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Part 2 – Risk Assessment

Inorganic Arsenic in Rice and Rice Products on the Swedish Market 2015

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Contents

Definitions and abbreviations

AF	Assessment factor
BMD	Benchmark dose - the dose that corresponds to a specified effect/risk level. BMD is calculated by fitting a dose-response model to data; on the basis of the fitted model, the dose that gives a defined effect/risk increase can be obtained.
BMDL	Lower 95 per cent confidence limit on the benchmark dose. BMDL measures uncertainty in BMD. BMDL represents the starting point for establishing the tolerable daily intake (TDI)
Efsa	European Food Safety Authority
EU	European Union
IARC	International Agency for Research on Cancer (France)
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MOE	Margin of exposure - the margin between the dose that caused a ten per cent increase in tumour frequency in animals and the dose that humans are normally exposed to
NNR	Nordiska näringsrekommendationer (Nordic nutrition recommendations)
NRC	National Research Council (USA)
RP	Reference Point
SAMOE	Severity-adjusted margin of exposure
TDI	Tolerable daily intake - the highest quantity of a substance that a person can consume each day throughout a lifetime without a appreciable health risk
WHO	World Health Organization
Whole grain rice	Equivalent to brown rice or husked rice, in Swedish “Fullkornsris”

Preface

The Swedish National Food Agency works in the interests of the consumer for safe food, good drinking water, fair practices in the food trade and good eating habits.

The European Food Safety Authority (Efsa) has assessed along with many other international authorities, that arsenic is a substance that should be avoided as much as possible. The Swedish National Food Agency has been working for many years mapping the sources of consumers' consumption of arsenic. Rice and rice products represent one third of the total exposure to arsenic in Sweden.

In 2013, the Swedish National Food Agency investigated the arsenic content in a selection of products intended for children. The results of the investigation also led to several companies subsequently working to reduce the arsenic content in their products. This project is part of the Swedish National Food Agency's work to map the occurrence of arsenic in various foods and to investigate the intake of arsenic from various types of food. It is also part of work on a more long-term objective, to induce rice producers to work more actively to ensure that the rice raw material has a lower arsenic content and in this way reduce consumers' intake of arsenic.

With effect from 1 January 2016, maximum levels are being introduced for inorganic arsenic in rice and certain rice products within the European Union (EU) and in the longer term also globally (CODEX Alimentarus[1]). As a result of the maximum levels being introduced, it will be possible to take control measures for inorganic arsenic in rice and rice products. Since 2014, the Swedish National Food Agency has been accredited for analysing inorganic arsenic in foods and will perform such testing. The analytical method (prEN16802) will become the European standard for analysis of inorganic arsenic in 2016. The European Commission is also encouraging its member states to collect as much data as possible during 2015 and 2016 on arsenic in all types of food, including foods where there is no stated maximum level. The purpose is to better be able to assess the risks of arsenic in various foods in the EU's inner market and to be able to set relevant maximum levels for arsenic.

The occurrence of arsenic in food is due to both natural causes and human activity, such as mining. Arsenic is an element that occurs naturally in various concen-

[1] Codex Alimentarus is an international organisation that was created in 1963 by the UN bodies FAO and WHO for the purpose of producing international standards for safe foods, integrity in food handling and free trade in foods.

trations in bed-rock and sediments. In areas with minerals that contain arsenic, the arsenic can be dissolved out into the surrounding ground water and in this way become available to plants, animals and people.

Arsenic is found in many different chemical compounds and these are normally divided into two main groups: organic and inorganic arsenic. The inorganic form is carcinogenic and is considered to be the more toxic form for humans. A food may contain both forms at the same time. Ground water that contains arsenic contains mainly the inorganic form, while the organic form of arsenic dominates in marine fish and shellfish. Rice is one of the foods that contains the highest amount of inorganic arsenic, as well as some organic arsenic.

This investigation intends to answer the questions:

- How much inorganic arsenic is found in the rice and rice products that are available on the market in Sweden?
- What is the average intake of inorganic arsenic in children and adults?
- Is there a risk that people with coeliac disease have a higher intake of inorganic arsenic, since replacement products are often based on rice?
- Is the content of inorganic arsenic in rice dependent on how the rice is prepared before consumption?
- Are the new maximum levels for inorganic arsenic in rice at the right levels, i.e. do they adequately protect consumers to a too high inorganic arsenic exposure?
- Does the Swedish National Food Agency need to give advice about the consumption of rice and rice products, and if so what?

This report, the Swedish National Food Agency's report serial number 16/2015 *Inorganic Arsenic in Rice and Rice Products on the Swedish Market 2015,* consists of three parts.

- *A Survey of Inorganic Arsenic in Rice and Rice Products: Part1,* reports on the content of inorganic arsenic that is found in rice and rice products on the Swedish market. This section of the report also describes how the preparation of rice can affect the inorganic arsenic content.
- *Risk Assessment: Part 2* describes the risks that inorganic arsenic can lead to, with the aid of scenario analyses and with the application of the Swedish National Food Agency's so-called Risk Thermometer.

Based on the two scientific sub-reports concerning the survey and risk assessment, as well as on other scientific literature, consideration was then given as to whether, and which, measures could be taken to reduce consumers' intake of inorganic arsenic. Other relevant factors have also been included in this assessment, for example whether it is possible for consumers to follow a given advice about consumption of rice and rice products, how such advice may be perceived, how it can be applied by the target groups, what opportunities exist for testing and whether the consequence of a measure is in proportion to the risk and benefit of a specific food.

- *Risk Management: Part 3* reports on the considerations and assessments that resulted in the measures that the Swedish National Food Agency considers to be justified in order to manage the occurrence of inorganic arsenic in rice and rice products and to reduce exposure to inorganic arsenic in both the short and long term.

The purpose of the report is to clearly show the Swedish National Food Agency's reasons for the measures that have been decided upon.

Swedish National Food Agency, 25 September 2015

Thanks to

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Toxicologist Celia Fischer for valuable assistance in calculating arsenic exposure.

Summary

The greater part of exposure to inorganic arsenic in Sweden occurs via certain foods. The Swedish National Food Agency's survey shows that rice is the greatest single exposure source for inorganic arsenic (27-31 per cent) for the population of Sweden. The median exposure per kilo body weight per day from foods, including rice, is estimated to be approximately 0.07 µg for adults, 0.10 µg for 11/12 year-olds, 0.13 µg for 8/9 year-olds and 0.18 µg for 4 year-olds.

The Swedish National Food Agency's so-called "Risk Thermometer" has been used to evaluate the risks. The risk thermometer has five different risk classes and the estimated exposure to arsenic in food classify, generally speaking, in risk class 3. For children, and especially young children, the exposure is close to or above the limit of what is generally acceptable from a health perspective. The acceptable arsenic exposure is regarded to be approximately 0.15 µg per kilo body weight per day, of which 0.045 µg per kilo body weight per day, or 30 per cent, comes from rice.

For adults, average consumption of rice does not involve any increased health risk. It cannot be excluded, however, that for part of the adult population arsenic exposure from food may be higher than desirable.

Hazard identification

Arsenic is an element that occurs naturally in various concentrations in bed-rock and sediments. In areas with minerals that contain arsenic the arsenic can be dissolved into the ground water. Arsenic represents a global problem because of contamination of water, soil and food.

Arsenic occurs in two main forms: organic and inorganic. Ground water contains mainly inorganic arsenic, which is the most toxic form to humans. The inorganic form occurs mainly as trivalent (arsenite) and pentavalent (arsenate), which is significant for acute toxicity and absorption by plants, for example. Generally speaking, trivalent arsenic compounds are more reactive and have higher toxicity. Some foods, notably fish and shellfish, can contain very high levels of arsenic in the form of organic compounds such as arsenobetaine and arsenosugars, which are not considered to represent health risks. In the data register of the European Food Safety Authority (Efsa), however, 98 per cent of the reported values are for total content of arsenic in food (EFSA 2014).

