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Monitoring of Heavy Metals (Lead, Cadmium, Total Mercury) in Health Functional Foods Distributed in Korea

Ji-Yeong Kim[1], Ji-Wan Kim[1], Young Kyoung Kim[2], Hyun Chung[3], Choong-In Yun[4], Young-Jun Kim[1,4]*

[1]*Department of Food Science and Biotechnology, Seoul National University of Science and Technology, Seoul, Korea*
[2]*Korea Health Functional Food Association-Affiliated Korea Functional Food Institute, Seongnam, Korea*
[3]*KnA Co., Ltd., Yongin, Korea*
[4]*Research Institute of Food and Biotechnology, Seoul National University of Science and Technology, Seoul, Korea*

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ABSTRACT - Health functional foods (HFFs) containing Korean notified functional ingredient products and individually recognized functional ingredient products have become essential components of daily diets. However, previous studies have primarily reported heavy metal concentrations in specific products, which do not adequately reflect actual intake levels or long-term exposure risks. This study evaluated concentration levels and chronic daily intake of lead (Pb), cadmium (Cd), and mercury (Hg) in 432 HFFs distributed in Korea. Pb and Cd were analyzed by inductively coupled plasma mass spectrometry (ICP-MS) following microwave digestion, while Hg was quantified using thermal decomposition/cold vapor atomic absorption spectrometry (CV-AAS). Method validation confirmed excellent linearity ($R^2 \geq 0.999$), accuracy (86-107% recovery), and precision (RSD 2.37-9.00%). Pb ranging from 0.0011-0.9750 mg/kg (mean 0.0391 mg/kg), Cd from 0.0000-0.2160 mg/kg (mean 0.0113 mg/kg), and Hg from 0.0001-0.0485 mg/kg (mean 0.0009 mg/kg). The estimated chronic daily intakes (CDI) were 0.0035 μg/kg b.w./day for Pb, 0.0008 μg/kg b.w./day for Cd, and 0.0002 μg/kg b.w./day for Hg. Psyllium husk contributed 55.47% to Pb CDI, proteins 29.67% to Cd CDI, and polydextrose 33.33% to Hg CDI. These levels were within Ministry of Food and Drug Safety (MFDS) limits and comparable to international data, providing baseline data for safety management of HFFs.

Key words: Heavy metals, Health functional food, Chronic daily intake, Korea, Monitoring

Health functional foods (HFFs) are classified and regulated differently worldwide—as dietary supplements by the Food and Drug Administration (FDA) in the United States, food supplements under European Food Safety Authority (EFSA) in the European Union, natural health products by Health Canada, and health supplements by the Dubai Municipality in the United Arab Emirates—according to Jairoun et al.[1)]. As consumer interest in health management continues to increase, the consumption of HFFs has steadily expanded. The domestic HFFs market has shown an average annual growth rate of approximately 4.1% over the past five years (2020 to 2024), indicating that HFFs have become part of routine dietary intake[2)]. On a global scale, the HFFs market is expected to reach approximately USD 2,139.7 billion by 2026[3)]. According to Article 3, Paragraph 1 of the Health Functional Food Act, HFFs are defined as foods manufactured or processed using ingredients or components with beneficial functions for the human body[4)]. In contrast to conventional foods, HFFs are typically consumed repeatedly over long periods, making the safety assurance of HFFs critical for consumer health protection.

The Ministry of Food and Drug Safety[5)] (MFDS) establishes and manages functional claims and specification standards for HFFs. However, many of these ingredients are derived from plant materials, minerals, and marine resources, and may therefore be susceptible to heavy metal contamination originating from cultivation environments, soil and marine pollution, and manufacturing and processing steps. Overseas studies have reported the detection of heavy metals such as lead (Pb), cadmium (Cd), and mercury (Hg) in HFFs. To address long-term dietary exposure to heavy metals, the FDA launched the 'Closer to Zero' to reduce contaminant levels in foods to the lowest feasible levels[6)].

Due to their toxic nature and the hazards linked to long-

*Correspondence to: Young-Jun Kim, Department of Food Science and Biotechnology, Seoul National University of Science and Technology, Seoul 01811, Korea
Tel: +82-2-970-6734, Fax: +82-2-970-9736
E-mail: Kimyj@seoultech.ac.kr

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term exposure, these metals are regulated in foods under established maximum limits, which require ongoing monitoring of dietary intake[7]. In Korea, food safety studies have also emphasized the need for exposure based risk assessment that reflects actual intake levels rather than relying solely on compliance with concentration limits[8]. Recently, domestic studies have increasingly evaluated food safety using dietary exposure assessments based on real consumption data rather than simple concentration measurements of individual components[9].

