CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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DISCUSSION PAPER ON ARSENIC IN RICE
(Prepared by the Electronic Working Group led by China)

BACKGROUND

1.   The 4th Session of the Codex Committee on Contaminants in Food (CCCF) decided to establish an Electronic Working Group to develop a discussion paper on the feasibility of establishing MLs for arsenic in rice.[1] Iran had previously submitted a proposal to the CCCF for new work on an ML for arsenic in rice. The preparation of this discussion paper document was led by China. The list of participants of the electronic working group is attached as Appendix I.

2.   The discussion paper was proposed to review the current knowledge and provide a summary of possible risk management options including the feasibility of setting MLs in rice for consideration at the 5th session.[1].

3.   Since the ultimate goal of the risk management options is to provide information on reducing arsenic exposure in rice, especially for inorganic arsenic in rice, this paper will focus on information related to available risk management option to reduce arsenic exposure in rice including exploring the possibility of developing MLs for total or inorganic arsenic in rice, in view of the availability of sufficient occurrence and exposure data, and the 2010 evaluation by the Joint FAO/WHO Expert Committee on Food Additives at its 72nd meeting (FAO/WHO) . Shorter discussions on toxicology, analysis, and exposure of arsenic and its species form are also included.

INTRODUCTION

4.   Arsenic is described as a metalloid because it displays properties intermediate of those typical for metals and non-metals. It occurs in group 15 of the Periodic table along with nitrogen and phosphorus, and, consequently, the chemistry of arsenic is similar in many respects to that of these two essential elements. These chemical similarities may be the reason that arsenic occurs at high levels in many marine organisms, and hence in many seafoods (Francesconi and Edmonds, 1997). For example, the inorganic ion arsenate occurs in seawater together with the structurally similar phosphate. Marine algae appear unable to distinguish between these two oxoanions; in their efforts to take up essential phosphate they inadvertently take up the potentially toxic arsenate. The process of detoxification begins by methylation leading to methylated organoarsenic compounds. Arsenobetaine is structurally similar to glycine betaine $[(CH_3)_3N^+CH_2COO^-]$, a nitrogen betaine which is used as an osmolyte by aquatic organisms to maintain osmotic balance under conditions of changing salinity, i.e. when ambient salinity is high, an organism's glycine betaine level is high. The coincidental structural similarity between arsenobetaine and glycine

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[1] ALINORM 10/33/41, para. 106 – 107

betaine might explain why arsenobetaine levels are much higher in marine animals than they are in freshwater animals.

5.   Although arsenic forms species under reducing conditions with the arsenic atom in oxidation state -3 and +3, the most stable arsenic species found under normal environmental conditions contain the arsenic atom in oxidation state +5. Consequently, the vast majority of arsenic species found in organisms and in foods also contain arsenic in oxidation state +5 (e.g. arsenate, dimethylarsinate, arsenobetaine, arsenosugars). Table 1 summarises the major arsenic species found in foods, and some relevant human metabolites.

6.   **Arsenic species in food.**Most data reported for arsenic in food describe the content of total arsenic, i.e. the sum of all arsenic species. The total arsenic analyses providing these data can be readily performed in analytical laboratories equipped for trace element determinations. Since the discovery of arsenobetaine in lobster in 1977, over 50 organoarsenic compounds have been reported in marine organisms, many of which are used as food items. Most of these compounds, however, are not commonly reported, or they occur at trace levels only. Analyses that provide information about the type of arsenic (i.e. arsenic species) are much more difficult to perform, and relatively few laboratories are able to provide these data. Such data, however, are becoming increasingly important because different foods can contain different types of arsenic species, and because these species have very different toxicities.
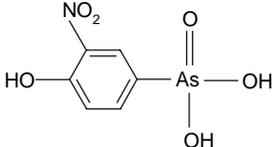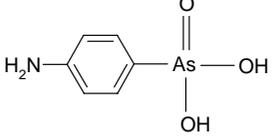
7.   **Inorganic arsenic species in food.** Inorganic arsenic in the environment comprises species mainly in the +3 or +5 oxidation state, present as thio complexes or, primarily, as the oxoanions arsenite and arsenate. The analytes (i.e. the species that are actually measured) are usually arsenite and arsenate, and hence data are often recorded as these two species. Similarly, in food samples inorganic arsenic is often reported as arsenite and arsenate even though it is likely bound to thio groups in peptides or proteins in the food itself. Because food products of terrestrial origin generally contain low concentrations of total arsenic, their inorganic arsenic content is also low. Rice, however, appears to be an exception because it contains significant amounts of inorganic arsenic with concentrations often between 0.1 to 0.4 mg arsenic/kg dry mass and sometimes considerably higher (Sun et al., 2008; Meharg et al., 2009). Although fish and other seafood have a high total arsenic content (typically 2-60 mg arsenic/kg dry mass, SCOOP, 2004; Julshamn et al., 2004), their levels of inorganic arsenic are typically <0.2 mg arsenic/kg dry mass (Edmonds and Francesconi, 1993; Sloth et al., 2005; Sirot et al., 2009). There are, however, some notable exceptions. For example, the edible marine alga hijiki (*Hizikia fusiforme*, also called hiziki), can contain inorganic arsenic (present as arsenate) at concentrations of >60 mg/kg (FSA, 2004), and blue mussel (*Mytilus edulis*) has shown inorganic arsenic concentrations up to 30 mg/kg dry mass (Sloth and Julshamn, 2008). The arsenic content of various food items is discussed in detail.

8.   **Inorganic arsenic species in water.** Concentrations of arsenic in groundwater, major sources of drinking water in many parts of the world, are usually less than 10 µg/L but they can reach 5000 µg/L in some areas (Smedley and Kinniburgh, 2002). Surface waters are also used for drinking water, but they generally contain lower arsenic concentrations than do groundwaters. Essentially all the arsenic in drinking water is present as inorganic arsenic. In oxygenated conditions, such as found in most surface waters, the arsenic is present mainly as arsenate. In some groundwaters, however, arsenite can be the dominant species under certain reducing environmental conditions (Postma et al., 2007).

Table 1: Names, abbreviations, and chemical structures for arsenic species referred to in this report (from EFSA Scientific Opinion on Arsenic in Food)

Name	Abbreviation	Chemical structure[a]	Relevance/comment
Inorganic arsenic	iAs		Sum of As(III) and As(V).
Arsenite	As(III)	$As(O^-)_3$	Trace to low levels in most foods; highly toxic.
Arsenate	As(V)	$O=As(O^-)_3$	Trace to low levels in most foods; a major form in water; highly toxic.
Arsenobetaine	AB	$(CH_3)_3As^+CH_2COO^-$	Major arsenic species in most seafoods; non-toxic.
Arsenosugars[b]			Major (edible algae) or significant (molluscs) arsenic species in many seafoods.
Arsenolipids[c]		e.g.	Newly discovered arsenic species present in fish oils and fatty fish; likely to be present in other seafoods as well.
Trimethylarsonio propionate	TMAP	$(CH_3)_3As^+CH_2CH_2COO^-$	Minor arsenic species present in most seafoods.
Methylarsonate	MA	$CH_3AsO(O^-)_2$	Trace arsenic species of some seafoods and terrestrial foods; a significant human urine metabolite of iAs.
Methylarsonite	MA(III)	$CH_3As(O^-)_2$	Not usually detected in foods; detected in some human urine samples as a metabolite of iAs; a toxic species thought to be important for arsenic's mode of toxic action.
Dimethylarsinate	DMA	$(CH_3)_2AsO(O^-)$	Minor arsenic species in seafoods and some terrestrial foods; the major human urine metabolite of iAs, arsenosugars and arsenolipids.
Thio-dimethylarsinate	Thio-DMA	$(CH_3)_2AsS(O^-)$	A minor human urine metabolite of inorganic arsenic and arsenosugars.

Table 1: Continued

Name	Abbreviation	Chemical structure[a]	Relevance/comment
Dimethylarsinite	DMA(III)	$(CH_3)_2AsO^-$	Not detected in foods; detected in some human urine samples as a metabolite of iAs; a very unstable (reactive) species that is very difficult to measure; highly toxic species considered by some researchers to be central to arsenic's mode of toxic action.
Trimethylarsine oxide	TMAO	$(CH_3)_3AsO$	Minor arsenic species common in seafood.
Tetramethylarsonium ion	TETRA	$(CH_3)_4As^+$	Minor arsenic species common in seafood.
Arsenocholine	AC	$(CH_3)_3As^+CH_2CH_2OH$	Trace arsenic species found in seafood; is readily oxidised to arsenobetaine in biological systems.
Roxarsone			Used in the United States of America as a poultry feed additive to enhance growth; banned in Europe; not usually detected in food.
Arsanilic acid			Previously used as a drug and as an animal food additive; also used as its sodium salt (atoxyl).

