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Research Article

A Study of Toxic Metal Contents in Selected Cosmetics in The Federal Capital Territory and Products Safety Regulations in Nigeria

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Abstract

The use of cosmetics is increasing rapidly in Nigeria. Cosmetics and personal care products are one significant source of exposure to dangerous and unregulated chemicals, including heavy metals, that can pose serious health risk to the consumer. Cosmetics contain a range of chemicals for specific functions in connection to their intentional uses and are strictly regulated in some countries whilst some other countries do not have regulations. Even where regulations exist, similarities and differences exist in the different government bodies among countries of the world. This research work studied the toxic metal contents in selected cosmetics in the Federal Capital Territory (FCT) and the safety regulations of these products in Nigeria. Commonly applied products from popular cosmetics manufacturers including eye pencils, hair shampoos and bath soaps were analyzed using standard methods. From the results, the toxic metals concentrations in the eye pencils are in the order Pb > Zn > Fe > Cu > Ni > Cd > Co > Cr > Hg. In the hair shampoo samples, the order of the toxic metals levels is Fe > Pb > Cr > Cd > Zn > Co > Ni > Cu > Hg. In the bath soap samples, the levels of the toxic metals are Fe > Co > Ni > Cu > Cd > Zn > Pb > Hg > Cr. The mean Ni contents (0.320 ± 0.004 mg/kg) in the samples of bath soaps are slightly higher than the tolerance limits but the levels of Hg, Pb, Cd, Co, Cr, and Zn in samples of hair shampoo and bath soaps are within the tolerance limits of the regulatory bodies. While the National Agency for Food and Drug Administration and Control (NAFDAC) has regulations on the pre-market approval, proper labelling of cosmetic products, expiry date, and name and address of the manufacturer, it has none on post-marketing reporting system to help check the response of the product from the end users.

Keywords: Cosmetics regulations, product safety, toxic metal

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Introduction

Various countries of the world including Nigeria, EU, USA, Canada, Japan, India, Malaysia,China, and many others have defined cosmetics differently: The EU Cosmetics Directive (2009) defines a cosmetic product as any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and or/correcting body odours and/or protecting them or keeping them in good condition.

In the United States, the definition of products as cosmetics or drugs depends on their intended use on the basis of claims made about the product, consumer perception (which may be established through a product's reputation or the presence of ingredients with a well known therapeutic use). According to the Federal Food, Drug, and Cosmetic (FD&C) Act, a product may be regarded solely as a drug, solely as a cosmetic or (in contrast to the position in the EU) as both a drug and a cosmetic.The FD&C Act defines cosmetics as articles (other than soaps consisting of an alkali salt of a fatty acid and making no claims other than cleansing) intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance (Abdullah *et al.*, 2012).

Under Pharmaceutical Affairs Law (PAL) of Japan, the term cosmetic applies to products (other than quasi-drugs) designated to be applied to the body by rubbing, spraying or other similar applications with the aim of cleansing, beautifying or making it more attractive or modifying its appearance and of maintaining the skin and hair in good condition, to the extent that the action of the product on the human body remains moderate (Abdullah *et al.*, 2012).

The Canadian regulation defines cosmetics as any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes. This definition includes toothpaste (nonfluoride), skin lotions, cleansers, shampoos, conditioners, hair dyes, personal care products and soaps (Abdullah *et al.*, 2012).

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The current regulations of the Peoples Republic of China define cosmetics as those daily used chemical products applied on the surface of any part of the human body (such as skin, hair, nails and lips) by way of smearing, spraying or other similar methods to keep the body clean, to get rid of undesirable smell, to protect the skin, to make up the face and to increase the beauty of the appearance (Abdullah *et al.*, 2012).

The Bureau of Indian Standards (BIS) regulates cosmetics products in India under the Drugs and Cosmetics Act 1940, Rules 1945 and Labelling Declarations. BIS sets the standards for cosmetics products listed under Schedule 'S' of the Drugs and cosmetics Rules 194518 and provides the specification for cosmetics products in the Indian Standards (IS) 6608:2004 and 9875:1990 respectively (Srikanth, 2011).

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC, 2019a) defines a cosmetic to include any substance or mixture of substances intended to be rubbed, poured, sprinkled or sprayed, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the complexion, skin, hair or teeth and includes deodorants and detergent powder. NAFDAC, in exercise of the powers conferred by sections 5 and 29 of the National Agency for Food and Drug Administration and Control Act 1993 and of all other powers, has the enabling to Regulate and Prohibit Unsafe Cosmetics products.

A cosmetic can generally be defined as any substance or preparation for human use for the purpose of cleansing, beautifying or altering the appearance such as personal toiletry products, beauty products and fragrances, attachments, creams and lotions, etc. Undoubtedly cosmetics are now being used by many people to improve their appearance. In the UK for example, The Daily Mail newspaper reported (http://www.dailymail.co.uk/femail/article-1041224) that in a 2006 survey, British women spent £3,000 a year on beauty products and treatment, with 81% of women wearing make-up everyday to feel confident. Another survey reported that British women even spent more on their appearance than on their health.
(http://guide2herbalremedies.com/british-women-spend-beauty-health).