Pb, Cd, and Hg are toxic to humans and are not essential elements for biological functions, yet they are widely distributed in the environment and recognized as highly hazardous substances that can adversely affect human health[10]. According to the National Institute of Food and Drug Safety Evaluation[11] (NIFDS), lead can affect the nervous system, and cadmium is classified as a substance that has been confirmed to be carcinogenic in humans. The EFSA[12] also classifies Pb, Cd, and Hg as naturally occurring compounds and regulates their levels in food as chemical contaminants. Pb exposure has been reported to affect multiple physiological systems at the cellular and tissue levels. Chronic exposure is associated with hematological disorders such as anemia, as well as toxic effects on the kidneys, liver, cardiovascular system, and reproductive system. Long term exposure has also been linked to increased genotoxicity and elevated cancer risk[13]. Cd has a long biological half-life and readily accumulates in the body. Chronic exposure induces oxidative stress and inflammatory responses, leading to renal tubular dysfunction, and inhalation exposure has been associated with lung tissue damage and reduced pulmonary function[14]. Accidental exposure to Hg in humans can result in increased blood pressure[15]. In addition, Hg and methylmercury (MeHg) have been detected in domestically distributed seafood, raising concerns regarding the management of HFFs containing marine derived ingredients[16].

Previous studies have primarily reported heavy metal concentrations in each product, which do not reflect actual intake levels or long-term exposure risks. Therefore, this study quantified the contents of Pb, Cd, and Hg in 335 notified functional ingredient products and 97 individually recognized functional ingredient products distributed in Korea. Pb and Cd were analyzed using inductively coupled plasma mass spectrometry (ICP-MS), while mercury was measured using a mercury analyzer. The analytical results were evaluated based on concentration distributions and product type characteristics, and chronic daily intake (CDI) was calculated from consumption data of HFFs, and the contribution of each product to total heavy metal exposure was separately assessed.

These findings provide baseline data for assessing heavy metal exposure from HFFs and for supporting future safety management and standard setting.

Materials and Methods

Samples

Pb, Cd, and Hg contents were analyzed in Korean HFFs selected based on weighted high-consumption, high-frequency, and contamination risk indicators.

The total sample size (n=432) was determined using a weighted scoring system considering production volume, intake frequency, and product-specific non-compliance rates. Samples were collected from the top 19 notified functional ingredient categories by production volume, along with one additional category representing individually recognized functional ingredients, resulting in a total of 20 categories covering various product types. Product-specific sample sizes are probiotics (n=60), individually recognized functional ingredient products (n=97), vitamins & minerals (n=67), red ginseng (n=27), indigestible maltodextrin (n=10), theanine (n=11), methylsulfonylmethane (MSM, n=20), proteins (n=11), fructooligosaccharide (n=9), edible oil containing EPA & DHA (n=21), aloe gel (n=11), red yeast rice (n=11), garcinia cambogia extracts (n=10), milk thistle extracts (n=11), polydextrose (n=5), psyllium husk dietary fiber (n=10), saw palmetto fruit extracts (n=10), propolis extracts (n=11), green tea extracts (n=10), and marigold flower extracts (n=10).

Samples consisted of 13 different product types (powder, tablet, capsule, pill, liquid, granule, flake, paste, syrup, gel, jelly, bar, and film). These were homogenized by grinding in a mortar and pestle. For products difficult to grind manually, a mechanical grinder or blender was used to obtain a homogeneous powder. For powdered and liquid forms, approximately 10 individual packages were pooled.

Standards and reagents

Certified reference materials (CRMs) of Pb (Cat. No. 105-02-015, Korea Research Institute of Standards and Science, KRISS, Daejeon, Korea), Cd (Cat. No. 105-02-006, KRISS), and Hg (Cat. No. 105-02-019, KRISS) were used as reference standards for quantitative analysis. Standard solutions were prepared by dilution of these CRMs in 10% nitric acid (Junsei, Tokyo, Japan).

Analytical method verification

Method verification was performed by evaluating linearity, limit of detection (LOD), limit of quantitation (LOQ), accuracy, and precision, in accordance with the guidelines of the AOAC validation guidelines[17].

Calibration curves for Pb, Cd, and Hg were prepared using seven concentration levels, and linearity was evaluated by linear regression analysis. LOD and LOQ were determined using LOD=3σ/S and LOQ=10σ/S, where σ is the standard deviation of the y-intercept and S is the slope of the calibration curve.

Accuracy and precision were evaluated using CRMs of Pb (Cat. No. 108-01-008, KRISS), Cd and Hg (Cat. No. 108-02-004, KRISS) were analyzed. Accuracy was calculated as the percentage ratio of measured to certified values. Precision was determined as relative standard deviation (RSD) from intra-day (seven replicate analyses within a day) and inter-day (seven replicate analyses over three consecutive days).

In addition, reference material T07586 (Food Analysis Performance Assessment Scheme, FAPAS, York, UK) was used for external proficiency testing.

