CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CF/10 CRD 6**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Tenth Session
Rotterdam, The Netherlands, 4-8 April 2016

(Comments submitted on by Senegal, Thailand, USA and Consumers International)

Draft maximum level for inorganic arsenic in husked rice (at Step 7)

SENEGAL

Position: la délégation sénégalaise propose de suspendre temporairement les recherches portant sur les LM d'arsenic inorganique dans le riz décortiqué jusqu'à ce que les travaux sur le Code des bonnes pratiques au sujet de la prévention et de la réduction de la présence d'arsenic dans le riz soient finalisés.

Justification: la suspension temporaire de la recherche sur les Limites maximales (LM) permettra au Sénégal et à l'Afrique de bénéficier de plus de temps pour générer des données sur la présence d'arsenic dans le riz décortiqué et pour conduire des évaluations afin de décider d'une LM parfaitement ajustée au contexte national ou régional.

THAILAND

Thailand considers the analyzed data from the new submitted data and the data provided in 2014. We support the establishment of ML for inorganic arsenic in husked rice at 0.35 mg/kg including a footnote regarding analysis of total arsenic as a screening tool. The ML of 0.35 mg/kg in which the intake reduction is 4.3% and the violation rate is 1.8%, is an appropriate level that can protect consumer health and do not have adverse effect on trade.

USA

The United States does not object to the adoption of the ML of 0.35 mg/kg for inorganic arsenic in husked rice at Step 8. This level provides some measure of reduction in inorganic arsenic intake (a reduction of 4.3%) without a significant impact on international trade (with a violation rate of 1.8%).

The United States supports accompanying the ML for inorganic arsenic in husked rice with a note on analysis of total arsenic as a screening method, such as the following:

"Countries or importers may decide to use their own screening when applying the ML for inorganic arsenic (As-in) in rice by analyzing 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 should be conducted to determine if the As-in concentration is above the ML."

CONSUMERS INTERNATIONAL

Consumers International (CI) appreciates the opportunity to submit comments to the Codex Committee on Contaminants in Food (CCCF) of the Codex Alimentarius Commission (Commission) regarding the draft maximum level (ML) for inorganic arsenic (iAs) in husked rice at Step 6. Rice is a leading source of iAs exposure, and the adoption of rigorous standards for husked rice is necessary to protect consumer health. After review, however, CI does not believe the proposed ML of 0.35 mg/kg is adequate to protect consumers. The standard affects a small proportion of world husked rice and will not have any impact in the G10 geographic cluster, among others. CI instead proposes 0.15 mg/kg as a more protective standard.

The importance of rigorous standards is based in part on the range and severity of adverse health effects associated with iAs exposure. iAs is a human carcinogen, according to the Joint FAO/WHO Expert Committee on Food Additives, the WHO's International Agency for Research on Cancer, and the U.S. Environmental Protection Agency (USEPA). iAs exposure causes bladder, lung, and skin cancer, and has been associated with kidney, liver, and prostate cancer. iAs exposure also has been associated with cardiovascular disease, diabetes mellitus, and birth defects, and can harm the neurodevelopment of children and infants. There is emerging evidence that exposure to iAs can compromise immune function.

For cancer endpoints, the most appropriate acceptable risk level is 1x10E-6, or one excess cancer case per 1,000,000 exposed. As explained below, current risk levels greatly exceed that threshold, ranging from 6.75E-05 when mean iAs and rice consumption are modeled to 6.21E-04 when high iAs and rice consumption are modeled. A 0.35 mg/kg standard would not meaningfully reduce exposure or risk.

A 0.35 mg/kg ML would affect just 1.8% of world husked rice, according to the Electronic Working Group (EWG) analysis, and would have little or no impact in certain geographic clusters considered by the EWG. This means the draft ML would not meaningfully reduce iAs exposure or cancer risk in much of the world; it is not an adequate public health protection. By contrast, a 0.15 mg/kg ML would affect a far greater proportion and reduce iAs exposure and cancer risk globally. If the Commission does not adopt the 0.15 mg/kg standard, it should at least adopt a standard low enough to affect 10-20% of world husked rice to ensure meaningful reductions in iAs exposure and cancer risk among consumers worldwide. The EWG calculated that even a 0.25 mg/kg standard would impact just 7.5% of the market.