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USFDA (2015) reported that average American women use 12 personal care products and/or cosmetics a day and the total products they use contain 168 different chemical ingredients.

Also, cosmetic products now attract a much wider market commonly divided on the basis of cosmetics categories, sale mode, gender and geography (Business Wire, 2014). In the past, cosmetics used to be associated almost exclusively with women but now they have become important for both genders (Euromonitor, 2007) and all age groups, young and old alike. Cosmetics are produced on a larger scale and their sales are now astounding. In 2006 for instance, approximately 11 billion personal care products were sold within the United States, causing annual cosmetic sales to reach $6,235 billion dollars, and in the EU, the cosmetic industry is worth £67 billion (Asia Pacific Cosmetic and Toiletries Market Overview, 2005; Bangkok Post, 2010; Business Wire, 2014).It was reported that Malaysians spent an estimated $500 million in 2006 on cosmetics, which almost doubled within a year (Asia Pacific Cosmetic & Toiletries Market Overview, 2005); and that four out of every ten Malaysian women used whitening products (http://www.synovate.com/consumer-insights/infact/issues). As the sales of cosmetics increase around the world, including online sales (Zhai *et al.*, 1998), the problems concerning the safety of such products have also become a global problem.

The National Pharmaceutical Control Bureau of Malaysia (NPCB), which is responsible for controlling the cosmetics on the market, revealed that out of the whitening products used, many of them contained prohibited ingredients such as hydroquinone acid, tretinoin and mercury (Zuraida, 2009). Cosmetics contain a range of chemicals (*vide infra*) for specific functions in connection to their intentional uses. They include ultra-violet (UV) filters (to protect the skin from the damaging effect of sunlight), colourants or pigments (to fix the appearance), hardeners (to solidify), preservatives (to prevent the growth of microorganisms), fragrances (perfumes or scents), antioxidants (to help prevent skin damage and to improve product stability), emollients/moisturizers (to soften the skin by reducing evaporation/dryness), surfactants (used as foaming agents), and emulsifiers (to help water and oil soluble ingredients for mixing). These ingredients may be synthetic or naturally occurring chemicals. Apart from chemical substances used intentionally in cosmetics, which presence is allowed and strictly ruled by relevant regulations, other toxic and hazardous chemicals including heavy

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metals of accidental origin may also be present (CIREP, 1990). Most commonly, chemicals are absorbed through the skin (epidermal or dermal absorption) (Pratchyapruit *et al.,* 2007; Omolaoye *et al.,* 2010), the most hazardous chemicals including heavy metals penetrate through mucous membranes (including oral ingestion such as licking the lips) (Gondal *et al.*, 2012 Khalid *et al.*, 2013; Soares and Nascentes, 2013), inhalation (from hairsprays and perfumes), and the gastrointestinal tract (as in toothpaste).

With the rise in popularity of cosmetic products, there has been a similar rise in reports (Granum and Lovik, 2011) of hazardous substances in cosmetics. The effects of these have sometimes been lethal. In Cambodia for example, there was a death due to a Vietnamese-made skin whitening cream believed to contain dangerous chemicals (http://www.bangkokpost.com/news/local/34119/skin-cream-linked-to-bride-death). As far back as the 1930s there were health scares involving cosmetics such as Koremlu cream (Smith, 2011) and Lash Lure (Forbes and Blake, 1934; Harner, 1993; Jamieson, 1993) and sometimes there were tragic consequences. Many literatures have reported different ailments damaging human lives as a result of heavy metals and toxic chemicals in cosmetic products (Soares and Nascentes, 2013; Zakari *et al.,* 2014; Borowska *et al.*, 2015). Available health and safety information shows that toxic chemicals in cosmetics products are known or suspected to cause cancer, reproductive health problem, learning and developmental disabilities, immune system disorders and other health risk implication (USFDA, 2013). The toxicological effects of cosmetics have been reported to include local irritation (Naveed, 2014), skin irritation or damage (Zhai *et al.*, 1998), eye and respiratory tract irritation, genotoxicity (Kortenkamp, 2006), carcinogenicity (Gylseth, 2014), breast cancer risk (Santen *et al.,* 2015; Myers *et al.,* 2015), allergy (Darbres andCharles, 2010; Marks *et al.*, 2003; Ortiz and Yiannias, 2004). There is no guarantee that similar catastrophic cases will not happen again in the future. The issue then arises as to whether such incidents could be safeguarded by a regulatory mechanism, i.e. by ensuring only safe cosmetic products reach the market. Product safety regulations play a fundamental role. Product safety refers to the regulatory control by governmental authorities of the marketing of products by means of criminal and/or administrative law. It functions as a preventive measure, particularly when consumers are not able to anticipate risks, and when so many new products are being introduced that are only supported by the claims of the manufacturers concerning their safety and effectiveness (Smith, 2011).

