

CODEX ALIMENTARIUS COMMISSION



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PROPOSED DRAFT MAXIMUM LEVELS FOR ARSENIC IN RICE (RAW AND POLISHED RICE)

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

BACKGROUND

1. The 5th session of the Committee on Contaminants in Foods (CCCF) (March 2011) agreed to initiate new work on maximum levels for arsenic in rice based on a discussion paper prepared by China.¹ The proposal was approved by the 34th session of the Codex Alimentarius Commission (July 2011).²
2. The 6th session of the CCCF (March 2012) agreed to retain the proposed draft maximum levels (MLs) for inorganic or total arsenic in rice at Step 4 until the Committee resumed the consideration of the MLs at its 8th session based on the outcome of proposals to be prepared by China following identification of additional relevant data and information provided by member countries, especially rice-producing countries, to GEMS/Food.³
3. The 7th session of the CCCF (April 2013) agreed that the Electronic Working Group (EWG) led by China and co-chaired by Japan would prepare a discussion paper on proposals for draft MLs for arsenic in rice and rice products for consideration at the next session. The Committee encouraged members to submit relevant data to the EWG, especially those from rice-producing countries, and data on *indica* rice, to reflect them into the discussion paper.⁴
4. China and Japan prepared the discussion paper with comments from the members of the electronic working group. The List of Participants can be found in Appendix VI. Conclusions and recommendations are presented in Appendix I. Background information providing the basis for the conclusions and recommendations are provided in Appendices II through V.
5. The Committee is invited to consider the conclusions and recommendations put forward in Appendix I in order to decide how to proceed further with the development of maximum levels for arsenic in rice and rice products. In considering the conclusions and recommendations, the Committee should give due account to the decision taken at its 6th session to retain at Step 4 the proposed draft maximum levels for inorganic or total arsenic in rice (raw) at 0.3 mg/kg and inorganic arsenic in rice (polished) at 0.2 mg/kg. This issue should also be considered in the framework of the possible development of a Code of practice for the prevention and reduction of arsenic contamination in rice under Agenda Item 13 (see CX/CF 14/8/13⁵).

¹ REP11/CF, para. 64, Appendix IV.

² REP11/CAC, Appendix VI.

³ REP12/CF, paras. 63 and 65.

⁴ REP13/CF, para. 110.

⁵ Working documents for consideration by the 8th Session of the Codex Committee on Contaminants in Foods are available on the Codex website at: <http://www.codexalimentarius.org/meetings-reports/en/> or by accessing the ftp-link: <ftp://ftp.fao.org/codex/meetings/cccf/cccf8>

APPENDIX I

PROPOSALS FOR MAXIMUM LEVELS FOR INORGANIC ARSENIC IN RICE AND RICE PRODUCTS

CONCLUSIONS

1. The EWG supported the elaboration of an ML(s) for iAs if any ML for arsenic in rice is to be developed.
2. Countries or importers may decide to use their own screening when applying the ML for iAs in rice by analyzing tAs in rice. If the tAs concentration is below the ML for iAs, no further testing is required and the sample is determined to be compliant with the ML for iAs. If the tAs concentration is above the ML for iAs, follow-up testing shall be conducted to determine if the iAs concentration is above the ML.
3. The EWG supported the elaboration of either (1) two MLs for both polished rice and husked rice, or (2) only one ML for polished rice. The following is the list of considered issues in relation to this:
 - There was a statistical difference in iAs concentrations between polished rice and husked rice;
 - 79% of rice traded internationally was polished rice and 10% husked rice;
 - For polished rice and husked rice, there were sufficient data available for establishing MLs while there were few data available for rice grain; and
 - Both polished and husked rice satisfied the criteria for selecting foods or food groups that contribute to exposure as provided in para. 11 in Section IV of the "Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Group" contained in the Procedural Manual.
4. Applying the ALARA principle to the available occurrence data, the EWG considered that 0.2 mg/kg in polished rice and 0.4 mg/kg in husked rice were the most appropriate MLs for iAs. These two MLs contribute to the reduction of iAs intake from the intake without any ML for iAs.
5. An ML for polished rice can be applied to husked rice after polishing it. Since iAs concentration in polished rice is influenced by the polishing rate, the EWG discussed a polishing procedure as a part of an analytical method. As three Members raised concern about the feasibility or economic impact of polishing rice in testing laboratories, the EWG did not proceed further with development of such procedure.
6. The EWG discussed a processing factor to estimate iAs concentration in polished rice from that in husked rice. Most of the Members who responded did not support it. With only data sets available for rice produced in China and Japan, it would not be feasible to determine a processing factor that can be used in the whole world.

RECOMMENDATIONS

7. The CCCF should consider whether to develop two MLs for iAs in polished rice and husked rice, or one ML for iAs only in polished rice.
8. Following a decision on the above, the CCCF should consider elaboration of ML(s) for iAs on a basis of the following values: in polished rice at 0.2 mg/kg and in husked rice at 0.4 mg/kg.
9. If the CCCF decides to develop the two MLs, it should note that, with these two MLs, there is some possibility that a sample complying with the ML for husked rice may not comply with the ML for polished rice, or vice versa. Therefore, the EWG recommends the CCCF to discuss guidance of applying MLs in advance of forwarding them to Step 8 in order to avoid any confusion in the application of MLs. The guidance may include the following:
 - For husked rice for consumption as such, the ML for husked rice should apply;
 - For polished rice and husked rice intended to be consumed as polished rice, the ML for polished rice should apply; and
 - For husked rice with purposes unspecified, the sample should be tested for husked and the ML for husked rice should apply and if it is polished during its distribution, the ML for polished rice should apply.
10. Whether the CCCF decides to develop two MLs for polished and husked rice or one ML for polished rice only, 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.
 - 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.
11. The EWG recommends the CCCF to encourage Members, especially rice-producing countries other than China and Japan, to provide additional data and information on iAs concentrations in husked and polished rice obtained from the same sample source and polishing rate as they are necessary for:

- establishing a processing factor;
 - developing a polishing procedure; and
 - calculating a percentage of samples complying with an ML for husked rice while not complying with that for polished rice, or vice versa, which may occur in international rice trade.
12. During the development of ML(s) for iAs in rice, the EWG recommends the CCCF to include the following text in the Schedule I of the GSCTFF in order to ease the burden on testing laboratories.
- “Countries or importers may decide to use their own screening when applying the ML for iAs in rice by analyzing tAs in rice. If the tAs concentration is below the ML for iAs, no further testing is required and the sample is determined to be compliant with the ML. If the tAs concentration is above the ML for iAs, follow-up testing shall be conducted to determine if the iAs concentration is above the ML.”
13. The EWG recommends the CCCF to ask JECFA to conduct exposure assessments on the proposed draft/draft MLs before moving them to Step 8. As the above estimation of iAs intake was calculated for the average rice consumption in each GEMS/Food cluster diet, intake of iAs by extreme rice eaters may also be considered in the next exposure assessments, if such data are available.

SUPPORTIVE INFORMATION ON PROPOSALS FOR MAXIMUM LEVELS FOR INORGANIC ARSENIC IN RICE AND RICE PRODUCTS

INTRODUCTION

1. At the 6th Session, the CCCF recognized the need for identifying suitable analytical methods for the determination of inorganic arsenic (iAs) in rice and to further collect occurrence data on arsenic in rice from Members, especially rice-producing countries, in order to allow the CCCF to resume the discussion on the MLs at its 8th session. In addition, the CCCF noted that the MLs could be set for iAs and that total arsenic (tAs) could be measured as screening for iAs concentrations.

2. A number of analytical methods for the determination of iAs, monomethylarsonic acid (MMA) and dimethylarsinic acid (DMA) in rice and rice products have been developed and are available. However, most of them were not internationally validated. Therefore, the EWG attempted to summarize information on available analytical methods for iAs in rice and rice products. The EWG also discussed the screening methods for estimating iAs concentrations in rice and rice products using respective tAs concentrations.

3. The EWG also attempted to develop options for the proposed draft MLs for iAs in rice and rice products, using all available occurrence data, in accordance with the relevant criteria and process for the establishment of MLs in the Codex Alimentarius Commission Procedural Manual and the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) and taking the following aspects into account:

- Arsenic species as it should be analyzed and to which the MLs apply;
- Type of rice and rice products as they should be analyzed and to which the MLs apply; and
- A processing factor to estimate iAs concentration in polished rice.

DEFINITIONS

4. In this paper, rice grain, husked rice and polished rice are defined respectively as follows:

Rice grain (paddy rice) is rice which has retained its husk after threshing (GC 0649¹).

Husked rice (brown rice or cargo rice) is paddy rice from which the husk only has been removed. The process of husking and handling may result in some loss of bran (CM 0649¹).

Polished rice (milled rice or white rice) is husked rice from which all or part of the bran and germ have been removed by milling (CM 1205¹).

ARSENIC SPECIES AS IT SHOULD BE ANALYZED AND TO WHICH THE MLS APPLY

5. Arsenic species known to be present in rice and rice products are arsenite, arsenate, MMA and DMA which can be classified into two forms, namely iAs (arsenite and arsenate) and organic arsenic (MMA and DMA). In accordance with the provision in the ninth bullet of second paragraph of "Establishment of maximum levels" in Annex I of the GSCTFF, which states that the contaminant as it should be analyzed and to which the ML applies should be clearly defined, the EWG considered the appropriate species or forms of arsenic to which the MLs should apply.

6. At the 72nd meeting, JECFA determined the lower limit (95% confidence interval) on the benchmark dose for a 0.5% increased incidence of lung cancer (BMDL_{0.5}) for iAs. JECFA did not perform a quantitative risk assessment of organic arsenic compounds including MMA and DMA, due to a general lack of data on both exposure and toxicity. JECFA did not perform a quantitative risk assessment for arsenite and arsenate separately either. For arsenite and arsenate, they should be combined and treated as iAs because there is interactive transformation between these two species during analytical procedure. Since The *Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods* in the Codex Alimentarius Procedural Manual states that the CCCF shall endorse MLs only for those contaminants for which JECFA has completed a safety assessment or has performed a quantitative risk assessment, thus the establishment of MLs for iAs in rice is justified.

7. Total arsenic concentration can be determined by using either of the two ways. One is to obtain the concentrations of each four species (arsenite, arsenate, MMA and DMA) and adding them up, and the other is to inclusively determine the total concentration using a single analytical method.

8. An ML should not apply to tAs, not only because JECFA did not perform quantitative risk assessment for organic As but also from the fact that there is no correlation between tAs and iAs concentrations in rice. The occurrence data provided by Members indicate that the ratio of iAs to tAs in rice largely varies among samples even if rice sampled was produced in the same country. For example, the percentage of iAs in tAs in the samples from USA varies from 12% to 100% for polished rice and 10% to 100% for husked rice (See Table 11 in Annex 1).

¹ Classification of Foods and Animal Feeds (CAC/MISC 4-1993).

9. As a conclusion, if an ML for arsenic in rice is to be developed, it should be set for iAs. Setting MLs for MMA and DMA could be reconsidered in the future if JECFA conduct quantitative risk assessments for these substances.

10. Moreover, all of the eight Members who provided their comments to the EWG supported the elaboration of an ML for iAs in rice.

TYPE OF RICE AND RICE PRODUCTS AS THEY SHOULD BE ANALYZED AND TO WHICH THE MLS APPLY

11. The EWG, when considering the type of rice to which the ML should apply, took into account the following descriptions in the *Establishment of Maximum Levels of contaminants* in Annex I of the GSCTFF:

- The product as it should be analyzed and to which the ML applies, should be clearly defined. In general, MLs are set on primary products.
- In general however, MLs should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient food and feed by using appropriate conversion factors.

12. According to the FAOSTAT, in 2010, 79% of rice traded internationally was polished rice, 10% husked rice and 11% rice grain (calculated from the amount of imported rice).

13. Although rice grain is the primary (raw) agricultural product of the rice crop, it is not regarded appropriate to set an ML for rice grain, for the following reasons:

- Only nine data points were provided for iAs concentrations in rice grain. All of these were provided by Canada and therefore, do not cover all the major rice producing regions; and
- It is difficult to estimate a concentration of iAs in rice grain from the concentration in polished or husked rice due to lack of the necessary information.

14. An ML could be set for husked rice because while husked rice is traded internationally, only at a similar amount as rice grain, it is eaten by a number of people after cooking without removal of its part (bran etc.) and arsenic concentration data in husked rice are available. It is important to note that the iAs concentration in husked rice is generally higher than that in polished rice².

15. As the major form of rice traded internationally and eaten by people is polished rice, the CCCF should also consider establishing an ML in polished rice.

16. The criteria provided in the para. 11 in Section IV of "Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Group" contained in the Codex Alimentarius Procedural Manual were used to assess the selection of type of rice. When using BMDL_{0.5} as a similar health hazard endpoint to the tolerable intake, the polished rice satisfies the requirement provided in a) of para. 11 (Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10% or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Consumption Cluster Diets). For husked rice, there was only one cluster that exposure exceeded 5% of BMDL_{0.5} but for the reasons provided in para. 14 of this document, the EWG considered that the husked rice satisfies the requirement provided in c) of para. 11 in Section IV (Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the GEMS/Food Consumption Cluster Diets. These would be considered on a case-by-case basis.).

17. In response to the question regarding type of rice to which the ML(s) should apply, all eight, except one, Members provided comments to the EWG supported elaboration of MLs in husked rice and polished rice. One Member supported elaboration of an ML in only polished rice. For the reasons described in paras 14 to 16 including data availability, it seems possible to establish MLs in polished rice and husked rice. However, it should be kept in mind that, with these two MLs, there is a possibility of a sample complying with the ML for husked rice while after polishing not complying with the ML for polished rice, or vice versa.

18. From 1048 data points of iAs concentrations in husked rice and polished rice obtained from the same sample source, the numbers of samples within a specified concentration range were identified (sample concentrations above or not above 0.4 mg/kg in husked rice and 0.2 mg/kg in polished rice). Table 1 below indicates 1015 (97%) out of 1048 were below or equal to the specified concentrations for both husked and polished rice, 25 (19+6, 2.4%) were above either of the specified concentrations for husked or polished rice. Considering that the above discussion is based on the data provided only by China and Japan, the percentage of discrepancy may not be the same in other rice producing countries.

Table 1 Number of samples in the specified concentration range

		Polished rice	
		≤ 0.2 mg/kg	> 0.2 mg/kg
Husked rice	≤ 0.4 mg/kg	1015	6
	> 0.4 mg/kg	19	8

² In the case of cadmium, its concentration is similar in husked and polished rice.

19. For imported rice, considering that 79% of rice traded internationally is polished rice and only 10% is husked rice, most of samples obtained from traded rice for laboratory analysis would be polished rice, setting an ML only for polished rice may be sufficient. For rice produced and consumed within the same country, both husked rice and polished rice are distributed in the domestic market. Therefore, setting the MLs for both polished rice and husked rice should be considered.

