A COMPARATIVE PERSPECTIVE ON THE STATUTORY REGULATION OFENDOCRINE DISRUPTORS BETWEEN SOUTH KOREA AND INDIA

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Abstract - The India Government should beregulated Endocrine DisruptorsSubstances (EDS) called environmental hormonessubstancesbecause Endocrine Disruptors Substances affect the reproductive systems of human beings and animals. This paperexamined to concentrate on three kinds of chemical material - bisphenol-A, nonylphenol, and phthalate - among the 70 blacklisteddesignatedas environmental hormones by WWF and Stockholm Convention through comparative law study on the regulation act of Endocrine Disruptors Substances in South Korea and India. This study shows the necessity of the regulatory schemeon after understanding the current actual status of regulation on (EDS)status through news articles reviewing of scientificresearch paper, the government data, and by using interdisciplinary approach method.Because India Government does not regulate on the endocrine disruptor substances, based on the findings of this study, India government should enhance the level of regulation to curb environmental hormone pollution through legal revisions.

Index Terms - BPA, Endocrine Disruptor, Environmental hormone, nonylphenol, and phthalate.

I. INTRODUCTION

This paper suggests that prepare the bill on the regulation that has the concrete and equivalent international standards through the environmental legislation on the Endocrine Disruptor Substances including, three substances, bisphenol, nonylphenol, and phthalate to India Government. Emerging evidence indicates that there is an association between exposure of Endocrine Disruptors Substances(EDCs) and certain health related problems like reproductive complications and diabetes.[]Moreover, exposure toEDCs may affect one sex over the other as sexually dimorphic fetal responses, which contribute to placental stress.[2] In regard to this disease susceptibility, animal studies have shown that nutrition and environmental exposure during development can alter the epigenome.[2]This study examines to concentrate on three substances, bisphenol-A, nonylphenol, and phthalate, which are endocrine disruptors that, in India, have been detected in toothpaste, soap, and, even children's toys.

On Bisphenol-A, recent studies have revealed that certain chemicals in plastics are leaching into our food and water supplies. Some such study, in Bhopal, India, exposed the presence of BPA (bisphenol-A), a structural component in polycarbonate beverage bottles, in children,[] in baby bottles, canned foods, such as soup, canned vegetables, and beans, plastics, food, beverages and certain thermal paper receipts.[]Another study that found the antioxidant activity of lycopene has a significant potential to curtail testicular damage from such BPA's exposure.[6] Secondly, Nonylphenol, which has been detected in detergents[7]and isusedasan emulsifier in a skin-whitening topicalnanogel, [8] is lethal at concentrations of 50 (LC_{50}) an amount estimated using a semi-static system in response to 4-nonylphenol.[9] Harms caused by nonylphenol exposure include reproductive harms as seen in a study conducted on a fish farm near Parappanangadi, Malappuram district, Kerala, India. In that study, analysis revealed that when fish were exposed to nonylphenol at one-fifth (178 µg/ L) and one-tenth (89 µg/ L) of LC_{50} concentrations for 24, 72 and 96 hours, imbalances occurred in the reproductive organs of the fish.[] Thirdly, Phthalates have been found in a variety of personal care items, like deodorant, toothpaste, soap and other cosmetic products,[]as well as plastics, rubber, wiring and ink toner.[]A study of raw tea, including loose tea, branded tea and herbal tea—all contained in plastic bags—revealed that the tea was contaminated with dibutyl phthalate (DBP) (0.038 mg kg−1).[] Di-(2-ethylhexyl) phthalate (DEHP) exposure has demonstrated an antiuterotrophic effect (causing harm to the uterus).[] When exposed to rats, DBP caused remarkable degeneration in neurological cells, particularly in the cortical and cerebellar neurons.[]

Abovementioned researches, however, as existing studies mainly are experimental researches, do not attain the stage of the legislation that completely prohibits the Endocrine disruptor substances. India government does not prohibit the nonylphenol, there is not the related article in the act or rule of chemical substances. Furthermore, nevertheless these

substances have a detrimental effect on humans, even children products, the Government of India do not forbid usage of bispehnol-A and phthalate substances but permit restrictive usage. Authors insist that the government forbid these substances for health of citizens in India. As implication, it is not only citizen's health in India but also is related to the export of companies in India.

Especially, the signification of this study is that there is not the comparative study on the environmental lawbetween India and South Korea until today, especially, on the regulation of endocrine disruptor substances or the environmentalhormone substance.

