CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/CF 15/9/7**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

9th Session
New Delhi, India, 16 – 20 March 2015

PROPOSED DRAFT MAXIMUM LEVELS FOR INORGANIC ARSENIC IN HUSKED RICE

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

Codex Members and Observers wishing to submit comments at Step 3 on the proposed draft maximum levels for inorganic arsenic in husked 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 **28 February 2015**. Comments should be directed:

to:	with a copy to:
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Note: The conclusions and recommendations are for consideration by Codex members, international observer organizations and the Committee. The proposed MLs are for comments at Step 3 by Codex members and international observer organizations and for consideration by the Committee. Codex members and observers are kindly invited to consider supporting information in Appendices I, II and III when submitting comments on the recommendations in particular the proposed MLs in paragraph 6.

INTRODUCTION

1. The Committee on Contaminants in Food (CCCF) at its 8th Session (April 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 the support for the establishment of an ML of 0.2 mg/kg for polished rice. It agreed to forward the ML for iAs in polished rice at 0.2 mg/kg to the Codex Alimentarius Commission for adoption at Step 5/8. The 37th Session of the Commission (July 2014) adopted the ML as proposed[2].

2. With regard to an ML in husked rice, the CCCF could not reach agreement as divergent views were expressed as to what the ML for husked rice should be in terms of protection of human health while not having a negative impact on international trade, in particular as rice was a major staple food in Asian countries and the ML established may affect availability of rice. However, in view of the relevance of this matter for many Codex members, the CCCF encouraged countries, especially rice-producing countries to submit data to GEMS/Food. Data submitted could then be considered in the EWG in order to facilitate the discussion of this matter at the 9th CCCF before taking a final decision on the feasibility to establish an ML for this product. In view of this, the remaining recommendations on the development of a “polishing procedure” and the establishment of a worldwide “conversion factor” were not considered.

1 REP14/CF paras 35-47
2 REP14/CAC paras 79-82 and Appendix III

3. A proposal to defer the establishment of an ML for husked rice until more occurrence data based on the implementation of a code of practice (COP) to contain arsenic contamination be collected did not receive much support as the development and implementation of a COP would take some time, while measures should be taken by CCCF to reduce human health risk to iAs exposure from both types of rice.

4. The CCCF agreed to re-establish the EWG led by China and co-chaired by Japan to prepare a proposed draft ML for husked rice for circulation and comments at Step 3 and further consideration by the 9th CCCF.

5. The EWG considered proposals for MLs for iAs in husked rice based on submitted data. Background information in support of the recommendations is presented in Appendix I. A summary of the data submitted is presented in Appendix II. Information on development of processing factor to estimate iAs concentration in polished rice is presented in Appendix III. The list of participants to the EWG is attached as Appendix IV.

RECOMMENDATIONS

6. Concerning an ML for husked rice, the CCCF should discuss the numerical value of an ML for iAs in husked rice. During the discussion in the EWG, the following MLs are proposed for consideration by the CCCF:

- 0.25, 0.3, 0.35 and 0.4 mg/kg. The violation rate and relative reduction are 11.7% and 12%; 4.9% and 6.3%; 1.9% and 2.5%; and 0.7% and 1.3%, respectively.

If the CCCF agrees on a numerical value, the CCCF should:

- Agree to include a footnote regarding analysis of total arsenic as a screening tool; and
- Consider whether guidance for application of the ML is necessary.

7. If the CCCF is unable to reach consensus on an ML, it should postpone the development of an ML for husked rice. In this case, the CCCF should:

- discuss the mechanism to exclude the possibilities that rice that may not comply with the ML for polished rice may be distributed in the form of husked rice (e.g. development of a processing factor – see Appendix III); and
- request Members for further collection of data.

8. Concerning methods of analysis, the CCCF should

- identify an appropriate method; and
- request the Committee on Methods of Analysis and Sampling (CCMAS) to convert the appropriate method into criteria.

APPENDIX I

BACKGROUND INFORMATION ON THE DEVELOPMENT OF THE PROPOSED MAXIMUM LEVELS FOR INORGANIC ARSENIC IN HUSKED RICE

MAXIMUM LEVEL FOR INORGANIC ARSENIC IN HUSKED RICE

9. In response to the request of the CCCF, 2738 records for iAs concentrations in husked rice were provided by 9 members: Brazil, Canada, China, the European Union, Japan, the Republic of Korea, Singapore, Thailand and the United States of America through GEMS/Food or directly. A summary of the data is shown in Appendix II.

10. The possible levels discussed at the 8th Session were 0.25, 0.3 and 0.4 mg/kg[3]. The Procedural Manual states that the Limit of quantification (LOQ) of the methods of analysis should be no more than 1/5 of the specified ML[4]. 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. As a result, 31 data points were excluded from statistical analysis.

11. It should be noted that, as the ML for iAs in polished rice of 0.2 mg/kg was adopted by the Commission, there should be some link between ML of iAs in polished rice and concentrations of iAs in husked rice for the control of husked rice.

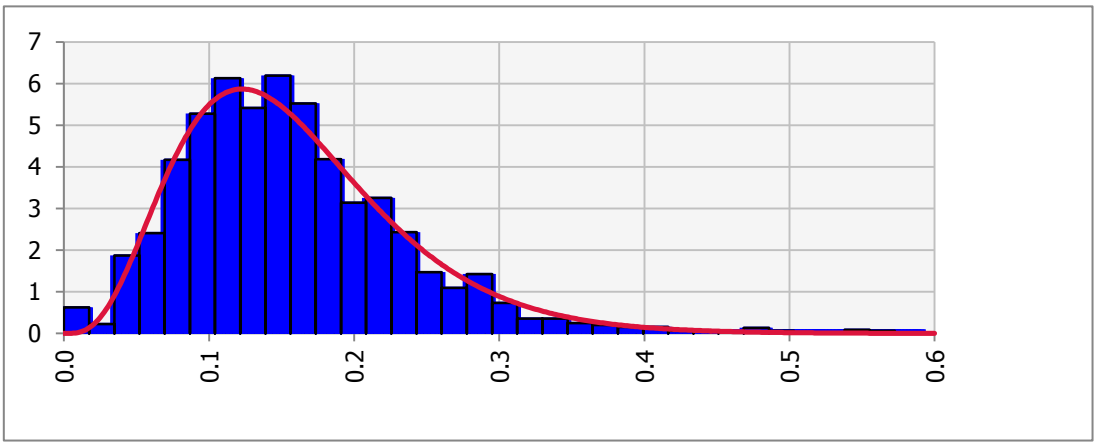
Distribution curves and estimation of ML

12. The occurrence data of iAs in husked rice provided by nine Members were merged, although they may belong to different populations, and distribution curve was drawn. The Gamma distribution model was selected as recommended by @Risk software as the best fit model for the distribution (Fig. 1).

13. On the gamma distribution model, Monte Carlo Simulation (n=100 000) was conducted 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 each of the values discussed at the 8th CCCF (0.25, 0.3 and 0.4 mg/kg) and 0.35 mg/kg which was derived on a basis of a value between 0.3 and 0.4 with violation rate of 2-3% in accordance with the proposal made at the 8th Session (Table 1).

