

Supplement EU maximum levels for inorganic arsenic in rice and rice products through consumption recommendations for the protection of infants, young children and children

Updated BfR Opinion No. 017/2015 of 06 February 2014¹

Rice and rice-based products, such as rice cakes or rice flakes for creamed rice, can contain relatively high levels of inorganic arsenic. Inorganic arsenic is classified as carcinogenic for humans by international panels and no intake quantity can be defined as safe for human health with regard to its carcinogenic effect (cf. BfR Opinion No. 018/2015 of 24 June 2014). In the European Union, the introduction of maximum levels for inorganic arsenic in rice and rice products is being discussed on the basis of the health assessment of the European Food Safety Authority (EFSA)². The German Federal Institute for Risk Assessment (BfR) has assessed the proposed maximum levels for rice and rice products from a health point of view and comes to the conclusion that the maximum level of 0.2 milligrams of inorganic arsenic per kilogram recommended for white rice is only suitable to avoid particularly high levels in rice. The proposal to introduce lower maximum levels for products used in the manufacture and preparation of baby food such as rice flakes/creamed rice is endorsed by the BfR. The Institute points out, however, that even under the assumption of concentrations of inorganic arsenic at the level of the recommended maximum limit of 0.1 milligrams per kilogram, the exposure of infants and young children to inorganic arsenic in rice flakes/creamed rice can still be high due to the fact that children consume comparatively large quantities of food in relation to their body weight. For this reason, the BfR considers accompanying measures as necessary. For example, it should be recommended that parents do not feed children and infants exclusively on the basis of rice or rice-based cereal products such as rice cakes or creamed rice/rice flakes, and rather alternate them with products based on other cereal types.

Subject of the assessment

The German Federal Institute for Risk Assessment (BfR) assessed the maximum levels for arsenic in rice and rice products proposed by the EU Expert Committee "Industrial and Environmental Contaminants" and by the European Commission. These are proposed maximum levels of inorganic arsenic for all listed food categories. The BfR also assessed whether the proposed maximum levels of arsenic in rice and rice products are suitable for protecting the health of consumers in Germany from negative effects caused by arsenic in rice and rice products. The BfR bases its opinion on the proposed maximum levels for inorganic arsenic in rice and rice products on data on the occurrence of inorganic arsenic in rice and rice products from the food monitoring authorities of the federal states, transmitted by the Federal Office of Food Safety and Consumer Protection (BVL), and data from a project investigating the occurrence of inorganic arsenic in rice and rice products of one federal state, which were subjected to a health assessment in Opinion No. 018/2015 of 24 June 2014.

¹ The opinion was supplemented by the contents of a further opinion of 17 September 2014

² To date, the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) of the European Commission has approved maximum levels of inorganic arsenic in food for the following food categories:

Milled rice, not parboiled (polished and white rice); parboiled rice and husked rice;

, rice waffles, rice wafers, rice crackers and rice cakes; rice destined for the production of food for infants and young children.

According to the draft regulation of 13 March 2015, the introduction of maximum levels is planned for 1 January 2016.

Result

The BfR welcomes the plan to introduce maximum levels of inorganic arsenic in rice and rice products and particularly endorses the introduction of especially low maximum levels for rice-based products used to prepare food for infants and young children.

On the proposed maximum level for **white rice (milled rice)** of **0.2 mg/kg** of inorganic arsenic:

A maximum level at the proposed value of 0.2 mg/kg of inorganic arsenic for white rice (milled rice) would only be suitable for preventing particularly high levels of inorganic arsenic in grains of rice.

On the proposed maximum level for **brown rice (husked rice)** of **0.25 mg/kg** of inorganic arsenic:

The scope of measurement results on inorganic arsenic in brown rice and rice products on the German market (data from the food monitoring authorities of the federal states and from a project of one federal state) that is available to the BfR is not sufficient to assess the proposed maximum level of inorganic arsenic for brown rice with regard to the resulting effects on consumer health.