(a): The simpler arsenic species are also often referred to in their protonated forms such as As(III) arsenous acid, H_3AsO_3; As(V) arsenic acid, H_3AsO_4; MA methylarsonic acid, $CH_3AsO(OH)_2$; DMA dimethylarsinic acid $(CH_3)_2AsO(OH)$; MA(III) methylarsonous acid $CH_3As(OH)_2$; DMA(III) dimethylarsinous acid $(CH_3)_2AsOH$.

(b): Over 20 arsenosugars have been reported as natural products; they differ by having different R groups on the aglycone portion of the molecule, and by replacing the oxygen on the arsenic atom with either a sulfur atom or a third methyl group (see Francesconi and Edmonds (1997)). Most of the arsenic present as arsenosugars, however, is contained in just four compounds based on the structure drawn above and with (i) R=$CH_2CHOHCH_2OH$;
(ii) R=$CH_2CHOHCH_2OP(O)(OH)OCH_2CHOHCH_2OH$; (iii) R=$CH_2CHOHCH_2OSO_3H$; and (iv) R=$CH_2CHOHCH_2SO_3H$

(c): Nine arsenolipids have been reported so far (2009) as natural products, all of which contain the dimethylarsinoyl group $[(CH_3)_2As(0)-]$ bound to either one of several long chain fatty acids, or to long chain hydrocarbons. Many more arsenolipids are present in foods – their structures are currently unknown.

TOXICOLOGY AND HEALTH EFFECTS FROM EPIDEMIOLOGY

9.   Arsenic toxicity depends on the chemical form and its solubility and varies among animal species and with route of administration. Generally, trivalent arsenic is more toxic than the pentavalent forms. Oral administration of inorganic arsenicals to laboratory animals has a number of effects, including effects on the cardiovascular, respiratory, gastrointestinal, haematological, immune, reproductive and nervous systems. MMA^V administration to experimental animals has been shown to have effects on the gastrointestinal tract, kidney, thyroid and reproductive system, with the effect seen at the lowest doses being diarrhoea. DMA^V has effects on the urinary bladder, kidneys, thyroid and fatal development.

10.   Arsenic was evaluated by JECFA at its 10th, 27th, 33rd and 72nd meetings. Inorganic arsenic has been evaluated on a number of occasions by IARC (1973, 1978, 1980, and 2004).

11.   In 1973, IARC concluded that there was a causal relationship between skin cancer and exposure to inorganic arsenic in drugs, in drinking-water with a high arsenic content or in the occupational environment and that the risk of lung cancer was clearly increased in certain smelter workers who inhaled high levels of arsenic trioxide. However, the causative role of arsenic was uncertain, as the influence of other constituents of the working atmosphere could not be determined. In 1980, IARC concluded that there was sufficient evidence that inorganic arsenic compounds are skin and lung carcinogens in humans (Group 1). In 2004, IARC concluded that there was sufficient evidence in humans that arsenic in drinking-water causes cancers of the urinary bladder, lung and skin, whereas the evidence for carcinogenicity in experimental animals was limited. In 2009, IARC again concluded that arsenic in drinking-water causes cancers of the urinary bladder, lung and skin and that the evidence was "limited" for cancers of the kidney, liver and prostate.

12.   At its 27th meeting (1983), JECFA concluded that "on the basis of the data available the Committee could arrive at only an estimate of 0.002 mg/kg b.w. as a provisional maximum tolerable daily intake for ingested inorganic arsenic; no figure could be arrived at for organic arsenicals in food" This was based on the observation that arsenicism can be associated with water supplies containing an upper arsenic concentration of 1 mg/l or greater and that a concentration of 0.1 mg/l may give rise to presumptive signs of toxicity. Assuming a daily water consumption of 1.5 litres, the Committee concluded that inorganic arsenic intakes of 1.5 mg/day were likely to result in chronic arsenic toxicity and that daily intake of 0.15 mg may also be toxic in the long term to some individuals. The Committee noted that the International Programme on Chemical Safety (IPCS) had estimated that an arsenic concentration of 0.2 mg/l in drinking water would lead to a 5% lifetime risk of skin cancer, but that skin cancer did not occur in the absence of other toxic effects due to arsenic.

13.   At its 33rd meeting (1988), JECFA considered information relevant to assessing the significance of organoarsenicals in fish. The previous evaluation was confirmed by assigning a provisional tolerable weekly intake (PTWI) of 0.015 mg/kg bw for inorganic arsenic, "with the clear understanding that the margin between the PTWI and intakes reported to have toxic effects in epidemiological studies was narrow". The Committee noted that the organic forms of arsenic present in seafood needed different consideration from the inorganic arsenic in water.

14.   At its 72nd Meeting (2010), JECFA considered previously reviewed toxicological data and all information related to the toxicology and epidemiology, exposure assessment, including biomarker studies, analytical methodology, speciation and occurrence in food and drinking-water, in order to re-evaluate and review the PTWI for inorganic arsenic. The literature relating to arsenic is extensive, and the present Committee used three recent reviews—by the United States Agency for Toxic Substances and Disease Registry, the European Food Safety Authority (EFSA) and the International Agency for Research on Cancer (IARC) —as the starting point for its evaluation and also took into account newer studies that were considered to be informative for the evaluation. The classification of arsenic as a carcinogen was originally based on evidence of skin cancers. Studies in Taiwan, China, and other regions where high exposures to arsenic in drinking-water occurred have confirmed the relationship. Significant associations between exposure to high levels of ingested arsenic in drinking-water and bladder cancer have been observed in

ecological studies from Chile, Argentina and Taiwan, China, and cohort studies in Taiwan, China. Some of the studies showed an association only in smokers. In studies from Chile, Argentina and Taiwan, China, exposure to arsenic at high concentrations in drinking-water has been shown to be associated with lung cancer. Again, when smokers and non-smokers were compared, the associations were stronger in the smokers. The inorganic arsenic lower limit on the benchmark dose for a 0.5% increased incidence of lung cancer ($BMDL_{0.5}$) was determined from epidemiological studies to be 3.0 μg/kg bw per day (2–7 μg/kg bw per day based on the range of estimated total dietary exposure) using a range of assumptions to estimate total dietary exposure to inorganic arsenic from drinking water and food. The Committee noted that the provisional tolerable weekly intake (PTWI) of 15 μg/kg bw (equivalent to 2.1 μg/kg bw per day) is in the region of the BMDL0.5 and therefore was no longer appropriate. At its 72nd Meeting (2010), JECFA withdrew the previous PTWI.

15.   Epidemiological studies in different regions of the world have consistently demonstrated a strong association between long-term inorganic arsenic ingestion and skin lesions, typically in the form of hyperkeratosis, hyperpigmentation or hypopigmentation. Observations of skin lesions following low chronic exposure have suggested that these characteristic dermal changes aresensitive indications of the toxic effects of inorganic arsenic.

16.   Available epidemiological studies indicate a positive relationship between high concentrations of inorganic arsenic in drinking-water and sensitive endpoints for peripheral and central neurotoxicity. There is some evidence that exposure of children to inorganic arsenic in areas with elevated arsenic concentrations (>50 μg/l) in drinking-water produces effects on cognitive performance, but so far this is not conclusive.

17.   The main adverse effects also reported to be associated with long-term ingestion of inorganic arsenic by humans are developmental effects, cardiovascular disease, neurotoxicity and diabetes, cancer and skin lesions.

ANALYTIC METHODS

18.   The most common detection techniques for arsenic are inductively coupled plasma mass spectrometry (ICP-MS), ICP-atomic emission spectroscopy (ICP-AES) and hydride generation coupled with atomic absorption spectroscopy (HG-AAS) or atomic fluorescence spectroscopy (HG-AFS). ICPAES is generally adequate for determination of total arsenic in foods, and its sensitivity can be improved by coupling to HG. ICP-MS has the highest sensitivity without derivatization. HG-AAS and HG-AFS have limits of detection (LODs) in the microgram pe**r** kilogram range, which is adequate for all foods. For speciation with HG-based detection systems, some organoarsenic species require oxidation to species that form volatile arsines prior to their detection.

19.   **Total arsenic analysis** Samples prepared for total arsenic determination are mineralized by either wet or dry methods. Microwave is the most common closed system used in wet mineralization, although temperatures higher than those that can be achieved by microwave are needed for the complete degradation of some organoarsenic species. This leads to an underestimation of total arsenic in some foods when HG-based detection systems are used. Recent developments, such as microwave-induced combustion methods, are solving this problem. In dry mineralization, addition of ashing aids is necessary to avoid arsenic losses by volatilization.