Analytical method for Pb and Cd

Standard and Specification of Food Chapter 8. General Test Methods, 9. Harmful substances in food 9.1 Heavy metals (9.1.2 Lead and 9.1.4 Cadmium). Microwave digestion followed by ICP-MS (Agilent 7800, Agilent Technologies, Santa Clara, CA, USA) measurement.

Approximately 0.1-0.5 g of a homogeneous sample (1-3 g for samples with high moisture samples) was accurately weighed into teflon microwave digestion vessels and treated with concentrated nitric acid using a pipette (Eppendorf Research plus 200-1000 μL, Eppendorf AG, Hamburg, Germany).

The mixtures were digested using vessels in a microwave digestion system (CEM Corporation, Matthews, NC, USA). Microwave digestion was performed by ramping from 60°C to 180°C over 25 min, followed by a 30 min hold at 180°C, and then cooling to 60°C over 30 min. After digestion, the resulting solutions were gently evaporated to near dryness using a heat block (MIULAB, Ningbo, China). The digests were diluted with ultrapure water to a final nitric acid concentration below 10% (v/v) and analyzed for elemental concentrations by ICP-MS.

ICP-MS analysis was performed with sample uptake for 30 s and stabilization for 30 s at 0.5 rps, sample injection volume of 1.0 mL, nebulizer flow rate of 1.0 L/min Ar gas, and radio frequency (RF) power set to 1550 W, using He collision mode while monitoring Pb at m/z 208 and Cd at m/z 111, with an external calibration curve ranging from 0.1-100 μg/mL.

Analytical method for Hg

Standard and Specification of Food Chapter 8. General Test Methods, 9. Harmful substances in food, 9.1 Heavy metals (9.1.6 Mercury) specifies thermal decomposition followed by Mercury analyzer (Hydra II, Teledyne Leeman Labs, Hudson, MA, USA) with CV-AAS measurement.

The solid samples (10-300 mg, after chopping or homogenization) or liquid samples (0.1-0.5 mL) were weighed into a nickel boat prior to transfer. The prepared sample was introduced into the combustion unit, dried at 300°C for 90 s, thermally decomposed at 800°C for 150 s with oxygen supplied at 350 mL/min, followed by catalyst treatment at 600°C for 60 s. Released mercury vapor was trapped as gold amalgam in the amalgamator, desorbed at 600°C for 30 s.

Chronic daily intake (CDI)

In this study, heavy metal exposure was estimated by calculating the chronic daily intake (CDI). The CDI was calculated using the standardized equation proposed by the USP[18], as shown in Equation (1).

$$\mathrm{CDI} = \frac{\mathrm{C(mg/kg)} \times \mathrm{DI(g/day)}}{\mathrm{BW(kg)}} \quad (1)$$

In this equation, concentration (C) represents the monitored concentrations of Pb, Cd, and Hg in HFFs, and daily intake rate (DI) reflects the recommended daily intake of the sampled products, taking into account their product types, serving size per intake, and daily intake frequency. The weight or volume per product type was also derived from the product information on the monitored items and applied accordingly. The CDI was calculated by multiplying C and DI and dividing by body weight (BW), where BW represents the average adult body weight (60 kg).

Results and Discussion

Analytical method verification

Linearity, LOD, and LOQ

As shown in Table 1, the ICP-MS method demonstrated excellent linearity for all target heavy metals. Calibration curves constructed at seven concentration levels showed high R^2 values (≥0.999) across the tested ranges, with concentration levels of 0.1 to 100 ng/mL for Pb and Cd, 0.1 to 10 ng/mL for Hg. In addition, LOD and LOQ values were determined for all analytes.

Accuracy and Precision

The accuracy and precision results obtained using CRMs are summarized in Table 2, expressed as recovery and RSD values, respectively. Recoveries for Pb, Cd, and Hg ranged from 86% to 107%. Intra-day precision (n=7) showed RSD values of 3.70-5.98%, while inter-day analysis (n=21) exhibited RSD values of 2.37-9.00%. All values fell within acceptable AOAC guideline ranges[17,19].

Table 1. Calibration results of heavy metals (Pb, Cd, Hg)

Parameters	Lead (Pb)	Cadmium (Cd)	Mercury (Hg)
Range (ng/mL)	0.1-100	0.1-100	0.1-10
Points	7	7	7
Calibration curve equation	y=18954x-8744.5	y=2097.9x-72.305	y=16818x+574.35
Regression coefficient (R^2)	0.9993	1.0000	0.9999
LOD (ng/mL)[1)]	0.0035	0.0173	0.0093
LOQ (ng/mL)[2)]	0.0116	0.0577	0.0311

[1)]Limit of detection.
[2)]Limit of quantification.