On the proposed maximum level for **white parboiled rice (parboiled milled rice)** of **0.3 mg/kg** of inorganic arsenic
and

on the proposed maximum level for **brown parboiled rice (parboiled husked rice)** of **0.25 mg/kg** of inorganic arsenic:

The BfR does not recommend following the suggestion to introduce a higher proposed maximum level of inorganic arsenic in white parboiled rice (parboiled milled rice) and in brown parboiled rice (parboiled husked rice). Based on the data on the occurrence of inorganic arsenic in parboiled rice available to the BfR from food monitoring and from a project of one federal state, it is not possible to determine whether the introduction of a higher maximum level of inorganic arsenic is necessary for parboiled rice due to the different levels as compared to white rice.

On the proposed maximum level for **rice products (puffed rice, rice cakes, rice crackers, rice doughnuts)** made from **white rice (milled rice)** of **0.25 mg/kg** of inorganic arsenic
and

on the proposed maximum level for **rice products (puffed rice, rice cakes, rice crackers, rice doughnuts)** made from **brown rice (husked rice)** of **0.3 mg/kg** of inorganic arsenic:

As long as the causes of the occurrence of comparatively high levels of inorganic arsenic in rice products – such as rice cakes – are not known, the BfR recommends refraining from introducing separate maximum levels of inorganic arsenic in rice products that are higher than the maximum levels for white or brown rice.

In the view of the BfR, a recommendation on consumption levels can serve the purpose of limiting the intake of inorganic arsenic in children as a result of the consumption of rice products such as rice cakes.

In February 2014, the BfR already communicated an opinion on a proposed maximum level of 0.2 mg inorganic arsenic per kg for rice and rice products (white rice). From the perspective of consumer health protection, the value proposed at that time for a maximum level regulation for rice products is preferable.

On the proposed maximum level for **food for infants and young children (white rice (milled rice))** intended for the production of food for infants and young children) of **0.1 mg/kg** of inorganic arsenic:

The introduction of a maximum level of 0.1 mg/kg would be a suitable measure to significantly reduce the exposure of infants and young children to inorganic arsenic as a result of the consumption of rice-based food for infants and young children. However, even under the assumption of inorganic arsenic contents at the proposed maximum level of 0.1 mg per kg, infants and young children would still take in comparatively high amounts of inorganic arsenic through the consumption of these products.

As a further measure to lower the intake of inorganic arsenic in young children and children, the BfR recommends that a consumption recommendation be issued. This should inform consumers, on the one hand, that infants and children should not be fed exclusively on the basis of rice-based foods. On the other hand, it should recommend varying rice-based products with products based on other cereal types. The BfR also recommends defining maximum levels of inorganic arsenic in rice-based food for infants and young children not for the raw ingredient rice intended for the production of infants and children's food but for the powdered product itself "as sold".

In addition, the BfR holds the view that the causes of the comparatively high levels of inorganic arsenic in food for infants and young children as compared to the levels in the source products (raw ingredients) should be clarified.

Reasoning

With respect to the carcinogenic effect of inorganic arsenic, no intake level that is not associated with an increased risk of cancer can be derived. In its Opinion No. 018/2015 on arsenic levels in rice and rice products, the BfR therefore comes to the conclusion that health risks relating to carcinogenic effects are possible due to the intake of inorganic arsenic via rice and rice products. In the BfR opinion, values for the margin of exposure (MOE)³ regarding the intake of inorganic arsenic through the consumption of rice and rice products were determined to be comparatively low for consumers in Germany (MOE values of 9 to 500 for children with moderate levels of consumption, MOE values of 2 to 143 with high levels of consumption (P95); MOE values of 37 to 1,000 for adults with moderate levels of consumption, and MOE values of 12 to 320 with high levels of consumption).

³ The margin of exposure is calculated as a ratio between human exposure (extent of contact with a substance) and the effect dose determined or modelled in a study for a given incidence of tumours (here, for example, $BMDL_{01} = 95\%$, lower confidence limit (L) of a benchmark dose (BMD) that corresponds to an additional risk of cancer ("extra risk") of 1%).

These low MOE values show that a small margin exists between the intake quantity of inorganic arsenic through the consumption of rice and rice products estimated in the exposure model and the $BDML_{01}$ values (0.3 to 8 $\mu\text{g}/\text{kg}$ BW per day) derived from epidemiological studies on the connection between exposure to inorganic arsenic in drinking water and adverse effects. Comparatively low MOE values for the intake quantities of inorganic arsenic resulting purely from the long-term consumption of certain rice products such as rice cakes also result for individual population groups. The low MOE values mean that reducing the exposure to inorganic arsenic from rice and rice products in consumers of all age groups is of high priority. The levels of inorganic arsenic in food should be kept as low as reasonably achievable (ALARA principle). In its Opinion 018/2015, the BfR therefore recommends that possibilities to reduce exposure to inorganic arsenic through the consumption of rice and rice products be reviewed for consumers in all age groups.