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The Cosmetic industry is one of the complex industries as manufacturers and distributors face new legislations more than ever before. Today the cosmetic industry makes use of new and advance technologies that creates new cosmetics with more properties. The increase demand of cosmetics with more effectiveness has led to increased research in this particular area. Presently, manufacturers are using new technologies including nanotechnology or nanoparticles for manufacturing products (Al-Saleh *et al.,* 2009).The different government bodies regulate the sales and manufacture of cosmetics all over the globe. Though there are many regulatory bodies separately for each country, the aim of all these regulatory bodies is the same and it is to ensure that the cosmetics are properly labeled, safe to use, and cause no adverse effects on consumer health (European Commission, 1999). In the United States and the European countries, the cosmetic regulations are extensive since these are the two largest markets in the world for cosmetic products (Gagliardi and Dorato, 2007).

Cosmetics products are strictly regulated in some countries whilst some other countries do not have regulations. The European Union undoubtedly has some of the most advanced chemicals regulations in the world. The EU established the Cosmetics Directive in 1976 (Directive 76/768/EC) to protect consumers from unsafe cosmetics. In 2013, this Directive was replaced with a new regulation (Regulation (EC) No 1223/2009) (European Cosmetics Directive, 2009), in which, each state party has to transpose into their own legal system. The new regulation is a part of legislation which is governing cosmetics products. Under EU law, all cosmetics/body care products must list the chemical ingredients, but many chemicals can come under a single group name such as perfume. The EU takes a precautionary approach to chemicals regulation, its regulation lists over 1200 various toxic substances and heavy metals (Pb, Cd, As, Ni, Hg etc) whose presence are prohibited in cosmetics products. This contrasts with the U.S.A regulations, which do not adopt a precautionary approach and where only 11 ingredients are prohibited or restricted (USFDA, 2015). In June 2015, the EU Regulation (EC No 1272/2008) on Classification, Labeling and Packaging (CLP) came into force which included new provisions to ensure the general public was made aware of the health hazards of substances and mixtures.

A directive, by definition, is a legislative act that serves to direct, indicate or guide. A directive in the EU represents a guide that every member country has to transpose into its national legislation. However, because some

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countries are stricter than others about adoption of laws, sometimes rules are not equally applied everywhere as intended, resulting in the need to draft multiple versions of the directive specific to each country. On the other hand, a regulation is a legislative act that imposes clear and detailed rules. A regulation is not required to be incorporated into the national laws, but is immediately enforceable in all member states. The EU Cosmetic Directive (76/768/EEC) was originally issued on July 27, 1976, as an initial means of ensuring the safe sale and distribution of cosmetic products within the EU Community market. With a primary goal of protecting overall consumer health, the Directive included rules on the composition, labelling and packaging of cosmetic products. But as the cosmetic industry advanced, utilizing new, groundbreaking technologies and innovations, the legislation supporting it needed to change/evolve, too. On 30th November 2009 the Cosmetic Regulation 1223/2009was adopted, so as to replace the EU Cosmetic Directive. The aim of creating regulations is to implement a much better approach to ensure the product safety and faster enforcement, and only translation into the languages of the EU member countries is required.

Despite the fact that cosmetics products are not ruled by a uniform regulation regarding substances known to be hazardous, manufacturers should be mandated to include warnings on product labels worldwide (Klaschka, 2012). A closer examination of comparisons between these jurisdictions demonstrates that all have recognized the importance of cosmetics safety but each of them has approached its implementation in a different way (Zakaria, 2012). Similarities and differences exist in cosmetics regulation among countries of the world. Features common to cosmetics regulation in global markets include full responsibility of the manufacturer for the safety of products, in-market surveillance by regulatory authorities, and no restrictions on sales channels (do not require prior approval before marketing their products). The main differences between regulatory regimes for cosmetics in the markets are controls over ingredients through positive and negative lists and requirements for maintaining data on product safety and efficacy. Table 1 shows a comparison of cosmetic regulations across some international markets**.**

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Table 1: Cosmetic regulations across some international markets

Contents	USA	EU	India	Nigeria
Authority	FDA	EMEA	CDSCO	NAFDAC
Rules and Regulations	Food, Drug and Cosmetic Act.	Council Directive 76/768 EEC.	Drugs and Cosmetic Act.	Governing Council, NAFDAC Act Cap N1 LFN 2004
Pre-Market Approval	Not Required.	Not Required.	Required under state government licensing.	Required
Labelling	Should comply with the FD&C and FP&L.	Based on Council Directive 76/768 EEC.	Should comply with part xv of D&C Rules 1945.	Should comply with NAFDAC Cosmetics Products Labelling Regulations.
Expiry Date	Not Required.	Date of minimum durability, if durability < 30 months; Period after opening, if durability > 30 months.	Indicated as "use before date".	Required
Post-marketing Reporting System	Yes	Not Available	Not Available	Not Available
Name and Address of Manufacturer	Not Available	Not Available	Not Available	Required

NAFDAC (2019a), Srikanth (2011), Farr (1996).