Table 2. Accuracy and precision of the analytical method for heavy metals (Pb, Cd, Hg) using CRM

Analyte	Certified value (mg/kg)	Accuracy[1,2)] (%)	Intra-day[3)]		Inter-day[4)]	
			Measured value[2)] (mg/kg)	Relative standard deviation (%RSD)	Measured value[2)] (mg/kg)	Relative standard deviation (%RSD)
Lead (Pb)	0.2159[5)]	102.15±4.60	0.2188±0.01	3.70	0.2205±0.01	4.51
Cadmium (Cd)	0.0764[6)]	85.63±7.71	0.0636±0.003	5.98	0.0654±0.006	9.00
Mercury (Hg)	1.5500[7)]	106.86±2.53	1.6735±0.02	5.37	1.6564±0.039	2.37

[1)]n=21.
[2)]Average±SD.
[3)]Seven replicate analyses/day.
[4)]Seven replicate analyses/3 days.
[5)]KRISS CRM (108-01-008, Rice flour for elemental analysis).
[6,7)]KRISS CRM (108-02-004, Infant formula for elemental analysis).

Table 3. FAPAS proficiency test results for heavy metals (Pb, Cd, Hg)

FAPAS sample	Analyte	Assigned value (μg/kg)	Result (μg/kg)	z-score
T07586 (powdered brown rice)	Lead (Pb)	69.7	73.22	0.2
	Cadmium (Cd)	21.5	20.33	-0.2
	Mercury (Hg)	36.7	40.76	0.5
T07575 (barley flour)	Lead (Pb)	36.1	37.97	0.2
	Mercury (Hg)	39.9	37.62	-0.3

Proficiency Test

The results of the FAPAS proficiency testing are presented in Table 3. Two FAPAS test materials (T07586, T07575) were analyzed, and the z-scores obtained for Pb, Cd, and Hg were all within ±0.5, demonstrating excellent agreement between the measured values and the assigned reference values.

Analytical Results of HFFs

MFDS[5)] has established common limits for lead (Pb) and cadmium (Cd) in HFFs at 1.0 mg/kg and 0.3 mg/kg, respectively. In contrast, the limits of elemental contaminants proposed by the U.S. Pharmacopeial Convention[20)] (USP) are 0.5 μg/g for lead, 0.5 μg/g for cadmium, and 1.5 μg/g for mercury. Compared to the Korean regulatory limits for HFFs, the USP limit is more stringent for Pb but less stringent for Cd.

In the present study, the concentrations of Pb, Cd, and Hg were determined in 432 HFFs. As summarized in Table 4, the concentrations of all three heavy metals were generally distributed within low ranges. In particular, individually recognized functional ingredients accounted for the second largest proportion among functional ingredients, thus indicating their representativeness for HFFs.

Pb concentrations ranged from 0.0011-0.9750 mg/kg and a mean concentration of 0.0391 mg/kg, with the highest level observed in a psyllium husk dietary fiber product. Cd concentrations ranged from 0.0000-0.2160 mg/kg and the overall mean Cd concentration was 0.0113 mg/kg. The highest concentration was observed in vitamins and minerals

Table 4. Concentrations of heavy metals (Pb, Cd, Hg) in health functional foods (mg/kg)

Food type	No. of Sample	Lead (Pb)		Cadmium (Cd)		Mercury (Hg)	
		Range	Overall average	Range	Overall average	Range	Overall average
Probiotics	60	0.0041-0.4430	0.0276	0.0003-0.0788	0.0069	0.0001-0.0055	0.0007
Individually recognized functional ingredients	97	0.0013-0.2020	0.0193	0.0000-0.1610	0.0106	0.0001-0.0072	0.0010
Vitamins & Minerals	67	0.0022-0.1940	0.0311	0.0002-0.2160	0.0236	0.0001-0.0077	0.0009
Red Ginseng	27	0.0025-0.1200	0.0268	0.0003-0.0485	0.0100	0.0001-0.0485	0.0028
Indigestible maltodextrin	10	0.0048-0.0230	0.0105	0.0001-0.0043	0.0010	0.0002-0.0012	0.0006
Theanine	11	0.0040-0.0956	0.0281	0.0001-0.0802	0.0121	0.0002-0.0014	0.0005
MSM (methyl sulfonylmethane, dimethylsulfone)	20	0.0026-0.0444	0.0145	0.0001-0.0189	0.0025	0.0001-0.0012	0.0004
Proteins	11	0.0018-0.0281	0.0125	0.0002-0.0148	0.0082	0.0001-0.0014	0.0005
Fructooligosaccharide	9	0.0044-0.0469	0.0161	0.0002-0.0025	0.0011	0.0001-0.0012	0.0007
Edible oil containing EPA & DHA	21	0.0036-0.0429	0.0113	0.0001-0.0140	0.0016	0.0001-0.0033	0.0006
Aloe gel	11	0.0019-0.0350	0.0101	0.0000-0.0036	0.0007	0.0003-0.0022	0.0008
Red yeast rice	11	0.0146-0.0432	0.0304	0.0071-0.0797	0.0315	0.0002-0.0023	0.0010
Garcinia cambogia extracts	10	0.0100-0.7910	0.2080	0.0056-0.0659	0.0368	0.0001-0.0014	0.0006
Milk thistle extracts	11	0.0048-0.0996	0.0301	0.0006-0.0228	0.0066	0.0002-0.0047	0.0011
Polydextrose	5	0.0011-0.0074	0.0035	0.0001-0.0025	0.0011	0.0002-0.0021	0.0010
Psyllium husk dietary fiber	10	0.0371-0.9750	0.3595	0.0065-0.0372	0.0243	0.0001-0.0009	0.0005
Saw palmetto fruit extracts	10	0.0307-0.3260	0.1238	0.0020-0.0264	0.0098	0.0001-0.0029	0.0007
Propolis extracts	11	0.0054-0.3710	0.0845	0.0002-0.0610	0.0133	0.0001-0.0050	0.0012
Green tea extracts	10	0.0081-0.0915	0.0323	0.0010-0.1040	0.0195	0.0002-0.0021	0.0005
Marigold flower extracts	10	0.0085-0.1700	0.0404	0.0005-0.0174	0.0031	0.0002-0.0007	0.0004