20.   **Arsenic speciation analysis** Methodological research in the last decade has been targeted to arsenic speciation. Quantitative extraction of arsenic species from food matrices is one of the main methodological problems, and efficiencies vary widely, depending on the nature of the matrix and the method used. Polar solvents assisted by ultrasound, accelerated solvent extraction or microwave are commonly used. Extraction of arsenite is especially difficult to achieve, because of binding to thiol groups in proteins. Separation of arsenic species is most commonly achieved by high-performance liquid chromatography (HPLC). Multidimensional chromatography (different columns and conditions) may be needed for samples with a large number of arsenic species; up to 23 species have been found in seaweed and seafood, for example.

Further difficulties are that the elution may not be quantitative under certain conditions, and the eluent may change the arsenic oxidation state.

21.   **Inorganic arsenic analysis** Most of the current work on arsenic speciation has targeted the characterization of arsenic species profiles in food products, without special attention to inorganic arsenic. There is a current need for validated and horizontal methods for selective extraction and determination of inorganic arsenic and for certified reference materials for inorganic arsenic in foods. Further, it would be more appropriate to report total inorganic arsenic rather than arsenite and arsenate, because various extraction/analytical procedures may change the oxidation state.

22.   Validated methods, such as those adopted by the International Organization for Standardization (ISO), AOAC International, or the European Organization for Standardisation (CEN), are required for enforcement purposes. For total arsenic, including in cereal grains and grain products, there exists validated method (AOAC method, EN).   There is a need for validated methods for selective extraction and determination of inorganic arsenic in food matrices and for certified reference materials for inorganic arsenic.

23.   Since there are no reference materials for arsenic speciation analysis, it is needed that efforts should be paid to develop a rice flour reference material containing both inorganic and organic arsenic species. Such natural sample can be obtained in some ming-impacted paddy soils in China, such as Hunan province, south central China.

LEVEL OF TOTAL AND INORGANIC ARSENIC IN FOOD COMMODITIES

24.   In 2010, the 72th meeting of JECFA assessed the levels and patterns of arsenic contamination in food commodities, including in rice, on the basis of occurrence data from the literature and from data submitted by Australia, Brazil, France, Japan, New Zealand and Singapore. The total number of analytical results (single or composite) evaluated was 17 498. Table 2 summarizes the ranges of total arsenic concentrations by food category, based on results with quantified values (minimum to maximum). The highest total arsenic concentrations have been found in seaweed, fish and shellfish, mushrooms and fungi, rice and rice products and some meat products. The levels in the remaining food products usually do not exceed 1 mg/kg. In some food groups, the number of non-detectable/non quantifiable results was high (n = 9081), e.g. with milk products (66%), meat and meat products (74%), eggs and egg products (65%), bakery wares (70%), cereals other than rice (80%) and vegetables other than mushrooms (86%).

25.   More recently, methods for the determination of inorganic arsenic have become available. Levels of inorganic arsenic were obtained from the literature and from data submitted by Japan, France and Singapore (minimum to maximum). The total number of analytical (single or composites) results evaluated at the 72nd meeting was 1737 (Table 3). Levels of inorganic arsenic in foods and beverages usually do not exceed 0.1 mg/kg, with mean values generally less than 0.03 mg/kg. However, seaweed, rice and some fish and seafood commodities have higher inorganic arsenic levels, as do food crops grown in arsenic-contaminated soils, which will be discussed in greater detail in Para 26-31. Although drinking water is well known to significantly contribute to inorganic arsenic exposure, some studies suggest that rice and rice-based products could also contribute significantly to inorganic arsenic exposure. Other possible contributors to dietary inorganic arsenic exposure were fish and seafood, cereals, root vegetables, seaweed, food supplements, mushrooms and tea. As rice-based products are often used in weaning foods for infants, exposure of infants to arsenic is of great importance and should be assessed.

Table 2 Summary of available data on total arsenic concentrations in food products (from JECFA 2010)

Food categories	n	n<LOR[a]	Range(mg/Kg)
Diary products and analogues			
Milk and milk power	284	65	0.001-0.15
Milk products	92	61	0.010-0.35
Fats and oils	39	0	0.003-0.18
Meat and meat products			
Meat	4977	4124	0.004-0.78
Offal	2074	1096	0.009-0.45
Meat products	50	20	0.003-3.25
Eggs and egg products	171	111	0.003-0.04
Confectionery products	186	61	0.002-1.13
Sweeteners	138	21	0.003-0.26
Bakery wares	71	49	0.002-0.25
Beverages			
Alcoholic beverages(except rice distilled spirits)	462	64	0.001-0.05[b]
Rice distilled spirits	8	2	0.050-1.64[b]
Non-alcoholic beverages	120	16	0.001-0.26[b]
Vegetables/fruits/nuts/seaweed			
Friuts	966	800	0.005-2.20
Vegetables(except mushrooms and fungi)	2503	2164	0.001-1.27
Mushrooms and fungi	302	60	0.011-5.79
Nuts and oilseeds	70	15	0.005-0.88
Dried seaweeds	953	3	0.114-236
Cereals and cereals products			
Cereals(except rice)	410	325	0.007-0.43
Rice	1693	0	0.002-1.83
Breakfast cereals	17	10	0.017-0.27
Pasta	19	9	0.003-0.18
Fish and fish products			
Marine fish	1409	0	0.10-62
Shellfish	171	0	0.090-66
Freshwater fish	238	0	0.060-4.72
Baby food products	75	5	0.001-4.66

LOR, limit if reporting (detection or quantification limit)
[a] Results presented for detected values only (not detected [ND]=0).
[b] Data expressed as mg/l.

Table 3. Summary of available data on inorganic arsenic concentrations in food products [a] (from JECFA 2010)

Food products	n	n<LOD	Concentration range(mg/Kg)
Dried seaweed	539	4	0.1-130
Rice	0837	0	0.01-0.51
Fish and fish products	325	1	0.001-1.2
Vegetables	36	1	0.008-0.61

[a] Results presented for detected values only (ND=0).

26.   In the seaweed *Hizikia fusiforme*, inorganic arsenic is more than 50% of total arsenic, with levels usually ranging from 30 to 130 mg/kg. In other seaweed species, inorganic arsenic is less than 15% of total arsenic, with levels normally below 2 mg/kg. The proportion of inorganic arsenic in rice varies from 17% to 100% of total arsenic and in vegetables from 33% to 74%, with maximum concentrations of 0.5 and 0.6

mg/kg, respectively. The proportion of inorganic arsenic usually does not exceed 10% of the total arsenic in fish and fish products, but it was found to reach 15% in shellfish from areas with some degree of arsenic contamination.

27.   Rice (*Oryza sativa* L.) takes up high amounts of arsenic, but speciation of arsenic in rice varies between different regions, with a higher inorganic content in rice grown in Asia compared with the USA and EU, but higher total arsenic levels in rice from US and EU except the contaminated areas such as Bangladesh and Chile.

28.   Variability in total arsenic in rice. Total arsenic concentration in rice varied from 0.005 to 0.710 mg/kg using 204 commercial rice samples purchased mostly in retail stores in upstate New York and supplemented with samples from Canada, France, Venezuela, and other countries. Reported levels of total arsenic in rice are < 0.01–2.05 mg /kg for Bangladesh, 0.31–0.70 mg/kg for China and < 0.10–0.76 mg/kg for Taiwan, China, 0.03–0.044 mg/kg for India, 0.11–0.66 mg/kg for the U.S., 0.03–0.47mg/kg for Vietnam, and 0.08–0.38 mg/kg for Italy and Spain (Williams et al., 2005; Duxbury et al., 2003; Caroli et al., 2002, 2007; Pizarro et al, 2003). By combining the data set with literature values global "normal" range of 0.08-0.20 mg/ kg for As concentration in rice was derived. The average total arsenic concentrations for rice from the U.S. and Europe (both 0.198 mg/kg) were statistically similar and significantly higher than rice from Asia without contamination (0.07 mg/kg). Using two large data sets from Bangladesh, it was found that arsenic contaminated irrigation water, but not soil, led to increased grain total arsenic concentration. Wide variability found in U.S. rice grain was primarily influenced by region of growth rather than commercial type, with rice grown in Texas and Arkansas having significantly higher mean arsenic concentrations than that from California (0.258 and 0.190 versus 0.133 mg/kg). Rice from one Texas distributor was especially high, with 75% of the samples above the global "normal" range, suggesting production in an arsenic contaminated environment.

