

*Original Research*

# Toxic Elements in Commercial Infant Food, Estimated Dietary Intake, and Risk Assessment in Poland

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## **Abstract**

This paper presents results of heavy metals determination in infant foods available in Poland during a monitoring programme in 2009-13. This study investigated levels of lead, cadmium, arsenic, and mercury in infant formulae and other infant foods intended for consumption during the first 6 to 12 months of life, and an intake of heavy metals was assessed. Food consumption data based on the artificial feeding scheme of infants established by the Mother and Child Institute in Poland were taken into account to estimate dietary exposure. The reported levels of elements in infant foods are comparable with contamination of such products in other countries. The mean values for lead do not exceed 0.013 mg/kg (90<sup>th</sup> percentile, 0.028 mg/kg). Lead levels in infant formulae (as sold, mainly powder) did not exceed 0.010 mg/kg, while mean contamination was 0.005 mg/kg. The highest mean cadmium level of 0.010 mg/kg was reported in vegetable meal (90<sup>th</sup> percentile, 0.017 mg/kg); in infant formulae (undiluted) milk-based it was below 0.003 mg/kg, and for soya-based it was 0.009 mg/kg. Arsenic and mercury contents – highest in fish-based infant foods – did not exceed 0.18 mg/kg and 0.013 mg/kg, respectively. In rice products for infants arsenic did not exceed 0.14 mg/kg. The estimated mean lead exposure was from 0.09 µg/kg b.w. per day for 6-month-old infants to 0.53 µg/kg b.w. per day for 1-year-old children, which was approximately 17% and equal to the respective Benchmark Dose Lower Confidence Limit (BMDL<sub>01</sub>) established by the European Food Safety Authority (EFSA) at 0.50 µg/kg b.w. per day. Mean exposure to cadmium ranges from 0.02 to 0.4 µg/kg b.w. per day, and for 12-month-old infants can slightly exceed the tolerable weekly intake (TWI) value established by EFSA. Dietary cadmium intake represents 2.5-47% of the provisional tolerable monthly intake (PTMI) value established by the Joint FAO/WHO Expert Committee of Food Additives (JECFA). Intake of arsenic and mercury was below respective reference value. Calculated mean dietary exposure to arsenic for children under 1 year old was between 0.11 and 0.99 µg/kg b.w. per day (4-33% BMDL<sub>0.5</sub> value), and to methylmercury 0.01-0.08 µg/kg b.w. per day (7-41% of the TWI value for methylmercury).

**Keywords:** heavy metals, risk assessment, infant foods, dietary intake

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## Introduction

Infants are the population group most vulnerable to the toxic effects of heavy metals due to the higher absorption of metals by the gastrointestinal tract, faster metabolic processes, an incompletely developed detoxification system, and higher food consumption in relation to body weight [1-3]. Additionally, the undeveloped blood-brain barrier allows elements noxious to infant health (primarily lead and mercury compounds) to accumulate in the brain, causing dysfunction of the central nervous system [4]. Exposure to heavy metals during growth and development can result in long-term effects on the health of children [5]. Infant foods are the main source of heavy metals intake by this population, primarily due to contamination of raw materials used and rarely by food processing itself [6-8].

Commercially available infant foods have become an important part of the diet of many infants and toddlers because of their mineral and vitamin content that fulfills dietary requirements of these target groups [9-11]. The European Commission has defined specific maximum levels for toxic elements in foodstuffs designated for this population group, only for lead in infant formulae and ready-to-use follow-on formulae at 0.02 mg/kg, cadmium in processed cereal-based foods, baby foods for infants and young children at 0.04 mg/kg, and in infant formulae and follow-on formulae in the range 0.005-0.02 mg/kg, depending of the type of products (Commission Regulation 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, as amended; last amendment 12 May 2014).

In 2010 the Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) identified lead for developmental neurotoxicity and cardiovascular effects in young children, and nephrotoxicity in adults as the critical effects for the risk assessment. The respective benchmark dose lower confidence limits (BMDLs) established by EFSA were:

- For developmental neurotoxicity in young children BMDL<sub>01</sub>, 0.50 µg/kg body weight (b.w.) per day
- Effects on systolic blood pressure in adults BMDL<sub>01</sub>, 1.50 µg/kg b.w. per day
- Effects on prevalence of chronic kidney disease in adults BMDL<sub>10</sub>, 0.63 µg/kg b.w. per day

The CONTAM Panel concluded that the current provisional tolerable weekly intake (PTWI) at 25 µg/kg b.w. is no longer appropriate as there is no evidence for the existence of a threshold for critical lead-induced effects and withdrew that value. In children, an elevated blood lead level is inversely associated with a reduced intelligence quotient (IQ) [12]. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) also withdrew the PTWI value based on dose-response analyses and did not establish a new level, which could be considered a health protective [13].

Moreover, EFSA established a tolerable weekly intake (TWI) for cadmium at 2.5 µg/kg b.w. [14]. In 2010, JECFA considering the long half-life of cadmium, and taking into account the negligible effect of daily exposure on overall exposure, decided to express the tolerable intake as a

monthly value of provisional tolerable monthly intake (PTMI) at 25 µg/kg b.w., which was not in line with the EFSA risk assessment [13].

For arsenic, the CONTAM panel of EFSA established BMDL<sub>01</sub> values between 0.3 and 8 µg/kg b.w. per day for lung, skin, and bladder cancer, as well as skin lesions [15]. JECFA for arsenic computed BMDL<sub>0.5</sub> to be 3.0 µg/kg b.w. per day (2.0 µg/kg b.w. per day – 7.0 µg/kg b.w. per day) [16].

In 2010, JECFA adopted PTWI for inorganic mercury at 4.0 µg/kg and for organic mercury at 1.6 µg/kg b.w. [16]. In the final opinion of 2012, EFSA established a TWI for methylmercury at 1.3 µg/kg b.w. [17].

This paper presents results of detailed investigations performed for infant foods intended for consumption during the first six and 12 months of life. Obtained data were used to perform specific exposure assessments associated with intake of toxic elements by one of the most vulnerable target groups of the population.

## Experimental Procedures

### Samples

Approximately 1,000 samples of commercially available products for infants were sampled and tested for lead, cadmium, mercury, and arsenic levels by sanitary-epidemiological stations during the monitoring program, prepared and coordinated by the Department of Food Safety in the National Institute of Public Health-National Institute of Hygiene (NIPH-NIH) and performed in Poland in 2009-13. Samples were taken in all provinces in Poland from the retail market in line with NIPH-NIH guidelines and in accordance with requirements of Commission Regulation No. 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD, and benzo(a)pyrene in foodstuffs, amended by Regulation No. 836/2011.