products. Hg concentrations ranged from 0.0001-0.0485 mg/kg and the overall mean Hg concentration was 0.0009 mg/kg, with the highest level was observed in red ginseng products.

In comparison, Bandara et al.[21] assessed heavy metal exposure in whey protein powder supplements and reported concentrations of Pb, Cd, and Hg. The concentrations measured per serving of whey protein products, with Pb ranging from 0.0001-0.0018 mg/kg, Cd ranging from 0.0000-0.0013 mg/kg, and Hg ranging from 0.0000-0.0003 mg/kg. When compared with the protein products among the notified functional ingredient analyzed in the present study, Pb concentrations were observed to exceed the reported range, whereas Cd and Hg concentrations were found to fall within the corresponding ranges reported for whey protein supplements.

Furthermore, the overall concentration levels observed in the present study were comparable to those reported by Augustsson et al.[22]. In synthetic, marine non-fish-oil, marine fish-oil, and terrestrial plant-based products, where Pb concentrations ranged from 0.0005-1.7000 mg/kg with an overall mean of 0.1562 mg/kg, Cd concentrations ranged from 0.0005-1.5000 mg/kg with an overall mean of 0.0788 mg/kg, and Hg concentrations ranged from 0.0005-0.0380 mg/kg with an overall mean of 0.0027 mg/kg. Taken together, these results suggest that the heavy metal contamination levels in HFFs are comparable to those previously reported in diverse dietary supplements.

CDI of HFFs

The CDI of Pb, Cd, and Hg was estimated based on monitored concentrations, and the results are summarized in Table 5. For Pb, CDI estimation included all 432 products, with estimated Pb exposure ranged from <0.0001-0.1186 μg/kg b.w./day, and a mean Pb CDI of 0.0035 μg/kg b.w./day. The estimated CDI of Cd ranged from <0.0001-0.0353 μg/kg b.w./day, and the mean Cd CDI was 0.0008 μg/kg b.w./day. For Hg, the estimated CDI ranged from <0.0001-0.0056 μg/

Table 5. Chronic daily intake to heavy metals (Pb, Cd, Hg) level in health functional foods (μg/kg b.w./day)

