Bundesinstitut für Risikobewertung

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EU maximum levels for cadmium in food for infants and young children sufficient - Exposure to lead should fundamentally be reduced to the achievable minimum

BfR Opinion No. 026/2018 of 7 August 2018

Cadmium and lead occur naturally in the Earth's crust from where they can be released through natural and anthropogenic processes and find their way into the food chain. As these substances can be harmful to human health, strict legal regulations already apply in the European Union to food for infants and young children. These have to be validated consistently, however, and adapted as required. In doing so, the latest results of official food and veterinary monitoring are included in the process.

On the basis of the data on occurrence in food obtained from the Federal Control Plan (FCP) 2015, and Monitoring 2015, the German Federal Institute for Risk Assessment (BfR) has made a health assessment of the occurrence of lead and cadmium in food for infants and young children. On behalf of Germany, the BfR comes to the conclusion that where the products tested in the categories "baby formula in powder form" and "ready to eat", as well as "processed cereal-based foods in powder form" and "ready to eat" are concerned, no health impairment through cadmium is currently likely. This applies to children in the age group 0.5 to < 3 years, both at average and high consumption. From the data available, the BfR does not derive any necessity to lower the maximum levels from a health point of view.

The "margin of exposure" (MoE) approach was applied in the frame of the examination of the occurrence of lead in food for infants and young children. With substances such as lead, for which no statement on a "safe" uptake quantity is possible, this approach provides indications of the degree of urgency with which measures are required. The $BMDL_{01}$ value for developmental neurotoxicity of 0.5 micrograms (µg) per kilogram (kg) body weight per day served as the basis for the health assessment of the uptake of lead by infants and young children. The uptake of lead was below this value in children with average consumption of the tested products as well as high consumers. Fundamentally, however, the BfR holds with the estimation that no safe intake quantity can be derived for lead where the developmental neurotoxic effects in children are concerned. Exposure should therefore be reduced accordingly to the minimum achievable level.

Breast milk remains the ideal nutrition for infants. Because of the health advantages for both mother and child, the BfR recommends that infants be breastfed exclusively up to the beginning of the fifth month and thereafter for as long as the mother and child care to do so once complementary food has been introduced. If infants are not or not fully breastfed, however, they require industrially produced baby food. These products contain vital nutrients and continue to offer parents an alternative to breastfeeding. The general rule is that children should be given complementary food from their fifth month of life at the earliest and from the seventh month at the latest to supplement breast milk or breast milk substitute products.

1 Object of the assessment

The BfR has made a health assessment regarding the occurrence of lead and cadmium in food for infants and young children on the basis of the results of the Federal Control Plan (FCP) 2015 and Monitoring 2015.

BfR Risk Profile: Cadmium levels in baby and infant food (Opinion No. 026/2018)					
A Affected group(s)	**Infants and young children**				
B Probability of a health impairment through the regular high intake of formulae or processed cereal-based foods in powder form or ready-to-eat	Practically excluded	**Unlikely**	Possible	Probable	Certain
C Severity of the health impairment through the regular high intake of formulae or processed cereal-based foods in powder form or ready-to-eat	**No information possible**				
D Reliability of the available data	High: The most important data are on hand and free of contradiction	**Moderate: Some important data are missing or contradictory**	Low: Numerous important data are missing or contradictory		
E Controllability by the consumer [1]	**Control not necessary**	Controllable through precautionary measures	Controllable through avoidance	Not controllable	

Squares highlighted in dark blue indicate the properties of the risk assessed in this opinion (more detailed information on this is contained in BfR Opinion No. 026/2018 of 07 August 2018).

Explanations

The risk profile is intended to visualise the risk outlined in the BfR Opinion. It is not intended for the purpose to comparing risks. The risk profile should only be read in conjunction with the corresponding opinion.

Row C – Severity of the health impairment:
The severity of the potential risk cannot currently be quantified on the basis of the available data.

Row E – Controllability by the consumer
[1] – The information contained in the row “Controllability by the consumer” should not be seen as a recommendation from the BfR; it has a purely descriptive character.

GERMAN FEDERAL INSTITUT FOR RISK ASSESSEMENT (BfR)

2 Result

Cadmium

Health impairments through the uptake of cadmium via the consumption of foods for infants and young children in the food categories “baby formula in powder form” and “ready to eat”, as well as “processed cereal-based foods in powder form” and “ready to eat” are currently unlikely for children in the age group 0.5 to < 3 years, both at average and high consumption (95th percentile of consumption). The BfR came to this conclusion after assessing the available data on occurrence from the Federal Control Plan (FCP) 2015 and Monitoring 2015.

The current maximum levels for cadmium for foods for infants and young children lie in the range of the 95th percentile of the levels determined in the FCP and Monitoring 2015.

Lead

The exposure of children in the age group 0.5 to < 3 years through the intake of lead via the consumption of foods for infants and young children in the food categories “baby formula in powder form” and “ready to eat”, as well as “processed cereal-based foods in powder form” and “ready to eat” lie below the $BMDL_{01}$ value for developmental neurotoxicity of 0.5 micrograms (µg) per kilogram (kg) body weight per day for children with average consumption as well as high consumers on the basis of the levels indicated in the FCP and Monitoring 2015. As no safe uptake quantity can be given for lead with regard to its effect on developmental neurotoxicity in children, however, exposure should generally be reduced to the achievable minimum.

3 Justification

3.1 Agent and hazard potential

Definitions of terminology

Directive 2006/141/EC *on infant formulae and follow-on formulae* uses the following definitions:

- Infants: children under the age of twelve months
- Young children: children aged between one and three years
- Infant formulae: foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants *until the introduction of appropriate complementary feeding*
- Follow-on formulae: foodstuffs intended for particular nutritional use by infants *when appropriate complementary feeding is introduced* and constituting the principal liquid element in a progressively diversified diet of such infants.

