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Review Article

Regulation in India of Heavy Metals in Food Items: A Critical Analysis

Madhubanti Sadhya[1] and Monalisa Saha[2]*

[1]Assistant Professor of Law at NLSIU, India

[2]Assistant Professor of Law at The University of Burdwan, India

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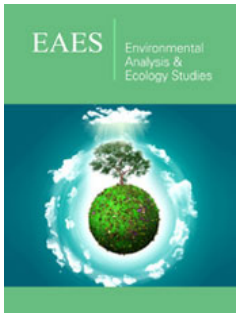

***Corresponding author:** Monalisa Saha, Assistant Professor of Law at The University of Burdwan, India

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Abstract

There are various types of heavy metals naturally occurring in the atmosphere. Ingestion of such metals even in small concentrations can lead to a variety of health ailments that are problematic to treat and are often irreversible. It is difficult for the human body to escape the slow onslaught of these heavy metals since nearly all types of consumer products sold and bought in the market contain traces of a wide range of heavy metals that somehow always find their way into the products. All of this has increased the burden of diseases of the state, reduced the general efficiency of the workforce and is the latent cause of many unexplained deaths. This paper is particularly concerned with the range of heavy metals that humans ingest through direct consumption of food items. There have been few regulations introduced under the Food and Safety Act, 2006 in India, but the authors have located many studies that reveal the continued presence of heavy metals in both food items and food packaging materials which suggests that the present system is not working as well as is necessary. The article is divided into five sections (I, II, III, IV & V). Section I introduces the concept of heavy metals and how they are omnipresent in the environment and in various things that humans come in contact with. Section II elaborates upon the dark side of heavy metals and explains the various irreversible health conditions resulting from heavy metal ingestion. Section III culls out the relevant provisions from the legal instruments that concern regulation of heavy metals in India. Section IV clarifies how inspite of various laws, the presence of various heavy metals in large quantities is a reality in several food items even today. Finally, Section V concludes and suggests a way out.

Heavy Metals and their Omnipresence

Heavy metals are naturally occurring on the earth's crust [1] which have eventually found their way into soil, air and water bodies due to erosion over the years. Heavy metals are usually defined on the basis of atomic number, atomic mass or density. When the atomic number of any metal is above 20, or the atomic mass is above 23 or the density is above 5g cm` it is characterized as heavy metals. Out of the 118 elements that have been identified as earth's essential building blocks by scientists, there are around 99 elements that could be called heavy metals according to the above criteria. Some examples of heavy metals according to this parameter are gold, silver, platinum, copper, selenium, zinc, cobalt, iron, tin, lead, tungsten, gold, iridium, rhodium, and platinum. But beyond a certain concentration all elements, be it heavy or light may be toxic. But when an element is not harmful in smaller concentrations, we do not consider it toxic. What is interesting is that not even all heavy metals are toxic in nature at small concentrations. In fact, some of them are considered essential for various bodily functions, like selenium which works like an antioxidant and some heavy metals like gold, which are non-corrosive and non-reactive in nature are called "noble metals". Noble metals like gold, silver, platinum are not considered toxic heavy metals even though they fulfil the criteria of atomic number, atomic mass and density as mentioned above.

There are many other heavy metals with positive effects on the human body. Like, copper aids in the transports of electrons and oxygen, cobalt aids in cellular metabolism [1] etc. But on the other hand, certain heavy metals that represent the "dark side of chemistry" are those that