Ground water that is contaminated with arsenic is used in many countries for irrigation of crops, including grain and root and leaf vegetables. Of these crops, rice appears to be particularly susceptible to absorbing and storing high levels of arsenic (Zhu et al., 2008). Even where such water is not used, raised levels of arsenic have been demonstrated in rice (Meharg et al., 2009). Absorption of inorganic arsenic from rice in the gastrointestinal tract is as high as from drinking water, over 90 per cent (Zheng et al., 2002; Brandon et al, 2014).

Exposure assessment

Material and method

In spring and autumn 2003, the Swedish National Food Agency performed a dietary survey on children. The children recruited from 56 municipalities were a representative selection of Sweden's municipalities. The survey included 590 4 year-olds, 889 school children in the second year (8/9 years old) and 1,016 in the fifth year (11/12 years old). Each child kept a food diary to list all consumption of food and drink over a period of four consecutive days. The Swedish National Food Agency's national food survey Riksmaten 2010-11 offered a representative selection of 5,000 people aged 18-80 and resident in Sweden the chance to participate in a survey that was conducted between May 2010 and July 2011. The participants, a total of 1,797 people, recorded everything they ate and drank for four days in a web-based diet record and answered about fifty questions in a questionnaire.

Portion sizes

Portion sizes were estimated with the aid of the Food Template, a leaflet with drawn illustrations of foods and photographs of portion sizes, as well as portion sizes in baby food jars.

Levels of arsenic in food

Levels of arsenic in foods have been determined by the Swedish National Food Agency and these are reported in *Part 1 A Survey of Inorganic Arsenic in Rice and Rice Products*. The average levels used for exposure estimates are given below in Table 1. The division of foods in Table 1 is based on designations that were used in the Swedish National Food Agency's surveys Riksmaten 2010-11 and Matkorgen 2010 (Food Basket 2010).

Exposure

Exposure estimates have been performed for that part of the population that consumes rice and rice products. In the Swedish National Food Agency's food habits surveys, approximately half the individuals reported some level of rice consumption. (Amcoff et al., 2012; Enghardt Barbieri et al., 2006). Thus these data represent the basis for risk assessment for the group of individuals in Sweden who consume rice.

Exposure to inorganic arsenic has been calculated per day as well as per kilo body weight per day. In the calculation, individual weights have been used for adults and children. The average weights used in calculation of various scenarios are: 74 kg for adults, 42 kg for 11/12 year-olds, 31 kg for 8/9 year-olds and 18 kg for 4 year-olds. For 2 year and 8 month old children, average weights were used from a study performed by Niklasson and Albertsson-Wickland, 2008: 12.8 kg and 8.5 kg respectively.

Results and discussion

The exposure estimates are based on a total of 1,377 children and 745 adults. 2,495 children of various ages and 1,797 adults took part in the dietary surveys, but not all reported consumption of rice. It total, 64 per cent of the children and 46 per cent of the adults stated that they ate rice during the survey periods. Levels of inorganic arsenic in different food categories are reported in Table 1. The highest reported arsenic level is for rice, while the lowest level was found in the "Soft drinks" food group. Among the rice types, the average level is highest for whole grain rice.

Table 1. Foods and average levels of inorganic arsenic that represent the basis for calculating exposure to inorganic arsenic.

Food group	Inorganic arsenic µg/kg[a]	Year of sampling	Reference /description
Cereals *(flour, cakes, breakfast cereals, pasta, bread)*	10.6	2010	The Swedish National Food Agency's Food Market basket 2010 project - content analyses 2014 of homogenates of each food group
Bakery *(cakes, buns, pizza, biscuits)*	1.5		
Meat *(including meat products, beef, lamb, chicken, processed meat)*	1		
Fish *(including fish products, fresh and frozen, fish in cans, shellfish)*	13.4		
Dairy *(milk, yoghurt, cheese, cream, cottage cheese)*	0.7		
Egg *(fresh eggs)*	1		
Cooking fat *(butter, margarine, mayonnaise, cooking oil)*	1		
Vegetables *(root vegetables, fresh, frozen, canned)*	1.4		
Fruit *(fresh, frozen, canned, juice, squash, nuts)*	2.6		
Potatoes *(fresh, mashed potato powder, French fries, crisps)*	1.2		
Sugar and similar *(granulated, honey, sweets, ketchup, ice cream, sauces, dressing)*	4.6		
Soft drinks *(soft drinks, mineral water, beer)*	0.6		
Rice, cooked[b]	-	2015	content analyses 2015 of specific foods
Basmati rice, n=17	20.9		
Jasmine rice, n=18	22.8		
Long grain, parboiled[c], n=7	28.9		
Raw rice, whole grain, long grain, n=7	40.9		
Wild rice, n=1	36.7		
Glass noodles, rice noodles, n=3	23.3		
Rice dishes	28.4[d]		
Persian rice	28.4[d]		
Glass noodles, cooked with salt	28.4[d]		

[a] Note: In calculating average levels, levels below the limit of detection (LOD) have been set at LOD/2. For more detailed information about levels, see *Part 1 A Survey of Inorganic Arsenic in Rice and Rice Products.*
[b]Subgroups of "Rice" refer to consumption according to Riksmaten 2010-11 and Riskmaten 2003. Stated average levels correspond to a third of the results for dry rice (100g of dry rice corresponds to approximately 300g of cooked rice).
[c]Parboiled = steam-treated rice
[d]These rice types were not analysed in *Part 1* but since consumption data exists, these levels have been estimated using a weighted average value for basmati rice, jasmine rice, parboiled rice and whole grain rice (n = 49)

The total intake of inorganic arsenic from all foods is presented in Table 2. The median intake of inorganic arsenic per kg body weight was higher in children than in adults. The median intake of inorganic arsenic per kilo body weight per day was lower in 11/12 year-olds than in 4 and 8/9 year-olds. The median intake among 4 and 8/9 year-olds was 0.134 – 0.181 µg per kilo body weight per day, while the 95th percentile varied between 0.210 and 0.265 µg per kilo body weight per day (Table 2). Among 11 year-olds, the median intake of inorganic arsenic was 0.099 µg per kilo body weight per day and the 95th percentile was 0.160 µg per kilo body weight per day. Among adults, no difference was observed between women and men.

Table 2. Total exposure to inorganic arsenic from food for the part of the population that consumes rice/rice products.

	µg per day	**µg per kg body weight per day**
Adults (N = 745)		
Average	4.9	0.068
Median	4.7	0.065
P95	7.7	0.109
Women (N = 449)		
Average	4.5	0.068
Median	4.4	0.065
P95	6.7	0.108
Men (N = 296)		
Average	5.6	0.068
Median	5.3	0.066
P95	8.6	0.111
4 year-olds (N = 337)		
Average	3.4	0.185
Median	3.3	0.181
P95	4.9	0.265
8/9 year-olds (N = 476)		
Average	4.2	0.138
Median	4.0	0.134
P95	6.3	0.210
11/12 year-olds (N = 564)		
Average	4.2	0.102
Median	4.1	0.099
P95	6.2	0.160

4 year-olds had a higher average daily inorganic arsenic intake than 8/9 and 11/12 year-olds counted per person. For both children and adults, the intake of inorganic arsenic from rice was higher than from other food groups. The intake of inorganic arsenic from all foods decreases with age (Table 3).

Among adults and children, rice represented the largest exposure source for inorganic arsenic (27 - 31 per cent of the total intake of inorganic arsenic), followed by the Cereals food group, which included among other things flour, cakes, breakfast cereals, pasta and bread (Figure 1). According to Table 4, rice is normally consumed about 2-3 times a week and 5-7 times a week corresponds to high consumption.

Table 3. Exposure to inorganic arsenic from each food group (µg per kilo body weight per day) for the part of the population that consumes rice/rice products.