20. As a conclusion, an ML(s) of iAs could be set for both polished rice and husked rice, or only for polished rice.

ANALYTICAL METHODS FOR INORGANIC ARSENIC

Sample Preparation

21. 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.

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

23. 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.

Inorganic Arsenic Determination

24. The 8th bullet of second paragraph in the section “Establishment of maximum levels” in Annex I of the GSCTFF states, “MLs should not be lower than a level which can be analyzed with methods of analysis that can readily be set up and applied in food and feed control laboratories, unless public health considerations necessitate a lower ML which can only be controlled by means of a more elaborate and sensitive method of analysis with an adequate lower detection limit. In all cases, a validated method of analysis should be available with which a ML can be controlled.”

25. Information on analytical methods for iAs in rice was provided by seven Members along with the occurrence data on iAs concentrations in rice, which is summarized in Appendix III of this document (including the information below). Analytical methods using liquid chromatography with inductively coupled plasma mass spectrometry (LC-ICP/MS) were the most commonly used among these Members and atomic absorption spectrometry (AAS) was used by one Member. However, most of these methods were not internationally validated.

26. In 2013, Japan conducted an international collaborative study involving four countries for international validation of an analytical method using LC-ICP/MS for iAs in rice: both *japonica* and *indica* type (Ukena *et al.*, accepted 2013).

27. In addition, a collaborative study of the solid-phase extraction (SPE) method for iAs in a rice meal sample gave a HorRat value of 1.6 among 10 German laboratories. The laboratories used either HG-AAS or ICP-MS for iAs determination (Rasmussen *et al.*, 2013).

CONVERSION FACTOR OF TOTAL ARSENIC TO INORGANIC ARSENIC

28. As analytical methods for determining tAs in rice are more convenient, time-saving and less expensive than those for determining iAs, the EWG discussed establishing a conversion factor to estimate iAs concentrations from measured tAs concentrations.

29. In order to obtain the above mentioned conversion factor, the tAs concentrations and iAs concentrations determined for the same samples were extracted from the list of all occurrence data provided by Members. And then, the ratio of iAs to tAs of each sample was calculated (see Table 17 in Appendix IV). Since arsenic concentrations largely differ depending on the cultivated location of the rice, the ratios were compiled for each country where rice sampled were cultivated (Australia, China, Japan, Thailand and USA). Based on these data sets, scatter graphs and histograms were prepared (see Figure 7 in Appendix IV).

30. As a result, for both polished and husked rice, the ratios of iAs/tAs varied widely among samples even if rice sampled was produced in the same country, and the histograms for five countries also showed widely varying shapes.

31. The varying ratios between iAs and tAs indicated that it would be difficult to agree on one fixed conversion factor for estimating iAs concentrations from tAs concentrations in all rice varieties available in the world market. In response to the question regarding developing one as a conversion factor, eight Members who responded expressed divergent views (two for and six against; one opposing Member proposed an option for screening).

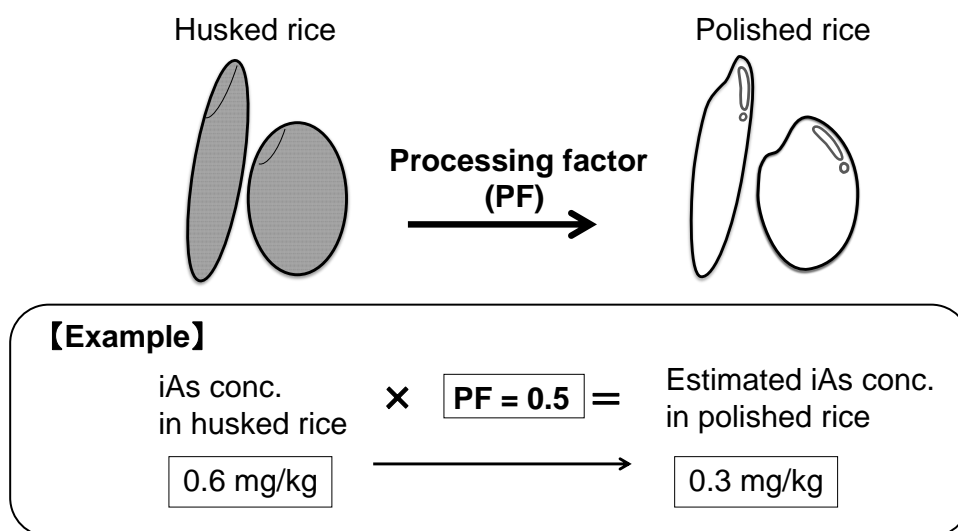
32. Therefore, as an alternative to a fixed conversion factor, countries or importers may decide to use their own screening when applying the ML for iAs in rice by analyzing tAs in rice. If the tAs concentration is below the ML for iAs, no further testing is required and the sample is determined to be compliant with the ML. If the tAs concentration is above the ML for iAs, follow-up testing shall be conducted to determine if the iAs concentration is above the ML.

PROCESSING FACTOR TO ESTIMATE INORGANIC ARSENIC CONCENTRATION IN POLISHED RICE

33. 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.

34. The EWG discussed whether a processing factor could be established to estimate iAs concentration in polished rice from that in husked rice (see Figure 1). 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.

Figure 1 Processing factor



35. 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”) (see Table 12 in Annex 2, 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 Figure 4 in Annex 2). 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 (see Figure 4 in Annex 2). From these means and standard deviations values, five hypothetical processing factors were obtained for each distribution model (mean, mean±SD, mean±2SD, see Table 2 below) (Annex 2 for details).

Table 2 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

36. 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 (see para. 61).

37. Table 13 in Annex 2 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.

38. The EWG noted a possibility of calculating the processing factors for each concentration range (see Table 14 in Annex 2) because it is known that the higher iAs concentration in husked rice is, the more iAs can be removed after polishing (see Figure 5 of Annex 2). However, it was difficult to calculate those due to the lack of data, especially data on high iAs concentrations.

39. 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 (see Figure 5 in Annex 2) 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.

MAXIMUM LEVELS FOR INORGANIC ARSENIC IN POLISHED AND HUSKED RICE

Occurrence Data on Arsenic in Rice Provided by Members

40. Ten countries and one NGO (Australia, Canada, China, Indonesia, Japan, Kenya, Philippines, Singapore, Thailand, USA and FoodDrinkEurope) provided occurrence data in response to a data call conducted after the 7th Session of the CCCF.

41. GEMS/Food provided occurrence data of nine Members and one NGO (Australia, Brazil, China, EU, Indonesia, New Zealand, Singapore, Thailand, USA and FoodDrinkEurope) to the EWG.

42. The occurrence data previously provided by five Members (Australia, China, EU, Japan and USA) that were used in the discussion of the 6th Session of the CCCF were also used. When the same data sets were provided by the originating country and GEMS/Food, only one data set was considered in the following discussion.

43. Since the EWG considered that an ML(s) for arsenic in rice should be set for iAs (see para. 9), data on iAs in husked and polished rice were used as a basis for discussion. The EWG only used the occurrence data when the types of rice (polished/husked rice) were clearly identified. The occurrence data of cooked rice were not used because it is difficult to estimate the iAs concentration in polished or husked rice from the concentration of cooked rice. The third bullet in second paragraph of "Establishment of maximum levels" in the GSCTFF states, "Foods that are evidently contaminated by local situations shall be excluded in this evaluation." Therefore the EWG excluded the occurrence data of 28 rice samples that were reported to be cultivated in the land evidently contaminated with As.

44. There are many censoring methods for data reported to be below the LOQ or the limit of detection (LOD). In this discussion paper, the censoring method provided by GEMS/Food was applied to the occurrence data. For the concentration reported to be below the LOQ or LOD, if the LOQ was reported, the EWG used one half of the LOQ as the concentration of sample in question. If the LOQ was not reported, the EWG used one half of the LOD as the concentration of sample in question. The percentage of the number of data points reported to be below the LOQ or LOD to all the data points with respect to each country is shown in Table 3.

Table 3 Number of data used for statistical analysis

Country/NGO	iAs						tAs					
	Polished rice			Husked rice			Polished rice			Husked rice		
	Number of data points used statistical analysis	Number of data points below the LOD or LOQ	Percentage of data points below the LOD or LOQ	Number of data points used statistical analysis	Number of data points below the LOD or LOQ	Percentage of data points below the LOD or LOQ	Number of data points used statistical analysis	Number of data points below the LOD or LOQ	Percentage of data points below the LOD or LOQ	Number of data points used statistical analysis	Number of data points below the LOD or LOQ	Percentage of data points below the LOD or LOQ
Australia	37	1	2.7	37	0	0	126	1	0.8	60	0	0
Brazil	23	0	0	3	0	0	67	0	0	31	0	0
Canada	193	0	0	112	0	0	193	0	0	112	1	0.9
China	516	11	2.1	445	0	0	913	1	0.1	443	0	0
EU	216	15	6.9	129	4	3.1	574	36	6.3	273	12	4.4
Indonesia	-	-	-	-	-	-	25	25	100	-	-	-
Japan	640	0	0	1200	0	0	640	0	0	1200	0	0
Kenya	-	-	-	-	-	-	-	-	-	8	1	13
Philippines	-	-	-	-	-	-	63	58	92	6	6	100
Singapore	23	18	78	16	9	56	279	47	17	31	5	16
Thailand	354	158	45	285	47	16	479	232	48	324	44	14
USA	363	0	0	308	0	0	363	0	0	305	0	0
FoodDrinkEurope	-	-	-	-	-	-	1355	7	0.5	-	-	-

45. Based on the occurrence data mentioned in paras 40 to 44, the number of samples, and mean, median and standard deviation of iAs and tAs concentrations in rice were determined using statistical methods provided in the instructions for electronic submission of data on chemical contaminants in food to GEMS/Food programme, in accordance with the proportion of non-quantified data to all data. These results are compiled in Table 7 and Table 8 in Annex 1, with respect to country, type of rice and subspecies of rice (*japonica*, *indica*). In addition, concentrations in sampled rice whose origins were specified as “domestic” are also compiled in Table 9 and Table 10 in Annex 1.

46. The occurrence data on iAs in rice were provided by nine Members. The occurrence data provided by four Members include 366 analytical data of imported samples. Therefore, the occurrence data all together satisfy the provision in the *establishment of Maximum Levels* in Annex I of the GSCTFF, “Proposals for MLs in products should be based on data from various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade.”

47. Members providing no less than 25 iAs data at or above the LOQ were identified. For these Members, histograms of iAs concentrations in husked and polished rice were drawn (see Figure 3 in Annex 1). The histogram of each country showed typical distribution curve for nation-wide surveillance for contaminant in food (i.e. single skew in the lower concentration, tail in the higher concentration), which indicates that the data sets of each country were collected in an unbiased manner, and can be used as the basis of the discussion (Table 7 in Annex 1).

48. In order to evaluate the difference of iAs concentrations in rice produced in different areas, iAs concentrations in polished and husked rice produced in six countries were compared. The medians of iAs concentration in polished and husked rice produced in six countries ranged from 0.05 to 0.12 mg/kg and from 0.10 to 0.20 mg/kg respectively (see Table 9 and Table 10 in Annex 1). In five of the six countries, the numbers of analytical results on iAs concentrations in both polished and husked rice were sufficient for applying the Kruskal-Wallis test. According to the test, there were differences in iAs concentrations among these five countries for both polished and husked rice. In addition, the following were found for polished and husked rice produced in five countries (A, B, C, D and E):

iAs concentration in polished rice

- The concentrations in polished rice produced in countries A and B were significantly different from those in countries C, D and E at 5% level of significance; and
- C, D and E were statistically isolated.

iAs concentration in husked rice

- The concentrations in husked rice produced in countries A, B and C were significantly different from those in countries D and E at 5% level of significance; and
- D and E were statistically isolated.

49. Inorganic arsenic concentrations of two rice subspecies (*japonica* and *indica*) were compared using the Mann-Whitney U test. For polished rice, while the result showed a statistical difference between *japonica* and *indica* at 5% level of significance, the medians of iAs concentration in polished rice for *japonica* and *indica* were similar at 0.11 and 0.09 mg/kg, respectively. It should be noted that the data set of each rice subspecies is regionally biased. On the other hand, for husked rice, no statistical difference was found between *japonica* and *indica* (Table 7 in Annex 1).

50. Results of analysis are summarized as follows:

- Judging from the shapes of histograms, the data set provided by these Members were collected in an unbiased manner;
- Inorganic arsenic concentrations in rice varied among the six producing countries but their medians were different from country to country; and
- For subspecies of rice (*japonica* and *indica*), there was a statistical difference between iAs concentrations in polished rice. However, the medians of iAs concentration of these two subspecies were not so greatly different.

Distribution Curves and Estimation of ML Proposals for Inorganic Arsenic in Rice

51. Distribution curves were drawn for polished and husked rice respectively because there was a significant difference in iAs concentrations between polished and husked rice.

52. The occurrence data provided by different Members were merged as a single population, although there were statistical differences among countries (see para. 48) and between subspecies (see para. 49). The reasons are as follows:

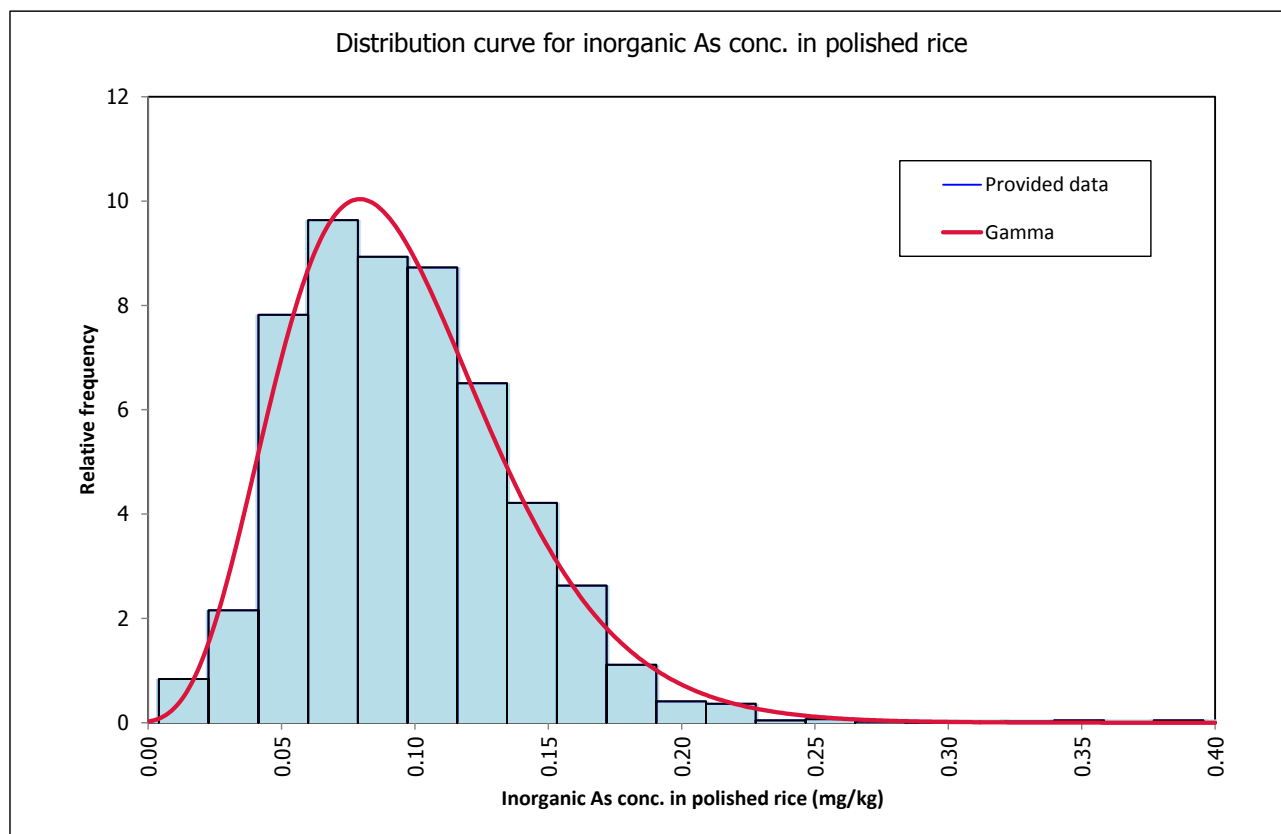
- There were not sufficient data available to develop a distribution curve for each combination of country/subspecies; and
- The occurrence data included data from imported rice.

