CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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PROPOSALS FOR MAXIMUM LEVELS FOR INORGANIC ARSENIC IN HUSKED RICE

(Prepared by the Electronic Working Group chaired by Japan and co-chaired by China)

Codex Members and Observers wishing to submit comments on the draft ML of 0.35 mg/kg for inorganic arsenic in husked rice should do so in reply to CL 2015/32-CF while taking into account the analysis presented in this document and the discussion held and conclusions made at the 9th Session of the Committee.

INTRODUCTION

1. The 8th Session of the Committee on Contaminants in Food (March 2014) considered the proposed draft maximum level (ML) for inorganic arsenic (iAs) in polished and husked rice[1]. The CCCF noted wide support for the establishment of MLs for iAs in husked rice and polished rice and agreed to forward the ML for iAs in polished rice of 0.2 mg/kg to the Codex Alimentarius Commission for adoption at Step 5/8. The 37th Session the Commission (July 2014) adopted the ML[2]. The CCCF could not reach agreement on an ML in husked rice.

2. The 9th Session of the Committee (March 2015) revisited the matter of ML for inorganic arsenic in husked rice. The CCCF noted general support for the establishment of an ML for iAs in husked rice, but that divergent views from Members were expressed on numerical values of the ML. As a compromise solution, the CCCF agreed on an ML for husked rice at 0.35 mg/kg with a violation rate around 2%, and to send this proposal with a note on analysis of total arsenic as a screening method to the Commission for adoption at Step 5.

3. In accordance with the opinions on the need for more geographically representative data, the CCCF agreed to re-establish the electronic working group (EWG), chaired by Japan and co-chaired by China, to further consider new/additional data provided by countries, in particular main rice-producing countries and countries where husked rice was a major staple food. The CCCF should then consider the outcome of the analysis performed by the EWG based on the previously available and new/additional data to confirm or change the ML of 0.35 mg/kg at the 10th Session. The CCCF encouraged countries that had concerns to submit data to GEMS/Food so that the ML could be finalised at the 10th Session of the CCCF[3].

4. The Committee also agreed that the question "whether the Committee on Methods of Analysis should be asked to consider whether available methods of analysis for iAs in rice were of sufficient precision to support the implementation of an ML with two significant figures" should be considered by the EWG.[4]

5. The Commission at its 38th Session in 2015 adopted the draft ML at Step 5[5].

6. The EWG analysed new/additional data along with the data submitted previously, and considered the ability of methods of analysis to determine compliance to an ML with two significant figures. The list of participants to the EWG is attached to this document as Appendix I.

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[1] REP14/CF paras 35-47
[2] REP14/CAC paras 79-82 and Appendix III
[3] REP15/CF paras 66-69 and Appendix V
[4] REP15/CF para 65
[5] REP15/CAC paras 71-73 and Appendix IV

Brief Summary of Previous Findings[6]

7. The analysis of 2659 data provided in 2014 by nine Codex Members on iAs in husked rice indicates the violation rate and relative reduction of intake for each proposal as follows: 11.7% and 12% for an ML at 0.25 mg/kg; 4.9% and 6.3% for an ML at 0.3 mg/kg; 1.9% and 2.5% for an ML at 0.35 mg/kg; and 0.7% and 1.3% for an ML at 0.4 mg/kg.

8. A proposal of 0.25 and 0.3 mg/kg would result in significant reduction in the intake of iAs from husked rice relative to the percentage of $BMDL_{0.5}$ in only the clusters with higher husked rice consumption while even in these clusters husked rice is not the most important cereal grain consumed.

9. The following percentage of polished rice derived from husked rice that contains higher concentrations of iAs than each ML proposal complies with the ML for polished rice (0.2 mg/kg): 94% in case of an ML at 0.25 mg/kg for husked rice; 86% in case of an ML at 0.3 mg/kg; 76% in case of an ML at 0.35 mg/kg; and 69% in case of an ML at 0.4 mg/kg. The CCCF did not agree to establish a processing factor from husked rice to polished rice, which was estimated to be 0.51 or 0.44.

MAXIMUM LEVEL FOR INORGANIC ARSENIC IN HUSKED RICE

10. In response to the request of the CCCF made at its 9th Session, 1202 records for iAs concentrations in husked rice were provided by 6 Members: Canada, India, Indonesia, Kenya, the Republic of Korea and Sweden.

11. Newly submitted data (1202 records) were combined with the data provided in 2014 for consideration of the 9th CCCF by 8 Members (2659 records)[7]. The combined data includes 3861 records of 12 Members from 5 Regions: Kenya from Africa; China, India, Indonesia, Japan, the Republic of Korea and Thailand from Asia; the European Union and Sweden from Europe; Brazil from Latin America and the Caribbean; and Canada and the United States of America from North America. A summary of the data is shown in Appendix II.

12. The data provided by Indonesia ranged between 0.00055 and 0.0016 mg/kg, which are lower than the LOQ of analytical methods commonly used by other countries. Information on the validation of the analytical methods for data from Indonesia, Kenya and the Republic of Korea was not provided although the EWG requested.