The products under analysis were: infant formulae and follow-on formulae samples, soya-based infant formulae; milk- and rice-based products for infants; rice gruel, wheat gruel, and mixed cereals for infants (all these products were sold mainly as powder); ready-to-eat puréed infant foods including vegetable meals, vegetable and meat meals, fish-based infant food, and fruit-based desserts; and juices, biscuits, herbal teas, and teas with herbs and fruits. Samples from domestic production dominated, along with products from other EU Member States (i.e., France, Germany, the Netherlands, Czech Republic, Belgium, Spain) which comprised about 30% of the total. All samples were analysed as sold (they were not reconstituted prior to analysis).

### Sample Preparation

Samples were treated by using different methods of digestion depending on the element investigated. For lead and cadmium determination, samples were prepared by microwave digestion according to: EN 14083:2003 or by dry ashing based on EN 14082:2003, and for arsenic deter-

mination by dry ashing according to EN 14546:2005. Samples for mercury determination were analyzed directly or after pressure digestion according to EN 13806:2002.

### Trace Elements Analysis

Contents of elements noxious to health were determined using atomic absorption spectrometry (AAS). Lead and cadmium were determined using flame atomic absorption spectrometry (FAAS) after extraction of metal complexes with ammonium pyrrolidine dithiocarbamate (APDC) to organic solvent according to Methodology Publications of the National Institute of Hygiene [18] or graphite furnace atomic absorption spectrometry (GFAAS). Arsenic was determined using hydride generation atomic absorption spectrometry (HGAAS), and mercury was determined using the "cold vapour" technique (CVAAS).

### Quality Assurance

Validated analytical methods meeting criteria set in the legislation were applied. Laboratories of Sanitary-Epidemiological Stations participating in these studies are accredited according to EN ISO/IEC 17025:2005 and apply internal and external quality procedures. Quality control involved the use of reference materials with certified contents of metals. The laboratories also verified their proficiency in these methods by participating in interlaboratory proficiency tests organized by, i.e., the Laboratory of the Department of Food Safety – National Reference Laboratory located in NIPH-NIH (Poland) and the Food and Environment Research Agency (UK) – Food Analysis Performance Assessment Scheme (FAPAS). The NIPH-NIH Reference Laboratory itself participates in proficiency tests organized by, i.e., the European Union Reference Laboratory Heavy Metals in Feed and Food (EU-RL-HM) – Joint Research Centre, Institute for Reference Materials and Measurements, Belgium (JRC-IRMM) and FAPAS.

### Statistical Evaluation

Statistical assessment of results was performed according to the substitution method used by EFSA for the treatment of left-censored data – LC (below limit of detection (LOD)). For results reported to be below the LOD, the value equal to the LOD (upper bound – UB), zero (lower bound – LB) or half the LOD (medium or middle bound – MB) were used [19]. Different numbers of results below LOD were observed in the analyzed samples. Depending on element and foodstuff, left-censored data (LC) were between 90% for mercury in herbal and fruit teas and 5% for cadmium in vegetable meals.

## Results and Discussion

Concentrations of the investigated elements in the analyzed samples of infant foods as sold are presented in Tables 1-4. The concentrations of toxic elements are presented as a mean, median, and 90<sup>th</sup> percentile (P90), lower (LB), middle (MB) and upper bound (UB).

Table 1. Lead content in different types of commercially available infant foods in the Polish market (mg/kg).

Product	Pb			
	n	Mean	Median	P90
Infant formula, follow-on formula	112	LB: 0.0024	LB: 0.0000	LB: 0.0065
		MB: 0.0051	MB: 0.0050	MB: 0.0099
		UB: 0.0077	UB: 0.0080	UB: 0.0118
Milk and rice-based products	58	LB: 0.0024	LB: 0.0000	LB: 0.0066
		MB: 0.0046	MB: 0.0048	MB: 0.0100
		UB: 0.0069	UB: 0.0050	UB: 0.0200
Infant formula soya-based	22	LB: 0.0037	LB: 0.0000	LB: 0.0089
		MB: 0.0060	MB: 0.0053	MB: 0.0099
		UB: 0.0082	UB: 0.0070	UB: 0.0155
Rice gruel for infants	185	LB: 0.0054	LB: 0.0000	LB: 0.0146
		MB: 0.0083	MB: 0.0050	MB: 0.0146
		UB: 0.0112	UB: 0.0100	UB: 0.0200
Wheat gruel for infants	74	LB: 0.0030	LB: 0.0000	LB: 0.0100
		MB: 0.0056	MB: 0.0048	MB: 0.0100
		UB: 0.0082	UB: 0.0075	UB: 0.0200
Mixed cereals for infants	65	LB: 0.0040	LB: 0.0000	LB: 0.0090
		MB: 0.0064	MB: 0.0050	MB: 0.0100
		UB: 0.0089	UB: 0.0090	UB: 0.0192
Biscuits for infants	49	LB: 0.0104	LB: 0.0020	LB: 0.0282
		MB: 0.0126	MB: 0.0050	MB: 0.0282
		UB: 0.0147	UB: 0.0100	UB: 0.0282
Vegetable meals ready-to-eat	49	LB: 0.0049	LB: 0.0000	LB: 0.0142
		MB: 0.0072	MB: 0.0050	MB: 0.0142
		UB: 0.0094	UB: 0.0100	UB: 0.0142
Vegetable-meat meals ready-to-eat	64	LB: 0.0054	LB: 0.0000	LB: 0.0148
		MB: 0.0077	MB: 0.0050	MB: 0.0148
		UB: 0.0100	UB: 0.0100	UB: 0.0185
Fish-based infant foods ready-to-eat	47	LB: 0.0053	LB: 0.0040	LB: 0.0110
		MB: 0.0073	MB: 0.0050	MB: 0.0110
		UB: 0.0093	UB: 0.0100	UB: 0.0110
Fruits desserts for infants	43	LB: 0.0052	LB: 0.0000	LB: 0.0163
		MB: 0.0075	MB: 0.0050	MB: 0.0163
		UB: 0.0098	UB: 0.0100	UB: 0.0163
Juices for infants	69	LB: 0.0049	LB: 0.0030	LB: 0.0150
		MB: 0.0061	MB: 0.0050	MB: 0.0150
		UB: 0.0074	UB: 0.0050	UB: 0.0150
Herbal teas for infants	45	LB: 0.0041	LB: 0.0000	LB: 0.0106
		MB: 0.0064	MB: 0.0050	MB: 0.0134
		UB: 0.0086	UB: 0.0100	UB: 0.0150
Herbal and fruit teas for infants	60	LB: 0.0046	LB: 0.0007	LB: 0.0106
		MB: 0.0071	MB: 0.0050	MB: 0.0151
		UB: 0.0096	UB: 0.0080	UB: 0.0237

n – number of samples, LB – lower bound, MB – middle bound, UB – upper bound, P90 – 90<sup>th</sup> percentile

Table 2. Cadmium content in different types of commercially available infant foods in the Polish market (mg/kg).