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	0.158	-
0.4 mg/kg	0.156	0.7
0.35 mg/kg	0.154	1.9
0.3 mg/kg	0.148	4.9
0.25 mg/kg	0.139	11.7



[3] REP 14/CF para. 37

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

14. The General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) states in its Annex I Criteria for the Establishment of Maximum Levels in Food and Feed[5] that ML should be as low as reasonably achievable. However, while protection of human health is of utmost importance, as rice is a major staple food in many Asian and African countries, it should be taken into consideration that the ML established may affect availability of rice significantly. From this point of view, it is not appropriate to allow a high violation rate. Thus, the proposed ML of 0.25 mg/kg with a high violation rate of 11.7% does not seem appropriate.

15. Annex I of the GSCTFF (CODEX STAN 193-1995) also states that numerical values for MLs should preferably be regular figures unless this may pose problems in the acceptability of the MLs. The values indicated in the Annex are with one significant figure. With this criterion, proposals of 0.25 and 0.35 mg/kg are less preferable. This leaves the proposals of 0.3 and 0.4 mg/kg with the violation rate of 4.9 and 0.7%, respectively.

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 would take until 2017 if proceeding as planned[6].

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[7] (October 2014) available on the GEMS/Food website and the mean concentrations in Table 1.

18. The results are shown in Table 2. In summary, the intakes of iAs from husked rice in different clusters were estimated to be in a range between 0 and 0.082 µg/kg bw/day corresponding to a range of 0 to 2.8% of the $BMDL_{0.5}$ of 3.0 µg/kg-bw/day (JECFA, 2010). Higher intakes were calculated for those clusters (namely, G03, G13, G17 in descending order) consisting of many countries in Africa (and some outside of Africa) with higher consumption values of husked rice. The effect of setting an ML for iAs on reduction of dietary iAs intake from husked rice was more significant in these clusters than in other clusters. As anticipated, the reduction effect is the highest with a proposal of 0.25 mg/kg and insignificant with a proposal of 0.4 mg/kg. However, it should be noted that the violation rate for the proposal of 0.25 mg/kg is higher than 10% making the availability of husked rice less than 90% of the supply.

19. It should also be noted that, 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 trade item, constituting only about 10% of rice traded, according to the FAOSTAT.

5 Annex I in the General Standard for Contaminants and Toxins in Foods and Feed (CODEX STAN 193-1995)
6 REP 14/CAC para. 96 and Appendix VI, REP14/CF Appendix VIII
7 IEDIcalculation0217clustersfinal.xlsm

Table 2 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	1.30	31.05	4.79	0.25	2.16	2.43	1.62	0.42	1.06	-	5.02	13.53	3.48	1.96	0.10	8.84	
No ML																		
Intake (ug/kg bw/d)*	0.003	0.003	0.082	0.013	0.001	0.006	0.006	0.004	0.001	0.003	-	0.013	0.036	0.009	0.005	0.000	0.023	
% of $BMDL_{05}$**	0.1	0.1	2.7	0.4	0.0	0.2	0.2	0.1	0.0	0.1	-	0.4	1.2	0.3	0.2	0.0	0.8	
ML=0.25 mg/kg																		
Intake (ug/kg bw/d)*	0.003	0.003	0.072	0.011	0.001	0.005	0.006	0.004	0.001	0.002	-	0.012	0.031	0.008	0.005	0.000	0.020	
% 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	
Relative reduction of intake ***																		12%
ML=0.3 mg/kg																		
Intake (ug/kg bw/d)*	0.003	0.003	0.077	0.012	0.001	0.005	0.006	0.004	0.001	0.003	-	0.012	0.033	0.009	0.005	0.000	0.022	
% of $BMDL_{05}$**	0.1	0.1	2.6	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	
Relative reduction of intake ***																		6.3%
ML=0.35 mg/kg																		
Intake (ug/kg bw/d)*	0.003	0.003	0.080	0.012	0.001	0.006	0.006	0.004	0.001	0.003	-	0.013	0.035	0.009	0.005	0.000	0.023	
% of $BMDL_{05}$**	0.1	0.1	2.7	0.4	0.0	0.2	0.2	0.1	0.0	0.1	-	0.4	1.2	0.3	0.2	0.0	0.8	
Relative reduction of intake***																		2.5%
ML=0.4 mg/kg																		
Intake (ug/kg bw/d)*	0.003	0.003	0.081	0.012	0.001	0.006	0.006	0.004	0.001	0.003	-	0.013	0.035	0.009	0.005	0.000	0.023	
% of $BMDL_{05}$**	0.1	0.1	2.7	0.4	0.0	0.2	0.2	0.1	0.0	0.1	-	0.4	1.2	0.3	0.2	0.0	0.8	
Relative reduction of intake***																		1.3%

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

** BMDL0.5 value: 3.0 µg/kg bw/day 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

20. The Policy of the Codex 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[8].

21. These criteria were established assuming the comparison of calculated intakes with the PTDI or PTWI. Although the contribution to the intake of iAs from husked rice is at most 2.7% (G03) of the $BMDL_{0.5}$, it is not appropriate to apply the above criteria for comparison of the calculated intakes of iAs from husked rice with the $BMDL_{0.5}$.

Impact of ML Proposal on Enforcement

22. The CCCF at its 8th session was informed that with the MLs both in polished and husked rice, there were some possibilities that a sample complying with the ML for husked rice would not comply with the ML for polished rice, or *vice versa.* A total of 1557 data on iAs in husked and polished rice from the same sample source in China and Japan (collected by the EWG established by the 7th Session of the CCCF and by this EWG) were analysed for different ML proposals for husked rice in relation to the ML of 0.2 mg/kg adopted for polished rice. As shown in Table 3, setting an ML at 0.25 mg/kg would lead to the highest discrepancy resulting in 84.2% of the samples from the same rice grain source meeting both the MLs for polished rice and husked rice. With ML proposals of 0.3, 0.35 and 0.4 mg/kg, rates for consistency of results from the same rice grain source meeting both the MLs are 93.8%, 97.1% and 98.1%, respectively.

Table 3 Number of samples in the specified concentration range

		Polished rice	
		≦0.2 mg/kg	> 0.2 mg/kg
Husked rice	≦0.25 mg/kg	1295 (83.2%)	4 (0.3%)
	> 0.25 mg/kg	243 (15.6%)	15 (1.0%)
	≦0.3 mg/kg	1445 (92.8%)	4 (0.3%)
	> 0.3 mg/kg	93 (6.0%)	15 (1.0%)
	≦0.35 mg/kg	1499 (96.3%)	7 (0.4%)
	> 0.35 mg/kg	39 (2.5%)	12 (0.8%)
	≦0.4 mg/kg	1518 (97.5%)	10 (0.6%)
	> 0.4 mg/kg	20 (1.3%)	9 (0.6%)

Annual variability of iAs concentration

23. To consider annual variability, 3 pairs of data from the same country sampled in different years were compared using the Mann-Whitney U test[9]: data from China (samples collected in 2011 and between December 2013 and June 2014), the Republic of Korea (in 2013 and 2014) and Thailand (in 2013 and 2014) resulted from husked rice domestically collected by random sampling[10]. The summary of data and histograms for each data were shown in Table 4 and Fig. 2.