have been found to have toxic effects even in low concentrations. For example, mercury, cadmium, arsenic, chromium, thallium, lead [1] etc. Cobalt, nickel, chromium, are known to be carcinogenic; thallenium has the potential to cause neurological disorder and even lead to the damage of the central nervous system [1]; arsenic is known to be mutagenic and is linked to diabetics, nickel is allergenic; silver, copper, zinc and selenium are known to have the capacity to cause disruption in the functioning of the endocrine [1]. These dark heavy metals are freely [2] moving around in the air, water and soil in the ecosystem and are also released due to various anthropogenic activities, ranging from (agro)industrials, medical, technological and transport [2]. Therefore, it is a reality for several consumer products to contain various types of such heavy metals in various concentrations. Consumer products are final goods that are purchased by the end user for final consumption. There are many types of products ranging from food, paints, clothing, personal care products (like cosmetics etc.), toys, electronic equipment, jewellery, packaging materials, pharmaceuticals products [3], furniture, McDonald's drinking glasses [4], bottled juices [2], medicinal/ health supplements/remedies, religious powders (kajal/Surma) [5] that usually contain a combination of cadmium, lead, mercury and arsenic [5]. This paper is particularly concerned with food items and food packaging materials that contain heavy metals. The authors intend to understand the nature and concentrations of heavy metals in various food items and food packaging materials sold in India and assess the regulatory framework that governs the same.

Heavy Metals and its Effect on Health

Irrespective of the source of heavy metals, once heavy metals find their way into the body they can cause tremendous adverse effects on human health, and especially that of children. It is not well known amongst the populace that a range of neurological and cognitive developmental disorders, auto immune diseases, Attention Deficit Hyperactivity Disorder (ADHD), delayed speech, Parkinson's, autism, depression, diabetics, delinquent behaviour, dyslexia and depressed immune system have been linked to heavy metal toxicity [6]. It is very important that we focus on understanding the source, impact and treatment for heavy metals because it seems to have an impact on human health far greater than the other known culprits. For instance, high cholesterol is a known cause of heart attack, but the fact that the chances of heart attack, stroke and death increases significantly if one's blood lead levels rises beyond 2 units is less known amongst the common people [6]. It is also not a factor that is generally considered by doctors who may not be practitioners of functional medicine. Checking for heavy metal toxicity is just not a regular method of diagnosis or clinical findings. It is usually the last cause that is tested for. When a person exhibits unexplained behavioral traits or develops an inexplainable condition, the doctors focus on first treating the symptoms and only when they realize that no amount of the known forms of treatment lines are working do, they go in for checking metal toxicity. Even when one is able to identify a situation of metal toxicity, it is extremely difficult to identify the source. Humans could be ingesting such heavy metals, from anywhere: right from the food they consume, to the paint factory they may live next to, to the furniture they use to the clothing they wear.

Even if one were to factor in a check for heavy metal, the next challenge before the doctors is to decide on the nature of test that they should select for their patient to undergo. This is because there are a range of heavy metals whose presence in the body cannot be identified by a standalone method. For instance, if a person has been on a fish diet and the doctors suspect heavy metal toxicity, they would probably first check for mercury load in the body. A blood test could be useful in this regard. However, since the human body replaces blood every three months, it may not be possible to ascertain the presence of any old or long exposure to heavy metals through a simple blood test if the patient has not been on a fish diet in the previous 90 days. Then, other testing mechanisms may have to be explored. An antibody test, or the method of chelation could help identify the presence of toxic metals. An antibody test in the body may reveal the presence of various types of heavy metals that the human body's natural detox system may be trying to fight on its own. Chelation is a known method to remove and identify lead toxicity. A chelator or a binding agent is used to bind heavy metals that is tested for in the urine sample of a patient [7]. Then there are heavy metals like lead that is known to deposit itself on the bones [6] and other heavy metals which if a person is exposed to for a long time could be deposited in various other internal organs of the body that cannot be identified through a simple blood test. Once identification of such heavy metals is done, the next step is to treat the condition resulting from such metal toxicity. For instance, arsenic is known to cause diabetes- so we need to treat diabetes as a disease. But these efforts would not make much sense if we do not remove the heavy metal toxicity in the body and work alongside this to remove the source of such metal toxicity. As has been explained before there are many sources of heavy metals. This paper is concerned with identifying the heavy metals and their concentration in food and food packaging items in India and to assess the regulatory regime surrounding it.