Cadmium

Cadmium occurs naturally in the Earth’s crust and is released by both natural and anthropogenic processes. It is ubiquitous in the environment. Cadmium has a long biological half-life in the human body (ten to 30 years) and accumulates in the liver and kidneys in particular. The most sensitive toxicological endpoint of cadmium is renal toxicity. In their opinion of January 2009, the European Food Safety Authority (EFSA) derived a tolerable weekly intake

(TWI) of cadmium of 0.0025 milligrams (mg) (the equivalent of 2.5 µg) per kg body weight (EFSA 2009) on the basis of the effect of cadmium on the kidneys.

Lead

Lead occurs naturally in the Earth's crust and is released by both natural and anthropogenic processes. It is ubiquitous in the environment. Lead has a long biological half-life in bone (ten to 30 years) and accumulates mainly in this organ. Toxic effects of lead affect haematosis, the kidneys, the cardiovascular system and central nervous system. In their opinion published in 2010, EFSA comes to the conclusion that the internationally established provisional tolerable weekly intake (PTWI[1]) for lead as a reference value for health risk assessment is no longer appropriate to sufficiently protect consumers from the possible health effects of lead exposure via food. More recent data substantiate that even very small quantities of lead can produce damaging effects in the body. This means that no intake quantity without any health-impairing effects can be given, which is the reason why EFSA is suggesting the use of the "margin-of-exposure (MoE[2]) approach". The EFSA Panel on Contaminants in the Food Chain (CONTAM) has identified developmental neurotoxicity in children[3] and cardiovascular effects and nephrotoxicity in adults as critical effects for risk assessment. The corresponding BMDL values[4] in µg per litre (l) (equivalent to an alimentary uptake in µg per kg body weight per day) derived from blood lead levels were: developmental neurotoxicity: $BMDL_{01}$, 12 µg per l (0.50 µg per kg body weight per day); effects on systolic blood pressure: $BMDL_{01}$, 36 µg per l (1.50 µg per kg body weight per day); effects on the prevalence of chronic kidney disease: $BMDL_{10}$, 15 µg per l (0.63 µg per kg body weight per day). The $BMDL_{01}$ value of 0.5 µg per kg body weight per day is used in the following for the health assessment of the uptake of lead by infants and young children.

Maximum levels of cadmium and lead in food for infants and young children

Maximum levels for food for infants and young children are determined in Regulation (EU) 2015/1005 for lead and Regulation (EU) No. 488/2014 for cadmium amending Regulation (EU) No. 1881/2006. Table 1 provides an overview of the regulated foods and corresponding maximum levels.

[1] Preliminary estimation of the quantity of a substance which can be ingested weekly over an entire lifetime without the occurrence of any health impairments.

[2] MoE = as a dimensionless number, the Margin of Exposure stipulates the ratio between a defined point on the dose-response curve at which a slight but measurable adverse effect exists in animal studies or epidemiological studies and the estimation of exposure for certain population groups. The MoE does not imply any statement about the "safe" uptake quantity in the sense of a tolerable daily intake quantity. It is used when no dose without effect can be determined experimentally and it provides risk management with indications about the degree of urgency with which measures are required.

[3] "Young children" EFSA (2010)

[4] BMDL = Benchmark Dose Lower Confidence Limit; the $BMDL_x$ value equates to the statistical unilateral lower limit of the 95% confidence interval of the dose or concentration which causes an increase in the frequency/extent of an effect by x %.

Table 1: Maximum levels of cadmium and lead in food for infants and young children

Cadmium (Regulation (EU) No. 488/2014)			Lead (Regulation (EU) 2015/1005)		
Food group		Max. level (mg per kg)	Food group		Max. level (mg per kg)
3.2.19.	Infant formulae and follow-on formulae		3.1.2.	Infant formulae and follow-on formulae	
a.	Powdered formulae manufactured from cow's milk proteins or protein hydrolysates	0.010	a.	Powder	0.050
b.	Liquid formulae manufactured from cow's milk proteins or protein hydrolysates	0.005	b.	Liquid	0.010
c.	Powdered formulae manufactured from soya protein isolates alone, or in a mixture with cow's milk proteins	0.020			
d.	Liquid formulae manufactured from soya protein isolates alone, or in a mixture with cow's milk proteins	0.010			
3.2.20.	Processed cereal-based foods and other baby foods	0.040	3.1.3.	Processed cereal-based foods and other baby foods	0.050

It should be noted that with cadmium and lead, maximum levels for infant and follow-on formulae have been determined for the commercially available powder form on the one hand and for liquid food on the other. For processed cereal-based food and other baby food, the maximum levels relate to the commercially available produce (Regulation (EU) No. 1881/2006) without differentiating the product condition.

3.2 Exposure

3.2.1 Occurrence

Foods for infants and young children were examined for cadmium and lead within the scope of Monitoring 2015 and the FCP 2015. 444 data records from the FCP were evaluated for both lead (Pb) and Cadmium (Cd), along with 77 (Pb) and 78 (Cd) from the monitoring of foods for infants and young children, which were grouped together in line with the maximum levels set out in Regulations (EU) 2015/1005 and No. 488/2014. In Monitoring 2015, however, only data for cereal porridge was collected. No differentiated examination of powdered and ready-to-eat foods could be made. The FCP data used here does not give any clear description of the form of the food as a powder or ready-to-eat product. On the basis of the description and evaluations in the FCP 2015 report, however, it is assumed that virtually all samples analysed were in powder form (BVL 2015a, BVL 2015b).

Values below the limits of detection and quantification (LOD/LOQ) were taken into account in accordance with the modified lower bound, medium bound and upper bound approaches. With the modified lower bound, the values below the detection level were set to zero and the values below the quantification level to the detection level. If there was no information on the detection level, the corresponding value was also set to zero. The medium bound takes into consideration the values below the LOD/LOQ at half the value of each respective LOD/LOQ. Finally, the values below the LOD/LOQ are set at the corresponding LOD/LOQ in the upper bound approach.