24. With regard to the data from China, 2 data sets from different years were available: 507 data from samples collected between December 2013 and June 2014; and 435 data from samples collected in 2011. iAs concentrations in husked rice of two data sets were statistically different ($p<0.01$). While 0.6% of husked rice was above the specified concentration at 0.3 mg/kg in 2013-2014, 9.7% in 2011.

8 Section IV, paras 10-11 in the Procedural Manual.

9 The analytical value being less than LOQ is replaced with 0 for the analysis.

10 It is not appropriate to compare two dataset resulted from the methods of analysis with different LOQs. Data for the analysis are resulted from the method of analysis with the same LOQ. The data from the Republic of Korea were analyzed because no samples contained iAs at less than LOQ.

25. Analysis of the data from Thailand indicated that husked rice collected in 2013 (n=176) contained iAs at significantly higher concentrations ($p<0.05$) than those collected in 2014 (n=81) although the medians for them were similar (0.13 mg/kg and 0.11 mg/kg, respectively).

26. According to the data of the Republic of Korea, the concentrations of iAs in husked rice collected in 2014 (n=150) were statistically higher ($p<0.01$) than that in 2013 (n=89).

27. As a summary, it was found that there is significant annual variability in the concentrations of iAs in husked rice although it is not possible to exclude a possibility that this variability was caused by taking samples from different locations or from different agricultural practices. Similar tendency may be likely in concentrations of iAs in polished rice.

28. To speculate on the highest and lowest possible concentrations of iAs in husked rice, data from 3 countries were combined into 2 datasets: a “high” dataset (n=730) consisting of the data from China in 2011, the Republic of Korea in 2014 and Thailand in 2013; and a “low” dataset (n=677) consisting of the data from China collected between 2013 and 2014, the Republic of Korea in 2013 and Thailand in 2014, although they may belong to different populations and they may not cover whole range of variability. Each of the combined datasets was modelled in a lognormal distribution and the mean and violation rate were estimated for each proposed ML (Table 5).

29. In the “low” dataset, setting the ML at 0.3, 0.35 or 0.4 mg/kg for iAs in husked rice does not contribute to reduction of iAs intake as shown by no change in mean concentration. In other words, there is no need to establish MLs on the commodity in this situation.

30. In the “high” dataset, setting an ML for iAs in husked rice contributes to reduction of iAs concentrations. For example, introduction of an ML at 0.3 mg/kg will decrease the mean concentration for iAs from 0.172 mg/kg to 0.161 mg/kg. However, the mean concentration in the “low” dataset with No ML is much lower (0.126 mg/kg). Since data were collected in the same countries, the difference in concentration between 2 datasets is considered not to be due to the soil but to be due to other factors, such as weather or practices.

31. It should also be highlighted that setting the ML at 0.3 mg/kg will result in a high violation rate in the “high” dataset, e.g., an ML at 0.3 mg/kg results in a violation rate of 6.5%. However, the violation rate was 0.5% in the “low” dataset.

32. The concentration of iAs concentration in rice fluctuates and high concentrations or low concentrations of iAs may be observed in husked rice grown in various countries. However, to date, the information available is insufficient to cover the whole range of potential variability and to identify cause(s) of variability. This annual variation may seem to necessitate further data collection on husked rice as well as polished rice in different years for establishment of an ML for husked rice. However, it should also be kept in mind that, if new data confirm significant annual variation, the CCCF should review the ML of iAs in polished rice from the same point of view.

33. It should be noted that little is known about the variation and that for further discussion, additional data and information are necessary.

Table 4. Annual variation in iAs concentrations in husked rice

Country	Year	Number of samples	Samples < LOQ	LOQ	Mean* (mg/kg)	Median (mg/kg)	1st quartile (mg/kg)	3rd quartile (mg/kg)	P**
China	2011	435	0	0.009	0.21	0.20	0.15	0.25	< 0.01
	2013-2014	507	0		0.14	0.13	0.10	0.16	
Republic of Korea	2013	89	0	0.0007	0.080	0.077	0.065	0.093	< 0.01
	2014	150	1	0.03	0.11	0.087	0.078	0.14	
Thailand	2013	145	30	0.1	0.13	0.13	0.10	0.16	< 0.05
	2014	81	30		0.12	0.11	< 0.1	0.15	

* Calculated by replacing <LOQ with 1/2LOQ if necessary.

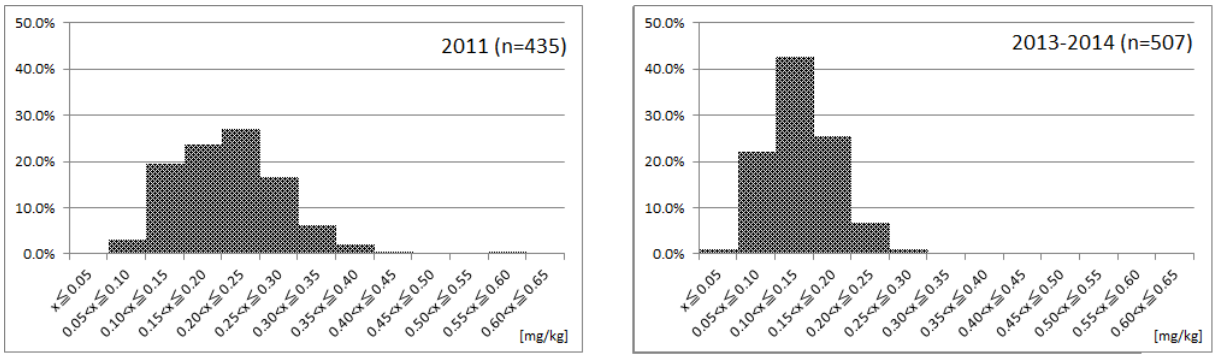
** Significance of difference between data of different years from the same country.

Table 5. Summary of “high” and “low” concentrations from samples taken in different years

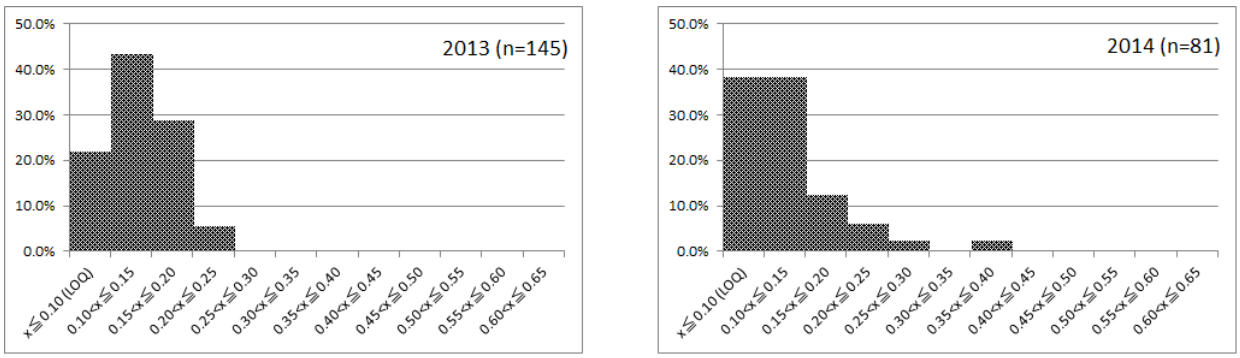
ML at:	High*		Low**	
	Mean (mg/kg)	Violation rate (%)	Mean (mg/kg)	Violation rate (%)
No ML	0.172		0.126	
0.25 mg/kg	0.149	15.6	0.124	2.0
0.3 mg/kg	0.161	6.5	0.126	0.5
0.35 mg/kg	0.167	2.5	0.126	0.2
0.4 mg/kg	0.170	1.0	0.126	0.2