The global harmonization of cosmetic regulations has demonstrated that many countries in the world want to improve their cosmetic regulations. The main reasons for this are to guarantee the health of consumers and the safety of cosmetic products everywhere (WHO, 2011). Other reasons relate to the desire to standardize the common standards for these products, give equal opportunities for trade, and an enhanced ability for authorities to properly monitor and control the markets. All of these improvements need to be made because cosmetics are now very popular consumer products and many are not safe and cause adverse effects (Zakaria, 2015). Harmonization of cosmetic

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standards has been a challenge for Association of South East Asian Nations (ASEAN countries) because it meant a change of regulatory style from registration to notification and from pre-market approval to post-market surveillance of cosmetic products (Schneider, 2009).

The use of cosmetics is increasing rapidly in Nigeria. Cosmetics and personal care products are one significant source of exposure to dangerous and unregulated chemicals, including heavy metals that can pose serious health risk to the consumer. Repeated uses of cosmetic products containing hazardous chemicals directly on the bodies lead to the high potential for immediate absorption or ingestion in humans. Available health and safety information shows that toxic chemicals in cosmetics products are known or suspected to cause cancer, reproductive health problems, learning and developmental disabilities, immune system disorders, and other health risk implication (USFDA, 2013). This research work studied the toxic metals contents (Hg, Pb, Cd, Cu, Co, Fe, Cr, Ni and Zn) in selected cosmetics in the Federal Capital Territory (FCT) and products safety regulations in Nigeria.

Materials and Methods

Sample Collection

Samples of commercial cosmetic products were purchased from different markets in the Federal Capital Territory of Abuja in Nigeria. Among the three categories of cosmetics analyzed, three samples each were eye pencil (E), hair shampoo (HS), and bath soap (BS). In all, three different brands and total of nine samples were collected for analysis. These samples were selected because they are popular and commonly applied cosmetics.

Reagents and Standards

Analytical grade nitric acid (65%, Sigma Aldrich) and perchloric acid (70–72%, Sigma Aldrich) were used for sample preparation. Calibration standards for the heavy metals were prepared from the certified standard stock solution in the range 0.5 to 10 ppm. All the solutions were prepared with de-ionized water.

Sample Preparation

All plastics and glass wares were washed, rinsed many times with tap water and then soaked in 5% HNO_3 solution for 24 h and followed by rinsing with deionized water before use. Solid samples were dried in an

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oven at 105 °C to constant weight and then stored in desiccators. 3.5 g of each of the dried samples was weighed into a porcelain crucible and dry ashed in a muffle furnace by stepwise increase of the temperature to 550 °C for 1 h. The ash samples were digested with a few drops of 1 mol/dm^3 HNO_3, and evaporated to dryness on a hot plate in a fume cupboard (Ayenimo *et al.*, 2010), cooled and then filtered with Whatman No. 42 (Saeed *et al.*, 2011), and diluted to the 100 cm^3 mark of the volumetric flask. The same procedure was repeated three times for each sample.

Determination of Toxic Metals

Pb, Cd, Cu, Co, Fe, Cr, Ni, and Zn were determined according to the standard method of AOAC (1990) using the atomic absorption spectrophotometer (model 230ATS). Mercury (Hg) was determined using Cold Vapor Atomic Absorption Spectrophotometer (CVAAS) method. Each sample analysis was replicated three times.

Statistical Analysis

The package of Microsoft excel 2010 was used for statistical analyses. Values in the text are shown in tabulated form as mean ± SD.

Results and Discussions

The results of the toxic metal concentration in the samples of commonly used cosmetic eye pencils are presented in Table 2. The concentrations of lead in all the samples ranged from 0.028 ± 0.007 mg/kg (in bath soaps) to 194.3 ± 0.033 mg/kg in eye pencil samples. The Pb concentrations in the cosmetics samples were observed to follow the order: eye pencil > hair shampoo > bath soap. These levels of Pb are similar to the reported mean values of 123.2 mg/kg Pb of Nigerian samples of eye pencils by Nnorom *et al.* (2005), and much higher than the findings by Al-Dayel *et al.* (2011) who reported Pb range of 4.41 to 11.9 mg/kg for Saudi Arabia samples of eye shade. The Pb levels in the eye pencil samples are extremely higher than the maximum permissible limit of 10 mg/kg stipulated by Health Canada (2011). The high concentration of Pb observed in the eye pencil samples could be attributed to the Pb containing ingredients used in their making which are composed mainly of galena (PbS), amorphous carbon, zincite (ZnO), (H_3BO_3), (Pb_3O_4), magnetite (Fe_3O_4), goethite (FeO(OH)), cuprite (Cu_2O), and talc ($Mg_3Si_4O_{10}(OH)_2$). The extremely high levels of lead the samples of eye pencils

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make them unsafe for human use considering the health effects associated with lead poisoning such as anemia, colic, neuropathy, nephropathy, sterility and coma, among others (Table 6; Landrigan, 2013).

