

*Part 3 – Risk management*

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

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# Definitions and abbreviations

<b>ALARA</b>	“as low as reasonably achievable” - a procedure for setting the maximum level for the toxic substance that is as low as possible in practice without shutting off parts of trade on the global market.
<b>As(V)</b>	Pentavalent arsenic, which is included in arsenate. Arsenate and arsenite represent the main components of what is called inorganic arsenic in food.
<b>As(III)</b>	Trivalent arsenic, which is included in arsenate. Arsenate and arsenite represent the main components of what is called inorganic arsenic in food.
<b>BfR</b>	Bundesinstitut für Risikobewertung – The German Federal Institute for Risk Assessment
<b>BMD</b>	Benchmark dose - the dose or exposure level that corresponds to a specified effect or risk level. BMD is calculated by adapting a dose-response model to data; on the basis of the adapted model, the dose that gives a defined effect/risk increase can be obtained. A confidence limit that measures uncertainty in the BMD is also calculated (see BMDL).
<b>BMDL</b>	Lower confidence limit on the benchmark dose - BMDL is the lower 95 per cent confidence limit for BMD. BMDL measures uncertainty in BMD. BMDL represents the starting point for establishing the tolerable daily intake (TDI).
<b>Codex</b>	Codex Alimentarius Commission (CAC) is an international organisation formed by the UN bodies FAO and WHO. Codex produces international standards for safe foods, integrity in food handling and free trade in foods.
<b>Efsa</b>	European Food Safety Authority
<b>EC</b>	European Community, which was the name from 1967 to 1993 of the present European Union (EU).
<b>EU</b>	European Union
<b>IARC</b>	International Agency for Research on Cancer (France)
<b>Jecfa</b>	Joint FAO/WHO Expert Committee on Food Additives
<b>NNR</b>	Nordic nutrition recommendations (Nordiska näringsrekommendationer)
<b>NRC</b>	National Research Council (USA)
<b>RP</b>	Reference Point (health-based reference point)
<b>TDI</b>	Tolerable daily intake - calculated as the highest quantity of a substance that a person can consume each day throughout a lifetime without a health risk.
<b>WHO</b>	World Health Organization
<b>Whole grain rice</b>	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 Alimentarius<sup>1</sup>). 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 concentrations in bed-rock and sediments. In areas with minerals that contain arsenic, the

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<sup>1</sup> Codex Alimentarius 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.

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: Part 1*, 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

# Summary

The WHO classifies arsenic as carcinogenic and Efsa's latest risk assessment of arsenic found that exposure to arsenic in Europe is close to the limit that can be considered as not safe. Efsa is therefore encouraging member states to reduce arsenic exposure as much as possible (IARC 2004; IARC 2012 and Efsa, 2009, 2014).

Rice and rice products account for about a third of the arsenic we are exposed to from food in Sweden, which is a relatively high contribution from a single food commodity. Rice and rice products have approximately 10 times higher arsenic content than other cereals (such as pasta and bread) and potatoes.

High exposure to arsenic for a long time increases the risk of developing several forms of cancer. During 2011-2012, the Swedish National Food Agency analysed a large number of foods intended for children for various metals, including arsenic. As a result of this survey, the Swedish National Food Agency now advise to avoid giving rice drinks to children aged under six.

This project is a continuation of the Swedish National Food Agency's work on arsenic in food. The project investigated the inorganic arsenic content of 102 different rices and rice products. The results show that rice contains inorganic arsenic in various concentrations and that the levels of inorganic arsenic is high, especially in the rice cakes and whole grain rice that were investigated.

## **Among other things, the survey shows**

That a varied consumption of foods, which includes rice and rice products four times a week for children and six times a week for adults, does not involve any increased risk because of exposure to inorganic arsenic from rice or rice products.

The levels of inorganic arsenic in rice drinks and rice cakes are relatively high, and in combination with unbalanced consumption this could lead to a high intake of inorganic arsenic.

Cooking rice with a substantial surplus of water that is then poured off can reduce the inorganic arsenic content in rice by up to 70 per cent.

The products in the survey that were specifically intended for persons with coeliac disease, such as pasta and bread made from rice flour, do not contain elevated levels of inorganic arsenic.

That arsenic exposure from rice and rice products can be considerable has been noted globally and the WHO and the EU have therefore been working on defining maximum levels for how much inorganic arsenic can be present in rice and certain rice products. However, this survey, with scenario analyses, shows that the new maximum levels in the EU for inorganic arsenic in rice and rice products will not have the desired effect of reducing arsenic exposure from rice and rice products in a satisfactory way.

The Swedish National Food Agency's advice will therefore continue to apply after the maximum levels are introduced on 1 January 2016.

### **The Swedish National Food Agency's advice to consumers**

- Do not give rice drinks to children aged under six (pre-school age).
- Do not give rice cakes to children aged under six (pre-school age). Children aged over six and adults may eat rice cakes occasionally, depending on how much of other rice products are being eaten.
- Limit consumption of rice and rice products (*such as rice porridge, rice noodles and rice porridge snacks*) to four times per week (children) or six times per week (adults). The average consumer of rice and rice products in Sweden today eats rice and rice products approximately three times per week.
- When eating rice, you should not always choose whole grain rice.