* Combination of data from China (2011), Rep. Korea (2014) and Thailand (2013)

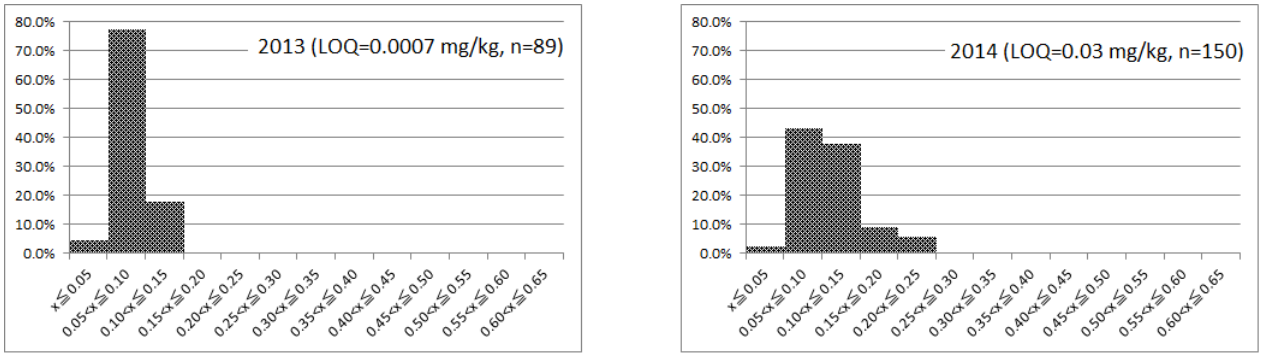
** Combination of data from China (2013-2014), Rep. Korea (2013) and Thailand (2014)



iAs concentrations in husked rice: data from China



iAs concentrations in husked rice: data from Thailand



iAs concentration in husked rice: data from the Republic of Korea

Fig. 2 Distribution of iAs concentration in samples collected in different years

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

- According to the distribution of combined occurrence data and the ALARA Principles, a value of 0.35 and 0.4 mg/kg are appropriate for ML for iAs in husked rice;
- 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 a major component in the consumption of cereals; and
- Annual variability of iAs concentration in husked rice is significant while there have been insufficient data to know if the data cover whole range of variation and cause of variation, which may necessitate further data collection.

Discussion in EWG

35. In response to the request to express preference to the options (ML at 0.3, 0.35 or 0.4 mg/kg or postponement), nine members and one observer replied as follows.

36. Except one member, which preferred postponement of decision, all others showed preference to one of numerical values (0.25, 0.3, 0.35 or 0.4 mg/kg) as the data available seemed to be sufficient to estimate distribution curves and problem on international trade of husked rice due to lack of an ML was identified. The rationales of these preferences are shown below.

- 0.25 mg/kg: Violation rate would be less than half of what is indicated in this document in their surveillance. An ML at 0.35 mg/kg or 0.4 mg/kg was not acceptable in view of reduction of exposure.
- 0.3 mg/kg: Although achievability is lower, the primary concern, due to much higher trading volume, is polished rice. Polished rice from husked rice that meets an ML of 0.3 mg/kg should be able to meet the 0.2 mg/kg ML. There is a reasonable impact to reduction of iAs intake.
- 0.35 mg/kg: The violation rate is suitable and the reduction of intake of iAs is not low when compared with the ML at 0.4 mg/kg.

  N.B. Methods of analysis to provide a value to two significant figures should be available.
- 0.4 mg/kg: It is based on the occurrence data available to the EWG.
- Postponement: Husked rice is not a very important commodity in food consumption and trade; and MLs should be based on the implementation of GMP and/or GAP. Inorganic arsenic in husked rice can be controlled based on the ML for polished rice using a mechanism such as a factor.
- Against postponement: Data available seemed to be sufficient to estimate distribution curves. Problem on international trade of husked rice due to lack of an ML was identified.

OUTSTANDING ISSUES RELATED TO THE ML(s) for iAs

Methods of analysis

37. As it is necessary to use appropriate methods of analysis for enforcement of the MLs, many Codex standards include “Methods of analysis and sampling” section to specify which methods should be used to check whether a sample complies with an ML.

38. As some countries indicated that it is not easy to analyse iAs in rice when discussing the ML for iAs in polished rice at the 8th Session, the CCCF agreed to include the following text in the Standard[11]:

> *Countries or importers may decide to use their own screening when applying the ML for As-in in rice by analysing total arsenic (As-tot) in rice. If the As-tot concentration is below the ML for As-in, no further testing is required and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML.*

39. This text should also apply to an ML for iAs in husked rice, if one is to be established. This text still necessitates analysis of iAs of the samples whose total arsenic concentration exceeds the ML for iAs. It is inevitable as the substance to be controlled is iAs because iAs is considered to be the substance of highest toxicological concern among arsenic substances and it is not possible or appropriate to establish one conversion factor between total and iAs in husked or polished rice.

[11] REP14/CF para. 37 and Appendix III

40. The following methods of analysis are validated and considered to be suitable for the purpose of enforcement of the MLs for iAs in rice (both polished and husked):

- Journal of AOAC International, Volume 97, Number 3, May-June 2014, pp. 946-955[12]

  Speciation and Determination of Inorganic Arsenic in Rice Using Liquid Chromatography-Inductively Coupled Plasma/Mass Spectrometry: Collaborative Study

- CEN/TS 16731:2014

  Foodstuffs - Determination of hydride-reactive arsenic compounds in rice by atomic absorption spectrometry (Hydride-AAS) following acid extraction

- prEN 16802

  Foodstuffs - Determination of elements and their chemical species - Determination of inorganic arsenic in foodstuffs of marine and plant origin by anion-exchange HPLC-ICP-MS following water-bath extraction

41. The CCCF may list these methods in the Standard. In this case, one method should be selected as "Reference Methods" (Type II methods) where the others will be classified as "Alternative Approved Methods" (Type III methods).

42. Alternatively, the CCCF may choose setting numerical values for the performance criteria that the methods of analysis used for testing should meet. If the CCCF decides to develop the numerical value for the criteria, it should also take into account the following facts:

- At least one existing method should meet the criteria.
- With the methods, the concentration of iAs is calculated as the sum of the concentrations of As(III) and As(V). The CCMAS was of the view that further consideration of the criteria approach for multi analyte methods was necessary[13] and is considering development of a criteria approach for methods which use a "sum of components"[14].

43. Instead, the CCCF may choose to ask the CCMAS for help. If so, the CCCF should recommend one specific method and request the CCMAS to convert that method into appropriate criteria[15].