Food type	No. of Sample	Lead (Pb)		Cadmium (Cd)		Mercury (Hg)	
		Range	Overall average	Range	Overall average	Range	Overall average
Probiotics	60	<0.0001-0.0133	0.0006	<0.0001-0.0016	0.0001	<0.0001-0.0001	<0.0001
Individually recognized functional ingredients	97	0.0001-0.0192	0.0030	<0.0000-0.0270	0.0011	<0.0001-0.0035	0.0003
Vitamins & Minerals	67	<0.0001-0.0038	0.0008	<0.0001-0.0353	0.0012	<0.0001-0.0003	<0.0001
Red Ginseng	27	0.0002-0.0060	0.0021	<0.0001-0.0064	0.0008	<0.0001-0.0024	0.0002
Indigestible maltodextrin	10	0.0009-0.0049	0.0026	<0.0001-0.0014	0.0003	0.0001-0.0004	0.0002
Theanine	11	0.0001-0.0020	0.0010	<0.0001-0.0016	0.0003	<0.0001-0.0001	<0.0001
MSM (methyl sulfonylmethane, dimethylsulfone)	20	0.0001-0.0067	0.0012	<0.0001-0.0014	0.0002	<0.0001-0.0004	0.0001
Proteins	11	0.0050-0.0218	0.0106	0.0005-0.0173	0.0062	0.0001-0.0018	0.0006
Fructooligosaccharide	9	0.0004-0.0035	0.0013	<0.0001-0.0002	0.0001	<0.0001-0.0001	0.0001
Edible oil containing EPA & DHA	21	0.0001-0.0022	0.0004	<0.0001-0.0003	<0.0001	<0.0001-0.0004	<0.0001
Aloe gel	11	0.0012-0.0128	0.0056	0.0001-0.0007	0.0003	<0.0001-0.0056	0.0013
Red yeast rice	11	0.0001-0.0014	0.0005	0.0001-0.0007	0.0003	<0.0001-<0.0001	<0.0001
Garcinia cambogia extracts	10	0.0004-0.0264	0.0077	0.0003-0.0022	0.0015	<0.0001-0.0001	<0.0001
Milk thistle extracts	11	0.0001-0.0043	0.0012	<0.0001-0.0008	0.0002	<0.0001-0.0002	<0.0001
Polydextrose	5	0.0029-0.0086	0.0063	0.0002-0.0066	0.0024	0.0005-0.0039	0.0020
Psyllium husk dietary fiber	10	0.0056-0.1186	0.0639	0.0010-0.0072	0.0046	<0.0001-0.0002	0.0001
Saw palmetto fruit extracts	10	0.0003-0.0055	0.0025	<0.0001-0.0003	0.0002	<0.0001-<0.0001	<0.0001
Propolis extracts	11	0.0003-0.0042	0.0019	<0.0001-0.0005	0.0002	<0.0001-0.0004	0.0001
Green tea extracts	10	0.0002-0.0020	0.0009	<0.0001-0.0052	0.0007	<0.0001-0.0001	<0.0001
Marigold flower extracts	10	0.0001-0.0038	0.0011	<0.0001-0.0001	0.0001	<0.0001-0.0001	<0.0001

kg b.w./day, with a mean Hg CDI of 0.0002 μg/kg b.w./day. In Abdulla et al.[23] study, the average daily intakes of Pb, Cd, and Hg were 0.88, 0.83, and 0.09 μg/day, respectively, corresponding to approximately 0.0147, 0.0138, and 0.0015 μg/kg b.w./day for a 60 kg adult, which are comparable to the exposure levels estimated in the present study.

In accordance with the established parameters for natural health products by Health Canada[24], the maximum allowable daily exposure levels for Pb, Cd, and Hg are 0.14, 0.09, and 0.29 μg/kg b.w./day, respectively. Furthermore, the USP[25] applies permitted daily exposure (PDE) limits, originally derived from toxicological thresholds for pharmaceuticals, to the assessment of elemental impurities in dietary supplements. When normalized to a 60 kg adult, these correspond to approximately 0.083 μg/kg b.w./day for Pb and Cd and 0.250 μg/kg b.w./day for Hg. The estimated CDI values in the present study were considerably lower than both reference values, indicating that the exposure levels associated with the consumption of HFFs are within acceptable safety margins.

Contribution to CDI from HFFs

The contribution of HFFs to the overall CDI of Pb, Cd, and Hg was evaluated by calculating the proportion of each ingredient's detected concentration relative to the total CDI to identify major contributors to exposure. The results of the contribution analysis are presented in Fig. 1. For Pb, psyllium husk dietary fiber was the largest contributor, accounting for 55.47% of the total CDI. For Cd, proteins showed the highest contribution to total exposure, contributing 29.67%. For Hg, polydextrose was the primary contributor, accounting for 33.33% of the total CDI.

These results reflect variations in consumption-related factors, including intake frequency, sales volume and