Table 2: Toxic Metal Concentrations in commonly used Cosmetic Eye Pencils (mg/kg)

Sample	Sample Code	Hg	Pb	Cd	Cu	Co	Fe	Cr	Ni	Zn
Eye Pencil	E-01	0.026 ± 0.009	201.2 ± 0.012	0.095 ± 0.001	6.228 ± 0.007	0.342 ± 0.001	181 ± 0.090	ND	0.426 ± 0.003	1743 ± 0.002
	E-02	0.016 ± 0.003	219.3 ± 0.072	1.942 ± 0.006	13.800 ± 0.002	0.822 ± 0.003	1425 ± 0.050	0.084 ± 0.005	1.890 ± 0.001	334.8 ± 0.034
	E-03	0 .018 ± 0.001	162.5 ± 0.015	0.755 ± 0.001	54.600 ± 0.006	0.621 ± 0.002	281.7 ± 0.015	ND	0.702 ± 0.001	278.4 ± 0.015
Mean ± SD (n = 3)		0.020 ± 0.004	194.3 ± 0.033	0.930 ± 0.003	38.228 ± 0.005	0.595 ± 0.002	629.2 ± 0.052	0.028 ± 0.002	1.006 ± 0.002	785.4 ± 0.017

Mean ± SD; ND = not detected

Iron, like zinc, is considered to be a metal of insignificant toxicological effect, but a long exposure from cosmetic products may cause cellular death or colorectal cancer as a result of cumulative effects (Senesse *et al.,* 2004). Iron in cosmetic products supports skin regeneration (Trojanowska *et al.,* 2015). It takes part in the synthesis of collagen, and it has moisturizing properties. Iron compounds have a well-established role in dyes in many cosmetic products. The concentrations of Fe in the cosmetic products were highest (629.2 ± 0.052 mg/kg) in the eye pencil samples and lowest (31.130 ± 0.004 mg/kg) in the hair shampoos. The levels of Fe in this finding are higher than the mean value of 97.2 mg/kg among some eye pencil samples (Nnorom *et al.*, 2005). Very high Fe concentrations that ranged from 1000 to 3760 mg/kg for eye shade samples from Saudi Arabia have been reported (Al-Dayel *et al.*, 2011). These values of Fe are very high compared with the recommended standards of 40 mg/kg by NAFDAC (2019b) as shown in Tables 3, 5, and 6. This could be attributed to the use of iron containing compounds as ingredients in cosmetic products.

Mercury levels ranged from 0.020 ± 0.004 mg/kg (in the eye pencil samples) to 0.023 ± 0.015 mg/kg (in the hair shampoos). Among the cosmetic products, the levels of mercury follow the order Hair Shampoos > Bath Soaps > Eye

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Pencils. It was observed from the result that the mercury contents of all the analyzed samples were higher than the recommended value of 1.0 mg/kg (WHO, 2011) and 0.3 mg/kg (Health Canada, 2011).

Unfortunately, in some cases, cosmetics manufacturer intentionally refuse to list Hg as ingredient in their products thereby, hiding the information and misleading the consumer. This should be discouraged or appropriately sanctioned by regulatory bodies. Organic mercury (RHg) is lethal. Organic mercury compounds are quite toxic as they tend to diffuse through the body and are easily absorbed through the skin, notably methyl mercury and dimethyl mercury (USEPA, 2012).

Table 3: Toxic Metal Concentrations in Commonly used Cosmetics Hair Shampoo (mg/kg)

Sample	Sample Code	Hg	Pb	Cd	Cu	Co	Fe	Cr	Ni	Zn
Hair Shampoo	**HS**-01	0.027 ± 0.022	1.784 ± 0.011	0.078 ± 0.023	0.056 ± 0.007	0.180 ± 0.012	43.87 ± 0.124	ND	0.095 ± 0.386	0.598 ± 0.000
	HS-02	0.015 ± 0.011	1.632 ±0.023	0.064 ± 0.020	0.083 ± 0.005	0.161 ± 0.002	21.30 ± 0.003	ND	0.071 ± 0.453	0.391 ± 0.060
	HS-03	0.028 ± 0.012	1.812 ± 0.012	0.439 ± 0.014	0.094 ± 0.001	0.205 ± 0.008	28.76 ± 0.004	1.009 ± 0.002	0.092 ± 0.521	0.231 ± 0.001
Mean ± SD (n = 3)		0.023 ± 0.015	1.748 ± 0.010	0.194 ± 0.003	0.078 ± 0.004	0.182 ± 0.007	31.130 ± 0.004	0.336 ± 0.006	0.086 ± 0.001	0.407 ± 0.002

Mean ± SD; ND = not detected

These organic mercury (allylmercury and alkylmercury) compounds are the most dangerous as they form conjugates with cysteine that mimic another amino acid methionine, which is then actively distributed through the body or ecological system (ATSDR, 2012; WHO, 1990). The adverse effects of inorganic mercury contained in skin lightening soaps and creams include kidney damage, rashes, skin discoloration and scarring, and reduction in the skin's resistance to bacterial and fungal infections (WHO, 2011).