Discussion in EWG

44. In response to the request to express preference to the options (listing appropriate methods, criteria developed by CCCF or requesting CCMAS to convert a method into criteria), seven members replied. These members agreed that the CCCF should request the CCMAS to convert an appropriate method into criteria in line with the current CCMAS work. Some members reminded the EWG that the decision of the 8th session on the ML for polished rice regarding analysis of total arsenic as a screening tool should also apply to the ML for husked rice.

"Polishing procedure" and "conversion factor".

45. As the CCCF could not reach consensus on the ML for husked rice, it did not consider the remaining recommendations on the development of a "polishing procedure" and the establishment of a worldwide "conversion factor". The working paper prepared for the 8th Session[16] concluded that as Members expressed divergent views and the EWG could not reach a consensus, development of the polishing procedure as a part of an analytical method should be discussed at the 8th Session of the CCCF.

46. At the 8th Session, some Members indicated difficulties in polishing husked rice at the laboratories for the purpose of analysis.

47. The working paper prepared for the 8th Session also considered a processing factor to estimate the concentration of iAs in polished rice from that in husked rice. As the ML for polished rice was adopted by the Codex Alimentarius Commission, the same processing factor, if one is available and appropriate, can be used to determine the compliance of husked rice in comparison with the ML for polished rice. However, all of those Members of EWG who responded did not support the establishment of such processing factors for the reasons stated in the paper.

48. The extract of the relevant parts of the discussion is attached as Appendix III on this paper.

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12 http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/2014/00000097/00000003/art00041
13 REP13/MAS para. 47
14 REP14/MAS paras 60-61
15 Working instructions for the implementation of the criteria approach in Codex, Section II in the Procedural Manual
16 CX/CF 14/8/6 (ftp://ftp.fao.org/codex/meetings/cccf/cccf8/cf08_06e.pdf)

49. If the CCCF confirms the decision of the 8th Session to develop also an ML for husked rice, the eWG recommends the CCCF to discuss guidance of applying MLs in order to avoid any confusion in the application of MLs. The guidance may be such as:

- For husked rice to be consumed as polished rice, the ML for polished rice should apply;
- If polished rice derived from husked rice that does not comply with the ML for husked rice complies with the ML for polished rice, the polished rice should be considered as complying with the Standard.

50. The eWG recommends the CCCF to discuss the following issues taking the feasibility or economic impact of rice polishing in testing laboratories into account. If the CCCF decides to develop a provision related to both or either of the following issues, the CCCF should consider including them/it in the Schedule I of the GSCTFF, although the working paper prepared for the 8th Session concluded negatively.

- A polishing procedure including polishing rate in the laboratory; and/or
- A processing factor to estimate the iAs concentration in polished rice from that in husked rice.

Discussion in EWG

51. In response to the request to express preference to the options with regard to development of a processing factor and guidance, seven members and one observer replied. As at the 8th Session of the CCCF, development of polishing procedure in laboratories was not supported.

52. Some members, who supported development of numerical ML, did not agree to develop a processing factor because it was not necessary. Some members did not agree to develop guidance because it was unnecessary or even it would create confusion.

53. One member, which was in favour of postponement, supported discussion on a processing factor as a mechanism to control husked rice to compare with the ML for polished rice.

54. Two members supported to discuss guidance of applying MLs at the CCCF session because the ML should apply to the type of rice as sold and consumed. One of them was of the view that confusion was foreseen in their country if MLs were set on both husked and polished rice and proposed the following guidance:

"For husked rice to be consumed as polished rice, the ML for polished rice should apply."

APPENDIX II

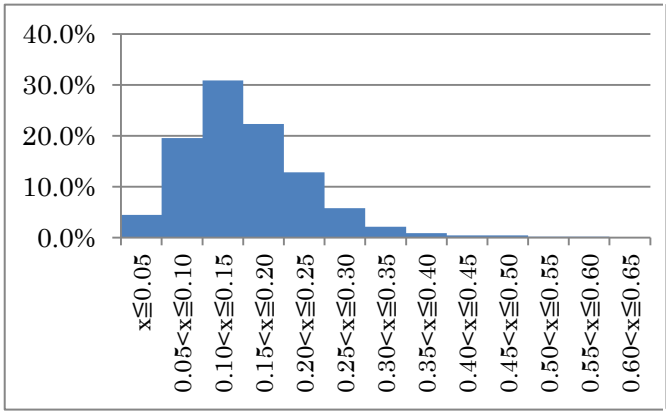
Summary of occurrence data on iAs in husked rice from GEMS/Food database

Country	Year	Number of samples	LOQ [mg/kg]	Number of <LOQ	mean [mg/kg]				Median [mg/kg]	1st quartile [mg/kg]	3rd quartile [mg/kg]
					True	Best estimated*	Upper bound**	Lower bound**			
Brazil	2010	3	0.005	0	0.19				-	-	-
Canada	2009-2012	137	-	0	0.12				0.12	0.087	0.15
China	2013-2014	507	0.009	0	0.14				0.13	0.10	0.16
	2011	435	0.009	0	0.21				0.20	0.15	0.25
European Union	2004-2014	132		5		0.16			0.14	0.12	0.18
Japan	2012	600	0.02	0	0.21				0.20	0.15	0.24
Republic of Korea	2014	11	0.0007	0	0.087				0.087	0.079	0.094
	2014	150	0.03	1		0.11			0.10	0.078	0.14
	2013	89	0.0007	0	0.080				0.077	0.065	0.093
Singapore	2010, 2013	9	0.17	4		0.10			0.10	0.080	0.12
Thailand	2014	81	0.1	30		0.12			0.11	< 0.1	0.15
	2013	145	0.1	30		0.13			0.13	0.10	0.16
	2013	31	0.04	1		0.11			0.099	0.087	0.13
	2012	90	0.015	0	0.12				0.12	0.095	0.16
	2011	19	0.137	16			0.14	0.025	< 0.137	< 0.137	< 0.137
United States of America	2013	187	0.01	0	0.094				0.080	0.060	0.12
	2012	112		0	0.16				0.15	0.12	0.18

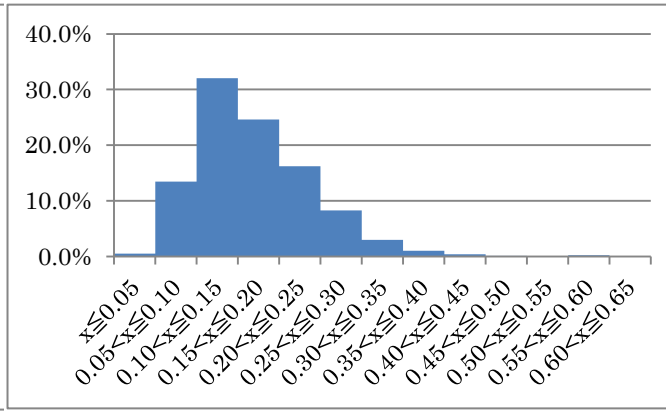
*Best estimated mean was calculated by replacing <LOQ with 1/2LOQ in case the proportion of <LOQ is less than or equal to 60%.

**Upper and lower bound were calculated by replacing <LOQ with 0 and LOQ, respectively, in case the proportion of <LOQ is more than 60%.