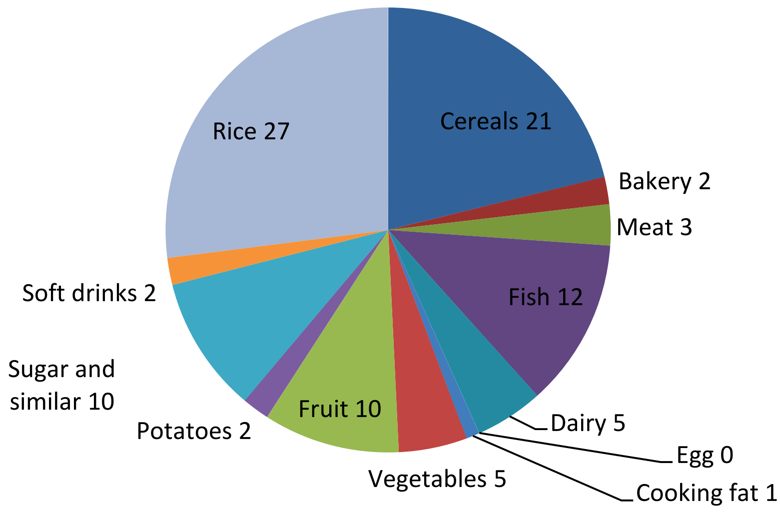
Group	Adults			4 year-olds			8/9 year-olds			11/12 year-olds		
	Average	Median	P95	Average	Median	P95	Average	Median	P95	Average	Median	P95
Cereals	0.015	0.013	0.031	0.038	0.037	0.072	0.030	0.027	0.058	0.022	0.020	0.045
Bakery	0.001	0.001	0.005	0.003	0.002	0.007	0.002	0.002	0.006	0.002	0.001	0.005
Meat	0.002	0.002	0.004	0.006	0.005	0.010	0.005	0.004	0.009	0.003	0.003	0.006
Fish	0.008	0.006	0.025	0.013	0.011	0.027	0.011	0.009	0.023	0.009	0.007	0.021
Dairy	0.003	0.003	0.007	0.016	0.015	0.030	0.012	0.011	0.022	0.008	0.007	0.016
Egg	0.000	0.000	0.001	0.000	0.000	0.002	0.000	0.000	0.001	0.000	0.000	0.001
Cooking fat	0.000	0.000	0.001	0.001	0.001	0.002	0.000	0.000	0.001	0.000	0.000	0.001
Vegeta-bles	0.004	0.003	0.007	0.004	0.003	0.010	0.003	0.003	0.009	0.002	0.001	0.005
Fruit	0.007	0.006	0.015	0.028	0.026	0.054	0.015	0.014	0.032	0.008	0.007	0.020
Potatoes	0.001	0.001	0.004	0.005	0.005	0.011	0.004	0.004	0.010	0.003	0.003	0.007
Sugar and simi-lar	0.006	0.006	0.014	0.016	0.014	0.033	0.010	0.009	0.025	0.007	0.006	0.017
Soft drinks	0.001	0.001	0.004	0.002	0.001	0.008	0.002	0.002	0.007	0.002	0.002	0.006
Rice	0.019	0.015	0.042	0.053	0.045	0.122	0.042	0.035	0.104	0.036	0.029	0.084

Table 4. Rice consumption and corresponding number of portions per week

Consumer group	Rice consumption (g/day)		portions size[a] (g)	Number of portions a week	
	median	P95		median consumer	high consumer
4 year-olds	29	81	91	2-3	6-7
8/9 year-olds	38	113	117	2-3	6-7
11/12 year-olds	42	119	143	2	5-6
adults	44	114	147	2	5-6

[a]Estimated portion size for rice (basmati rice, whole grain rice, parboiled rice, jasmine rice), see Table 10.

Adults



Children

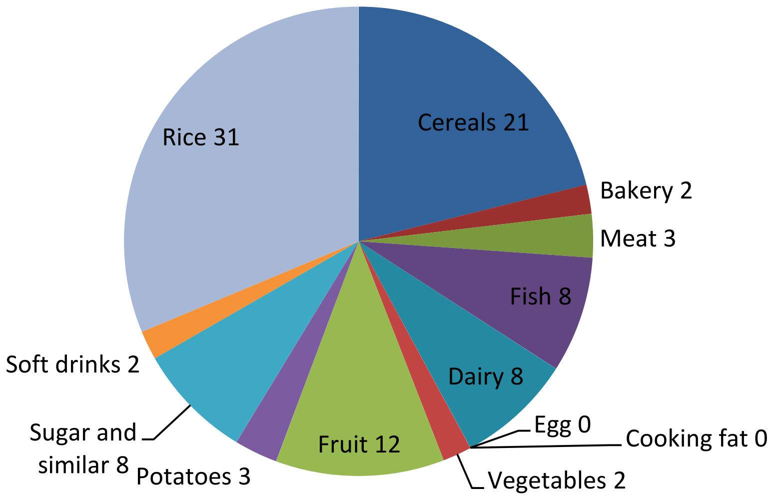


Figure 1. Percentage contribution to total inorganic arsenic exposure from various foods for adults and children (based on average intake of inorganic arsenic from each food). The Cereals food group includes flour, cakes, breakfast cereals, pasta and bread.

Efsa has made intake calculations for inorganic arsenic via the diet (Efsa 2014). In the European population (adults and children) it was found that grain-based products (not rice-based) gave the largest contribution (15-18 per cent) to total arsenic exposure via the diet. The next food group was dairy products, which contributed 8-15 per cent of the total arsenic intake. If we look at individual foods, however, it should be noted that the largest contribution came from rice, which is estimated to contribute 8-11 per cent.

Hazard characterisation

Inorganic arsenic is a human carcinogen and after many years' exposure can lead to tumours in the skin, lungs, bladder and kidneys (IARC 2004, 2012). There have also been reports of an association between arsenic exposure and peripheral vascular damage, liver damage and diabetes (NRC 2001, WHO 2001, 2004). These effects have mainly been studied in adult individuals. Arsenic is easily transferred to the foetus (Concha et al., 1998), but very little is excreted in breast milk (Fängström et al., 2008). Epidemiological studies indicate that children can be more sensitive to arsenic than adults. Exposure to relatively low levels of arsenic in drinking water (<50 µg/L) has been shown to increase the risk of foetal and infant mortality (Rahman et al., 2007), reduced foetal weight (Rahman et al., 2009), and effects on the child's cognitive development in the form of reduced verbal abilities and intelligence (Tyler & Allan, 2014). It also appears that exposure in early life or as a foetus can increase the risk of developing lung or bladder cancer later in life (Steinmaus et al., 2014).

Inorganic arsenic is metabolised in the body through methylation to methylarsonic acid (MMA) and dimethylarsinic acid (DMA). These metabolites are excreted in the urine. While the dimethylated metabolite can be considered a detoxification mechanism, the proportion of the monomethylated form has been associated with an increased risk of adverse health effects (Vahter 2009). There are large variations in the metabolism of arsenic at individual and population levels, which is partly genetic (Engström 2011). The World Health Organization (WHO) has classified arsenic as a human carcinogen (IARC 2004; IARC 2012). The risk of cancer from long-term exposure to drinking water containing 10 µg arsenic per litre has been estimated as approximately three cases of lung or bladder cancer per 1000 individuals (NRC 2001). This estimation greatly exceeds the tolerable limit of one extra case of cancer per 100,000 individuals, , which is normally considered "acceptable" when setting health-based guidance values.

Efsa has established a health-based reference value ($BMDL_{01}$) for inorganic arsenic (EFSA 2009). The $BMDL_{01}$ is the lower confidence limit for the dose that corresponds to a risk increase of 1 per cent (i.e. 1 case in 100 persons). Efsa presents the reference value as a range from 0.3 to 8 µg per kilo body weight per day. This range reflects how the result depends on choice of study, critical health effect (cancer in lungs, skin and bladder or skin changes) and the assumption of what proportion of the exposure comes from water and other foods respectively. The Joint FAO/WHO Expert Committee on Food Additives (Jecfa) later established a $BMDL_{0.5}$ of 3.0 µg per kilo body weight per day for lung cancer (FAO/ WHO 2011). $BMDL_{0.5}$ is the lower confidence limit for the dose that corresponds to a risk increase of 0.5 per cent (i.e. 1 case in 200 persons), for lung cancer in this case.