29.   Inorganic arsenic levels in rice in the USA: Schoof et al. (1999) used market basket survey techniques to analyze 40 food commodities expected to account for 90 % of the dietary inorganic arsenic intake. Consistent with earlier studies, total arsenic concentrations were highest in the seafood ranging from 0.160 mg/kg in freshwater fish to 2.360 mg/kg in marine fish, followed by the raw rice ranging from 0.196 mg/kg to 0.335mg/kg. The highest inorganic arsenic concentrations were found in raw rice at 0.074±0.010 mg/kg. Heitkemper et al. (2009) analyzed 60 rice samples collected directly from the fields in four major rice-producing states in the US, and reported an average total arsenic content of 0.210 ± 0.190mg/kg, while average inorganic arsenic levels were 0.091±0.032 mg/kg. US rice samples with higher levels of total arsenic have higher levels of DMA; however, inorganic arsenic levels, regardless of the total arsenic content, rarely exceed 0.15 mg/kg dry weight.

30.   Inorganic arsenic level in rice in the EU: In a UK study, total arsenic concentrations in pure baby rice ranged from 0.120 to 0.470 mg/kg with a median of 0.220 mg/kg while inorganic arsenic levels ranged from 0.060 to 0.160 mg/kg, with a median of 0.110 mg/kg. The percentage of inorganic to total arsenic ranged from 33 % to 68 % with a median of 57 % (Meharg et al., 2008). In a Swedish study, the mean concentration of total arsenic in long grain brown rice of 0.240 mg/kg was similar to that of parboiled white rice at 0.210 mg/kg, whereas the average concentration in white rice was considerably less at 0.100 mg/kg. The concentration of inorganic arsenic averaged0.110 mg/kg, or 64 % of the total arsenic (Jorhem et al., 2008). Arsenic content in rice has also been analysed in a Spanish study (Torres-Escribano et al., 2008), where the mean concentration of total arsenic in the 31 samples of European origin was 0.197 mg/kg. This value was close to the mean value of 0.18 mg/kg found in 7 samples of European rice in a UK study (Williams et al, 2005). Torres-Escribano and colleagues also evaluated the inorganic arsenic level in raw rice originating from either Europe or Asian countries and found that it ranged from 0.027 to 0.253 mg/kg. The percentage of inorganic arsenic over the total arsenic varied between 27 and 93 %. Williams et al. (2005) analyzed 51 samples of raw rice produced in Europe, Asia and the USA and showed a variation of inorganic arsenic ranging from 10 to 86 %. Both studies also observed that the mean concentration of inorganic arsenic is 1.7 or 1.8 times higher in brown rice than in white rice. Some common food items (bread, rice, milk, pork

meat, chicken meat, cabbage and potatoes) from the Slovak Republic were collected and analysed for total arsenic concentrations. Rice contained the highest average concentration of total arsenic at 0.158 mg/kg. The major proportion of the arsenic in rice seemed to be inorganic.

31.   Inorganic arsenic level of rice in China: The CDC laboratory in China analyzed 41 rice samples from 13 provinces using LC-HG-AFS, inorganic arsenic concentrations ranged from 0.023 to 0.142mg/kg. Samples from Hunan, Guangxi and Sichuan provinces had higher concentrations of inorganic arsenic, which were consistent with the distribution of arsenic bedrock in these provinces. In another study, 22 rice samples from 13 provinces of China were analyzed for their arsenic content. The total arsenic concentration ranged 0.065-0.274mg/kg with an average value of 0.114mg/kg. Speciation analysis, including arsenite (As(III)), arsenate (As(V)), DMA and MMA, was performed by using HPLC-ICPMS for the extraction of arsenic from milled rice powder. The inorganic arsenic (As(III) + As(V)) species was predominant, accounting for approximately 72% of the total arsenic in rice, with a mean concentration of 0.082 mg/kg. The dietary exposure to inorganic arsenic from rice was estimated to be about 25 times higher than exposure from drinking water, when using the WHO and China National drinking water guideline of 0.01mg/L.

DIETARY EXPOSURE

32.   In the document, arsenic means total arsenic when not otherwise mentioned.

33.   In its 27th meeting, JECFA assessed arsenic dietary exposure. Only values for total arsenic were given for several European countries, the USA, Canada and the Republic of Korea; these ranged from 10 to 200 µg/day from food (0.17–3.33 µg/kg bw per day, assuming a body weight of 60 kg). Estimated dietary exposures to total arsenic from water ranged from 15 to 750 µg/day (0.25–12.5 µg/kg bw per day), assuming a consumption of 1.5 litres of water per day, which imply arsenic concentrations in water of 10 µg/L and 500 µg/L. Water and seafood were the major sources of total arsenic, with other foods making minor contributions.

34.   At 72nd JECFA meeting in 2010, the focus was on dietary exposure to inorganic arsenic; however, the majority of dietary exposure estimates submitted for evaluation were for total arsenic. A summary of reported national inorganic arsenic estimates is given in Table 4, with ranges taken from studies conducted in various countries. Reported mean dietary exposure to inorganic arsenic in the USA and various European and Asian countries ranged from 0.1 to 3.0 µg/kg bw per day.

Table 4. Summary of inorganic arsenic dietary exposure estimates (from JECFA 2010)

Country/region	Mean exposure (µg/Kg bw per day)	Upper-percentile exposure(µg/Kg bw per day)
Europe		
Europe [a] (EFSA)	0.21-0.61 adult	0.36-0.99 adult (95th)
	0.31-1.39 child 1-8 years	0.61-2.66 child 1-8 years (95th)
	0.03-1.63 infant 12 months	----
Belgium [b]	0.10 all	0.16 all (90th)
France TDS [c]	0.10 adult	0.27 adult (95th)
	0.14 child 3-14 years	0.34 child 3-14 years (95th)
United Kingdom TDS [c]	0.02-0.12 adult	0.05-0.16 adult (97.5th)
	0.03-0.20 child 1-18 years	0.08-0.40 child 1-18 years(95th)
	0.45 infant 12 months	0.74 infant (95th)
North America		
Canada TDS [c]	0.29 (total arsenic) all	
USA TDS ,other studies [d]	0.08-0.20 adult	0.16-0.34 adult(95th)
	0.12-0.32 child 1-6 years	---
	0.24-1.19 infant 12 months	----
South America		
Chile [e]	2.08-21.48 adult	
Asia		
Bangladesh [f]	1.68-3.00 adult	
China TDS [c]	0.24-0.76 adult	
China, Province of Taiwan [g]	0.91 adult	
Japan TDS, other study [h]	0.36-0.46 adult	0.83-1.29 adult (95th)
Japan[i]	0.31 adult (ND=0),	
	0.61 adult (ND=LOQ/2)	

TDS, total diet study
[a] Individual dietary records for 19 European countries, different scenarios using conversion factors ,drinking-water included.
[b] Individual dietary records for Belgium, Analyzed inorganic values for fish and seafood commodities only, drinking-water not included.
[c] total diet study; France 2001-2002 TDS, 10% total arsenic assumed to be inorganic, drinking-water included; Canada 1985-1988 TDS, conversion factors applied to total arsenic, drinking-water not included; China 2007 TDS analyzed inorganic arsenic, drinking-water included; United Kingdom 2006 TDS analyzed inorganic arsenic, drinking-water included, previous TDSs did not.
[d] Various studies based on individual dietary records for USA from 1986-1987 Nationwide Food Consumption Survey or 1994-1996,1998 supplement Continuing Survey on Food Intakes by Individuals(CSFII),inorganic arsenic level from a market basket survey of inorganic arsenic in food, drinking-water included in some studies.
[e] Small community in Chile, drinking-water included, seasonal contamination of river water used as drinking-water source.
[f] Small community in Bangladesh, total arsenic reported, assumed 70% total arsenic is inorganic, drinking-water not included.
[g] Small community in Taiwan, China, rice and yams only included with analyzed inorganic arsenic values, drinking-water not included.
[h] Two studies; Japan 2000TDS, drinking-water included, conversion factors applied to total arsenic; other study of woman in fishing and rice faming communities, analyzed inorganic arsenic or fish, shellfish, seaweed and edible algae, Japan TDS values for other foods, drinking-water not included.
i Individual dietary records for Japan 2008, based on inorganic arsenic contents in cooked rice and two composite food groups for market basket survey (Group A: vegetables and seaweed, Group B: fish, cephalopods and shellfish). LOQ is 0.02 mg/kg. Drinking-water is not included.

35.   In 2009, EFSA identified the food subclasses of cereal grains and cereal based products, followed by food for special dietary uses, bottled water, coffee and beer, rice grains and rice based products, fish and vegetables, as largely contributing to the inorganic arsenic daily exposure in the general European population.

36.   The main factors influencing dietary exposure to inorganic arsenic are the water supply, the types of foods consumed and the food preparation methods. Drinking-water was a major contributor to the overall dietary exposures to inorganic arsenic and, depending on the concentration, can also be an important source of inorganic arsenic in food through food preparation and possibly irrigation of crops, particularly rice.