Copper concentrations in the cosmetic samples was lowest (0.078 ± 0.004 mg/kg) in the hair shampoos and highest (38.228 ± 0.005 mg/kg) in the eye pencils. Copper content of the eye pencils in this finding was similar to the range of 14.4 to 37.3 mg/kg reported by Al-Dayel *et al.* (2011) for eye shade

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samples from Saudi Arabia. However, the levels of Cu in this present work are higher than the mean values of 0.264 mg/kg and 0.596 mg/kg for non-medicated and medicated soaps, respectively (Ayenimo *et al.*, 2010). This means that the sample of the eye pencils might not be safe for use. The high concentration of the copper observed in the eye pencil could be due to the frequent use of copper containing compounds as pigments in these types of facial cosmetics.Copper has been shown to have spermicidal effects in humans, dermal exposure to metallic copper may cause pruritic dermatitis (Nnorom *et al.*, 2005).

The concentrations of cobalt were lowest (0.182 ± 0.007 mg/kg) in the hair shampoos and highest (0.595 ± 0.002 mg/kg) in the eye pencil samples. These values are lower than in the eye shade samples of Saudi Arabia that ranged from 1.28 to 31.3 mg/kg (Al-Dayel *et al.*, 2011). The Co contents in these cosmetics are within the permissible limits of 4.0 mg/kg by WHO (2011) and 25.0 mg/kg by Health Canada (2011).

Table 4: Toxic Metal Concentrations in Commonly used Cosmetics Bath Soaps (mg/kg)

Sample	Sample Code	Hg	Pb	Cd	Cu	Co	Fe	Cr	Ni	Zn
Bath Soap	**BS**-01	0.018 ± 0.003	0.019 ± 0.011	0.090 ± 0.006	0.185 ± 0.001	1.120 ± 0.011	21.900 ± 0.023	ND	0.422 ± 0.006	0.020 ± 0.002
	BS-02	0.021 ± 0.002	0.023 ± 0.004	0.012 ± 0.005	0.198 ± 0.006	0.143 ± 0.001	43.200 ± 0.048	ND	0.322 ± 0.002	0.032 ± 0.001
	BS-03	0.026 ± 0.007	0.041 ± 0.006	0.031 ± 0.018	0.072 ± 0.003	0.087 ± 0.002	81.200 ± 0.035	ND	0.216 ± 0.004	0.060 ± 0.004
Mean ± SD (n = 3)		0.022 ± 0.004	0.028 ± 0.007	0.044 ± 0.009	0.151 ± 0.003	0.450 ± 0.005	48.770 ± 0.005	ND	0.320 ± 0.004	0.037 ± 0.002

Mean ± SD; ND = not detected

Nnorom *et al.* (2005) reported a mean value of 100.9 mg/kg of Zn in samples of eye pencils. Higher levels of Zn that ranged from 38.6 to 2000 mg/kg have been reported for eye shade samples from Saudi Arabia. Ayenimo *et al.* (2010) reported mean Zn concentrations of 0.544 and 0.682 mg/kg for non-medicated and medicated soaps, respectively. Zinc is not a metal of significant toxicological importance. Cosmetics containing zinc fulfill different functions depending on the type of compound present. Zinc can act

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protectively, or give conditioning effects or antibacterial properties. Zinc salts increase adhesion and improve the application of the cosmetic (Bartzatt, 2017). Exposure to high levels of Zn is known to cause neurological and gastrointestinal disorders (Bartzatt, 2017). The concentrations of zinc ranged from 0.037 ± 0.002 mg/kg (in the bath soaps) to 785.4 ± 0.017 mg/kg (in the eye pencils). However, the concentration of Zn from this study is very high especially in eye pencil compared with the recommended standards of 25 mg/kg by WHO (2011) as reported in Table 3. This could be dangerous to health when used.

The concentrations of chromium were 0.336 ± 0.006 mg/kg (in the hair shampoos) and were not detected in the bath soaps. The levels of Cr in this study are very low compared to the findings of Nnorom *et al.* (2005) and Al-Dayel *et al.* (2010) who reported the mean value of 39.9 mg/kg in some eye pencils and a range of 5.89 to 7000 mg/kg in eye shade samples, respectively. However, the levels of Cr from this study are similar to the findings of Ayenimo *et al.* (2010) who reported a range of 0.010 to 0.295 mg/kg for non-medicated soaps, and 0.422 to 0.886 mg/kg for medicated soaps. Exposure to Cr can cause skin cancers, and severe redness and swelling of the skin.

