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ORIGINAL RESEARCH article

Quality control of selected cosmetics marketed in Libya for traces of toxic heavy metals: urgent need of guidelines harmonization

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Abstract: Heavy metals and trace elements such as lead (Pb), mercury (Hg), cadmium (Cd), arsenic (Ar), nickel (Ni), Chromium (Cr), cobalt (Co), copper (Cu), mercury (Mg), iron (Fe) and aluminum (Al) are detected in various types of herbal cosmetics. Heavy metals and elements can accumulate at high concentrations causing serious risks to human health when consumed. In this study, the levels of potential heavy metals of Pb, Ar, Cd, and Ni were quantitatively determined using atomic absorption spectroscopy. Samples of Henna leaves, Henna paste, Khol stones and baby Talcum powder were collected randomly from different public markets in Tripoli City, Libya. The results were evaluated by using different international guidelines, US-FDA, EU regulation, German (BVL), World Health Organization (WHO) and Canadian Guidelines. Because of controversial global guidelines, the study urgent the ultimate need for setting up harmonized minimum levels of heavy metals in cosmetics that could be applicable worldwide. Generally, the presence of a higher concentration of some of the studied heavy metals was observed, and the effect of these heavy metals at higher levels will be more harmful to consumer health after prolonged usage. In conclusion, nationally, the need for developing and updating the national specification for cosmetics by the Libyan National Centre for Standardization and Metrology (LNCSM) to protect consumers from more catastrophic cosmetic hazards is urgently required.

Introduction

Since old ages humans looked after their appearance and beauty, starting by using clay, tree leaves and natural pigments, therefore, cosmetics have been used for centuries. Traditionally, in North Africa and the Middle East, certain products were applied every day and at social events. Henna and Khol are the most old and popular cosmetics applied as a powder, past or eyeliners [1, 2]. Henna is extremely popular in Libya as it is part of culture and traditions. Various Henna are products present as a powder, pasta, shampoo or a plant extract from the genus *Lawsonia*. The Henna plant is a small shrub existing in Western Asia [3]. The products with various colors are available in the Libyan market, and some of them are locally produced, while some are imported from Sudan, India, and Pakistan. Kohl is an ancient cosmetic, traditionally, made by grinding stibnite, it has widely been used in the South to contour and/or darken the eyelids and as mascara for the eyelashes [4]. Kohl is often mixed with other chemical substances and is applied to eyebrows, it is, and present as powders but most products exist in solid form and are applied by wooden sticks around the eyes. It is mostly

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purchased and imported from India and Pakistan. Talcum powder, however, is used frequently for babies in large quantities. Talcum powder is an important industrial mineral and it is hydrated magnesium silicate. Two types of talc, industrial and cosmetic are used in paper, plastics, rubber, paint, and cosmetic manufacturing work. Cosmetic powder is packaged as a compact powder or a loose powder, which is used for makeup and contains heavy metals such as Cd, Co, Pb, Cu, and Cr [5]. A study on 30 different brands of talcum powder showed metals are present within safe limits, but the excess use of talcum powder affects the health of the consumer [6]. Heavy metals such as Pb, Mg, Ca, Ar, Ni, and Al are detected in various types of, herbal cosmetics [7]. They are toxic because they tend to bio-accumulate in plants and animals, bio-concentrate in the food chain and attack specific organs in the body and causing serious risks to health when consumed, Pb, Cd, and As which are classified as extremely toxic to humans, accumulate in internal organs over time [8].