Distribution curves and estimation of ML

13. The occurrence data of iAs in husked rice provided by 12 Members were merged, although they may belong to different populations, and a distribution curve was drawn. Many new data submissions necessitated new statistical analysis. As chi square value for Log Logistic distribution was lower than those for Log Normal or Gamma distributions, we used Log Logistic distribution model as the best fit model for the distribution (Fig. 1).

14. On the Log Logistic distribution model, Monte Carlo Simulation (n = 100 000) was conducted using @Risk software to estimate the mean concentration of iAs in husked rice and the potential violation rate for each ML proposal. Each mean was calculated from the distribution model by excluding any concentration data above the draft ML (in this case, 0.35 mg/kg). However, other MLs were included (see Table 1), in particular an ML of 0.3 mg/kg, which some delegations supported at the 9th Session of the CCCF.

Table 1 Estimation of mean concentration of iAs in husked rice and potential rate of violation at each ML proposal

ML proposal	Mean concentration (mg/kg)	Concentration > ML proposal (%)
No ML proposal	0.141 (0.158)	-
0.4 mg/kg	0.137 (0.156)	1.0 (0.7)
0.35 mg/kg	*0.135 (0.154)*	*1.8 (1.9)*
0.3 mg/kg	0.132 (0.148)	3.4 (4.9)
0.25 mg/kg	0.127 (0.139)	7.3 (11.7)

* Previous values prior to addition of further/additional data are shown in parentheses

6 CX/CF 14/8/6, CX/CF 15/9/7

7 The LOQ of 0.1 mg/kg was used as a cut-off point and data from analytical methods with the LOQ higher than 0.1 mg/kg were not used. See Appendix II for further information.

