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EVALUATION OF RISKS AND NECESSITY OF REGULATIONS OF THE USE OF NICKEL, CADMIUM AND LEAD IN JEWELLERY

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Abstract. Such metals as nickel, cadmium and lead may influence human health even in low concentrations. Therefore their use in jewellery is considered to be dangerous. Nickel in the alloy can cause allergic contact dermatitis whereas cadmium and lead in children's jewellery can influence the development of different organs and systems. For that reason the use of nickel, cadmium and lead in jewellery should be regulated by the government structures. A number of countries have already successfully implemented the regulations that restrict the use of these metals in jewellery. Hopefully, their experience will help to implement such regulations worldwide in order to provide the safety of consumers by avoiding the use of nickel, cadmium and lead in jewellery alloys.

Keywords: nickel, cadmium, lead, nickel allergy, children, health effects, standards, regulations.

FORMULATION OF THE PROBLEM.

The use of nickel, cadmium and lead in jewellery has been chosen as the object of this article due to the fact that these metals are the common cause of various disorders in the general population. The research has shown that these metals can influence human organism even in low concentrations therefore their use in jewellery is a risk to human health, especially for children and people who are inclined to various allergic reactions.

ANALYSIS OF RESEARCH AND PUBLICATIONS.

Today we are provided with an extensive database of detailed research of the health effects of nickel. Thyssen J. and Menné T. in their articles examine the problem of contact dermatitis as well as nickel allergy. Fernanda Torres and Antonella Tosti analyse the statistics of nickel allergy in the world as well as the reasons of this allergy, preventative and therapeutic strategies which help to avoid or cope with allergic contact dermatitis. The toxic effects of cadmium and lead on human body are also well studied. Many studies over the years have yielded evidence that cadmium may contribute to kidney and prostate cancers in humans. (Waalkes MP. Mutat) A limited number of epidemiologic studies have examined associations between cadmium and the development of other hormone-dependent cancers such as those of the breast and the endometrium. However, there are still controversies about the risks of using cadmium and lead in jewellery. Most scientists agree that mostly children under 6 years old are in danger as they are more likely to ingest it orally. The main difficulty of studying the effects of low-level exposure of cadmium and lead on human health is that the results of their permeation and accumulation in the organism during childhood may appear throughout the whole life, so the research may last for years. Nevertheless, M. Nathaniel Mead in the article "Cadmium Confusion: Do Consumers Need Protection?" proves that there are real risks in the use of cadmium in children's jewellery. Another research carried out by Bruce P. Lanphear, Richard Hornung, Jane Khoury and other scientists from all over the world confidently proves the neurobiological effects of low-level exposure of lead among children.

There are, however, much less publications about the regulations of the use of nickel, cadmium and lead in jewellery. The problem of unregulated use of different metals in jewellery alloys remains in many countries, in which the safety of jewellery does not get a proper

attention.

THE PURPOSE OF THE ARTICLE.

The purpose of this article is to analyse the effects of nickel, cadmium and lead on human organism and to examine the already existing experience of implementing regulations of their use in jewellery in order to develop a complex strategy and practical recommendations on the government regulations which restrict the use of nickel, cadmium and lead in jewellery alloys.

THE MAIN MATERIAL.

Nickel is an important cause of allergic contact dermatitis (ACD) in the general population, both among children and adults, with a worldwide prevalence of around 8.6%. The prevalence among young females is even higher, around 17% [2]. Among dermatitis patients, the prevalence of metal allergy is even higher. Most cases are due to nonoccupational exposure. Nickel allergy affects women 3 to 10 times more than men and is usually due to daily contact with jewellery, garments and wristwatches.

Nickel is the number one allergen in frequency of positive patch test reactions. Reports from the North American Contact Dermatitis Group (NACDG) revealed that 16.2% of the US population showed a positive reaction to nickel, documenting an increase from 14.3% in the 1994–1996 study period. In Central Europe, 12.9% of the patch tested population is positive to this metal. In another study of the European Surveillance System of Contact Allergies 20% of 9871 tested patients were sensitized to nickel, with the highest prevalence in Italy (32.2%), and lowest in Denmark (9.7%). Duarte showed that in adolescents with a positive patch test reaction, 31% were allergic to nickel, making it the most common allergen in this age group.