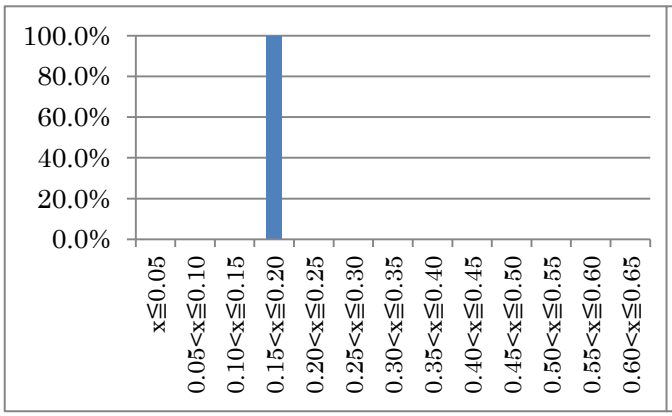
Histograms for occurrence data of iAs in husked rice



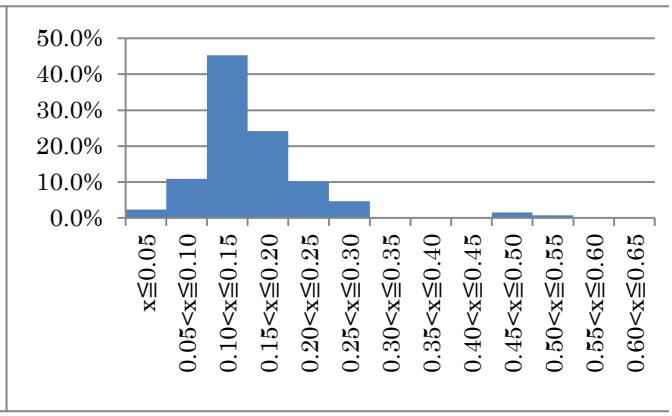
Total



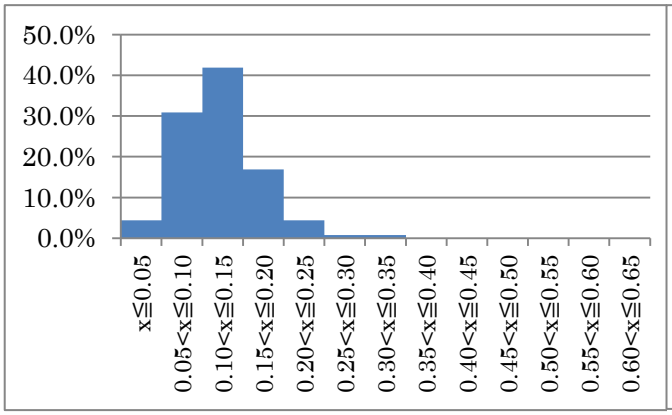
China



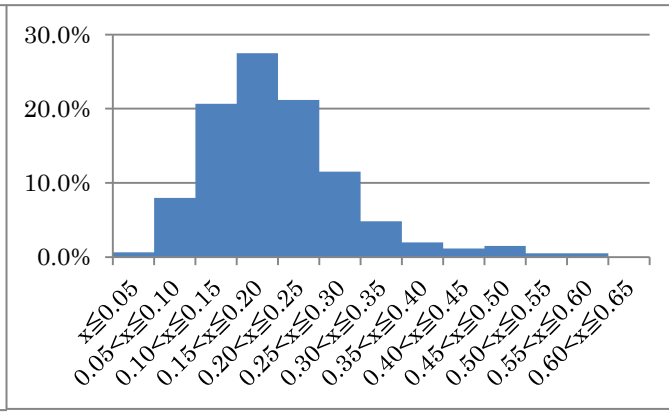
Brazil



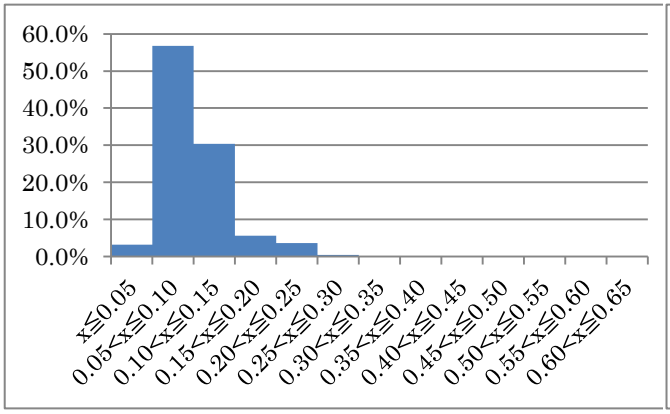
EU



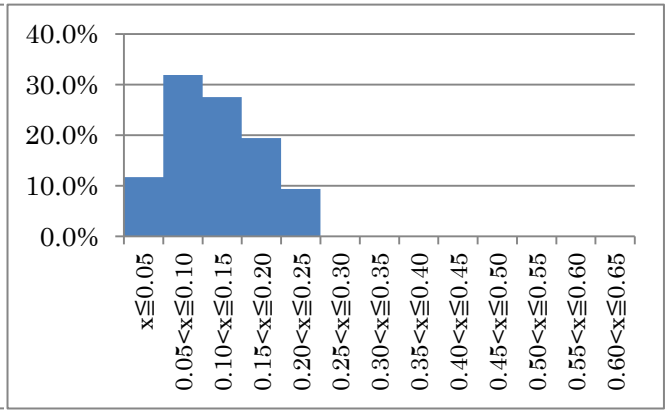
Canada



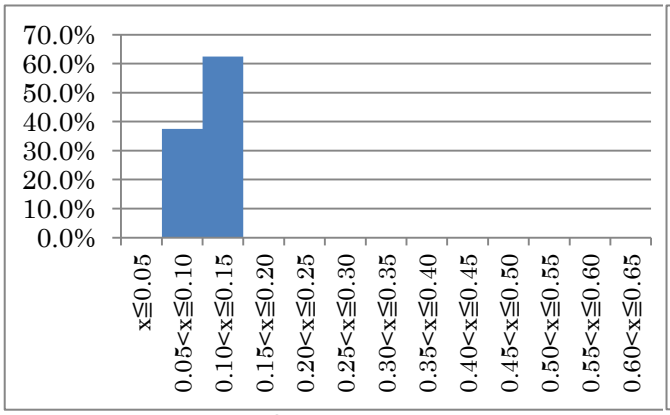
Japan



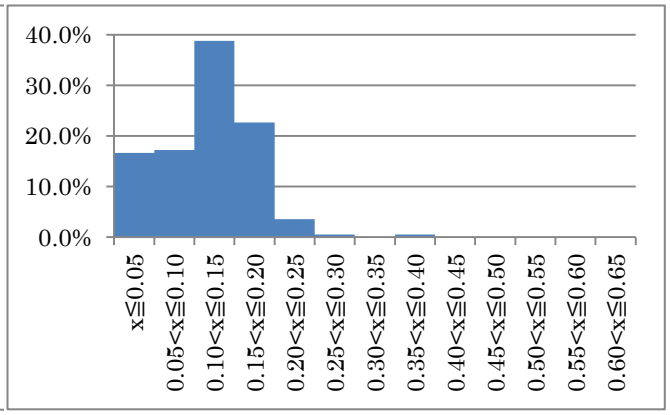
Republic of Korea



United States of America



Singapore



Thailand

APPENDIX III

Processing factor to estimate iAs concentration in polished rice

"*Sample Preparation*

55. An ML for polished rice can be applied to husked rice after polishing it. The term "polishing rate" hereafter used means a ratio of the weight of bran removed by polishing to the original weight of husked rice. The iAs concentration in polished rice is influenced by the polishing rate: the higher the polishing rate is, the more the iAs concentration decreases. The polishing rate varies but is usually around 10%. The polishing procedure as a part of an analytical method needs to be determined before moving the MLs to Step 8. A Member pointed out that there is a need to internationally validate polishing procedure as a part of an analytical method.

