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Perspectives-minireview

Heavy Metal Risk Management: Case Analysis

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To prepare measures for practical policy utilization and the control of heavy metals, hazard control related institutions by country, present states of control by country, and present states of control by heavy metals were examined. Hazard control cases by heavy metals in various countries were compared and analyzed. In certain countries (e.g., the U.S., the U.K., and Japan), hazardous substances found in foods (e.g., arsenic, lead, cadmium, and mercury) are controlled. In addition, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommends calculating the provisional tolerable weekly intake (PTWI) of individual heavy metals instead of the acceptable daily intake (ADI) to compare their pollution levels considering their toxicity accumulated in the human body. In Korea, exposure assessments have been conducted, and in other countries, hazardous substances are controlled by various governing bodies. As such, in Korea and other countries, diverse food heavy metal monitoring and human body exposure assessments are conducted, and reducing measures are prepared accordingly. To reduce the danger of hazardous substances, many countries provide leaflets and guidelines, develop hazardous heavy metal intake recommendations, and take necessary actions. Hazard control case analyses can assist in securing consumer safety by establishing systematic and reliable hazard control methods.

Key words: Hazardous substances, Risk management, Case analysis, Heavy metal

INTRODUCTION

Recently, in Korea and in other countries, attention has been concentrated on health hazards and changes in the ecology caused by endocrine disruptors, agricultural chemicals, and heavy metals. Hazardous substances contained in foods are known to not only have strong direct toxicity in the human body but also act to chronically disturb the endocrine system (Calafat, 2012). Accordingly, studies assessing amounts of hazardous substance intake via food intake and related degrees of hazards have been conducted throughout the world, and individual countries have prepared food safety control institutions to regulate hazards. Mercury, for example, is used in fluorescent lamps, batteries, and measuring instruments (Ministry of Environment, 2006), and organic mercury has been linked to central nervous system toxicity, immunotoxicity, genetic toxicity,

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reproductive toxicity, teratogenicity, and nephrotoxicity. Similarly, although lead is widely used in our daily lives, humans poisoned by lead show symptoms such as headaches, sleep disturbances, and central nervous system disorders. Cadmium exists in the air, water, soil, and foods, and if poisoned by cadmium, humans can develop fractures. In the 2010 JECFA meeting, it was proposed that considering cadmium's long half-life, indicating the tolerable intake monthly would be more appropriate than indicating it weekly. Thus, cadmium intake is now specified according to tolerable monthly intake levels (25 µg/kg bw/month) rather than weekly intake levels (JECFA, 2010b). Aluminum also exists in soil, water, animal and plant bodies, and so on, and poisoned individuals can suffer from conditions including hypercalcemia, anemia, and progressive encephalopathy. JECFA judged that aluminum compounds could affect the nervous and reproductive systems at levels lower than the level that had been reported earlier (7 mg/kg bw) and readjusted the PTWI of aluminum to 1 mg/kg bw (FAO/WHO JECFA). Although setting limits for hazardous substances is a basic step for control, assessing the dangers

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of hazardous substances and performing exposure assessments are also important. Hazard assessments are important tools that can be utilized in estimating hazards to human health and safety and establishing related countermeasures to reinforce food safety. The present study aims to prepare efficient and scientific methods to utilize policies and control measures through the comparison and analysis of domestic/foreign heavy metal control methods, present states of control, and hazard assessments in Korea and in other countries.

Hazard control related institutions by country. In the U.S., for food safety control, a multifold system operated by six departments (DHHS (Department of Health & Human Services), USDA (U.S. Department of Agriculture), DOC (Department of Commerce), DOJ (Department of Justice), EPA (Environmental Protection Agency), FTC (Federal Trade Commission)) has been established. Similarly, in the U.K., an independent governmental organization, the Food Standards Agency (FSA), was established in 2000 and all food safety administration related activities were unified to be conducted by the FSA. Governmental organizations for food safety in Japan comprise the Ministry of Health, Labor, and Welfare (MHLW) (containing the Department of Food Safety) and the Ministry of Agriculture, Forestry, and Fisheries (MAFF) (containing the Bureau of Consumption/ Safety). In Europe, China, and Australia, food safety is controlled adequately by each country, and international food control is conducted through the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the CODEX Alimentarius Commission.