Jefca's main reference point ($BMDL_{0.5}$) of 3.0 µg per kilo body weight per day refers to cancer (lung cancer) specifically, while Efsa's range of reference points also includes skin lesions (Efsa 2009). Jecfa's assessment has taken Efsa among others into account (2009). Jecfa's final assessment, however, is based on newer data from Chen et al. (2010a) which was not available for Efsa's assessment: Chen et al. (2010a) reports results from a (prospective) cohort study of 6,888 individuals from north east Taiwan aged 40 or more (and the follow-up period was about 12 years). The Swedish National Food Agency has used the health-based reference value that Jecfa produced specifically for lung cancer, since 1) it is based on a newer evaluation and data base (FAO/WHO 2011) and 2) skin changes (pigment changes and hyperkeratosis, i.e. the stratum corneum thickens, especially on the palms and soles of the feet) that are covered in Efsa's range of reference points (Efsa 2009) are considered to be a less serious effect than cancer. Jecfa also made an assessment for cancer of the bladder (data from Chen et al. 2010b) which gave higher BMD and BMDL values than those for lung cancer.

Jefca's analysis evaluated data using several different models that describe the connection between arsenic exposure and cancer risk. A $BMDL_{0.5}$ value of 3.0 µg per kilo body weight per day corresponded to the result of the most conservative model (quantal linear), i.e. the model that gave the lowest BMD value. Note that available epidemiological data describes how the content of arsenic in drinking water correlates with cancer risk. In order to determine how the risk relates to the actual intake of arsenic from food, an assessment must be made of how much water the studied population consumes directly and indirectly (when making food) and how much arsenic they are exposed to from other foods. Jecfa also made an analysis of how the BMD and BMDL value depends on these assumptions/ assessments. This is reported in Table 5 with regard to the most conservative model (quantal linear). Based on the data in Table 5, a $BMD_{0.5}$ of 4.5 µg per kilo body weight per day and a BMDL of 30 µg per kilo body weight per day were selected since the results of analyses of the significance of different assumptions did not greatly differ.

Table 5. BMD values for inorganic arsenic with regard to lung cancer given various scenarios for intake via food and consumption of water

Arsenic exposure via food (µg/day)[a]	Water consumption (litres per day)	$BMD_{0.5}$ (µg/kg body weight per day)[b]	$BMDL_{0.5}$ (µg/kg body weight per day)[b]
75	3	4.5	3.0
50	4	3.0	2.0
50	2	3.0	2.0
200	2	6.1	4.0
200	4	6.1	4.0

[a] Jecfa (FAO/WHO 2011) converted data on content of arsenic in drinking water to intake of arsenic via food. As a starting point, average exposure of 75 µg per day from food and direct and indirect consumption of 3 litres of water per day and an assumed body weight of 55 kg were identified. The sensitivity of these results was assessed by assuming arsenic exposure from food of between 50 and 200 µg per day and direct and indirect water consumption of 2 to 4 litres per day. Estimated intake via food and data on corresponding risks of lung cancer are used in the modelling and calculation of BMDs and BMDLs for each scenario.

[b] BMD and BMDL for the most conservative model (quantal linear), i.e. the model that gave the lowest BMD values. For this model, the results did not significantly differ between different scenarios. A BMD and BMDL of 4.5 and 3.0 respectively are used as a basis for this risk assessment.

Risk characterisation

Method

The Swedish National Food Agency has developed a new tool for risk characterisation that is called the "Risk Thermometer" (Sand et al 2015). The risk thermometer is based on the traditional principle for risk characterisation where the estimated exposure to a substance in food is compared with the substance's health-based reference value, such as health-based reference point (RP) or tolerable daily intake (TDI). The difference between the RP or TDI, and the exposure is often called the margin of exposure (MOE). The RP or TDI is based on the critical health effect that the risk assessment is based on. The methodology in the risk thermometer is different in that the severity of the critical health effect is also considered in a systematic manner, i.e. cancer is judged to be more serious than skin lesions, for example. The underlying risk characterisation measure in the risk thermometer is therefore called the severity-adjusted margin of exposure (SAMOE):

$$SAMOE = \frac{RP}{AF_{BMR} \times AF \times SF \times E} \quad (1)$$

- RP (health-based reference point): May be a BMD, NOAEL (no observed adverse effect level) or a LOAEL (lowest observed adverse effect level). The BMD_{10} represents the standard in the risk thermometer, i.e. a reference point that corresponds to a 10 per cent increase in risk or effect. The BMD_{10} is the RP that is normally used. However, the reference point established by Jecfa arsenic corresponds to a risk increase of 0.5 per cent ($BMD_{0.5}$ = 4.5 µg per kilo body weight per day and $BMDL_{0.5}$ = 3.0 µg per kilo body weight per day). This is accounted for in the risk thermometer by application of an extrapolation factor for response adjustment, AF_{BMR} (see equation 1). This is a generalisation of the principle in traditional risk assessment of using an extra factor for extrapolation from a LOAEL to a NOAEL. Extrapolation upward by a factor of 20 (AF_{BMR} = 1/20) imply linear extrapolation from $BMD_{0.5}$ to BMD_{10}. Half this factor is instead used in this assessment, i.e., a factor of 10 (AF_{BMR} = 1/10), in order to take into account any non-linear relationship in the dose range in question (that is to say that a substance's effect is not linearly dose dependent in the range $BMD_{0.5}$ - BMD_{10}). Illustrations of data in Jecfa (2011) indicate that the relationship between dose and risk is not necessarily linear all the way from $BMD_{0.5}$ to BMD_{10}. A factor of 10 gives a somewhat more conservative assessment than a factor of 20.

- AF ("assessment factors"): An AF = 100 is used as standard: a factor of 10 for extrapolation between animals and humans and a factor of 10 to take into consideration sensitive individuals. Since the BMD in the case of arsenic is based on human data, the Swedish National Food Agency considers a factor of 10 for extrapolation between animals and humans to be unnecessary, which gives a total AF = 10.

- SF (severity factor): SF describes the severity of the critical health effect (cancer in the case of arsenic). This parameter distinguishes the SAMOE from a traditional MOE. The value of the SF may be 1, 3,16, 10, 31,6 or 100. A health effect classification scheme has been developed as a basis for determining the value of SF (Sand et al., 2015, Table 3). Cancer is in the most severe category with SF=100 (note that skin lesions, which are also considered in Efsa's range of reference points (Efsa 2009) are considered to have an SF=10). An SF of 100 corresponds to the extra factor suggested by Efsa (2005) in order to take into account the nature of the health effect in the specific case of substances that are both genotoxic and carcinogenic. For substances of this type, the principle upon which the risk thermometer is based (i.e. systematically using a factor to take into consideration the severity of the critical health effect) thus agrees with Efsa (2005). Both Efsa (2009) and Jecfa (FAO/WHO 2011) discuss that arsenic is not directly DNA reactive, which could be a reason for a threshold dose for arsenic. However, because of uncertainty with regard to the shape of the dose-response curve, Efsa decided that it was not appropriate to establish a TDI, which is traditionally done when the critical health effect has a threshold dose after which the effects arise. Also, Jecfa removed its provisional tolerable weekly intake (PTWI) of 15 µg per kilo body weight per week for arsenic as a consequence of the new analysis. In a quantitative risk assessment perspective, both Efsa and Jefca seemingly treat arsenic in a way that is similar to that for substances that are both carcinogenic and genotoxic.

- E (exposure): Various scenarios for arsenic exposure have been used in this assessment, corresponding to the median and 95th percentile for adult individuals, 11/12 year-olds, 8/9 year-olds and 4 year-olds (Tables 2 and 3).

In the risk thermometer, the SAMOE value is classified in one of five risk classes. These risk classes describe different levels of health concern (Table 6). Exposure that are categorised in risk classes 1 and 2 are not regarded to represent a health risk in a long-term perspective. Risk class 3, in the middle of the scale, is currently regarded to represent a grey zone in a health perspective. Exposure that are categorised in risk classes 4 and 5 are, however, regarded to represent a potential health risk.

There is uncertainty with regard to all parameters that define SAMOE (RP, AF, AF_{BMR}, SF, and E; see SAMOE equation 1). This is also taken into account in the risk thermometer, so that a uncertainty interval for the SAMOE is also established, depending on the uncertainties in the input parameters. Detailed information about all parts of the methodology upon which the risk thermometer is based may be found in the Swedish National Food Agency's report number 8 (Sand et al., 2015).