CI's position is based in part on extensive research on iAs in rice and analysis of consumer exposure and risk conducted by Consumers Union of the United States (CU), a CI member. CU's research includes market basket studies and risk assessments published in Consumer Reports magazine and in a detailed report.[1] These studies have indicated that while in husked rice purchased in the U.S., iAs generally occurs at concentrations well below 0.35 mg/kg, the lower concentrations still pose significant risks to rice consumers, especially members of subpopulations who depend on rice as a staple food.

CU pooled data on iAs in husked rice samples (n=165) from CU studies published in 2012 and 2014, as well as data collected by the U.S. Food and Drug Administration (USFDA) in 2012-2013. In the pooled dataset, mean and 95th-percentile iAs were 0.15 mg/kg and 0.23 mg/kg, respectively (Table 1). If the Commission adopts 0.35 mg/kg as the standard, the 'violation rate' in the U.S. would be 0% and iAs exposure in the U.S. would be unchanged. Indeed, using a global dataset, the EWG also estimated that under this standard, there would be no change in iAs occurrence in husked rice in the G10 geographic cluster, which includes the U.S. We therefore do not believe that a 0.35 mg/kg standard would provide any public health protection for consumers in G10 countries. By contrast, if the Commission adopts a 0.15 mg/kg standard, CU's analysis indicates that about 42% of the U.S. husked rice market would be affected and mean and 95th-percentile iAs would decline to 0.12 mg/kg and 0.15 mg/kg, respectively.

Table 1: 'Violation Rate' and Inorganic Arsenic Occurrence in U.S. Husked Rice, by Maximum Limit

Maximum Limit (mg/kg)	'Violation Rate' (%)	Inorganic Arsenic (mg/kg)		
		Mean	95th-percentile	Maximum
0.35	0	0.15	0.23	0.25
0.25	0	0.15	0.23	0.25
0.20	11	0.14	0.20	0.20
0.15	42	0.12	0.15	0.15

Unlike the 0.35 mg/kg standard, a 0.15 mg/kg standard would reduce iAs exposure and risk. For example, among U.S. rice consumers, mean exposure to iAs in husked rice in the U.S. would be 3.60E-05 under a 0.15 mg/kg standard, compared to 4.50E-05 under the proposed 0.35 mg/kg standard (Table 2). Based on this change, and using USEPA's unit risk of 1.5 per mg/kg/day, which was published in 1988 and is likely to underestimate unit risk, the 0.15 mg/kg standard would reduce the excess lifetime cancer risk associated with mean iAs in husked rice by 20% (Table 2). A more recent unit risk proposed by USEPA in 2010 is 25.7 per mg/kg/day, which is 17 times higher than the 1988 value. USEPA is reassessing this value under political pressure, but below we present risks estimated using the higher unit risk as well.

[1] Consumer Reports Food Safety and Sustainability Center. Analysis of Arsenic in Rice and Other Grains. Accessed: March 15, 2016. Available: http://www.greenerchoices.org/pdf/CR_FSASC_Arsenic_Analysis_Nov2014.pdf.

Table 2: Average Exposure and Risk: Mean iAs, All U.S. Consumers

Maximum Limit	Mean iAs (mg/kg)	Intake Rate* (kg/day)	Exposure (mg/kg/day)	Risk (UR = 1.5)	Risk (UR = 25.7)
0.35	0.15	0.024	4.50E-05	6.75E-05	1.16E-03
0.25	0.15	0.024	4.50E-05	6.75E-05	1.16E-03
0.20	0.14	0.024	4.20E-05	6.30E-05	1.08E-03
0.15	0.12	0.024	3.60E-05	5.40E-05	9.25E-04