### **The Swedish National Food Agency's continuing work**

Information and advice to consumers about inorganic arsenic in rice is a short-term measure to reduce exposure to inorganic arsenic from food in Sweden. Since the problem of high levels of inorganic arsenic in rice and rice products mainly arises from naturally high levels of arsenic in bed rock, soil and water, long-term measures are of greater significance for managing the problem in the longer term, from both a national and international public health perspective.

For this reason, the Swedish National Food Agency is informing affected companies about the survey results and conclusions from the project and encourage companies to seek rice raw materials with as low arsenic levels as possible, or to develop methods to reduce the level of arsenic in products. This may be done, for example, by cooking rice with excess water that is then discarded. In this way, companies are themselves given the opportunity to influence consumer exposure to inorganic arsenic. Since the new maximum levels for inorganic arsenic in rice and rice products do not appear to adequately protect consumers from a high intake of arsenic, voluntary efforts from companies are extra important.



The Swedish National Food Agency is also informing Efsa, the European Commission and Codex about the survey results and project conclusions. The Swedish National Food Agency's action in respect of the European Commission and Codex will also help in the longer term to reduce exposure to inorganic arsenic nationally and internationally.

When the new maximum levels come into force in 2016, authorities in Europe, including the Swedish National Food Agency, will have the opportunity by means of control projects to sample and analyse rice and rice products. The Swedish National Food Agency will also perform further survey projects to investigate levels of inorganic arsenic in foods on the Swedish market.

# Background

## Levels of inorganic arsenic in rice and rice products

A total of 102 rices and rice-based products were included in the survey. The 102 products included 63 rice (basmati, jasmine, long-grain, round-grain, whole grain), 11 rice cakes, 9 fresh rice porridges, 6 breakfast cereals, 5 rice drinks, 4 gluten-free breads, 3 noodles and 1 gluten-free pasta. The products include brands from the large food producing chains, as well as less common brands and organic products. In general, the results show:

- Rice cakes have the highest level of inorganic arsenic, with an average of 152 µg/kg (maximum 322 µg/kg).
- Whole grain rice and raw rice have the next-highest level with an average of 117 µg/kg (maximum 177 µg/kg).
- Basmati and jasmine rice have a significantly lower inorganic arsenic content than other types of rice (average levels of 63 and 69 µg/kg respectively).
- For the fresh (“soft”) rice products, the average level was 14 (10-17) µg/kg and for rice drinks 8 (5-10) µg/kg.
- The study included 18 organic products. The results show that there is no significant difference between organic and conventionally cultivated products in levels of inorganic arsenic.
- Of the rice where the package stated the country of origin, 28 were from Asia, 15 from Europe and 1 from Africa. Almost a third of the rice did not state the country of origin on the package. From the rice analysed, no significant differences can be seen based on country of origin.
- The rice-based bread group included 3 hard types and one soft. These were found on the supermarket shelves for allergy-related products. Compared with the 11 rice cakes analysed, levels are lower in the products intended for coelias. The average level in the rice cakes is 152 µg inorganic arsenic/kg compared with 42 µg/kg for the rice-based bread.
- To investigate whether preparation and cooking affected the inorganic arsenic levels, six different types of rice were also analysed before cooking, after rinsing, after cooking where all the water was absorbed and after cooking where cooking water was left and discarded. Rinsing before cooking did not result in any significant reduction in inorganic arsenic levels. On the other hand, the inorganic arsenic levels was reduced by between 40 and 70 per cent if the rice was cooked with an excess of water that was then discarded, compared with when all the cooking water was absorbed.
- In order to estimate the general intake of inorganic arsenic in the Swedish population, an analysis was also made of food samples that were included in the Swedish National Food Agency’s earlier study, Matkorgen (Food Basket) 2010. The highest levels of inorganic arsenic were found in the food groups (average content): Fish 13 µg/kg, Cereals 11 µg/kg, Sugar and similar 5 µg/kg

and Fruit 3 µg/kg. In the food groups Meat, Egg, Dairy, Cooking fat, Bakery, Soft drinks, Vegetables and Potatoes, the level of inorganic arsenic was below the limit of detection, 1-2 µg/kg.

## **Risk assessment of arsenic in rice**

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

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 the more toxic form for humans. A foodstuff may contain both forms at the same time. Ground water that contains arsenic contains primarily the inorganic form, while the organic form of arsenic dominates in marine fish and shellfish. Rice is the food that contains the highest level of inorganic arsenic, but it also contains some organic arsenic.

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, elevated levels of arsenic have been demonstrated in rice (Meharg et al., 2009). Absorption of 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).

### **Intake of inorganic arsenic from food in Sweden**

The total intake of inorganic arsenic in Sweden from all foods is reported in *Part 2, Risk assessment*, in the Swedish National Food Agency's report 16/2015. Exposure estimates have been performed for the 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).