Law and Heavy Metals in Food Items/Food Packaging Materials

The relevant legal instruments for the purpose of this discussion are: The Food Safety Standard Act 2006, The Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 (as amended in 2020), and the Food Safety and Standard (Packaging) Regulations, 2018.

Food items

The law that is of particular relevance is Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011. This has been amended on 7th August 2020 and it has come into force on 1st of July 2021 [8]. This regulation lists out various metal contaminants, toxic compounds that are naturally occurring and other crop contaminants that are considered harmful for human health and seeks to limit them. There are eleven heavy metals upon which extra emphasis have been placed are: lead, copper, arsenic, tin, cadmium, chromium, nickel, selenium, antimony, methyl mercury and mercury. The Regulation also seeks to limit certain

types of toxic compounds called mycotoxins, that tend to grow on a variety of food items like cereals, spices, nuts, dried fruits when these food items are left in warm, damp and humid conditions. Not all mycotoxins can be eliminated during food processing and therefore need to undergo specific treatment to be removed. The Regulation identifies a range of mycotoxins that pose risk to the health of humans and livestock: aflatoxins, ochratoxin A, patulin, fumonisins, zearalenone and nivalenol/deoxynivalenol [8]. However, since the study of mycotoxins and their regulation is out of the scope of this paper, the authors will not delve any deeper into the same.

Specifically, Table 1 of the 2011 Regulations identifies the heavy metals and lays out different concentration limits of the same in various food articles that have been identified in the second column. It is the duty of both the domestic and the international food manufacturer who seeks to sell their items in India to ensure that the metal concentrations do not exceed the legal limit that has been set. In Table 2 the various limits for crops contaminants and naturally occurring toxic substances are laid out. According to the Table 1, lead concentration in baking powder should not exceed 10ppm, or in canned mushrooms should not be more than 1.0ppm or in canned fish should not be more than 5.0ppm or in concentrated soft drinks should not be more than 0.5ppm; or in edible oil and fats should not be more than 0.5ppm, or in fish should not be more than 0.3ppm, or in ready to drink fruit juices should not be more than 0.05ppm. An interesting thing is that it has also a limit mentioned for 'food items not specified' in the table. The limit set for lead concentration in such unidentified items should not exceed 2.5ppm.

Table 1: The Maximum content of identified heavy metals that is permitted in specified food items (Only the portion relevant to this article has been reproduced from the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011).

Name of Metal Contaminant	Article of Food	Parts per Million (mg/kg or mg/L)
(1)	(2)	(3)
1. Lead	Agar	5
2. Copper	Ammonium hydrogen carbonate	5
3. Arsenic	Agar	3
4.Tin	Canned (citrus fruits, stone fruits, vegetables, fruit cocktail, mangoes, pineapple, raspberries, strawberries, tropical fruit salad).	250
5. Cadmium	*Bivalve Molluscs*	2
6. Mercury	Alumina used in preparation of lake colour	1
7. Methyl Mercury (Calculated as the element)	All foods	0.25
8. Chromium	All fishery products	12
9. Nickel	All hydrogenated, partially hydrogenated, interesterified vegetable oils and fats such as vanaspati, table margarine, bakery and industrial margarine, bakery shortening, fat spread and partially hydrogenated margarine, bakery shortening, fat spread and partially hydrogenated soyabean oil	1.5
10. Selenium	Mineral water , expressed in mg/L	0.05
11. Antimony	Mineral water , expressed in mg/L	0.005

Table 2: The Maximum content of identified crop contaminant that is permitted in specified food items (Only the portion relevant to this article has been reproduced from the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011).

S. No.	Name of the Contaminants	Article of the food	Limit µg/kg
(1)	(2)	(3)	(4)
1	Total Aflatoxins	Cereal and cereal products	15
2	Aflatoxin B1	*Arecanut* or Betelnut	10
3	Aflatoxin M1	Milk (Liquid)	0.5
4	Ochratoxin A	Wheat, rye, barley	20
5	Patulin	Apple juice	50
6	Deoxynivalenol	Wheat	1000‖.