* Intake Rate is for U.S. whole population, consumers only, uncooked

Table 3: Average Exposure and Risk: Mean iAs, U.S. Asian Consumers

Maximum Limit	Mean iAs (mg/kg)	Intake Rate* (kg/day)	Exposure (mg/kg/day)	Risk (UR = 1.5)	Risk (UR = 25.7)
0.35	0.15	0.144	2.70E-04	4.05E-04	6.94E-03
0.25	0.15	0.144	2.70E-04	4.05E-04	6.94E-03
0.20	0.14	0.144	2.52E-04	3.78E-04	6.48E-03
0.15	0.12	0.144	2.16E-04	3.24E-04	5.55E-03

* Intake Rate is for U.S. Asian population, consumers only, uncooked

Table 4: High Exposure and Risk: 95th-percentile iAs, All U.S. Consumers

Maximum Limit	95th-P iAs (mg/kg)	Intake Rate* (kg/day)	Exposure (mg/kg/day)	Risk (UR = 1.5)	Risk (UR = 25.7)
0.35	0.23	0.024	6.90E-05	1.04E-04	1.77E-03
0.25	0.23	0.024	6.90E-05	1.04E-04	1.77E-03
0.20	0.20	0.024	6.00E-05	9.00E-05	1.54E-03
0.15	0.15	0.024	4.50E-05	6.75E-05	1.16E-03

* Intake Rate is for U.S. whole population, consumers only, uncooked

Table 5: High Exposure and Risk: 95th-percentile iAs, U.S. Asian Consumers

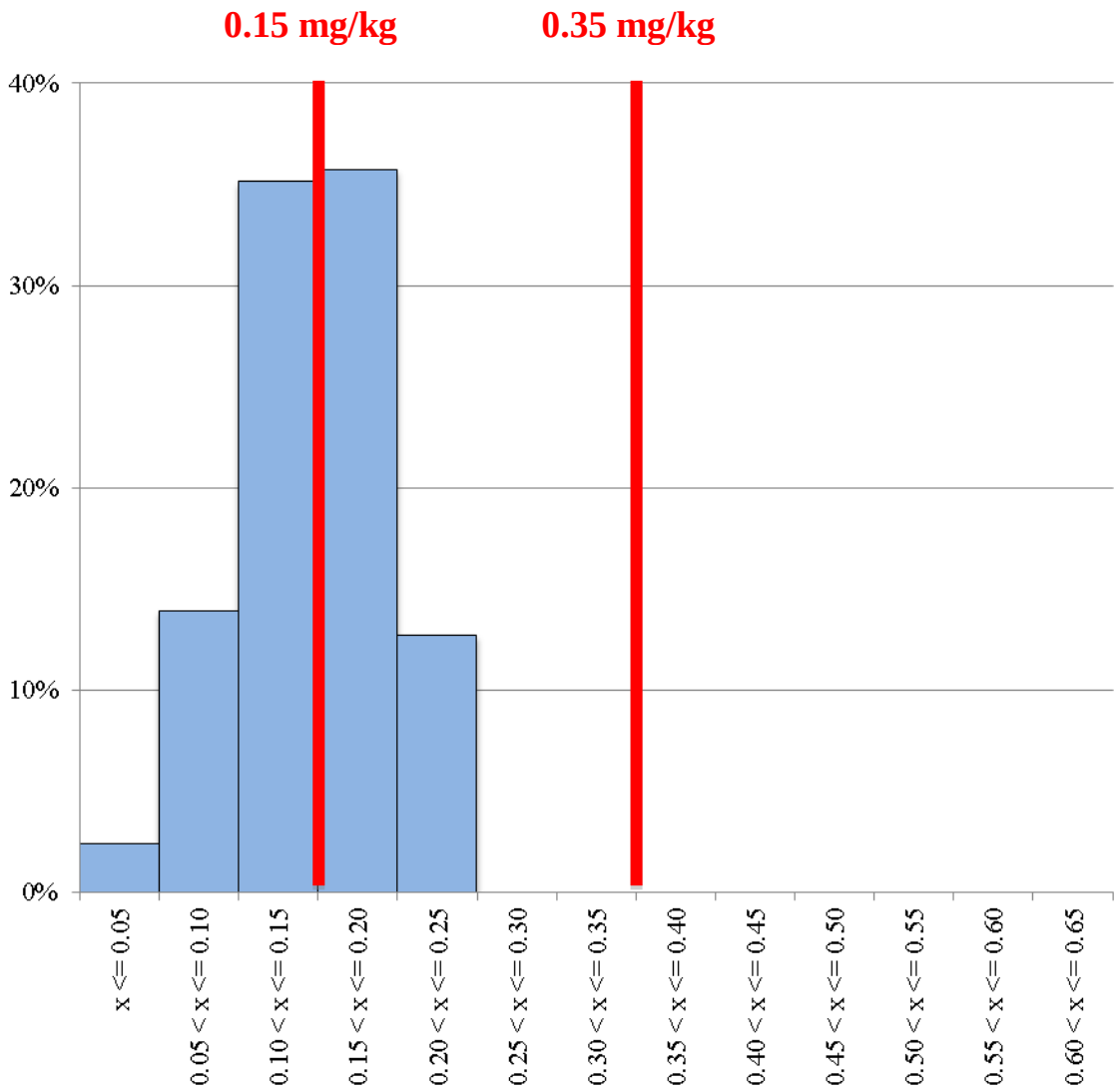
Maximum Limit	95th-P iAs (mg/kg)	Intake Rate* (kg/day)	Exposure (mg/kg/day)	Risk (UR = 1.5)	Risk (UR = 25.7)
0.35	0.23	0.144	4.14E-04	6.21E-04	1.06E-02
0.25	0.23	0.144	4.14E-04	6.21E-04	1.06E-02
0.20	0.20	0.144	3.60E-04	5.40E-04	9.25E-03
0.15	0.15	0.144	2.70E-04	4.05E-04	6.94E-03