Alarm points concerning consumer safety came from studies conducted by Environmental Defense in Canada that have found heavy metals such as Pb, Ar and Sb were found as ingredients that were not listed on the product label [9]. A similar study has identified high levels of Hg in cream cosmetics. Endocrine-disrupting chemicals have also been identified in cosmetic products [10]. A study in Nigeria found an elevated level of lead in facial talcum powders and other metals in personal care products Fe, Pb, and Ni in selected consumer products, heavy metals toxicity to humans is well reported [11, 12]. The human skin has been reported in a study to absorb soluble Pb as evidenced by its increased concentration in sweat, blood, and urine within six hours of its application on the skin [13]. Cd is a human carcinogen as per the WHO. Ar, on the other hand, has a high affinity for keratin and can be easily found in the hair and nail. Acute overexposure to Ar results in skin eruptions, nail striation, and alopecia [14]. Severe damage to the brain and kidneys in adults and children was found to be linked to exposure to Pb levels resulting in permanent damage to multiple organ systems and some cases death. Heavy metals can be harmful to the human body in low concentrations as there is no effective excretion mechanism. Pb gives rise to adverse effects in several organs and systems as the blood, central nervous system, kidneys, reproductive and immune systems [15]. Cd is persistent and accumulates in the kidney and liver of vertebrates, producing severe diseases in these organs [16]. Previous studies reported that cosmetic products exposed users to low concentrations of toxic heavy metals [17]. Thus, regular monitoring of heavy metals and chemicals used or present as impurities in the manufacture of cosmetics products should be emphasized.

Cosmetic products are rubbed or washed on the human skin making it vulnerable to a wide variety of ingredients. Despite the protecting role of the skin against exogenous contaminants, some of the ingredients can penetrate the skin and produce systemic exposure signs such as dermal exposure is expected to be the most significant route to the skin [18]. As these products are raw materials obtained from natural sources or cultivated in large areas of farms and mountains, they certainly contain other natural sources compounds such as heavy metals and minerals or the presence of pesticides and detergents used for the preparations or washing of the last products for marketing [12]. The economic benefit of these products urged to facilitate the continuous flow to reach more marketplaces and press for more production under a few steps of surveillance and quality control (QC) sampling and tests. The USA Cosmetics Industrial Review (CIR) focuses on the potential of the ingredients to cause short-term dermatological reactions such as rashes and eye irritation, but not their potential to cause long-term health problems such as cancer or reproductive harm [19]. The potential toxicity of Ar, Pb and Hg are ranked 1st, 2nd and 3rd in the top 20 heavy metal hazards list due to their hazardous effects [20]. In the huge growth of the cosmetics industry, there were a lot of reports and scientific evidence about the danger of heavy metal traces in cosmetics which represents a threat to consumer's health, however, less attention was paid to safety, and this action has dragged our attention to focus and devoting more work for improving the safety and effectiveness of the products throughout imposed strong QC requirements since the user's safety is the first line to be considered.

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In the context of the quality and safety of cosmetics, QC of cosmetics is important to ensure the efficacy and safety of products starting with their raw materials. The application of any medicaments creams or powder, however, is not different than the application of Henna past to the arms and thighs or rubbing a sun protective lotion all over the body and covering wider areas of exposed skin, nevertheless, we do not carry out strong QC testing as we do for the antibiotic, cortisone or local anesthetic creams. Strictly imposed regulations and standards are increasingly important for manufacturers of cosmetics to monitor and test the elemental compositions of their products to ensure consumer safety and health. Materials and products that conform to the respective specifications can be distributed. It is necessary to use defined test methods to perform the appropriate controls. Having the right analytical tools directly at-line or in an internal QC lab helps to reduce the number of samples sent to an external lab and with this allows for faster reaction times. Manufacturers can minimize impurities in cosmetics by following good manufacturing practices (GMP). These include testing ingredients and the finished products to make sure they meet certain manufacturing rules, despite numerous controls in the manufacturing process, production by the principles of GMP and campaigns for the safe use of cosmetics, these elements are still present even in the best quality products. There are clear differences between countries in QC requirements and heavy metals levels, unluckily, international standards for impurities in cosmetics are currently absent. Different values of minimum limits for heavy metals were applicable in different countries. However, in other countries are not, these difficulties hampered the agreement between continental regions to assist harmonization requirements worldwide. So, the use of heavy metals in cosmetic products has always been a complicated issue around the world and remains so far. Ensuring the absence of heavy metals, unfortunately, it is practically impossible to avoid the presence of heavy metals completely. European regulation 1223/2009/EC [21], admits the presence of metal impurities in the finished products if technically traces are inevitable and small enough to be technically unavoidable. Such presence shall be tolerated only if they have respected GMP to ensure that the end product is safe. As related to trends of heavy metals tracing, Germany published orientation values for heavy metals in cosmetic products during the past years, nevertheless, these limits were out of date and recalculated by the German Federal Office of Consumer Protection and Food Safety (BVL) [22] can fix the lowest possible limits about heavy metals in cosmetics. The newly updated limits are now being used in Germany's market surveillance.