The proposed maximum levels are discussed below with regard to the arsenic levels in products on the German market, on which the health assessment in BfR Opinion 018/2015 was based. The data on the occurrence of inorganic arsenic in rice and rice products came from:

1. Food monitoring in 2010 and 2011, transmitted by the German Federal Office of Consumer Protection and Food Safety (BVL)
2. The project of one federal state investigating the occurrence of inorganic arsenic in rice and rice products.

Tab. 1: Number of measured levels of inorganic arsenic that are above the proposed maximum levels for white rice (milled rice) (0.2 mg/kg), for white parboiled rice (parboiled milled rice) (0.3 mg/kg) or for brown rice (husked rice) (0.25 mg/kg), data from food monitoring in 2010 and 2011

	N	> 0.2 mg/kg	>0.25; >0.3
White rice (apart from that listed below)*	190	3	
White rice, parboiled	38	0	0
Brown rice**	10	0	0

* Without information on processing; rice (not specified further), round-grain rice, long-grain rice are grouped together here

N: Number of analysis results

** Designated as "Rice, unpolished" in the data transfer

Tab. 2: Number of measured levels of inorganic arsenic that are above the proposed maximum levels for white rice (milled rice) (0.2 mg/kg), for white parboiled rice (parboiled milled rice) (0.3 mg/kg), for brown rice (husked rice) (0.25 mg/kg), for rice products (puffed rice, rice cakes, rice crackers, rice doughnuts) manufactured from white rice (milled rice) (0.25 mg/kg) or for white rice intended for the production of food for infants and young children (0.1 mg/kg), data from the project of one federal state in 2010–2011

	Valid N	> 0.2 mg/kg	> 0.25 mg/kg	> 0.3 mg/kg
White rice (apart from that listed below)	70	4**		
White rice, parboiled	4		0	0
Brown rice*	6	2	0	0
Rice cakes	51		26***	14
Puffed rice, chocolate rice and rice crackers	10		0	0
	Valid N	> 0.1 mg/kg	> 0.2 mg/kg	
Creamed rice, rice flakes***	25	23	8	

*Designated as "Natural and whole-grain rice" in the data transfer

** 1 sample= 0.2 mg/kg

***2 samples= 0.25 mg/kg

On the proposed maximum level of **inorganic arsenic in white rice (milled rice)** of **0.2 mg/kg**:

The levels of inorganic arsenic in white rice without information on processing (e.g. "parboiled") were viewed in relation to the proposed maximum level for white rice of 0.2 mg/kg.

In the levels of inorganic arsenic reported by the food monitoring authorities in 2010 and 2011 (LB 0.07 mg/kg, UB 0.086 mg/kg), three values were above the proposed maximum level (1.5%) (Table 1). In the rice samples analysed in the project of one federal state (mean value 0.1 mg/kg), four values were above the proposed maximum level for inorganic arsenic (5%) (Table 2).

According to this, a maximum level at the proposed value would only be suitable for preventing particularly high levels of inorganic arsenic in grains of rice.

On the proposed maximum level of **inorganic arsenic in brown rice (husked rice)** of **0.25 mg/kg**:

Only a small number of analysis results on the occurrence of inorganic arsenic in brown rice from food monitoring and from the project of one federal state are available to the BfR. A health assessment of the proposed maximum level of inorganic arsenic in brown rice is not possible based on these data. The proposed maximum level of inorganic arsenic in brown rice (0.25 mg/kg) was not exceeded in the available measurement results (Tab. 1 and 2).

In the levels of inorganic arsenic reported by the food monitoring authorities in 2010 and 2011 (LB 0.089 mg/kg, UB 0.099 mg/kg), there was also no value above the proposed maximum level of 0.2 mg per kg for white rice. In the results on inorganic arsenic in brown rice reported by one federal state (mean value 0.141 mg/kg), two of six measurement results exceeded the value of 0.2 mg inorganic arsenic per kg.