* Intake Rate is for U.S. Asian population, consumers only, uncooked

CU has presented these data in meetings with the USFDA and the U.S. Department of Agriculture ("USDA"), which represent the U.S. government at the Commission. USFDA has been conducting a risk assessment for iAs in rice since 2012, although its assessment is not yet complete. Despite not completing its risk assessment, a USFDA representative stated at a March 2016 public meeting that the U.S. government will not oppose the draft ML of 0.35 mg/kg and that its risk assessment will not directly affect its position. It was not explained why the U.S. government has taken this position in the absence of a risk assessment, and we hope CCCF will take this fact into account during deliberations.

CI does not believe that the draft ML provides appropriate protections for husked rice consumers. CI recommends that the Commission adopt 0.15 mg/kg as a more protective standard that achieves important reductions in iAs exposure and risk, especially for the many consumers globally who eat rice as a staple food. Please contact us with questions about this comment or CU's research and analysis.

Appendix 1: Inorganic Arsenic Occurrence in Husked Rice in the U.S.



Appendix 2: Exposure to Inorganic Arsenic in Husked Rice in the U.S., and Cancer Risk

Data on iAs Occurrence in Husked Rice

CU pooled data on iAs in husked rice samples (n=165) from CU studies published in 2012 and 2014, as well as data collected by USFDA in 2012-2013 (Figure 1). CU has provided additional details on these data, including the analytical methods used, in a 2014 report, available online.[2]

iAs Exposure and Cancer Risk

We used the pooled data on iAs occurrence in husked rice to estimate iAs exposure as lifetime average daily dose (LADD; mg/kg/day) as follows:

$$LADD = C \times IR / BW,$$

where C is concentration (mg iAs/kg rice), IR is intake rate (kg rice/day), and BW is bodyweight (kg). C was estimated by mean iAs in the pooled dataset. For IR, we used values from the USEPA's Exposure Factors Handbook, which presents consumer-only rice intake values for the general population and subpopulations, including Asians.[3] The intake values are presented as g of rice consumed per kg of bodyweight per day, and we multiplied each value by 80 kg and divided by 1,000 to estimate kg of rice consumed day. For BW, we used 80 kg, which was also obtained from the Exposure Factors Handbook.[4]