The next heavy metal of concern is copper. The limit of copper in coffee beans should not be more than 30ppm, in cocoa powder should not be more than 70ppm, in hard boiled sugary confectionary should not be more than 5.0ppm, in tea should not be more than 150ppm, in soft drinks should not be more than 7.0ppm, in tomato ketchup should not be more than 50ppm, and in 'unspecified food items' should not be more than 30ppm. The limit for arsenic in fish and crustaceans should not be more than 76ppm, in hard boiled sugar confectionary should not be more than 1.0ppm, in milk should not be more than 0.1ppm, in vegetable oil should not

be more than 0.1ppm. The limit for Cadmium in fish should not be more than 0.3ppm, for unspecified food articles should not be more than 1.5ppm, for leafy vegetables should not be more than 0.2ppm, for potato should not be more than 0.1ppm, and for wheat should not be more than 0.2ppm. The limit for mercury in fish should not be more than 0.5ppm, in salt should not be more than 0.1ppm, in vegetables should not be more than 1.0ppm, in packaged drinking water should not be more than 0.001ppm, in non-predatory fish, crustaceans, cephalopods, and in molluscs should not be more than 0.5ppm. The limit for Chromium in all fishery products should not be more than 12ppm, mineral water should not be more than 0.05ppm, refined sugar should not be more than 0.02ppm. There are also limits for other heavy metals like tin [9], methyl mercury[1], nickel[2], selenium[3], antimony[4].

Food packaging materials

The concern regarding food packaging materials is that the constituents or the contaminants of the packaging materials could find their way into the food items and thereby into the human body. The Food Safety and Standard (Packaging) Regulations, 2018 came into force on 1st July 2019. It lays out various standards for food packaging to ensure that contaminants of any nature do not make their way into food items. The focus of this paper is limited to understanding the prohibitions that are in place for heavy metals in food packaging material. Reg 3(8) of the 2018 Regulations, categorically bans the use of recycled plastic as a packaging material since it is generally considered to be poorer quality of plastic. Ink[5] that is used on packaging labels has also been of concern. So, the new regulations specifically require adhering to the Indian Standards while printing labels. It also bans the uses of newspaper[6] in the wrapping of food items because the ink could melt and deposit itself onto the food item [10]. Reg 2(g) which talks about "primary packaging material" distinguishes it from the "secondary packaging materials spoken about in Reg 2(h). The former defines the material that comes into direct contact with the food and the latter comprises materials that "encloses the primary food packaging". It also defines something called a migration limit under Reg 2(i) which basically sets the limit on the amount of substance that is permissible to be transferred from the packaging material onto the food item.

Reg 3(7) prohibits Tin containers from being reused. Reg 4(3)(a)(iii) states that if copper or brass utensils and containers are not lined properly with tin and are still used to prepare food items, it would be in violation of the Regulations. Reg 4(4)(c) lists out a range of metals that may be found in plastic packaging and that which has the potential of being transferred onto the food item. Table 3 specifically lists out seven heavy metals and their respective permissible migration limit (in mg/kg) onto food items. For instance, the maximum permissible migration limit for copper in plastic packaging materials is 5.0mg/kg while for iron it is 48.0mg/kg and for zinc it is 25.0mg/kg. Schedule I, II and III lists out the Indian Standard respectively for various paper/board packaging materials; metals and metal alloyed packaging materials and plastic packaging materials that may come in contact with food products. And Schedule IV lists out the suggestive packaging materials depending on the food article in question. For instance, it appears that tin is a popular choice of container since it is listed as a valid type of packaging material for milk products; fat, oils and fat emulsions, fruit & vegetable products; cereals and cereal products etc.