Product	Cd			
	n	Mean	Median	P90
Infant formula, follow-on formula	119	LB: 0.0010	LB: 0.0000	LB: 0.0030
		MB: 0.0012	MB: 0.0006	MB: 0.0030
		UB: 0.0015	UB: 0.0010	UB: 0.0030
Milk and rice-based products	62	LB: 0.0014	LB: 0.0010	LB: 0.0032
		MB: 0.0016	MB: 0.0010	MB: 0.0032
		UB: 0.0017	UB: 0.0014	UB: 0.0032
Infant formula soya-based	22	LB: 0.0033	LB: 0.0020	LB: 0.0089
		MB: 0.0034	MB: 0.0020	MB: 0.0089
		UB: 0.0036	UB: 0.0020	UB: 0.0089
Rice gruel for infants	198	LB: 0.0038	LB: 0.0017	LB: 0.0113
		MB: 0.0041	MB: 0.0019	MB: 0.0119
		UB: 0.0044	UB: 0.0020	UB: 0.0119
Wheat gruel for infants	86	LB: 0.0047	LB: 0.0042	LB: 0.0090
		MB: 0.0047	MB: 0.0042	MB: 0.0090
		UB: 0.0047	UB: 0.0042	UB: 0.0090
Mixed cereals for infants	74	LB: 0.0034	LB: 0.0030	LB: 0.0077
		MB: 0.0035	MB: 0.0030	MB: 0.0077
		UB: 0.0036	UB: 0.0030	UB: 0.0077
Biscuits for infants	49	LB: 0.0066	LB: 0.0064	LB: 0.0109
		MB: 0.0066	MB: 0.0064	MB: 0.0109
		UB: 0.0067	UB: 0.0064	UB: 0.0109
Vegetable meals ready-to-eat	49	LB: 0.0096	LB: 0.0080	LB: 0.0174
		MB: 0.0096	MB: 0.0080	MB: 0.0174
		UB: 0.0097	UB: 0.0080	UB: 0.0174
Vegetable-meat meals ready-to-eat	64	LB: 0.0069	LB: 0.0060	LB: 0.0133
		MB: 0.0070	MB: 0.0060	MB: 0.0133
		UB: 0.0070	UB: 0.0060	UB: 0.0133
Fish-based infant foods ready-to-eat	47	LB: 0.0066	LB: 0.0061	LB: 0.0119
		MB: 0.0067	MB: 0.0061	MB: 0.0119
		UB: 0.0067	UB: 0.0061	UB: 0.0119
Fruits desserts for infants	43	LB: 0.0016	LB: 0.0003	LB: 0.0035
		MB: 0.0018	MB: 0.0006	MB: 0.0035
		UB: 0.0020	UB: 0.0010	UB: 0.0035
Juices for infants	69	LB: 0.0009	LB: 0.0008	LB: 0.0020
		MB: 0.0010	MB: 0.0009	MB: 0.0020
		UB: 0.0012	UB: 0.0010	UB: 0.0020
Herbal teas for infants	45	LB: 0.0003	LB: 0.0000	LB: 0.0010
		MB: 0.0006	MB: 0.0005	MB: 0.0010
		UB: 0.0009	UB: 0.0008	UB: 0.0016
Herbal and fruit teas for infants	60	LB: 0.0009	LB: 0.0000	LB: 0.0027
		MB: 0.0011	MB: 0.0005	MB: 0.0027
		UB: 0.0014	UB: 0.0010	UB: 0.0027

n – number of samples, LB – lower bound, MB – middle bound, UB – upper bound, P90 – 90<sup>th</sup> percentile

Table 3. Arsenic content in different types of commercially available infant foods in the Polish market (mg/kg).

Product	As			
	n	Mean	Median	P90
Infant formula, follow-on formula	118	LB: 0.0029	LB: 0.0000	LB: 0.0073
		MB: 0.0067	MB: 0.0040	MB: 0.0129
		UB: 0.0105	UB: 0.0050	UB: 0.0240
Milk and rice-based products	62	LB: 0.0092	LB: 0.0029	LB: 0.0260
		MB: 0.0121	MB: 0.0100	MB: 0.0260
		UB: 0.0149	UB: 0.0120	UB: 0.0359
Infant formula soya-based	22	LB: 0.0096	LB: 0.0065	LB: 0.0210
		MB: 0.0110	MB: 0.0070	MB: 0.0210
		UB: 0.0123	UB: 0.0100	UB: 0.0210
Rice gruel for infants	197	LB: 0.0585	LB: 0.0450	LB: 0.1404
		MB: 0.0595	MB: 0.0450	MB: 0.1404
		UB: 0.0605	UB: 0.0450	UB: 0.1404
Wheat gruel for infants	86	LB: 0.0034	LB: 0.0000	LB: 0.0120
		MB: 0.0066	MB: 0.0045	MB: 0.0120
		UB: 0.0098	UB: 0.0065	UB: 0.0240
Mixed cereals for infants	73	LB: 0.0068	LB: 0.0000	LB: 0.0180
		MB: 0.0102	MB: 0.0100	MB: 0.0180
		UB: 0.0137	UB: 0.0117	UB: 0.0240
Biscuits for infants	49	LB: 0.0067	LB: 0.0000	LB: 0.0164
		MB: 0.0087	MB: 0.0045	MB: 0.0180
		UB: 0.0107	UB: 0.0060	UB: 0.0182
Vegetable meals ready-to-eat	49	LB: 0.0040	LB: 0.0000	LB: 0.0130
		MB: 0.0061	MB: 0.0050	MB: 0.0144
		UB: 0.0082	UB: 0.0060	UB: 0.0144
Vegetable-meat meals ready-to-eat	62	LB: 0.0029	LB: 0.0000	LB: 0.0117
		MB: 0.0058	MB: 0.0028	MB: 0.0175
		UB: 0.0087	UB: 0.0050	UB: 0.0198
Fish-based infant foods ready-to-eat	47	LB: 0.0663	LB: 0.0530	LB: 0.1781
		MB: 0.0666	MB: 0.0530	MB: 0.1781
		UB: 0.0670	UB: 0.0530	UB: 0.1781
Fruits desserts for infants	43	LB: 0.0032	LB: 0.0000	LB: 0.0136
		MB: 0.0055	MB: 0.0025	MB: 0.0166
		UB: 0.0079	UB: 0.0050	UB: 0.0166
Juices for infants	69	LB: 0.0037	LB: 0.0000	LB: 0.0130
		MB: 0.0058	MB: 0.0030	MB: 0.0156
		UB: 0.0078	UB: 0.0050	UB: 0.0156
Herbal teas for infants	45	LB: 0.0036	LB: 0.0000	LB: 0.0120
		MB: 0.0071	MB: 0.0025	MB: 0.0180
		UB: 0.0107	UB: 0.0050	UB: 0.0200
Herbal and fruit teas for infants	60	LB: 0.0013	LB: 0.0000	LB: 0.0033
		MB: 0.0045	MB: 0.0025	MB: 0.0100
		UB: 0.0077	UB: 0.0050	UB: 0.0200

n – number of samples, LB – lower bound, MB – middle bound, UB – upper bound, P90 – 90<sup>th</sup> percentile



Table 4. Mercury content in different types of commercially available infant foods in the Polish market (mg/kg).