Nickel concentrations were highest (1.006 ± 0.002 mg/kg) in the eye pencil samples and lowest (0.086 ± 0.001 mg/kg) in the hair shampoos. The levels of Ni in this study are lower than the mean value of 12.1 mg/kg for some eye pencils (Nnorom *et al*., 2005), and the range of 6.01 to 46.8 mg/kg for samples of eye shade from Saudi Arabia (Al-Dayel *et al*., 2011). The values from the present study are within the recommended standards of 0.2 mg/kg (WHO, 2011) and 0.4 mg/kg (Health Canada, 2011). Contact allergies associated with Ni exposure arise due to the ability of nickel to bind to amino acid residues to form Ni complexes proteins. Nickel represents the main cause of contact dermatitis and minimal amount of other toxic metals can trigger pre-existing allergy. Nickel dermatitis produces erythematic and eczema of the hands and other areas of the skin that is in contact with nickel. It can be concluded that these cosmetic samples may be safe for use.

Tables 5 and 6 showed that mean levels of Pb (194.3 ± 0.033 mg/kg), Cu (38.228 ± 0.005 mg/kg), and Zn (785.4 ± 0.017 mg/kg) in the samples of eye pencil are extremely higher than the permissible levels of both the WHO

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(2011) and Health Canada (2011). While the mean levels of Fe (48.770 ± 0.004 mg/kg) in the samples of bath soap and hair shampoos are higher than the WHO (2011) permissible limits of 30.0 mg/kg in cosmetics, they are within the acceptance levels by Health Canada (2011). The use of cadmium in cosmetics products is due to its colour property as it has been used as a color pigment in many industries. Table 5 showed that the mean concentration of cadmium in the samples was highest (0.930 ± 0.003 mg/kg) in eye pencil and lowest (0.044 ± 0.009 mg/kg) in the bath soaps. The order of cadmium concentrations in the samples is as follows: eye pencils > hair Shampoos > bath soaps.

Nnorom *et al.* (2005) had reported a mean value of 0.7 mg/kg Cd among Nigerian samples of eye pencils. Among the samples of eye shades from Saudi Arabia, Al-Dayel (2011) reported a range of not detected to 0.266 mg/kg, while Ayenimo *et al.* (2010) reported mean values of 0.024 and 0.252 mg/kg of Cd in non-medicated and medicated soaps, respectively. The levels of Cd in the cosmetics samples in this work were below the permissible limits of 3 mg/kg by WHO (2011) and Health Canada (2011). This implies that the results obtained for Cd in the cosmetic samples are likely safe for consumption without causing a significant health risk associated with cadmium toxicity (Table 6).

Table 5: Mean Concentrations of Toxic Metals in Sampled Cosmetics in Comparison with Regulatory Levels

Toxic metal	Eye Pencil	Hair Shampoo	Bath Soap	WHO 2011 (mg/kg)	Health Canada (2011) (mg/kg)
Hg	0.020 ± 0.004	0.023 ± 0.015	0.022 ± 0.004	1.0	0.3
Pb	194.3 ± 0.033	1.748 ± 0.010	0.028 ± 0.007	10.0	10.0
Cd	0.930 ± 0.003	0.194 ± 0.003	0.044 ± 0.009	3.0	3.0
Cu	38.228 ± 0.005	0.078 ± 0.004	0.151 ± 0.003	15.0	10.0
Co	0.595 ± 0.002	0.182 ± 0.007	0.450 ± 0.005	4.0	25.0
Fe	629.20 ± 0.052	31.13 ± 0.004	48.770 ± 0.004	30.0	40.0
Cr	0.028 ± 0.002	0.336 ± 0.006	ND	0.5	1.5
Ni	1.006 ± 0.002	0.086 ± 0.001	0.320 ± 0.004	0.2	0.4
Zn	785.4 ± 0.017	0.407 ± 0.002	0.037 ± 0.002	25.0	20.0

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Table 6: Recommended Limits for Toxic Metals in Cosmetics (mg/kg)

Toxic Metal	[2,3] Limits in Cosmetics	[3]Toxicity
[1] **Hg**	0.3	anxiety, depression, nerve damage and nervous system toxicity, reduces skin resistance to infections, can cause seizures, numbness and memory loss, reproductive, immune and respiratory toxicity.
[2] **Pb**	10	Damage the Fetal, brain, disease of the kidneys, circulatory and Nervous system and immunity.
[2] **Cd**	3	Kidney damage, renal disorder, human carcinogen
[1]**Cu**	10	Liver damage, Wilson disease, insomnia
[1]**Co**	25	Carcinogen, lungs problem, vomiting and nausea, vision and heart ailments
[1]**Fe**	40	Vomiting, dizziness, nausea, headache and weight loss
[1]**Cr**	1.5	Headache diarrhea, nausea, vomiting and carcinogenic
[1]**Ni**	0.4	Dermatitis, nausea, chronic asthma, coughing, human carcinogen
[1]**Zn**	20	Depression, lethargy neurological signs.