The median intake of inorganic arsenic per kg body weight is higher in children than in adults. Among adults, no difference was observed between women and men. Among adults and children, rice represents the greatest individual exposure source for inorganic arsenic (27-31 per cent of the total intake of inorganic arsenic), followed by the "Cereals" food group, which includes flour, cakes, breakfast cereals, pasta and bread, among other things. According to the survey, rice is normally consumed about 2-3 times per week and 5-7 times per week corresponds to high consumption.

## Health effects

Inorganic arsenic is carcinogenic and many years' exposure can lead to tumours in the skin, lungs, bladder and kidneys (IARC 2004, 2012). There have also been reports of a connection 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 hardly at all to breast milk (Fångström 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 and secreted in urine. There are great differences in the metabolism of arsenic between different individuals, which is partly genetic (Engström 2011).

The WHO classifies arsenic as carcinogenic (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 1,000 exposed persons (NRC 2001). This risk is higher than the low-risk level of one extra case of cancer per 100,000 exposed persons, which is normally considered "acceptable" when setting health-based reference values.

Efsa has established a health-based reference value (BMDL<sub>01</sub>) for inorganic arsenic (EFSA 2009). BMDL<sub>01</sub> 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) established a couple of years after Efsa a BMDL<sub>0.5</sub> of 3.0 µg per kilo body weight per day for lung cancer (FAO/WHO 2011). BMDL<sub>0.5</sub> 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.

In this risk assessment, 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 more relevant evaluation and data base (FAO/WHO 2011) and 2) skin changes (pigment changes and hyperkeratosis) that are covered in Efsa's

range of reference points /Efsa 2009) are considered to be a less serious effect than cancer.

### **Risk characterisation**

In this risk assessment, the Swedish National Food Agency has used a new tool for risk characterisation that is called the “Risk Thermometer” (Sand et al. 2015) The risk thermometer compares the estimated exposure to a substance in food with the substance’s health-based reference value, such as health-based reference point (RP) or tolerable daily intake (TDI). The risk thermometer also takes into account the seriousness of the health effect in a systematic way. This is to say that cancer is judged to be more serious than skin changes.

In the risk thermometer, exposure to a substance is placed in one of five risk classes. These risk classes describe different levels of health urgency. Generally speaking, one can say that exposure that is placed in risk classes 1 and 2 does not represent a health risk in a long-term perspective. Risk class 3 is currently judged to represent a grey zone in a health perspective. Exposure that is placed in risk classes 4 and 5 is judged to represent a potential health risk.

### ***Median exposure***

According to this survey, median exposure to inorganic arsenic solely from rice and rice products 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 great uncertainty in this classification in an upward direction (i.e. towards risk class 3). Median exposure for 4 year-olds is in risk class 3, but 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 solely from rice and rice products corresponding to the 95th percentile is in risk class 2 for adults and risk class 3 for children. 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. 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.

In summary, the results show that an estimated exposure to arsenic in food generally falls 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. Taking into account the estimated uncertainties, it cannot be excluded that arsenic exposure from food is also higher than the desirable level for a small portion of the adult population.

### **Measures that could reduce arsenic levels in rice**

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 discarded (see Figure 10 in the Swedish National Food Agency report 16/2015 *Part 1, A Survey of Inorganic Arsenic in Rice and Rice Products*).

This method should be able to reduce levels of arsenic in the consumption rice, but how great an effect this has on exposure is open to discussion, since not all rice consumed consists of ordinary cooking rice (especially for small children). It can, however, represent an illustration of what changing production processes could achieve in reducing arsenic levels.

### **Scenario analyses**

Scenario analyses have been performed to assess the intake from rice and rice products on the Swedish market. This represents assessment of the risk in the consumption of individual products over a long period. It should be noted, however, that consumption of only one type of rice product for most of a person's life is not probable, which makes this assessment theoretical.

The assumption is that the middle of risk class 3 represents a risk-based reference for total exposure to inorganic arsenic (that can be likened to a TDI; 0.15 µg per kg body weight per day). According to the survey, rice contributes on average to about 30 per cent of the total intake of arsenic from food. On this basis an acceptable intake from rice is calculated to be 0.045 µg inorganic arsenic per kg body weight per day.

### ***Critical number of portions per week***

For children, an exposure of 0.045 µg per kg body weight per day corresponds on average to 3-4 portions of rice per week as part of a normal meal (basmati rice, whole grain rice, jasmine rice, parboiled rice, rice porridge and rice noodles). For whole grain rice, 2 portions represents the acceptable weekly intake. This also applies to rice porridge 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 of rice per week as part of a normal meal (basmati rice, whole grain rice, jasmine rice, parboiled rice, rice porridge and rice noodles).

### ***Critical levels of arsenic in rice***

One question is whether the levels that form the basis for the calculations are in accordance with the coming regulation for inorganic arsenic in rice. That is to say, will the proposed maximum levels for rice and rice products help to reduce exposure to inorganic arsenic among consumers?