In the definition of different maximum levels for inorganic arsenic in white and brown rice, the BfR recommends that the assignment of red rice to one of the maximum level categories should also be regulated. No measured values on the occurrence of arsenic in red rice are available to the BfR, either from the data collected by one federal state (2010) or from the data from the food monitoring authorities.

On the proposed maximum level of **inorganic arsenic in white parboiled rice (parboiled milled rice)** of **0.3 mg/kg**

and

on the proposed maximum level of **inorganic arsenic in brown parboiled rice (parboiled husked rice)** of **0.25 mg/kg**:

With respect to the "parboiled rice" category, it was not evident from the data set of the food monitoring authorities from 2010 and 2011 (Tab. 1) or from the data set from the project of one federal state in 2010–2011 (Tab. 2) whether the sample material was white or brown parboiled rice. As Tables 1 and 2 show, the levels of inorganic arsenic were not above the proposed maximum levels for any of the analysed samples.

Only a small number of analysis results on the occurrence of inorganic arsenic in parboiled rice from the project of one federal state are available to the BfR. Based on these data, it is not possible to decide whether the difference in the occurrence in parboiled rice as compared to white rice necessitates the introduction of a higher maximum level of inorganic arsenic in parboiled rice.

The BfR does not recommend following the suggestion to introduce a higher proposed maximum level for inorganic arsenic in white parboiled rice (parboiled milled rice) than in brown parboiled rice (parboiled husked rice).

On the proposed maximum level of **inorganic arsenic in rice products (puffed rice, rice cakes, rice crackers, rice doughnuts)** made from **white rice (milled rice)** of **0.25 mg/kg**

and

on the proposed maximum level of **inorganic arsenic in rice products (puffed rice, rice cakes, rice crackers, rice doughnuts)** made from **brown rice (husked rice)** of **0.3 mg/kg**:

For the rice products "Rice cakes" and "Puffed rice, chocolate rice and rice crackers", it was not clear from the transmitted data whether the products in question were made from brown rice (natural and whole-grain rice) or white rice.

Of the 10 samples of puffed rice, chocolate rice and rice crackers analysed, no samples contained more than the proposed maximum level of inorganic arsenic in rice products made from white rice (milled rice) of 0.25 mg per kg. Due to the low number of samples and the uncertainty on the percentage of rice contained in the analysed rice products, it is not possible to make a statement on the effect of the proposed maximum levels for this product group based on the available data.

In rice cakes, the level of inorganic arsenic in a large proportion of the analysed samples (47%) was above the proposed maximum level for rice products made from white rice (milled rice) of 0.25 mg per kg (Table 2). The mean value of levels of

inorganic arsenic in rice cakes was 0.26 mg per kg; the 95th percentile was 0.425 mg per kg.

In the view of the BfR, a maximum level of inorganic arsenic at the proposed value would be suitable to considerably reduce the levels of inorganic arsenic in rice cakes and to lower consumer exposure. However, the maximum level would also be exceeded by a large proportion of products currently on the market.

In February 2014, the BfR already communicated an opinion on an earlier proposed maximum level of inorganic arsenic of 0.2 mg/kg for rice and rice products (white rice). From the perspective of health risk assessment, the lower proposed maximum level of 0.2 mg/kg for rice products suggested at that time is preferable.

As long as the causes of the occurrence of comparatively high levels of inorganic arsenic in rice products – such as rice cakes – are not known, the BfR recommends refraining from introducing separate maximum levels of inorganic arsenic in rice products that are higher than the maximum levels for white or brown rice.

To reduce the intake of inorganic arsenic due to the consumption of rice cakes, particularly in children, the BfR also proposes considering a recommendation on consumption levels, because the EFSA opinion (2014) also refers to the unusually high levels of inorganic arsenic in rice waffles.

Furthermore, the BfR recommends clarifying the reasons for the comparatively high levels of inorganic arsenic in rice waffles.