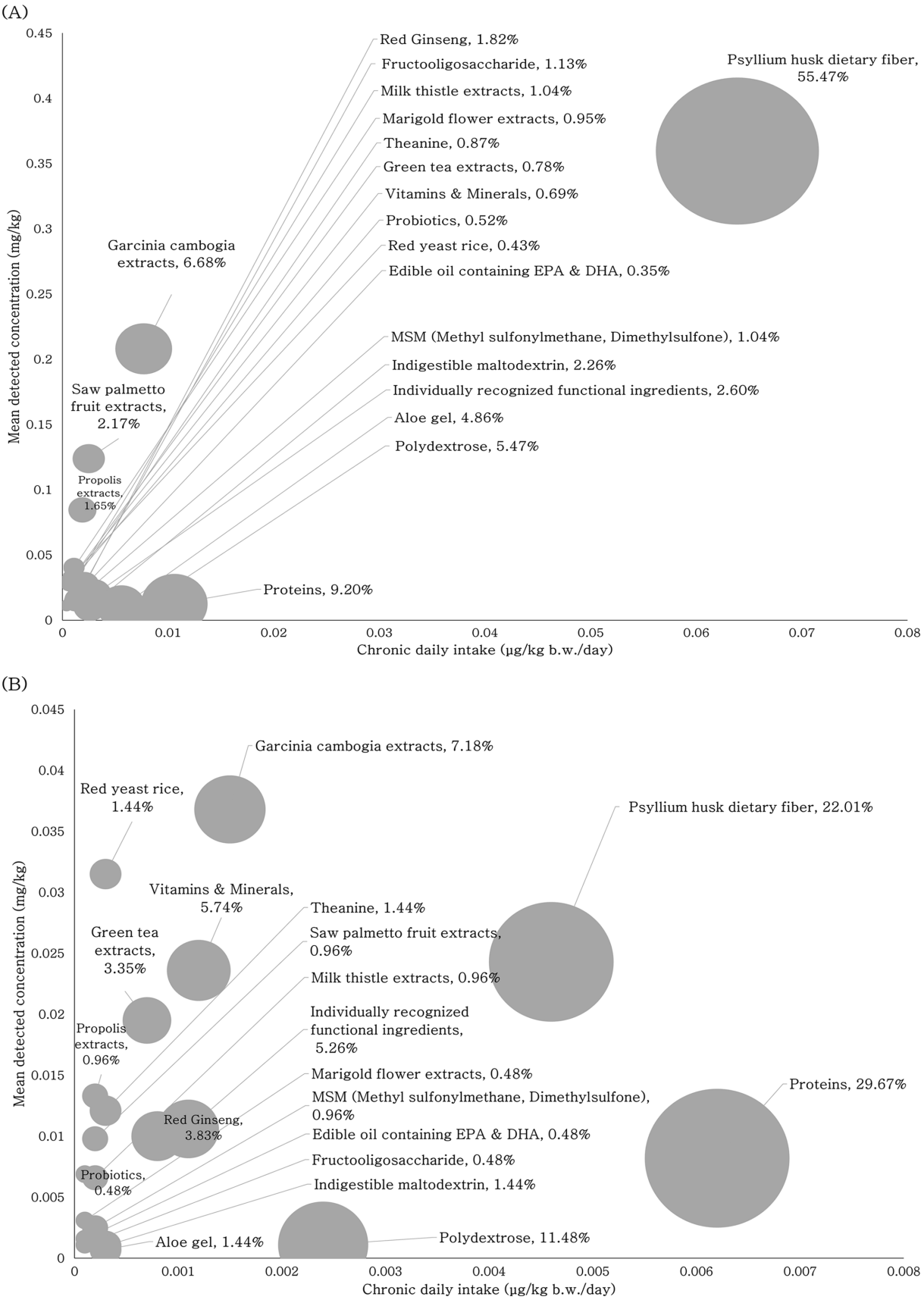

Fig. 1. Contribution to CDI (%) of (A) lead, (B) cadmium, and (C) mercury from health functional foods. Values <0.0001 were set to 0.0001.

