



Agenda Item 5

CX/CF 12/6/8-Add.1  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON CONTAMINANTS IN FOODS

#### Sixth Session

Maastricht, The Netherlands, 26 – 30 March 2012

### PROPOSED DRAFT MAXIMUM LEVELS FOR ARSENIC IN RICE

*Comments at Step 3 submitted by Benin, Colombia,  
Costa Rica, Cuba, Egypt, European Union, Indonesia, Japan, Kenya, Mali, Thailand and USA*

#### BENIN

Benin suggests to adopt the proposed draft ML at Step 4 for total arsenic or inorganic arsenic at 0.3 mg/kg in raw rice. Benin is a rice importing country.

#### COLOMBIA

Colombia welcomes the invitation to participate in the document with comments and sends its contributions:

#### Methods of analysis

As reported in the document, inorganic As poses a higher risk than organic As, but laboratory methods for analysing arsenic are highly complex, and in a country such as Colombia are not available. Therefore it is important to consider that this maximum level be set for total As and for inorganic As.

According to the above, it is required that in its evaluation of methods of analysis the Codex Committee on Methods of Analysis and Sampling (CCMAS) considers the availability and possibility of accessing the required technology for carrying out these analyses in developing countries, so that this aspect does not become an obstacle for those countries to be able to determine whether the rice which is consumed and produced meets the maximum levels established.

#### Levels for total AS and inorganic As in rice products

In the period between November 2010 and March 2011, total AS was monitored in 81 samples from the departments of Meta and Huila, which represent 28.1% of the annual rice production in Colombia. The samples were analysed by the INVIMA's National Reference Laboratory.

The sampling frame of the study consists of the principal rice processing mills in the Departments of Meta and Huila according to the annual production volume in the year 2009, represented by 17.2% to 10.9% respectively, which is the share of Meta and Huila in the national production.

The laboratory results show that only 3 out of the 17 rice samples collected in the Department of Huila were found to have quantifiable levels of this contaminant; by contrast the results of the department of Meta indicate that this product shows average levels of 0.0904 mg/kg AS in the rice grown and processed in this region.

The PTWI (provisional tolerable weekly intake) for As has internationally been reported as 0.015 mg/kg bw based on epidemiological reports that show toxic effects, which is to say that an average person may have a weekly consumption level of 0.9 mg.

In order to to exceed the weekly level of 0.9 mg, a person should consume about 9.6 kg rice, that is to say, seven times the average weekly consumption per capita In Colombia, in line with the report of the ENSIN survey on food consumption in the country, which reports that the average rice consumption per capita amounts to 189 g/day, which is equal to 1.3 kg/week. This indicates that it is not very likely that this AS source poses a relevant risk for human health.

Comparison between the data for total AS in rice found in the study carried out in Colombia between 2010 and 2011 and the proposal of a maximum level of 0.2 mg/kg for inorganic As in polished rice, permits the conclusion that the rice analyzed in Colombia with the highest concentration would not exceed these limits, and keeping in mind that the As content found is not a source that represents a risk intake, however as the document indicates and considering the tolerable intake, the limits are considered appropriate.

Considering what the document points out in relation to the difficulty of setting an ML for As based on default factors, portion sizes and assumed MLs, we think it is relevant to compile more information on the contribution of As from the rice consumption and other foodstuffs that can be important sources for this compound, in such a way that it can be established whether the proposed MLs of 0.3 mg/kg for total As and 0.2 mg/kg for inorganic As in unprocessed rice are appropriate to protect the health of the population.

In the same way we consider it is necessary to establish or carry out a study on whether the indicated MLs are safe for prepared rice since, as it has been pointed out, water is a potential source of As. The former in line with what paragraph 27 of document CX/CF 12/6/8 says *"it would be appropriate to limit the establishment of MLs to rice and its products as they can contribute significantly to inorganic As dietary exposure. Therefore, the MLs should be established for rice and rice-based products"*.