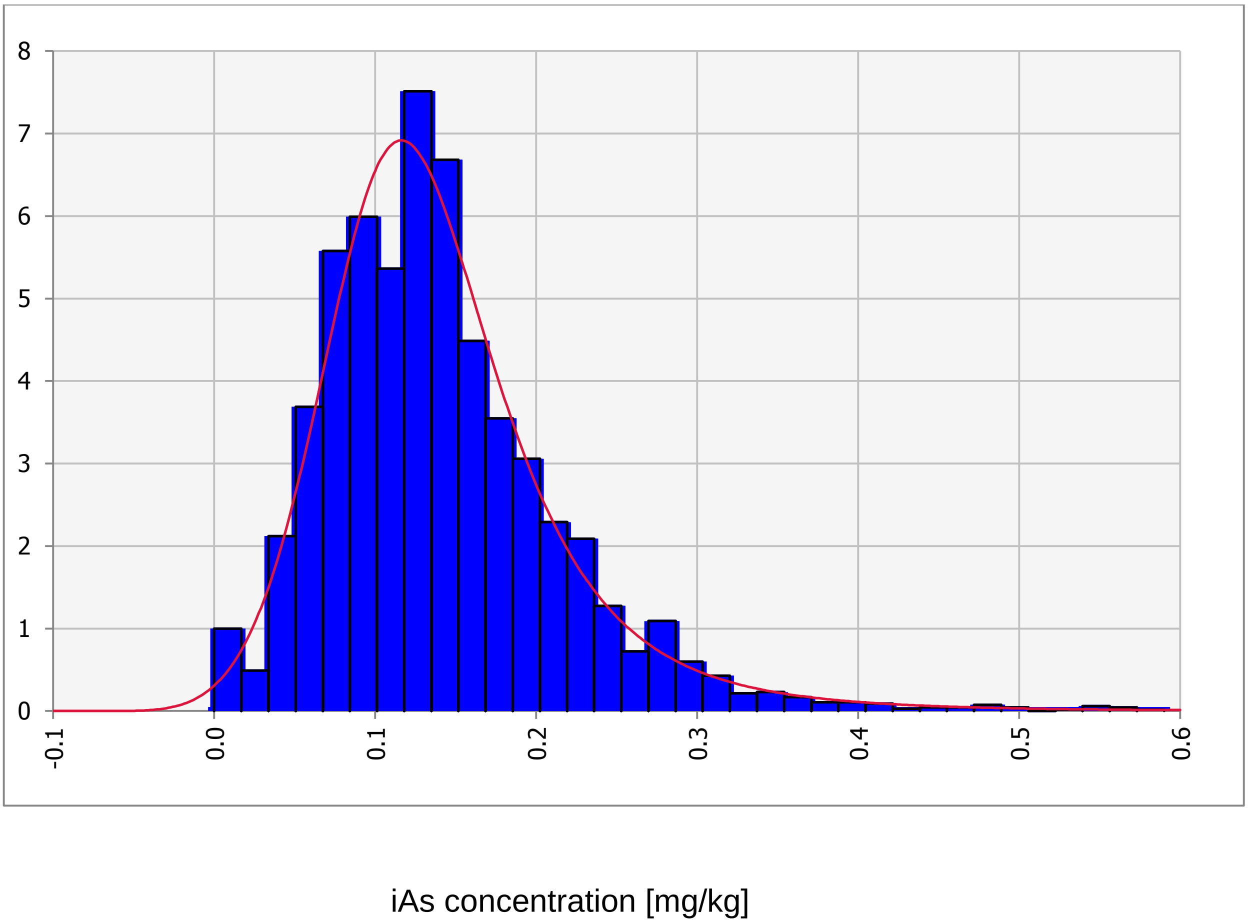

Fig. 1 Distribution of inorganic arsenic in husked rice

15. The *General Standard for Contaminants and Toxins in Foods and Feed* (CODEX STAN 193-1995) states in its Annex I Criteria for the *Establishment of Maximum Levels in Food and Feed*[8] that ML should be as low as reasonably achievable. Since rice is a major staple food in many Asian and African countries, there should be good balance between consumer health protection and the availability of rice for consumption. From this point of view, the violation rate should not be very high as it reduces the availability of rice. However, it should be noted that the level of consumption of husked rice, according to the GEMS/Food Cluster Diets, is lower than that of polished rice and constitutes a minor portion of the total consumption of cereals (see para 18).

16. Annex I of the GSCTFF further states that, where possible, MLs should be based on appropriate practices such as GMP and/or GAP 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. The importance of the Code of Practice (COP) for the prevention and reduction of arsenic contamination in rice was recognized by both CCCF and the Commission but a proposal made at the 8th Session to defer the establishment of an ML for husked rice until more occurrence data based on the implementation of a COP did not receive much support. The development and implementation of a COP appear to be taking longer than expected[9].

Impact of ML Proposal on iAs Intakes

17. In order to affirm that iAs intake from husked rice complying with the ML satisfies the criteria in the GSCTFF, the EWG estimated long-term iAs intakes from husked rice using the long-term intake calculation template[10] (October 2014) available on the GEMS/Food website and the mean concentrations in Table 1. The inclusion of newly submitted data has resulted in the slightly lower mean concentration at all proposal levels, including no ML.

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8 Annex I in the General Standard for Contaminants and Toxins in Foods and Feed (CODEX STAN 193-1995)

9 REP 14/CAC para 96 and Appendix VI, REP14/CF Appendix VIII

10 IEDIcalculation0217clustersfinal.xlsm (available at http://www.who.int/entity/foodsafety/areas_work/chemical-risks/IEDIcalculation0217clustersfinal.xlsm)

18. The results are shown in Table 2. In summary, the intakes of iAs from husked rice in different clusters were estimated to be between 0 and 0.073 µg/kg bw/day corresponding to 0 to 2.4% of the $BMDL_{0.5}$ of 3.0 µg/kg-bw/day (JECFA, 2010). The highest intakes were calculated for those clusters (namely, G03, G13, G17 in descending order) consisting of countries in Africa (and some outside of Africa) with higher consumption of husked rice. The effect of setting an ML for iAs on reduction of dietary iAs intake from husked rice was more significant for these clusters than for other clusters.

19. Introduction of the draft ML of 0.35 mg/kg adopted at Step 5 by the 38th Session of the Commission (2015) will reduce intake of inorganic arsenic from husked rice by 4.3% with the violation rate of 1.8%. If a lower ML is introduced, the percentage reduction of intake of inorganic arsenic will be higher; 6.4% for an ML of 0.3 mg/kg and 9.9% for an ML of 0.25 mg/kg. However, the lower the proposed ML, the higher the violation rate. An ML of 0.25 mg/kg would result in the violation rate of 7.3%, and thus availability of husked rice would be 92.7% of the supply.

20. According to the consumption values in the GEMS/Food template, even in the clusters with the higher consumption of husked rice (8.84-31.05 g/person/day), husked rice is not the most important food item among cereal grains – mean consumption of husked rice is less than that of polished rice (17-74% of the consumption of polished rice) and constitutes a minor portion of total consumption of cereal grains (3.3-12% of total cereal grains). It should also be noted that husked rice is not a major contributor in rice trade, constituting only about 10% of rice traded, according to the FAOSTAT[11].

21. The Policy of the *Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups* lists the criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin. They refer to foods or food groups for which exposure to the contaminant or toxin contributes approximately 10% or 5% or more of the tolerable intake (or similar health hazard endpoint) in one or two or more, respectively, of the GEMS/Food Consumption Cluster Diets. Even when the contribution is less than 5% in any of the cluster diets, if a food or food group has a significant impact on exposure for specific groups of consumers, establishing MLs should be considered on a case-by-case basis[12].

22. These criteria were established assuming the comparison of calculated intakes with the PTDI or PTWI[13]. Although the contribution of the intake of iAs from husked rice is at most 2.4% (G03) of the $BMDL_{0.5}$[14], it is not appropriate to apply the above criteria for comparison of the calculated intakes of iAs from husked rice with the $BMDL_{0.5.}$

<u>Methods of Analysis</u>

23. The EWG is requested to consider "whether CCMAS should be asked to consider whether available methods of analysis were of sufficient precision to support the implementation of an ML with two significant figures". The methods for the verification of the draft ML should:

(1) meet Codex method performance criteria shown in the Codex guideline[15]; and

(2) have sufficient capacity to determine compliance with an ML with two significant figures.