Table 3: Food Safety and Standard (Packaging)Regulations, 2018.

SI. No.	Substances	Maximum Migration Limit (mg/Kg)
1	Barium	1
2	Cobalt	0.05
3	Copper	5
4	Iron	48
5	Lithium	0.6
6	Manganese	0.6
7	Zinc	25

Heavy Metals in Food Items and Food Packaging Products

Packed food items have become unpopular food choices due to the high content of preservatives, sugar, sodium for those who are health conscious. But now there is another cause of worry and that is the presence of heavy metals in these items that somehow find their way into the food items from the environment (air, water, soil) or are produced during the manufacturing process or through the packaging materials. Several scientific studies undertaken in India have found the presence of heavy metals in regular food items that commonly form a part of the dietary intake of Indian households. A study conducted in Kolkata in 2014 across 20 local markets to assess the level of heavy metal concentration in samples of eight common food items such as rice, red lentil, spice (cumin), locally made snack (biscuit), leafy vegetable (red spinach), fish, chicken and medicinal herb (tulsi) found that the red spinach recorded the high mean concentration of lead (32.11mg/kg-1 or 32.11ppm). The mean concentration of arsenic was found to be highest in fish (2.52mg/kg-1 or 2.52ppm), followed red spinach (0.47mg/kg-1 or 0.47ppm) [11]. Another study conducted in Varanasi between September 2004 and March 2005 examined the presence of heavy

[1]Ibid, Item no. 7

[2]Ibid, Item no. 9

[3]Ibid, Item no. 10

[4]Ibid, Item no. 11

[5]Ibid, Regulation 3(9)

[6]Ibid, Regulation 3(11)

metal concentrations (zinc, cadmium, copper and lead) in three Indian vegetables (spinach, cauliflower and lady's finger) collected simultaneously from the site of production and the market. The findings of the study reflected that heavy metal concentrations in vegetables were lesser at the site of production and generally exceeded the permissible limits at the market sites, although the presence of cadmium was found to be higher than permissible standards even at the sites of productions.

Another interesting finding of this study was that the concentration of heavy metals in vegetables was impacted by a number of factors in addition to the site of sample collection. Some of the determinants of heavy metal concentration included the physical and chemical nature of the soil at the site of production, absorption capacities of the vegetables, atmospheric deposition of heavy metals, generally influenced by a number of environmental factors, nature of the vegetable and the surface are exposed to the atmosphere, other anthropogenic activities such as use of metal-based pesticides and the location of the market and production sites. Similar studies undertaken to determine the presence of heavy metals in canned meat found the presence of heavy metals above permissible limits. Forty-eight samples of frozen and canned pork meat procured from retail outlets in Chennai tested to examine the presence of cadmium, chromium, copper, lead and zinc. 95.83% of the samples had cadmium more than the maximum permissible limit[7]. Lead was found to be in excess of the maximum limit[8] specified in 25% of the samples and zinc was in excess of the permissible limits[9] in 20.83% of the samples. The presence of chromium was also found to be more than the permissible limits [12]. Although the results of this study were tested against the standards laid down by the US Food and Drug Administration and the Meat Food Products Order, 1973 issued under the erstwhile Department of Agriculture, Ministry of Agriculture, Government of India, they would be in violation of the permissible limits even under the extant Regulations in India.

Another recent study that involved the assessment of heavy and toxic metal concentrations of lead, cadmium, arsenic and mercury in broiler chicken conducted in four major cities of Tamil Nadu, revealed that lead concentrations in breast (MRL 0.1mg/kg) and liver (MRL 0.5mg/kg) samples exceeded the maximum residue level in all cities [13]. Similarly, arsenic was found to be in excess of excess of MRL of 0.1mg/kg in the chicken breast samples in all cities. The findings of these studies substantiate the concerns raised with respect to presence of heavy metals in food items and the threat to human health delineated in this article. If the presence of toxic metals in food items is not disconcerting enough, studies undertaken to examine the concentration of heavy metals in food packaging materials in India further exacerbate the cause of concern. In a study published in 2019, 10 commercially available and commonly used food packaging paper and paperboards were examined to check the presence of 14 heavy metals, including arsenic, lead, nickel, tellurium, titanium, chromium, barium, vanadium. The samples included paper plate, cake box, fruit tray, tissue paper, coffee cup, pastry box, sweet box, pizza box, French fries box, and paper bags frequently used and readily available in the local markets. The highest concentration of aluminium, arsenic, copper, iron, nickel and vanadium was found in Pizza boxes.