## **COSTA RICA**

Costa Rica welcomes the opportunity to be able to express comments on document CX/CF 12/6/8 proposed draft Maximum levels for arsenic in rice.

- Costa Rica agrees with setting an ML of 0.3 mg/kg for total As, both for brown rice and polished rice.
- Costa Rica thinks that an ML for As should be set for rice based processed products intended for vulnerable groups such as infants and young children.

### **Justification:**

Costa Rica understands that even though it is advisable to set an ML for inorganic As both in brown rice and polished rice, currently there are no reliable data available on the inorganic As content in rice nor internationally accepted low-cost validated analytical methods.

A lower level in foods for infants and young children is considered because exposure in these groups is higher due to their low body weight in relation to the food intake, especially because rice is a common base present in foods which are daily consumed by these age groups.

## **CUBA**

We have examined the reference document and Cuba is [in principle] in agreement.

## **EGYPT**

We would like to inform you that Egypt fully supports the development of a Code of Practice. On the other hand, we would like to call your kind attention that MLs for Arsenic in rice should be based on risk assessment studies.

## **EUROPEAN UNION**

Regarding arsenic in rice, the EUMS prefer to establish maximum levels for inorganic arsenic in raw rice. The EUMS consider sufficient robust data are available at this moment to establish such levels. If further data collection would be considered necessary, it should focus on occurrence data for inorganic arsenic in raw rice and processed rice.

The report of the seventh interlaboratory comparison organised by the European Union Reference Laboratory for heavy metals in feed and food has demonstrated that the measured concentration of inorganic arsenic in rice is not dependent of the analytical method applied. Nevertheless, the European Committee for Standardization is currently working on a method for the determination of inorganic arsenic in food of plant origin and of marine origin.

Regarding the proposed formulation of the maximum level for arsenic in rice, the EUMS consider the last bullet point of the recommendation could be better presented by specifying that the maximum level applies to inorganic arsenic. In addition, the use of a footnote could further clarify that the maximum level can be controlled by measuring total arsenic as a screening method, but that exceeding of the maximum level needs to be confirmed by determining the level of inorganic arsenic.

Maximum Level for Arsenic	
Raw rice	0.3 mg/kg inorganic As *
Polished rice	0.2 mg/kg inorganic As *

\* Analysis for total arsenic can be used as a screening method, but exceeding of the maximum level shall be confirmed using an analytical method determining the level of inorganic arsenic.

## INDONESIA

Indonesia wishes to thank China and the members of the electronic working group for their extensive work on the document "Proposed draft maximum levels for arsenic in rice". We also appreciate the opportunity to comment on this issue. As the largest rice eaters per capita in the world, Indonesia is concerned to the levels of arsenic in rice as major contributor to dietary exposures.

For the purpose of this issue, in 2011 Indonesia conducted a survey on arsenic in rice. The survey was carried out in five provinces of rice production centers. The sample was polished rice from Ciherang and IR 64 varieties. Those varieties were consumed by most Indonesia people. 38 polished rice samples were collected and analyzed for total As using AOAC 986.5 (ICPMS) and inorganic As using a method employing extraction of inorganic As with polymeric cation exchange-SPE cartridge and determination with ICP-MS. Recovery test of inorganic arsenic added to polished rice resulted in recovery range of 105.37-108.78% (RSD = 1.59%) and 82.48-88.17% (RSD = 3.08%) respectively. The limit of detection and the limit of quantification was 0.002 mg/kg and 0.007 mg/kg respectively.

The result of analysis of total and inorganic As levels in rice is as follow:

Total As		Inorganic As	
Min-max mg/kg	Mean mg/kg	Min-max mg/kg	Mean mg/kg
0.0647 - 0.1050	0.0893	0.0637 - 0.1027	0.0872

In elaborating maximum level, the Committee should consider principle of *the establishment of Maximum Levels (ML)* in Annex I of the GSCTFF where MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Indonesia asks the committee to take into account several points for establishing ML of total or inorganic arsenic, as follow:

1. There is no health reference for inorganic arsenic, therefore there should be set for health reference for arsenic.
2. There should be a consensus for analytical methods of inorganic arsenic in rice
3. There should be a Certified Reference Materials (CRM) in rice matrix

Considering the points aforementioned, at this stage Indonesia is of the opinion that it is still premature to establish the MLs of total or inorganic arsenic.