Occurrence of cadmium, Monitoring and FCP 2015

With foods made from cow's milk proteins or protein hydrolysates (powder), hereinafter referred to as "baby formula in powder form", and complete meals, high percentages (77% and 50% respectively) lie below the detection and quantification limits (LOD/LOQ) for cadmium. With a mean cadmium level of 0.003 mg per kg and/or a 95th percentile of 0.007 mg per kg (medium bound), the maximum level that applies to foods made from cow's milk proteins (powder) of 0.01 mg per kg is not reached. Overall, the maximum level for cadmium was exceeded by one sample of baby formula in powder form. The highest levels of cadmium in the examined food products for infants and young children are to be found in processed cereal-based food (powder) with 0.019 mg per kg (mean, medium bound) and/or 0.037 mg per kg in the 95th percentile (medium bound). A maximum level of 0.040 mg per kg was set for processed cereal-based food, a level which was not quite reached through the 95th percentile of the measured levels. There were a total of six samples in FCP and two in Monitoring which exceeded the maximum level for cadmium in processed cereal-based food.

Table 2: Occurrence of cadmium in foods for infants and young children (FCP 2015, Monitoring 2015)

Food groups	Cadmium in foods for infants and young children in mg per kg							
	N	% <LOD/ LOQ	Modified lower bound[1]		Medium bound[2]		Upper bound[3]	
			mean	P95	mean	P95	mean	P95
Food made from cow's milk proteins or protein hydrolysates (powder)*	257	77	0.001	0.006	0.003	0.007	0.005	0.007
Food made from soya protein isolates alone, or in a mixture (powder)	20	0	0.013	0.017	0.013	0.017	0.013	0.017
Processed cereal-based food (powder)*	199	11	0.019	0.037	0.019	0.037	0.019	0.037
Rusk or biscuits for infants and young children	30	3	0.013	0.021	0.013	0.021	0.013	0.021
Complete meals for infants and young children	16	50	0.005	0.017	0.005	0.017	0.006	0.017

*Each containing one sample of ready-to-eat food for infants and young children
Modified lower bound: Values <LOD =0, Values <LOQ=LOD
Medium bound: Values < LOD/LOQ=1/2 LOD/LOQ
Upper bound: Values <LOD/LOQ=LOD/LOQ

The data on occurrence in the food group "Complete meals for infants and young children" were not taken into consideration when estimating exposure due to the small number of samples and composition of the group from a wide range of different complementary foods containing meat, fish or fruit. The data on occurrence in rusk and biscuits were not included in the exposure estimation either.

EFSA opinion on the occurrence of cadmium (2009), comparison

With values ranging from 0.0037 to 0.0073 mg per kg, higher levels of cadmium went into the intake estimation conducted by EFSA (2009) for food for infants and young children compared to the current intake estimation. With 0.0177 mg per kg, the mean cadmium level determined by EFSA (2009) for processed cereal-based food in powder form lay in a range similar to the level of 0.019 mg per kg determined in the FCP and Monitoring 2015.

Occurrence of lead

With 44 to 85%, the FCP and Monitoring 2015 data for lead in food for infants and young children show a high percentage of values below the limits of detection and quantification

(Table 3). Differences in the occurrence in baby formula and processed cereal-based food in powder form in the 95th percentile of the medium and upper bound can be explained by the considerable differences in the limits of detection and quantification between the individual laboratories.

Table 3: Occurrence of lead in food for infants and young children (FCP 2015, Monitoring 2015)

Food group	Lead in food for infants and young children (mg per kg)							
	N	% <LOD/ LOQ	Modified lower bound[1]		Medium bound[2]		Upper bound[3]	
			mean	P95	mean	P95	mean	P95
Food made from cow's milk proteins or protein hydrolysates (powder)*	257	72	0.005	0.026	0.010	0.026	0.016	0.039
Food made from soya protein isolates alone, or in a mixture (powder)	20	85	0.005	0.043	0.009	0.043	0.014	0.043
Processed cereal-based food (powder)*	198	72	0.004	0.016	0.008	0.016	0.013	0.030
Rusk or biscuits for infants and young children	30	77	0.005	0.015	0.007	0.015	0.009	0.015
Complete meals for infants and young children	16	44	0.009	0.041	0.010	0.041	0.010	0.041

*Each containing one sample of ready-to-eat food for infants and young children
[1]Modified lower bound: Values <LOD =0, Values <LOQ=LOD
[2]Medium bound: Values < LOD/LOQ=1/2 LOD/LOQ
[3]Upper bound: Values <LOD/LOQ=LOD/LOQ

On average and in the 95th percentile, the levels of lead in baby formula in powder form are below the maximum level of 0.05 mg per kg for foods made from cow's milk proteins or protein hydrolysates (powder). This applies to all individual values for lead in this food category measured within the scope of FCP. The average levels and 95th percentile for processed cereal-based foods (powder) examined in the FCP as well as in Monitoring are also below the maximum level of 0.05 mg per kg. One individual value measured in the FCP was above the maximum level for lead in processed cereal-based food.

The data on occurrence in the food group "Complete meals for infants and young children" were not taken into consideration in the exposure estimation due to the small number of samples and the composition of the group from a wide range of different complementary foods containing meat, fish or fruit. The data on occurrence in rusk and biscuits were not included in the exposure estimation either.

Occurrence of lead, EFSA opinion (2012), comparison

EFSA made an estimate of the intake of lead by young children (aged 0.5 to 6 years) in 2012 in which it listed a mean level of 0.003 – 0.004 mg per kg for baby formula in powder form, a level which lies below the lead level of 0.01 mg per kg measured in the FCP and Monitoring 2015. With 0.013 mg per kg, the value for cereal-based foods lay slightly above the level of 0.008 mg per kg determined in the FCP and Monitoring 2015. It should be taken into consideration here that the data included in the EFSA opinion also came from other European countries, which means they are only comparable to a limited degree.

