approved the proposal for new work on maximum levels for arsenic in rice as proposed by the Committee. In taking this decision, it was clarified that the matter of establishing MLs for arsenic in rice matter had been thoroughly discussed in the CCCF, including the need for further data, but that it was agreed that there was a need for work to proceed. It was also explained that China as the lead country of the new work had been requested to develop a paper to explain whether the MLs would be for total or inorganic arsenic. Several delegations highlighted the importance of establishing MLs for arsenic in rice for this important commodity.[2]

3. The EWG focused on the following aspects: 1) The analytical methods for total and/or inorganic arsenic currently in use, and collaborating or performance test reports at national or international level. 2) Available raw data for total and/or inorganic arsenic in rice, used to produce the distribution curve. 3) The comments for this latest version, especially for whether ML(s) should be set on total and/or inorganic arsenic, ML level and in what products (rice only or rice based products).

1 REP11/CF, para. 64 and Appendix IV.
2 REP11/CAC, paras. 140-142 and Appendix VI.

4. Information in support of the proposed draft maximum level recommended by the EWG for consideration by Codex members and observers at the 6th Session of the Committee is presented in Appendix I. The information contained in this Appendix complements the information already provided in the discussion paper presented for consideration at the 5th Session of the Committee held in March 2011 (see CX/CF 11/5/10[3]). Therefore, information already provided in the discussion paper has not been reproduced in Appendix I. However, in order to have an integral view of the main issues surrounding rice contamination with arsenic it is recommended to read the information presented in Appendix I in conjunction with the information contained in CX/CF 11/5/10 that led the EWG to recommend the following proposed draft Maximum Level for Arsenic in Rice as requested by the 5th Session of the CCCF.

REQUEST FOR COMMENTS

5. The recommendations of the EWG for comment at Step 3 and consideration by the 6th Session of the Codex Committee on Contaminants in Foods at Step 4 are presented here after. The background information to support these recommendations is presented in Appendix I. The list of participants is in Appendix II.

Recommendations

- It is preferable to set MLs specifically for inorganic As rather than total As. However to do this further data needs to be sourced as currently there is insufficient robust occurrence data for inorganic As in raw commodity and processed rice products to set ML's.

- The Committee should ask the Codex Committee on Methods of Analysis and Sampling (CCMAS) to establish the method for determination of inorganic As in rice. The sampling method for contaminants directives （EC 333/2007） should be made available to CCMAS as potential starting point.

- Consideration should be given to the value of developing a Code of Practice which could address factors which influence inorganic As levels in rice and rice products e.g As content of soil and water, processing and cooking procedures.

- If a ML is set based on the level of current knowledge then it could be set with reference to both total and inorganic As i.e draft MLs for As in raw rice (brown) would be proposed at 0.3 mg/kg, whether for inorganic As or total As; or 0.2 mg/kg only for inorganic As in polished rice. It might be measured for total As first, and then measured as inorganic As if the total As measurement exceeds 0.3 mg/kg.

| | |
|---|---|
| Raw Rice | Maximum Level for Arsenic<br>0.3 mg/kg (whether inorganic As or total As) |

6. Codex Members and Observers are kindly invited to send their comments on the proposed draft Maximum Level for Arsenic in Rice at 0.3 mg/kg (inorganic As or total As) including the other recommendations above for consideration by the 6th Session of the Codex Committee on Contaminants in Foods.

[3] This working document is available for downloading at: ftp://ftp.fao.org/codex/meetings/cccf/cccf5/cf05_10e.pdf

APPENDIX I

The information contained in this Appendix complements the information provided in the discussion paper CX/CF 11/5/10 presented at the 5th Session of the CCCF which led to the recommendation to establish maximum levels for arsenic in rice by the CCCF. Both CX/CF 11/5/10 and Appendix I to CX/CF 12/6/8 provides the technical support for the proposed draft ML for As in rice as presented in paragraph 5 of this document.

ANALYTICAL METHODS

7. In addition to the information already presented in CX/CF 11/5/10, the Table 1 summarizes the overall information for analytical methods collected from the EWG members.

Table 1. Summary of available methods of analysis As in rice from various countries

| Country | Total As | Inorganic As |
|---|---|---|
| Australia | ICP-MS – internationally validated | ICP-MS – not internationally validated |
| Brazil | ICP-MS and HG-AAS plus graphite furnace atomic absorption | None |
| China | ICP-MS and HG-AFS — national validation | HPLC method coupled with ICP-MS or HG-AFS – national validation |
| Colombia | ICP-MS and HG-AAS | None |
| European Union | Various – internationally validated | Various – internationally validated |
| Korea | No information | HPLC method coupled with ICP-MS |
| Japan | AOAC 986.15 (AAS) | HPLC coupled with ICP-MS – no information on validation status |
| US | ICP-MS – not internationally validated | HPLC coupled with ICP-MS – not internationally validated |