24. Information on some analytical methods became available (Appendix III). These methods all use LC-ICP-MS.

25. Method A is internationally validated (Indonesia, Japan, Singapore and Thailand) for the analysis of inorganic arsenic (and two other organic arsenic compounds) in husked and polished rice (both indica and japonica types) and confirmed to satisfy the criteria in the Codex guideline. According to the analysis of variation of standard curves and the result of an international collaborative study using Youden-paired samples, the method demonstrated its capability to detect a 0.01 mg/kg difference of concentration at 0.35 mg/kg.

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[11] http://faostat.fao.org/

[12] Section IV, paras 10-11 in the Procedural Manual.

[13] PTDI: Provisional Tolerable Daily Intake; PTWI: Provisional Tolerable Weekly Intake

[14] 95% lower confidence limit on the benchmark dose for an 0.5% response

[15] Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance Thereof, Section II in the Procedural Manual

26. As for Method B, a collaborative trial (ring-trial) organised in the European Union[16] demonstrated that laboratories using the method can report realistic analytical results with 2 significant figures with an expanded measurement uncertainty of 0.09 mg/kg. The precision of the analytical methods currently available for the determination of inorganic arsenic in rice are able to monitor and enforce MLs with two significant figures, as further demonstrated by the dedicated proficiency test IMEP-107 for the determination of total and inorganic arsenic in rice[17].

27. Method C was developed in Canada and it was not collaboratively studied or validated for a specific ML. Assuming that the concentration of inorganic arsenic is a simple sum of As(III) and As(V), the various performance parameters would be half the value that would be expected if the ML were a single entity. The method when validated for quantitative determination of arsenic in infant rice cereals and rice-based protein powder, demonstrated applicable range covering the Codex requirement for in organic arsenic at 0.35 mg/kg and LOQ, LOD, RSD_r and recovery satisfying the Codex requirements.

28. Method D was developed in Chile and validated in a single laboratory. The method satisfied the criteria required by the Procedural Manual when an ML is set at 0.2 mg/kg or higher.

29. Method E was developed in the USA and validated by a collaborative trial. The method satisfied the criteria required by the Procedural Manual when an ML is set at 0.2 mg/kg or higher.

30. Method F was also developed in the USA and validated in a single laboratory. The method satisfied the criteria required by the Procedural Manual when an ML is set at 0.2 mg/kg or higher.

31. An HPLC-ICP-MS method was developed by the Republic of Korea and no validation information was available. LOD, LOQ and recovery for As(III) and As(V) were reported to be 0.0003 and 0.0002 mg/kg, 0.0010 and 0.0006 mg/kg, and 97.6% and 105.6%, respectively.

32. An SPE-ICP-MS method (term used by Indonesia) was developed in Indonesia and tested in a proficiency testing for rice. LOD, LOQ, RSD and recovery were reported to be 0.00015 mg/kg, 0.00047 mg/kg, 1.67% and 96.91%, respectively.

33. In view of the availability of analytical methods, it seems that an ML with two significant figures can be used although measurement uncertainty should be taken into consideration. If the Committee feels that more consideration of this issue is needed, we recommend that this question be referred to CCMAS.

<u>Summary</u>

34. The summary of the above analysis is as follows:

- If the draft ML at 0.35 mg/kg for inorganic arsenic in husked rice is introduced, the intake of inorganic arsenic from husked rice will be reduced by 4.3% and the violation rate will be 1.8%.
- The reduction in intake and violation rate for proposed MLs are: 9.9% and 7.3% for an ML at 0.25 mg/kg; 6.4% and 3.4% for an ML at 0.3 mg/kg; and 2.8% and 1.0% for an ML at 0.4 mg/kg, respectively.
- In view of the availability of methods of analysis, the Committee can proceed with an ML with two significant figures for adoption.

DISCUSSION

35. Based on the analysis above, eight EWG members commented on whether the draft ML at 0.35 mg/kg for inorganic arsenic in husked rice was suitable in view of risk reduction, violation rate and capability of methods of analysis and to propose a different ML if the draft ML was not agreeable as follows.

36. Five members supported the draft ML because of achievability, availability of analytical methods for enforcement and some reduction of intake without a significant impact on international trade. The others did not support the draft ML.

37. One member proposed an ML of 0.3 mg/kg because it would result in a reasonable reduction of exposure and consist with the ML for polished rice.

38. One member proposed an ML of 0.25 mg/kg because it would result in a favourable reduction (13%) with a high violation rate and it would be more consistent with the ML for polished rice.

39. One member proposed an ML at 0.5 mg/kg because rice is staple food in Asia, the incidence of levels higher than the surveillance could not be ruled out on account of the widespread occurrence of inorganic arsenic in the samples covered under the current brief study, and the ML could be lowered when the COP was implemented.