The concentration of manganese, lead and tellurium were highest in paper plates. Fruit trays also had the presence of tellurium in high concentrations, whereas the highest concentration of barium and chromium were found in pastry boxes. These metals were also found to be the highest in French fries boxes and Coffee cups [14]. While plastic has generally been found to be harmful for human health, the results of this study indicate that packaging materials made out of paper used in several popular fast food items also pose significant threat to the health of ultimate consumer of these food products. This re-emphasizes the need for greater regulatory oversight of not only the food items but also the packaging material, especially in a post pandemic India, where people are greatly resorting to food delivery apps to make up for their experiences of dining out which has been curtailed.

Conclusion

It turns out that there have been some attempts made by the legislature in recognizing that ingestion of heavy metals from various food items and food packaging materials is a real possibility. There are enough scientific studies being carried out to understand the impact of such heavy metals on the environment and the health of humans. The acceptable standards of ingestion of these metals has been changing over time. Right from the fear that the Roman empire fell possibly from lead poisoning since lead pipes were used to carry water [15] we have come a long way. Lead has been gradually sought to be limited in paints, in fuel and now in various food items and packaging materials that it has found its way into. It is true that not all heavy metals impact the human body the same way and to the same extent, but the authors here have tried to show the general lack of awareness of the potential that a group of heavy metals have in altering our everyday life. Both perishable food items and packaged food items have been shown to have heavy metal trace in them. Though the laws that have been studied here are recent promulgations, there were older regulations that sought to remove various contaminants and toxins from out food items that have somehow not been implemented as effectively as is required. It is evident that Indians are ingesting toxic food items on a regular basis and our laws are not effective to prevent the same in spite of the tedious mandates that have been laid out. It is important to note a few things that came up in the various empirical studies that the authors studied: for instance, that, while a food item tested at the site of production may be well within the permissible limit, the results may greatly vary when tested at the market site of prior to consumption.

[7]0.1mg kg-1 as stipulated by Food and Agriculture Organization.

[8]2.5ppm as stipulated by the Meat Food Products Order.

[9]50ppm as stipulated by the Meat Food Products Order.

This makes it incumbent on the regulators to be cautious of the kind of food product being tested and the site at which heavy metal concentration is assessed. While, it may be fine to test a packaged food product at the time of packaging, the same standards may not be feasible for perishable food items. One of the conclusions drawn is that the presence and concentration of heavy metals in vegetables is greatly impacted by the mode of transportation, marketing systems, interval of time between production and consumption and other allied factors in production including site which could increase the concentration levels of heavy metals [16]. Therefore, the legal instrument should recognize these various steps and require testing for heavy metals at these various stages to ensure that the final products that consumers purchase and consume do not have items that have higher concentrations of heavy metals than what is considered safe. However, over regulation can often depress business and drive away investors from this sector. It is therefore desirable that supportive regulatory structures are in place where regulators work in collaboration with food and food packaging manufacturers to adhere to the standards that are considered necessary to reduce the burden of diseases resulting from heavy metal concentration, instead of just focusing on penalizing the offenders. Besides for a country that struggles to monitor the implementation of its laws and is struggling under the pressure of corrupt inspectors, it is perhaps more desirable to chalk out an incentive plan for those food manufacturers and food packaging manufacturers that are in compliance with the law.

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