37.   The proportion of total exposure to inorganic arsenic arising from food relative to the proportion from water increases as the concentration of inorganic arsenic in the water decreases. The amount of water consumed varies according to the region, temperature, physical activity and also types of food consumed since foods such as, soup and rice can either contain high quantities of water or take up large quantities of water. This can result in a total water consumption of between 1.5 and 5 litres per day. Arsenic contamination of groundwater is widespread, and there are a number of regions where arsenic contamination of drinking-water is important. Areas affected include southern Asia (e.g. Bangladesh, India), South-east and East Asia (e.g. China, including Taiwan, Mongolia, Viet Nam), the Americas (e.g. Argentina, Canada, Chile, Mexico, USA) and Europe (e.g. Finland, Hungary, Romania). Contaminated water that is used for drinking and food preparation would normally contain arsenic at concentrations between 0.01 and 0.200 mg/L. However, concentrations above 0.200 mg/kg have been reported in some areas.

38.   According to the conclusion of the 72nd JECFA meeting, the ranges of dietary exposure to inorganic arsenic for North America and Europe were similar but in general were lower than those reported for countries in Asia, with highest in Bangladesh, for which mean dietary exposure to inorganic arsenic was estimated to be up to 3 times than in other Asian countries. Because arsenic is speciated in rice as both inorganic arsenic and DMA, the higher exposure levels found in the Bangladeshis might also be the result of higher rice consumption. Even the Bangladeshi community living in the United Kingdom (UK) has a ca. 30-fold higher consumption of rice than white Caucasians. In order to assess the impact of this difference in rice consumption, urinary arsenicals of 49 volunteers in the UK (Bangladeshi n = 37; white Caucasians n = 12) were monitored along with dietary habits. Total urinary arsenic and speciation analysis for DMA, MMA and inorganic arsenic was conducted (Cascio et al., 2011). Although no significant difference was found for total arsenic median between Bangladeshis group (28.4μg/L) and white Caucasians (20.6 μg/L), the sum of medians of DMA, MA and inorganic arsenic for the Bangladeshi (17.9μg/L) was found to be over 3-fold higher than for the Caucasians (3.50 μg/L). Especially, urinary inorganic arsenic was significantly higher (p < 0.001) in the UK Bangladeshis median (0.630 μg/L) than in the white Caucasians median (0.250 μg/L).

39.   For countries in Asia and other countries where rice is a staple food, rice and water were the major contributors to total inorganic arsenic dietary exposures, with wheat and vegetables being minor contributors. Although total arsenic levels are higher in fish and shellfish than in other foods, consumption of fish and shellfish does not have a major influence on dietary exposure to inorganic arsenic, as the majority of arsenic in fish and in the edible portion of shellfish is organic. In Europe and North America, where wheat-based products and potatoes are staple foods, rice may not account for such a high proportion of the dietary exposure to inorganic arsenic.

ENVIRONMENTAL AND AGRICULTURAL EFFECT

40.   The cultivation of rice requires large volumes of water and long term use of arsenic contaminated groundwater for irrigation may result in increased total and inorganic arsenic concentration in the agricultural soil and eventually accumulation in rice plants. The other major source of arsenic in paddy soils is mining and smelting of base metals through water discharge and air deposition, Paddy rice has a much enhanced total and inorganic arsenic accumulation compared with other cereal crops, partly due flooding conditions under which arsenic is released into soil pore water. Therefore, practical measures are urgently needed to decrease arsenic transfer from soil to grain.

41.   In Bangladesh, both shallow tube-wells (STW) and deep tube-wells (DTW) are used in large numbers (approximately 2.6 million) to irrigate about 2.5 million ha of land, which contributes significantly to the country's food grain production. About 86% of the total groundwater withdrawn is utilized in the agricultural sector (WRI, 2000). Arsenate and phosphate are analogues, and addition of one of the elements

to soil may affect the uptake and availability of the other. Supported by Bangladesh IRRI-PETRRA, Jahiruddin tried to assess the arsenic status in the irrigation water-soil-rice plant system. The results of pot experiments demonstrate that the total arsenic concentration in rice grain increased with increasing application of arsenic added either through irrigation water or direct addition to the soil; however, all concentrations were below 1 ppm. Again, the straw arsenic concentrations in all cases were much greater than 1 ppm. There was a residual effect of both soil- and water -added arsenic on the second crop (T. Aman rice). Xu et al (2008) investigated the dynamics of arsenic speciation in the soil solution under both flooded and aerobic conditions and compared arsenic accumulation in rice shoot and grain in a greenhouse experiment. Flooding of soil led to a rapid mobilization of arsenic, mainly as arsenite, in the soil solution. Arsenic concentrations in the soil solution were 7-16 and 4-13 times higher under flooded conditions than under aerobic conditions in the control without arsenic addition and in the + arsenic treatments (10 mg/kg As as arsenite or arsenate), respectively. Arsenate was the main arsenic species in the aerobic soil. Arsenic accumulation in rice shoots and grain was markedly increased under flooded conditions; grain arsenic concentrations were 10-15-fold higher in flooded conditions than in aerobically grown rice. With increasing total arsenic concentrations in grain, the proportion of inorganic arsenic decreased, while that of DMA increased. The concentration of inorganic arsenic was 2.6-2.9 fold higher in the grain from the flooded treatment than in that from the aerobic treatment. The results demonstrate that a greatly increased bioavailability of arsenic under the flooded conditions is the main reason for an enhanced arsenic accumulation by flooded rice, and growing rice aerobically can dramatically decrease the arsenic transfer from soil to grain.

42.   So far, most of the published reports focused mainly on the uptake of arsenic in the rice plant irrigated with arsenic contaminated water and soil through a green house pot experiment. More data based on field investigations are needed.

43.   In India, a small field study in the 17 arsenic-affected villages of Chakdaha block, Nadia district. West Bengal was conducted to investigate the transfer of arsenic from irrigation water and soil to rice plants. Results showed that the level of arsenic in irrigation water (0.11±0.012 and 0.76±0.014 mg/L) significantly exceeded the WHO permissible limit of 0.01 mg/L for drinking water and was also above the FAO permissible limit of 0.10 mg/L for irrigation water. The paddy soil gets contaminated by the irrigation water and thus enhances more probable conditions for bioaccumulation of arsenic in rice plants. The total soil arsenic concentrations ranged from 1.38±0.108 to 12.27±0.094 mg/kg dry weight, which was below the maximum acceptable limit for agricultural soil of 20.0 mg/kg as recommended by the European Community. In the rice plant, the highest accumulation of arsenic was noticed in the root (7.19±0.166 to 18.63±0.155 mg/kg) and the lowest in the grain (0.25±0.014 to 0.73±0.009 mg/kg). The results clearly showed that the total arsenic content in rice plant is correlated to the degree of arsenic contamination of irrigation water and soil. Regardless of the sampling locations the arsenic accumulation follows the order of root > straw > husk > grain. Consumption of rice straw containing considerable amount of arsenic (1.17±0.014 to 4.15±0.033) by cattle could potentially lead to increased arsenic levels in meat or milk. Because the total arsenic in raw rice is not taken in human body due to its distribution in root, straw, husk and grain parts, the most important attention should paid to grain parts. Although any rice sample from the study area concentration of total arsenic in the grain part did not exceed 1.0 mg/kg, the proportion of inorganic arsenic should be clarified. The maximum permissible limit of total arsenic is 1 mg/kg for seafood where organic arsenic comprises above 90 % of the total arsenics. This limit could be less for rice since about 0-80 % of arsenic in rice grain is inorganic.

EFFECTS OF RICE GRAIN VIRIATES AND MILLING FOOD PROCESSING

44.   Rice is a cereal that has the tendency to accumulate arsenic in comparison to other grain crops tested to date, with whole grain (brown) rice having higher arsenic levels than polished (white). It is reported here that rice bran, both commercially purchased and specifically milled for this study, have levels of inorganic

arsenic, reaching concentrations of ~1 mg/kg dry weight, around 10-20 fold higher than concentrations

found in bulk grain (Sun et al, 2008). Although pure rice bran is used as a health food supplement, perhaps of more concern is rice bran solubles, which are marketed as a super food and as a supplement to malnourished children in international aid programs. While the concentration of total arsenic in rice is low, about 50% of it is present as inorganic arsenic. Five rice bran solubles products were tested, sourced from the United States of America and Japan, and were found to have 0.61-1.9 mg/kg inorganic arsenic. Manufacturers recommend ~20 g servings of the rice bran solubles per day, which equates to a 0.012-0.038 mg intake of inorganic arsenic.

45.   The initial cleaning of grain, the milling of the whole cereal and the processing of different milling fractions to manufacture foods can all change the level relative to the level in the raw harvested crop. Washing or soaking rice and seaweed and discarding the water before cooking reduce arsenic levels, especially inorganic forms. Decreases in arsenic levels with boiling have been described for rice, pasta, seaweed and seafood products, except where the water used is contaminated with arsenic, when levels may increase.