3.2.2 Consumption data

Consumption data from the VELS[5] study (Heseker et al. 2003; Banasiak et al. 2005) were used as the data basis for the consumption of food for infants and young children. This study was conducted throughout Germany between 2001 and 2002 on 816 infants and young children aged from six months to less than five years. On two occasions, the parents kept three-day consumption records of all foods consumed by each child. The consumption data of the children in relation to individual body weight was used as the basis for calculating intake.

The present evaluations on consumption relate to data from the VELS study for children aged from six months to under three years. In line with the maximum level regulation of lead and cadmium (Table 1), consumption data were evaluated separately as baby formula or processed cereal-based food and a distinction was also made between the consumption of powder and the ready-to-eat product in each instance (Table 4). No intake estimation could be made for food made from or with soya protein isolates, for which a maximum level was set in Regulation (EU) No. 488/2014, as the proportion of consumers in the VELS study was too low at 1%. Average consumption (mean value) and high consumption (95th percentile, "high consumers") are examined for every age group exclusively in the respective groups of consumers of food for infants and young children.

Table 4: Consumption of food for infants and young children in children aged 6 months to under three years (Basis: VELS study, consumers only, long-term consumption)

		Quantity consumed in g per kg body weight per day (Basis: consumers only, long-term consumption)		
		0.5 to < 3 years (n=435)	0.5 to < 1 year (n=95)	1 to < 3 years (n=340)
Baby formula in powder form	Percentage of consumers	10 %	31 %	5 %
	Mean value	3.2	3.9	2.0
	95th percentile	8.2	8.6	7.4
Baby formula – ready to eat	Percentage of consumers	25 %	66 %	14 %
	Mean value	27.3	32.4	20.2
	95th percentile	54.5	61.8	39.1
Processed cereal-based food in powder form	Percentage of consumers	31 %	62 %	22 %
	Mean value	2.0	2.9	1.2
	95th percentile	6.8	7.8	4.1
Processed cereal-based food – ready to eat	Percentage of consumers	35 %	73 %	24 %
	Mean value	9.4	14.9	4.9
	95th percentile	31.9	38.4	12.1

3.2.3 Intake estimation

The chronic exposure of infants and young children to cadmium and lead through the consumption of baby formula and cereal porridge on the basis of the data on occurrence contained in the FCP and Monitoring 2015 is presented in Table 5 and Table 8. The intake esti-

[5] VELS-Study = "Consumption study to determine the food intake of infants and young children for the estimation of an acute toxicity risk through residues of plant protection products":
http://download.ble.de/02HS007.pdf

mate is based on mean levels in the food groups (medium bound) and mean consumption quantities ("average consumers") or consumption quantities in the 95th percentile ("high consumers"). As there can be a significant difference between the consumption behaviour of infants in their first year of life and young children aged 1 to 3 years, a differentiated examination was made for the children aged 0.5 to < 1 year and from 1 to < 3 years in addition to intake for all infants and small children (0.5 to < 3 years).

For risk characterisation (see Chapter 3.3), intake of cadmium as well as of lead was compared with the respective toxicological reference values. To this end, the tolerable weekly intake (TWI) for cadmium of 2.5 µg per kg body weight and week was used. The MoE approach was used for lead in order to determine the margin between the $BMDL_{01}$ value of 0.5 µg per kg body weight per day for developmental neurotoxic effects and the exposure of children to lead from the consumption of food for infants and young children. The corresponding results have been included in the following tables for the sake of clarity.

Finally, total intake of lead as well as of cadmium was evaluated throughout all food groups for infants and young children considered in the assessment. This intake estimate was calculated by way of example in the sense of a worst case scenario for the group of consumers who had the highest exposure to cadmium or lead through the consumption of one of the foods considered from the group of foods for infants and young children (Table 6 for cadmium; Table 10 for lead).

3.2.3.1 Intake of cadmium

Only one data set each was available for the occurrence of cadmium and lead in ready-to-eat food for infants and young children (baby formula and processed cereal-based food). For this reason, the data on levels in powder and a reconstitution factor of seven were used to estimate the intake through ready-to-eat food for infants and young children. This equates to a level of cadmium for ready-to-eat baby formula of < 0.001 mg per kg (mean, medium bound) and 0.001 mg per kg (95th percentile, medium bound). A level of 0.003 mg per kg (mean, medium bound) and 0.005 mg per kg (95th percentile, medium bound) was calculated for ready-to-eat processed cereal-based food.

Table 5: Intake of cadmium via food for infants and young children (Basis: VELS, consumers only; FCP and Monitoring 2015, mean levels, medium bound)

	Intake of cadmium in µg per kg body weight and day (Basis: consumers only, medium bound)					
	0.5 to < 3 years		0.5 to < 1 year		1 to < 3 years	
	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]
Baby formula in powder form						
Percentage of consumers	10 %	10 %	31 %	31 %	5 %	5 %
Cd intake	0.010	0.024	0.012	0.026	0.006	0.022
TWI exhaustion	2.7 %	6.9 %	3.3 %	7.2 %	1.6 %	6.2 %
Baby formula – ready to eat						
Percentage of consumers	25 %	25 %	66 %	66 %	14 %	14 %
Cd intake	0.012	0.023	0.014	0.026	0.009	0.017
TWI exhaustion	3.3 %	6.5 %	3.9 %	7.4 %	2.4 %	4.7 %
Processed cereal-based food in powder form						
Percentage of consumers	31 %	31%	62 %	62%	22 %	22 %

Cd intake	0.038	0.128	0.055	0.148	0.024	0.077
TWI exhaustion	10.5 %	36.0%	15.4 %	41.5%	6.6 %	21.6 %
Processed cereal-based food – ready to eat						
Percentage of consumers	35 %	35 %	73 %	73 %	24 %	24 %
Cd intake	0.026	0.086	0.040	0.104	0.013	0.033
TWI exhaustion	7.2 %	24.1 %	11.3 %	29.1 %	3.7 %	9.2 %

[1] Average consumers: mean consumption x mean content (medium bound)
[2] High consumers: 95th percentile of consumption x mean content (medium bound)

It can be seen from Table 5 that, with a daily intake of 0.148 µg per kg body weight, consumption of products from the food group “processed cereal-based foods in powder form” leads to the highest intake of cadmium in high consumers in the age group 0.5 to < 1 year. A lower intake of 0.055 µg per kg body weight results for average consumers in the same age group.