Product	Hg			
	n	Mean	Median	P90
Infant formula, follow-on formula	113	LB: 0.0004	LB: 0.0000	LB: 0.0010
		MB: 0.0007	MB: 0.0005	MB: 0.0010
		UB: 0.0010	UB: 0.0010	UB: 0.0020
Milk and rice-based products	61	LB: 0.0004	LB: 0.0000	LB: 0.0012
		MB: 0.0006	MB: 0.0005	MB: 0.0012
		UB: 0.0009	UB: 0.0010	UB: 0.0019
Infant formula soya-based	22	LB: 0.0009	LB: 0.0005	LB: 0.0020
		MB: 0.0009	MB: 0.0005	MB: 0.0020
		UB: 0.0013	UB: 0.0010	UB: 0.0020
Rice gruel for infants	180	LB: 0.0005	LB: 0.0000	LB: 0.0020
		MB: 0.0009	MB: 0.0006	MB: 0.0020
		UB: 0.0013	UB: 0.0010	UB: 0.0020
Wheat gruel for infants	76	LB: 0.0002	LB: 0.0000	LB: 0.0010
		MB: 0.0006	MB: 0.0005	MB: 0.0010
		UB: 0.0009	UB: 0.0010	UB: 0.0011
Mixed cereals for infants	66	LB: 0.0005	LB: 0.0000	LB: 0.0015
		MB: 0.0008	MB: 0.0005	MB: 0.0015
		UB: 0.0011	UB: 0.0010	UB: 0.0017
Biscuits for infants	48	LB: 0.0005	LB: 0.0000	LB: 0.0018
		MB: 0.0007	MB: 0.0005	MB: 0.0018
		UB: 0.0010	UB: 0.0010	UB: 0.0018
Vegetable meals ready-to-eat	49	LB: 0.0003	LB: 0.0000	LB: 0.0010
		MB: 0.0006	MB: 0.0005	MB: 0.0010
		UB: 0.0009	UB: 0.0010	UB: 0.0010
Vegetable-meat meals ready-to-eat	62	LB: 0.0006	LB: 0.0000	LB: 0.0014
		MB: 0.0009	MB: 0.0005	MB: 0.0014
		UB: 0.0012	UB: 0.0010	UB: 0.0020
Fish-based infant foods ready-to-eat	47	LB: 0.0063	LB: 0.0056	LB: 0.0127
		MB: 0.0063	MB: 0.0056	MB: 0.0127
		UB: 0.0064	UB: 0.0056	UB: 0.0127
Fruits desserts for infants	41	LB: 0.0003	LB: 0.0000	LB: 0.0010
		MB: 0.0005	MB: 0.0005	MB: 0.0010
		UB: 0.0008	UB: 0.0010	UB: 0.0011
Juices for infants	68	LB: 0.0002	LB: 0.0000	LB: 0.0010
		MB: 0.0004	MB: 0.0003	MB: 0.0010
		UB: 0.0007	UB: 0.0005	UB: 0.0010
Herbal teas for infants	44	LB: 0.0004	LB: 0.0000	LB: 0.0010
		MB: 0.0006	MB: 0.0005	MB: 0.0010
		UB: 0.0008	UB: 0.0010	UB: 0.0010
Herbal and fruit teas for infants	60	LB: 0.0002	LB: 0.0000	LB: 0.0009
		MB: 0.0005	MB: 0.0005	MB: 0.0009
		UB: 0.0008	UB: 0.0010	UB: 0.0010

n – number of samples, LB – lower bound, MB – middle bound, UB – upper bound, P90 – 90<sup>th</sup> percentile

## Lead Contamination

Content of lead, taking into consideration mean MB contamination, was lower as compared with results obtained during studies performed in Poland in 2004-08 [20, 21]. Mean lead content in tested samples of infant formula and follow-on formula was 0.005 mg/kg, 90<sup>th</sup> percentile MB were below 0.010 mg/kg. The highest value of lead was detected in a sample of powdered infant formula at 0.056 mg/kg, but after reconstitution did not exceed the permitted maximum level 0.020 mg/kg set by Commission Regulation No.1881/2006, as amended. Obtained results for infant formulas were just slightly higher than those reported in other European countries. According to EFSA, the mean (MB) was in the range 0.003-0.004 mg/kg [22] – significantly lower than reported in Pakistan for commercially available milk-based and soya-based infant formula (mean values 0.0287-0.097 mg/kg and 0.098-0.119 mg/kg, respectively) [23].

The survey conducted by the Food Standards Agency in the U.K. indicates lower contamination of infant formulae as compared with results obtained in Poland (mean was in the range 0.002-0.003 mg/kg). Infant formulae based on cow's milk proteins contribute less to lead intake than soya milk formulae, the mean (MB) is 0.006 mg/kg (the highest reported result was 0.025 mg/kg for follow-on formula – the product as sold) and was comparable with results reported in the U.K. for this group of products (mean 0.007 mg/kg) [24]. Contents of lead in milk and rice-based products were just slightly lower as compared with infant formulas. Lead levels in the products sampled in Poland were lower than those reported in Germany [2]. Detected rice gruel contamination was significantly higher than for other cereal-based products for infants. Studies conducted in Sweden confirm this dependence [7]. Average lead content in rice gruel was 0.008 mg/kg, as compared with mean value 0.006 mg/kg for mixed cereals and wheat gruel. Highest lead content at 0.120 mg/kg was reported in pure rice gruel.

Mean lead content in biscuits was 0.012 mg/kg, median 0.005 mg/kg, and 90<sup>th</sup> percentile was below 0.030 mg/kg. Reported lead contamination of biscuits in Poland was significantly lower than in other EU countries with mean (MB) 0.019 mg/kg [22], which is comparable with contamination found in the U.K. [24].

Lead content in ready-to-eat solid infant foods, i.e., vegetable meals, meals based on vegetables and meat, fish-based infant foods, and fruits, as well as for herbs and fruit teas, approx. 0.007 mg/kg (mean) did not differ significantly and was comparable with contamination reported in Germany for solid baby foods [2]. Lead contamination of vegetable meals and meat and vegetable-based meals, as well as fruit purée, was slightly lower from that reported by other EU Member States [22, 24].

Mean MB lead contamination in herbal teas and juices for infants was comparable and did not create any health hazard.

## Cadmium Contamination

Contamination of vegetable meals, vegetable and meat meals, biscuits, and fish-based infant foods with cadmium was in the range 0.007-0.010 mg/kg (mean MB), median 0.006-0.008 mg/kg, and 90<sup>th</sup> percentile 0.010-0.017 mg/kg, and was comparable with results collected by EFSA from EU Member States [25]. The highest content of cadmium in vegetable meals was 0.044 mg/kg in a meal based on spinach and potatoes. The survey conducted in the U.K. showed higher cadmium content in aforementioned groups of products except fish-based meals, whose contamination was similar to that reported in Poland [24].