56. Three Members raised concern on the feasibility or economic impact of polishing rice in testing laboratories.

57. Since Members expressed divergent views and could not reach a consensus, development of the polishing procedure as a part of an analytical method should be discussed at the 8th Session of the CCCF."

"*Processing factor to estimate inorganic arsenic concentration in polished rice*

58. As about 80% of rice traded internationally is polished rice and only about 10% is husked rice, most of samples obtained from traded rice for laboratory analysis would be polished rice. On the other hand, for domestically produced rice, both husked rice samples and polished rice samples can be obtained for analysis. Husked rice may be consumed as such or polished before or during distribution. If an ML is developed for polished rice only, in order to check the compliance of a husked rice sample with the ML, there is a need for a certain conversion factor to estimate iAs concentration in polished rice from that in husked rice.

59. The eWG discussed whether a processing factor could be established to estimate iAs concentration in polished rice from that in husked rice (see Fig. 3). If a husked rice sample is analyzed for iAs, the possible iAs in polished rice will be estimated using the iAs concentration in husked rice and the processing factor, and the estimated iAs concentration in polished rice will be compared with the ML. In order to determine the processing factor, the eWG carried out statistical evaluation as described in the following paragraphs.

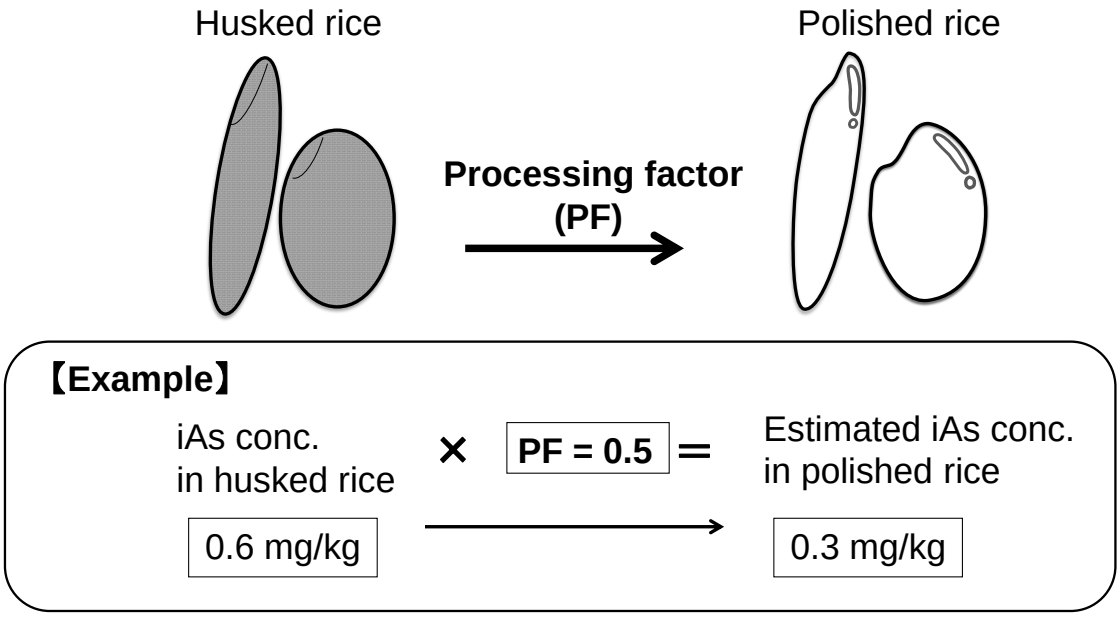


Fig. 3 Processing factor

60. First, the hypothetical processing factors were determined. Among all the available occurrence data, iAs concentrations in husked and polished rice obtained from the same sample source were identified (hereinafter referred to as “the original data set”) (n=1048, China and Japan). From the original data set, data on husked rice with iAs concentration of no less than 0.2 mg/kg (hereinafter referred to as Group 1) and 0.3 mg/kg (hereinafter referred to as Group 2) were extracted respectively and the ratios of iAs concentration in polished/husked rice were calculated. As, at low concentrations, in particular lower than or close to the limit of quantification (LOQ), measurement uncertainty is significantly large affecting the calculation of ratios, one cut-off value was selected at about five times the LOQ. The other cut-off value of 0.3 mg/kg was selected to cover a greater decrease of iAs after polishing when the iAs concentration in husked rice is higher. Using these ratios, distributions were developed for Group 1 and Group 2 respectively (see Fig. 4). In order to assess normality of each distribution, the Kolmogorov-Smirnov test was performed. Both distributions were deemed to be normal at 5% level of significance. The mean ratios of iAs in polished rice to husked rice for Group 1 and Group 2 were estimated to be 0.51 and 0.44, and standard deviations (SD) were estimated as 0.12 and 0.10 respectively. From these means and standard deviations values, five hypothetical processing factors were obtained for each distribution model (mean, mean±SD, mean±2SD, see Table 6 below).

Table 6 Hypothetical processing factors for Group 1 and 2

	Mean	Mean + SD	Mean + 2SD	Mean − SD	Mean − 2SD
Group 1	0.51	0.63	0.75	0.39	0.27
Group 2	0.44	0.54	0.64	0.34	0.24

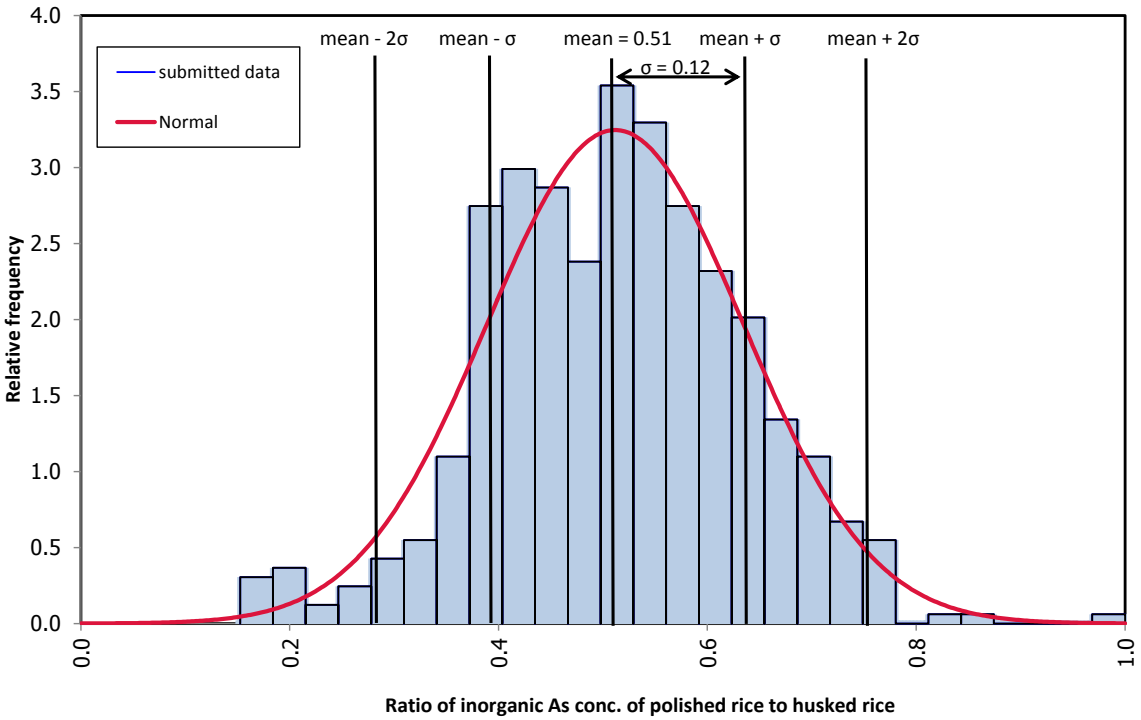
61. Next, iAs concentrations in polished rice were estimated by multiplying the concentrations in husked rice of the original data set by each hypothetical processing factor. And then the calculated iAs concentrations in polished rice were compared with the actual measured concentrations in polished rice and the proposed draft ML at 0.2 mg/kg.

