CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/CF 16/10/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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

PROPOSALS FOR MAXIMUM LEVELS FOR INORGANIC ARSENIC IN HUSKED RICE

Comments at Step 6 (in reply to CL 2015/32-CF) submitted by Chile, Colombia, Costa Rica, Ecuador, Egypt, El Salvador, Ghana, India, Indonesia, Japan, Kenya, Peru, Republic of Korea and AU

CHILE

Chile appreciates the work done by Japan and China and considers that the value proposed of 0.35 mg / kg for inorganic arsenic in husked rice ensures consumer protection and simultaneously does not impact in a great way the trade of this commodity, according to the evidence presented in CX / CF 16/10/5, thus Chile supports the proposed maximum level of 0.35 mg / kg

COLOMBIA

Colombia reports that we still don't have a position concerning the document on proposed maximum levels for inorganic arsenic in husked rice.

This is so because our national government, through the Health and Agriculture sectors, mainly, is consolidating information of rice samples that have been analysed in laboratories, to determine the possible occurrence of inorganic arsenic levels and develop relevant interventions for the over levels that may have occurred.

Thus, although the INVIMA has data that have been collected over several years, it is necessary to have their analysis with the different sectors in order to have a country position.

As a result, we request the discussion on maximum levels for inorganic arsenic that could be allowed for husked rice, to be postponed.

COSTA RICA

Costa Rica appreciates the opportunity for providing comments. In that sense, it has reviewed and analyzed the document and for the time being the country does not have data to rebut the level approved at the previous meeting. Therefore, it supports maintaining the level.

ECUADOR

(I) General Comments:

Ecuador wishes to thank Japan and China for their efforts to carry out the proposed maximum levels for arsenic in husked rice; in that regard Ecuador considers it is important to establish a maximum level for this subject, in order to protect consumer health and maintaining fair practices in food trade.

Given that Ecuador belongs to the G05 group (GEMS/Food cluster diets 2012), whose husked rice consumption is 0.25 g/person/day, a figure that is detailed in Table 2 of CX/CF 16/10/5: "*Estimates of the arithmetic mean of iAs intake in husked rice"*; Ecuador would support the level of 0.35 mg/kg, because with an average intake of G05 (0.001 ug/kg bw/day), the percentage of BMDL 0.5 is 0.0% and would not represent a significant problem in the intake to cause poisoning from iAs; therefore this level would not affect the health of the Ecuadorian consumer.

According to a study by the Department of Food Science and Biotechnology (DECAB) of the National Polytechnic School of Ecuador, it was found that the arsenic content in rice in several rice growing areas of the country (coast of Ecuador), arsenic concentration does not exceed the proposed level of 0.35 mg/kg, which would not jeopardize the country's domestic production or trade of this item.

Finally, according to data from the Central Bank of Ecuador in 2015, Ecuadorian exports of husked rice were 0.03 t (tonnes), while no import statistics of this item for this year were reported; for this reason, and in order not to stop trade by tariff barriers to exports of Ecuadorian rice and control rice imports from various sources, Ecuador supports the proposed level.

EGYPT

I would like to thank the Electronic Working Group and inform you that Egypt Supports 0.25 mg/kg as a ML of arsenic.

EL SALVADOR

El Salvador in general supports establishing a ML for arsenic in husked rice. However, the proposed value of 0.35 mg/kg requires further discussion in the Committee, since several members in the EWG proposed different values.

GHANA

Position: We support the compromise ML value of 0.35 mg/kg for inorganic arsenic (iAs) in husked rice and the recommendation of the eWG that a footnote regarding analysis of total arsenic as screening tool be included when the ML is approved.

Rationale: Considering that husked rice is an important component of the diet of several populations, ML for iAS must be established with the aim of protecting public health whilst ensuring that availability of rice is not distorted. The decision to establish ML for iAS in husked rice should therefore be based on a level that ensures reduction in the dietary consumption of iAS without having significant impact on international trade in rice. Based on the four proposed ML scenarios, we believe the draft ML of 0.35mg/kg which could reduce the intake of iAS from husked rice by 4.3% corresponding to a new violation rate of 1.8% is a good compromise.