46.   The level of inorganic arsenic in the rice consumed also varies, depending on food processing and preparation methods. The UK Food Standards Agency (FSA) has carried out recent research on the levels of arsenic present in rice and rice products as well as the effect of cooking on arsenic concentrations. The FSA has completed a survey of total and inorganic arsenic in 60 samples of rice drinks. Arsenic was detected in all samples of rice drinks at low concentrations. An average concentration of 0.023 mg/kg of total arsenic and 0.012 mg/kg of inorganic arsenic was found. If toddlers and young children (ages $1 - 4.5$ years) consume rice drinks instead of breast milk, infant formula or cows' milk, the FSA estimates that their intake of inorganic arsenic could be increased by up to 4-fold if combined intakes for high-level consumption of rice drinks at the mean concentration of inorganic arsenic plus average exposure from the rest of the diet are considered.

47.   A field level experiment was conducted in Bangladesh to investigate the influence of cooking methods on arsenic retention in cooked rice. Rice samples were collected directly from a severely arsenic affected area and also from an unaffected area, to compare the results. Rice was cooked according to the traditional methods employed by the population of subjected areas. Total arsenic concentrations were 0.40 ± 0.03 and 0.58 ± 0.12 mg/kg in parboiled rice of arsenic affected area, cooked with excess water and 1.35 ± 0.04 and 1.59 ± 0.07 mg/kg in gruel for BRRI dhan28 and BRRI hybrid dhan1, respectively. In non-parboiled rice, total arsenic concentrations were 0.39 ± 0.04 and 0.44 ± 0.03 mg/kg in rice cooked with excess water and 1.62 ± 0.07 and 1.74 ± 0.05 mg/kg in gruel for BRRI dhan28 and BRRI hybrid dhan1, respectively. Total arsenic content in rice, cooked with limited water (therefore gruel was absorbed completely by rice) were 0.89 ± 0.07 and 1.08 ± 0.06 mg/kg (parboiled) and 0.75 ± 0.04 and 1.09 ± 0.06 mg/kg (non-parboiled) for BRRI dhan28 and BRRI hybrid dhan1, respectively. Water used for cooking rice contained 0.13 and 0.01 mg/L arsenic for contaminated and non-contaminated areas, respectively. Arsenic concentrations in cooked parboiled and non-parboiled rice and gruel of non-contaminated area were significantly lower (*p<0.01*) than that of contaminated area. The results imply that cooking of arsenic contaminated rice with arsenic contaminated water increases its concentration in cooked rice.

48.   Changes to the total arsenic content and to arsenic species might take place during the preparation of food for human consumption. The various processes may cause a considerable increase or decrease in the concentrations of arsenic in food commodities and thus in the actual dietary exposure to arsenic. Almost all the arsenic present in contaminated cooking water may be retained during boiling of rice. Devesa et al. (2008) recently summarised the effects of thermal treatments on the concentrations of total arsenic and arsenic species in food in a comprehensive review. Changes to total arsenic content of the food can occur due

to losses (solubilisation) to the cooking medium or preservation solution. Additionally, arsenic species can be converted to other arsenicals during food preparation. In general, these changes are not great, but they can be significant after cooking at high temperatures, such as might be reached on the surface of the food during frying or grilling (Hanaoka et al., 2001; Torres-Escribano et al., 2008). Several studies have focussed on how cooking rice in contaminated water affects the contents of arsenic in the processed product as this was found to be of special importance in arsenic-endemic areas where rice plays a vital role as the main source of energy and protein intake for the people living there. Results were found by Torres-Escribano et al. (2008) who investigated the effect of cooking on total and inorganic arsenic concentrations in various brands of rice. They found a higher inorganic arsenic concentration in brown rice compared to white rice which might indicate that part of the arsenic is attached to components of the bran. Consequently, polishing brown rice to obtain white rice may lead to a substantial decrease in arsenic concentration. In their study, the cooking process mimicked one of the processes normally applied in Spanish households: boiling in water with an initial rice to water ratio of 1:4 until all the liquid has evaporated. Prior to cooking the water was spiked with various concentrations of arsenate ranging from 0.1 to 1 mg/L to emulate the concentrations in water from arsenic-endemic areas. After cooking the inorganic arsenic concentration in the analyzed rice samples increased between 3 and 99 times with mean rice retention of 89±13 % of the arsenic in the cooking water. Comparable results were also reported by Ackerman et al. (2005) who found an absorption of arsenic by rice from the total volume of water used in cooking between 89 and 105 % (rice to water ratio 1:1 to 1:4). While the aforementioned studies mainly focused on the retention of arsenic by rice from contaminated water, other investigations tested the effects of cooking rice in non contaminated water. Sengupta et al. (2006) tested the three major rice cooking procedures followed globally. Using low arsenic water (arsenic <0.003 mg/L), the traditional method of the Indian subcontinent (wash until clear; cook with rice to water ratio of 1:6; discard excess water) removed up to 57 % of the arsenic from rice containing arsenic at 0.20-0.54 mg/kg. Approximately half of the arsenic that had been removed was associated with the wash water and half was found in the discard water. With low arsenic water, the contemporary method of cooking unwashed rice at a rice to water ratio of 1:1.5-2.0 until no water remains did not modify the arsenic content. Preliminary washing until clear did remove 28 % of the rice arsenic. The results were not influenced by water source (tubewell, dug well, pond or rain), cooking vessel (aluminium, steel, glass or earthenware), or the absolute weight of rice or volume of water. Raab et al. (2009) systematically investigated total arsenic and inorganic arsenic in different rice types (basmati, long-grain, polished (white) and wholegrain (brown) that had undergone various forms of cooking in non-contaminated water. The effects of rinse washing, low water volume (rice to water ratio 1:2.5) and high water volume (rice to water ratio 1:6) cooking, as well as steaming, were investigated. Rinse washing was effective at removing about 10 % of the total and inorganic arsenic from basmati rice, but was less effective for other rice types. While steaming reduced total and inorganic arsenic rice content, it did not do so consistently across all rice types investigated. Low volume water cooking did not remove arsenic. High volume water cooking did effectively remove both total and inorganic arsenic for the long-grain and basmati rice by 35 % and 45 % for total and inorganic arsenic content, respectively, compared to uncooked (raw) rice. This study indicates that rinse washing and a high volume of non-contaminated cooking water are effective in reducing the arsenic content of cooked rice, specifically the inorganic component (Raab et al., 2009). Cooking rice with arsenic contaminated water can actually contribute even more to total dietary arsenic exposure than that from the rice itself.

RISK MANAGEMENT CONSIDERATION

Pre-harvest Control

49.   Prevention and control practices for the pre-harvest management of arsenic contamination of cereal grains will be discussed. These strategies include the timing and application rate to control the irrigated water and the use of cultivars that may be low in arsenic accumulation. Experimental results have indicated that growing rice aerobically greatly reduce arsenic accumulation in rice grain. Aerobic treatment either before or after rice flowering can reduce arsenic in rice grain, however, the percentage of inorganic arsenic I higher under aerobic conditions (Xu et al., 2008; Li et al., 2009). The other option to reduce arsenic in rice

grain is the development of rice cultivars low in grain arsenic. Zhang et al. (2008) has identified quantitative trait loci in rice chromosomes that are associated with arsenic concentrations in rice shoots and grains. More recent field studies in China, India and Bangladesh have further strengthened that selecting cultivars can be an efficient approach to reducing arsenic in rice grain, but need to consider gene and environment interactions (Norton et al., 2009).

50.   Soil amendment can also be effective in reducing arsenic uptake by rice. Pot experiment has demonstrated that the application silicon fertilizers can be useful in reducing arsenic accumulation in rice grain (Li et al., 2009). Related to this, a recent study has shown that mutation of a gene controlling silicon uptake in rice can drastically reduce arsenic uptake by rice (Ma et al, 2008).

Post-harvest Control and Decontamination

51.   As proposed earlier that, much of arsenic in the rice grain is concentrated in the rice bran, milling can effectively reduce arsenic in rice. Care should also be taken in making products from rice bran. More detailed data need to be collected from the Member States.

Risk Management Strategies in Various Countries

52.   Codex Alimentarius has set a number of standards for total arsenic, such as maximum permissible concentrations for several food commodities, e.g. 0.01 mg/L for natural mineral water; 0.1 mg/kg for edible fats and oils, fat spreads and blended spreads (including margarine and minarine), certain animal fats (e.g. lard, rendered pork fat edible tallow), olive oils and olive pomace oils, and 21 vegetable oils; and 0.5 mg/kg for food grade salt.

53.   While some countries around the world have established maximum levels (MLs) for total arsenic in general food, most focus on raw cereals and/or cereal-based foods as well as sea food. A few countries have also established MLs for inorganic arsenic. Most focus on raw cereals and/or cereal-based foods as well as seafood (Table 5).