For analyzing the present circumstances ofacts and regulations related to chemical substances between South Korea and India, authors introduce the interdisciplinary approach methodas the most important research methodto examine necessity of regulation and the present circumstances ofacts and regulations related to chemical substances in India and South Korea. This method using with the literatures and research papers from interdisciplinary way will help to further embody regulation and to decideconcretely the legal boundaries. On interdisciplinary approach method, some scholar insist skeptical one,[]however, the study on the establishment of the educational policy for improvement of the achievement for the study of studentsin rural areas,[]and research on correlation of food quality and DNA[] improved the affirmative effect.

In this study, for a fact-finding survey, authors studied India and South Korea government's statistical data, reports on the regulation of the chemical substances in plastics products and toy of the children. Furthermore, authors reviewed International standards and South Korean Government's acts and rules and the prohibition chemical substances lists ofWWF(World Wild Fund) and POPs, the Stockholm Convention, United Nations through internet, and research papers and statistics from South Korea and India.

As the finding, India government do not regulate the prohibition of usage of nonylphenol, Bisphenol is prohibited but many companies is exceeding the allowance for the usage of it in India. Phthalates is used in toys that are made with plastic or vinyl, tea, food or milk containers in India.

The conclusion obtained by analyzing these data is logically that the India government has to legalize on regulation of the endocrine disruptor substances at least three kinds of chemical substances, bisphenol-A, nonylphenol, phthalates. The focus will be directed at selected instances following as: in chapter II, authors discuss the environmental endocrine disruptors and POPs substances, and residual status and the current circumstances of usage pesticides in India. In chapter III, we will look at the usage current circumstance of bisphenol-A, nonylphenol, phthalate in India, and review Health Effect of Endocrine Disruptor Substances in India. Authors analyzed in chapter IV, regulation status of India, and in chapter V, the regulation in South Korea. Chapter VI shows prohibition standards of children product in South Korea.Chapter VII shows the Indian government should establish more detailed laws and standards to better control like selling prohibition of environmental hormone pollutants and, imposition of penalties.

II. THE STATUS OF REGULATION ON ENDOCRINE DISRUPTORS SUBSTANCES IN INDIA

A. Bisphenol-A

India Government prohibit the use on the bisphenol-A in the Manufacture, Storage and Import of Hazardous Chemical (Amendment) Rules, 2000 (Ministry of Environment and Forests, 2000b).[] However, theGovernment of India does not prohibit the Nonyl Phenol and Phthalates. For the first-time writers will present on BPA.

BPA has been detected in plastic products and PET bottles as phthalate Bisphenol-A is used in the manufacturing of polycarbonate plastics. BPA is reported to be a possible endocrine disruptor causing harmful effects in reproductive system. It is not used in manufacturing PET resins (Gupta and Bhan, 2016, p.15).[]BPA is used for polycarbonate ester plastic goods. Recently, several institutes in India issued a report stating that BPA should be banned (Gupta and Bhan, 2016, p.18).[]Recently, the press in India reported on danger of BPA in PET bottles (Market Research Future, 2017) and already warned that chemicals in plastic baby bottles can weaken kid's teeth (IANS, 2016b).[]

B. Nonylphenol

In India, nonylphenol, referred to as alkali phenol, is traded in the market without regulation (RNR Market Research, 2017).[] One survey detected nonylphenol levels of 898.7 mg/kg to 3 mg/kg in eight kinds of cotton underwear produced for men in India and less than 3 mg/kg in one type of underwear for women (Environment Agency, 2013).[] Furthermore, restriction clause on nonylphenol is written even in the Hazardous Chemicals Handbook (Carson and Mumford, 2012, p.241).[]Furthermore, World Wildlife Fund designated nonylphenol, as Endocrine Disruptor (Environmental Hormone Chemicals).In the case of China, which is in a political and economic rivalry with India, it introduced a bill to regulate nonylphenol in 2011. But India has not yet banned nonylphenol.[]However, India Government remains to be used nonylphenol.