INDIA

General Comments:

1. India appreciates the work done by the EWG. However, India does not support draft ML at 0.35 mg/kg for inorganic arsenic in husked rice:

Rationale:

The EWG is of opinion that newly submitted data has resulted in the slightly lower mean concentration at all proposed level however it is quite obvious because in the instant case mean was calculated from the distribution model by excluding concentration data above the draft ML (i.e. 0.35 mg/Kg). Therefore, figures of mean concentrations and %Concentrations > ML proposal given in Table 1 (CX/CF 16/10/5) are not the representatives of the entire data but represent only the data lower than the draft ML.

Accordingly, India is of considered opinion that EWG may revisit the draft ML at 0.35 mg/kg for inorganic arsenic in husked rice by taking into consideration the entire concentration data without any exclusion of concentrations higher than draft ML.

2. Further, India would like to reiterate its position for setting up of an ML of 0.5 mg/kg for inorganic arsenic in husked rice.

Rationale:

(i) As mentioned at para 15 and 20 of the Agenda, husked rice is not the most important food item among cereal grains – mean consumption of husked rice is less than that of polished rice and constitutes a minor portion of total consumption of cereal grains (3.3-12% of total cereal grains). It is also noted that husked rice is not a major contributor in rice trade, constituting only about 10% of rice traded, according to the FAOSTAT. So it is not necessary to fix the ML stringently for iAs in husked rice.

(ii) It has been seen that there is widespread presence of inorganic arsenic (98.7%) in the husked rice in the monitoring data which was provided by India on a limited study conducted in the given short period of time. A total of 520 samples of husked rice were analyzed during the short period of 3 months (July-September, 2015) and out of which inorganic arsenic was detected in 513 samples (98.7%). This widespread presence of arsenic in almost all the samples could be attributed to the prevalence of the contaminant in the natural environment, specifically ground water. Though the maximum level of arsenic detected in the samples in the given short study was 0.29 mg/kg only, the incidence of levels higher than this cannot be ruled out on account of the widespread occurrence of the contaminant in the samples covered under the current brief study. Such occurrences could have been evident if an elaborated monitoring study for a longer duration, spanning at least a year, were conducted.

(iii) The major rice growing countries such as China, India, Indonesia, Bangladesh, Thailand, Vietnam, Japan, Burma, Philippines, South Korea and Pakistan contributes more than 85% of global rice production. As per the CX/CF 16/10/5, Agenda item 5, Appendix II, Figure II the maximum level of iAs in detected in husked rice samples from Canada, China, EU, India, Japan, R. Korea, Thailand and USA are 0.34, 0.57, 0.55, 0.29, 0.59, 0.26, 0.39 and 0.25 mg/kg respectively. This widespread presence of iAs in the samples could be attributed to the prevalence of the contaminant in the natural environment, specifically ground water. Though the max level of iAs detected in the samples is 0.59 mg/kg, the incidence of higher than 0.59 mg/kg could not be ruled out on account of the widespread occurrence iAs in the environment.

(iv) Further, arsenic being a naturally occurring contaminant in the environment, its prevalence and occurrence levels in rice could be effectively managed through application of sound agricultural practices and measures. Thus, it would be important that the code of practice, currently being developed by the Committee, as and when finalized is applied in the field to reduce arsenic contamination of rice. Thereafter, the ML for arsenic in rice, as decided at present, could be reviewed for further reduction based on the fresh monitoring data post implementation of the code of practice.

INDONESIA

Indonesia proposes the ML of 0,35 mg/kg for inorganic arsenic in husked rice. Indonesia considers that the exposure iAs based on per capita intake for polished rice is 87% PTDI of iAs. Since the average consumption for husked rice in Indonesia lower than polished rice therefore the exposure of inorganic arsenic estimated lower than 87% PTDI.