Table 6. Relationship between the risk thermometer (SAMOE, risk class and the level of health concern) and traditional risk assessment metrics (columns marked grey) in the case of arsenic.

SAMOE	Risk class	Concern level	MOE ($BMD_{0.5}$/exposure)	Risk[a] Linearly extrapolated from $BMD_{0.5}$ = 4.5
< 0.01	class 5	high	< 1	> 5 out of 1,000
0.01 – 0.1	class 4	moderate-to-high	1 - 10	5 out of 1,000 to 5 out of 10,000
0.1 – 1	class 3	low-to-moderate	10 - 100	5 out of 10,000 to 5 out of 100,000
1 - 10	class 2	no-to-low	100 - 1,000	5 out of 100,000 to 5 out of 1,000,000
> 10	class 1	no	> 1,000	< 5 out of 1,000,000

[a]Comparison with the cancer risk estimates that are traditionally made, for example, by the United States Environmental Protection Agency (EPA) for genotoxic carcinogens. When MOE = 1 exposure = $BMD_{0.5}$ which corresponds to 5 cases in 1,000 individuals. With linear extrapolation a line is drawn in this case between $BMD_{0.5}$ and the background risk. The risk according to this line can then be calculated for an exposure between 0 and $BMD_{0.5}$ according to the equation risk = exposure x 0.005/$BMD_{0.5}$. For each lowering of the exposure by a factor of 10, the risk is reduced in the same way, i.e. by a factor of 10. Note that the results of linear extrapolation may depend on which BMD or BMDL represents the starting point. $BMD_{0.5}$ has been chosen here because FAO/WHO (2011) successfully calculated such a low BMD; a lower starting point means less (shorter) extrapolation to the desired low dose level. Note that risks calculated by linear extrapolation does not necessarily give a good measurement (or point estimate) of the real risk. Rather, these measurements should be considered as upper limits for possible risk. EPA's target range for cancer risk assessment is 1 case in 10,000 to 1 case in 1,000,000 (EPA 2005).

Results: assessment of estimated exposure

Median exposure

According to Table 7, the median exposure to arsenic exclusively from rice is in risk class 2 for adult individuals and for 11/12 and 8/9 year-old children. For 8/9 year-olds, however, there is high uncertainty in this classification in the upward direction (i.e. towards risk class 3). The median exposure for 4 year-olds is in risk class 3, but the uncertainty in this classification is high in a downward direction (i.e. towards risk class 2). When exposure from foods other than rice is also taken into consideration, the median arsenic exposure is in risk class 3 for all consumer groups. Uncertainty in this classification is low in an upward direction (i.e. towards risk class 4).

High exposure

Arsenic exposure from rice and rice products corresponding to the 95th percentile is in risk class 2 for adults and risk class 3 for children (Table 8). The uncertainty in the classification is high in an upward direction (towards risk class 3) for adults and low in an upward direction (towards risk class 4) for children. When exposure from foods other than rice is also taken into consideration, the 95th percentile for arsenic exposure is consistently in risk class 3 for all groups. The uncertainty in the classification is low in an upward direction (i.e. towards risk class 4) for adults and 11/12 year-old children and moderate for 8/9 and 4 year-old children.

Interpretation of results

As mentioned, risk class 3 (the middle of the scale) is currently regarded to represent a grey zone in a health perspective. As noted in the report on the risk thermometer (Sand et al., 2015, Text box 3) it is regarded that an exposure that is close to a health-based reference value (such as tolerable daily intake, TDI) or similar will most likely classify in risk class 3. On this basis, and the fact that the risk thermometer scale is common to all chemicals/health effects, the central point of risk class 3 (which technically means a SAMOE of 0.316) is currently considered to be a reference that in a balanced manner takes into account traditional risk assessment practice where an exposure that is below the health-based reference value (such as TDI) is considered to be safe.

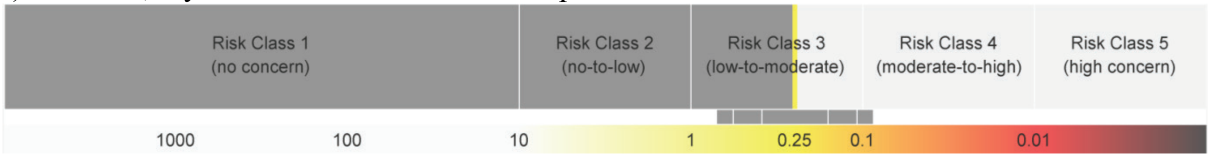
With regard to the point estimate of the SAMOE, an arsenic exposure from food (including rice) corresponding to the median and the 95th percentile for four year-old children is in the upper part of risk class 3 (SAMOE = 0.25 and 0.17 respectively, Tables 7 and 8). This is also the case for the 95th percentile for 8/9 and 11/12 year-old children (SAMOE = 0.21 and 0.28 respectively, Table 8). Other exposure situations correspond to the lower part of risk class 3 or risk class 2. It should, however, be noted that the uncertainty in the SAMOE value is approximately a factor of 8 (the ratio between the 95th and 5th confidence limits, Tables 7 and 8). The range of the estimated uncertainty interval covers a large part of risk class 3 in many cases (Figure 2).

In summary, the results show that an estimated exposure to arsenic in food is generally classified into risk class 3, and for children (especially 4 year-olds) the exposure is close to or above the limit for what is acceptable from a health perspective (Figure 2). Also, taking into account the estimated uncertainties, it cannot be excluded that arsenic exposure from food is higher than the desirable level for a small portion of the adult population. On the basis of current data it is, however, difficult to unequivocally state that arsenic exposure from food on the Swedish market represents a significant (long-term) cancer risk in practice. It should also be noted that it is the sensitive individual that represents the focus in this risk assessment, in line with traditional practice (AF = 10; see equation 1).

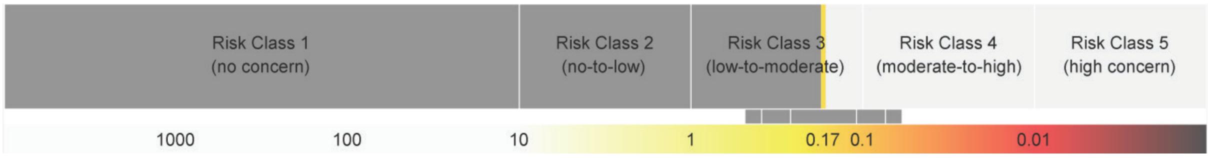
<u>Measures that could reduce arsenic levels in rice</u>

Food cooking studies by the Swedish National Food Agency indicate that the arsenic content in various types of rice can be reduced by up to 70 per cent, that is to say a factor of 3, when an excess of water is used when cooking and is then poured off (see Figure 10, *Part 1 A Survey of Inorganic Arsenic in Rice and Rice Products).* For the highest exposure group (4 year-olds) arsenic exposure corresponding to the 95th percentile is 0.122 µg per kilo body weight per day for rice and 0.265 µg per kilo body eight per day for food in total (Table 8). A reduction in exposure from rice by a factor of 3 thus gives total exposure from food (corresponding to the 95th percentile) of 0.18 µg per kilo body weight per day[(0.122/3) + (0.265 - 0,122) = 0.18]. It can be noted that an exposure of 0.18 µg per kilo body weight per day corresponds to the median for 4 year-olds that is quite centrally located in risk class 3 (Figure 2, SAMOE = 0.25). Similarly the 95th percentile for adults would approach the median that corresponds to the lower part of risk class 3 (Figure 2). This hypothetical example may overstate the effect since not all rice consumed is necessarily in the form of ordinary cooking rice, especially in the case of small children. It can, however, represent an illustration of what a change in preparation processes could achieve.