C. Phthalates

Although the Government of India require the concentration of phthalate on vinyl in toys as much as $\leq$ 0.1% (Government of India 2011),the regulatory standards and requirements on phthalates should be

upgraded to minimize.However,generally, lead, antimony, Di-(2-ethylhexyl) phthalate (known as DEHP) and chromium are detected in polyethylene terephthalate (PET) bottles, children's toys and plastic medicine bottles (Gupta and Bhan, 2016, p.18).[] 'Medicines including phthalate are dibutyl phthalate (DBP), diethyl phthalate (DEP), diethylhexyl phthalate (DEHP), polyvinyl acetate phthalate (PVAP), cellulose acetate phthalate (CAP) and hydroxypropyl methylcellulose phthalate (HPMCP)' (Gupta and Bhan, 2016, p.14).[]Furthermore, these substances have even been found in certain fragrances, shampoo, hairspray, shaving creams and other cosmetics (Mohapatra, 2016, p.16).[]

III. THE STATUS OF REGULATION ON ENDOCRINE DISRUPTORS SUBSTANCES IN SOUTH KOREA

A. Food and Container

The standards and Specifications concerning Apparatus, Containers and Packages are based on the Clause 1 Article 9, Food Sanitation Act (2016).[]The contents of act is as follows: The Minister of Food and Drug Safety shall determine and publicly announce the following matters concerning apparatus, containers and packages sold or used for business, when necessary for public health, 1. Standards for the manufacturing methods, 2. Specifications for apparatus, containers, package and raw materials thereof. Apparatus, containers and packages, the standards and specifications for which are determined under paragraphs (1) [writers…], shall be manufactured, in accordance with such standards, and no one shall sell apparatus, containers and packages that fail to meet such standards and specifications, or manufacture, import, store, transport, display such apparatus, containers and packages for sale or use them for business.

B. Common Produce Standards and Specification (Korean FDA, 2015a)[]

(1)Sa. When manufactured, apparatuses, containers and packages should not be printed on the surface that foods will directly contact. The printing inkapplied to the non-food-contact side should besufficiently dried before packaging. In this case, the quantity of detected benzophenone in the ink compound must be less than 0.6 mg/L.

(2)Ka. When manufactured, apparatuses, containers and packages should not use di-(2-ethyl-hexyl)-phthalate, (DEHP). However, this standard does not apply in cases in which there is no risk that diethylhexyl phthalate will migrate into foods.

C.Specification in Use (Korean FDA, 2015b)[]

(1) Di-(2-ethylhexyl) adipate(DEHA) shall not be used in the manufacture of cling wraps, except there is no possibility that di-(2-ethylhexyl) adipate migrates into foods.

(2) Production of Baby Bottles (including the teat/ mg/L)

For the production of baby bottles, the manufacturer should not use di-n-butyl-phthalate (DBP), benzyl-n-butyl-phthalateBBP, and BPA (Korean FDA, 2015a).[]

(3)Act on the Medical Devices[] and Regulations for Approval, Notification and Review of Medical Devices, []Number 3 of Article 5 (Safety, Active Principle Matter, Medical Devices of Raw Material Use) in Regulation haveprescribed,according to clause 1 of article 6-3 in the act on the medical devices, raw materialor medical devices that have problem in safety and validity are designated. Following as: that have regulated Fluid set that contains phthalates such as Di-(2-ethylhexyl)-phthalate (DEHP), Dibutyl phthalate (DBP) or Benzyl butyl phthalate (BBP) (Korean FDA, 2014).[]The number 3 of clause 1 of article 3 in the act on the medical devices restricts the licensure on production about medical devices that is in immediate contact with a human body directly or indirectly as medical devices using or containing raw materialthat the Minister of Food and Drug Safety designates that have problem in safety and validity.

D. Specifications for Major Material

"These Standards and Specifications ensure the distribution of safe equipment, containers and package. Furthermore, the purpose of these standards and specifications is to contributeto the safetyof consumers through the prevention of harm to the public health as specifying standards on hazards substances that may be transferred to food from equipments, containers and packages used in direct contact with food or food additives."(Korean FDA, 2013).[]

(1)A Permitted Limit on Phthalates in Plastic Product (synthetic resins Product) - Plastic product or poly vinyl chloride product refers products that is 'containing above 50% of vinyl chloride among the base polymers' (Korean FDA, 2013).[] Five kinds of chemical materials arecontrolled by the enforcement regulation.

1-1 Phthalate in Poly vinyl chloride: PVC, Limitation for Elution (mg/L)

a) Di-n-butyl Phthalate, DBP: < 0.3
b) Benzyl-n-butylphthalate, DEHP: < 30
c) Di(2-ethylhexyl) phthalate: < 1.5
d) Di-n-octylphthalate, DNOP: < 5
e) Diisononyl Phthalate and Di-isodecyl phthalate, DIDP: < 9 (in the sum total)

(2)Bisphenol in Poly vinyl chloride: PVC, Limitation for Elution (mg/L)

Bisphenol A (as sum of phenol, bisphenol A and p-tert-butylphenol): not more than 2.5 (However, migrant specification of bisphenol A is not more than 0.6).