Table 5 Maximum levels for total and inorganic arsenic in rice for various countries

Country	Regulatory Authorities	Maximum Level
Australia	FSANZ	• 1 ppm for total arsenic (cereles)
China	Ministry of Health	• 0.2 ppm inorganic arsenic in rice and rice products*
European Union	European Commission	• Call for EFSA Risk Assessment
India		• 1.1 ppm for total arsenic (other food not given ML specific)
Singapore*	Agri-Food and Veterinary Authority	• 1 ppm for total arsenic (other food not given ML specific)
UK	Food Standard Agency	• 1 ppm for total arsenic (all food, not given ML specific)

*

54.   Food Standard Agency of Australia and New Zealand (FSANZ) has established MLs with 1 mg/kg for total arsenic in cereals in provisions of its Food Codex Standard 1.4.1 Contaminants and Natural Toxicants: 2 maximum levels of metal contaminants in food. FSANZ also established MLs for inorganic arsenic in molluscs and seaweed (edible kelp) (1 mg/kg), as well as fish and crustacean (2 mg/kg).

55.   China have established MLs for total arsenic in many foods, including 0.01 mg/L for drinking water, 0.5 mg/kg for raw cereals and/or cereal-based foods (excepted rice and rice-based products), vegetables, edible fugues, meat and its products, sugar, condiments, milk powder, coca and its products included in chocolates, and 0.1 mg/kg for the oil and fats as well as raw milk. China also established MLs for inorganic arsenic in rice and rice-based products (0.2 mg/kg), fish and fish-based condiments (0.1 mg/kg), other sea food and seafood-based condiments (0.5 mg/kg), cereal-based infant formula (0.2 mg/kg), and sea weed-based infant formula (0.3 mg/kg). The formerly established ML for inorganic arsenic in rice was 0.15mg/kg, but will be changed into 0.2 mg/kg according to China's Ministry of Health notified WTO of GB2762

maximum levels of contaminants in food as G/SPS/N/CHN/312).

56.   There is no Europe-wide regulation for arsenic in food, although harmonized requirements for arsenic in drinking water are set by Council Directive 98/83/EC[2] on the quality of water intended for human consumption. This Directive stipulates that Member States shall set limit values of 0.01 mg/L for arsenic in water intended for human consumption. Commission Directive 2003/40/EC of 16 May 2003[3] establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters, and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters, sets a ML for arsenic in natural mineral water of 0.01 mg/L. Moreover, performance characteristics for the analytical determination of arsenic are set both in Council Directive 98/83/EC[2] as well as in Commission Directive 2003/40/EC[3].

Upon request of the European Commission, the European Food Safety Authority (EFSA) has delivered a scientific opinion on arsenic in food[4] to evaluate the risks to human health related to the presence of arsenic in foodstuffs (including drinking water) concluding that the overall range of BMDL01 values of 0.3 to 8 µg/kg b.w. per day should be used in the risk characterisation for inorganic arsenic. On the basis of the scientific opinion of EFSA, the Commission will consider risk management measures, including setting maximum levels for arsenic in foodstuffs. Under Article 5 of Regulation (EEC) No 315/93[5], Member States may maintain their national provisions, subject to compliance with the provisions of the Treaty, in case Community provisions have not been adopted. At least nine Member States have made use of this provision. The MLs for arsenic range from 0.005 mg/L (set in Germany) for commercial table water and rock water with a claim that these products are suitable for preparing baby food, up to 5 mg/kg set mostly for spices, herbs and seasonings in several Member States.

57.   In England and Wales[6], arsenic levels are regulated by the Arsenic in Food Regulations 1959 (as amended). Equivalent legislation applies in Scotland and Northern Ireland (the Arsenic in Food (Scotland) Regulations 1959 (as amended) and the Arsenic in Food Regulations (Northern Ireland) 1961 (as amended)). These indicate a general limit of 1 mg/kg for total arsenic in food and a specific limit of 0.1 mg/kg for non-alcoholic beverages, ready to drink, not otherwise specified. The UK Regulations were set before the carcinogenic nature of inorganic arsenic was known. Arsenic occurs naturally in a wide range of foods at low levels but most arsenic in the diet is present in the less toxic, organic form. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), has therefore concluded that exposure to inorganic arsenic should be as low as reasonably practicable.

58.   India have established MLs for total arsenic in many foods with provisions from Regulation 8.1.1 (1) ranging from 0.05 mg/L (ppm) for infant milk and infant food, to 5 mg/kg for dried herbs and spice, as well as dried food colouring other than synthetic colouring, riboflavin. MLs have also been set for milk,vinegar, and turmeric whole and powder (0.1 ppm). Juice of orange, grape, apple, tomato, pineapple and lemon, pulp and pulp products of any fruit (0.2 ppm); carbonated water (0.25 ppm); soft drink intended for consumption after dilution except carbonated water, ice-cream, iced lollies and similar frozen confections (0.5 ppm); hard boiled sugar confectionery, and iron fortified common salt (1.0 ppm); dehydrated onions, edible gelatin, liquid pectin (2.0 ppm); preservatives, anti-oxidants, emulsifying and stabilising agents and synthetic food

[2] Official Journal L 330, 5.12.1998, p. 32.

[3] Official Journal L126, 22.5.2003, p. 34-39.

[4] EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Arsenic in Food. EFSA Journal 2009; 7(10):1351. [199 pp.]. doi:10.2903/j.efsa.2009.1351. Available online: www.efsa.europa.eu

3 Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1–3)

5   In England and Wales, arsenic levels are regulated by the Arsenic in Food Regulations 1959 (SI 1959/831 as amended). Equivalent legislation applies in Scotland and Northern Ireland (the Arsenic in Food (Scotland) Regulations 1959 (SI 1959/928 as amended) and the Arsenic In Food Regulations (Northern Ireland) 1961 (SR 1961/98 as amended))

colours (dried based 4.0 ppm), chicory-dried or roasted (3.0 ppm). For all foods not non-specified food, including in rice and rice-based products, and MLs of 1.1ppm has been set.

59.   Japan has established MLs for total arsenic in soft drink beverage (including mineral water) in provisions of Specifications and Standards for Food, Food Additives, etc. under Food Sanitation Law, 0.05 mg/L for the water used as the raw materials, and "Not detected" for the final product when analyzed by the specified method (LOD is 0.2 ppm). In addition, maximum residue limit 1 ppm is set for potato, tomato, cucumber (including gherkin), spinach, pulp of citrus *natsudaidai*, peach, strawberry and grape, 3.5 ppm is set for peels of citrus *natsudaidai*, apple and Japanese pear which come from lead arsenate used as a pesticide.

60.   Malaysia have established MLs for total arsenic in many foods in provisions of Food Regulations 1985 [Regulation 360A (7)] 26th Schedule 0.05 mg/L for natural mineral water, and1mg/kg for some food.

61.   Singapore (Agri-Food and Veterinary Authority of Singapore) have established MLs for total arsenic in many food in 10th Schedule Regulation 31(1), range from 0.1 mg/L (ppm) for edible oils and fats, infant formula and baby food, milk and milk products in tin, to 5 mg/kg for some beverages not specified, as well as other colors (on dry matter) included in caramel. Between them, a few MLs have set for fruit and vegetable juice, wine, beer, cider, brandy, gin, rum, whisky, Chinese wine, liqueur, alcoholic cordial or cocktail, and other alcoholic liquor not specified(0.2 ppm); ice-cream, iced lollies and similar frozen confections, concentrated soft drinks both used in the manufacture of soft drink and intended for consumption after dilution (0.5 ppm); fish, crustaceans and mollusks, canned fish and meat, meat extract and hydrolyzed protein, chicory(dried or roasted), coffee beans, cocoa powder (calculated on dry, fat free substance), curry powder, dried or dehydrated vegetables, eggs (preserved or salted), fresh fruits and vegetables, fruit products and vegetables in tins, pickles, sugars, tea, tomato ketchup and other sauces, flavorings, 1.0 ppm; dried herbs and spices (including mustard) , 1.5 ppm; baking powder, cream of tartar, edible gelatine, tomato puree, paste or powder containing 25% or more total solids, 2.0ppm. All other food not specified (included in rice and rice-based products) is set at 1.0 ppm.

CONCLUSION AND RECOMMENDATIONS

62.   Arsenic contamination of rice is a potential problem local or worldwide. Inorganic arsenic levels in rice vary from year to year and from region to region depending on weather conditions soil contamination and rice varieties. Tools are being developed to forecast the likelihood of contamination and/or to assist in the soil and water arsenic contamination level. Rice as a staple food can be a significant dietary contributor to human arsenic exposure due to its high consumption rate and its preparation. Cooking rice with arsenic contaminated water can actually increase the concentration in rice and further contribute to total dietary arsenic exposure. So far, practical intervention and control approaches for arsenic in foods are limited, apart from processing possibilities (JECFA, 2010).