## JAPAN

Japan appreciates the effort of China in leading the electronic working group and developing the working document and is pleased to offer the following comments.

### General Comment

1. For the reasons below, CCCF should elaborate an ML based on sound science and in accordance with the Codex principles and policies.
  - The *Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)* stipulates as follows:
    - "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence";
    - "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist"; and

- "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations".
- The *Risk Analysis Principle Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods* in the *Procedural Manual* stipulates as follows:
  - "CCCF's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food";
  - "CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise";
  - "CCFA/CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food"; and
  - "Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, CCCF shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCCF".
- The *establishment of Maximum Levels* in Annex I of the *General Standard for Contaminants and Toxins in Food and Feed (GSCTFF)* stipulates as follows:
  - "MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade";
  - "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";
  - "In all cases, a validated method of analysis should be available with which a ML can be controlled";
  - "The contaminant as it should be analyzed and to which the ML applies should be clearly defined"; and
  - "The product as it should be analyzed and to which the ML applies, should be clearly defined".

2. Based on above, Japan provides the following comments on the proposed draft MLs for arsenic in rice from multiple viewpoints as below.

#### Type of rice to which the ML applies

3. According to the above Codex principles relevant to the MLs establishment, the product to which the ML applies should be clearly defined. Especially for arsenic in rice, milling reduces arsenic in rice significantly as mentioned in CX/CF 11/5/10. Therefore, in order to avoid a potential trade conflict between exporter and importer, the type of rice, rice grain, husked rice or milled rice, to which the ML applies should be clearly defined.

#### Arsenic species which should be analyzed

4. According to the above Codex principles relevant to the MLs establishment, CCCF shall endorse maximum levels only for those contaminants for which JECFA has performed a quantitative risk assessment. Regarding arsenic, the 72nd JECFA conducted risk assessment of inorganic arsenic but not total or any organic arsenic. The proportion of inorganic arsenic to total arsenic varies significantly (10% - 93%) as mentioned in this working document. Therefore, an ML in rice should be set for inorganic arsenic.

ML for inorganic arsenic in rice

5. According to the above Codex principles relevant to the MLs establishment, it is premature to elaborate proposed draft MLs at this stage as there is a need to establish validated method of analysis for determination of inorganic arsenic in rice and to collect occurrence data for inorganic arsenic in rice from various countries and sources as recommended in 72nd JECFA and the working document. Japan supports that the CCCF requests members to submit the information, and is ready to provide such information in addition to the data already submitted.

Additional Information

Table 1 in paragraph 7, page 3

6. Concerning the state of the method for inorganic arsenic in rice used in Japan, we are willing to update the information as follows (proposed insertion is underlined and proposed deletion is ~~struck out~~):

Country	Total As	Inorganic As
Japan	AOAC 986.15 (AAS)	HPLC coupled with ICP-MS – <del>no information on validation status</del> <u>single laboratory validation</u> (a collaborative study is being carried out in Japan)

**KENYA**

The purpose and scope of the project

This project aims to establish a maximum level for arsenic in rice.

We support the development of the user friendly method by CCMAS to be used internationally to analyse Arsenic in rice.

We prefer to do total Arsenic since the proportion of organic is 80% while taking into account that inorganic Arsenic is 0.2mg/kg and total to be 0.3mg/kg

It is convenient and cheaper to do total Arsenic in rice.

**MALI**General comment:

Mali congratulates China for the work done under his chairmanship for the preparation of the working document

Specific comments:

- Precise the type of arsenic (inorganic or total) for the determination of the maximal limits;
- Mali approves « 0,3 mg/kg of arsenic inorganic » » as maximal limits.