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[16] I. Fiamegkos et al., IMEP-41: Determination of inorganic As in food, a collaborative trial, JRC technical report JRC94325 (2015) (available at https://ec.europa.eu/jrc/sites/default/files/IMEP-41%20Final%20report1.pdf)

[17] M.B. de la Calle et al., IMEP-107 Total and inorganic arsenic in Rice, JRC Scientific and Technical Report EUR24341 EN (2010) (available at https://ec.europa.eu/jrc/sites/default/files/eur24314en.pdf)

Table 2 Arithmetic mean estimates of iAs intakes from husked rice taking into consideration the impact of ML proposal scenarios

	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17	Relative reduction ***
Consumption of husked rice (g/person/d)	1.17	1.3	31.05	4.79	0.25	2.16	2.43	1.62	0.42	1.06	-	5.02	13.53	3.48	1.96	0.01	8.84	
No ML																		
Intake (ug/kg bw/d)*	0.003	0.003	0.073	0.011	0.001	0.005	0.006	0.004	0.001	0.002	-	0.012	0.032	0.008	0.005	0.000	0.021	
% of $BMDL_{05}$**	0.1%	0.1%	2.4%	0.4%	0.0%	0.2%	0.2%	0.1%	0.0%	0.1%	-	0.4%	1.1%	0.3%	0.2%	0.0%	0.7%	
ML=0.25 mg/kg																		
Intake (ug/kg bw/d)*	0.002	0.003	0.066	0.010	0.001	0.005	0.005	0.003	0.001	0.002	-	0.011	0.029	0.007	0.004	0.000	0.019	9.9%
% of $BMDL_{05}$**	0.1%	0.1%	2.2%	0.3%	0.0%	0.2%	0.2%	0.1%	0.0%	0.1%	-	0.4%	1.0%	0.2%	0.1%	0.0%	0.6%	
ML=0.3 mg/kg																		
Intake (ug/kg bw/d)*	0.003	0.003	0.068	0.011	0.001	0.005	0.005	0.004	0.001	0.002	-	0.011	0.030	0.008	0.004	0.000	0.019	6.4%
% of $BMDL_{05}$**	0.1%	0.1%	2.3%	0.4%	0.0%	0.2%	0.2%	0.1%	0.0%	0.1%	-	0.4%	1.0%	0.3%	0.1%	0.0%	0.6%	
ML=0.35 mg/kg																		
Intake (ug/kg bw/d)*	0.003	0.003	0.070	0.011	0.001	0.005	0.005	0.004	0.001	0.002	-	0.011	0.030	0.008	0.004	0.000	0.020	4.3%
% of $BMDL_{05}$**	0.1%	0.1%	2.3%	0.4%	0.0%	0.2%	0.2%	0.1%	0.0%	0.1%	-	0.4%	1.0%	0.3%	0.1%	0.0%	0.7%	
ML=0.4 mg/kg																		
Intake (ug/kg bw/d)*	0.003	0.003	0.071	0.011	0.001	0.005	0.006	0.004	0.001	0.002	-	0.011	0.031	0.008	0.004	0.000	0.020	2.8%
% of $BMDL_{05}$**	0.1%	0.1%	2.4%	0.4%	0.0%	0.2%	0.2%	0.1%	0.0%	0.1%	-	0.4%	1.0%	0.3%	0.1%	0.0%	0.7%	

For further information on clusters (G01-17), please refer to GEMS/Food database (https://extranet.who.int/gemsfood/)

* Body weight: 60 kg except G09 for which 55 kg was used.

** $BMDL_{0.5}$ value: 3.0 μg/kg bw/day as estimated at the 72nd JECFA.

*** Relative reduction of intake is calculated using the following equation: {(Intake of iAs without ML) – (Intake of iAs with proposed ML)} / (intake of iAs without ML) x 100

APPENDIX I

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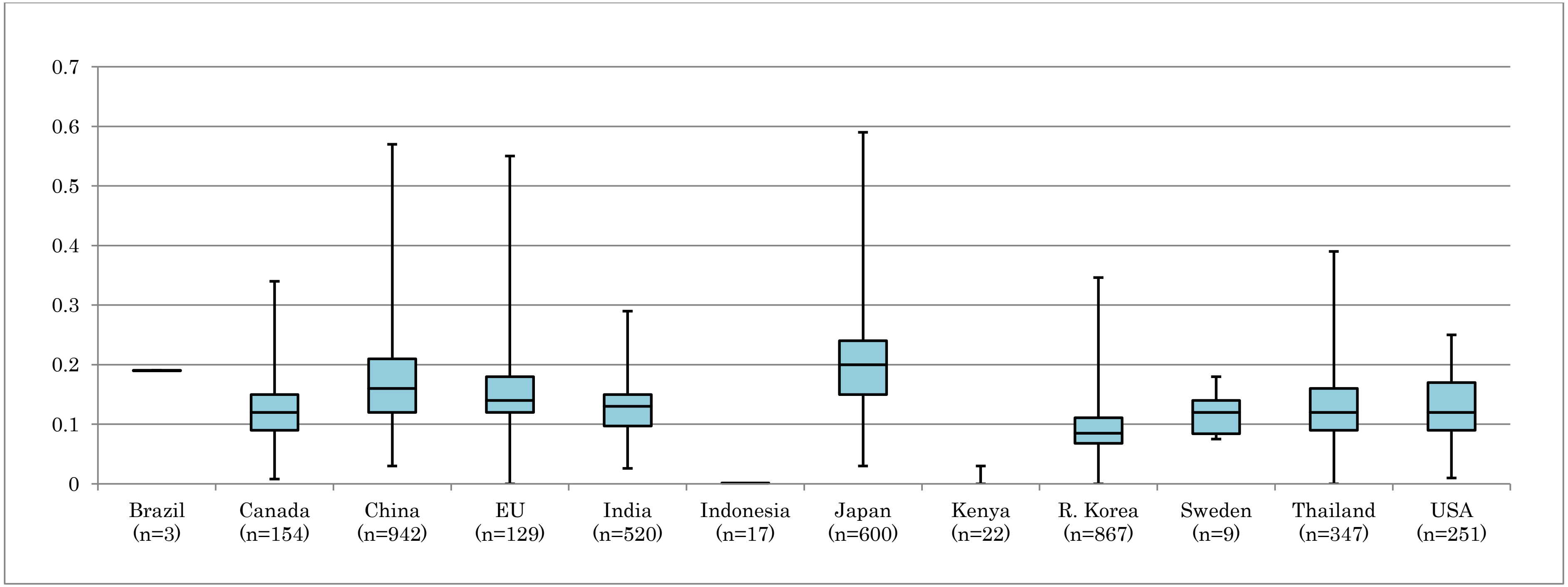
APPENDIX II