(3) Limitation for Elution - New Restrictions on Nonylphenol in ROK.

'On September 30, 2016, South Korea's Ministry of the Environment issued an amendment to the K-REACH regulation. The amendment adds new restrictions on NP and NPEs. Nonylphenol (NP) and Nonylphenol ethoxylates (NPEs) are commonly used in the production of plastics, detergents, paints, biocides, and cosmetics.

The restriction under K-REACH applies to the import, sale, storage, transport or use of such substances. K-REACH requires that the quantity of the substance shall not exceed 0.1% for products or components within. The new substance restrictions, listed below, will be implemented on July 1, 2018' (GreenSoft Technology, Inc., 2016).[]

IV. SOUTH KOREAN REGULATIONS ON CHILDREN PRODUCTS CONTAINING ENDOCRINE DISRUPTORS

1. Common Safety Standards for Children's Products (Korean Agency for Technology and Standards, n/d)[]

The updated Bureau of Indian Standards' guideline 'seeks to limit the use of . . . toxic chemical[s] in [children's] toys [however,] . . . unless a safety certification for toys is made mandatory, such directives may prove futile' (Mishra and Gupta, 2015, p.38).[]

In ROK, The ministry of Environment of ROK recentlyresearch on exposure "fact-finding from Hazardous Chemicals on 4,000 items of Children's Products.

The 15 groups for productsis following as: Book Bag, metal accessories, mat for infants, wooden toy, stationery (note, water bottle, pencil vase, erasers, clip), utensils for wrinkling of water (ball, tube, beach ball), pouch for water bottle, Blocks, sports equipment (ball, suncap, catch ball), accessories (a mirror, a hair pin), a tumbling doll, a skipping rope, a gym-ball, plastic doll and so on"(Choi, 2015, p.5).[]

2. Studied chemical substances: Total 35 kinds

Heavy metal (8 kinds: Cd, Ni, Pb, Cu, Cr, Ba, Zn, Co), Phthalates (5 kinds: DEHP, DBP, BBP, DINP, DNOP), Azo dye (22 kinds) Study team have researched as focusing on azo dye defected from 22 kinds of Azo dye (Choi, 2015, p.5).[] They have, simultaneously, studied on Nonyl Phenol as chemical material of the restriction, including new hazards, Perfluorooctanesulfonic acid (PFOS), Perfluorooctanoic acid (PFOA) (Choi, 2015, p.11).[]

3. Safety Requirements on Harmful Materials

South Korea regulate Harmful Chemical Materials(Korean Ministry of Trade, Industry and Energy, 2015a, p.4)[]following as;

Table 1. Harmful Chemical Materials

Harmful Materials		Permissible Level
Eruption of	Antimony (Sb)	60 mg/kg
	Arsenic (As)	25 mg/kg
Hazardous Element	Barium (Ba)	1,000 mg/kg
	Cadmium (Cd)	75 mg/kg
	Chromium (Cr)	60 mg/kg
	Plumbum (Lead, Pb)	90 mg/kg
	Hydrargyrum (Mercury, Hg)	60 mg/kg
	Selenium (Se)	500 mg/kg
Hazardous Element Content	Total Plumbum (Lead, Pb)[2]	300 mg/kg
	Total Cadmium (Cd)	75 mg/kg
Total Content of Phthalate Plasticizer	DEHP (Diethylhexyl phthalate)	Sum Total 0.1%
	DEP (Dibutyl phthalate)	
	BBP (Butyl benzyl phthalate)	
	DINP (Di isononyl phthalate)	
	DIDP (Di isodecyl phthalate)	
	DNOP (Di-n-octyl phthalate)	

A. Eruption of Hazardous Element: Among children products intended to be put in children's mouths, or children products that children under 36 months will use, this level will apply to the paintwork (including coating) or synthetic resin, paper products.

B.Total Plumbum: In the case of paint and surface coating, it will apply less than 90 mg/kg. However, this standard will not apply to the functional products like electrical and electronic equipment.

C. Total Content of Phthalate Plasticiser:For products not intended to be put in children's mouths, apply the DEHP, DBP and BBP standards.

For products intended to be put in children's mouths, apply the DEHP, DBP, BBP, DINP, DIDP and DNOP standards. These standards also apply to synthetic resin products that coat textile and leather goods.

Furthermore, among products that children do not use by putting in their mouths, but that have a total DEHP, DBP, BBP, DINP, DIDP or DNOP concentration that exceeds 0.1%, the manufacturer should put a warning on the product, which reads: 'WARNING! Do not put this in your mouth, because, if you do, you may ingest phthalate plasticiser'.