JAPAN

For the draft ML for inorganic arsenic (iAs) in husked rice, the current value of 0.35 mg/kg is the most appropriate because the violation rate of 1.8% and 1.9% for the ML of 0.35 mg/kg calculated by the EWG established at the last session and the previous session on a basis of the data available for the EWG, respectively, are within the acceptable range of violation rate. Therefore, Japan proposes that the ML of 0.35 mg/kg should be advanced to Step 8 for final adoption by the Commission.

It should be noted that even in cluster G03, in which consumption of husked rice is the highest among clusters in GEMS/Food, the ratio of estimated intake of iAs from husked rice to the toxicological endpoint (JECFA) for 0.35 mg/kg as ML is 2.3% of $BMDL_{05}$ and not different from the ratios for 0.3 or 0.25 mg/kg as ML (2.3 or 2.2% of $BMDL_{05}$, respectively) (Table 2 of CX/CF 16/10/5) (cf. In cluster G09, in which consumption of polished rice is the highest among clusters in GEMS/Food, the ratio of estimated intake of iAs from polished rice to the toxicological endpoint for 0.2 mg/kg as ML is 13.4% of $BMDL_{05}$ according to the analysis in CX/CF 14/8/6). It indicates that lower MLs (0.3 or 0.25 mg/kg) would not contribute to further reduction of health risk from iAs in husked rice than the ML at 0.35 mg/kg.

According to the Japanese data on iAs in husked rice and polished rice (n=600 for each; the data were used CX/CF 14/8/6), the median of the ratio of the iAs concentration in polished rice to that in the corresponding husked rice is 0.60 (5^{th} percentile, 0.42; and 95^{th} percentile, 0.79; see Fig. 1 below). When considering an ML for iAs in husked rice, the CCCF must keep in mind that the Codex ML for iAs of 0.2 mg/kg in polished rice was adopted by the 37^{th} Session of the Commission in 2014. Calculation of the iAs concentration in husked rice using the above-mentioned ratio and the iAs in polished rice at the adopted ML (0.2 mg/kg) results in the median value of 0.33 mg/kg with 5^{th} percentile at 0.26 mg/kg and 95^{th} percentile at 0.48 mg/kg. The calculated median value of 0.33 mg/kg is very close to the current draft ML at 0.35 mg/kg, which indicates that the current draft ML for husked rice is consistent with the Codex ML for polished rice.

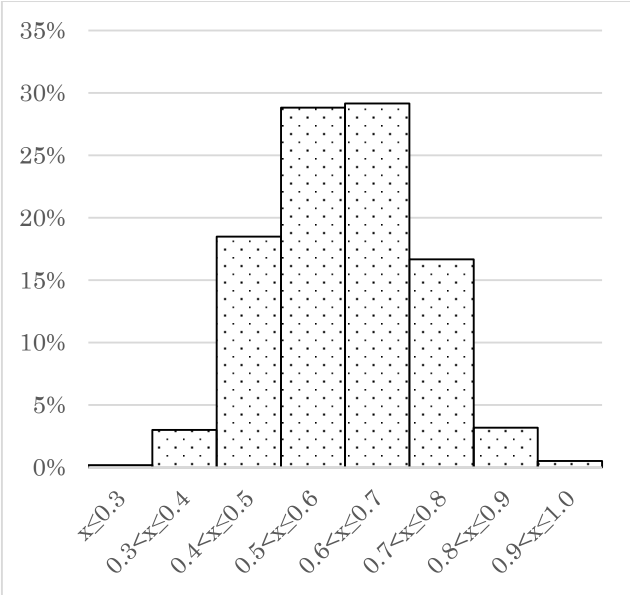

Fig. 1 Distribution of ratio of iAs concentration in polished rice to that in husked rice. Inorganic arsenic concentration in corresponding polished rice.

Adopted Codex ML for polished rice of 0.2 mg/kg divided by the ratio gives estimation of iAs concentrations in husked rice when the concentration in polished rice is 0.2 mg/kg.