Table 1: Modified new reduced limits of selected heavy metal in cosmetics applicable in Germany

Element	*Cosmetic product limits (mg/kg)*	*Toothpaste (mg/kg)*
Lead (PB)	2.0_a	0.5
Cadmium (Cd)	0.1	0.1
Mercury (Hg)	0.1	0.1
Arsenic (As)	0.5_a	0.5
Antimony (Sb)	0.5	0.5

a: For the products make-up powder, rouge, eye shadow, eyeliner, Kajal, carnival make-up

Table 2: Commonly used official limits of selected heavy metals applicable in some countries separately

Standards	*Lead (Pb)* **µg/g**	**Arsenic (As) µg/g**	**Cadmium (Cd) µg/g**	*Nickle (Ni)* **µg/g**
FDA	5.0	5.0_C-3.0_{CA}	NK	NK
WHO	10	3.0	0.3	0.1
Health Canada	10	1.0	3.0	3.0
BVL Germany	2.0	0.5^T	0.1^T	0.1
EU	0.5	**	0.5	**

C: in cosmetics, CA is in color additives, T in toothpaste

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The European Commission issued the Commission Regulation (EU) 2022/1176, to introduce a transparent market surveillance system for cosmetics including banned ingredients of skin products, however, no yet mention of new heavy metals trace rules or limits in cosmetics Although the FDA-GMP agreed to include the ISO 22716:2007 guidelines for industry guidelines, the FDA encouraged manufacturers to follow these guidelines and not strictly required them to be applied before marketing. The European Cosmetics Toiletry Perfumary Association (Coliba) and CTFA Cosmetics Toiletry Fragrance Association set up a guideline for stability testing of cosmetics in accelerated and normal conditions including physical and chemical integrity and appearance, however, testing of stability for the shelf life does not contain any influence of the presence of heavy metals and its effect on the stability of the formulation product [23]. FDA issued Cosmetics GMP guidelines specifying that under the law, cosmetics must not be manufactured under conditions that would allow them to become contaminated or harmful, only color additives must have FDA approval for their intended uses before marketing. Although huge work was done to highlight the harmful of these products the restrictions rules and enforcement are yet so far to be achieved. Thus, the main goal of this work is to focus on the need for unified international guidelines to evaluate cosmetics products for heavy metals and find out how much the impact of these differences between these guidelines on the last decision of accepting or refusing or withdrawing from the market.

Materials and methods

Sampling and pretreatment: Before analysis, the Henna leaves samples were dried at 85 °C in an air-ventilated oven for 12-24 hrs., then grounded into a fine powder using a mixer grinder, and sieved through a 250 µm mesh stored in sealed bags for further work. All reagents and chemicals used were of good or high purity. Metal standards were prepared each day. Known amounts of the certified standard stock solution (1000 ppm, Merck, Darmstadt Germany) were added to the three probes to give final concentrations in the range of 0.5 - 60 ppm for the selected metal except for Pb the range was 5.0-250 µg/ml. The concentration levels were driven by apparatus prescriptions, Ni: 0.5, 1.5 and 8 µg/ml; for As: 2.5, 10, 15 and 20 µg/ml. There was a good linear relationship between absorbance and standard concentration of the metals used. The linear correlation coefficients (r^2) for the metals were in the range of 0.9822-1.000. The limit of detection was estimated as the lowest concentration in calibration for a selected metal, and the limit of quantification (LOQ) values was defined as three times the LOD value was calculated for each metal. The accuracy of the method was determined by measuring the recovery of metal by spiking the standard solution of each metal for three concentrations and was found to be in the range of 0.89%-99.5%. All the solutions were prepared in double-distilled water. Dilution correction was applied for samples diluted or concentrated during analysis. The glassware was cleaned and immersed in 6.0% nitric acid for 24 hrs. Teflon beakers were treated with 6.0% nitric acid and washed with ultrapure water.