53. The EWG adopted the model which @RISK presented as the most similar to each distribution and also visually fit for iAs in polished and husked rice respectively. As a result, the Gamma distribution model and the Lognormal distribution model were adopted and applied to distribution of iAs in polished and husked rice respectively, and the mean concentrations of iAs were calculated for each model. For the reference, at 5% level of significance in the Kolmogorov-Smirnov test, there was no model which fitted the each distribution curve for iAs concentrations in polished and husked rice.

54. Furthermore, from the distribution models identified above, ML proposals (three ML proposals for polished rice and four ML proposals for husked rice, see Figure 2 below) were estimated. By applying each ML proposal and the scenario that rice with iAs concentrations larger than each ML proposal would be excluded from the market, the mean of iAs in samples hypothetically remaining in the market was determined (see Figure 2 below). Each of the means was used for estimating iAs intake from rice in the next section. (For information, distribution curves developed based on tAs concentrations in polished and husked rice are shown in Annex 3.)

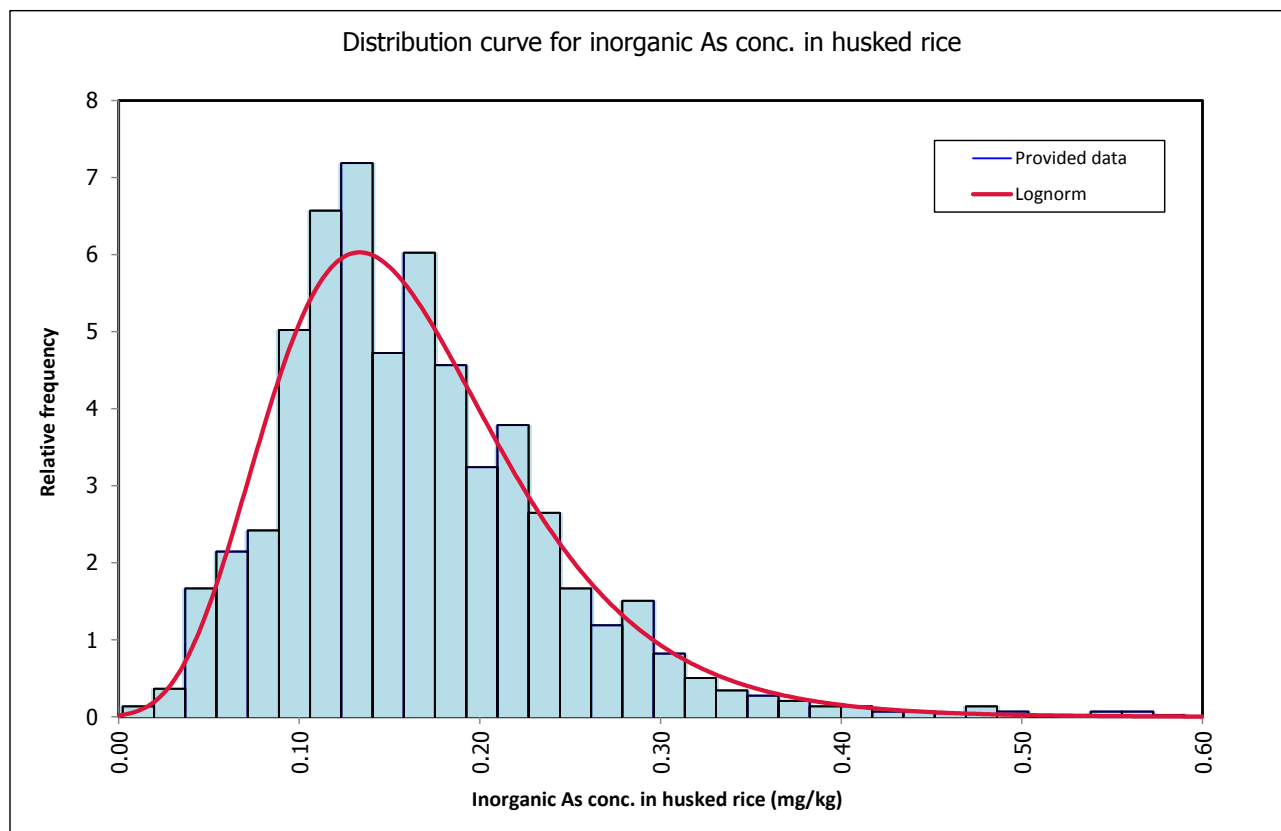
Figure 2 Impact of different ML proposal scenarios for iAs in (a) polished rice and (b) husked rice

(a) Impact of different ML proposal scenarios for iAs in polished rice.



ML proposal (mg/kg)	Mean* (mg/kg)	Percentage > ML proposal
no ML	0.096	
0.1	0.061	41
0.2	0.092	2.0
0.3	0.096	0.0

*Each mean was calculated from the distribution model with excluding range above a given ML proposal in the model.

(b) Impact of different ML proposal scenarios for iAs in husked rice.

ML proposal (mg/kg)	Mean* (mg/kg)	Percentage > ML proposal
no ML	0.165	
0.2	0.093	27
0.3	0.138	5.2
0.4	0.158	0.8
0.5	0.163	0.1

*Each mean was calculated from the distribution model with excluding range above a given ML proposal in the model.

Impact of ML Proposal on Inorganic Arsenic Intakes

55. In order to affirm that iAs intakes from husked and polished rice satisfy the criteria in the GSCTFF (see para. 16), the EWG estimated iAs intakes from husked and polished rice using consumption data of rice in the GEMS/Food consumption cluster diets⁸. For reference, the EWG also estimated reductions of iAs intake when these ML proposals were applied to rice.

56. The EWG first estimated iAs intakes from rice in different cluster diets based on current levels in rice (i.e. no ML established for iAs in rice), by multiplying means of iAs concentration in polished and husked rice under the scenario of applying no ML to each consumption data of polished and husked rice in the GEMS/Food consumption cluster diets. Then the estimated iAs intakes were compared to the BMDL_{0.5} of 3.0 µg/kg-bw/day (JECFA, 2010).

57. For consumption data of rice, 17 GEMS/Food consumption cluster diets developed in 2012 and 13 GEMS/Food consumption cluster diets developed in 2006 were used and compared (see Table 4 below). The 17 GEMS/Food consumption cluster diets (2012) for rice were not available online but were on the progress toward successful completion and could be used for calculation. On the other hand, the 13 GEMS/Food consumption cluster diets (2006) for rice were already available online. Since the iAs intakes from polished and husked rice estimated using the 13 GEMS/Food consumption cluster diet (2006) were larger than those estimated using the 17 GEMS/Food consumption cluster diet (2012), standing on more safety side, the EWG decided to base its discussion on the 13 GEMS/Food consumption cluster diet (2006) (see Table 5 below).

⁸ <http://www.who.int/foodsafety/chem/gems/en/index1.html>

58. As a result, the estimated iAs intake from polished rice of each cluster was between 0.01 - 0.60 $\mu\text{g}/\text{kg}\text{-bw}/\text{day}$. The clusters that had relatively high iAs intake from polished rice were cluster diets G and L. The percentages of iAs intake to the $\text{BMDL}_{0.5}$ were 20% in the cluster diets G and L. The estimated iAs intake from husked rice of each cluster was between 0.001 - 0.25 $\mu\text{g}/\text{kg}\text{-bw}/\text{day}$. The cluster that had the highest iAs intake from husked rice was cluster diet K, and the percentage of iAs intake to the $\text{BMDL}_{0.5}$ was 8.4% (see Table 5 below).

59. From these results, the EWG noted that iAs intakes from polished rice on two cluster diets (i.e. cluster diets G and L) exceeded 10% of the $\text{BMDL}_{0.5}$. For iAs intakes of husked rice, no cluster exceeded 10% but one cluster (cluster diet K) exceeded 5% of the $\text{BMDL}_{0.5}$ (see Table 5 below).

60. Next, the EWG estimated reductions of iAs intake for each ML proposal mentioned in para. 54. By multiplying the means of iAs concentrations in polished and husked rice calculated in para. 54 to the consumption data of polished and husked rice respectively, iAs intakes from polished and husked rice were estimated (see Table 5). Reduction rates of iAs intake from the scenario of not applying ML to applying seven ML proposals were compared for the cluster that has the highest estimated iAs intake derived from polished or husked rice (cluster diet G for polished rice, cluster diet K for husked rice). In addition, a violation rate of each scenario was calculated. The EWG compared the reduction rate of iAs intake and the percentage above the ML proposal of each scenario and discussed the most appropriate MLs in polished and husked rice among the ML proposals.

61. As a conclusion, the ML proposals for iAs at 0.2 mg/kg in polished rice and 0.4 mg/kg in husked rice were considered as the most appropriate respectively. These two MLs contribute to the reduction of iAs intake from rice and at the same time the violation rate were relatively low (violation rates were 2.0% for polished rice and 0.8% for husked rice). Therefore, these two MLs were deemed to be as low as reasonably achievable⁹. ML proposals of 0.1 mg/kg in polished rice and 0.2 and 0.3 mg/kg in husked rice contribute to the reduction of iAs intake, however, violation rates are high. Therefore, these three ML proposals were not deemed to be as low as reasonably achievable⁹. For ML proposals of 0.3 mg/kg in polished rice and 0.5 mg/kg in husked rice, violation rates are almost zero and they do not contribute to the reduction of iAs intake (see Table 6 below).

62. In response to the question regarding developing MLs for iAs of 0.2 mg/kg in polished rice and 0.4 mg/kg in husked rice, there was discussion on which type of rice the ML should apply to, however, there was no objection to specific figures.

63. A Member suggested that the CCCF may consider asking JECFA to perform further exposure assessment on the proposed MLs before the final adoption at the Codex Alimentarius Commission. Considering that the above calculations were based on the data of average rice consumption in each cluster, groups that consume rice in large amounts may also be taken into account when performing further exposure assessment, if enough data are available.

⁹ "MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer" in the third bullet of second paragraph in "Establishment of maximum levels" in Annex 1 of the GSCTFF (ALARA principle).

Table 4 Rice consumption in the (a) 17 GEMS/Food Consumption Cluster Diets (2012) and (b) 13 GEMS/Food Consumption Cluster Diets (2006)**(a) 17 GEMS/Food Consumption Cluster Diets (2012)**

	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
Consumption of rice (g/person/day)																	
Polished rice	33.95	9.33	36.52	82.30	144.42	65.90	9.63	5.26	261.94	28.61	0	62.19	23.87	211.09	10.41	12.85	49.90
Husked rice	1.17	1.30	31.05	4.56	0.25	2.16	2.43	1.62	0.42	1.06	0	4.78	13.53	3.46	1.82	0.01	8.84

(b) 13 GEMS/Food Consumption Cluster Diets (2006)

	A	B	C	D	E	F	G	H	I	J	K	L	M
Consumption of rice (g/person/day)													
Polished rice	44.7	31.4	91.2	24.2	8.4	12.2	375.5	63.3	35.7	44.7	146.4	372.2	34.2
Husked rice	46.3	0.3	3.4	9.0	4.3	0.5	1.4	1.0	2.3	29.5	92.0	9.1	0.4

Table 5 Mean estimates of iAs intakes from rice for the (a) 17 GEMS/Food Consumption Cluster Diets (2012) and (b) 13 GEMS/Food Consumption Cluster Diets (2006), taking into consideration the impact of ML proposal scenarios for iAs in polished rice or husked rice

(a) 17 GEMS/Food Consumption Cluster Diets (2012)

		iAs intake from rice ($\mu\text{g}/\text{kg}$ bw/day) for 17 GEMS/Food consumption cluster diets*																
		G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
iAs intake from polished rice																		
Proposal scenario																		
No ML		0.054	0.015	0.058	0.132	0.231	0.105	0.015	0.008	0.419	0.046	0.000	0.099	0.038	0.338	0.017	0.021	0.080
(Percentage**)		1.8	0.5	1.9	4.4	7.7	3.5	0.5	0.3	14.0	1.5	0.0	3.3	1.3	11.3	0.6	0.7	2.7
ML 0.1 mg/kg		0.034	0.009	0.037	0.083	0.146	0.067	0.010	0.005	0.265	0.029	0.000	0.063	0.024	0.214	0.011	0.013	0.050
(Percentage)		1.1	0.3	1.2	2.8	4.9	2.2	0.3	0.2	8.8	1.0	0.0	2.1	0.8	7.1	0.4	0.4	1.7
ML 0.2 mg/kg		0.052	0.014	0.056	0.126	0.222	0.101	0.015	0.008	0.402	0.044	0.000	0.095	0.037	0.324	0.016	0.020	0.077
(Percentage)		1.7	0.5	1.9	4.2	7.4	3.4	0.5	0.3	13.4	1.5	0.0	3.2	1.2	10.8	0.5	0.7	2.6
ML 0.3 mg/kg		0.054	0.015	0.058	0.131	0.231	0.105	0.015	0.008	0.418	0.046	0.000	0.099	0.038	0.337	0.017	0.021	0.080
(Percentage)		1.8	0.5	1.9	4.4	7.7	3.5	0.5	0.3	13.9	1.5	0.0	3.3	1.3	11.2	0.6	0.7	2.7
iAs intake from husked rice																		
Proposal scenario																		
No ML		0.003	0.004	0.085	0.013	0.001	0.006	0.007	0.004	0.001	0.003	0.000	0.013	0.037	0.009	0.005	0.000	0.024
(Percentage)		0.1	0.1	2.8	0.4	0.0	0.2	0.2	0.1	0.0	0.1	0.0	0.4	1.2	0.3	0.2	0.0	0.8
ML 0.2 mg/kg		0.002	0.002	0.048	0.007	0.000	0.003	0.004	0.003	0.001	0.002	0.000	0.007	0.021	0.005	0.003	0.000	0.014
(Percentage)		0.1	0.1	1.6	0.2	0.0	0.1	0.1	0.1	0.0	0.1	0.0	0.2	0.7	0.2	0.1	0.0	0.5
ML 0.3 mg/kg		0.003	0.003	0.072	0.011	0.001	0.005	0.006	0.004	0.001	0.002	0.000	0.011	0.031	0.008	0.004	0.000	0.020
(Percentage)		0.1	0.1	2.4	0.4	0.0	0.2	0.2	0.1	0.0	0.1	0.0	0.4	1.0	0.3	0.1	0.0	0.7
ML 0.4 mg/kg		0.003	0.003	0.082	0.012	0.001	0.006	0.006	0.004	0.001	0.003	0.000	0.013	0.036	0.009	0.005	0.000	0.023
(Percentage)		0.1	0.1	2.7	0.4	0.0	0.2	0.2	0.1	0.0	0.1	0.0	0.4	1.2	0.3	0.2	0.0	0.8
ML 0.5 mg/kg		0.003	0.004	0.084	0.012	0.001	0.006	0.007	0.004	0.001	0.003	0.000	0.013	0.037	0.009	0.005	0.000	0.024
(Percentage)		0.1	0.1	2.8	0.4	0.0	0.2	0.2	0.1	0.0	0.1	0.0	0.4	1.2	0.3	0.2	0.0	0.8
iAs intake from rice***		0.057	0.018	0.144	0.144	0.232	0.111	0.022	0.013	0.420	0.049	0.000	0.113	0.075	0.347	0.022	0.021	0.104
(Percentage)		1.9	0.6	4.8	4.8	7.7	3.7	0.7	0.4	14.0	1.6	0.0	3.8	2.5	11.6	0.7	0.7	3.5

* Calculations assume a 60 kg body weight.