8. The Institute for Reference Materials and Measures (IRMM) of the European Commission Joint Research Center (JRC) issued the Report of the seventh interlaboratory Comparison organized by the European Union- Reference Laboratory for Heavy Metals in Feed and Food, IMEP-107: total and inorganic As in rice. The expert laboratories for total As (7) and for inorganic As (6) that participated in the establishment of the assigned value for IMEP-107, used various methods of analysis. All results agree within a range of about 9% (95% confidence interval), which indicates that the concentration of inorganic As is not method dependent in rice. Interestingly, the expert laboratories found a better agreement on the concentration of inorganic As than on the total As for which a wider dispersion of results was observed. A total 103 laboratories from 35 countries registered to participate in the performance validation exercise by their own methods using different instruments, 98 laboratories (2 from Canada and 22 from the Asia-Pacific region) reported the result for total As and 32 participants reported results for inorganic As. Except for EU laboratories, the countries participating laboratories were from Canada(2), Israel (3) and the Asia-Pacific region, e.g. China (7) and Macau (1), Malaysia (4), New Zealand (2), Singapore (2), Thailand (3).The result showed that no particular problem related to the determination of inorganic As in rice was detected in the proficiency test and the performance of the participating laboratories was satisfactory（de la Calle et al., 2011）. The performance of the participating laboratories was shown to be similar for total and inorganic As. Although the number of laboratories who determined inorganic As was considerably less than the number of laboratories who determined total As, the results showed that the option of introducing possible maximum levels for inorganic As should be considered in further discussions on risk management.

9. The U.S. Food and Drug Administration (FDA) uses ICP-MS method for measuring As in foods (CFSAN/ORS/DBC/CHCB April 25, 2011, Draft method for FDA's Elemental Analysis Manual (EAM), and HPLC coupled with ICP-MS for inorganic As (FDA Elemental Analysis Manual Section 4.10; Heitkemper et al., 2009). None of these methods have been directly validated through AOAC International (AOAC) or the European Organization for Standardizations (CEN).

10. Food Standards Australia and New Zealand (FSANZ) used an ICP-MS based method for As levels in rice. The limit of reporting for total arsenic is 0.0005-0.025 mg/kg depending on the matrix. Recently a method for testing arsenic speciation has been developed but has not yet undergone national and international proficiency test performance evaluation due to a lack of i) suitable proficiency providers and ii) a suitable reference standard

11. China and Korea have issued the national standard by using the HPLC method coupled with ICP-MS for measuring inorganic As in foods, including in rice. And China also developed a cheap method by using HLPC coupled with HG-AAS (GB 5009.11).

12. In Brazil and Colombia, the laboratories are analyzing the total As detection. In Colombia, the most common techniques for analysis are ICP-MS and HG-AAS, while in Brazil, in addition to these techniques, the graphite furnace atomic absorption is also used.

13. In Japan, total As in husked rice is analyzed using AOAC 986.15 (AAS), and inorganic As in husked rice is analyzed using a method employing extraction of inorganic As with 0.15 mol/L nitric acid and determination with HPLC coupled with ICP-MS for inorganic As in husked rice （Nagaoka et al., 2008; Maitani et al., 2010）. A recovery test with 0.2 mg/kg of total arsenic added to husked rice resulted in a recovery range of 90–107% with the relative standard deviation (RSD) below 5.3%. The limit of quantification of the method was 0.01 mg/kg and the limit of detection was 0.003 mg/kg. A recovery test with 0.01 or 0.02 mg/kg of inorganic arsenic added to husked rice resulted in a recovery range of 82–106% with RSD below 8.6%. The limit of quantification of the method was 0.01 mg/kg and the limit of detection was 0.003 mg/kg.

14. One hindrance to national and international validation is a lack of suitable proficiency test providers for As speciation performance evaluation. Since there are no reference materials for As speciation analysis, it is needed that efforts should be paid to develop a rice flour reference material containing both inorganic and organic As species. Such natural sample can be obtained in some ming-impacted paddy soils in China, such as Hunan province, south central China.

15. In summary, considering that inorganic As is of more concern toxicologically than organic As it would be preferable if ML(s) was set specifically for inorganic As. However, as currently there are a number of method(s) available for inorganic arsenic in rice, which have undergone various levels of validation, input from CCMAS is required to provide recommendations and guidance as to which method(s) are suitable for the analysis of arsenic in rice. In order to assist CCMAS in this objective the results from the EU validation project, referred to in this section, and results from any other national validation projects should be provided to CCMAS.

16. CCMAS should also be requested to provide guidance on sourcing suitable reference material(s) for analysis of inorganic As in rice and sampling methodology.

LEVEL OF TOTAL AND INORGANIC AS IN RICE COMMODITIES

17. The following information was provided to supplement that already provided in CX/CF 11/5/10. Table 2 summarizes the overall information collected from the EWG members.