Rice is mainly planted in paddy field under flooded condition in Asia. However, the water level in paddy field changes and the surface may even get dry depending on climate and weather. If there is sufficient water in paddy field, the soil in paddy field is reductive and its redox potential is low. Under such a reductive condition, the solubility of cadmium (Cd) is low while that of arsenic is high. On the contrary, under the oxidative condition (high redox potential) of soil where no water is on the surface of soil in paddy field, the solubility of arsenic is low while that of Cd is high. Therefore, continuing flooded condition (corresponding to FLD in the studies explained later) results in low concentrations of Cd and high concentrations of iAs in rice and long period of dry condition (corresponding to WAS in the studies explained later) results in low concentrations of iAs and high concentrations of Cd (Fig. 2, 3).

Growth stage	description	Cultivation management	Duration (days)
Germination		Sowing in seedbed	
Leaf development	Imperfect leaf unrolled, tip of first true leaf visible	In seedbed	30
	First leaf unfolded		
	2 leaves unfolded		
	3-4 leaves unfolded	Transplanting	
Tillering	Beginning of tillering	Flooded	30-
	2-3 tillers detectable		
		Mid-summer drainage	
	Maximum number of tillers detectable	Drained	7-1
Stem elongation		Water management control (FLD/ WAS/ IF1/ IF2)*	
Booting			
Inflorescence emergence, heading	Beginning of panicle emergence		21
	Middle of panicle emergence: neck node still in sheath	Water management control	
	End of panicle emergence		21
Flowering, anthesis			
Development of fruit		Drainage	
Ripening		Drained	7
Senescence		Harvesting	

Fig. 2 Relationship between the growth stage and flooding in the studies.

* FLD (flooded condition): paddy field was kept flooded

WAS (water saving condition): water was added intermittently when surface of soil in paddy field was dry.

IF1 (intermittent flooding): water is added every 7 days (until middle of panicle emergence) and then every 4 days. Once water is added, paddy field is kept flooded for a day and then drained.

IF2: water is added every 4 days until 3 weeks after heading. Once water is added, paddy field is kept flooded for a day and then drained.