Mean cadmium content in infant formulae and follow-on formulae was comparable (mean MB 0.0012 mg/kg) with milk- and rice-based products (mean MB 0.0016 mg/kg). Infant formulae based on cow's milk proteins contribute less to cadmium intake than soya milk formulae. The mean in this case is 0.0034 mg/kg and is lower than that reported by other European countries [24]. The highest cadmium content in a soya-based infant formula sample was 0.012 mg/kg but did not exceed the permitted maximum level of 0.020 mg/kg set by Commission Regulation No. 488/2014, amending Regulation (EC) No. 1881/2006. Cadmium contamination of infant formulas was lower as compared with results from previous studies conducted in Poland [26]. Cereal-based products can contribute significantly to dietary cadmium intake. Mean cadmium levels in tested samples of wheat gruel were 0.0047 mg/kg, for rice gruel 0.0041 mg/kg, and 90<sup>th</sup> percentile value was 0.009 mg/kg and 0.012 mg/kg, respectively. The highest value was reported in pure rice gruel intended for consumption by 4-month-old infants: mean 0.0490 mg/kg and was higher than maximum level of 0.040 mg/kg set by the Commission Regulation No. 488/2014. Cadmium levels in mixed cereal samples were lower, and mean MB was 0.0035 mg/kg.

The results reported in Pakistan [7, 27, 28] indicate higher contamination of cereal-based infant foods than in Poland. Content of cadmium in other infant foods, i.e., juices, fruit-based desserts, herbal teas, and teas with the addition of fruits was lower compared with the above-mentioned infant foods. The mean value ranged from 0.0006 mg/kg for herbal teas to 0.0018 mg/kg for fruit desserts.

## Arsenic Contamination

Arsenic content in rice gruel and fish-based infant foods was significant: mean MB for rice gruel was 0.060 mg/kg, median 0.045 mg/kg, and 90<sup>th</sup> percentile value 0.140 mg/kg; for fish-based infant foods 0.067 mg/kg, median 0.053 mg/kg, and 90% value 0.178 mg/kg. Highest content of arsenic for these two groups of products was reported in the sample of rice gruel at 0.297 mg/kg and in cod fish with vegetables dinner sample at 0.195 mg/kg. Arsenic contamination of fish-based infant foods in Poland was lower than that reported in Norway (mean 1.10 mg/kg) [10], Spain (mean 0.619 mg/kg [29]), and the U.K. (mean 0.145 mg/kg) [24]. The surveys conducted in Spain and the U.K. [24] also indicated higher contamination of pure infant rice

with total arsenic than reported in Poland; mean was 0.126 mg/kg (fresh weight) and 0.183 mg/kg, respectively. Other Spanish data show the mean values of arsenic contamination at 0.089 mg/kg for pure rice conventional products and at 0.168 mg/kg for organic products produced using organic farming methods [30]. Similarly higher results than in Poland were observed in other EU member states, mean LB was 0.1496 mg/kg and UB 0.1575 mg/kg [15]. A Swedish investigation showed lower contamination of rice than in Poland (mean contents of arsenic in infant products based on rice ranged from 0.017 mg/kg to 0.033 mg/kg [7].

Arsenic is present in rice and rice products mainly as an inorganic form being more toxic than organic compounds; intake of inorganic arsenic by infants can create a health hazard [29, 31, 32]. For infants, rice products can contribute significantly to total exposure to arsenic, even up to 31% [15]. Content of arsenic in other infant foods was low and did not create any health hazard; mean ranged from 0.004 mg/kg to 0.012 mg/kg; median 0.003-0.010 mg/kg; and 90% value 0.010-0.026 mg/kg. Reported arsenic levels in domestic investigations were lower than results obtained in other EU member states [15].

## Mercury Contamination

The reported mean mercury contents were low and did not pose a health hazard except for fish-based infant foods. Fish and fishery products are the main source of methylmercury (MeHg) exposure in humans, especially in infants and children [17, 33-35]. Fish-containing dishes had the highest levels of mercury. The mean contents (MB) for this group of products were 0.0063 mg/kg (median 0.0056 mg/kg, 90% value – 0.0127 mg/kg), which is comparable with results reported in Norway [10]. Similar values in baby food containing fish were reported in other EU member states [24, 35]. Contamination of other products with mercury was significantly lower and ranged from 0.0004 mg/kg for juices to 0.0009 mg/kg for rice gruel. The highest value of mercury was found in a vegetable and fish-based infant dinner sample, at 0.0185 mg/kg.

## Estimation of Intake of Toxic Elements

The calculation of dietary exposure of infants was performed based on the artificial feeding scheme of infants established under The Mother and Child Institute in Poland for 3-month-old infants weighing 6 kg who fully fed on infant formulae based on milk or soya, and 12-month-old infants weighing 10 kg, consuming additionally puréed infant foods and cereals-based formulae [36]. Additionally, manufacturers' feeding recommendations as labeled on the products (mainly formulas) were taken into consideration to assess dietary exposure of infants. Health risk assessment was performed taking into account current reference values for elements including the verification introduced recently by EFSA and JECFA. To assess the dietary exposure to noxious elements from commercially available infant food mean and high contamination levels (P90), middle bound

(MB), and upper bound (UB) values were taken into account. This assessment assumes an infant diet consisting exclusively of commercial baby food.

The calculated intake is based on the obtained analytical results of heavy metals contamination of undiluted, commercial baby foods (as sold).

However, be aware that the real intake of elements under study by infants is higher, primarily due to contamination of water used to reconstitute infant formulas and other dried foods before feeding, in accordance with manufacturers' recommendations.

In the case of lead and cadmium the calculated intake of metals is presented additionally, including water contamination.

Intake of elements noxious to health by 3- and 12-month-old infants based on middle bound (MB) contamination level and mean consumption is presented in Figs. 1-5. Overall intake of heavy metals by 3- and 12-month-old infants with investigated infant food (without water), based on additional assumptions (90<sup>th</sup> percentile MB and UB as well as mean MB and UB) is presented in Figs. 6 and 7.