Sample collection and preparation: Cosmetic products were purchased from different shops (Tripoli, Libya, winter, 2022). These include different three brands of talcum powder, Henna leaves and paste imported by different stockholders and distributors except Henna Past is produced locally as homemade. Solid samples (1.0 g) were weighed in Teflon vessels (to avoid metallic contamination) and digested with a mixture of 6.0 ml of 65.0% nitric acid and 2.0 ml of 30.0% hydrogen peroxide was added, evaporated near dryness on a hot-plate for 10 min then the vessels left to cool then filtered with Whatman's No. 42 filter paper and <0.45 µm millipore filter paper. It was then transferred quantitatively to 50.0 ml volumetric flask topped up to the mark with deionized water. The digested 50.0 ml filtrate solution was transferred into an acid-rinsed polyethylene sample container with the label for analysis. The Atomic Absorption Spectrophotometer (Shimadzu, AAS-6300) was used for the determination of heavy metal concentration in various cosmetics products at the Drug and Food Control Center lab. Results were reported in mg/kg, and the absorbance measured was converted to

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concentrations using standard calibration curves. Standards of the metals of interest, found from Fluka Analytical (Sigma Aldrich, UK), the quantification of selected elements by duplicate determinations were performed and the percentage of RSD or (±cd) was calculated.

Results and discussion

As shown in **Table 3**, the concentration in (µg/g) of Pd, Ar, Cd and Ni were quantitatively determined in three brands of Henna leaves, three brands of Henna paste, three brands of Khol stones and three brands of baby Talcium powder. A good correlation of the concentration levels with absorbance was permitted to calculate the concentration with good standard deviations, samples were detected in comparable ranges above the limit of detection except in some metals the detection was lower than LOD due to minor concentration. The total average concentration of the subjected heavy metals showed that lead is the highest metal over the range according to the most used international guideline limits.

Table 3: The concentration in (µg/g) of some heavy metals in the cosmetics products in the Libyan market

Sample	Lead±SD	Arsenic±SD	Nickle±SD	Cadmium±SD
LEAV1	21.3±0.9	1.4±2.1	ND	0.8±3.1
LEAV2	08.2±2.9	1.7±0.4	ND	0.04±2.3
LEAV3	11.9±2.1	0.8±1.8	0.08±2.2	0.09±4.1
PAS1	29.2±3.1	3.5±1.9	0.09±2.3	1.7±3.6
PAS2	05.6±3.2	2.9±3.1	ND	1.2±4.5
PAS3	41.2±1.2	1.4±0.9	0.1±4.1	ND
BWD1	09.1±0.8	0.8±3.3	ND	ND
BWD2	33.6±1.6	1.9±0.7	0.08±4.8	0.8±4.9
BWD3	07.6±3.4	2.2±2.5	ND	ND
Koh1	54.4±3.1	3.4±1.1	0.05±5.9	0.07±3.1
Koh2	102.1±1.4	4.5±3.1	0.2±3.1	1.2±5.1
Koh3	89.8±0.6	1.4±2.5	1.5±5.5	ND

Where: LEAV (Henna leaves), PAS (Henna paste), BWD (Talc Baby powder), Koh (Kohl), ND (Not Detected)