On the proposed maximum level of **inorganic arsenic in food for infants and young children with white rice (milled rice)** intended for the production of food for infants and young children of **0.1 mg/kg**:

The BfR welcomes the proposal to introduce a maximum level of inorganic arsenic in rice-based food for infants and young children. No data on levels of inorganic arsenic in rice intended for the production of food for infants and young children are available to the BfR. The data on the occurrence of inorganic arsenic in cereal porridge and cereal flakes transmitted by the BVL and the project of one federal state did not contain information on whether or not the products involved were designated as food for infants and young children. All available data on levels of inorganic arsenic in the products "Gluten-free cereal porridge", "Creamed rice" and "Rice flakes" were viewed in relation to the proposed maximum level of inorganic arsenic in rice-based food for infants and young children of 0.1 mg/kg.

In the data transmitted by the federal state, the levels of inorganic arsenic in the rice product "Instant rice-based baby food" (designated as creamed rice, rice flakes in the data transfer) were higher than in white rice. The cause of the higher levels of inorganic arsenic in the rice product as compared to white rice is not known. The extent to which the level of inorganic arsenic in the source raw ingredient alone determines the level of inorganic arsenic in the processed product is therefore unclear. For this reason, the BfR recommends defining maximum levels of inorganic arsenic in rice-based food for infants and young children not for the rice intended for the production of the food for infants and young children but for the powdered product itself "as sold".

The proposed maximum level of inorganic arsenic of 0.1 mg/kg for rice-based food for infants and young children was exceeded in a high percentage of the analysed products in the data transmitted by the food monitoring authorities (61.5%, Table 1) and in the data collected by one federal state (92%, Table 2). Furthermore, the levels of inorganic arsenic in the samples analysed in the project of one federal state were above the proposed maximum level of 0.2 mg/kg for white rice in 32% of cases (8 of 25 analysed samples, 5 of these from the "Rice flakes" category and 3 from the "Creamed rice" category) (Table 2).

In the view of the BfR, the introduction of a maximum level of 0.1 mg/kg would be a suitable measure to significantly reduce the exposure of infants and young children to inorganic arsenic as a result of the consumption of rice-based food for infants and young children.

However, even assuming that inorganic arsenic levels are at the proposed maximum level of 0.1 mg per kg, infants and children would still take in comparatively high amounts of inorganic arsenic through the consumption of these products. For example, a quantity of 20 g rice flakes was recommended according to the recipe (information on the package) for preparing an infant formula food for a baby aged over 4 months or porridge from the 7th month. For a child aged between 6 months and less than one year, the consumption of a daily portion prepared in this way, with a level of 0.1 mg/kg inorganic arsenic, would result in an intake of 0.25 µg/kg body weight per day⁴. This would correspond to MOE values of 1 to 32 (BMDL₀₁ 0.3 to 8 µg/kg body weight/day). For a child aged between one and less than two years, this would result in an intake of 0.12 µg/kg body weight/day⁵, corresponding to MOE values of 3 to 67.

As a measure to reduce the intake of inorganic arsenic through the consumption of rice-based food for infants and young children, the BfR therefore recommends that a consumption recommendation be issued. On the one hand, this should inform consumers that infants and children should not be fed exclusively on the basis of rice-based foods and, on the other hand, it should recommend varying rice-based products with products based on other cereal types. In addition, the BfR holds the view that the causes of the comparatively high levels of inorganic arsenic in food for infants and young children as compared to the levels in the source products (raw ingredients) should be clarified.

Based on a request submitted by the BfR, the occurrence of inorganic arsenic and total arsenic in rice cakes and rice-based baby food will now be analysed within the scope of national and federal state food monitoring programmes as part of Project 7 "Total arsenic and inorganic arsenic in rice and in specific rice products" (project monitoring 2014) in order to improve the database for the health assessment of these products.

⁴ Body weight according to VELs study 8.9 kg (Heseker et al. 2003)

⁵ Body weight according to VELs study 11.2 kg (Heseker et al. 2003)

Additional information on this topic on the BfR website

Arsenic in Rice and Rice Products

BfR Opinion 018/2015 of 24 June 2014

<https://www.bfr.bund.de/cm/349/arsenic-in-rice-and-rice-products.pdf>

Questions and answers on arsenic levels in rice and rice products

FAQ of the BfR dated 4 August 2015

<https://bfr.bund.de/cm/349/frequently-asked-questions-on-arsenic-levels-in-rice-and-rice-products.pdf>

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