Table 2 Total and inorganic As levels in rice from various countries

| Country | Total As | | Inorganic As | |
|---|---|---|---|---|
| | Min-max mg/kg | Mean mg/kg | Min-max mg/kg | Mean mg/kg |
| Australia | 0.05-1.20 | 0.29 | - | - |
| China | 0.08-5.71 | 0.29 | <0.04-0.45 | 0.13 |
| Japan | 0.04-0.43 | 0.17 | 0.04-0.37 | 0.15 |
| EU | 0.01-1.98 | 0.16 | 0.02-1.88 | 0.14 |
| UK | 0.12-0.47 | 0.22 (median) | 0.06-0.16 | 0.11 (median) |
| USA | 0.04-0.41 | 0.21 | 0.025-0.157 | 0.091<br>(different study to min-max values) |
| Mercosur | | 0.05-0.13 (parboiled)<br><0.02-0.03 (polished rice)<br>0.1 (whole grain) | | |
| Sweden | | 0.24 (longgrain brown rice)<br>0.21 (parboiled white rice)<br>0.1 (white rice) | | 0.110 |
| Spain | | 0.197 | 0.027-0.253 | |
| Slovak Republic | | 0.158 | | |

18. Data from Australia: In the period 1995-98, 112 milled rice samples were collected and analyzed by a commercial producer, for total As, 1% of these samples exceeded the current Australian New Zealand 1 mg/kg ML for total As in rice. The total As concentrations of minimum, maximum, and average, median, 90th percentile, 95th percentile and 99th percentile were 0.05 mg/kg, 1.2 mg/kg, 0.29 mg/kg, 0.31 mg/kg, 0.40 mg/kg, 0.43 mg/kg, 1.04 mg/kg, respectively. Limited data from composite rice samples taken during Australia's most recent Total Diet Survey (23rd ATDS, 2008) revealed total As in rice concentration ranged from 0.07 mg/kg to 0.12 mg/kg.

19. Data from China: From the overall available rice data in 283 brown samples collected in 2003, 2004 and 2005, the minimum, maximum, average, median, 90th percentile, 95th percentile and 99th percentile for total As concentration were 0.08 mg/kg, 5.41 mg/kg, 0.29 mg/kg, 0.20 mg/kg, 0.38 mg/kg, 0.48 mg/kg, 2.030 mg/kg respectively. The CDC laboratory in China analyzed 41 rice samples from 13 provinces using LC-HG-AFS, inorganic As concentrations ranged from 0.023 to 0.142 mg/kg. Samples from Hunan, Guangxi and Sichuan provinces had higher concentrations of inorganic As, which were consistent with the distribution of As bedrock in these provinces. In another study, 22 rice samples from 13 provinces of China were analyzed for their As content. The total As concentration ranged from 0.065-0.274 mg/kg with an average value of 0.114 mg/kg. Speciation analysis, including arsenite (As(III)), arsenate (As(V)), DMA and MMA, was performed by using HPLC-ICP-MS for the extraction of As from milled rice powder. The inorganic As (As(III) + As(V)) species was predominant, accounting for approximately 72% of the total As in rice, with a mean concentration of 0.082 mg/kg. The 500 samples of peddy rice have been collected in more than 20 provinces in China, peddy, husked or polished rice on same sample in 2010 and analyzed for total and inorganic As in order to observe the processing effect. Combining data from the partly already analyzed 400 brown rice samples from the peddy rice collected in 2010 and 41 samples in the previous China CDC study, the overall statistical values for inorganic As concentration were respectively <0.04 mg/kg, 0.45 mg/kg, 0.13 mg/kg, 0.12 mg/kg, 0.21 mg/kg, 0.24 mg/kg, 0.32 mg/kg in all 441 brown samples. The analysis has been carried out in about 400 samples, concentration of inorganic As in polished rice was as average 45.5% compared to that in brown rice (range from 12.6%~99.3%) in 400 samples analyzed, which suggested that the polished rice can reduced the inorganic As significantly.

20. Data from Japan: Surveillance was conducted to investigate occurrence of total arsenic and inorganic arsenic in 600 husked rice samples from 2003 to 2005 in Japan. Total As in husked rice was analyzed using AAS method, and inorganic As in husked rice was analyzed using HPLC- ICP-MS method. The average of concentration for total arsenic and inorganic arsenic were in the range of 0.16–0.18 mg/kg and 0.14–0.16 mg/kg, respectively. The minimum, maximum, average, median, 90th percentile, 95th percentile and 99th percentile for total As concentration were 0.04 mg/kg, 0.43 mg/kg, 0.17 mg/kg, 0.16 mg/kg, 0.25 mg/kg, 0.27 mg/kg, 0.34 mg/kg, respectively, the statistical values for inorganic As concentration were 0.04 mg/kg, 0.37 mg/kg, 0.15 mg/kg, 0.15 mg/kg, 0.22 mg/kg, 0.25 mg/kg, 0.31 mg/kg, respectively.