Present states of control by country. JECFA currently recommends calculating the provisional tolerable weekly intake (PTWI) of individual heavy metals instead of the acceptable daily intake (ADI) to compare their pollution levels considering their toxicity accumulated in the human body. Several of the heavy metals' tolerable weekly intakes (TWIs) are as follows: cadmium 25 µg . kg bw/month (JECFA, 2010b), methyl mercury 1.6 µg.kg bw/week (JECFA, 2003), and total mercury 4 µg.kg bw/week (JECFA, 2010a). To protect consumers' health and establish fair food trade practices, CODEX established food related laws, and it follows its general procedure (eight steps) and emergency procedure (five steps) when establishing criteria for hazardous substances (CODEX Alimentarius Commission, CODEX). The FSA in the U.K. simultaneously conducts hazard assessment, hazard control, and hazard information exchange activities. It also conducts hazard control in five steps divided by section. In Japan, stepwise pluralistic food control is implemented and production stages are controlled by MAFF. The Ministry of Health, Labor, and Welfare (MHLW) controls the distribution/processing/ selling stages. The European Union, employs the Rapid Alert System for Food and Feed (RASFF) to quickly exchange information when any hazardous food is found and to establish a unified food safety control system (European Commission, 2009).

Present states of control by hazardous substance. Individual countries and institutions have established PTWI levels and carcinogenicity levels by heavy metal item.

Mercury-containing products in Korea include fluorescent lamps, mercury batteries, measuring instruments (temperature, pressure), and medical materials (Ministry of Environment, 2006), and mercury can be divided into metallic mercury and inorganic mercury. Inhaling metallic mercury steam quickly and in large amounts can cause breathing difficulties and, in severe cases, emotional instability, carpopedal shivers, or multicentric nervous system symptoms. As noted previously, organic mercury has been linked to central nervous system toxicity, immunotoxicity, reproductive toxicity, teratogenicity, and nephrotoxicity. Examples of organic mercury control standards by country are as follows: Korea: fish and shellfish 0.5 mg/kg, deep-sea fish 1.0 mg/kg (Lee *et al.*, 2005); Japan: 0.3 mg/kg (Matsuyama et al., 2011); the U.S.: 1.0 mg/kg (FDA, 2004); WHO/FAO: 1.0 mg/kg; CODEX: 0.5/1.0 mg/kg (deep-sea fish) (CODEX Alimentarius Commission, 1991). Exposure to organic mercury is controlled in accordance with the standards of each country.

Lead is mainly discharged from car exhaust gases and various industrial settings, and it exists in various environments (e.g., air, water, soil, dust, foods, crops). Humans are exposed to lead through daily living, and globally, the average daily intake for adults is estimated to be approximately 200 µg. In 1993, JECFA revised the PTWI of lead from 0.05 mg/kg bw to 0.025 mg/kg bw (Caldas and Machado, 2004). However, in the 2010 73rd JECFA meeting, it was confirmed that lead reduces children's IQ and increases adults' systolic blood pressure (by approximately 3 mmHg); thus, it was concluded that the PTWI standard was no longer appropriate. Accordingly, the relevant PTWI standard was withdrawn (JECFA, 2010b).

Cadmium is present in almost all foods; in particular, it is present in large quantities in grains, fish, shellfish, and seaweed. As a result of the 2010 JECFA meeting, the PTWI of cadmium was set to 25 μ g/kg bw (JECFA, 2010b). CODEX adopted maximum tolerable standards for grains at 0.2 mg/kg and vegetables (stems) at 0.2 mg/kg (0.1 mg/kg) (in five levels initially, now eight levels). Moreover, CODEX determined the maximum tolerable standards for rice at 0.4 mg/kg and fish, shellfish, and cephalopods at 0.1 mg/kg (in five levels) (Yamada, 2002). The Europe Food Safety Agency (EFSA) specified the TWI of cadmium as 2.5 μ g/kg bw (EFSA, 2009). Currently, cadmium is classified as belonging to carcinogenicity standard Group 1 (IARC, 2012).

Monitoring and hazard assessment in Korea.