** Percentage to the BMDL_{0.5} value (3.0 $\mu\text{g}/\text{kg}$ bw/day) computed at the 72nd JECFA

*** iAs intake from rice (sum of iAs intake from polished rice and husked rice) when no ML applies to both polished and husked rice

(b) 13 GEMS/Food Consumption Cluster Diets (2006)

iAs intake from rice ($\mu\text{g}/\text{kg}$ bw/day) for 13 GEMS/Food consumption cluster diets*													
	A	B	C	D	E	F	G	H	I	J	K	L	M
iAs intake from polished rice													
Proposal scenario													
No ML	0.071	0.050	0.146	0.039	0.013	0.019	0.600	0.101	0.057	0.071	0.234	0.595	0.055
(Percentage **)	2.4	1.7	4.9	1.3	0.4	0.6	20.0	3.4	1.9	2.4	7.8	19.8	1.8
ML 0.1 mg/kg	0.045	0.032	0.092	0.024	0.008	0.012	0.380	0.064	0.036	0.045	0.148	0.377	0.035
(Percentage)	1.5	1.1	3.1	0.8	0.3	0.4	12.7	2.1	1.2	1.5	4.9	12.6	1.2
ML 0.2 mg/kg	0.069	0.048	0.140	0.037	0.013	0.019	0.576	0.097	0.055	0.069	0.225	0.571	0.052
(Percentage)	2.3	1.6	4.7	1.2	0.4	0.6	19.2	3.2	1.8	2.3	7.5	19.0	1.7
ML 0.3 mg/kg	0.071	0.050	0.146	0.039	0.013	0.019	0.600	0.101	0.057	0.071	0.234	0.594	0.055
(Percentage)	2.4	1.7	4.9	1.3	0.4	0.6	20.0	3.4	1.9	2.4	7.8	19.8	1.8
iAs intake from husked rice													
Proposal scenario													
No ML	0.127	0.001	0.009	0.025	0.012	0.001	0.004	0.003	0.006	0.081	0.253	0.025	0.001
(Percentage)	4.2	0.0	0.3	0.8	0.4	0.0	0.1	0.1	0.2	2.7	8.4	0.8	0.0
ML 0.2 mg/kg	0.072	0.000	0.005	0.014	0.007	0.001	0.002	0.002	0.004	0.046	0.142	0.014	0.001
(Percentage)	2.4	0.0	0.2	0.5	0.2	0.0	0.1	0.1	0.1	1.5	4.7	0.5	0.0
ML 0.3 mg/kg	0.107	0.001	0.008	0.021	0.010	0.001	0.003	0.002	0.005	0.068	0.212	0.021	0.001
(Percentage)	3.6	0.0	0.3	0.7	0.3	0.0	0.1	0.1	0.2	2.3	7.1	0.7	0.0
ML 0.4 mg/kg	0.122	0.001	0.009	0.024	0.011	0.001	0.004	0.003	0.006	0.078	0.242	0.024	0.001
(Percentage)	4.1	0.0	0.3	0.8	0.4	0.0	0.1	0.1	0.2	2.6	8.1	0.8	0.0
ML 0.5 mg/kg	0.126	0.001	0.009	0.024	0.012	0.001	0.004	0.003	0.006	0.080	0.250	0.025	0.001
(Percentage)	4.2	0.0	0.3	0.8	0.4	0.0	0.1	0.1	0.2	2.7	8.3	0.8	0.0
iAs intake from rice***	0.198	0.051	0.155	0.063	0.025	0.021	0.604	0.104	0.064	0.152	0.487	0.620	0.056
(Percentage)	6.6	1.7	5.2	2.1	0.8	0.7	20.1	3.5	2.1	5.1	16.2	20.7	1.9

* Calculations assume a 60 kg body weight.

** Percentage to the BMDL_{0.5} value (3.0 $\mu\text{g}/\text{kg}$ bw/day) computed at the 72nd JECFA

*** iAs intake from rice (sum of iAs intake from polished rice and husked rice) when no ML applies to both polished and husked rice

Table 6 Rate of decrease in iAs intake from rice and percentage above the ML proposal in the distribution model for each ML proposal scenario

ML proposal (mg/kg)	Rate of decrease in iAs intake from rice (%)	Percentage >ML proposal
Polished rice		
0.1	36	41
0.2	4.0	2.0
0.3	0.1	0.0
Husked rice		
0.2	23	27
0.3	8.2	5.2
0.4	2.2	0.8
0.5	0.5	0.1

Table 7 Summary of occurrence data on iAs in rice provided by Members

Type of rice	Total number of samples	Number of <LOD	Number of <LOQ	Mean (mg/kg)			Median (mg/kg)	SD (mg/kg)
				True*	Best estimated**	Upper bound***		
By country								
Australia	Polished rice	37	1	1	0.05		0.05	0.03
	Husked rice	37	0	0	0.10		0.10	0.05
Brazil	Polished rice	23	0	0	0.09		0.09	0.03
	Husked rice	3	0	0	0.16		0.16	0.002
Canada	Polished rice	193	0	0	0.07		0.07	0.04
	Husked rice	112	0	0	0.12		0.12	0.05
China	Polished rice	516	11	11	0.11		0.10	0.04
	Husked rice	445	0	0	0.21		0.20	0.08
EU	Polished rice	216	15	15	0.09		0.09	0.04
	Husked rice	129	4	4	0.15		0.13	0.07
Japan	Polished rice	640	0	0	0.12		0.12	0.04
	Husked rice	1200	0	0	0.18		0.17	0.08
Singapore	Polished rice	23	13	18		0.09	0.01	-
	Husked rice	16	2	9	0.09		-	0.02
Thailand	Polished rice	354	8	158	0.07		0.07	0.03
	Husked rice	285	9	47	0.12		0.13	0.04
USA	Polished rice	363	0	0	0.09		0.09	0.03
	Husked rice	308	0	0	0.12		0.12	0.05
By Subspecies								
<i>japonica</i>	Polished rice	820			0.11		0.11	
	Husked rice	1470			0.17		0.16	
<i>indica</i>	Polished rice	912			0.09		0.09	
	Husked rice	655			0.17		0.16	
All data combined	Polished rice	2365			0.10		0.09	
	Husked rice	2535			0.17		0.15	

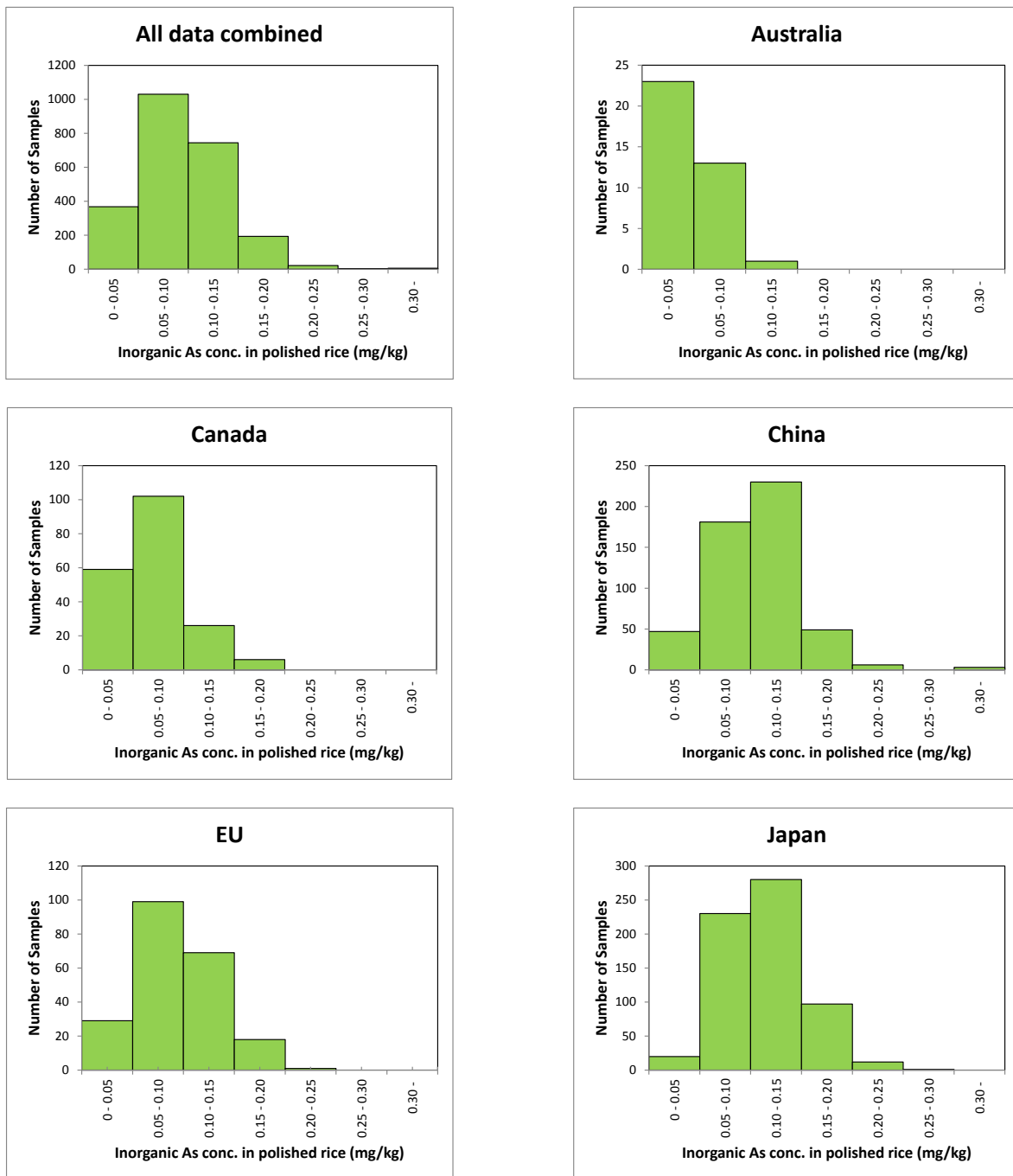
* In this paper, the number of <LOQ is zero, true mean was calculated.

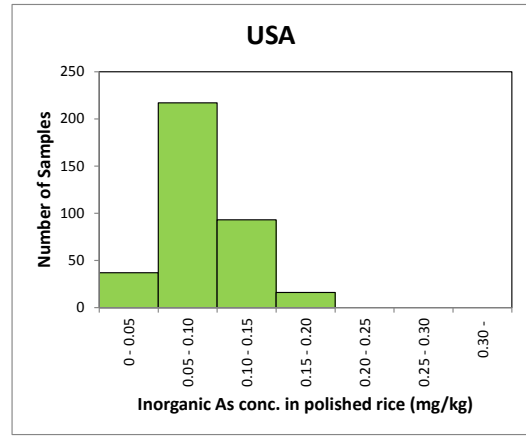
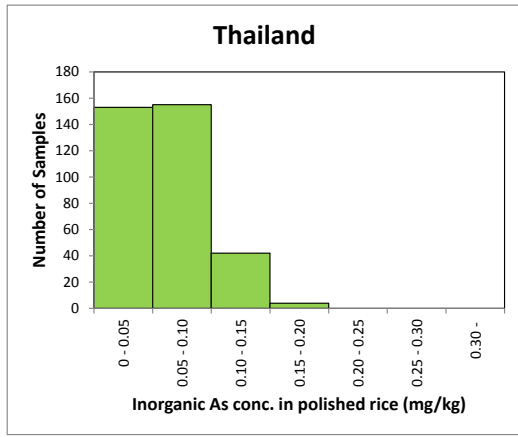
** In this paper, the proportion of <LOQ is less than or equal to 60%, the best estimated mean was calculated by replacing <LOQ with 1/2LOQs.

*** In this paper, the proportion of <LOQ is more than 60%, the upper bound and lower bound were calculated by replacing <LOQ with LOQs or zero.