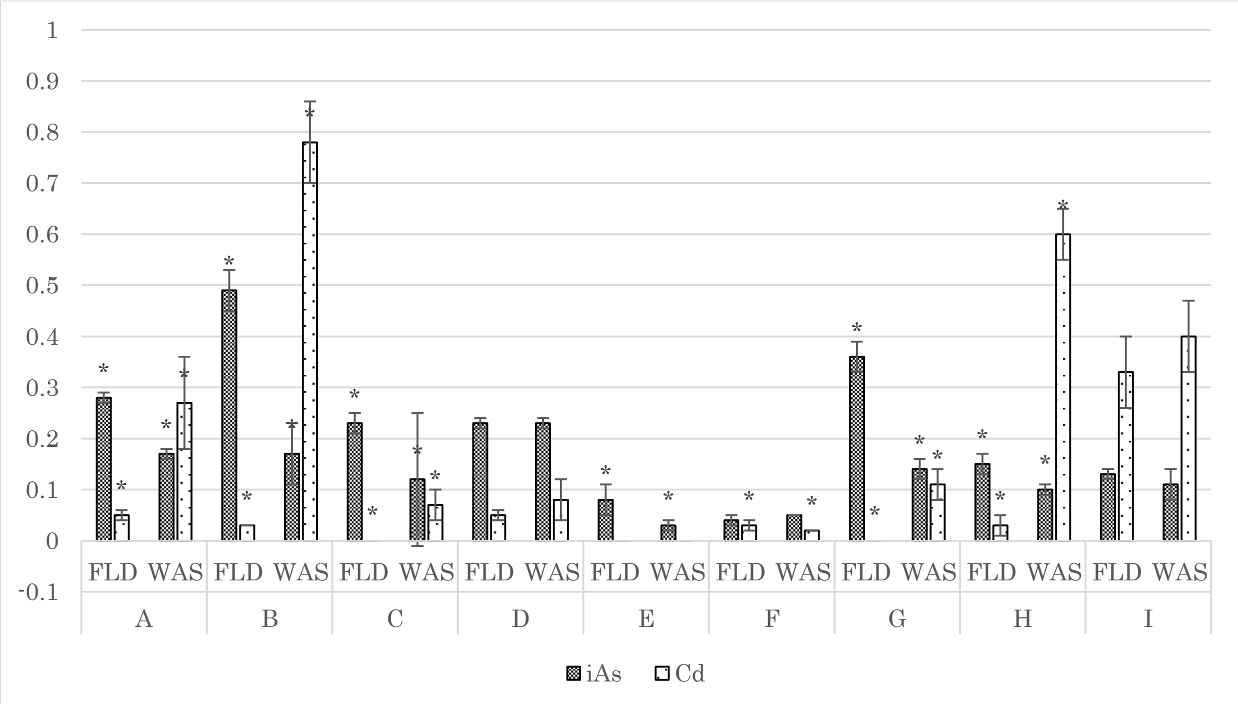

Fig. 3 Concentrations of inorganic arsenic and cadmium in husked rice grown under two water management systems in nine experimental fields Japan in 2013 (A – E) and 2014 (F – I). Bars and whiskers represent mean and standard deviation (n=3 or 4). Bars with asterisk mean that the concentrations in rice from the same region under different water managements are significantly different (Fisher's least significant difference test, $p<0.05$).

The studies were conducted in nine experimental fields selected from nine Prefectures (one field in each Prefecture) in Japan spreading from Northeastern Honshu Island to Kyushu Island. Relationship between the growth stage and flooding is shown in Fig. 2.

If WAS (water saving condition) was used instead of FLD (flooded condition), the concentrations of iAs decreased in 6 locations out of 9 while those of Cd increased in 5 locations, two of which showed higher Cd concentrations than the Codex ML (0.4 mg/kg).

Reference: Ishikawa, S. et al., Low-cadmium rice cultivar can simultaneously reduce arsenic and cadmium concentrations in rice grains, *Soil Science and Plant Nutrition* (in press). DOI:10.1080/00380768.2016.1144452

The Japanese Government introduced a risk management measure in order to reduce Cd concentration in rice – requesting farmers to grow rice under continuous flooded condition in paddy field. As a result, Cd concentrations in rice successfully reduced in 2009-10 compared to those in 1997-98. It was also found that planting rice in flooded condition reduces low-temperature damage of rice. Measures to reduce iAs in rice, which requires contrary measures to reduce Cd in view of redox potential of soil, may increase Cd concentration in rice. In an ongoing study in Japan to develop a measure to reduce both iAs and Cd as much as possible, cases where insufficient reduction of iAs concentration and/or high Cd concentration were observed (Fig. 2 and Table 1). To replace practices currently used to reduce Cd with those similar to what had been used before, it is necessary to obtain farmers consent to do so. In addition, in a similar way to measures to reduce Cd, it may take some or more years to show effects in reduction of iAs in rice.

Table 1 iAs and Cd concentrations in husked rice under various water management control

Water management control	Year	iAs [mg/kg]	Cd [mg/kg]
FLD	2013	0.49 ± 0.04	0.03 ± 0.00
IF1	2013	0.24 ± 0.04	0.42 ± 0.78
IF2	2014	0.33 ± 0.02	0.10 ± 0.04
	2015	0.38 ± 0.03	0.03 ± 0.01

Unpublished data. No statistical analysis was conducted due to insufficient number of samples (Mean ± SD of 4 samples from 2 experimental fields). Relationship between the growth stage and flooding is shown in Fig. 2.

Japan agrees to establish an ML for iAs in husked rice as early as possible in view of protection of consumers' health. Thus, taking into consideration all data and information currently available, an ML for iAs in husked rice should be 0.35 mg/kg.

KENYA

SPECIFIC COMMENT

We have noted that the countries which submitted data on husk rice is within the rate of 0.3 which provides a good balance between consumer health, availability of rice for consumption (reduction in violation).