21. Data from Mercosur (Brazil, and Uraguay, etc.): At the moment only total As levels are measured. The Brazil samples were purchased from a local market in Rio de Janeiro and analyzed by the Health Officials Laboratories with quantification graphite furnace atomic absorption technique. The average concentrations of total As were 0.05-0.13 mg/kg for parboiled rice, <0.02-0.03 mg/kg for polished rice and 0.10 mg/kg for whole grain（Batista et al., 2010). As in a total of 70 rice samples was determined with hydride generation combined with electrothermal atomization absorption atomic spectrometry (FI-ETAAS) with the detection limit is 0.050 mg/kg and the quantification limit 0.2 mg/kg in Uruguay. Some of them (n=49) were not detected and the rest (n=21) were detected but did not exceed the level of 0.2 mg/kg.

22. Data from the EU: According to the data collected from EU member states, 1075 samples of rice were analyzed for total As by ICP-MS ICP-AES, AFS or HG-AAS. The minimum, maximum, average, median, 90th percentile, 95th percentile and 99th percentile concentrations were 0.01 mg/kg, 1.98 mg/kg, 0.16 mg/kg, 0.12 mg/kg, 0.29 mg/kg, 0.38 mg/kg, and 0.75 mg/kg respectively. While 132 samples of brown, white, long grain, milled or parboiled rice were collected from Italy, Spain, France or imported from Argentina, Bolivia, Brazil, Canada, India, US, Uruguay, Thailand in 2004-2008. The inorganic As was analyzed by HPLC-ICP-MS or HG-AAS. The inorganic As concentrations of minimum, maximum, and average, median, 90th percentile, 95th percentile and 99th percentile were 0.02 mg/kg, 1.88 mg/kg, 0.14 mg/kg, 0.11 mg/kg, 0.18 mg/kg, 0.24 mg/kg, and 0.81 mg/kg respectively. More information is available in the Scientific Opinion on Arsenic in Food by the EFSA Panel on Contaminants in the Food Chain (CONTAM). In a UK study, total As concentrations in pure baby rice ranged from 0.120 to 0.470 mg/kg with a median of 0.220 mg/kg while inorganic As levels ranged from 0.060 to 0.160 mg/kg, with a median of 0.110 mg/kg. The percentage of inorganic to total As ranged from 33% to 68% with a median of 57% (Meharg et al., 2008). In a Swedish study, the mean concentration of total As in long grain brown rice of 0.240 mg/kg was similar to that of parboiled white rice at 0.210 mg/kg, whereas the average concentration in white rice was considerably less at 0.100 mg/kg. The concentration of inorganic As averaged 0.110 mg/kg, or 64% of the total As (Jorhem et al., 2008). As content in rice has also been analysed in a Spanish study (Torres-Escribano et al., 2008), where the mean concentration of total As in the 31 samples of European origin was 0.197 mg/kg. This value was close to the mean value of 0.18 mg/kg found in 7 samples of European rice in a UK study (Williams et al, 2005). Torres-Escribano and colleagues also evaluated the inorganic As level in raw rice originating from either Europe or Asian countries and found that it ranged from 0.027 to 0.253 mg/kg. The percentage of inorganic As over the total As varied between 27 and 93%. Williams et al. (2005) analyzed 51 samples of raw rice produced in Europe, Asia and the USA and showed a variation of inorganic As ranging from 10 to 86%. Both studies also observed that the mean concentration of inorganic As is 1.7 or 1.8 times higher in brown rice than in white rice. Some common food items (bread, rice, milk, pork meat, chicken meat, cabbage and potatoes) from the Slovak Republic were collected and analysed for total As concentrations. Rice contained the highest average concentration of total As at 0.158 mg/kg. The major proportion of the As in rice seemed to be inorganic.

23. Data from the USA: Schoof et al. (1999) used market basket survey techniques to analyze 40 food commodities expected to account for 90% of the dietary inorganic As intake. Consistent with earlier studies, total As concentrations were highest in the seafood ranging from 0.160 mg/kg in freshwater fish to 2.360 mg/kg in marine fish, followed by the raw rice ranging from 0.196 mg/kg to 0.335 mg/kg. The highest inorganic As concentrations were found in raw rice at 0.074±0.010 mg/kg. Heitkemper et al. (2009) analyzed 60 rice samples collected directly from the fields in four major rice-producing states in the US, and reported an average total As content of 0.210±0.190 mg/kg, while average inorganic As levels were 0.091±0.032 mg/kg. US rice samples with higher levels of total As have higher levels of DMA; however, inorganic As levels, regardless of the total As content, rarely exceed 0.15 mg/kg dry weight.