The EU regulation distinguishes between “White rice” (maximum level 200 µg/kg) and whole grain/parboiled rice (maximum level = 250 µg/kg). A maximum level should not be regarded as an average level but rather an upper percentile in a division of content. If data for basmati and jasmine rice are put together (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 this survey. If data for whole grain and parboiled rice are put together (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 content data (Table 9 in the Swedish National Food Agency report 16/2015, *Part 2, Risk assessment*). A consumption higher than the *average* consumption of rice in Sweden argues for an even lower maximum level.

### **Beneficial aspects**

Rice cannot be classified as a major source of any single nutrient in Sweden (EU regulation No. 1169/2011). For those who eat rice, it contributes to the intake of niacin equivalents, vitamin B6 and phosphorus. 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). Although rice is not the source of any single nutrient, rice is one of the key foods in Sweden, that is to say one of the foods that contribute 75 per cent of nutrient intake (Lundberg-Hallén et al., 2015). Rice and rice products contribute in Sweden 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).

## Conclusions

Based on average/median intake, rice represents the single largest source of exposure for inorganic arsenic (27-31 per cent) at population level in Sweden. Rice and rice products have levels of inorganic arsenic that are 8-12 times higher than other comparable foods (such as pasta, bread and potatoes). 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)  $\mu\text{g}$  per kilo body weight per day. The exposure estimates are associated with uncertainty (underestimate of consumption, use of standardised portion sizes), so the results give an estimation rather than a precise measurement of exposure.

The estimated exposure to arsenic in food is generally placed in 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 long-term perspective) is assessed to be approximately 0.15  $\mu\text{g}$  per kg body weight per day, of which 0.045  $\mu\text{g}$  per kg body weight per day (or 30 per cent) comes from rice and rice products. Taking into account the estimated uncertainties, it cannot be excluded that arsenic exposure from food is higher than the desirable level also for a part 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. Unbalanced consumption of certain rice products can give an exposure that is higher than what is considered to be acceptable. Given existing data, it is estimated that some children have a rice consumption that exceeds 3-4 portions per week (up to half of the younger children). For adults it is estimated that rice consumption is less than 6 portions a week.

Scenario analyses also show that maximum levels that is in line with acceptable arsenic exposure and consumption of rice is lower than what corresponds to the coming regulation.



# Risk management measures/ the Swedish National Food Agency's measures

Consumers in Sweden, as in the rest of Europe, are exposed to relatively high levels of inorganic arsenic. The levels are close to the limit of what can be considered acceptable for health. Efsa, the European Food Safety Authority, therefore considers that exposure to inorganic arsenic should be reduced.

About a third of the arsenic we are exposed to from food in Sweden comes from rice and rice products, which is a high contribution from a single food commodity. Other food groups, such as fish, other cereals (grains), fruit and dairy products, also contribute to our exposure to arsenic. These foods contain significantly lower levels of organic arsenic than rice and rice products, but since we eat a great deal of them, they also contribute to the total exposure. Since rice and rice products have, relatively speaking, the highest levels and are also the largest single source of arsenic exposure in Sweden, this is also the source that will give the greatest effect from efforts to reduce exposure. For this reason, the Swedish National Food Agency has decided on the following measures:

Give advice and information to consumers:

- Do not give rice drinks to children aged under six (pre-school age).
- Do not give rice cakes to children aged under six (pre-school age). Children aged over six and adults may eat rice cakes occasionally, depending on how much of other rice products are being eaten.
- Limit consumption of rice and rice products (*such as rice porridge, rice noodles and rice porridge snacks*) to four times per week (children) or six times per week (adults). The average consumer of rice and rice products in Sweden today eats rice and rice products approximately three times per week.
- When eating rice, you should not always choose whole grain rice.

Information:

- Cooking rice with a substantial surplus of water that is then discarded reduces the arsenic content in rice by up to 70 per cent.
- Basmati and jasmine rice have a significantly lower inorganic arsenic content than other types of rice in this survey. Even though levels in jasmine and basmati rice are lower than in other rice types, they are still too high, thus the advice on consumption should be followed.
- Products that are specifically intended for persons with coeliac disease, such as pasta and bread made from rice flour, do not contain higher levels of arsenic.

- Given that the maximum levels for inorganic arsenic in rice and some rice products will come into force on 1 January 2016, the Swedish National Food Agency will extend its current controls on rice and rice products to also include inorganic arsenic.
- The Swedish National Food Agency will continue its work of studying the occurrence of inorganic arsenic, including in foods other than rice, on the Swedish market. All results will be reported to Efsa.
- The Swedish National Food Agency is informing affected companies about the level of arsenic in the company's products that were included in the survey. All companies are encouraged to seek products with as low arsenic content as possible, or to investigate the possibility of manufacturing processes for rice products that reduce arsenic levels in the end product.
- All results are presented to the European Commission. Sweden encourages the European Commission to reconsider the maximum levels that will come into force in 2016. The maximum levels as currently decided are assessed not to contribute to reducing exposure to inorganic arsenic from rice and rice products in a satisfactory manner.
- All the results from the project are presented to Efsa.
- All the results are given to Codex. Sweden is working in Codex to introduce lower maximum levels than those now discussed. The proposed maximum levels are assessed not to contribute to reducing exposure to inorganic arsenic from rice and rice products in a satisfactory manner.