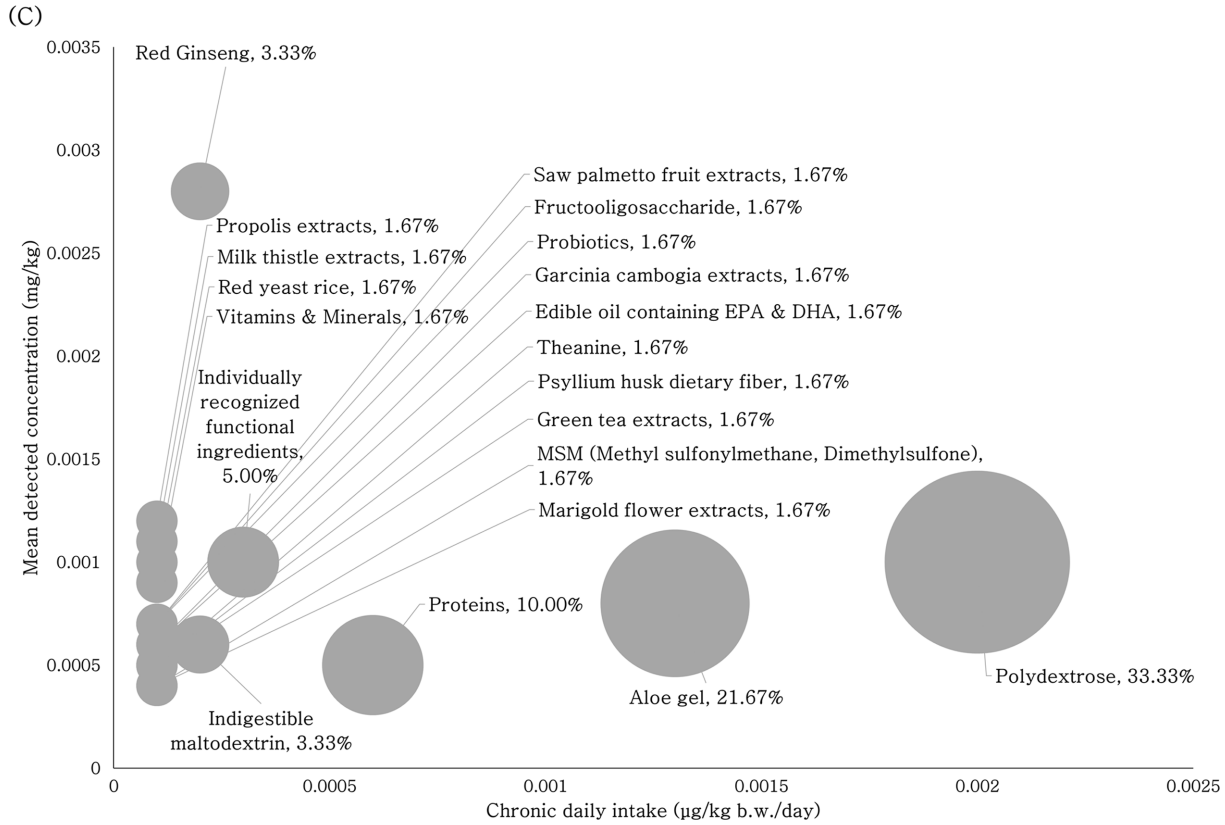

Fig. 1. (Continued) Contribution to CDI (%) of (A) lead, (B) cadmium, and (C) mercury from health functional foods. Values <0.0001 were set to 0.0001.

production volume across different formulation product types. Consequently, elevated contribution values do not necessarily indicate higher contaminant concentrations, but rather represent the combined influence of concentration and these consumption-related factors.

Overall, these results comprehensively describe the concentrations, CDI, and relative contribution of Pb, Cd, and Hg in HFFs and provide baseline data for heavy metal safety management in HFFs.

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국문요약

건강기능식품은 인체에 유익한 기능성을 가져, 전세계적으로 소비가 증가하고 있다. 이에 따라 중금속 오염 실태에 대한 모니터링이 중요하게 여겨지고 있다. 본 연구의 목적은 국내 유통 건강기능식품 고시형 원료 335개, 개별인정형 원료 97개에서 납 (Pb), 카드뮴 (Cd), 수은 (Hg)의 함량과 만성 일일 섭취량 (평균 노출량, CDI)을 평가하였다. 생산량, 섭취 빈도 및 오염 가능성을 종합적으로 고려하여 총 432개 제품을 선정하였으며, 납과 카드뮴은 ICP-MS로, 수은은 수은분석기를 이용하여 분석하였다. 분석법 검증 결과 직선성, 정확성, 정밀성 및 숙련도 시험에서 적합한 성능을 확인하였다. 모든 시료에서 중금속은 전반적으로 낮은 농도로 검출되었으며, 납은 0.0011-0.9750 mg/kg (평균 0.0391 mg/kg), 카드뮴은 0.0000-0.2160 mg/kg (평균 0.0113 mg/kg), 수은은 0.0001-0.0485 mg/kg (평균 0.0009 mg/kg) 범위로 나타났다. 이를 활용하여 CDI를 산출한 결과, 평균 노출량은 납 0.0035 μg/kg b.w./day, 카드뮴 0.0008 μg/kg b.w./day, 수은 0.0002 μg/kg b.w./day로 산출되었다. 또한, 노출 기여도 분석 결과, 건강기능식품 중 납의 경우는 차전자피 식이섬유 55.47%, 카드뮴의 경우 단백질 29.67%, 수은의 경우 폴리덱스트로스가 33.33%로 주요 기여 원료로 확인되었다. 이러한 결과는 생산량, 섭취 빈도 및 섭취량을 종합적으로 반영한 것으로, 기여도 값이 높다고 해서 해당 원료의 중금속 함량이 높은 것을 의미하지 않으며, 함량과 섭취 관련 요인이 복합적으로 작용한 결과로 해석된다. 또한, 전반적인 중금속의 검출 농도 및 노출 수준은 국내외 선행 연구와 유사한 수준으로 나타났으며, 본 연구 결과는 건강기능식품 중 중금속에 대한 노출 기반 위해성 평가 및 안전관리 정책 수립을 위한 기초자료로 활용될 수 있을 것으로 사료된다.

Conflict of interests

The authors declare no potential conflict of interest.

ORCID

Ji-Yeong Kim	https://orcid.org/0009-0001-8981-4531
Ji-Wan Kim	https://orcid.org/0009-0000-1044-2599
Young Kyoung Kim	https://orcid.org/0009-0007-4916-8137
Hyun Chung	https://orcid.org/0009-0000-0157-6229
Choong-In Yun	https://orcid.org/0000-0002-4305-678X
Young-Jun Kim	https://orcid.org/0000-0001-7232-6008

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