24. In summary, data presented above (Table 2), provide the distribution curve (Figure 1 and Table 3), show that the maximum values for inorganic As in rice do not generally exceed 0.2 mg/kg. However, in some cases including husked rice grown on uncontaminated soil in Japan and rice grown on soil which is naturally high in As, values exceeded 0.3 mg/kg. It should be noted that various analytical methods were used to measure the As (total and inorganic), various forms of rice were analysed e.g. husked, polished, parboiled and no information was provided on the sampling techniques. Therefore before a ML is recommended further analyses of the data is required to assess the validity of the various analysis methods used and any potential confounding effects resulting from other variables such as sampling technique and the state of the rice analysed e.g. husked, polished, brown, white. The fraction of inorganic As of total As showed wide variation ranging from approximately 10% to 93%. Again prior to recommending a ML and whether it should be set for total or inorganic As further investigation is recommended to identify factors which may influence this variation. Information provided in this paper indicates that soil type and processing stage can influence the level of inorganic As in rice.

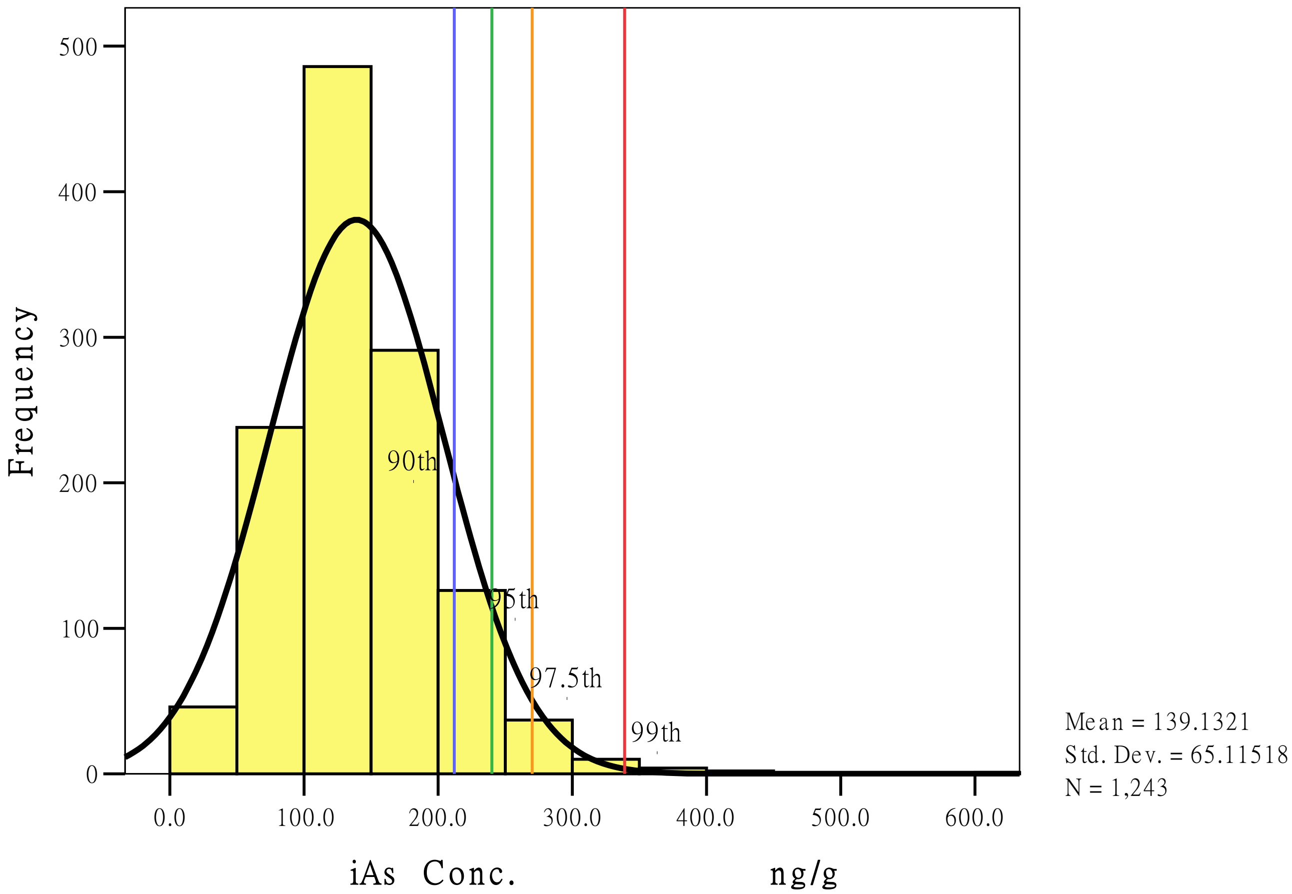


Figure 1. The distribution curve of inorganic arsenic concentration in overall rice samples
(Note: line blue, green, orange and red represent the 90th, 95th, 97.5th and 99th percentage of the inorganic arsenic concentration in overall 1243 rice samples collected, in which the value is 0.21, 0.24, 0.27 and 0.34 mg/kg respectively. The average is 0.14 mg/kg)