4. Safety Standards of Common Harmful Material on Children's Industrial Products

A. Coverage

This standard will generally apply to industrial products or the gadget of the product that child under the age of 13 uses or being used for child under the age of 13 age.However, if individual safety standard exists

shall be subject to the following individual safety standard. However, this standard shall not apply to the components of the product that may not be out of the reach of children (Korean Ministry of Trade, Industry and Energy, 2015b, p.3).[]

B. According to Art. 2.8 of the Quality Control and Safety Management of Industrial Products Act (2015), '[t]he term 'industrial products subject to safety certification' means industrial products prescribed by Ordinance of the Ministry of Trade, Industry and Energy, the hazards of which are deemed preventable through safety certification, among those deemed highly likely to cause harm to the life and health of consumers, damage to property, or harm to the natural environment due to their structure, quality of materials, methods of use, etc.'.[]

C. According to Article 2.9 of the Quality Control and Safety Management of Industrial Products Act (2015), The term ''industrial products subject to safety self-assurance' means industrial products prescribed by Ordinance of the Ministry of Trade, Industry and Energy, the hazards of which are deemed preventable through product testing only, among those deemed likely to cause hazards to the body of consumers due to their structure, quality of materials, or methods of use, etc.'.[]

D. According to Article 2.10 of the Quality Control and Safety Management of Industrial Products Act (2015), The term ''industrial products subject to safety and quality labeling requirements' means the industrial products prescribed by Ordinance of the Ministry of Trade, Industry and Energy that expose consumers to the risks of accident or harm in the course of handling, using, or transporting such products or whose ingredients, performance, specifications, etc. are hard to be identified by consumers'.[]

E. Definition of Term (Korean Ministry of Trade, Industry and Energy, 2015a)[]

a. Children's products means the goods or components or gadgets that child under 13 years of age use or the goods or components or gadgets being used for children under 13 years of age.

b. Harmful of Harmful Chemical Materials means damage for the life and the body, the property damage, or environmental damage.

c. Safety requirement of harmful material containing in industrial products for children shall be the same as in the above table 1.

d. These materials also apply to synthetic resin products. However, DINP, DIDP and DNOP shall apply to the industrial products manufactured for use in children's mouths (i.e. teethers, pacifiers, baby rattle).

CONCLUSION

Conclusion and a Proposal to the India Government to Develop Regulations for Environmental Hormones and to Boost Law Enforcement Efforts to Support those Regulations

To meet international environmental standards, various laws regarding pollution control are promulgated and, sometimes, modified to provide legal weapons for law enforcement. However, there are few detailed Acts with which to implement and enforce these laws: The Forest Act(1980),[] The Air (Prevention and Control of Pollution) Rules (1982),[] and Wildlife (Protection) Rules (1995).[] Furthermore, the IndianGovernment hasestablished new environmental protection policies,like The National Forest Policy (1988),[] Abatement of Pollution policy (1992),[] National Conservation Strategy and Policy Statement on Environment and Development (1992) (Environmental Education Centre, 2017a).[]According to the Environmental Protection Act (1986),[] the environment includes: '(a) Water, air, and land, b) The inter-relationship which exists among and between i) water, air, land; and ii) human beings, other living creatures, plants, microorganisms and property' (Environmental Education Centre, 2017b).[]

However, the Indian government did not establish an act or policy to restrict the use of endocrine disruptors. In fact, the Indian government does not control endocrine disruptor materials, it simply regulates some of the substances that the WWF has suggested should be banned entirely. Thus, the environmental laws, regulations and policies implemented by the Indian government are not even in accordance with WWF recommendations. Moreover, there is still an absence of laws in India related to certain environmental issues such as environmental hormone pollution, especially that arising from BPA, nonylphenol and phthalate pollutants.

Environmental protection in India has gradually progressed toward legal management. However, the protections still have many gaps, as the regulations and control standards are still far from perfect and, often, far more lax than international standards. For example, when comparing South Korea's standards to India's, it is clear that India's standards do not meet economic, social and health needs of the people to improve India's standard of living. Thus, the Indian government should establish more detailed laws and standards to better control like selling prohibition of environmental hormone pollutants. Only then can environmental pollutants, which appear in the production, storage, sale and use of hormone compounds, be reduced, and only then can economic, social and ecological environments develop harmoniously. Finally, the penalties can be imposed in proportion to the concentration of the endocrine disruptor in the products.

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