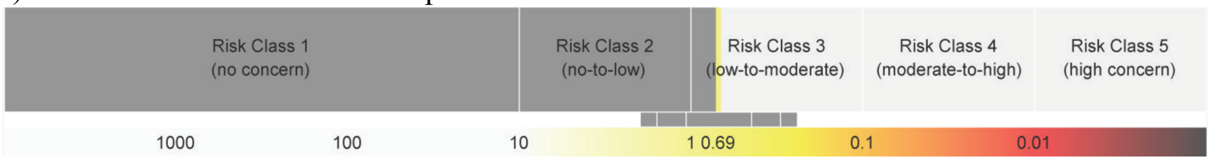
a) Children, 4 years: results for a median exposure to arsenic from food



b) Children, 4 years: results for the 95th percentile of exposure to arsenic from food



c) Adults: results for a median exposure to arsenic from food



d) Adults: results for the 95th percentile of exposure to arsenic from food

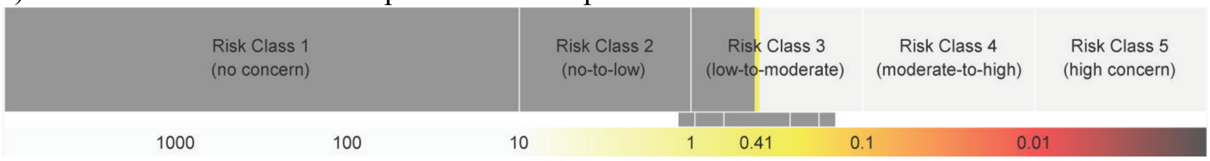


Figure 2. Results of the risk thermometer for 4 year-old children and adults who consume rice. The results for these groups correspond to the estimated extremes of arsenic exposure in each direction (see Tables 7 and 8). The wide grey bars show the size of the SAMOE value that classifies in one of five risk classes that describe different levels of health cocern. The thin grey bars show the uncertainty interval for the SAMOE value. The ends of the intervals describe the 5th and 95th confidence limit. Lines showing the 10th and 90th and the 25th and 75th confidence limits are also illustrated. For b) the 10th confidence limit overlaps to risk class 4: it is therefore assessed that there is some uncertainty in the risk classification in an upward direction. For c) the 75th confidence limit overlaps to risk class 2: it is therefore assessed that there is great uncertainty in the risk classification in a downward direction. See also the report on the risk thermometer (Sand et al., 2015, Table 5) for details regarding the assessment of uncertainty in the risk classification. The ratio between the 95th and 5th confidence limit of the SAMOE value is approximately 8: for all results, the uncertainty spans a great deal of risk class 3.

Table 7. Classification of median exposure to arsenic from rice and food (total)

Exposure scenario	**rice**	**rice**	**rice**	**rice**	**total**	**total**	**total**	**total**
Consumer group	adults	11/12 years	8/9 years	4 years	adults	11/12 years	8/9 years	4 years
Result								
Risk class[a]	2	2	2	3	3	3	3	3
Uncertainty class: UPP[b]	1	2	3	1	1	1	1	1
Uncertainty class: NER[b]	1	1	1	3	3	2	1	1
SAMOE[c]	3.0	1.6	1.3	1.0	0.69	0.45	0.34	0.25
MOE ($BMD_{0.5}$/exposure)	300	155	129	100	69	45	34	25
Input: risk classification								
Exposure[d]	0.015	0.029	0.035	0.045	0.065	0.099	0.134	0.181
$BMD_{0.5}$	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
AF_{BMR}[e]	10	10	10	10	10	10	10	10
AF inter-TK[f]	1	1	1	1	1	1	1	1
AF inter-TD[f]	1	1	1	1	1	1	1	1
AF intra-TK[f]	3.16	3.16	3.16	3.16	3.16	3.16	3.16	3.16
AF intra-TD[f]	3.16	3.16	3.16	3.16	3.16	3.16	3.16	3.16
Severity (SF)[g]	100	100	100	100	100	100	100	100
Input: uncertainty analysis								
UB for exposure	KS[h]	KS	KS	KS	KS	KS	KS	KS
LB for exposure	KS	KS	KS	KS	KS	KS	KS	KS
UB for $BMD_{0.5}$	6.75[i]	6.75	6.75	6.75	6.75	6.75	6.75	6.75
LB for $BMD_{0.5}$	3[j]	3	3	3	3	3	3	3

See Swedish National Food Agency report number 8 (Sand et al., 2015) for details of the risk thermometer.

[a] Risk class, see Table 6.

[b] Uncertainty in the risk classification, upwards (to higher risk class), or downward (to lower risk class) (Sand et al., 2015, Table 5):
1 = low uncertainty.
2 = moderate uncertainty.
3 = high uncertainty.

[c] Severity-adjusted margin of exposure (SAMOE) = $BMD_{0.5}$ / (AFs x SF x Exposure).

[d] Value for arsenic exposure from Tables 2 and 3.

[e] Factor for response adjustment, extrapolation of $BMD_{0.5}$ to BMD_{10}. A response of 10 per cent is standard in the risk thermometer.

[f] Factors for extrapolation between animals and humans, as well as taking sensitive individuals into account.

[g] Severity factor (SF) according to Sand et al., (2015, Table 3).

[h] KS: semi-quantitative standard used for UB (upper bound) and LB (lower bound) in the uncertainty model, according to Sand et al., (2015, Text box 2).

[i, j] Extrapolated UB = $BMD_{0.5}$ * $BMD_{0.5}$/$BMDL_{0.5}$ = 6.75, and LB = $BMDL_{0.5}$ = 3.0 have been used in the uncertainty model, according to Sand et al., (2015, Text box 2). The uncertainty in the BMD value is assumed to be symmetrical on the log-dose scale.

Table 8. Classification of the 95th percentile of arsenic exposure from rice and food (total).

Exposure scenario	rice	rice	rice	rice	total	total	total	total
Consumer group	adults	11/12 years	8/9 years	4 years	adults	11/12 years	8/9 years	4 years
Result								
Risk class[a]	2	3	3	3	3	3	3	3
Uncertainty class: UPP[b]	3	1	1	1	1	1	2	2
Uncertainty class: NER[b]	1	2	1	1	1	1	1	1
SAMOE[c]	1.1	0.54	0.43	0.37	0.41	0.28	0.21	0.17
MOE ($BMD_{0.5}$/exposure)	107	54	43	37	41	28	21	17
Input: risk classification								
Exposure[d]	0.042	0.084	0.104	0.122	0.109	0.16	0.21	0.265
$BMD_{0.5}$	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
AF_{BMR}[e]	10	10	10	10	10	10	10	10
AF inter-TK[f]	1	1	1	1	1	1	1	1
AF inter-TD[f]	1	1	1	1	1	1	1	1
AF intra-TK[f]	3.16	3.16	3.16	3.16	3.16	3.16	3.16	3.16
AF intra-TD[f]	3.16	3.16	3.16	3.16	3.16	3.16	3.16	3.16
Severity (SF)[g]	100	100	100	100	100	100	100	100
Input: uncertainty analysis								
UB for exposure	KS[h]	KS	KS	KS	KS	KS	KS	KS
LB for exposure	KS	KS	KS	KS	KS	KS	KS	KS
UB for $BMD_{0.5}$	6.75[i]	6.75	6.75	6.75	6.75	6.75	6.75	6.75
LB for $BMD_{0.5}$	3[j]	3	3	3	3	3	3	3

See Swedish National Food Agency report number 8 (Sand et al., 2015) for details of the risk thermometer.
[a] Risk class, see Table 6.
[b] Uncertainty in the risk classification, upwards (to higher risk class), or downward (to lower risk class) (Sand et al., 2015, Table 5):
1 = low uncertainty.
2 = moderate uncertainty.
3 = high uncertainty.
Severity-adjusted margin of exposure (SAMOE).
[d] Value for arsenic exposure from Tables 2 and 3.
[e] Factor for response adjustment, extrapolation of $BMD_{0.5}$ to BMD_{10}. A response of 10 per cent is standard in the risk thermometer.
[f] Factors for extrapolation between animals and humans, as well as taking sensitive individuals into account.
[g] Severity factor (SF) according to Sand et al., (2015, Table 3).
[h] KS: semi-quantative standard used for UB (upper bound) and LB (lower bound) in the uncertainty model, according to Sand et al., (2015, Text box 2).
[i, j] Extrapolated UB = $BMD_{0.5}$ * $BMD_{0.5}/BMDL_{0.5}$ = 6.75, and LB = $BMDL_{0.5}$ = 3.0 has been used in the uncertainty model, according to Sand et al., (2015, Text box 2). The uncertainty in the BMD value is assumed to be symmetrical on the log-dose scale.