Table 3 The overall frequency from concentration of inorganic and total arsenic in rice

| Concentration (mg/Kg) | Inorganic As | | | Total As | | |
|---|---|---|---|---|---|---|
| | n | Ratio% | Cumulative Ratio% | n | Ratio% | Cumulative Ratio% |
| < 0.010 | 16 | 1.3 | 1.3 | 0 | 0.0 | 0.0 |
| 0.010 ~ 0.050 | 35 | 2.8 | 4.1 | 123 | 5.8 | 5.8 |
| 0.050 ~ 0.100 | 270 | 21.7 | 25.8 | 364 | 17.1 | 22.9 |
| 0.100 ~ 0.150 | 507 | 40.8 | 66.6 | 578 | 27.2 | 50.1 |
| 0.150 ~ 0.200 | 263 | 21.2 | 87.8 | 457 | 21.5 | 71.6 |
| 0.200 ~ 0.250 | 103 | 8.3 | 96.1 | 246 | 11.6 | 83.1 |
| 0.250 ~ 0.300 | 32 | 2.6 | 98.6 | 116 | 5.5 | 88.6 |
| 0.300 ~ 0.350 | 10 | 0.8 | 99.4 | 99 | 4.7 | 93.2 |
| 0.350 ~ 0.400 | 2 | 0.2 | 99.6 | 58 | 2.7 | 96.0 |
| 0.400 ~ 0.450 | 2 | 0.2 | 99.8 | 26 | 1.2 | 97.2 |
| 0.450 ~ 0.500 | 0 | 0.0 | 99.8 | 12 | 0.6 | 97.7 |
| >0.500 | 3 | 0.2 | 100.0 | 48 | 2.3 | 100.0 |
| Total | 1243 | 100.0 | | 2127 | 100.0 | |

Note: Concentration data of inorganic and total As (iAs & tAs) of rice were provided from Japan (Total 600 rice samples collected in 2003, 2004 and 2005 for both iAs & tAs), China (Total 441 rice samples collected in 2009, 2010 and 2011 for iAs and 283 samples for tAs,), EU (Total 142 rice samples collected in 2004, 2006, 2007 and 2008 for iAs and 1075 samples for tAs), USA (Total 60 rice samples collected in 1980, 1981, 2001 and 2002 for iAs and 57 samples for tAs) and Australia (Total 112 samples collected in 1998 for tAs)

DIETARY EXPOSURE

25. Based on the information provided in CX/CF 11/5/10 it can be noted that in summary, dietary exposure of total As is mainly from rice, fish, shellfish, and seaweed, while that of inorganic As is mainly contributed from rice and fish, shellfish, excluding drinking water. Inorganic As is toxicologically more important than total As. The dietary exposure for inorganic As from rice was calculated for 13 WHO cluster diet by using the pooled data of the inorganic As concentration in rice provided from China, EU, Japan and USA, with the average, 90$^{th}$ 95$^{th}$, 97.5$^{th}$, and 99$^{th}$ percentage, i.e. 0.1 4 mg/kg, 0.21 mg/kg, 0.24 mg/kg, 0.27 mg/kg and 0.34 mg/kg respectively. Using data from Clusters G and L which showed the highest rice consumption the average inorganic As exposure from rice will be 0.9 μg/kg.bw per day if using the body weight of 60 kg, and 90$^{th}$ and 99$^{th}$ percentiles of exposure will be 1.32-1.33 μg/kg.bw per day and 2.14-2.16 μg/kg.bw per day, respectively. According to exposure assessment conducted by JECFA in 2010, $BMDL_{0.5}$ is 3.0 μg/kg bw per day (with the range of 2–7 μg/kg bw per day) from lung cancer epidemiological studies. If more robust information on the concentration of inorganic As in rice was available this would enable more robust dietary exposure assessments which would in turn provide better information for setting a possible ML.

Table 4. Diet Exposure for Inorganic As (iAS) in Rice for Various Cluster Diets (μg/kg.bw per day)

| Cluster Diet | A | B | C | D | E | F | G | H | I | J | K | L | M |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Rice Consumption (g) | 91.0 | 31.6 | 94.6 | 33.2 | 12.7 | 12.7 | 376.9 | 64.3 | 38.0 | 74.3 | 238.4 | 381.3 | 34.6 |
| Average iAs Intake | 0.21 | 0.07 | 0.22 | 0.08 | 0.03 | 0.03 | 0.88 | 0.15 | 0.09 | 0.17 | 0.56 | 0.89 | 0.08 |
| P90 iAs Intake | 0.32 | 0.11 | 0.33 | 0.12 | 0.04 | 0.04 | 1.32 | 0.23 | 0.13 | 0.26 | 0.83 | 1.33 | 0.12 |
| P95 iAs Intake | 0.36 | 0.13 | 0.38 | 0.13 | 0.05 | 0.05 | 1.51 | 0.26 | 0.15 | 0.30 | 0.95 | 1.53 | 0.14 |
| P97.5 iAs Intake | 0.41 | 0.14 | 0.43 | 0.15 | 0.06 | 0.06 | 1.70 | 0.29 | 0.17 | 0.33 | 1.07 | 1.72 | 0.16 |
| P99 iAs Intake | 0.52 | 0.18 | 0.54 | 0.19 | 0.07 | 0.07 | 2.14 | 0.36 | 0.22 | 0.42 | 1.35 | 2.16 | 0.20 |