In **Table 3**, the maximum level for each heavy metal as follows; Pb in Henna leaves and paste the maximum was 41.1 µg/g (1.2±SD) and in Talc baby powder was 33.6 µg/g (1.6±SD), however, in Kohl samples, Pb was at higher levels of 102.1 µg/g (1.4±SD). As in Henna products reached to 2.9 µg/g (3.1±SD), in Talc baby powder it was 3.2 µg/g (2.5±SD), in Khol samples Ar reached 4.5 µg/g (3.1±SD). Ni in Henna products was 0.9 µg/g (2.3±SD) in Talk baby powder it was 0.08 µg/g (4.8±SD), and in Khol it reached 1.5 (5.5±SD). About Cd in Henna products, the higher level was 1.7 µg/g (3.6±SD) in baby powder only 0.8 µg/g (4.9±SD) Cd was detected was higher than in Khol as 1.2 µg/g (5.1±SD). The distribution frequency of metals among the samples was; in the order of Pd > As > Cd > Ni. This was by other similar reported works [24-26]. By the selection of common guidelines used, the evaluation of the presence of these heavy metal traces will be subjected to the limits specified by each guideline. In the USA, only color additives must have FDA approval for their intended uses before marketing, the other heavy metals are not required for FDA approval before marketing but it should confirm the cosmetic labeling only. The new FDA meeting insisted on adding some GMP requirements to the old GMP guidelines issued in 2013 and evaluated and revised this year. In the European Union, the EU regulation (1223/2009) does not permit the presence of heavy metals except if it is in small traces that are unavoidable which is not identified yet, thus all the samples investigated exceeded the European regulations because they contained possible avoidable levels of heavy metal traces. According to the limits set by the German (BVL), all samples containing higher limits of Pb, for Arsenic (A and Cd) all samples passed the limit of 0.5 and 0.1 ppm, respectively, which is specified for only toothpaste which was not included in our studies, however for Ni the limit set as 0.1 ppm, only two samples passed this level (Khol

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2, 3). According to WHO limits, samples containing high levels of Pd and passed the level of 10 ppm except for three samples, for Ar the limit of three ppm was passed in three samples. For Ni only three samples are below the limit of 1.0 ppm of Ni, Cd, and only four samples are below the limit of 0.3 ppm. Using the Canadian Health limits, for Pd all the samples contained high levels of Pd, except four samples, for Ar, all samples passed the limit of 0.1 ppm. Regarding the levels of Cd and Ni the limit of three ppm, no samples exceed this limit. According to the variations of heavy metal limits applied in this work, therefore, most of the samples contained a high content of Pd in folds of concentration according to guidelines. Differences were high between the USA-FDA and EU regulations; some similarities can be noticed between WHO and Canadian guidelines for heavy metals levels, German levels were the lowest and can be adapted and developed towards avoidable and detected levels. Accordingly, trace heavy metals judgment is difficult due to the difference in each heavy metal limit between the guidelines and countries so the use of individual guidelines cannot be useful unless the minimum levels of these heavy metals are harmonized in one guideline and approved to be legally applicable during cosmetic manufacturing or aftermarket QC, besides standard procedures should be also presented concerning the complains. As they are determined and quantified in this study under possible available QC manner, trace heavy metals are still present even in the best quality products and despite the application of GMP taken by some manufacturers. The results of the study can be an important awareness of the need to minimize or stop the use of some heavy metals in cosmetic products. The contamination also comes from environmental sources of different temperate zones and industrial pollution. This work comes under the same advice of other work done in different parts of Libya [24] concluded that these products are considered a potential source of heavy metals poisoning due to their intensive use and increased body intake of heavy metals through percutaneous absorption or by inhalation. In this study, the application of international guidelines with different heavy metal limits was used to prove the need for harmonized acceptable heavy metal levels to be worldwide applicable. The results lead to the conclusion that constant control of metallic content or impurities in these products and other facial cosmetics should be seriously considered.

Conclusion: A consequence of the growing usage of cosmetics, it is necessary to pay special attention to producing safer ingredients for cosmetic products, quality controls should be recommended for products designed to enter into long-term contact with the skin such as creams, powders and paste, the procedures of post-market surveillance to ensure that safety and quality of products are monitored through manufacturing, transport and storage. Thus, there is a need to develop and update the national specification for cosmetics by the Libyan National Centre for Standardization and Metrology (LNCSM) to protect consumers from more catastrophic cosmetic hazards.

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