Results: scenario analyses

Scenario analyses have been performed to provide a scientific basis for assessing the intake from rice products on the Swedish market. This represents characterisation of the risk relating to consumption of individual products over a long period. It should be noted, however, that these analyses are more or less theoretical, because consistent consumption of only one type of rice product for most of one's life does not occur in practice.

As has been stated, the centre of risk class 3, i.e. SAMOE ≈ 0.3, represents a risk-based reference (which could be compared to a TDI). According to Figure 1, rice contributes on average with about 30 per cent of the total intake of arsenic from foods. Based on this, the critical/acceptable intake of rice can be calculated:

A SAMOE = 0.3 corresponds to an arsenic exposure of 0.15 µg per kg body weight per day [equation 1: RP = 4.5, AF = 10, AF_{BMR} = 1/10, SF = 100 and an exposure (E) of 0.15 gives a SAMOE = 0.3]. 30 per cent of 0.15 is 0.045 µg per kg body weight per day. As can be noted in Tables 7 and 8, based on real exposure data, situations where exposure from rice is less than 0.045 µg per kilo body weight per day correspond to a total intake of arsenic from food that gives a SAMOE over 0.3 (exposure from rice < 0.045 µg/kg body weight per day for adults in Tables 7 and 8, and for children 11/12 and 8/9 years old in Table 7).

It should be noted that the calculation of the reference intake of 0.045 µg per kilo body weight per day refers to a point estimate. There is uncertainty in the input parameters (RP, AF, AF_{BMR}, SF), which means that there is also uncertainty in the value of 0.045 (in both directions).

Critical number of portions a week
Table 9 shows the consumption per week of various rice products that give an arsenic intake of 0.045 µg per kg body weight per day (i.e. 7 x 0.045 = 0.315 µg per kg body weight. Underlying data may be found in Table 10.

For children, an exposure of 0.045 µg per kg body weight per day corresponds on average to 3-4 portions per week, with regard to rice products that are consumed as part of a normal/main meal (basmati rice, whole grain rice, jasmine rice, parboiled rice, rice porridge and rice noodles). For whole grain rice, 2 portions fills the acceptable weekly intake (for children of 8 months and 4, 8/9 and 11/12 years). This also applies to rice snacks for 4 year-olds and younger children and to rice porridge for 8 month-old infants. For children of 8 months and 2, 4, 8/9, and 11/12 years, 2, 3, 5, 8 and 11 rice cakes respectively correspond to the calculated acceptable weekly intake.

For adults, an exposure of 0.045 µg per kg body weight per day corresponds on average to 6 portions per week, with regard to rice products that are consumed as part of a normal meal (basmati rice, whole grain rice, jasmine rice, parboiled rice, rice porridge and rice noodles).

The calculated average values of 3-4 and 6 portions a week for children and adults, respectively, can be compared with the estimated rice consumption and corresponding number of portions per week as reported in Table 4.

For children, the median consumption of 2-3 times a week (Table 4) is close to the "critical" number of approximately 3-4 portions per week. The more detailed analysis shows that this primarily concerns the younger children. For 4 year-olds, the median exposure to arsenic from rice corresponds to the acceptable exposure of 0.045 µg per kg body weight per day (Table 7) and the median exposure to arsenic from food in total is close to the middle of risk class 3 (Figure 2). Rice consumption corresponding to the 95th percentile for children, amounting to 5-7 portions per week (Table 4), is above the critical level of approximately 3-4 portions a week. In line with this, it can be noted that exposure from food corresponding to the 95th percentile exceeds the middle of risk class 3 for all groups of children (Table 8, SAMOE < 0.3).

The estimated rice consumption for adults of 2 (median consumption) and 5-6 (corresponding to the 95th percentile) portions a week (Table 4) does not exceed the "critical" number of 6 portions per week. Similarly it can be stated that SAMOE for adults, with regard to total exposure from food, is greater than 0.3 and is thus not deemed to represent a significant risk (Tables 7 and 8).

Critical levels of arsenic in rice
As discussed earlier, the critical intake of arsenic from rice has been determined to 0.045 µg per kg body weight per day. Based on data of levels of arsenic in rice, the acceptable rice consumption is then calculated, as discussed above (Table 9). One question is whether the concentration levels (Table 10) that form the basis for the calculations in Table 9 agree with the coming regulation of arsenic in rice.

The EU regulation distinguishes between "White rice" (maximum level 200 µg/kg) and whole grain/parboiled rice (maximum level = 250 µg/kg); see *Part 1 A Survey of Inorganic Arsenic in Rice and Rice Products*. A maximum level should not be regarded as an average level but rather an upper percentile in a distribution for the arsenic concentration. If data for basmati and jasmine rice are merged (n = 35) the upper 95th percentile is approximately 100 µg/kg (dry rice). This could correspond to a maximum level for "white rice" that follows acceptable arsenic exposure and consumption of rice as calculated in Table 9. If data for whole grain and parboiled rice are merged (n = 14) the upper 95th percentile is approximately 158 µg/kg (dry rice) Thus, in both cases levels are obtained that are clearly lower than the existing maximum levels of 200 and 250 µg/kg respectively. Note that these estimates are matched against "critical" rice consumption in combination with observed concentration data (Table 9). A higher consumption of rice would call for an even lower maximum level.

Table 9. Consumed quantity per week of different rice products and corresponding number of portions per week that give an exposure of 0.315 µg/kg body weight per week.

Group	Product	Quantity corresponding to an exposure of 0.315 µg/kg body weight/week (0.045 µg/kg body weight/day)		
		Quantity (grams per week)	Number of portions per week	Average number of portions per week[a]
8 months	basmati rice	128	5	3
	whole grain rice	66	2	
	parboiled rice	93	4	
	jasmine rice	117	4	
	rice porridge	218	2	
	rice noodles	80	3	
	rice snack	173	2	-
	rice drink	319	11	
	gluten-free pasta	2347	63	
	rice breakfast cereal	39	4	
	rice cakes	18	2 (cakes)	
	gluten-free crispbread	63	6 (pieces)	
2 years	basmati rice	193	6	4
	whole grain rice	99	3	
	parboiled rice	139	4	
	jasmine rice	177	5	
	rice porridge	328	3	
	rice noodles	121	4	
	rice snack	260	2	-
	rice drink	480	10	
	gluten-free pasta	3535	79	
	rice breakfast cereal	58	6	
	rice cakes	26	3 (cakes)	
	gluten-free crispbread	95	10 (pieces)	
years	basmati rice	274	3	3
	whole grain rice	140	2	
	parboiled rice	199	2	
	jasmine rice	252	3	
	rice porridge	467	3	
	rice noodles	172	3	
	rice snack	370	2	-
	rice drink	683	5	
	gluten-free pasta	5031	57	

Group	Product	Quantity corresponding to an exposure of 0.315 µg/kg body weight/week (0.045 µg/kg body weight/day)		
		Quantity (grams per week)	Number of portions per week	Average number of portions per week[a]
	rice breakfast cereal	83	4	
	rice cakes	38	5 (cakes)	
	gluten-free crispbread	136	14 (pieces)	
8/9 years	basmati rice	471	4	3
	whole grain rice	241	2	
	parboiled rice	341	3	
	jasmine rice	432	4	
	rice porridge	801	4	
	rice noodles	295	4	
	rice snack	635	4	-
	rice drink	1172	5	
	gluten-free pasta	8632	69	
	rice breakfast cereal	142	7	
	rice cakes	65	8 (cakes)	
	gluten-free crispbread	233	23 (pieces)	
11/12 years	basmati rice	637	4	4
	whole grain rice	326	2	
	parboiled rice	461	3	
	jasmine rice	584	4	
	rice porridge	1085	4	
	rice noodles	400	3	
	rice snack	860	5	-
	rice drink	1587	7	
	gluten-free pasta	11689	83	
	rice breakfast cereal	192	10	
	rice cakes	88	11 (cakes)	
	gluten-free crispbread	316	32 (pieces)	
adults	basmati rice	1114	8	6
	whole grain rice	571	4	
	parboiled rice	806	5	
	jasmine rice	1022	7	
	rice porridge	1897	8	
	rice noodles	699	5	
	rice snack	1504	9	-
	rice drink	2775	17	

Group	Product	Quantity corresponding to an exposure of 0.315 µg/kg body weight/week (0.045 µg/kg body weight/day)		
		Quantity (grams per week)	Number of portions per week	Average number of portions per week[a]
	gluten-free pasta	20435	151	
	rice breakfast cereal	336	17	
	rice cakes	153	18 (cakes)	
	gluten-free crispbread	552	55 (pieces)	

[a] Average of number of portions for products that can normally be included as part of a larger meal.