SUMMARY OF OCCURRENCE DATA ON INORGANIC ARSENIC IN HUSKED RICE

Summary of data used for the analysis is shown in Figure II.1.

Figure II.1 Box plot for distribution of inorganic arsenic concentration in husked rice in each country



* The bottom and top of the box are the 1st and 3rd quartiles and the band inside the box is the median. The bottom and top of the whiskers are the minimum and maximum of all data. Analytical values less than LOQ are displayed as 0.

A. Data collected by the EWG in 2014

Data collected by the EWG in 2014 were summarised in Table II.1. Further information on these data is available in CX/CF 15/9/7. It should be noted that data from analytical methods with the LOQ higher than 0.1 mg/kg were not included in the table[18].

[18] The draft ML adopted by the Commission at Step 5 is 0.35 mg/kg. The Procedural Manual states that the LOQ of the methods of analysis should be no more than 1/5 of the specified ML (*Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance Thereof*, Section II in the Procedural Manual). However, in order to fully utilize the provided data, the LOQ of 0.1 mg/kg was used as a cut-off point and data from analytical methods with the LOQ higher than 0.1 mg/kg were not used.

Table II.1 Summary of data collected by the EWG in 2014

Member	Number of samples	Year	mean[19] [mg/kg]	Median [mg/kg]	1st quartile [mg/kg]	3rd quartile [mg/kg]	min[20] [mg/kg]	max [mg/kg]
Brazil	3	2010	0.19	0.19	0.19	0.19	0.19	0.19
Canada	137	2009-12	0.12	0.12	0.08	0.15	0.008	0.34
China	942	2011-14	0.17	0.16	0.12	0.21	0.03	0.57
European Union	129	2004-14	0.16	0.14	0.12	0.18	-	0.55
Japan	600	2012	0.21	0.20	0.15	0.24	0.03	0.59
Republic of Korea	250	2013-14	0.10	0.09	0.07	0.12	-	0.26
Thailand	347	2011-14	0.12	0.12	0.09	0.16	-	0.39
United States of America	251	2012-13	0.13	0.12	0.09	0.17	0.01	0.25
total	2659		0.16	0.15	0.11	0.20		

[19] Mean was calculated by replacing <LOQ with LOQ/2.
[20] Minimum concentration is not specified if the data consist of two or more subgroups that have different LOQs where the minimum analytical value in Subgroup (A) is smaller than the LOQ of Subgroup (B) and more than one sample(s) in Subgroup (B) showed the analytical value less than LOQ.