### Intake of Lead

The calculated mean intake of lead with infant foods as a result of reported contamination of products as sold, based on MB values of contamination, was by 12-month-old infants at 0.53 µg/kg b.w. per day, and 0.09 µg/kg b.w. per day by 3-month-old infants. Lead exposure based on 90<sup>th</sup> percentile MB assumption ranges from 0.17 µg/kg b.w. per day (infants) to 1.05 µg/kg b.w. per day (1 year olds), and at the 90<sup>th</sup> percentile contamination, UB assumption may even be 0.2 µg/kg b.w. for 3-month-old infants and 1.2 µg/kg b.w. for 12-month-olds. Even though this assumption does not take into account water used for formulae reconstitution, intake of lead in the aforementioned case is 2.5 times higher than BMDL<sub>01</sub> value for 12-month-old infants and 42% of BMDL<sub>01</sub> value for infants weighing 6 kg. Mean intake of lead (based on mean, middle bound levels of infant food contamination) by 12-month-old infants is approximately equal to the BMDL<sub>01</sub> value Benchmark dose lower confidence limit causing a 1% increase of neurodevelopment effects in children. Lead intake is highest with

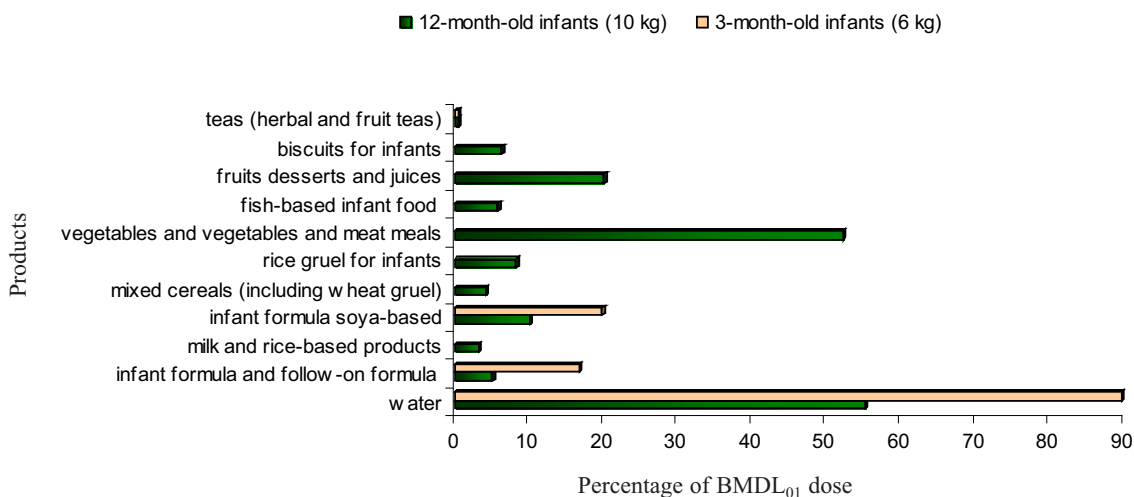


Fig. 1. Lead intake by infants (3 and 12 months old) based on middle-bound (MB) contamination level.

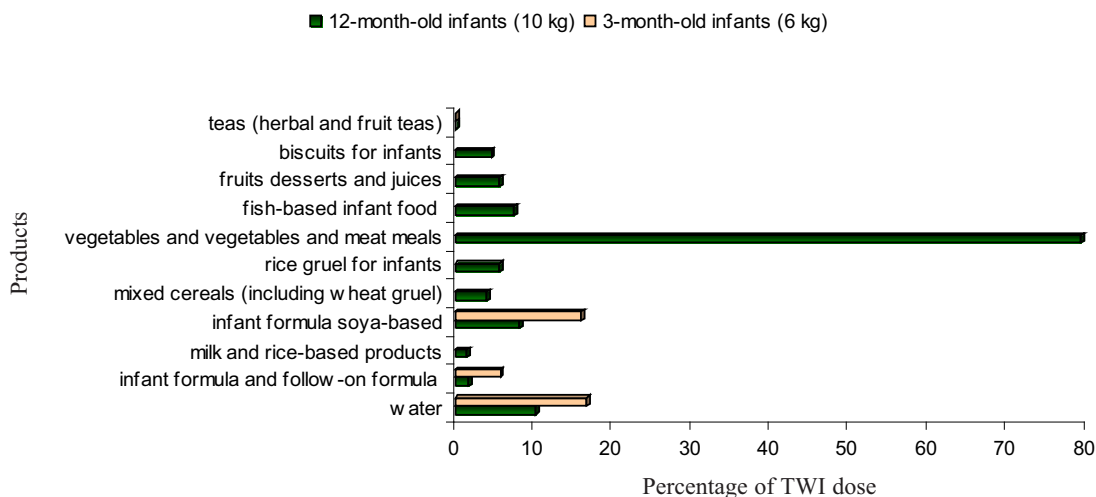


Fig. 2. Cadmium intake by infants (3 and 12 months old) based on middle-bound (MB) contamination level.

vegetable products, products with meat and vegetables, and fruit and juices. Mean intake by 3-month-old infants fed on exclusively milk- and soy-based infant formulae would cover 17% of BMDL<sub>01</sub> value.

Taking into account the contamination of water necessary for product reconstitution before feeding due to manufacturer's recommendations (mean tap water contamination in Poland), [37] mean total lead intake by 12-month-olds

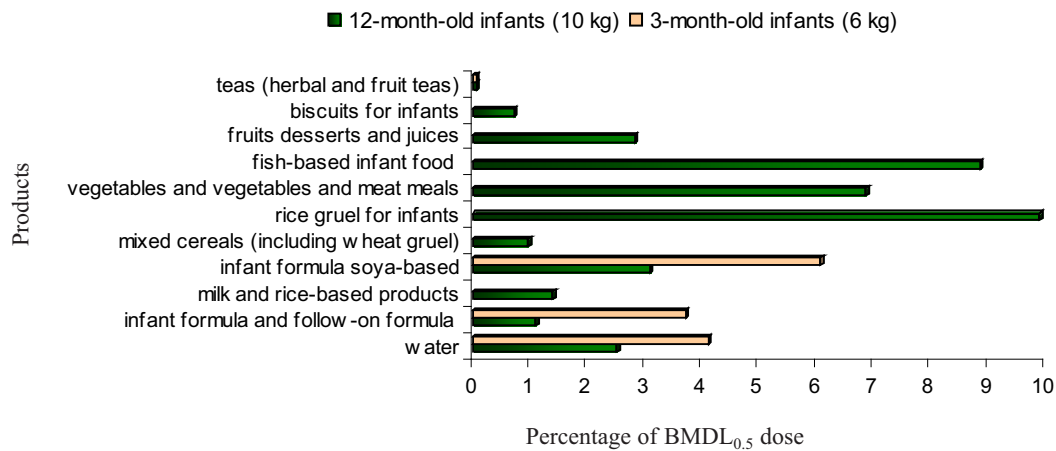


Fig. 3. Arsenic intake by infants (3 and 12 months old) based on middle-bound (MB) contamination level.