63.   For certain regions of the world where concentrations of inorganic arsenic in drinking-water exceed 0.05-0.10 mg/L, some epidemiological studies provide evidence of adverse effects. There are other areas where arsenic concentrations in water are elevated (e.g. above the WHO guideline value of 0.01 mg/L), but are less than 0.05 mg/L. Drinking water arsenic regulations from the WHO and in many countries (e.g. China, EU and U.S.) are set at 0.01 mg/L, which are based on the assumption that 1 L of water per day is consumed, i.e., 0.01 mg of arsenic/day, mainly inorganic arsenic from drinking water.

64.   Codex has not established maximum limit (ML) for arsenic or its species in rice and rice-based food products. Inorganic arsenic levels in rice-based foods tend to be lower than those in the raw grain, the reduction depending on the commodity, level of contamination and processing method. Rice milk might be used for infant and children and the available occurrence data for rice and rice-based foods suggest that these products can contribute to high inorganic arsenic intakes. While exposure to inorganic arsenic from processed rice products is likely to be low, people consuming polished rice and bran as a regular part of their diet can also be exposed to high levels of inorganic arsenic. At average concentration of inorganic arsenic

found in rice bran and rice milk and the manufacturers recommended rice bran soluble and rice milk consumption rate, inorganic arsenic intake exceeds 0.01 mg/day, remembering that rice bran solubles are targeted at malnourished children and that actual risk is based on mg/kg/day intake. ML in rice-based products need to be set for arsenic or its species, especial for inorganic arsenic.

65.   An inorganic arsenic exposure assessments conducted by JECFA in 2010 indicated that the PTWI of 15 μg/kg bw (equivalent to 2.1 μg/kg bw per day) is in the region of the $BMDL_{0.5}$ (3.0 μg/kg bw per day with the range of 2–7 μg/kg bw per day) from lung cancer epidemiological studies to be therefore was no longer appropriate. The Committee withdrew the previous PTWI.

66.   Rice is a staple food for a large proportion of the world population and is also an important commodity in international trade. Many countries have established MLs for total arsenic in rice while fewer have established MLs for inorganic arsenic in rice. The exposure estimates of dietary inorganic arsenic are based upon limited data on inorganic arsenic in food relative to total arsenic concentrations.

67.   The available information, considered against the Codex General Standard for Contaminants and Toxins in Food and Feed and the criteria contained in paragraph 11 of the Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups, suggests that it would be appropriate to limit the establishment of MLs to rice and its products as they can contribute significantly to inorganic arsenic dietary exposure.

68.   The CCCF may wish to consider, as one option, elaborating MLs for total and /or inorganic arsenic. According to Codex criteria for establishing MLs, MLs should be set at levels necessary to protect the consumer and as low as reasonably achievable but at a level that is (slightly) higher than the normal range of variation in levels in food that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. However, the variability in inorganic arsenic contamination of rice and rice-based products from region to region, and differences in countries' capabilities to forecast and control inorganic arsenic occurrence, and the nature of the occurrence data that were provided make it challenging to determine inorganic arsenic's normal range of variation in rice and rice-based food on a global scale and thereby apply the ALARA principle in establishing MLs. It is suggested that, at this time, the proposed MLs would apply to two options; one is for inorganic arsenic only, second is total arsenic. The original intent was that the proposed MLs be applicable to the total arsenic, which may mislead to toxicologically equivalent, because inorganic arsenic is most important factor for cancer risk. However, there is the lack of occurrence data and a validated interlaboratory analytical method for inorganic arsenic at this time, which suggests that this would be premature and should only be considered as a priority for future work. Currently available data suggest that the frequency of occurrence and levels of inorganic arsenic in rice are generally lower than for total arsenic and consequently, it may be considered that exposure to the inorganic arsenic would be controlled through the establishment of MLs for total arsenic.

69.   In elaborating MLs for rice and rice product (e.g. rice milk), the possibility of considering the occurrence data for raw commodities and appropriate processing factors was considered. However, given the wide variety of rice-based foods consumed, the differences in water arsenic level, food processing and preparation methods employed worldwide and the variability in the results of studies examining processing factors, such an approach is not currently feasible. Although many countries have set limits of arsenic in food including rice and rice-based products, the bases on which they were established are not known. More information on arsenic bioavailability and speciation data for different food is needed for improving exposure estimation and ultimately risk assessment which can be used as the basis of appropriate MLs for arsenic in foods, including rice. While setting a ML for inorganic arsenic in rice at this time is limited due to the lack of occurrence data and a validated interlaboratory analytical method, setting a ML for total arsenic in rice seems more reasonable.

70.   In elaborating MLs, the Committee should consider the following principle stipulated in the third, fourth and eighth indents of *the establishment of Maximum Levels* in Annex I of the GSCTFF.

- "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. Where possible, MLs should be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable and necessary to protect the consumer. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and significant economic aspects are at stake.

- 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. When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough.

- 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."

71. In light of the principles mentioned above, the Committee should collect the following data prior to elaboration ML in rice:

- natural occurrence data from more countries and sources since arsenic concentration in rice may be higher not only under flooded condition but also in rice grown on acidic soil;

- Analytical methods for inorganic arsenic in rice being routinely used by Codex members;

- Information for prioritizing the target chemical species for risk management because arsenic forms can be present in a variety of chemical forms with greatly varying toxicity; and

- Measures to control arsenic in rice being developed or already in use by Codex members.

72. The CCCF could consider the following MLs options, which have been proposed based on a review of mean occurrence levels (rather than a review of complete data sets, which were not available) and of current nationally enforced MLs:

a) Total arsenic in rice: 1 mg/kg or less

b) Inorganic arsenic in rice: 0.2 mg/kg as China does

c) Inorganic arsenic in rice-based foods for infants (up to 12 months) and young children (12 to 36 months): 0.2 mg/kg

73. Setting and implementing a 1 mg/kg maximum level of total arsenic in rice, in conjunction with good agricultural practices such as not using arsenic contaminated water for irrigation or grown rice aerobically, should contribute to the reduction of mean and higher percentile arsenic exposure levels by preventing the marketing of highly contaminated rice grains for food uses. Harmonised maximum levels for unprocessed rice would provide clear guidance and transparency for international trade. However based on the form and manner (i.e., aggregate data rather than distributions) in which the occurrence data was available, the working group could not assess worldwide the percentage of rice that would exceed the proposed MLs.

74. Setting and implementing a 0.2 mg/kg maximum level of inorganic arsenic in rice, should be open to discuss. The previous PTWI of 15 µg/kg bw have been withdrawal by the JECFA in 2010 due to approach

to $BMDL_{0.5}$. If default value of the previous PTWI will be used and assuming the body weight as 60kg, the daily exposure is about the 115µg inorganic arsenic. And the exposure from drinking water will be 15µg inorganic based on the WHO guideline and not considered the many areas exceed the 0.01mg/L ML in drinking water. Half of daily exposure from food is about 50µg inorganic arsenic. When considering 250 g of rice consumption, the 0.2 mg/kg from China ML for inorganic arsenic, will cost all remaining exposure minus that from drinking water and another half daily exposure from food. Data from China, US and some other countries support that the maximum value does not exceed 0.15µg/Kg inorganic arsenic in rice, except the contaminated soil and irrigated water. However, even on uncontaminated soil, inorganic arsenic concentrations in husked rice grown in Japan indicated that over 10% of the samples contained inorganic arsenic higher than 0.2 mg/kg. The data from Japan indicate that the draft ML of 0.2 mg/kg for inorganic arsenic in husked rice is unlikely to be achievable. The data need to be collected from husked and polished rice.

75.   Rather than consider MLs at this time, the CCCF may consider that further collection of data is necessary and that further examination of available and additional data is necessary before inorganic arsenic MLs are elaborated, in which case, it would be recommended that:

- Codex member states continue to monitor, or implement monitoring of, arsenic and its species form, particular in total and inorganic occurrence in rice and rice-base foods to provide a more complete picture of seasonal and regional differences. There is need for validated methods for selective extraction and determination of inorganic arsenic in food matrices and for certified reference materials, based on the JECFA recommendations.

- Member states should continue to be encouraged to submit complete data sets that include individual sample results rather than only aggregate data.

- The CCCF consider requesting that an assessment of the impact on dietary exposures of different MLs be undertaken by JECFA.

- The CCCF consider requesting that distribution curves be generated by JECFA for the total and inorganic arsenic levels in rice and foods derived from rice to evaluate the potential impact of proposed MLs on the availability of these staple foods and to permit consideration of whether MLs could be established based on the lowest achievable levels of total and inorganic arsenic on a global basis.

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