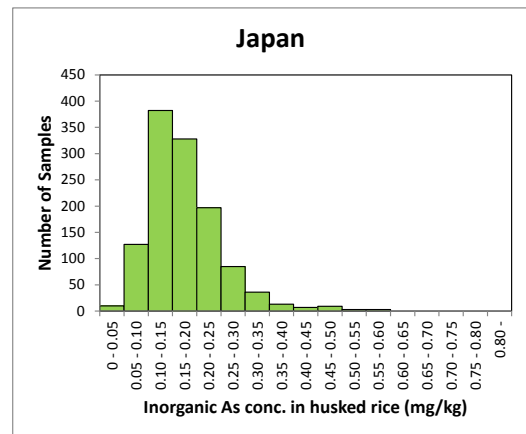
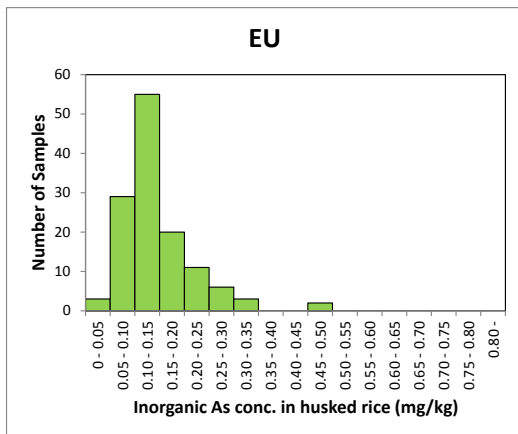
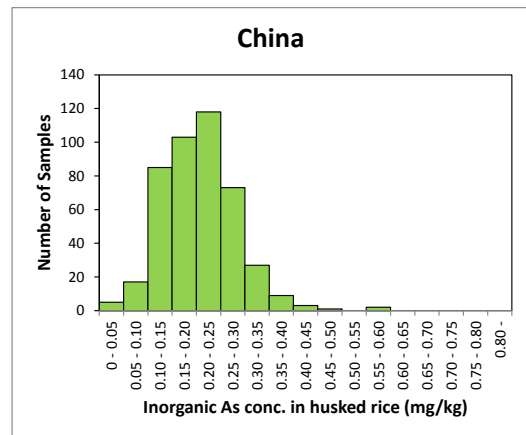
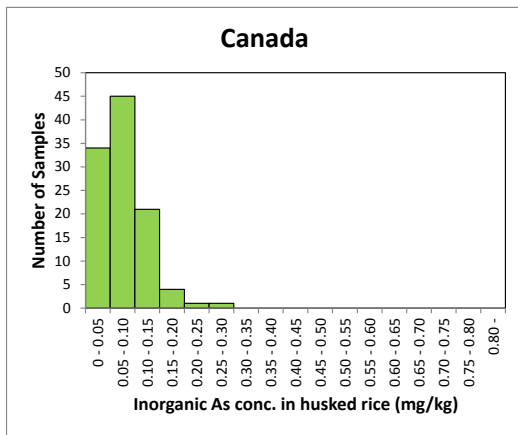
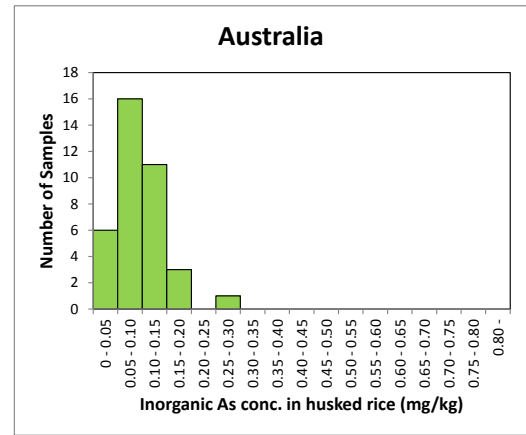
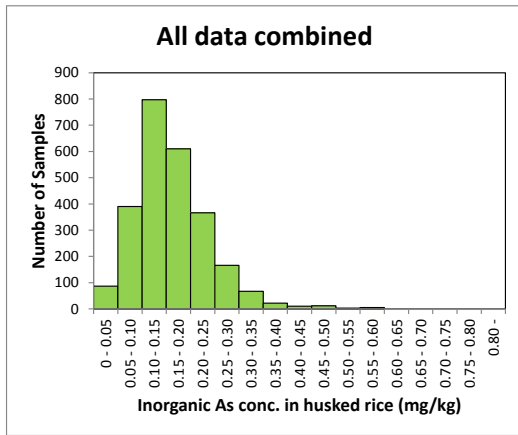
Figure 3 Histograms on iAs in (a) polished rice (b) husked rice for occurrence data provided by Members

(a) Polished rice





(b) Husked rice



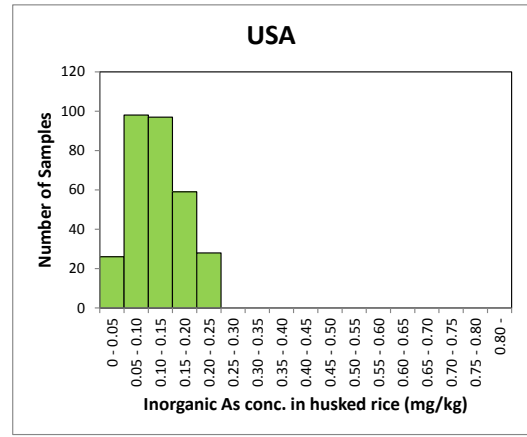
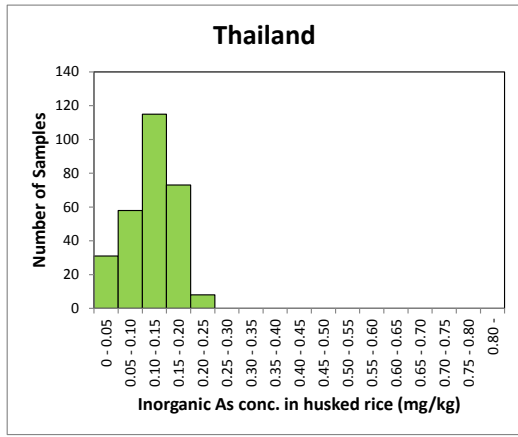


Table 8 Summary of occurrence data on tAs in rice provided by Members

	Type of rice	Total number of samples	Number of <LOD	Number of <LOQ	Mean (mg/kg)				Median (mg/kg)	SD (mg/kg)
					True	Best Estimated	Upper bound	Lower bound		
By country and NGO										
Australia	Polished rice	126	1	1		0.25			0.29	0.14
	Husked rice	60	0	0	0.27				0.24	0.18
Brazil	Polished rice	67	0	0	0.17				0.16	0.07
	Husked rice	31	0	0	0.17				0.15	0.12
Canada	Polished rice	193	0	0	0.14				0.12	0.09
	Husked rice	112	0	1		0.22			0.20	0.10
China	Polished rice	913	1	1		0.13			0.12	0.07
	Husked rice	443	0	0	0.25				0.24	0.09
EU	Polished rice	574	36	36		0.14			0.10	0.13
	Husked rice	273	12	12		0.19			0.14	0.18
Indonesia	Polished rice	25	7	25			0.01	0	-	-
	Husked rice	-	-	-					-	-
Japan	Polished rice	640	0	0	0.13				0.13	0.05
	Husked rice	1200	0	0	0.18				0.17	0.09
Kenya	Polished rice	-	-	-					-	-
	Husked rice	8	1	1		0.45			0.36	0.36
Philippines	Polished rice	63	27	58			0.06	0.01	-	-
	Husked rice	6	6	6			0.10	0	-	-
Singapore	Polished rice	279	41	47		0.11			0.11	0.06
	Husked rice	31	1	5		0.16			0.16	0.07
Thailand	Polished rice	479	70	232		0.12			0.10	0.05
	Husked rice	324	15	44		0.19			0.21	0.08
USA	Polished rice	363	0	0	0.20				0.18	0.12
	Husked rice	305	0	0	0.21				0.18	0.16
FoodDrinkEurope	Polished rice	1355	7	7		0.16			0.14	0.10
	Husked rice	-	-	-					-	-
By Subspecies										
<i>japonica</i>	Polished rice	889				0.13			0.12	
	Husked rice	1477			0.20				0.18	
<i>indica</i>	Polished rice	1127				0.14			0.13	
	Husked rice	716				0.23			0.22	
All data combined										
	Polished rice	5077	190	407		0.14			0.12	
	Husked rice	2793	35	69		0.21			0.19	

Table 9 Summary of occurrence data provided by Members on iAs in polished rice which origin was indicated as “domestic”

	Total number of samples	Number of <LOD	Number of <LOQ	Mean (mg/kg)				Median (mg/kg)	SD (mg/kg)	Percentage > ML proposal		
				True	Best estimated	Upper bound	Lower bound			0.1	0.2	0.3
Australia	37	1	1		0.05			0.05	0.03	2.7	0	0
Brazil	21	0	0	0.09				0.09	0.03	33	0	0
China	467	1	1		0.11			0.11	0.04	58	1.1	0
Japan	640	0	0	0.12				0.12	0.04	61	2.0	0
Singapore	2	2	2			0.28	0	-	-			
Thailand	354	8	158		0.07			0.05	0.03	13	0	0
USA	320	0	0	0.09				0.09	0.03	32	0	0

Table 10 Summary of occurrence data provided by Members on iAs in husked rice which origin was indicated as “domestic”

	Total number of samples	Number of <LOD	Number of <LOQ	Mean (mg/kg)				Median (mg/kg)	SD (mg/kg)	Percentage > ML proposal			
				True	Best estimated	Upper bound	Lower bound			0.2	0.3	0.4	0.5
Australia	37	0	0	0.10				0.10	0.05	2.7	0	0	0
Brazil	2	0	0	0.16				0.16	0.003	100	0	0	0
China	443	0	0	0.21				0.20	0.08	53	9.5	0.5	0.5
Japan	1200	0	0	0.18				0.17	0.08	29	5.9	1.8	0.5
Thailand	285	9	47		0.12			0.12	0.04	2.8	0	0	0
USA	302	0	0	0.12				0.12	0.05	9.3	0	0	0

Table 11 Summary of ratio of iAs to tAs and iAs to sum of 4 As species in rice samples

	Type of rice	Ratio of iAs to tAs					Ratio of iAs to sum of 4 As species				
		Number of data set	Mean	Median	Min	Max	Number of data set	Mean	Median	Min	Max
By rice samples which origin were indicated as "domestic"											
Australia	Polished rice	36	0.34	0.27	0.03	1.00	-	-	-	-	-
	Husked rice	37	0.50	0.44	0.23	0.86	-	-	-	-	-
China	Polished rice	466	0.76	0.79	0.13	1.00	153	0.75	0.77	0.34	0.92
	Husked rice	443	0.82	0.84	0.15	1.00	2	0.84	0.84	0.80	0.88
Japan	Polished rice	640	0.88	0.90	0.41	1.00	576	0.84	0.86	0.44	0.95
	Husked rice	1200	0.92	0.92	0.57	1.00	574	0.90	0.91	0.60	0.97
Thailand	Polished rice	182	0.59	0.56	0.33	1.00	12	0.65	0.65	0.47	0.72
	Husked rice	235	0.67	0.67	0.33	1.00	24	0.71	0.73	0.53	0.80
USA	Polished rice	320	0.49	0.49	0.12	1.00	311	0.51	0.51	0.13	0.88
	Husked rice	299	0.66	0.67	0.10	1.00	287	0.65	0.70	0.09	0.93
By subspecies of rice											
<i>japonica</i>	Polished rice	812	0.83	0.87	0.03	1.00	632	0.82	0.86	0.20	0.95
	Husked rice	1470	0.88	0.90	0.10	1.00	706	0.86	0.90	0.09	0.97
<i>indica</i>	Polished rice	729	0.65	0.66	0.14	1.00	360	0.61	0.63	0.13	0.94
	Husked rice	596	0.76	0.79	0.15	1.00	54	0.74	0.76	0.31	0.87
All data combined											
	Polished rice	1919	0.71	0.75	0.03	1.00	1344	0.73	0.78	0.13	0.96
	Husked rice	2331	0.82	0.87	0.10	1.00	1018	0.82	0.87	0.09	0.97

A Statistical Evaluation for Determining the Processing Factor to Estimate the iAs Concentration in Polished Rice from iAs Concentration in Husked Rice

1. Among all the available occurrence data, iAs concentrations in husked and polished rice obtained from the same sample source were identified (hereinafter referred as to “the original data set”) (see Table 12).

Table 12 Summary of the data sets used for the statistical evaluation for determining processing factors

Country	Number of data sets
China	448
Japan	600
Total	1048

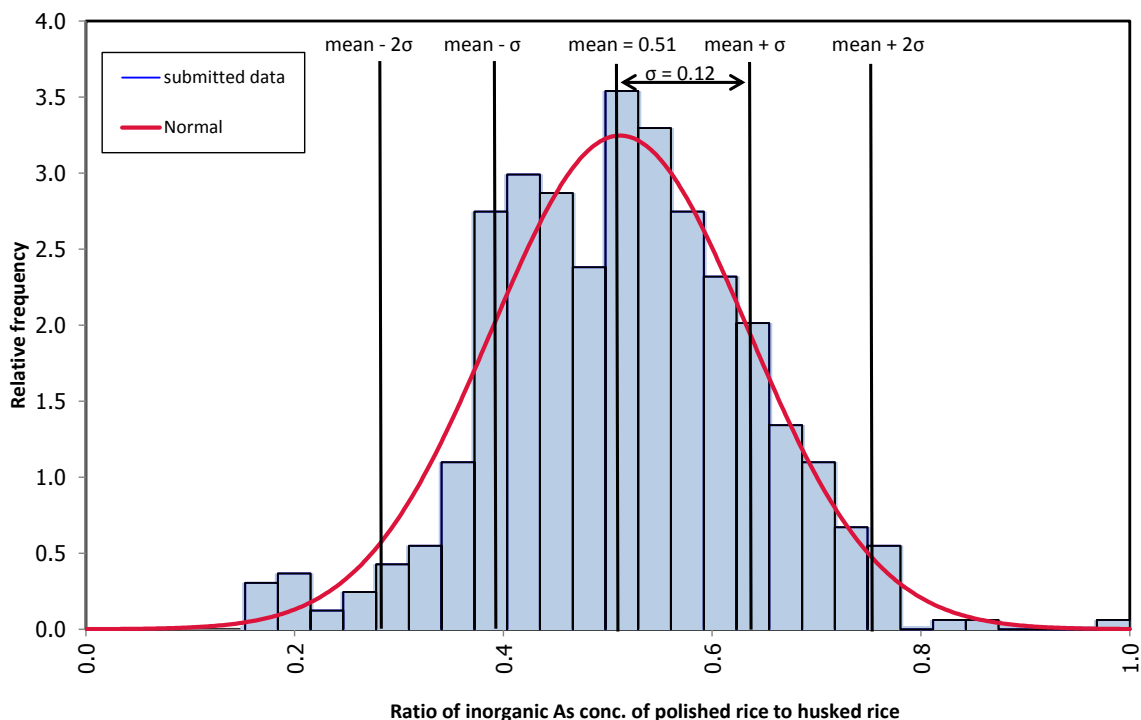
2. In the original data set, the LOQs for iAs concentration in husked rice were reported as around 0.03 mg/kg*. At low concentrations, in particular lower than or close to the LOQ, measurement uncertainty is significantly large affecting the calculation of ratios. Therefore, one cut-off value was selected at about five times the LOQ (i.e. 0.2 mg/kg). 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. And then, data sets 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 from the original data set and the ratios of iAs concentration in polished/husked were calculated.