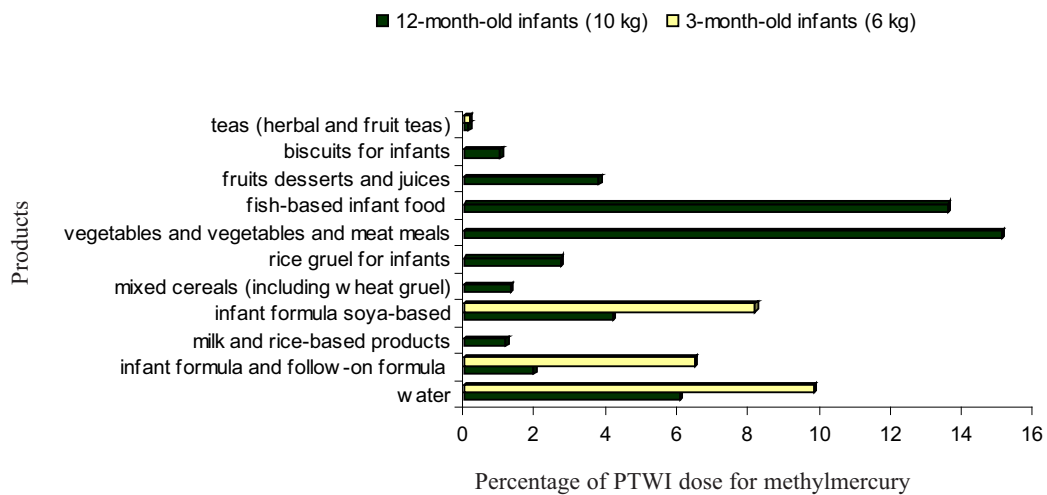


Fig. 4. Methylmercury intake by infants (3 and 12 months old) based on middle-bound (MB) contamination level.

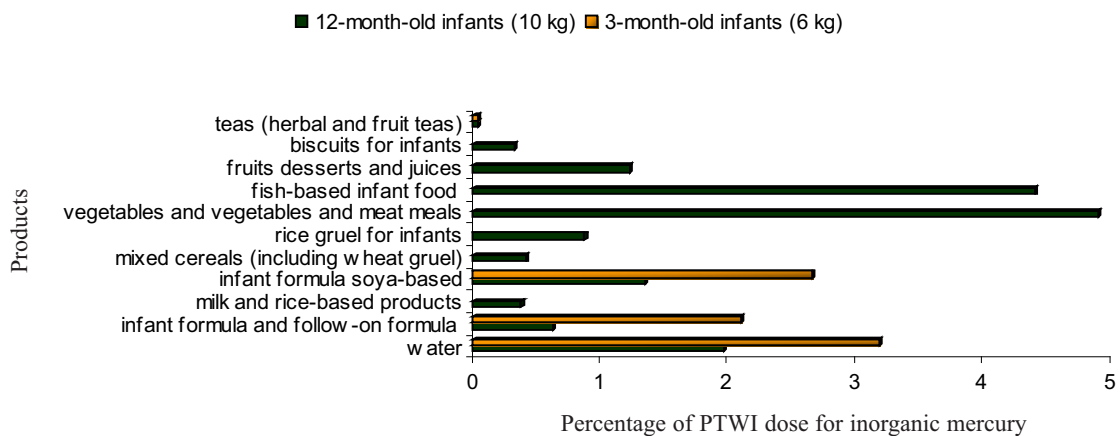


Fig. 5. Inorganic mercury intake by infants (3 and 12 months old) based on middle-bound (MB) contamination level.



would rise to 0.81 µg/kg b.w. per day (1.6 times higher than BMDL<sub>01</sub>) and by 3-month-olds to 0.54 µg/kg b.w. per day (equal approx. the BMDL<sub>01</sub> value). The margin of exposure (MOE) calculated for 3-month-old infants and 1-year-olds fed on infant and follow-on formulae and other commercially available baby food (prepared for feeding with the use of tap water) ranges between 0.9 for infants to 0.6 for 1-year-olds.

The actual lead level of tap water in Poland could cause a high increase of intake of this toxic element by infants: about 60% of BMDL<sub>01</sub> (12-month-old infants) – 90% of BMDL<sub>01</sub> (3-month-old infants).

The assessed maximum daily intake of lead for 3-month-olds is significantly lower than the maximum intake of lead from infant formula in the USA, at 3.4 µg/day [6]. The assessed upper bound mean exposure values for infants were as follows: 0.13 and 0.69 µg/kg b.w. per day (without water). Estimated average exposure for infants in EU fed with ready-to-consume infant formula was 0.63 µg/kg b.w. per day, calculated based on upper-bound assumptions [12], and was similar to that reported in Poland.

### Intake of Cadmium

Mean intake of cadmium resulted only from products as sold contamination, ranges from 6% of the TWI established by EFSA for 3-month-old infants (0.02 µg/kg b.w. per day) to 110% TWI for 12-month-old infants (0.39 µg/kg b.w. per day), which represents 2.5-47% of the PTMI value established by JECFA. Water used for product reconstitution increases the cadmium intake to 23-121% of the TWI (about 10-52% of PTMI), respectively. The highest intake of cadmium was assessed with vegetables and meat and vegetable products at 2.8 µg/kg b.w. per day. According to EFSA opinion, dominating contributors to cadmium exposure of infants are ready-to-eat meals, powder infant formulae, and cereal-based food for infants [25].

Intake of cadmium may be even higher for children allergic to cow milk proteins who consume soya products instead – 16% (with water 33% of TWI) for 3-month-old infants, which corresponds to 7% (14%) of the PTMI.

Cadmium exposure based on 90<sup>th</sup> percentile MB assumption without considering water ranges from 0.05 µg/kg b.w.

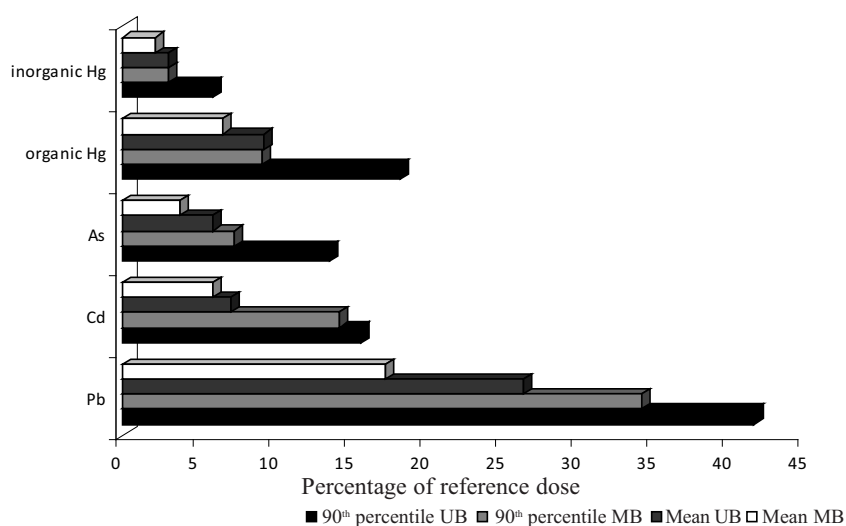


Fig. 6. Intake of elements noxious to health with investigated infant food by 3-month-old infants (without water).