The 1st~3rd national surveys of hazardous substances in biological samples: The Ministry of Environment and the Center for Disease Control & Prevention conducted studies to secure basic data for environmental health, to produce reference data for national in vivo heavy metals, and to determine environmental impact factors that affect health. Lead, cadmium, mercury, bisphenol A, phthalates, and others were analyzed to determine national blood concentrations. In the first investigation, 2,000 adult males and females were selected, while in the second and third investigations, 2,342 and 5,129 adult males and females were selected, respectively (Kim et al., 2005; Lee, 2007; Lee, 2008a). The results of the first investigation of heavy metal concentrations showed lead concentrations to be 3.06 µg/dl among males and 2.31 µg/dl among females, mercury concentrations to be $5.01 \,\mu\text{g}/l$ among males and $3.76 \,\mu\text{g}/l$ among females, and cadmium concentrations to be 1.55 μ g/lamong males and 1.48 µg/l among females. The blood heavy metal concentrations obtained in the second and third investigations were not significantly different but were lower than the values obtained in the first investigation (Kim et al., 2005; Lee, 2007; Lee, 2008a).

Investigation of mercury accumulation in vivo in fish and shellfish and mercury concentrations in freshwater environments in Korea: To protect citizens from exposure to mercury due to fish and shellfish intake, mercury concentration monitoring was conducted in major freshwater systems. From 2006 to 2008, mercury concentrations in common fish and shellfish species living in major freshwater systems in the basins of four major rivers throughout the country (e.g., streams, lakes, and reservoirs) were investigated (Ministry of Environment, 2006; Ministry of Environment 2007b; Lee, 2008b). The average mercury concentration was shown to be low at 6.5 ng/l, and among the types of water systems, reservoirs showed higher concentrations than lakes or streams. Among waters, lower regions showed higher concentrations than mid regions or upper regions. Mercury concentrations in 57 species of fish and shellfish were analyzed, and the total mercury concentrations were found to be $3.9\sim163.2~\mu g/kg$. The results of mercury monitoring for three years and cases from foreign countries were compiled to produce fish and shellfish monitoring guidelines, and a long-term roadmap for national hazardous substance ecology exposure assessment systems was presented (Ministry of Environment, 2006; Ministry of Environment, 2007b; Lee, 2008b).

A study on exposure and health effects of mercury: This study, conducted from 2005 to 2007, aimed to determine the general public's exposure to mercury contamination in the environment, the cause of the exposure, and the effect of the exposure on the general public's health (Kim et al., 2005; Kim et al., 2007). Questionnaire surveys and investigations into exposure levels and health impacts were

conducted with roughly 900 elementary school students throughout Korea. Exposure concentrations were calculated based on environmental media and food intakes, and the result was shown to be around 18.8 μ g. The elementary school students' average levels of exposure were around 2.13 ± 1.36 ppb in blood and 3.12 ± 2.71 μ g/g creatinine in urine. The blood mercury exposure concentrations of children residing in coastal regions were shown to be higher by at least two fold than children residing in inland areas (Kim *et al.*, 2005; Kim *et al.*, 2007).

A long-term development course on the scientific movement of toxic substance safety & management: A study of integrated exposure assessment bases was conducted to produce the information necessary to develop policies for the control of hazardous substances in foods and to provide advanced core information for control. Heavy metals such as mercury, methyl mercury, lead, and cadmium were analyzed in the first year in subjects consisting of 1,000 selected children under six and an adult population comprising 2,000 selected persons (Korea Food and Drug Administration, 2010).

Investigation of heavy metal concentrations in fish and shellfish in the Taean region in Korea: To investigate mercury concentrations in fish, shellfish, and freshwater environments as well as to prepare fish and shellfish monitoring guidelines in order to establish an ecology exposure assessment system, the Ministry of Environment analyzed a total of 228 samples of 33 species of fish and shellfish in the Taean region from November 2007 through August 2008 (Lee, 2009). The average total mercury concentrations in the Taean accident area were 29.98 ± 36.09 μ g/kg in fish and 13.28 \pm 8.60 μ g/kg in shellfish. The average, which were similar to mercury concentrations in coastal fish and shellfish. Changes in the in vivo metal element concentrations of oysters, a major inhabiting species in Taean, were analyzed, and the results revealed that in vivo metal element concentrations did not exhibit large differences over time (Lee, 2009).