PERU

GENERAL COMMENTS:

The area sown with rice in Peru between August 2011 and July 212 (crop year 2011 to 2012) was 387.677 hectares. The sowings at national level take place between January to March (40%) and the concentration on the harvest between April to July (61.1%). The rice production in 2012 was 2,999.14 MT with a national average yield of 7.292 kg/ha in 2011. Rice growing takes place **under flood irrigation conditions** and consumes between 12,000 and 14,000 m^3 water on the coast and between 16,000 and 18,000 m^3 in the jungle. Rice farmers are approximately 100.00 nationwide. 26.2% of the crop comes from agricultural units (AU) with surfaces under 5 hectares, 42.7% of UA between 5 and 20 hectares and 31.1% from large AU over 20 hectares. There are approximately 627 mills where drying is the "bottleneck" because the rice industry has not been renewed. 67 to 72% of paddy rice ends up being husked and consumed directly, with a per capita consumption of 63.5 kg year/person.

SPECIFIC COMMENTS:

Country position: "At this moment we do not have data which allow to take a position on it, therefore we abstain from issuing qualitative values. We are exploring the item for that purpose."

It is required more representative information of geographical areas of high rice production in order to consider the maximum level of 0.35 mg/kg for inorganic arsenic in husked rice, in spite of: (1) the results of analyzes based on additional data on which the electronic working group relied, (2) the suitability of the analytical methods available for testing inorganic arsenic in rice, even demonstrating its ability for detecting a difference in concentration of 0.01 mg/kg to 0.35 mg/kg.

REPUBLIC OF KOREA

The analytical method of arsenic in rice submitted by the Republic of Korea is validated through an inter-laboratory validation. Therefore, we would like to request this information to be included in the paragraph 31 under "Methods of Analysis."

AFRICAN UNION (AU)

Position: African Union supports the compromise ML value of 0.35 mg/kg for inorganic arsenic in husked rice.

Issue & Rationale: Rice is a major staple food in several African countries and protection of human health is of utmost importance. It should however be noted that ML established may affect availability of rice significantly. From this point of view, it is not appropriate to allow a high violation rate. The Africa Group agreed on an ML value of 0.4 mg/kg last year based on limited data from Kenya and a reasonable violation rate of 0.7%. A compromise value of 0.35mg/kg was however agreed upon at CCCF 9. The EU, Norway and Egypt had reservations about the accepted ML of 0.35mg/kg (with a violation rate of 1.9%).

In accordance with opinions on the need for more geographically representative data, CCCF9 agreed to re-establish the EWG to consider new/additional data to be provided by member countries. In this regard, a total of 1202 new data sets were submitted by 6 countries (Canada, India, Indonesia, Kenya, Korea and Sweden). Kenya submitted data on 22 samples of husked rice. The maximum arsenic concentration was 0.03mg/kg.

All data (original and new) were merged and reanalyzed statistically to obtain new mean concentrations and violation rates for the various MLs. The inclusion of newly submitted data resulted in slightly lower mean concentrations at all proposal levels as follows:

	ML: 0.4mg/kg	ML: 0.35mg/kg	ML: 0.3mg/kg	ML: 0.25mg/kg
Mean concentration (mg/kg)	0.137 (0.156)	0.135 (0.154)	0.132 (0.148)	0.127 (0.139)
Violation Rate (%)	1.0 (0.7)	**1.8 (1.9)**	3.4 (4.9)	7.3 (11.7)

*() Previous values prior to addition of additional/new data

Confirmation of the draft ML of 0.35mg/kg will reduce the intake of inorganic arsenic from husked rice by 4.3% and the violation rate will be 1.8% instead of 1.9% previously agreed upon during CCCF9.

Analytical methods involving the use of Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometry (LC-ICP-MS) are currently available with sufficient precision to support the implementation of the ML (0.35mg/kg) with two significant figures.

Important note: There is a possibility that some delegations may propose for work on maximum levels for inorganic arsenic in husked rice to be temporarily discontinued until the work on the Code of Practice for the prevention and reduction of arsenic contamination in rice is finalized. Should this situation arise, this position should be supported by Africa since it has always been our position to implement COP first before embarking on setting MLs. This will give Africa more time to generate data on arsenic in husked rice and evaluate for an appropriate ML for Africa