If this intake quantity is compared with the toxicological reference value for cadmium (TWI: 2.5 µg per kg body weight per week), a proportionate exhaustion of 41.5% results for high consumers of the food group “processed cereal-based food in powder form” in the age group 0.5 to < 1 year and 15.4% for average consumers in the same age group (see Chapter 3.1.3 Risk characterisation).

Table 6 shows total cadmium intake via the examined ”foods for infants and young children” for the group of consumers of “processed cereal-based foods in powder form”. This group was selected for the estimation of total intake in a worst case scenario because exposure was highest here compared to the other observed consumers of food for infants and young children (Table 5). Total intake relates to intake via processed cereal-based food in powder form and the additional intake of this group of consumers via the food groups “baby formula in powder form” and “ready to eat”, as well as “processed cereal-based food – ready to eat”.

Table 6: Total intake of cadmium via food for infants and young children for consumers of processed cereal-based food in powder form (Basis: VELS, consumers only; FCP und Monitoring 2015, medium bound)

	Intake of cadmium in µg per kg body weight and day (Basis: only consumers of processed cereal-based food in powder form, medium bound)					
	0.5 to < 3 years		0.5 to < 1 year		1 to < 3 years	
	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]
Total intake by consumers of processed cereal-based food in powder form						
Valid N	31 %	31 %	62 %	62 %	22 %	22 %
Cd intake	0.058	0.159	0.091	0.216	0.032	0.100
TWI exhaustion	16.3 %	44.6 %	25.5 %	60.5 %	8.9 %	27.9 %

[1] Average consumers: mean consumption x mean content (medium bound)
[2] High consumers: 95th percentile of consumption x mean content (medium bound)

The result of the estimation of total intake shows that in the group of consumers of “processed cereal-based food in powder form”, with average consumption quantities, cadmium intake exhausts less than 30% of the TWI value through the consumption of all observed “foods for infants and young children” in all age groups. High consumers in the age group 0.5 to < 1 Jahr achieve the highest intake quantities of cadmium of 0.216 µg per kg body weight per day, which equates to a TWI exhaustion of 60.5%.

In addition to this, exposure was calculated in a hypothetical scenario assuming that the levels in food for infants and young children were equivalent to the maximum levels (Table 7).

This calculation was not made for “processed cereal-based food – ready to eat” as no measured data on occurrence in this food group were included in the intake estimate. The exposure estimation for “processed cereal-based food – ready to eat” is based on the data on levels contained in “processed cereal-based foods in powder form”, which was included in the calculation using a reconstitution factor of seven (7).

Table 7: Intake of cadmium via food for infants and young children under the assumption of levels equivalent to the maximum levels (Basis: VELS, consumers only)

	Intake of cadmium in µg per kg body weight and day (Basis: consumers only, maximum level)					
	0.5 to < 3 years		0.5 to < 1 year		1 to < 3 years	
	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]
Baby formula in powder form						
Percentage of consumers	10 %	10 %	31 %	31 %	5 %	5 %
Cd intake	0.032	0.082	0.039	0.086	0.020	0.074
TWI exhaustion	9.1 %	23.0 %	11.0 %	24.0 %	5.5 %	20.8 %
Baby formula - ready to eat						
Percentage of consumers	25 %	25 %	66%	66 %	14 %	14 %
Cd intake	0.016	0.041	0.162	0.309	0.101	0.195
TWI exhaustion	4.5 %	11.5 %	45.4%	86.6 %	28.3 %	54.7 %
Processed cereal-based food in powder form						
Percentage of consumers	31 %	31 %	62 %	62 %	22 %	22 %
Cd intake	0.079	0.271	0.116	0.313	0.050	0.163
TWI exhaustion	22.2 %	76.0 %	32.6 %	87.6 %	14.0 %	45.5 %

[1] Average consumers: mean consumption x contents equivalent to maximum level
[2] High consumers: 95th percentile of consumption x contents equivalent to maximum level

The result of this hypothetical exposure estimation shows that average consumers reach the highest cadmium intake of 0.162 µg per kg body weight per day via the food group “baby formula - ready to eat” in the 0.5 to < 1 year age group, which equates to a TWI exhaustion of 45% (Table 7). For high consumers, the maximum cadmium intake is also in this age group in the scenario for “processed cereal-based food in powder form”, with a cadmium intake of 0.313 µg per kg body weight and day, which equates to a TWI exhaustion of 87.6%.

An estimation of the intake of cadmium through the consumption of soya-based baby formula could not be made due to the low number of consumers in the VELS study and resultant uncertainties. Furthermore, the BfR does not have any data on consumption by the youngest infants aged under six months, so no exposure estimate could be made for this age group either. It has to be assumed that the consumption of baby formula in relation to body weight is higher in this age group than in the older age groups considered here, whereas that of processed cereal-based food is lower.

3.2.3.2 Intake of lead

Only one data set each was available for the occurrence of cadmium and lead in ready-to-eat food for infants and young children (baby formula and processed cereal-based food). For this reason, the data on levels in powder and a reconstitution factor of seven were used to estimate intake through ready-to-eat food for infants and young children. This results in a level of

lead in ready-to-eat baby formula of 0.001 mg per kg (mean, medium bound) and 0.004 mg per kg (95th percentile, medium bound). A level of 0.001 mg per kg (mean, medium bound) and 0.002 mg per kg (95th percentile, medium bound) was calculated for ready-to-eat processed cereal-based food.