*In the data sets provided by China, only LODs were reported, therefore the LOQ was calculated as LOD (0.008)×3.3 = 0.03

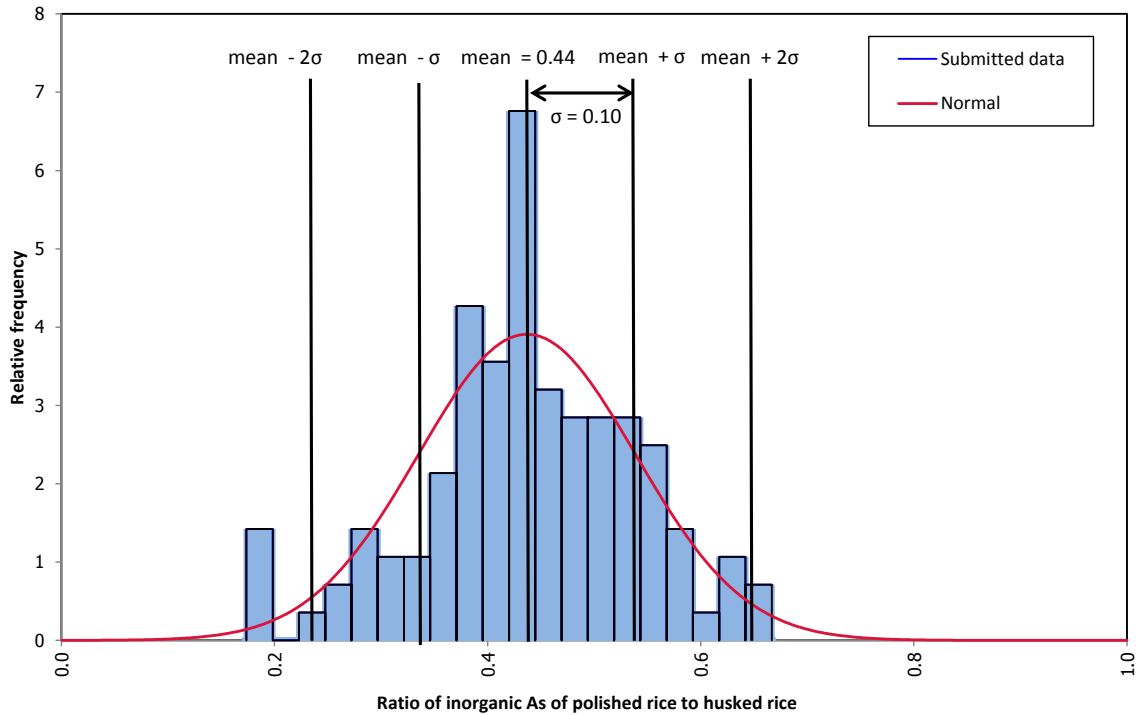
3. Using these ratios, distributions were developed for Group 1 and Group 2 respectively (see Figure 4). In order to assess normality of each distribution, the Kolmogorov-Smirnov test was performed. Both distributions were deemed to be normal at 5% level of significance. The mean ratios of iAs in polished 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 (see Figure 4). From these mean and standard deviations values, five hypothetical processing factors were obtained for each distribution model (mean, mean ± SD, mean ± 2SD).

Figure 4 Distribution models of ratios of iAs concentration in polished/husked rice

(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)



4. 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 a ML proposal at 0.2 mg/kg.
5. The Table 13 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.
6. A scatter graph for the relationship of iAs in husked rice to ratio of iAs in polished/husked rice is shown in Figure 5. From this information, it seems that the higher iAs concentration in husked rice is, the more iAs can be removed after polishing.
7. A possibility of calculating processing factors for each iAs concentration range in husked rice was examined. Table 14 shows the range of ratios of iAs in polished/husked rice for each concentration range of iAs in husked rice. The number of data sets in the iAs concentration range "0.2 < Conc. ≤ 0.3" was sufficient to calculate statistically confidence interval at 95%. On the other hand, the number of data sets in the upper iAs concentration ranges was not sufficient.

Table 13 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 + 2 σ	mean - σ	mean - 2 σ	mean	mean + σ	mean + 2 σ	mean - σ	mean - 2 σ
		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.

Figure 5 Scatter graph for the relationship of iAs in husked rice to ratio of iAs concentration in polished/husked rice

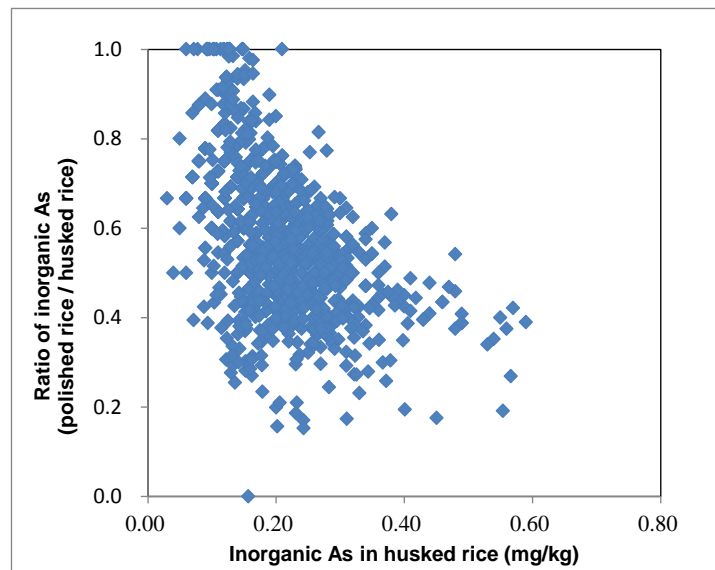


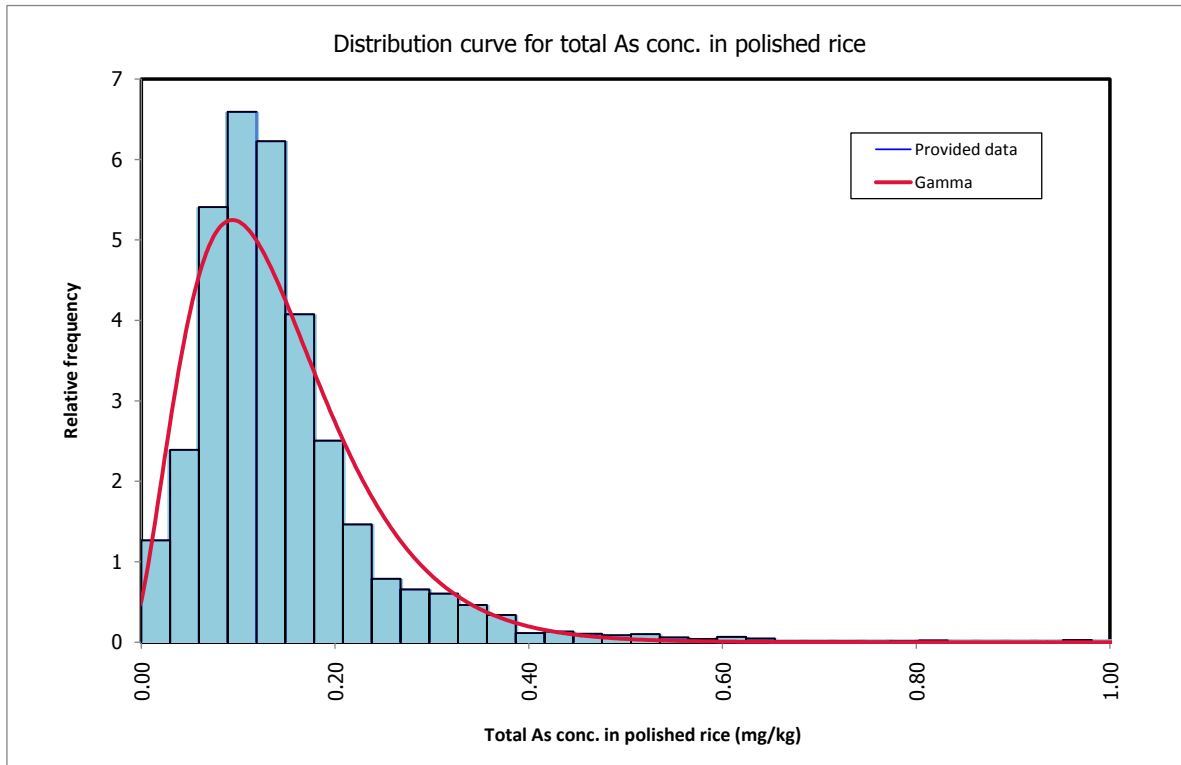
Table 14 The range of ratios of iAs in polished/husked rice for each concentration range of iAs in husked rice

iAs concentration in husked rice (mg/kg)	The range of ratios of iAs concentration in polished/husked		
	Number of data sets	Min	Max
0.2 < Conc. ≤ 0.3	381	0.15	1.0
0.3 < Conc. ≤ 0.4	75	0.17	0.65
0.4 < Conc. ≤ 0.5	19	0.18	0.54
0.5 < Conc. ≤ 0.6	8	0.19	0.42

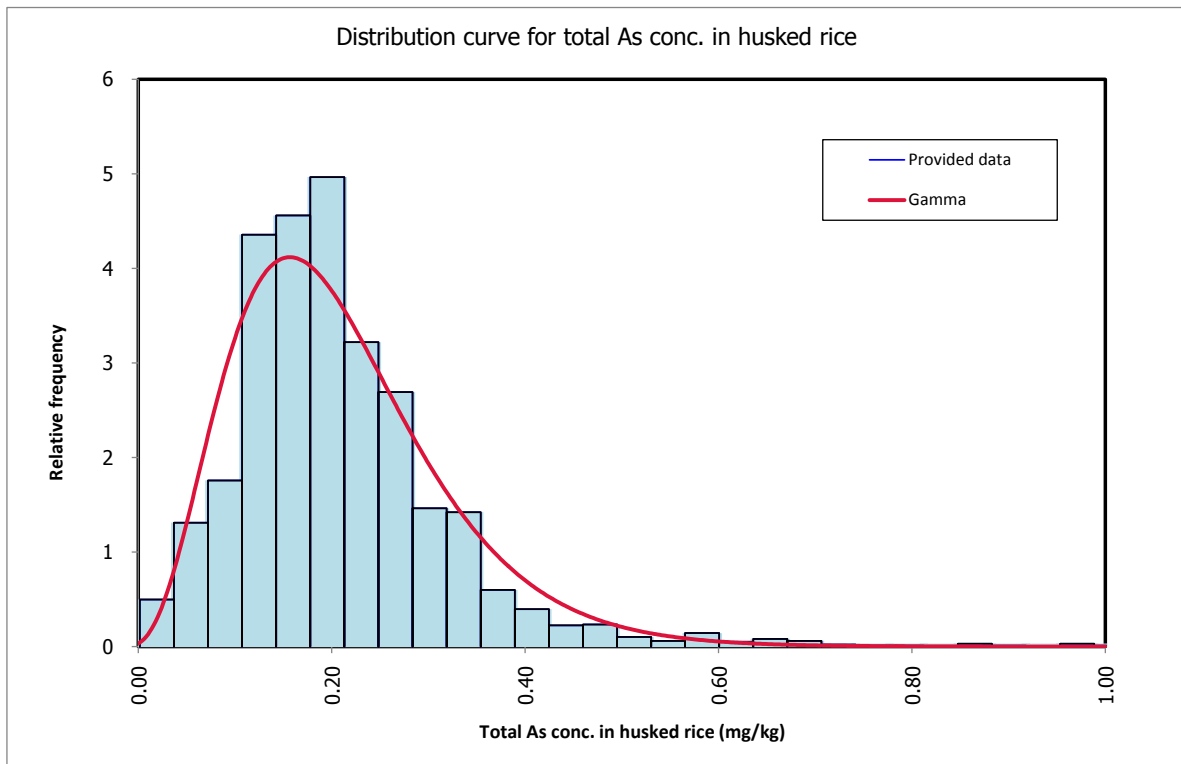
Distribution Curves for Total Arsenic in Rice

Figure 6 Distribution curves for tAs in (a) polished rice and (b) husked rice

(a) Polished rice



(b) Husked rice



APPENDIX III

Analytical Methods for the Determination of Inorganic Arsenic in Rice

1. In addition to the information already presented in CX/CF 12/6/8, the information on the analytical methods for the determination of iAs in rice is summarized in this Appendix based on the information provided by Members.
2. Table 15 summarizes the information on analytical methods for iAs in rice provided by the seven Members along with the occurrence data of iAs in rice. Liquid chromatography with inductively coupled plasma mass spectrometry (LC-ICP/MS) was the most commonly used among these Members, and atomic absorption spectrometry (AAS) was also used by one Member. However, most of them were not internationally validated.

Table 15 Summary of information on analytical methods for iAs in rice used by Members

Country	For iAs		LOD (mg/kg)	LOQ (mg/kg)	Reference
	Separation Method	Detection method			
Australia	LC	ICP-MS	0.005	0.02	Mahar <i>et al.</i> , 2013
Canada	LC	ICP-MS	0.0055	0.016	
China	LC	ICP-MS	0.00045	—	Zhu <i>et al.</i> , 2008
			—	—	Norton <i>et al.</i> , 2009
			0.008	—	Liang <i>et al.</i> , 2010
			—	—	Li <i>et al.</i> , 2013
	HCl extraction	AFS	0.002	0.005	
Japan	LC	ICP-MS	0.002 - 0.003	0.01 - 0.02	Ukena <i>et al.</i> , accepted 2013
Singapore	LC	ICP-MS	0.05	0.15	
	LC	ICP-MS	0.01 - 0.05	0.04 - 0.10	
Thailand	LC	FAAS	0.0045	0.015	Ruangwises <i>et al.</i> , 2012
	acid digestion, solvent	FAAS	0.041	0.137	
USA	LC	ICP-MS	0.0002 - 0.0034	0.0012 - 0.026	

Internationally Validated Methods of Analysis for iAs in Rice Used by Members**LC-ICP/MS**

3. Japan organized a collaborative study for international validation of an analytical method for iAs in rice, both *japonica* and *indica* type. In the method, arsenic species in rice including iAs, MMA and DMA, after extraction with 0.15 mol/L nitric acid, were separated with liquid chromatography and detected by inductively coupled plasma-mass spectrometry (ICP-MS).
4. The method was evaluated through the IUPAC/ISO/AOAC harmonized protocol. 16 laboratories from four countries participated in the study (one in Indonesia, two in Singapore, five in Thailand and eight in Japan) and 13 laboratories returned valid data.
5. 20 test portions of ten blind duplicates of *japonica* and *indica* type rice samples (both husked and polished) were used in this study.
6. Repeatability relative standard deviation (RSD_r) and reproducibility relative standard deviation (RSD_R) were calculated at 5 concentrations of iAs between 0.03-0.68 mg/kg. The RSD_r was in a range of 3.8-7.7% and the RSD_R was in a range of 10-36%.
7. These performance characteristics were found to be sufficient for determination of iAs at or higher than 0.03 mg/kg. Applicability of the method was estimated to be in a range of 0.02-2.0 mg/kg.