RISK MANAGEMENT CONSIDERATION

26. In addition to the information already provided in CX/CF 11/5/10, Table 5 on maximum levels for total and inorganic As in rice for various countries has been updated as follows:

Table 5. Maximum levels for total and inorganic As in rice for various countries

| Country | Regulatory Authorities | Maximum Level |
|---|---|---|
| Australia and New Zealand | Food Standards Australia New Zealand | 1 mg/kg for total As (cereals) |
| China | Ministry of Health | 0.15 mg/kg inorganic As in rice and rice products * |
| India | | 1.1 mg/kg for total As (rice only?) |
| Mercosur | Economic Block Composed by Argentina, Brazil, Paraguay and Uruguay | 0.3 mg/kg for total As (rice) |
| Singapore | Agri-Food and Veterinary Authority | 1 mg/kg for total As (other food not given ML specific) |
| UK | Food Standard Agency | 1 mg/kg for total As (all food, not given ML specific) |

* G/SPS/N/CH/312: the MLs will be adjusted into 0.2 mg/kg.

27. Rice is a staple food for a large proportion of the world population and is also an important commodity in international trade. Rice can be a significant dietary contributor to human As exposure due to its high consumption rate and its preparation. Cooking rice with As contaminated water can actually increase the concentration in rice and further contribute to total dietary As exposure. The available information, considered against the Codex General Standard for Contaminants and Toxins in Food and Feed and the criteria contained in paragraph 11 of the Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups, suggests that it would be appropriate to limit the establishment of MLs to rice and its products as they can contribute significantly to inorganic As dietary exposure. Therefore, the MLs should be established for rice and rice-based products.

DISCUSSION

28. As Contamination of rice is a potential problem. Therefore the CCCF 5th Session agreed to establish Codex MLs for As in rice. Inorganic As levels in rice vary due to a variety of reasons including weather conditions, soil type/contamination and rice varieties. Tools are being developed to forecast the likelihood of contamination and/or to assist in the soil and water As contamination level. An inorganic As exposure assessment conducted by JECFA in 2010 indicated that the PTWI of 15 μg/kg bw (equivalent to 2.1 μg/kg bw per day) is in the region of the $BMDL_{0.5}$ (3.0 μg/kg bw per day with the range of 2–7 μg/kg bw per day) from lung cancer epidemiological studies. This is therefore no longer appropriate. The Committee withdrew the previous PTWI. This complicates establishing MLs of As in rice.

29. According to Codex criteria for establishing MLs, MLs should be set at levels necessary to protect the consumer and as low as reasonably achievable (ALARA) but at a level that is (slightly) higher than the normal range of variation in levels in food that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. However, the variability in inorganic As content of rice and rice-based products, differences in countries' capabilities to forecast and control inorganic As occurrence, and the nature of the occurrence data that were provided make it challenging to determine inorganic As's normal range of variation in rice and rice-based food on a global scale and thereby apply the ALARA principle in establishing MLs.

30. MLs could apply to either inorganic or total As.

- Inorganic As is the area of most concern for human health. However if a ML is set with respect to inorganic As in rice, as a first step there needs to be internationally accepted validated method(s) which are widely available and not excessively expensive. The 72nd JECFA (2010), recommended establishment of a validated method for inorganic arsenic in rice.

31. For the possible setting of ML in the future, the EWG takes into consideration from following current nationally enforced MLs:

a) Total As in rice: from 0.3 mg/kg (Mercosur) to 1 mg/kg (FSANZ)
b) Inorganic As in rice: 0.2 mg/kg (China) or 0.3 mg/kg (considering Mercosur total As)
c) Inorganic As in rice-based foods for infants (up to 12 months) and young children (12 to 36 months): 0.2 mg/kg (China).

These levels in rice products, especially for infants and young children, should be lower than the levels for inorganic As in rice. Rice with (very) low inorganic As is available; producers should use this rice for the production of this category of food.

32. China and the European Commission considers it would be best to establish an ML for inorganic As in rice and rice-based products.