Table 8: Intake of lead via food for infants and young children (Basis: VELS, consumers only; FCP and Monitoring 2015, mean levels, medium bound)

	Intake of lead in µg per kg body weight and day (Basis: consumers only, medium bound)					
	0.5 to < 3 years		0.5 to < 1 year		1 to < 3 years	
	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]
Baby formula in powder form						
Percentage of consumers	10 %	10 %	31 %	31 %	5 %	5 %
Pb intake	0.034	0.085	0.041	0.089	0.020	0.077
MoE	14.7	5.9	12.2	5.6	25.0	6.5
Baby formula - ready to eat						
Percentage of consumers	25 %	25 %	66 %	66 %	14 %	14 %
Pb intake	0.040	0.081	0.048	0.092	0.030	0.058
MoE	12.5	6.2	10.4	5.4	16.7	8.6
Processed cereal-based food in powder form						
Percentage of consumers	31 %	31 %	62 %	62 %	22 %	22 %
Pb intake	0.016	0.055	0.024	0.064	0.010	0.033
MoE	31.3	9.1	20.8	7.8	50.0	15.2
Processed cereal-based food - ready to eat						
Percentage of consumers	35 %	35 %	73 %	73 %	24 %	24 %
Pb intake	0.011	0.037	0.017	0.045	0.006	0.014
MoE	45.5	13.5	29.4	11.1	83.3	35.7

[1] Average consumers: mean consumption x mean content (medium bound)
[2] High consumers: 95th percentile of consumption x mean content (medium bound)

It can be seen from Table 8 that the food group “baby formula - ready to eat” makes the biggest contribution towards the intake of lead via the consumption of food for infants and young children among high consumers in the age group 0.5 to < 1 year with a daily intake of 0.092 µg per kg body weight. With 0.048 µg per kg body weight, intake among average consumers of this food group in the same age group is considerably lower.

Table 9: Total intake of lead via food for infants and young children by consumers of baby formula – ready to eat (Basis: VELS, consumers only; FCP and Monitoring 2015, medium bound)

	Intake of lead in µg per kg body weight and day (Basis: only consumers of baby formula - ready to eat, medium bound)					
	0.5 to < 3 years		0.5 to < 1 year		1 to < 3 years	
	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]
Baby formula - ready to eat						
Percentage of consumers	25 %	25 %	66 %	66 %	14 %	14 %
Pb intake	0.062	0.123	0.079	0.125	0.039	0.104
MoE	8.1	4.1	6.3	4.0	12.8	4.8

[1] Average consumers: mean consumption x mean content
[2] High consumers: 95th percentile of consumption x mean content

Table 9 shows total lead intake via the examined ”foods for infants and young children” for the group of consumers of “baby formula - ready to eat”. This group was selected for the estimation of total intake in a worst case scenario because exposure was highest here compared to the other observed consumers of food for infants and young children (Table 8). Total intake relates to uptake via “baby formula - ready to eat” and the additional intake of this group of consumers via the food groups “baby formula in powder form” and “processed cereal-based food in powder form” and “ready to eat”. With 0.125 and 0.123 µg per kg body weight per day respectively, the highest intake quantities for lead resulted for high consumers in the age groups 0.5 to < 1 year and 0.5 to < 3 years.

In addition to this, exposure was calculated in a hypothetical scenario under the assumption that the levels in food for infants and young children were equivalent to the maximum levels (Table 10). For most of the foods examined, however, the 95th percentile of the levels of lead lies well below the current maximum levels, which means that this is a less realistic worst case assumption compared to cadmium. For lead too, the food group “cereal porridge – ready to eat” was not taken into consideration in this scenario either, as no data on measured levels in this food group were included in the intake estimation. The exposure estimation for “processed cereal-based food - ready to eat“ is based on data on the occurrence in “processed cereal-based food in powder form“, which were included in the calculation using a reconstitution factor of seven.

With 0.618 µg per kg body weight and day, the highest intake of lead was to be found in the youngest age group of 0.5 to under 1 year for high consumers of “baby formula - ready to eat”.

Table 10: Intake of lead via food for infants and young children under the assumption of levels equivalent to the maximum levels (Basis: VELS, consumers only)

	Intake of lead in µg per kg body weight and day (Basis: consumers only, maximum level)					
	0.5 to < 3 years		0.5 to < 1 year		1 to < 3 years	
	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]	Average consumers[1]	High consumers[2]
Baby formula in powder form						
Percentage of consumers	10 %	10 %	31 %	31 %	5 %	5 %
Pb intake	0.162	0.410	0.197	0.429	0.098	0.371
MoE	3.1	1.2	2.5	1.2	5.1	1.3
Baby formula - ready to eat						
Percentage of consumers	25 %	25 %	66 %	66 %	14 %	14 %
Pb intake	0.273	0.545	0.324	0.618	0.202	0.391
MoE	1.8	0.9	1.5	0.8	2.5	1.3
Processed cereal-based food in powder form						
Percentage of consumers	31 %	31 %	62 %	62 %	22 %	22 %
Pb intake	0.099	0.339	0.145	0.391	0.062	0.203
MoE	5.1	1.5	3.4	1.3	8.1	2.5

[1] Average consumers: mean consumption x contents equivalent to the maximum level
[2] High consumers: 95th percentile of consumption x contents equivalent to the maximum level

It was not possible to make an intake estimate on the consumption of soya-based baby formula due to the small number of consumers in the VELS study and resultant uncertainties.

Furthermore, the BfR does not have any data on consumption by the youngest infants aged under six months, which is why no exposure estimation could be undertaken for this age group. It has to be assumed that in relation to body weight, the consumption of baby formula in this age group is higher than in the older age groups observed here, and that the consumption of processed cereal-based food is lower. Due to the higher levels of lead in baby formula compared to processed cereal-based food, this would result in a higher overall exposure to lead.