62. Table 7 shows the number and percentage of true-positive, false-positive and false-negative. The above analysis indicates that for both Group 1 and 2, using the larger processing factors, the number of false-positive samples increases greatly while the number of false-negative samples does not decrease significantly. Based on this result, the processing factor of 0.51 for Group 1 or 0.44 for Group 2 is the most appropriate factor for estimating the iAs concentration in polished rice from that in husked rice in each grouping condition.

63. The eWG noted a possibility of calculating the processing factors for each concentration range because it is known that the higher iAs concentration in husked rice is, the more iAs can be removed after polishing. However, it was difficult to calculate those due to the lack of data, especially data on high iAs concentrations.

64. In response to the question regarding developing either 0.51 or 0.44 as a processing factor, all eight Members who responded did not support developing these figures as processing factors since the ratios of iAs/tAs concentrations varied widely among the 1048 samples and these available occurrence data were limited to rice cultivated in China and Japan. Additional data are needed in order to obtain appropriate processing factors.”

(a) Distribution model developed from Group 1 (husked rice with iAs concentration no less than 0.2 mg/kg)



(b) Distribution model developed from Group 2 (husked rice with iAs concentration no less than 0.3 mg/kg)

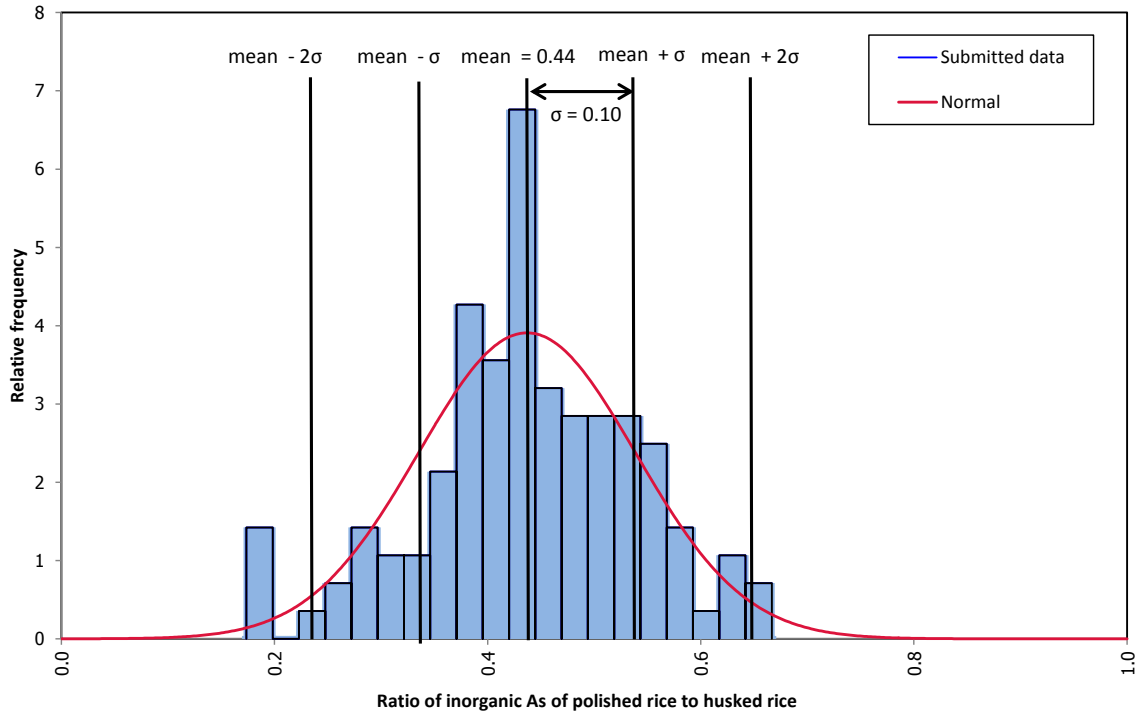


Fig. 1 Distribution models of ratios of iAs concentration in polished/husked rice

Table 7 Summary of estimation of iAs concentration in husked rice using the hypothetical processing factors (PF)

	Original data set* (n = 1048)	PF calculated from distribution model of ratio of iAs concentration in polished/husked rice in group 1 (data on husked rice with iAs conc. of no less than 0.2 mg/kg)					PF calculated from distribution model of ratio of iAs concentration in polished/husked rice in group 2 (data on husked rice with iAs conc. of no less than 0.3 mg/kg)				
		mean	mean + σ	mean + 2σ	mean − σ	mean − 2σ	mean	mean + σ	mean + 2σ	mean − σ	mean − 2σ
		0.51	0.63	0.75	0.39	0.27	0.44	0.54	0.64	0.34	0.24
N of > 0.2 mg/kg**	14	26	69	167	8	0	15	36	74	0	0
Percentage (%)	1.3	2.5	6.6	16	0.8	0	1.4	3.4	7.1	0	0
N of true-positive		8	11	12	4	0	7	9	11	0	0
Percentage (%) of true-positive		0.8	1.0	1.1	0.4	0	0.7	0.9	1.0	0	0
N of false-positive		18	58	155	4	0	8	27	63	0	0
Percentage (%) of false-positive		1.7	5.5	15	0.4	0	0.8	2.6	6.0	0	0
N of false-negative		6	3	2	10	14	7	5	3	14	14
Percentage (%) of false-negative		0.6	0.3	0.2	1.0	1.3	0.7	0.5	0.3	1.3	1.3

* data set used for estimation of PF

** In column “Original data set”, the value is actual number of polished rice which are >0.2 mg/kg in the data set used for estimation of hypothetical PF. In the others, each value is number of rice samples of which iAs conc. in polished rice are estimated >0.2 mg/kg by multiplying each iAs conc. in husked rice by each hypothetical PF.

APPENDIX IV

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