Table 10. Background data for scenario analyses

Group	Weight (kg)	product	Mean concentration (µg/kg)	Portion size (gram)[a]	Adjustment[b]
8 months	8.5	basmati rice	63	26	3
		whole grain rice	123	26	3
		parboiled rice	87	26	3
		jasmine rice	68	26	3
		rice porridge	12	100	1
		rice snack	16	90	1
		rice cakes	152	8	1
		gluten-free crispbread	42	10	1
		rice drink	8	30	1
		gluten-free pasta	3	37	2.63
		rice noodles	70	26	2.1
		rice breakfast cereal	69	10	1
2 years	12.8	basmati rice	63	33	3
		whole grain rice	123	33	3
		parboiled rice	87	33	3
		jasmine rice	68	33	3
		rice porridge	12	125	1
		rice snack	16	120	1
		rice cakes	152	8	1
		gluten-free crispbread	42	10	1
		rice drink	8	50	1
		gluten-free pasta	3	45	2.63
		rice noodles	70	33	2.1
		rice breakfast cereal	69	10	1
4 years	18.2	basmati rice	63	91	3
		whole grain rice	123	91	3
		parboiled rice	87	91	3
		jasmine rice	68	91	3
		rice porridge	12	150	1
		rice snack	16	175	1
		rice cakes	152	8	1

Group	Weight (kg)	product	Mean concen-tration (µg/kg)	Portion size (gram)[a]	Adjustment[b]
		gluten-free crispbread	42	10	1
		rice drink	8	150	1
		gluten-free pasta	3	88	2.63
		rice noodles	70	53	2.1
		rice breakfast cereal	69	20	1
8/9 years	31.3	basmati rice	63	117	3
		whole grain rice	123	117	3
		parboiled rice	87	117	3
		jasmine rice	68	117	3
		rice porridge	12	220	1
		rice snack	16	175	1
		rice cakes	152	8	1
		gluten-free crispbread	42	10	1
		rice drink	8	220	1
		gluten-free pasta	3	126	2.63
		rice noodles	70	74	2.1
		rice breakfast cereal	69	20	1
11/12 years	42.3	basmati rice	63	143	3
		whole grain rice	123	143	3
		parboiled rice	87	143	3
		jasmine rice	68	143	3
		rice porridge	12	250	1
		rice snack	16	175	1
		rice cakes	152	8	1
		gluten-free crispbread	42	10	1
		rice drink	8	240	1
		gluten-free pasta	3	140	2.63
		rice noodles	70	125	2.1
		rice breakfast cereal	69	20	1
adults	74	basmati rice	63	147	3
		whole grain rice	123	147	3

Group	Weight (kg)	product	Mean concen-tration (µg/kg)	Portion size (gram)[a]	Adjustment[b]
		parboiled rice	87	147	3
		jasmine rice	68	147	3
		rice porridge	12	230	1
		rice snack	16	175	1
		rice cakes	152	8	1
		gluten-free crispbread	42	10	1
		rice drink	8	161	1
		gluten-free pasta	3	135	2.63
		rice noodles	70	135	2.1
		rice breakfast cereal	69	20	1

[a] Portion sizes are mainly estimated on the basis of the Swedish National Food Agency's food consumption surveys (Riksmaten children 2003 and Riksmaten adults 2010-11).
[b] Certain analyses refer to dry content. These have been adjusted downwards by a factor since portion sizes refer to cooked rice.

Nutritional aspects

Rice does not have a significant amount of any single nutrient (EU regulation No. 1169/2011). Above all rice contributes to the intake of niacin equivalents, vitamin B6 and phosphorus, for which 100 grams corresponds to about 10 per cent of the daily reference intake (Table 11). In Sweden we eat an average of 25-30 grams of rice and rice products per person per day, which is about the same as for pasta (Amcoff et al., 2012, Table 13). Although rice does not have a significant amount of any single nutrient, rice is one of the key foods in Sweden, that is one of the foods that contributes with 75 per cent of nutrient intake (Lundberg-Hallén et al., 2015). Rice and rice products contribute to the intake of selenium and zinc; in the population at large the intake corresponds on average to four and five per cent respectively of the average requirement (Amcoff et al., 2012; NNR 2012).

Not everyone consumes rice or rice products to the same extent. If we only include those in the survey who ate rice or rice products (n=747) the rice products correspond on average to more than 25 per cent of the average requirement for vitamin B6, calcium, iron, phosphorus, selenium and zinc (Amcoff et al., 2012; NNR 2012). Rice is also an important part of the intake of carbohydrates and whole grains. Alternative sources of these nutruents may be found in Table 11.

Table 11. Contribution per 100 grams ready-to-eat to daily reference intake (per cent)

	Carbo-hydrates[1]	Whole grain[2]	Niacin equivalents	Vitamin B6	Ca	Fe	P	Se
Rice	8	0	8	7	3	1	8	5
Whole grain rice	10	47	17	10	1	3	15	2
Potatoes	6	0	14	14	1	3	6	0
Pasta	10	0	8	1	1	4	8	0
Whole grain pasta	11	69	16	4	2	11	16	5
Bulgur/couscous	6	0	11	4	1	4	10	1
Bulgur/couscous whole grain	9	46	18	6	2	8	18	2
Grain	5	0	20	8	1	5	8	1
Millet	5	27	6	7	0	8	8	1
Maize grain	6	0	2	1	0	2	3	1
Spelt	8	47	22	4	1	12	21	8
Quinoa	8	0	7	10	2	11	25	5

[1] Proportion of acceptable span (NNR 2012).
[2] Proportion of the Swedish National Food Agency's dietary advice for whole grain. Reference: The National Food Agency food database version 2015-03-04; Regulation (EU) No.1169/2011.

Conclusions

- Based on average/median intake, rice represents the single largest exposure source for inorganic arsenic (27-31 per cent) at population level in Sweden. Median exposure from food, including rice, is estimated to be approximately 0.07 (adults), 0.10 (11/12 year-olds), 0.13 (8/9 year-olds) and 0.18 (4 year-olds) µg per kilo body weight per day. The exposure estimates are associated with uncertainty (underestimation of consumption, use of standardised portion sizes), so that the results give an assessment rather than a precise measurement of exposure.

- The estimated exposure to arsenic in food is generally classified into risk class 3, and for children (especially younger children) the exposure is close to or above the limit for what is acceptable from a health perspective. According to the risk thermometer, acceptable arsenic exposure (in a lifetime perspective) is assessed to be approximately 0.15 µg per kg body weight per day, of which 0.045 µg per kg body weight per day (or 30 per cent) comes from rice and rice products. Also, taking into account the estimated uncertainties, it cannot be excluded that arsenic exposure from food is higher than the desirable level for a small portion of the adult population.

- Scenario analyses indicate that the acceptable arsenic exposure from rice corresponds to approximately 3-4 portions per week for children and 6 portions per week for adults. One-sided consumption of certain rice products can give an exposure that, according to our calculations, can lead to health risks with lifelong consumption. Given existing data, it is estimated that some children today have a rice consumption that exceeds 3-4 portions a week (up to half of the younger children). For adults it is estimated that rice consumption today is normally less than 6 portions a week.

- Scenario analyses also show that the maximum level that is in line with acceptable arsenic exposure and consumption of rice is lower than the maximum level that comes into force with effect from 1 January 2016.

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