A study of human body exposure to arsenic in **Koreans:** This study assessed residents' levels of exposure to arsenic through daily life in rural, coastal, and urban areas (Park, 2004). It analyzed the dynamic states of trivalent and pentavalent inorganic arsenic, MMA, and DMA as well as arsenic exposure related factors and explored biological reaction indicators sensitive to arsenic in urine. For each of these geographical areas, questionnaire surveys were administered to 354 adults who had never been occupationally exposed to arsenic and had resided in the relevant areas for at least three years. In addition, their blood and urine were collected to assess the degrees of their exposure to arsenic. The blood and urine arsenic levels among all subjects were distributed between 0.27 μ g/l and 0.57 μ g/ g creatinine, respectively, at the minimum and 26.57 μ g/land 21.26 µg/g creatinine, respectively, at the maximum. 146 J.A. Kim *et al.*

Less than $11.62 \,\mu\text{g/l}$ and $8,49 \,\mu\text{g/g}$ creatinine of blood and urine arsenic, respectively, were detected from those corresponding to the 95^{th} percentile of the survey subjects.

Monitoring of heavy metals in coastal fishery products in Gangwon region: For two years, from 2008 to 2009, the amounts of catch and fish species in coastal fishery products in the Gangwon region were investigated to monitor the contents of lead, cadmium, and mercury fishery products (Kim, 2010). A total of 630 specimens comprising 482 fish, 77 mollusks, and 71 shellfish were collected from six regional areas along the coast of the Gangwon region, and the heavy metal contents were monitored by season, region, and the ecological characteristics of habitats. For the investigation, the levels of lead, cadmium, and mercury detected in each individual were lower than the residual quantities permitted in Korea. The heavy metal contents generally did not show significant differences among the six regional areas along the coast of the Gangwon region, but significant differences were seen in fish. With regard to the contents of heavy metals in relation to the ecological characteristics of habitats, species living in lower layers showed higher contents of mercury and lead than species living in the middle layer.

Assessment of the hazard of inorganic arsenic in foods: The hazards of total arsenic and inorganic arsenic were assessed in 20 major foods exposed to arsenic, such as seaweed, fish, and shellfish, and 18 kinds of high consumption foods, such as grains, vegetables, and fruits (Lee and Chon, 2005). Samples were bought from large marts in 10 major cities throughout the country, and six arsenic compounds were separated and analyzed. Based on the results of the analyses, seaweed, such as laver, sea mustard, and kelp, contained traces of organic arsenic, such as AB, AC, and DMA, and some inorganic arsenic was also detected. The form of arsenic contained in most fish and shellfish was organic arsenic, such as AC, DMA and AsB, while in all of the samples inorganic arsenic comprising As (III) and As (V) was either detected in very small quantities or not detected at all. The results of analyses of arsenic contents in major foods exposed to large amounts of arsenic and in high consumption foods provide basic data for setting allowable standards for intakes.

Monitoring and hazard assessments in foreign countries.

NHEXAS (National Human Exposure Assessment Survey), U.S. (EPA): The NHEXAS was conducted from 1995 to 2006 to assess the occurrence of exposure to hazardous substances, the distribution of hazardous substances, and the effects of the hazardous substances. The region V field study was conducted on 250 persons residing in 32 counties in six state regions, while the Arizona field study was conducted on 249 persons permanently residing in Arizona and Arizona boundary regions. The

Maryland field study assessed 157 individual food items on 80 local residents in Maryland. The paths and levels of exposure to hazardous substances in environments were investigated. The results showed that arsenic, lead, and cadmium concentrations in liquid foods were much lower than those in solid foods. The distributions of the average daily intake of heavy metals showed that the average daily intake of chrome was the highest, followed by arsenic, cadmium, and lead in order of precedence in the case of solid foods. They also showed that the average daily intake of chrome was the highest followed by lead, arsenic, and cadmium in order of precedence in the case of liquid foods (EPA, 2006).