B. New/ Additional data

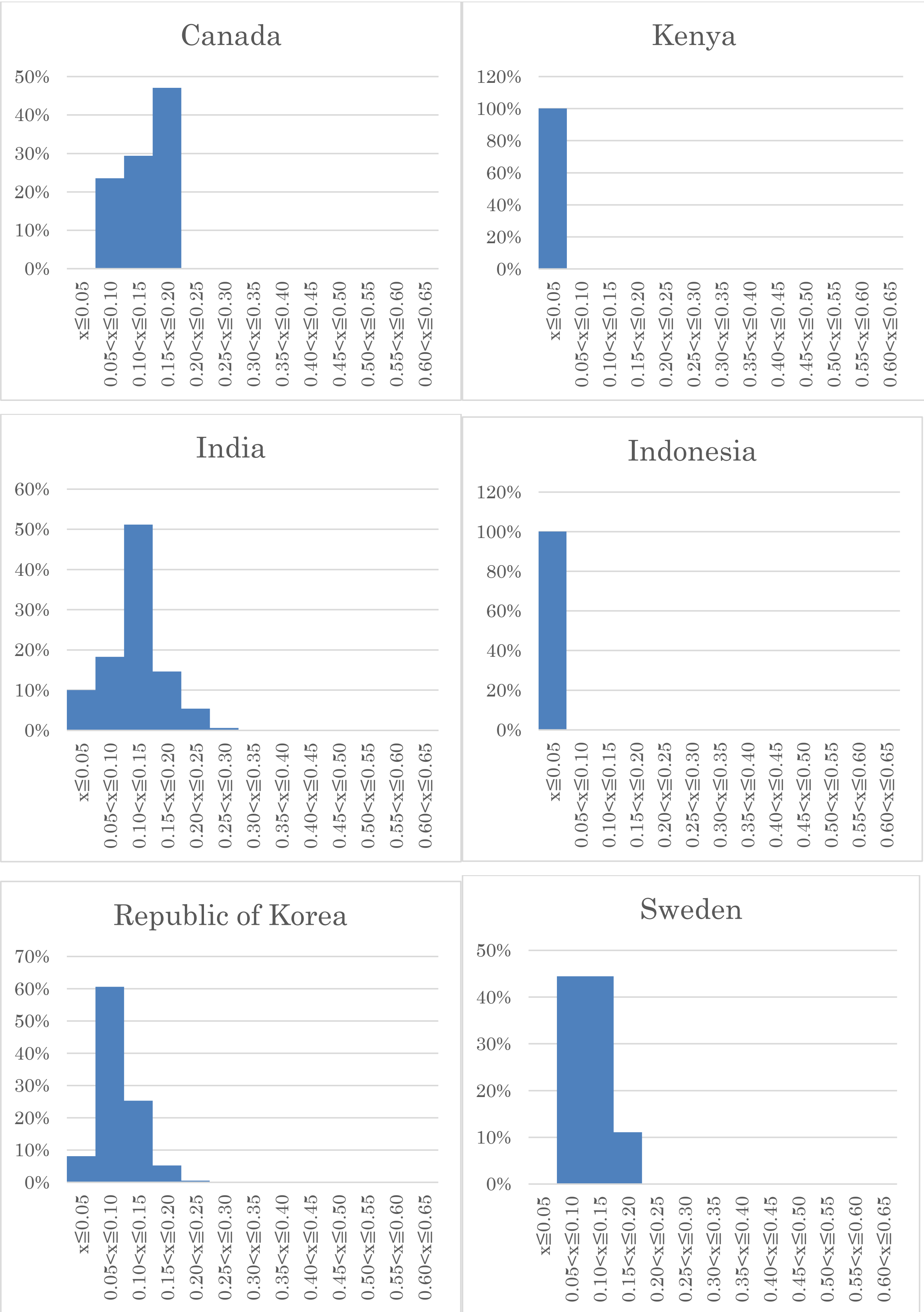
New/ additional data collected by the EWG of this year were summarised in Table II.2 and Figure II.2.

Table II.2 Summary of newly submitted data in 2015

Member	Number of samples	LOQ [mg/kg]	Number of <LOQ	mean [mg/kg]				Median [mg/kg]	1st quartile [mg/kg]	3rd quartile [mg/kg]	min [mg/kg]	max [mg/kg]
				True	Best estimated[21] *	Upper bound[22]	Lower bound[20]					
Canada	17	0.002 (As(III)) 0.014 (As(V))	0	0.14				0.14	0.10	0.18	0.065	0.19
India	520	0.025	0	0.12				0.13	0.097	0.15	0.026	0.29
Indonesia	17	0.0005	0	0.00097				0.00093	0.00078	0.0012	0.00055	0.0016
Kenya	22	0.005	19			0.007	< 0.005	< 0.005	< 0.005	< 0.005	< 0.005	0.030
Republic of Korea	617	0.0038	0	0.091				0.084	0.066	0.11	0.022	0.35
Sweden	9	0.005	0	0.12				0.12	0.084	0.14	0.075	0.18

[21] Best estimated mean was calculated by replacing <LOQ with LOQ/2 in case the proportion of <LOQ is less than or equal to 60%.
[22] Upper and lower bound were calculated by replacing <LOQ with 0 and LOQ, respectively, in case the proportion of <LOQ is more than 60%.

Figure II.1 Histograms of new/additional data



APPENDIX III

Information on Methods of Analysis that are Fit for Purpose

(Methods A-C)

	Requirement[23]	Performance of methods					
		Method A	Eval	Method B	Eval	Method C	Eval
Reference		Journal of AOAC International, 97(3), May-June 2014, pp. 946-955 (http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/2014/00000097/00000003/art00041)		(EU method)		D'Amato. M., Forte, G., and Caroli, S. Identification and Quantification of Major Species of Arsenic in Rice. J. AOAC Int. Vol. 87 (1), 238-243, 2004 Kohlmeyer, U., Jantzen, E., Kuballa, J., and Jakubik, S. Benefits of High Resolution IC-ICP-MS for the Routine Analysis of Inorganic Arsenic Species in Food Products of Marine and Terrestial Origin. Anal Bioanal Chem. Vol. 377, 6-13, 2003	
Validation		Internationally validated (Indonesia, Japan, Singapore, Thailand)	OK	Validated in collaborative trial (ring-trial) in the EU	OK		
Applicability	The method has to be applicable for the specified commodity	Applicable for polished rice and husked rice (both indica and japonica types)	OK	Applicable for polished rice, parboiled rice and husked rice	OK	Validated for infant rice cereal, pear-based pureed baby food, crustaceans, rice-based protein powder and water	