**THAILAND**

Thailand wishes to thank China for the extensive work on the establishment of ML for arsenic in rice. We also appreciate the opportunity to comment on this issue.

Principally, we do not oppose the elaborating ML for arsenic in rice because there is a benefit for consumer health. We also agree with the opinion that the ML for inorganic arsenic can provide better health protection than total arsenic because of the toxicity in the inorganic form.

However, we do not believe that the current data and information as explained in the paper are sufficient for the Committee to make a decision on the ML due to the following reasons:

1. The existing occurrence data are mostly in total arsenic. Also, there are very limited number and sources of data for inorganic arsenic. We strongly support the first recommendation that further data on inorganic arsenic needs to be sourced. Thailand has started collecting inorganic arsenic data since 2011 and will continue to do so if it is useful to the Committee.

2. The internationally validated method for determination of inorganic arsenic in rice is not available. This is the problem in many countries especially the developing countries. This also links to our previous point on the limitation of inorganic arsenic data.
3. There is a problem on assessing reliable risk for inorganic arsenic due to the reference health standard as PTWI of inorganic arsenic has been withdrawn by JECFA. Although the allowance of a benchmark dose lower confidence limit (BMDL) may be used to derive the risk estimation, there is a level of uncertainty in determining if the proposed ML provide adequate protection to consumer health.

Therefore, we believe that the available data and current situation do not allow the Committee to consider and advance the proposed draft ML. We fully agree with the Recommendation that the Committee should ask CCMAS to establish the method of analysis for inorganic arsenic, taking into account existing and future works on the validation. Also, the occurrence data should be further collected for consideration by the Committee.

## USA

- Consistent with the principles in the General Standard for Contaminants and Toxins in Food and Feed, the U.S. recommends further collection of data on arsenic levels from rice producing regions for evaluation before elaborating MLs for total and/or inorganic arsenic in rice.
- The U.S. agrees with the electronic Working Group's conclusion that there are currently insufficient data to establish MLs based on inorganic arsenic in rice. The U.S. also believes that more data are needed to establish an ML for total arsenic in rice.
  - The inorganic arsenic data reviewed in the paper are primarily from China and Japan, with limited numbers of samples from the U.S. and Europe.
  - Data from a wider range of rice-producing countries would be desirable, including information on the type of rice tested (paddy, husked, polished, etc.) and information on how rice type relates to arsenic levels, since arsenic levels vary with processing.
- The U.S. would support initiation of work on a Code of Practice to Reduce Arsenic (Inorganic Arsenic) in Rice, if there are agricultural and processing steps that can reduce arsenic (inorganic arsenic) in rice.
  - Factors like cooking may be addressed in supplementary consumer information in a Code of Practice (e.g., recommendations on information that can be supplied by national authorities).
- The U.S. also recommends replacing paragraph 9 as follows for accuracy, along with the following references:

The U.S. Food and Drug Administration (FDA) uses a microwave digestion and inductively coupled plasma-mass spectrometry (ICP-MS) method for measuring total arsenic in food including rice products (US FDA, 2011). High performance liquid chromatography (HPLC) coupled with ICP-MS is used for measuring arsenic species in rice (Heitkemper, et al., 2009). Neither method has been directly validated through AOAC International (AOAC) or the European Organization for Standardizations (CEN).

References for new paragraph:

1. D. T. Heitkemper, K. M. Kubachka, P. R. Halpin, M. N. Allen and N. V. Shockey, 2009, Survey of total As and As speciation in US-produced rice as a reference point for evaluating change and future trends, Food Addit. Contam., Part B, 2/2 (2009) 112-120.
2. US FDA, 2011, Analysis of Foods for As, Cd, Cr, Hg and Pb by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS), <http://www.fda.gov/downloads/Food/FoodSafety/FoodContaminantsAdulteration/Metals/UCM272693.pdf>.