



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON CONTAMINANTS IN FOODS

#### 9<sup>th</sup> Session

New Delhi, India, 16 – 20 March 2015

#### PROPOSED DRAFT MAXIMUM LEVELS FOR INORGANIC ARSENIC IN HUSKED RICE

*Comments at Step 3 submitted by Argentina, Egypt, El Salvador, Ghana, Japan, Kenya, Republic of Korea, Thailand, Uruguay, USA and AU*

#### ARGENTINA

Argentina has no comments regarding the document and the proposed levels.

#### EGYPT

Egypt proposes the following comments:

- Concerning ML for husked rice, we approve 0.25 mg/kg as a ML of arsenic,
- Egypt agrees to include a footnote regarding analysis of total arsenic as a screening tool.
- Egypt supports further collection of data as well as requesting CCMAS to convert the appropriate method into criteria.

#### EL SALVADOR

In spite of the fact that the production and consumption of husked rice is low in our country, we support a maximum level for inorganic arsenic (iAs). However, more data could be requested from member countries in order to establish a guideline level.

#### GHANA

##### COMMENT

Ghana supports the setting of Maximum Levels for Inorganic (iAs) Arsenic (0.4 mg/kg) for husked rice.

Ghana also supports the recommendation of the EWG that a footnote regarding analysis of total arsenic as screening tool be included when the ML is approved.

##### RATIONALE

Inorganic arsenic (iAs) compounds have been classified as Group 1 skin and lung carcinogens in humans. An ML (0.2mg/kg) has already been set for polished rice and there is the need to do same for husked rice to reduce the risk to humans, those in Africa in particular. It is worth noting that most of the rice produced in African countries is consumed in the husked form.

During CCCF8, some countries indicated difficulties associated with analysing for iAs in polished rice. It was agreed that a footnote be included in the Standard as follows:

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

This text should also apply to the ML for iAs in husked rice.

**JAPAN**

Japan thinks that if there is to be an ML for inorganic arsenic in husked rice, it should be at 0.4 mg/kg to be in line with the ML for inorganic arsenic in polished rice. Japan supports the inclusion of guidance for application of MLs in husked rice and polished rice "as sold and consumed".

An ML in husked rice is necessary to exclude the possibilities that rice that may not comply with the ML for polished rice may be distributed in the form of husked rice. If MLs are established for both polished rice and husked rice, there are some possibilities that a sample complying with the ML for husked rice would not comply with the ML for polished rice, or *vice versa*. The discrepancy should be as small as possible. According to a study contained in the working document, the rate for consistency of results from the same rice grain source meeting the MLs both for polished rice and husked rice is the highest (98%) when the ML in husked rice is set at 0.4 mg/kg.

It should be noted that negligible difference in reduction of intake of inorganic arsenic is estimated among introduction of proposed MLs. For example, comparing to an ML at 0.3 mg/kg, estimated intake of inorganic arsenic when an ML at 0.4 mg/kg is set is higher by only 0.1% of BMDL05 even in the cluster of GEMS/Food with the highest consumption of husked rice (G03).

During the work of the EWG, data were available from 9 countries, including only 4 countries among 10 major rice producing countries. If a lower ML is established, it would result in unnecessary barrier to trade of the commodity and negative impact on production, distribution and consumption of rice in some countries, especially in those whose data are not used for analysis by the EWG.

Thus, Japan is of the view that at this stage, an ML of 0.4 mg/kg is most appropriate. The CCCF should review the ML when measures in a COP under development by the Committee are implemented in producing countries and/or further information and data are available, as have been done for ochratoxin A.

**KENYA**

Kenya proposes 0.4mg/kg to be the numerical value on an MLs in husk rice and We would like to request CCMAS to convert appropriate method of analysis into the criteria.

**REPUBLIC OF KOREA**

The Republic of Korea agrees with the establishment of maximum level for inorganic arsenic in husked rice. We also support the development of guidance of applying MLs in order to avoid any confusion in the application of MLs. However, further discussion is required to agree on the appropriate MLs and guidance.

**THAILAND**

Thailand strongly agrees that the ML of inorganic arsenic should be established for husked rice. We would like to suggest that the ML of inorganic arsenic in husked rice should be set at the appropriate level that can protect consumer health and do not have adverse effect on trade such as the level having the violation rate of 2-5%. We also support the recommendation to include a footnote regarding analysis of total arsenic as a screening tool.