## **Motive for management decisions**

### **Consumer advice**

The Swedish National Food Agency considers that it is justified to inform consumers about levels of inorganic arsenic in rice and rice products and giving advice about appropriate rice consumption on the basis of these levels. This is to reduce exposure to arsenic from foods in Sweden, since rice is the food that makes the largest single contribution to arsenic exposure.

It is important to bear in mind that the consumption levels given in the advice apply to lifetime consumption. This means that occasional consumption that exceeds the advice cannot be seen as critical for health.

### **Do not give rice drinks to children aged under six**

- Rice drinks are often used as an alternative to cow's milk by people with a milk protein allergy or those who eat a vegan diet for a large part of their lives. Analysis of rice drinks has shown that the drinks contain relatively high levels of inorganic arsenic, which can mean that long-term consumption may lead to high exposure to arsenic.

- After the study of metals in baby and infant food in 2013, the Swedish National Food Agency decided on advice that children aged under six should avoid rice drinks. This study confirms earlier results and shows that young children (8 months) receive an unacceptable exposure to arsenic after only 2-3 dl of rice drink per week. If they also eat rice or rice products during the week, the exposure increases further.
- Based on the risk assessment performed, 8 and 11 year-olds can drink 5-6 glasses of rice drink per week (one glass = 2.5 dl) without exceeding the acceptable exposure level. If they also eat rice or rice products during the week, the exposure increases further.
- Adults can drink 11 glasses of rice drink per week (one glass = 2.5 dl) without exceeding the acceptable exposure level. If they also eat rice or rice products during the week, the exposure increases still further.

**Do not give rice cakes to children under 6. Children aged over seven and adults may eat rice cakes occasionally, depending on how much other rice products are being eaten.**

- The relatively high levels of arsenic in rice cakes mean that consumption of 2-4 rice cakes per week by small children gives an arsenic exposure that exceeds what is judged from a health point of view to be acceptable from rice and rice products as well as other foods. For small children, consumption of rice cakes means that the opportunity to eat rice as a basic food is limited. In principle, this type of food provides no important nutrients and usually contains salt.

**Limit consumption of rice and rice products (such as rice porridge, rice noodles and rice porridge snacks) to four times per week (children) or six times per week (adults). The average consumer of rice and rice products in Sweden today eats rice and rice products approximately three times per week.**

- Rice is a basic food in Sweden, along with potatoes and pasta, among other things. In Sweden, rice primarily contributes nutritionally to the intake of selenium and zinc. Rice consumption is part of a varied diet and there is no reason to refrain from eating rice because of arsenic levels. On the other hand, the scenario analyses show that about four portions per week for children and six portions per week for adults is the consumption of rice and rice products that should not be exceeded. This is so as not to exceed the quantity of arsenic that is judged from a health point of view to be acceptable from rice and rice products. Three portions of rice per week approximately corresponds to the median consumption of rice (among those who consume rice) in Sweden.
- The median consumption of rice in Sweden today is at an acceptable level from the point of view of exposure to arsenic from rice. Since this reflects median consumption, this means that half of Sweden's rice consumers are over this consumption level.

- Rice cakes, rice porridge snacks and rice breakfast cereals each make a relatively high contribution to arsenic exposure even with low consumption, and risk contributing to an exposure that cannot be considered acceptable. Consumption of this type of food means that the opportunity to eat rice as a basic food is limited. In principle, this type of food provides no nutrients. In the case of rice porridge snacks and breakfast cereals, these foods also give added sugar. Rice cakes can give an unnecessary contribution of salt. Consumption of only 1-2 portions of rice porridge snacks per week means that small children receive an exposure to arsenic that contributes to arsenic exposure being above acceptable levels. If they also eat rice or rice products during the week, the exposure increases further. From a nutritional point of view therefore, the advice is to limit consumption of rice cakes, breakfast cereals and porridge snacks, since arsenic exposure in relation to nutritional benefit is disproportionately great.

**When eating rice, you should not always choose whole grain rice.**

- Whole grain rice often contains higher levels of inorganic arsenic than white rice. The reason is that arsenic accumulates particularly in the husk, much of which remains in whole grain products. The scenario analyses show that 1-2 portions per week for children and 3-4 portions per week for adults is the quantity of whole grain rice that is acceptable, so as not to exceed the quantity of inorganic arsenic that is judged from a health point of view to be acceptable from rice and rice products and other foods together. Thus unbalanced consumption of whole grain rice gives a higher arsenic exposure than consumption of white rice. If you also eat other rice or rice products during the week, the exposure increases still further.
- At the same time, whole grain is in itself part of a diet that promotes health. However the contribution of nutrients from whole grain rice is limited compared with other whole grain products and the nutrients that we do get from rice are nutrients that are provided from eating a varied diet in Sweden. For this reason, the Swedish National Food Agency considers that the arsenic contributed by whole grain rice is unacceptable in some cases. This is because there are other whole grain products and other types of rice on the market to choose from.