NHANES (National Human and Nutrition Examination Survey), U.S. (CDC): In this study that assessed the health and nutritive conditions of adults and children in the U.S., substances such as heavy metals, phthalates, and polycyclic aromatic hydrocarbons (PAH) were analyzed. In the first examination (conducted in 2001), biological blood and urine samples were analyzed for a total of 27 items, and in the second examination (in 2003), 116 items were analyzed in approximately 2,200 subjects. In the third examination (in 2005), 148 items were assessed in approximately 2,500 subjects, and in the fourth examination (in 2009), 2,400 subjects participated in the analysis of 212 items (CDC, 2009; Calafat, 2012). In the results of the exposure assessments, the geometric mean of total urine arsenic was shown to be 8.30 μ g/l, that of lead was 0.64 μ g/l, that of cadmium was $0.21 \,\mu g/l$, and that of mercury was $0.45 \,\mu g/l$. This report provided exposure assessment information to public health related persons and researchers and was very helpful in determining the levels of environmental compounds (CDC, 2009).

GerES (Germany Environmental Survey), Germany: The GerES is a monitoring program in Germany intended to observe differences in exposure to environmental pollutants between groups and to provide related information. To date, it has been conducted four times: GerES I (1985/ 1986), GerES II (1990/1992), GerES III (1998), and GerES IV (2006). In this program, samples were analyzed through diverse methods of investigation (e.g., human body monitoring, diet monitoring, interviews, and environmental monitoring), and a food monitoring system was implemented in 1995. Lead concentrations decreased from 1990 to 1992, while copper concentrations increased. The GerES in Germany establishes databases of hazardous substances through investigations into human body exposure and prepares health guidelines to contribute to the protection of national health (Schulz et al., 2007).

ChildrenGenoNetwork (CGN program), Denmark: The CGN program employed human body monitoring work focusing on children's susceptibility to environmental pollution and genetic damage. Based on 24 families, 12 mothers having two children each became the subjects, and the

exposure levels of mothers and children in lead-contaminated areas and those in non-contaminated areas were compared. The levels of exposure of mothers and children in areas severely exposed to lead were higher (by as much as five times) than those of the control group.

Food assessment and monitoring, Japan (FSC): The Japan Food Safety Commission (FSC) conducted food assessments and monitoring to ensure the safety of the methyl mercury contained in fish and shellfish. The monitoring results showed the exposure was 1.1 μg/kg/week in 2003, and the average for 10 years (1994~2003) was 1.2 μg/kg/week. It was reported that, of the exposure, 84.2% originated from fish and shellfish, and 15.8% originated from other foods. It was assumed that methyl mercury was the source of exposure in seafood, and 75~100% of the total mercury in fish and shellfish was methyl mercury.

Lead and mercury exposure monitoring program, Austria (AGES): The Austrian Agency for Health and Food Safety (AGES) is an organization operated in accordance with Austrian food laws and policy guidelines; it conducts studies in diverse areas including food inspection, bacteriology, serology, and agriculture. AGES assessed and compared the exposure concentrations of lead and mercury among heavy metals and examined their effects on newborns. Samples were collected from mothers in a general hospital in Vienna in 2005 to analyze their placentas, cord blood, hair, and blood. The average lead concentration in the blood was 25 μ g/l, and that in the placentas was 13 μ g/l. The average mercury concentration in the blood was $0.7 \,\mu\text{g/l}$, and that in the placentas was $1.1 \,\mu\text{g/l}$. Therefore, it could be seen that lightweight fetuses were also exposed to heavy metals (Pb, Hg).

Large-scale human body monitoring program, France: In France, two institutions—the National Institute of Research and the Institute of Health and Medicine Research—conducted monitoring studies. Specifically nationwide monitoring studies of lead exposure and local monitoring studies of methyl mercury were conducted. In two local monitoring programs, studies were conducted on methyl mercury and endocrine disruptors for 10 years centering on Guyana, Institut de Veille Sanitare (InVS), and CIRE.

Heavy metal hazard control cases.

U.K. FSA produced leaflets for farmers: The FSA produced leaflets for farmers in order to protect livestock, businesses, and foods in the U.K. from lead poisoning. More than half of the agricultural events and accidents reported to the FSA every year are due to lead exposure or poisoning, and lead poisoning also induces nervous diseases and sterility in livestock. Therefore, farmers can prevent lead poisoning by checking if car batteries, old machines, peeling lead paint, and so on exist on their farms (FSA, 2009).