We then estimated excess lifetime cancer risk as follows:

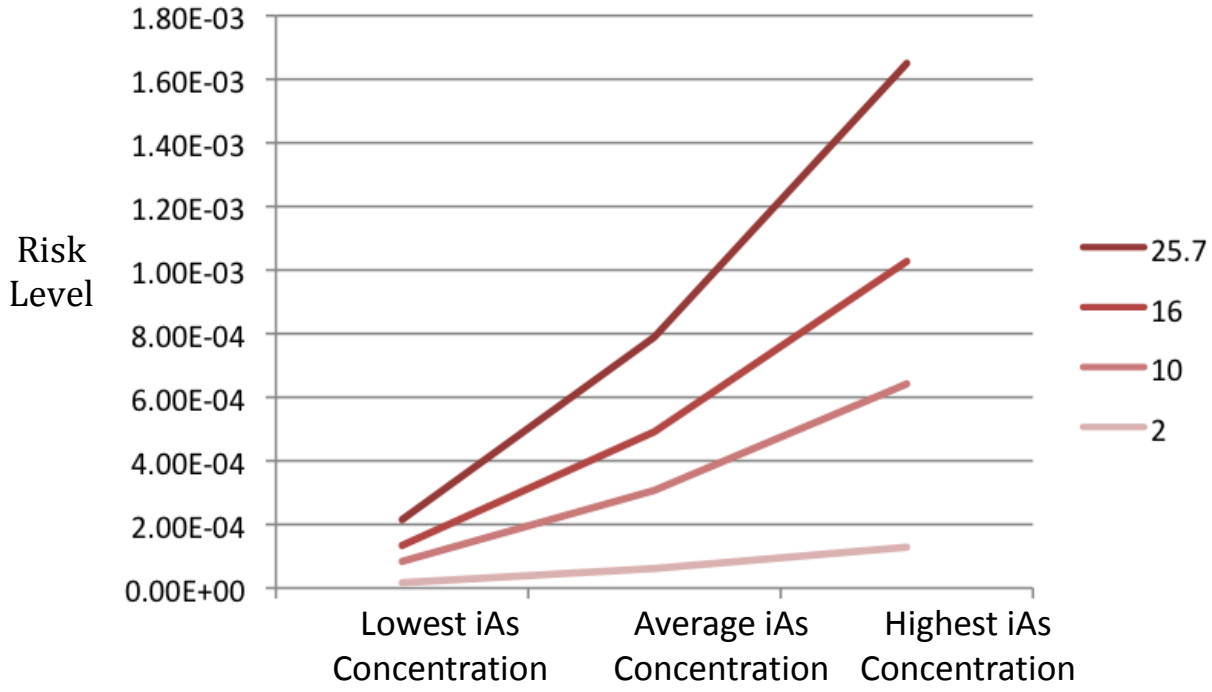
$$Risk = LADD \times Unit\ Risk,$$

where Unit Risk is the excess lifetime cancer risk per mg/kg/day of exposure. For Unit Risk, we used both 1.5 per mg/kg-day, which is the cancer-slope factor published by USEPA in 1988,[5] as well as 25.7 per mg/kg-day, which is a draft cancer slope-factor published by USEPA in 2010.[6]

[2] Ibid.
[3] USEPA. 2011. Exposure Factors Handbook. Tables 12-6 and 12-16. http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=526174.
[4] USEPA. 2011. Exposure Factors Handbook. Table 8-1. http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=526169.
[5] USEPA. IRIS Chemical Assessment Summary: Arsenic, Inorganic. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0278_summary.pdf#nameddest=canceroral.
[6] USEPA. IRIS Toxicological Review of Inorganic Arsenic (Cancer) (2010 External Review Draft). https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=219111.

Appendix 3: Cancer Risk Associated with Inorganic Arsenic in Rice (All) in the U.S., by Inorganic Arsenic Concentration and Unit Risk

All U.S. Consumers



U.S. Asian Consumers