Intake of lead – EFSA opinion 2012, comparison

The EFSA made an intake estimate of lead by young children (aged 0.5 to six years) in 2012. Data from the DONALD[6] study conducted in the years 2006-2008 was used here for Germany, but this data was not collected in a representative manner compared to the VELS study.

Average total intake of lead via all foods is given here as roughly 1.0 µg per kg body weight per day (medium bound). Accordingly, the figure for high consumers is approx. 1.4 µg per kg body weight per day (medium bound).

Due to the differences in the age groups observed and in the data basis for the consumption quantities, a comparison with this estimate of the intake of lead through the consumption of food for infants and young children would not appear expedient.

3.3 Risk characterisation and opinion on maximum levels

3.3.1 Cadmium

Comparison of the highest intake quantity of cadmium (high consumers of the food group “processed cereal-based food in powder form” in the 0.5 to < 1 year age group) with the toxicological reference value for cadmium (TWI: 2.5 µg per kg body weight per week) results in a proportional exhaustion of 41.5%, and 15.4% for average consumers in the same age group. Health risks for the age groups 0.5 to 3 year-old children through the intake of cadmium via “processed cereal-based food in powder form” are therefore unlikely.

Only one data set is available for the food group “processed cereal-based food - ready to eat”. The intake estimate for this food group was made on the basis of the data on occurrence in “processed cereal-based food in powder form”. With 29.1%, the highest TWI exhaustion with this food group resulted for children aged 0.5 to < 1 year (high consumers). Health risks for the age groups 0.5 to 3 year-old children through the intake of cadmium via “processed cereal-based food – ready to eat” are therefore unlikely.

Compared to processed cereal-based food, the consumption of “baby formula” by infants and young children results in a lower exhaustion of the TWI value for cadmium for all age groups. With 7.2%, the TWI exhaustion through consumption of the food group “baby formula in powder form” was highest in the age group of 0.5 to < 1 year-old children (high consumers). Only one data set is available for the food group “baby formula - ready to eat”. The intake estimate for this food group was made on the basis of the data on occurrence in “baby formula in powder form“. With 7.4%, the highest TWI exhaustion with this food group resulted for children aged 0.5 to < 1 year (high consumers). Health risks for the age groups 0.5 to 3

[6] DONALD-Study = DOrtmund Nutritional and Anthropometric Longitudinally Designed Study

year-old children through the intake of cadmium via “baby formula in powder form” and “ready to eat” are therefore unlikely.

If a closer look is taken at the estimation of total cadmium intake through all observed “foods for infants and young children” in the group of consumers of “processed cereal-based food in powder form”, the result of risk characterisation is also that the occurrence of health risks is unlikely. With average consumption quantities, less than 30% of the TWI value is exhausted. High consumers in the age group 0.5 to < 1 year have the highest total intake of cadmium through foods for infants and young children of 0.216 µg per kg body weight per day, which equates to a TWI exhaustion of 60.5%.

The foods observed should be seen as the main source of nutrition for these age groups. The intake of cadmium through the consumption of foods made from or containing soya protein isolates, which can have high levels of cadmium, and food for infants and young children based on other protein sources were not taken into consideration in this exposure estimation. No health assessment for children aged under six months was undertaken either. Although children of this age have a higher intake of food in relation to their body weight, higher intake of processed cereal-based food in relation to body weight, which made the biggest contribution towards exposure to cadmium in this exposure estimation due to the higher levels of cadmium they contain in comparison to baby formula, is not to be assumed.

When average consumption quantities are used as the basis, the hypothetical exposure estimation - made on the assumption that the levels in food for infants and young children are equivalent to the current maximum levels – produce the highest TWI exhaustion of 45% through consumption of the food group “baby formula - ready to eat” in the 0.5 to < 1 year age group. The maximum TWI exhaustion for high consumers was 87.6% in the same age group in the scenario for “processed cereal-based food in powder form”.

The currently valid maximum levels of cadmium permitted in food for infants and young children lie in the range of the 95th percentile of the levels determined within the scope of the FCP and Monitoring 2015.

3.3.2 Lead

Comparison of the highest uptake quantity of lead (high consumers of the food group “baby formula - ready to eat” in the 0.5 to < 1 year age group) with the $BMDL_{01}$ for developmental neurotoxicity produces an MoE of 5.4. For average consumers of this food group in the same age group, the MoE is 10.4.

For the food group “baby formula in powder form”, the lowest MoE resulted for children aged 0.5 to < 1 year (high consumers) with 5.6.

Compared to baby formula, the consumption of “processed cereal-based food” leads to lower uptake quantities of lead by infants and young children, and thereby to higher MoE values. With 7.8, the lowest MoE for children aged 0.5 to < 1 year (high consumers) resulted for the food group “processed cereal-based food in powder form”.

Only one data set is available for the food group “processed cereal-based food - ready to eat”. The uptake estimate for this food group was made on the basis of the data on occurrence in “processed cereal-based food in powder form“. With 11.1, the lowest MoE for this food group resulted for children aged 0.5 to <1 year (high consumers).

The exposure of infants and young children through the uptake of lead via the consumption of foods in the group of “food for infants and young children” observed here is below the $BMDL_{01}$ value for developmental neurotoxicity of 0.5 µg per kg body weight per day for children with average consumption, as well as for high consumers based on the levels reported in the FCP and Monitoring 2015. As no safe uptake quantity can be given for lead with regard to developmental neurotoxic effects in children, however, exposure should generally be reduced to the achievable minimum.

When comparing the estimation of total intakes of lead through all observed “foods for infants and young children” in the group of consumers of “baby formula - ready to eat” with the $BMDL_{01}$ value for developmental neurotoxicity, MoE values of 4.0 (group of high consumers aged 0.5 to < 1 year) to 12.8 (group of average consumers aged 1 to < 3 years) result.