Other Analytical Methods Used by Members (Not Internationally Validated)

8. Australia used a method employing extraction of iAs with 2% (v/v) nitric acid and determination with LC coupled with ICP-MS for polished rice and husked rice. The comparison of arsenic speciation by this method and XANES (X-ray absorption near edge structure) showed that similar arsenic species were detected indicating the appropriateness of using 2% (v/v) nitric acid for extraction of iAs prior to speciation (Maher W *et al.*, 2013).
9. China provided the information on four analytical methods for the determination of iAs using LC coupled with ICP-MS. Regarding extraction for inorganic arsenic, three methods employed extraction of iAs using 1% (v/v) nitric acid (Zhu YG *et al.*, 2008, Norton GJ *et al.*, 2009, Li G *et al.*, 2013). The other method employed extraction of iAs using 0.2 mol/L TFA (Trifluoroacetic acid) (Liang F *et al.*, 2012).

10. Thailand provided the information on one of four methods used for collecting occurrence data on iAs in rice. In the method, extraction was conducted by converting all iAs into arsenite using a reducing agent, and determination was conducted by the atomic absorption spectrometer without using chromatographic separation. The RSD_r across the four concentrations of fortified iAs ranged from 1.8 to 5.3% (Ruangwises S *et al.*, 2012).

11. The solid-phase extraction using anion exchange SPE cartridge for selective iAs quantification in wholemeal rice powder was tested collaboratively, where the German laboratories (N=10) used either HG-AAS or ICP-MS for iAs determination. The trial gave satisfactory results (HorRat value of 1.6) and did not reveal significant difference (*t* test, $p>0.05$) between HG-AAS and ICP-MS quantification (Rasmussen *et al.*, 2013).

APPENDIX IV

Calculation of a Conversion Factor of Total Arsenic to Inorganic Arsenic

1. In order to determine whether a conversion factor to estimate iAs concentration from tAs concentration in rice could be derived, first, the tAs concentrations and iAs concentrations determined for the same samples were extracted from the list of all occurrence data provided by Members. Table 16 summarizes data sets used for this calculation. And then, the ratio of iAs to tAs of each sample was calculated.
2. Since arsenic concentrations in rice largely differ depending on the cultivated location of the rice, the ratios were compiled for each country where rice sampled were cultivated (Australia, China, Japan, Thailand and USA). Based on these data sets, scatter graphs plotted concentration in tAs and iAs in each rice sample and histograms of ratio of iAs/tAs were developed (Figure 7). And the ranges of ratios of iAs/tAs for each concentration range of tAs in polished and husked rice are shown in Table 17 and Figure 8.
3. For both polished and husked rice, the ratios of iAs/tAs varied widely among samples even if rice sampled was produced in the same country, and the histograms for five countries also showed widely varying shapes.
4. The varying ratios between iAs and tAs indicated that it would be difficult to agree on one fixed conversion factor for estimating iAs concentration from tAs concentration in all rice varieties available in the world market.

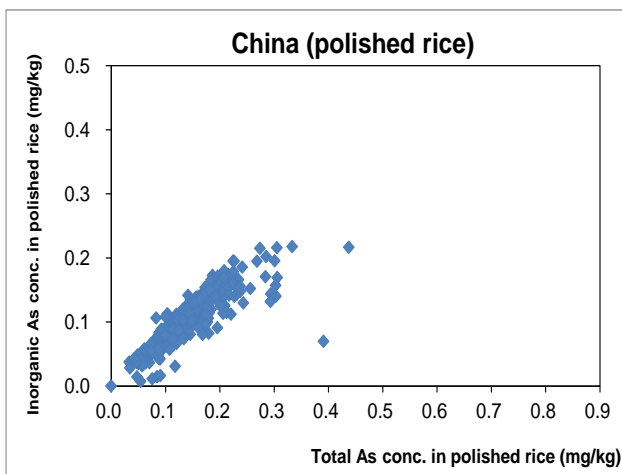
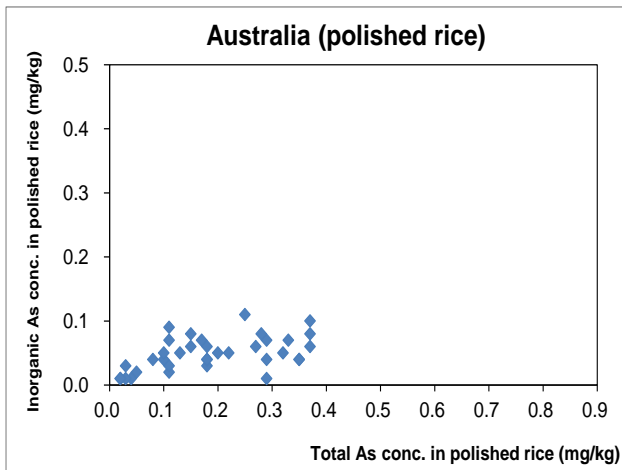
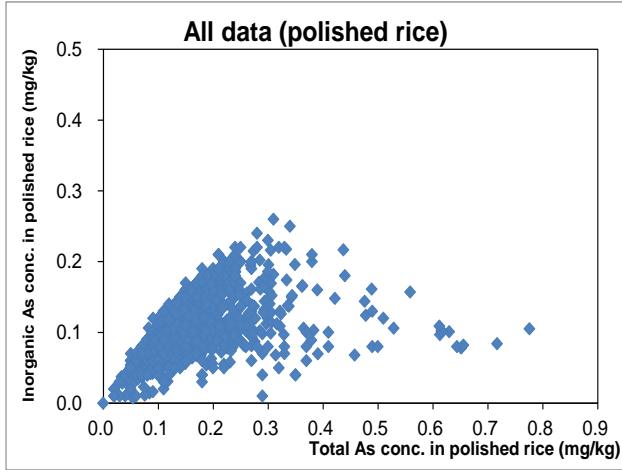
Table 16 Summary of the data set used for the calculation of conversion factor to estimate iAs concentration from tAs concentration in rice

Country	Number of samples in each data set							
	Polished rice				Husked rice			
	<i>japonica</i>	<i>indica</i>	Unknown	Total	<i>japonica</i>	<i>indica</i>	Unknown	Total
Australia	36	0	0	36	37	0	0	37
China	91	350	25	466	90	347	6	443
Japan	640	0	0	640	1200	0	0	1200
Thailand	0	182	0	182	0	235	0	235
USA	44	162	114	320	143	8	148	299
Total	811	694	186	1644	1470	590	154	2114

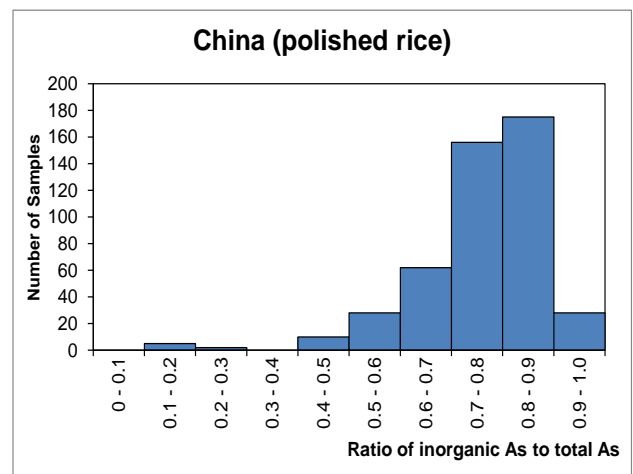
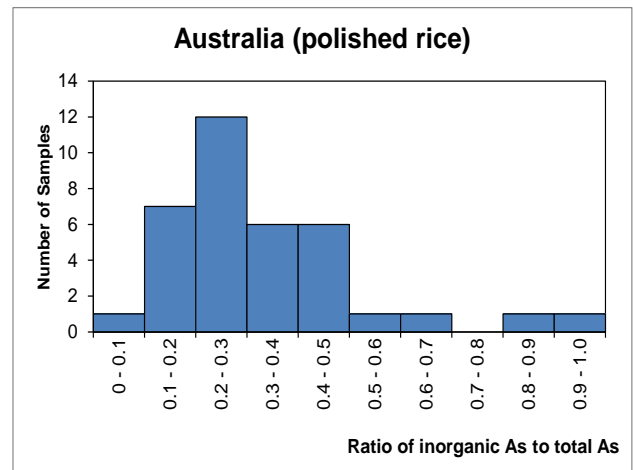
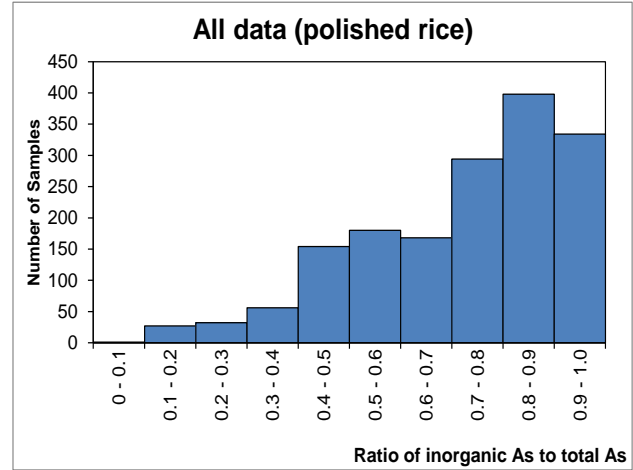
Figure 7

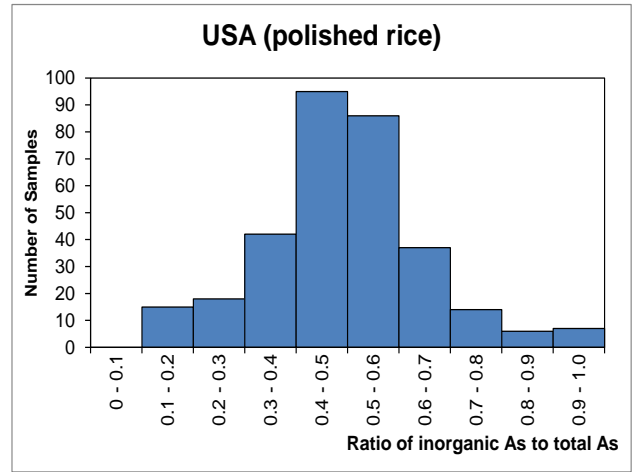
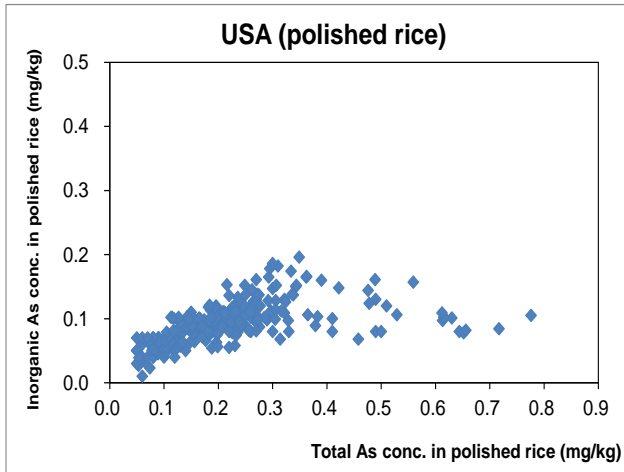
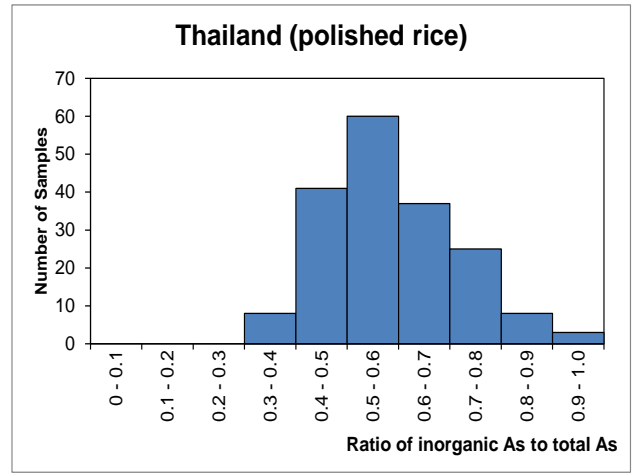
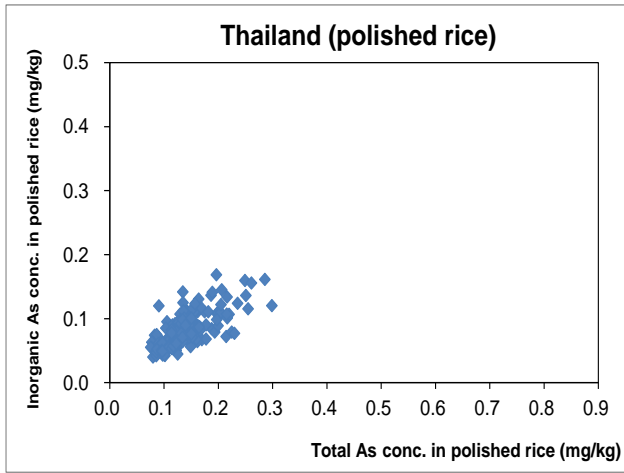
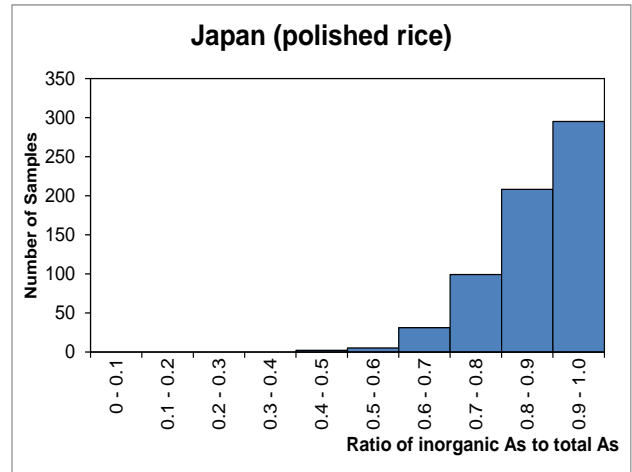
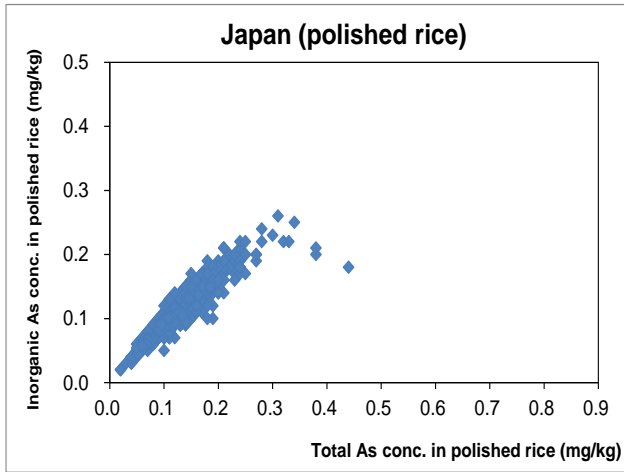
- (1) Scatter graphs for the relationship of iAs concentration to tAs in (a) polished rice and (b) husked rice
 - (2) Histograms of ratio of iAs/tAs in (a) polished rice and (b) husked rice
- (a) Polished rice