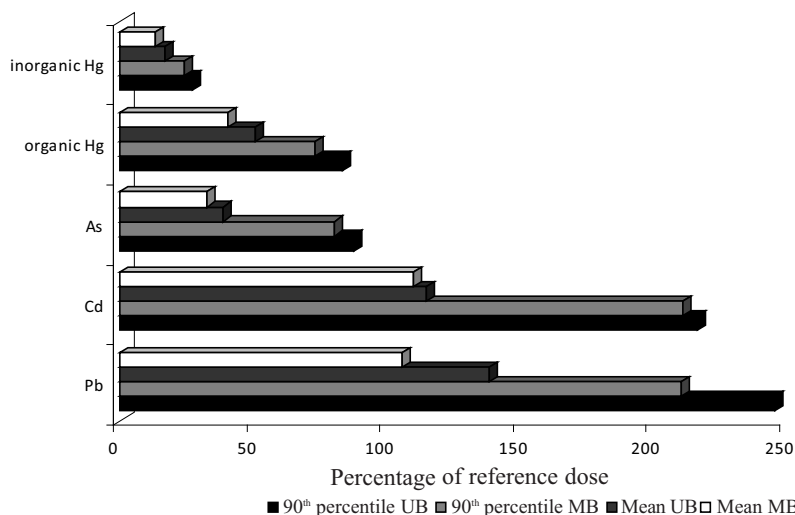


Fig. 7. Intake of elements noxious to health with investigated infant food by 12-month-old infants (without water).

per day (14% TWI) for infants to 0.76 µg/kg b.w. per day for 1-year-olds (2.1 times higher than the TWI value).

At the 90<sup>th</sup> percentile contamination levels based on UB assumption of contamination, cadmium intake by different age groups of infants ranges from 0.06 to 0.77 µg/kg b.w. per day and may exceed the TWI by about 2.2-times in relation to 1-year-old children (93% PTMI value). Exposure of 3-month-old infants at these levels of contamination was assessed to be 16% of TWI value (7% PTMI).

UB mean exposure values were 0.03 µg/kg b.w. per day for infants (7% TWI and 3% PTMI) and 0.41 µg/kg b.w. per day for 1-year-old children (115% of TWI value and 49% PTMI), and are lower than the exposure calculated by EFSA for infants (<1 year) at 3.5 µg/kg b.w. per day [25].

### Intake of Arsenic

Intake of arsenic does not exceed tolerable doses (approx. 33% of BMDL<sub>0.5</sub> value for 12-month-old infants and 4% for 3-month-old infants, which corresponds to exposure values 0.99 and 0.11 µg/kg b.w. per day – middle bound). Arsenic exposure based on 90<sup>th</sup> percentile MB assumption ranges from 0.22 µg/kg b.w. per day for 3-month-old infants to 2.4 µg/kg b.w. per day for 1-year-olds (7-81% BMDL<sub>0.5</sub> value). At the 90<sup>th</sup> percentile UB level of contamination intake by 12-month-olds is equal approximately to the BMDL<sub>0.5</sub> value (2.6 µg/kg b.w. per day) and corresponds with daily exposure estimated in the United States for infants [15]. The assessed MOE depending on contamination levels ranges from 1.1 for 12-month olds to 7.3 for 3-month olds. Estimated intake of arsenic by infants weighing 6 kg, at this level of contamination (UB, 90<sup>th</sup> percentile), was 0.4 µg/kg b.w. per day (14% BMDL<sub>0.5</sub> value). The highest intake of arsenic was assessed for rice gruel, fish-based baby foods, and vegetable and meat meals and infant formulas. Calculated mean upper-bound exposure of arsenic by 3-month-old infants was estimated to be 0.2 µg/kg b.w. per day (6% BMDL<sub>0.5</sub> value), and 1.2 µg/kg b.w. per day (39% BMDL<sub>0.5</sub>) by 12-month-olds.

The contamination of tap water in Poland with arsenic is relatively less essential than with lead and cadmium and causes an increase of arsenic intake about 3-4% of BMDL<sub>0.5</sub>.

### Intake of Mercury

Intake of mercury, assuming that total mercury is represented by its organic compounds (methylmercury – “worst case scenario”) does not exceed tolerable doses (1.3 µg/kg b.w. per week). Based on mean MB concentration of mercury in infants food, the dietary exposure to more toxic organic mercury from the investigated products ranged from 0.01 µg/kg b.w. per day for 3-month-old infants to 0.08 µg/kg b.w. per day for 12-month-olds (7-41% TWI value for organic mercury). Calculated mean MB intake of organic compounds of mercury with fish products in Poland by 1-year-old children was 0.025 µg/kg b.w. per day (14% TWI value for organic mercury), and is lower than that reported in Finland (mean: 0.028-0.032 µg/kg b.w. per day) [33].

Calculated intake of mercury based on 90<sup>th</sup> percentile of contamination and MB assumption ranges from 0.02 µg/kg b.w. per day for 3-month-old infants to 0.14 µg/kg b.w. per day for 1-year-olds (9-73% TWI value for organic mercury). Mercury exposure based on 90<sup>th</sup> percentile UB assumption of contamination ranges from 0.03 for infants to 0.15 µg/kg b.w. per day for 1-year-olds. Dietary intake in this case approximately equals the TWI for methylmercury (83%) for 12-month-olds and 18% of TWI value for 3-month-old infants.

Assuming that all the mercury represented in the investigated samples is inorganic (which is the more appropriate scenario), intake of mercury based on mean contamination and middle bound assumption corresponds to 2% of PTWI value adopted by JECFA (4.0 µg/kg b.w.) for 3-month-old infants and 13% for 12-month-olds. Taking into account 90<sup>th</sup> percentile middle bound assumption intake of mercury (as inorganic) will be in the range 3-24%, respectively. At the 90<sup>th</sup> percentile contamination of mercury, UB assumption intake ranges between 6% and 27% of PTWI value for 3-month-old infants and 1-year-olds. The use of tap water for commercial products reconstitution causes increased methylmercury intake of about 6-10% of TWI (about 2-3% of TWI for inorganic mercury).

This study indicates that fish-based infant food as well as vegetables, vegetable and meat, fruit desserts, and juices dominate contributors to mercury intake by infants. Ready-to-eat fruit-based foods also contributed the most to inorganic mercury exposure in French studies [38].

### Conclusions

The results of these studies indicate that the heavy metals levels in infant food from Polish markets are comparable with contamination in other countries. However, intake of these elements with food by 12-month-olds in some cases may exceed reference values established by EFSA and JECFA. Even though the levels of lead were lower than mean tap water contamination in all products under study, cadmium and lead can pose a health hazard for infants.

Drinking tap water used to prepare dishes may add significantly to heavy metals intake, especially for 3-month-old infants whose diet consists mainly of infant formulae, mainly in the case of lead and cadmium.

Another important issue is contamination of rice products with arsenic, which seems to be significant.

Furthermore, diets with rice and fish-based products contributed most to dietary arsenic intake. Fish-based infant foods as well as ready-to-eat meals based on vegetables and meat or only vegetables can also contribute to mercury intake.

It is important to mitigate health risks by imposing a set of maximum permissible levels for all toxic elements in infant foods into the applicable legislation, especially in foodstuffs that characterise higher toxic metals contamination. Manufacturers of infant foods should ensure the quality of their products by selecting raw materials.

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