**Cooking rice with a substantial surplus of water that is then discarded reduces the arsenic content in rice by up to 70 per cent.**

- As an individual consumer it is difficult to influence the intake of inorganic arsenic from food, since there are many sources. Obviously one way is to eat less rice and rice products, but for consumers who eat a good deal of rice as part of meals or as a whole meal, the way the rice is cooked can also be significant. When the rice is cooked in an excess amount of water, which is then discarded when the rice is cooked, the amount of arsenic in the rice is decreased by 40 to 70 per cent. In order to reduce exposure to arsenic, there is therefore good reason to inform that levels of arsenic in rice can be reduced if the rice is cooked in excess water that is then poured away when the rice is ready. The study shows that simply rinsing the rice before cooking has no great effect on the level of inorganic arsenic in the rice. Cooking rice in such a way that the water cooks in until the rice becomes dry does not affect the level of inorganic arsenic in the rice.
- Information that the level of arsenic in rice can be affected by preparation is very important for companies that produce rice products. Changing the production of rice products would probably have a considerably greater effect on arsenic exposure than the individual consumer's preparation of rice. This is because exposure to arsenic comes not only from the rice that is cooked at home but also from many other types of products (such as rice snacks, rice drinks and rice porridge).

**Basmati and jasmine rice have significantly lower inorganic arsenic levels than other types of rice in this survey. Even though levels in jasmine and basmati rice are lower than in other rice types, they are still sufficiently high that the advice on consumption should be followed.**

- In this survey, the average levels of inorganic arsenic in jasmine and basmati rice were significantly lower than in other rice types. This is also confirmed by other studies that show similar results. However levels do vary within the jasmine and basmati rice groups, which means that it cannot always be said that all jasmine or basmati rice has a lower level. The jasmine and basmati rices in this survey that had a higher level were in fact at a similar level to other rice types, which means that the consumption advice should be followed.

**Products that are specifically intended for persons with coeliac disease, such as pasta and bread made from rice flour, do not contain higher levels of arsenic.**

- Products that are specially intended for persons with coeliac disease do not contain higher levels of inorganic arsenic. For this reason, no special advice is given for these products. On the other hand the advice on rice consumption also applies to consumers with coeliac disease, for example.

### **Legislation, rules and controls**

The complete names of the regulations etc. that are referred to in this report may be found at the end of the document.

#### ***General principles and requirements***

Most food legislation within the EU is harmonised. This means that the same rules apply in all EU member states.

Regulation (EC) number 178/2002 determines among other things a number of general requirements for foods and trade in food, as well as requirements for food safety. According to article 14 of this regulation, food may not be put on the market if it is not safe. When determining whether a food may be harmful to health, consideration must be taken to the intended consumer groups' particular sensitivity. Infants and young children are examples of especially sensitive consumer groups.

It is the companies' responsibility to ensure that the requirements in the legislation are complied with, while it is the responsibility of the member states to monitor and control that the rules are applied. Article 7 of regulation (EC) No. 178/2002 also states the so-called precautionary principle. This principle enforces legislators and authorities to take immediate risk management measures in special cases where an assessment of available information identifies the possibility of harmful effects on health, but where there is scientific uncertainty. These measures may apply while awaiting further scientific information for a more comprehensive risk assessment.

#### ***Maximum levels for inorganic arsenic in foodstuffs***

The occurrence of certain contaminants in food is regulated by regulation (EC) No. 1881/2006. Until now no maximum level for arsenic in food has applied, but a decision to introduce maximum levels for inorganic arsenic in rice and certain rice products from the 1<sup>st</sup> of January 2016 has been taken by EU in Regulation No 2015/1006 (Table 1). In the preceding work for determining the maximum levels, Sweden has continuously contributed to the discussions and has presented all previous analysis results, including the data from the project "Contaminants and min-

erals in foods for infants and young children” (Bjerselius et al., 2013). The results in this report also emphasize the need for lower maximum levels than those now decided on.

*Table 1. The maximum levels for inorganic arsenic in foodstuffs that are introduced in the Commission’s regulation No 1881/2006 and that will be applied from 01/01/2016.*

<b>Foodstuff</b>	<b>Maximum level, mg/kg wet weight</b>	<b>Maximum level, µg/kg wet weight</b>
3.5 <b>Arsenic (inorganic)<sup>(1)(2)</sup></b>		
3.5.1 Non-parboiled, milled rice (polished or white rice )	0.20	200
3.5.2 Parboiled rice and husked rice	0.25	250
3.5.3 Rice waffles, rice wafers, rice crackers and rice cakes	0.30	300
3.5.4 Rice destined for the production of food for infants and young children <sup>(3)</sup>	0.10	100

<sup>(1)</sup> Sum of As(III) and As(V).