Source: [1]NAFDAC (2019b); [2]Al-Dayel *et al*. (2011); [3]Health Canada (2011)

Cosmetics are subject to regulatory controls. The regulatory authorities of cosmetics products in the various international markets (Table 1) showed that while pre-market approval, expiry date, and post-market reporting system are not required or available by some regulatory authorities, they are essential requirements by others. USFDA and EMEA of EU do not require pre-market approval or expiry date as with CDSCO in India or NAFDAC in Nigeria. Pre-market approval and name and address of manufacturer are essential requirements by NAFDAC in Nigeria, without which no NAFDAC registration number can be approved. Proper labelling of cosmetics products is an important requirement by all the regulatory authorities (Table 1). In Nigeria, labelling information of cosmetic products includes the brand name of the product (where applicable), the statement of identity of the product, lot or batch number, net content, expiry date, manufacturer's name, address, and country of origin, NAFDAC registration number, and storage conditions (NAFDAC, 2019a).

Unfortunately many cosmetics products in Nigeria neither provide a proper label of their product nor a full list of its content. Consequently, such manufacturers hide the vital product information from the consumers/users and expose them to avoidable fatalities. This is contrary to best safety

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practices (Klaschka, 2012; Ogus, 2004; European Commission, 1999; European Union, 2009). As in the U.S., manufacturers are responsible for ensuring that cosmetic products comply with the law before they are marketed. The manufacturer or importer of cosmetics is responsible for demonstrating that the product is safe for its intended use. Regulations are enforced at the national level, and each country in the EU has an authoritative body that is responsible for upholding compliance. In comparing how cosmetics safety is regulated between public regulation and self-regulation, it can be seen that cosmetics firms marketing products in the countries that exercise public regulation are under a heavier burden to verify that their products are safe. For example, cosmetics companies must conduct safety assessment tests and are not allowed to use certain chemical ingredients in their cosmetic formulations. While such a requirement is only voluntary in the USA; in the EU, a scientific committee is given the authority to review the safety of cosmetics ingredients. However, differences in regulatory frameworks for cosmetics have implications for stakeholders because of the global nature of the cosmetics industry.

From the consumer perspective, it is believed that chemical composition in cosmetic products has been tested for safety. Unfortunately, that is not always true due to inadequate control and regulation of cosmetics products in some countries. Consequently, users pay the price facing health problems and increase in the costs of health care. It is often argued by consumer advocates that consumers have inadequate information concerning the characteristics and efficacy of a product offered and that sellers will generally have superior information regarding these matters (Ogus, 2004). In product safety regulations, information regulation is regarded as one of the most essential elements. Cartwright (2006) describes information regulation as one of the most commonly used regulatory techniques in the consumer protection area. It is regarded as 'less interventionist' in character compared to many other forms of regulation. Regulatory intervention through information regulation would not be necessary if consumers had the full information on the characteristics of products offered in the market and if externalities does not exist in their purchasing decision (Ogus, 2004). However, as with many consumer products, conditions of information deficit and externalities do exist. Insisting that information be disclosed in some cases can be a solution to product safety problems. For example, if someone is allergic to nuts, then harm can be avoided if a product containing nuts is labelled conspicuously. Similarly, warnings of product risks are important if they are deemed to be an

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acceptable characteristic of the product. It is also of equal importance under the product safety regime, to place the responsibility of safety on the producer or manufacturer of products. This is a cardinal principle since they manufacture the products in the first place. All of the above are known as pre-market control approaches, in other words products are controlled *prior* to them being placed on the market. However, the responsibility on the producer does not stop after the product is released onto the market, but continues beyond. They also have a duty to monitor the products when they are on the market. This is called post-marketing obligations.

Post-marketing reporting system is very crucial as it provides the assessments for feedbacks from the consumers of the cosmetics products, as practiced by the USFDA. Such reporting system is absent among the EU, India or Nigeria cosmetics market.

Conclusion

In conclusion, cosmetics are subject to regulatory controls. A comparison between the different regulatory bodies showed that all have recognized the importance of cosmetics safety but each of them has approached its implementation in a different way. While NAFDAC has regulations on the pre-market approval, proper labelling of cosmetic products, expiry date, and name and address of the manufacturer, it has none on post-marketing reporting system to help check the response of the product from the end users. From the results, the toxic metals concentrations in the eye pencils are in the order Pb > Zn > Fe > Cu > Ni > Cd > Co > Cr > Hg. In the hair shampoo samples, the order of the toxic metals levels is Fe > Pb > Cr > Cd > Zn > Co > Ni > Cu > Hg. In the bath soap samples, the levels of the toxic metals are Fe > Co > Ni > Cu > Cd > Zn > Pb > Hg > Cr. The mean Ni contents (0.320 ± 0.004 mg/kg) in the samples of bath soaps are slightly higher than the tolerance limits but the levels of Hg, Pb, Cd, Co, Cr, and Zn in samples of hair shampoo and bath soaps are within the tolerance limits of WHO (2011) and Health Canada (2011).

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Recommendations

1. Regular monitoring of toxic metals and toxic chemicals that may be inherent in the manufacture of cosmetics products should be strengthened by relevant regulatory agencies such as NAFDAC in Nigeria.
2. Acceptable limits of potential contaminants in cosmetics must be enforced and the principle of good manufacturing practice such as labelling must be adhered to.
3. Need for harmonization of regulations of cosmetic products among countries in order to safeguard the public health.

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