(1) Scatter graphs



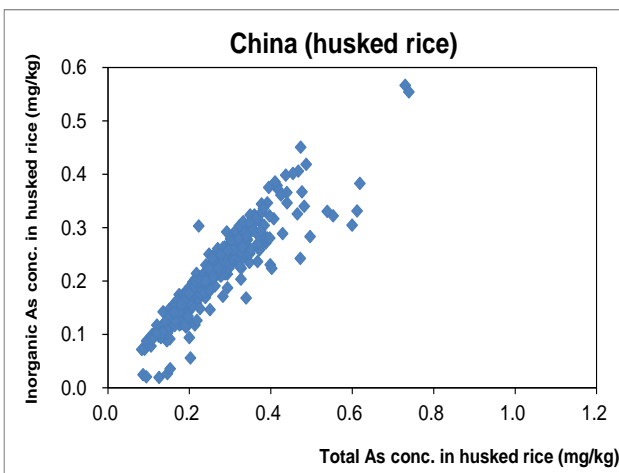
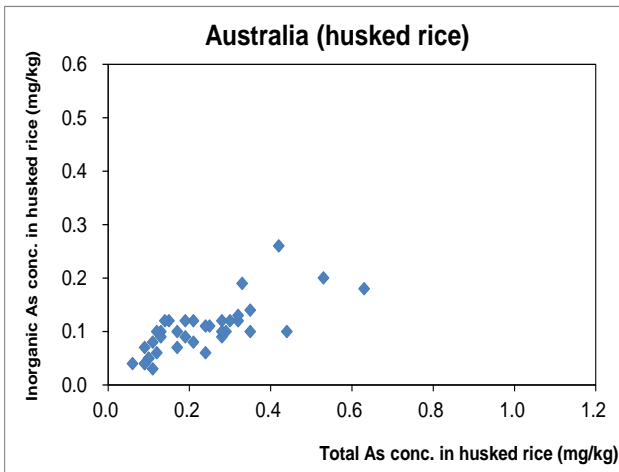
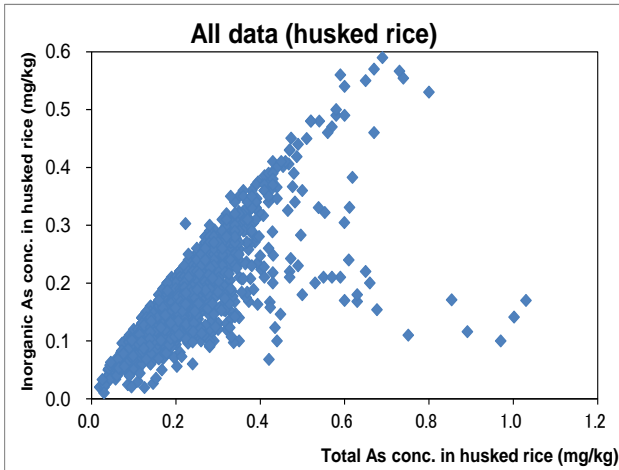
(2) Histograms



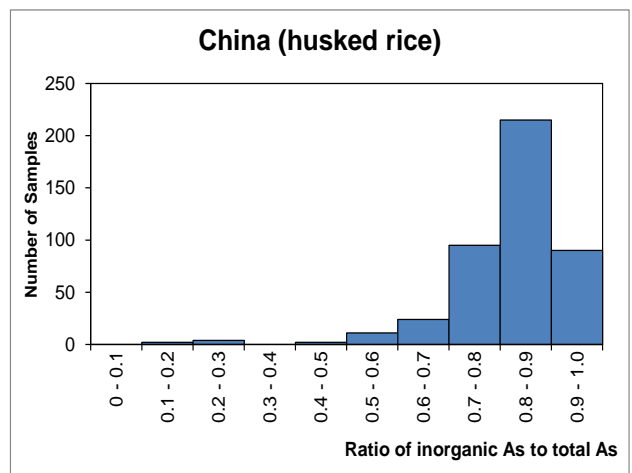
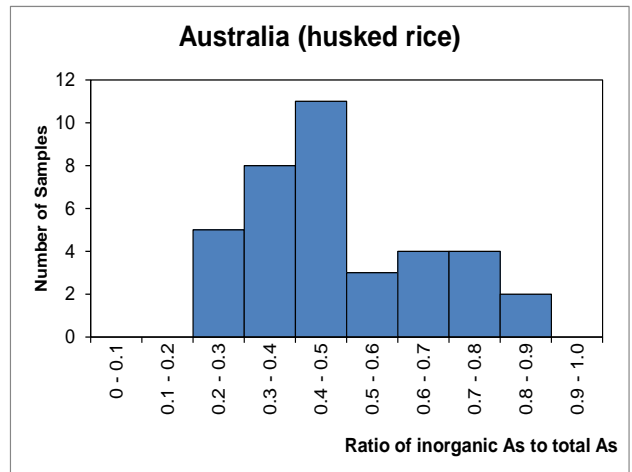
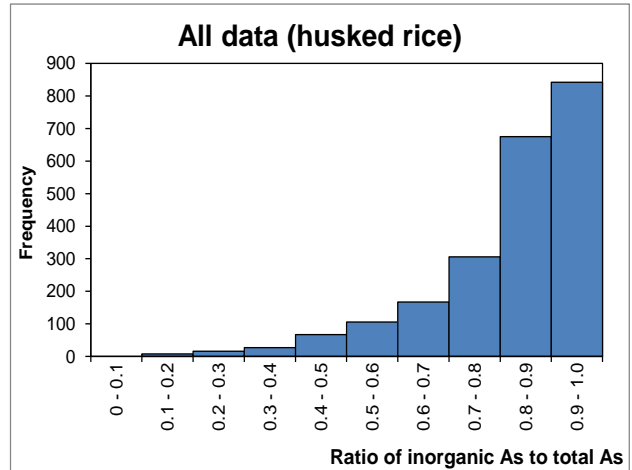


(b) Husked rice

(1) Scatter graphs



(2) Histograms



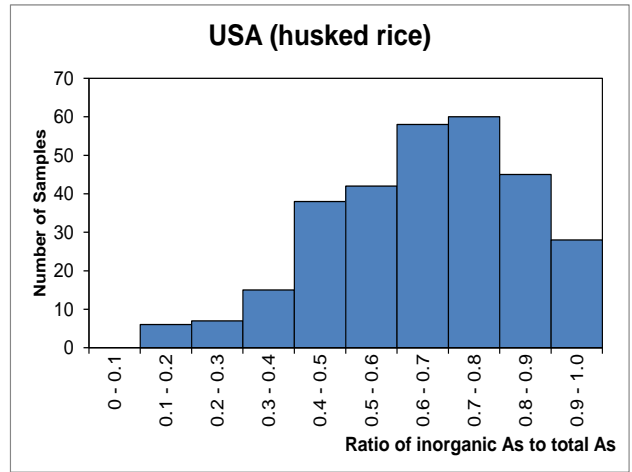
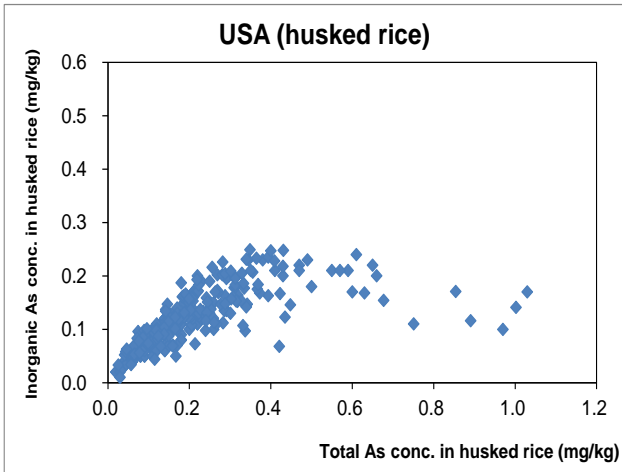
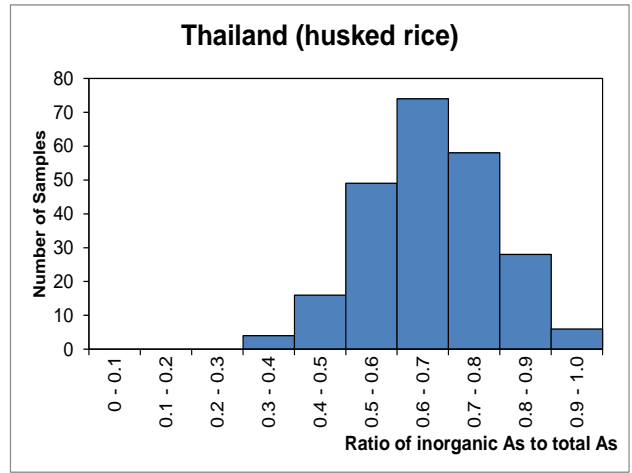
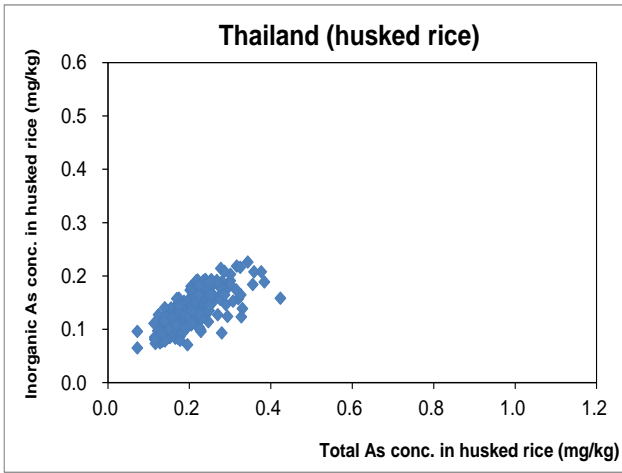
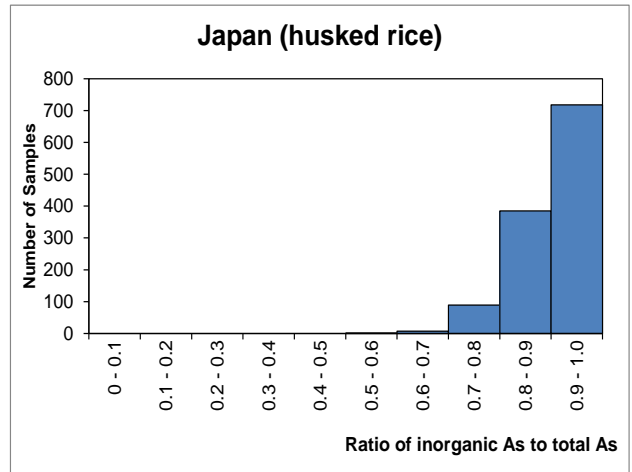
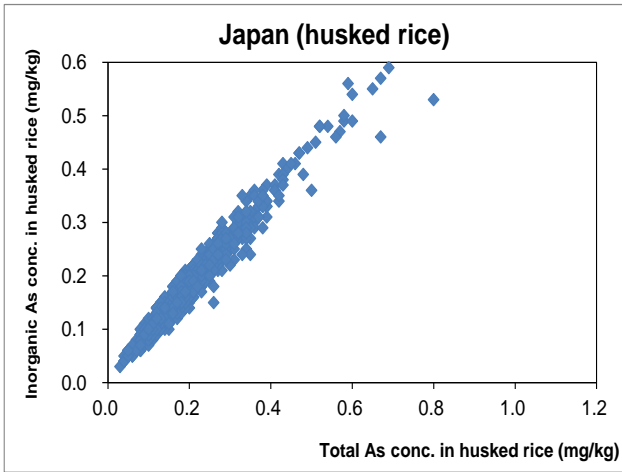
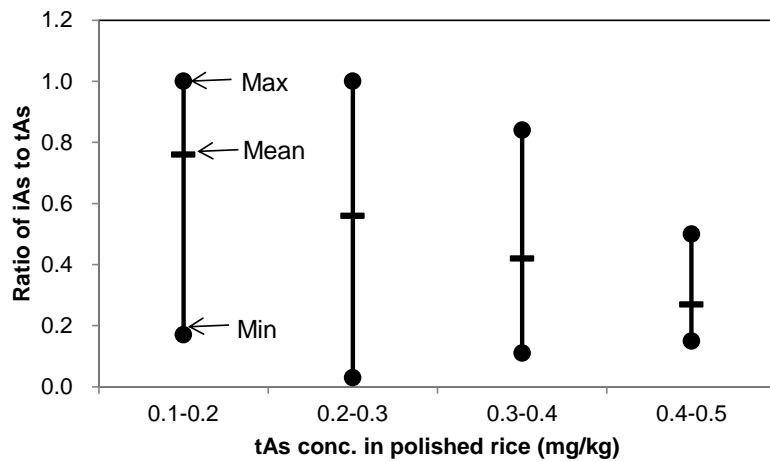


Table 17 Ratios of iAs to tAs in rice

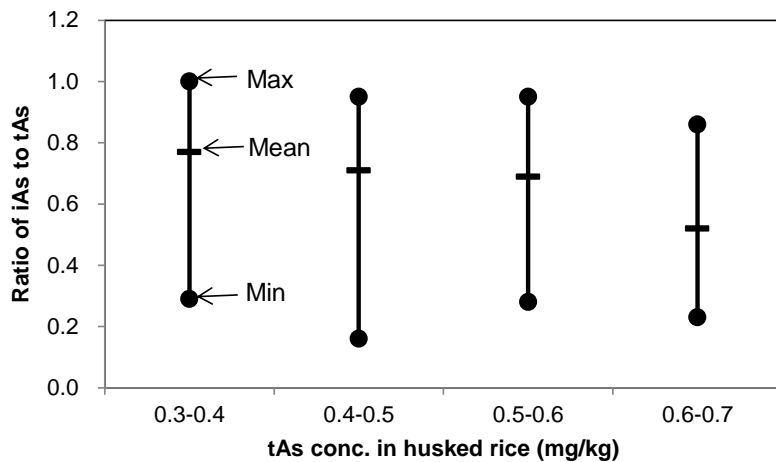
tAs conc. in rice (mg/kg)	Ratio of iAs to tAs			
	Numbers of data set	Mean	Min	Max
Polished rice				
0.1 < Conc. ≤ 0.2	1031	0.76	0.17	1.0
0.2 < Conc. ≤ 0.3	214	0.56	0.03	1.0
0.3 < Conc. ≤ 0.4	47	0.42	0.11	0.84
0.4 < Conc. ≤ 0.5	13	0.27	0.15	0.50
Husked rice				
0.3 < Conc. ≤ 0.4	226	0.77	0.29	1.0
0.4 < Conc. ≤ 0.5	53	0.71	0.16	0.95
0.5 < Conc. ≤ 0.6	19	0.69	0.28	0.95
0.6 < Conc. ≤ 0.7	12	0.52	0.23	0.86

Figure 8 The ranges of ratios of iAs to tAs in rice

(a) Polished rice



(b) Husked rice



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