EFSA relaxed the standard for intake of cadmium contents in foods: The EFSA announced that its food contaminant panel reduced the TWI of cadmium to $2.5~\mu g \cdot kg$ bw/week based on new analysis results. The European Commission requested that the EFSA assess human body health risks due to the existence of cadmium in foods in order to help hazard controllers in reviewing the maximum tolerable levels in foods. In addition, the EFSA conducted various studies, including one examining the relationship between urine cadmium levels and proteins discharged through urine, to obtain the new TWI (EFSA, 2009).

U.S. FDA enforced lead guidelines: The U.S. FDA enforces maximum value regulations and policies for lead in candies consumed by children. To satisfy consumers' right to know, the U.S. FDA provides sufficient information to consumers and takes actions to promote the manufacturing of good products and to protect the public's health. Although the current tolerable concentration of lead in candies is 0.5 ppm, the U.S. FDA's lead guidelines restrict the tolerable concentration of lead to a lower level of 0.1 ppm. The FDA considers regulatory measures in cases in which lead concentrations exceed 0.5 ppm through continuous monitoring (FDA, 2006).

Health Canada revised mercury intake restriction and mercury concentration assessments: Health Canada restricted the intake of canned tuna containing mercury for certain groups. Although tolerable mercury concentrations in foods and standard concentrations were specified, several fish products exceeded the standard values. Accordingly, intake was restricted for certain groups (women who may become pregnant, mothers, and children). In addition, Health Canada revised mercury assessments reflecting the standard under Canada's Food Guide (Health Canada, 2007).

The U.K. food safety strategy: The City of London developed a system to comprehensively approach food issues in order to ensure a healthy and sustainable food supply for citizens and organized the London Food Commission with 20 food experts. The commission organized and operated the Food Implementation Steering Group and served roles necessary to implement the project, such as consultation, information provision, project supervision, and stakeholder coordination (Reynolds, 2009).

DISCUSSION

In this paper, the present state of domestic/foreign control of heavy metals (e.g., mercury, methyl mercury, lead, cadmium) among hazardous substances and the results of related human body exposure assessments were compared and investigated. In Korea, the Ministry of Environment has conducted many studies (Kim *et al.*, 2005; Lee, 2007; Lee, 2008a) intended to determine *in vivo* concentrations of harmful chemicals in Korean people, and blood and urine

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heavy metal concentrations were determined and assessed. In addition, many studies (Korea Food and Drug Administration, 2010) have assessed the occurrence of exposure to hazardous substances and related impacts. Moreover, other studies (Lee, 2008b; Lee and Chon, 2005) have been conducted to monitor and analyze certain heavy metals.

In the case of countries other than Korea, the NHEXAS (EPA, 2006) provided information on exposure and prepared information to use in exposure study designs. The NHANES (CDC, 2009) also provided exposure assessment information to public health related persons and researchers. In addition, the GerES (Schulz et al., 2007) established databases of hazardous substances and prepared health guidelines based on representative exposure assessments. As such, in Korea and in foreign countries, the monitoring of heavy metals in foods and the assessment of human body exposure for hazard control as well as the preparation of related measures aimed at harm reduction are conducted in various ways. For the control of hazardous substances, many countries provide leaflets and guidelines, provide intake recommendations in relation to harmful heavy metals, and take necessary actions. In the U.K., leaflets aimed at preventing lead poisoning have been produced (FSA, 2009), while in Europe, the standard regarding cadmium intake in foods was recently relaxed (EFSA, 2009). The U.S. FDA has provided lead guidelines for foods consumed by children (FDA, 2006), while Health Canada has restricted mercury intake for susceptible groups (Health Canada, 2007). Along with these hazard control measures, in the U.K., the London Food Commission was recently organized to implement projects aimed at food safety development (Reynolds, 2009). Similarly, the Japan National Institute of Health Sciences (NIHS) decided to provide accurate food safety information to the public quickly through periodic updates.

This review of hazard control related institutions by country, the present states of control by heavy metals, and hazard control cases by heavy metals from various countries will be helpful in preparing measures for practical policy utilization and the control of heavy metals.

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