23 Criteria required by the Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance Thereof, Section II in the Procedural Manual when setting an ML at 0.35 mg/kg

	Requirement[23]	Performance of methods					
		Method A	Eval	Method B	Eval	Method C	Eval
Minimum applicable range	[ML-3S_R, ML+3S_R] Should be applicable between 0.14 and 0.56 mg/kg	Applicable between 0.02 and 2 mg/kg	OK			0.000674 – 1.50 mg/kg (for As(III)) 0.00329 – 1.05 mg/kg (for As(V))	OK
LOD	LOD ≤ ML x 1/10 (0.035 mg/kg)	0.002 – 0.01 mg/kg	OK	0.006 mg/kg	OK	0.00067 mg/kg (for As(III)) 0.0033 mg/kg (for As(V))	OK
LOQ	LOQ ≤ ML x 1/5 (0.07 mg/kg)	0.02 mg/kg	OK	0.02 mg/kg	OK	0.0020 mg/kg (for As(III)) 0.014 mg/kg (for As(V))	OK
Precision	HorRat(R) ≤ 2	HorRat(R): 0.57 –1.7 (0.03-0.68 mg/kg)	OK	HorRat (R) less than 2	OK	RSD_r 12-14% (for As(III)) 10-16% (for As(V))	
Recovery	80-110%	80-110%	OK			107-116% (for As(III)) 94-106% (for As(V))	OK
Notes		According to the analysis of variation of standard curves and the result of international collaborative study using Youden-paired samples, the method demonstrated its capability to detect 0.01 mg/kg difference of concentration at 0.35 mg/kg.					

(Methods D-F)

	Requirement[21]	Performance of methods					
		Method D	Eval	Method E	Eval	Method F	Eval
Reference		Method not published yet Extraction based in Rie R. Rasmussen & Yiting Qian & Jens J. Sloth. SPE HG-AAS method for the determination of inorganic arsenic in rice—results from method validation studies and a survey on rice products. Anal Bioanal Chem (2013). DOI 10.1007/s00216-013-6936-8 Quantitative determination by ICP/MS		FDA EAM 4.11 http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm328363.htm		Rice Technical Workers Group Proceedings Abstract. Chaney et al. adaptation of Petursdottir et al. (2013) method to apply method to US-FDA hotblock digestion with 0.28 M HNO_3 to extract As species. Measures inorganic As only in the presence of significant DMA; iAs is the key needed measure. Including Antifoam B in the hydride generation solutions is critical to reliable ICP-AES measurements but is not in original report.	
Validation		In House validation at the Institute of Public Health of Chile		Multi-lab (6 FDA and FERN labs)	OK	One lab.	
Applicability	The method has to be applicable for the specified commodity	Validation for rice flour		Rice and rice cereal (see Note below)	OK	Validated for inorganic As in both brown and milled rice using standards and samples analyzed for inorganic and other As species by US-FDA	
Minimum applicable range	[ML-3S_R, ML+3S_R] Should be applicable between 0.14 and 0.56 mg/kg	Applicable between 0.04 and 2 mg/kg	OK	Applicable between 0.02 and 2 mg/kg	OK	0.020 mg iAs/kg to 2 mg iAs/kg dry weight	OK

	Requirement[21]	Performance of methods					
		Method D	Eval	Method E	Eval	Method F	Eval
LOD	LOD ≤ ML x 1/10 (0.035 mg/kg)	0.027 mg/kg	OK	0.0024 mg/kg	OK	0.005 mg/kg with specific equipment used for hydride generation analysis.	OK
LOQ	LOQ ≤ ML x 1/5 (0.07 mg/kg)	0.04 mg/kg	OK	0.018 mg/kg	OK	0.020 mg/kg with specific equipment used for hydride generation analysis.	OK
Precision	HorRat(R) ≤ 2	HorRat(R): 0.57 (0.092 mg/kg)	OK	5-6% RSD for both reference materials and validation samples	OK	5% RSD for reference range and NIST samples.	OK
Recovery	80-110%	80-110%	OK	74-129%		95-105% of spikes	OK
Notes		This method assumes the concentration of inorganic arsenic as the sum of As(III) and As(V). The method was validated for quantitative determination of inorganic arsenic using the 1586b standard reference material of rice flour from NIST.		Although method validation materials were rice and rice cereal, the method has been used to analyse a variety of other rice-based foods including snack bars, crackers and beverages.		Adaptation of Petursdottir et al. method focused on powdered rice samples Original reference: Pétursdóttir, Á.H., N. Friedrich, S. Musil, A. Raab, H. Gunnlaugsdóttir E.M. Krupp and J. Feldmann. 2014 Hydride generation ICP-MS as a simple method for determination of inorganic arsenic in rice for routine biomonitoring. Anal. Meth. 6:5392-5396.	