- It was noted that the fraction of inorganic As in rice has wide variation ranging from 10% to 93%. Therefore setting ML(s) on total As can overestimate the risk.
- The IRMM/JRC Report of IMEP-107: "total and inorganic As in rice" shows that the performance of the participating laboratories is similar for total and inorganic As. From the analytical point of view there is no reason not to consider the option of introducing possible maximum levels for inorganic As in further discussion on risk management.
- Separate MLs could be used for vulnerable groups such as infants and young children since exposure in these groups is greater due to the low bodyweight in relation to food intake. In addition rice is a common food base for these age groups.
- Development of MLs for As in rice-based products could be established by applying processing factors calculated from inorganic As concentrations in raw product and the corresponding processed commodity resulting from appropriate processing studies.
- Setting and implementing a 0.2 mg/kg ML of inorganic As in rice is proposed according to China MLs. The previous PTWI of 15 µg/kg bw has been withdrawal by the JECFA in 2010 due to approach to BMDL 0.5. If the previous PTWI is used as the default and assuming a body weight of 60 kg, the daily exposure is about the 128 µg inorganic As. Based on the WHO guideline of 0.01 mg/L ML in drinking water, the daily exposure from drinking water will be 15 µg inorganic based on the consumption of 1.5 L and not considering the many areas where the ML in drinking water is likely to be exceeded. Half of remaining daily exposure is about 50 µg inorganic As. If considering 150-250 g of rice consumption, the 0.2 mg/kg for inorganic As from China ML or 0.3 mg/kg for total As (as currently used by from Mercosur in Economic Block Composed by Argentina, Brazil, Paraguay and Uruguay), will use all remaining exposure minus that from drinking water and another half daily exposure from food. Limited data provided from Australia, China, EU, Japan, US and some other countries support a possible maximum value of 0.3 mg/kg for inorganic As in rice. However in situations where rice is grown in contaminated soil and irrigated water and in some cases in Japan, inorganic As concentration in husked rice grown on uncontaminated soil exceeded 0.3 mg/kg. Additional data needs to be collected from various countries and sources. In addition, it is not appropriate to refer to the PTWI which was withdrawn by JECFA as it was not considered health protective. Second, it needs to be recognized that not everyone will be consuming 250 g of rice at a limit of 0.2 mg/kg. This argument similarly applies to estimating exposure from water, where it is assumed that everyone drinks 1.5 L and is exposed at the limit of 0.01 mg/L. And to add and subtract contributions from food, rice and water, (presumably to check how it compares against a withdrawn PTWI) without any regard for 'double counting' makes it very difficult to establish a limit for As on the basis of default factors, portion sizes and assumed MLs.

33. On the basis of the current status of analytical methods some countries, e.g., Australia, Brazil and Colombia, consider the ML should be set for total As.

- Draft MLs for As in raw rice should be proposed by applying the ALARA principle to available occurrence data of As from various countries and sources.
- The products to which the MLs apply, should be clearly defined.
- Even on uncontaminated soil, inorganic As concentrations in husked rice grown in Japan indicated that over 10% of the samples contained inorganic As higher than 0.2 mg/kg. The data from Japan indicate that the draft ML of 0.2 mg/kg for inorganic As in husked rice is unlikely to be achievable.
- Moreover, most occurrence data for inorganic As is based on the form and manner of aggregate data rather than distributions. Only the limited occurrence data was available only from Australia, China, EU, Japan, USA, the working group could not accurately assess the worldwide percentage of rice that would exceed the proposed MLs. Therefore, there is a need to continue data collection from various countries and sources.

34. Considering the above the EWG concluded that at this stage it is inappropriate to propose ML(s) for As, especially for rice-based products. There was a general consensus that as inorganic As is the more toxicologically relevant As species it would be most appropriate to set MLs for inorganic As. However this is dependent on sourcing more robust data on the inorganic As content in rice and rice products which itself is dependent on the availability of a suitable analytical method and reference source.

- Combining the above two options, draft MLs for As in raw rice (brown) would be proposed at 0.3 mg/kg, whether for inorganic As or total As, preferable for 0.2 mg/kg inorganic As. It might be measured for total As first, and then measured inorganic As if the total As measurement exceed the 0.3 mg/kg.

RECOMMENDATIONS

35. Considering that it would be preferable if MLs were set specifically for inorganic As rather than total As, there is a need to collect occurrence data for inorganic As in raw commodity and processed rice products from various countries and sources.

36. CCCF should ask the CCMAS to establish the method for determination of inorganic As in rice. The sampling method for contaminants directives（EC 333/2007）could be considered as the start point for the sampling method for measurement of total and inorganic As in rice.

37. Consideration should be given to the value of developing a Code of Practice which could address factors which influence inorganic As levels in rice and rice products e.g As content of soil and water, processing and cooking procedures, before proceeding with the establishment of MLs.

38. If a ML is set based on the level of current knowledge then it could be set with reference to both total and inorganic As i.e draft MLs for As in raw rice (brown) would be proposed at 0.3 mg/kg, whether for inorganic As or total As; or 0.2 mg/kg only for inorganic As in polished rice. It might be measured for total As first, and then measured as inorganic As if the total As measurement exceeds 0.3 mg/kg.

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