With regards to method of analysis, we support the method in Journal of AOAC International, Volume 97, Number 3, May-June 2014, pp. 946-955 for the purpose of enforcement of the MLs for inorganic arsenic in rice.

For polishing procedure and conversion factor, we are of the view that if the Committee could reach agreement in establishing the ML of inorganic arsenic in husked rice, polishing procedure and conversion factor are not necessary.

**URUGUAY**

Uruguay prefers to agree on a ML to iAs husked rice instead of establishing an alternative method of polishing in the testing laboratory because this step could be inaccessible to many laboratories and the harmonization of the method of polishing could be difficult.

Regarding the numerical value for the ML (EWG discussion, Annex I, par. 36) Uruguay agreed with the reasons given for the proposed 0.3 mg / kg value and considered appropriate to include a note regarding the analysis of total arsenic is a screening tool to determine iAs.

**USA**

- The U.S. believes that, although husked (brown) rice generally contains higher levels of inorganic arsenic than polished (white) rice, its contribution to overall risk is low due to husked (brown) rice representing a small percentage of overall rice in international trade.
- In this case, it may be appropriate to complete the work that is underway to elaborate a code of practice for the prevention and reduction of arsenic contamination of rice, implement it for several years, and then consider establishing a ML based on new occurrence data.
- If the Committee should decide to establish a ML for husked (brown) rice, it should follow the principle followed for establishing a ML for polished (white) rice, i.e., a level that provides some measure of reduction in inorganic arsenic intake without having a significant impact on international trade.

**AFRICAN UNION**

<b>RECOMMENDED AFRICAN POSITION</b>	<b>RATIONALE</b>
<p>AU supports the setting of Maximum Levels for Inorganic (iAs) Arsenic in husked rice.</p>	<ul style="list-style-type: none"> <li>• Inorganic arsenic (iAs) compounds have been classified as Group 1 skin and lung carcinogens in humans.</li> <li>• According to FAOSTAT 2010, 79% of rice traded internationally was polished rice, 10% was husked rice and 11% was rice grain.</li> <li>• An ML (0.2mg/kg) has already been set for polished rice and there is the need to do same for husked rice to reduce the risk to humans, those in Africa in particular.</li> <li>• It is worth noting that most of the rice produced in African countries is consumed in the husked form</li> </ul>
<p>AU supports the ML of 0.4 mg/kg</p>	<p>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 any ML established may affect availability of rice significantly. From this point of view, it is not appropriate to allow a high violation rate.</p> <p>The EWG has made four suggestions for ML. These are 0.25, 0.3, 0.35 and 0.4 mg/kg.</p> <p>Violation rates calculated for these MLs by the EWG are as follows:</p> <p>0.25mg/kg = 11.7%; 0.3mg/kg = 4.9%; 0.35mg/kg = 1.9%; 0.4mg/kg = 0.7%</p> <p>A violation rate of 11.7% at the proposed ML of 0.25 mg/kg is unacceptably high.</p> <p>Annex I of The General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (CODEX STAN 193-1995) states that numerical values for MLs should preferably be regular figures unless this may pose problems in the acceptability of the MLs. For this reason, values of 0.25 and 0.35 are less preferable.</p> <p>This leaves the proposals of 0.3 and 0.4 mg/kg with the violation rate of 4.9 and 0.7%, respectively. Based on the high violation rate at 0.3 mg/kg and limited data (8 samples) from Kenya that showed a mean value of <math>0.45 \pm 0.36</math> mg/kg for iAs, the Experts Group is proposing that we settle for the ML of 0.4mg/kg for iAs in husked rice.</p>

RECOMMENDED AFRICAN POSITION	RATIONALE
<p>AU supports the recommendation of the EWG that a footnote regarding analysis of total arsenic as screening tool be included when the ML is approved</p>	<p>To ensure enforcement of the ML, several Codex Standards include sections on “Methods of Analysis and sampling”.</p> <p>During CCCF8, some countries indicated difficulties associated with analysing for iAs in polished rice. It was agreed that a footnote be included in the Standard as follows:</p> <p><i>“Countries or importers may decide to use their own screening when applying the ML for As-in in rice by analysing total arsenic (As-tot) in rice. If the As-tot concentration is below the ML for As-in, no further testing is required and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML”</i></p> <p>This text should also apply to the ML for iAs in husked rice.</p>