The foods observed should be seen as the main source of nutrition for these age groups. The intake of lead through the consumption of foods made from or containing soya protein isolates, which have levels of lead similar to those for food produced on the basis of cow’s milk protein, and food for infants and young children based on other protein sources, were not taken into consideration in this exposure estimation. No health assessment was undertaken either for children aged under six months for whom a higher lead uptake is to be expected compared to older children, as they have a higher intake of baby formula in relation to their body weight.

When average consumption quantities are used as the basis, the hypothetical exposure estimation made on the assumption that the levels in food for infants and young children are equivalent to the current maximum levels for lead produce the lowest MoE value of 1.8 through consumption of the food group “baby formula - ready to eat” in the 0.5 to < 3 year age group. For high consumers, the lowest MoE value of 0.8 results for the age group 0.5 to < 1 year in the scenario for “baby formula - ready to eat”.

This, however, is based on the worst case assumption that foods with very high levels of lead are eaten constantly in large quantities over a longer period of time. The likelihood that this assumption will apply is very slight. For most of the foods examined, however, the 95th percentile of the levels of lead lies well below the current maximum levels. The low MoE values are therefore unlikely.

Fundamentally, the ALARA principle should be applied when establishing maximum levels for lead. ALARA stands for “As Low As Reasonably Achievable”, which means that exposure to a substance should be reduced to the greatest reasonably possible extent. According to the data of the FCP and Monitoring 2015, with 0.026 – 0.039 mg per kg (medium bound-upper bound for baby formula in powder form) and 0.016 – 0.030 mg per kg (medium bound-upper bound for processed cereal-based food in powder form), the levels of lead in the 95th percentile in “baby formula in powder form” lie slightly below the maximum level of 0.05 mg per kg established for this food category in Regulation (EU) 2015/1005 for infant formulae and follow-on formulae in powder form and for processed cereal-based food.

3.4 Conclusion

Cadmium

Based on the data on occurrence from the FCP and Monitoring 2015, health impairments for children in the age group 0.5 to < 3 years through the intake of cadmium via the consumption of food for infants and young children in the food categories “baby formula in powder form” and “ready to eat”, as well as “processed cereal-based food in powder form” and “ready to eat”, are unlikely with average as well as high consumption (95th percentile of consumption).

The current maximum levels for cadmium in food for infants and young children lie within the range of the 95th percentile of the levels determined in the FCP and Monitoring 2015.

Lead

Based on the data on occurrence determined in the FCP and Monitoring 2015, the exposure of children in the age group 0.5 to < 3 years to lead through the intake of food for infants and young children in the food categories “baby formula in powder form” and “ready to eat”, as well as “processed cereal-based food in powder form” and “ready to eat” lies below the $BMDL_{01}$ value for developmental neurotoxicity of 0.5 µg per kg body weight per day for children with average consumption as well as high consumers. As no safe uptake quantity can be given for lead, however, with regard to its developmental neurotoxic effect in children, exposure should be reduced to the achievable minimum as a basic principle.

More information on the topic of infants and young children at the BfR website

BfR Brochure “Breastfeeding recommendations for pregnant women”
https://www.bfr.bund.de/cm/364/stillempfehlungen-fuer-schwangere-englisch.pdf

BfR Opinion “Lead and cadmium do not belong in toys”
https://www.bfr.bund.de/cm/349/lead_and_cadmium_do_not_belong_in_toys.pdf

BfR Brochure “Checklist for the time after birth” (German only)
https://www.bfr.bund.de/cm/350/checkliste-fuer-die-zeit-nach-der-geburt.pdf

BfR “Opinions App”

4 References

Banasiak U, Heseker H, Sieke C, Sommerfeld C, Vohmann C (2005): Abschätzung der Aufnahme von Pflanzenschutzmittel-Rückstanden in der Nahrung mit neuen Verzehrsmengen für Kinder. Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz 1, 48:84-98.

Blume K., Lindtner O., Schneider K., Schwarz M., Heinemeyer G. (2010): Aufnahme von Umweltkontaminanten über Lebensmittel: Cadmium, Blei, Quecksilber, Dioxine und PCB; Informationsbroschüre des Bundesinstitut für Risikobewertung (BfR) [in print]

BVL (2015a): Bundesweiter Überwachungsplan 2015, BVL-Report 11.1, Berichte zur Lebensmittelsicherheit.
http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/02_BUEp_dokumente/BUEp_Bericht_2015.pdf?__blob=publicationFile&v=3

BVL (2015b): Monitoring 2015, BVL-Report 11.3, Berichte zur Lebensmittelsicherheit.
http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/01_lm_mon_dokumente/01_Monitoring_Berichte/archiv/lmm_bericht_2015.pdf?__blob=publicationFile&v=5

EFSA (2009): Cadmium in food, Scientific Opinion of the Panel on Contaminants in the Food Chain, EFSA Journal 2009; 980:1-139.

EFSA (2010): Lead in food, Scientific Opinion of the Panel on Contaminants in the Food Chain, EFSA Journal 2010; 8(4):1570. [151 pp.]. doi:10.2903/j.efsa.2010.1570. Available online: www.efsa.europa.eu

EFSA (2012): Lead dietary exposure in the European population. Scientific Report of EFSA, EFSA Journal 2012; 10(7): 2831.

Heseker H, Oeppining A, Vohmann C (2003): Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln (VELS). Forschungsbericht im Auftrag des Bundesministeriums für Verbraucherschutz, Ernährung und Landwirtschaft, Universität Paderborn.

Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC.

Commission Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

Commission Regulation (EU) No. 488/2014 of 12 May 2014 amending Regulation (EC) No. 1881/2006 as regards maximum levels of cadmium in foodstuffs.

Commission Regulation (EU) 2015/1005 of 25 June 2015 amending Regulation (EC) No. 1881/2006 as regards maximum levels of lead in certain foodstuffs.

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