<sup>(2)</sup> Rice, husked rice, milled rice and parboiled rice as defined in Codex Standard 198-1995

<sup>(3)</sup> Scientific Opinion on Arsenic in Food. EFSA Journal 2009; 7(10):1351..

All results from this survey are sent to Efsa’s database to be used in Efsa’s and the European Commission’s continuing work on contaminants in foods. The member states’ data contributes to the evaluation of further possible lowering the maximum levels in the EU.

All results from this survey are also being presented to the European Commission. Sweden encourages the European Commission to work towards lower maximum levels than those recently decided, since these have been shown not to adequately contribute to reducing the consumers’ exposure to inorganic arsenic from rice and rice products. Thus, the maximum levels will not solve the problem with too high arsenic exposure from rice and rice products and therefore the Swedish National Food Agency considers that the maximum levels must be supplemented with information and advice for consumers.

#### ***Continued control and monitoring of inorganic arsenic in food***

Responsibility for operational controls in the area of food is divided between the Swedish National Food Agency and local and county authorities. The control authorities and their remit are stated in Sections 23 and 25 of the Swedish Food Regulations (2006:813). The control authority responsible for controls of operators and trades make official decisions for enforcing the legislation.

In Sweden, responsibility for control over the foodstuffs that are included in this survey is divided between the Swedish National Food Agency and the local authority environmental and health protection committees. Control of food may be performed at the plant where the food is produced, but also later in the food chain. For example at the importer, wholesaler or retailer, where labelling can be checked. The majority of the foods in the survey have been produced abroad and control of production is performed in the country of origin. The Swedish National Food Agency is responsible for controlling the Swedish production, packing and labelling of rice and rice products at the Orkla, Barilla, Semper, Santa Maria and Lecora companies. The Swedish National Food Agency also performs checks at the head offices of the Orkla, Semper, Ica, Axfood, Coop and Lidl companies. The local control authorities are responsible for control of other facilities (such as warehouses and offices) and the other companies of concern in this study.

The maximum levels for certain rice types and rice products that will be enforced at the 1<sup>st</sup> of January 2016, will give the EU member states opportunities to pursue control of these types of product. An annual survey programme on certain contaminants, for example heavy metals, in vegetable foods is in place in Sweden since more than a decade. The survey programme is elaborated and performed at the Swedish National Food Agency. The programme on contaminants in vegetable foods is planned on a three year basis and is based, among other things, on risk.

Contaminants that are regulated are included in this testing programme. Analysis of rice and rice products will therefore be included in the annual survey programme on certain contaminants. Because of the present lack of information on the occurrence of inorganic arsenic in foods other than rice, the Swedish National Food Agency will also perform a survey project to investigate the levels of inorganic arsenic in other foods on the Swedish market. The results will be reported to the European Commission and Efsa according to recommendation (EU) No. 2015/1381.

According to Table 1, a lower maximum level of arsenic applies in rice intended for foods for children under 3 years of age. This maximum level is 100 µg inorganic arsenic per kg rice, to be compared to the maximum level of 200-250 µg per kg in rice. Subsequently, arsenic content of foods intended for infants and children under 3 years of age will be controlled referring to the lower maximum level. However, children generally also eat ordinary foods other than those especially intended for their age, such as rice, breakfast cereals, rice snacks and rice porridge. The question is to be further discussed at the NFA and in the EU how to handle/manage the risk for small children and infants when consuming food products not addressed for their age group and thus posing an increased risk in a long time run of hazardous high arsenic levels.



### **Information to companies, the European Commission, Codex and Efsa**

Information and advice to consumers about inorganic arsenic in rice is a rapid, short-term measure to be able to reduce exposure to inorganic arsenic from food in Sweden and specifically for rice. Since the problem of high levels of inorganic arsenic in rice and rice products mainly arises from naturally high levels of arsenic in bed rock, soil and water, more long-term measures are of greater significance for handling the problem in the longer term. The more long-term measures are of greater significance from both a national and an international public health perspective.

Companies affected are being contacted with information about their own products that have been included in the survey. All these companies are being urged to seek raw materials with as low arsenic content as possible, or to develop methods for reducing the levels of arsenic in the products, since the maximum levels that have been determined have not proved to adequately reduce exposure to inorganic arsenic from rice and rice products. In this way, companies are themselves given the opportunity to influence consumer exposure to inorganic arsenic.

Maximum levels for contaminants are set according to the so-called ALARA principle, which means that maximum levels are to be set as low as practically possible without excluding the market. Thus the ALARA principle does not take into consideration the actual exposure to arsenic from rice and rice products, but rather seeks to force levels down from the existing ones. Voluntary efforts from the companies will therefore be especially important for protecting consumers. The great differences in levels between rice cakes shows that it is obviously possible to produce rice cakes with lower arsenic levels. In rice drinks too, a reduction in levels can be seen compared with earlier studies (Bjerselius et al., 2013).

Our survey shows that it is not possible to point to rice from certain countries as being better or worse, since levels can vary greatly in the same country. Our study does, however, show that basmati and jasmine rice have somewhat lower levels than other types. Whole grain rice appears to generally have a higher content than other types of rice.

Changing the production of rice products would probably generally have a considerably greater effect on arsenic exposure than the individual consumer's preparation of rice. This is because exposure to arsenic comes not only from the rice that is cooked at home but also from many other types of products (such as rice porridge snacks, rice drinks and rice porridge).

The Swedish National Food Agency is also informing the European Commission and Codex about the survey results and project conclusions. The results clearly show that the maximum levels shortly to be introduced do not satisfactorily reduce exposure to inorganic arsenic from food in general and from rice as a raw material in particular. The purpose of the Swedish National Food Agency's action in respect of the European Commission and Codex is in the longer term to be able to influence exposure to inorganic arsenic nationally and internationally.

The Swedish National Food Agency is also informing Efsa about the survey results and project conclusions. The results clearly show that parts of the Swedish (rice eating) population are close to or above the health-based reference points that have been determined for inorganic arsenic.

### **Other factors that have affected the decision**

- Rice and rice products have levels of inorganic arsenic that are approximately 10 times higher than other comparable foods (such as pasta, bread and potatoes). The consumption of rice and rice products in Sweden alone contributes to about 30 per cent of the exposure to arsenic. It is therefore possible in a relatively simple manner to limit or reduce exposure to arsenic in Sweden.
- Comparing rice with potatoes and pasta, rice has a higher impact on the environment. Reducing rice consumption would thus not have negative effects on the environment.
- In 2015 the German risk assessment institute BfR made a similar risk assessment of inorganic arsenic in food. Its conclusion is that the inorganic arsenic exposure of the German population is close to or somewhat over the health-based levels that have been determined. Its conclusion and advice is that rice can be included in a varied and balanced diet, but that products such as rice cakes, rice breakfast cereals and rice porridge should be eaten in moderation and that the consumption of different cereal products should be varied. Parents are also advised not to give their children only rice-based drinks or rice porridge. People with coeliac disease are encouraged to vary rice-based products with maize, millet, buckwheat, amaranth or quinoa.
- In 2013, the Danish Veterinary and Food Administration (Fødevarestyrelsen) in Denmark issued advice that rice can be included in a varied healthy diet, but that rice cakes and rice drinks should not be given to children (no specific ages were stated). Variety is also encouraged, as well as not giving children rice porridge every day. The stated reason for the advice for rice products and children is children's relative consumption of food in relation to body weight.
- Great Britain advises that children aged between 1 and 4.5 years should not drink rice drinks as a substitute for breast milk, formula milk or cow's milk. This advice is also based on children's relatively high consumption in relation to body weight.

# Conclusion

## Consumer advice

The Swedish National Food Agency considers that it is justified in informing consumers about levels of inorganic arsenic in rice and rice products and in giving advice about appropriate rice consumption on the basis of these levels. This is to reduce exposure to arsenic from foods in Sweden, since rice is the food that makes the largest single contribution to exposure. For those who eat rice and rice products, this consumption contributes to a large part of the arsenic exposure. Parts of the Swedish population have an exposure to inorganic arsenic from rice that in certain cases is on the limit of what can be considered acceptable from a long-term perspective.

## Information to companies, the European Commission, Codex and Efsa

The Swedish National Food Agency is informing companies about the survey results and project conclusions. The Swedish National Food Agency is encouraging companies to seek rice raw material with as low arsenic content as possible, or to develop methods to reduce the level of arsenic in products. In this way, companies are themselves given the opportunity to influence consumer exposure to inorganic arsenic.

The Swedish National Food Agency is also informing the European Commission and Codex about the survey results and project conclusions. The results clearly show that the maximum levels shortly to be introduced do not satisfactorily reduce exposure to inorganic arsenic from food in general and from rice as a raw material in particular. The purpose of the Swedish National Food Agency's action in respect of the European Commission and Codex is in the longer term to be able to influence exposure to inorganic arsenic nationally and internationally.

The Swedish National Food Agency is also informing Efsa about the survey results and project conclusions. The results clearly show that parts of the Swedish population have an exposure to inorganic arsenic from rice that in certain cases is on the limit of what can be considered acceptable from a long-term perspective.

## Continued controls and monitoring of inorganic arsenic in food

When the new maximum levels come into force in 2016, authorities in Europe will have the opportunity by means of control projects to sample and analyse rice and rice products.

Analysis of arsenic in rice will therefore be planned into the Swedish National Food Agency's testing for foreign substances in vegetable products, to ensure that the maximum levels are not exceeded. The Swedish National Food Agency will also perform survey projects in the next few years to investigate levels of inorganic arsenic in other foods on the Swedish market. The results will be reported to the European Commission and Efsa according to recommendation (EU) No. 2015/1381.

Decided on 25 September 2015

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