Ear piercing is the most common cause of sensitization, and thus represents a strong risk factor for nickel allergy. Nickel ACD occurs when metallic items, corroded by human sweat, saliva, and other body fluids, release free nickel ions that act as haptens, inducing sensitization [2].

The only way to prevent recurrence is avoiding skin contact with metallic items that release nickel. It has been documented that this strategy results in a statistically significant decrease in the frequency of hand eczema in nickel-sensitive individuals. The epidemiology of metal allergy has recently changed in Europe as nickel allergy among ear-pierced Danish women has decreased following regulatory intervention on nickel release from

consumer products. In the United States, the prevalence of nickel allergy is still increasing, which may be explained by the absence of regulation [1].

The use of cadmium and lead in jewellery can cause a systematic influence on human organism if the ions of metal permeate the organism.

Lead is a toxic metal, which doesn't break down in the environment and accumulates in our body. High levels of lead have been found in jewellery, especially inexpensive children's jewellery. Exposures to lead can lead to a number of health problems, including: behavioural problems, learning disabilities, joint and muscle weakness, anaemia, organ failure. Children 6 years old and under are most at risk because their bodies are growing quickly. Jewellery containing lead poses a particular concern because children are prone to placing jewellery in their mouths, which can result in absorption of dangerous levels of lead [5].

An extensive database has provided a direct link between low-level lead exposure during early development and deficits in neurobehavioral-cognitive performance evident late in childhood through adolescence. The studies have demonstrated the presence of a constellation of neurotoxic and other adverse effects of lead at blood lead (BPb) levels at least as low as 10 µg/dl [6]. Furthermore, in 2005 a group of scientists published a detailed article with the results of the study that proved the association of intellectual deficits and blood lead concentration for children who had maximal blood lead levels < 7.5 µg/dL [7].

Cadmium has well-established renal, bone, and pulmonary effects, with less conclusive evidence for neurotoxic, teratogenic, and endocrine-disrupting effects. Even relatively low chronic exposure can cause irreversible renal tubule damage, potentially progressing to glomerular damage and kidney failure; bone loss often is seen in concert with these effects. Pulmonary effects, particularly lung cancer, are largely seen in occupationally exposed populations. [3]

The greatest risk with cadmium and lead is if children ingest it orally, for example by sucking the jewellery or managing to swallow it. There is also a risk that cadmium and lead can detach itself from the jewellery and end up on the hands and then enter the mouth via food. The skin does not absorb much of these metals so skin contact only does not involve a major risk [4].

Due to the risks which have been already listed, the restrictions of use of nickel, cadmium and lead in jewellery are necessary to provide safety for consumers all over the world. A number of the leading countries of the world have already implemented the regulations of these metals use.

The first step to control the use of nickel in European Union was the Nickel Directive which regulated the use of this metal in jewellery and other products that come into contact with the skin. The Nickel Directive imposes limits on the amount of nickel that may be released from jewellery and other products intended to come into direct and prolonged contact with the skin. These limits, known as migration limits, are:

- 0.2 µg/cm²/week for post assemblies which are inserted into pierced ears and other pierced parts of the human body;
- 0.5 µg/cm²/week for other products intended to come into direct and prolonged contact with the skin.

Since 1 June 2009, it has been subsumed into the REACH Regulation, specifically item 27 of Annex XVII to that regulation. Today EU Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulates the use of nickel, lead and cadmium.

REACH addresses the production and use of chemical substances, and their potential impacts on both human health and the environment [8]. The important provisions in REACH, governing the use of chemicals in jewellery are:

- Restricted chemicals falling under Annex XVII of REACH which include: Cadmium, Chromium (VI), Lead, Nickel (migration), Polycyclic aromatic hydrocarbons (PAHs).
- Substances of very high concern (SVHCs) on the Candidate List for the purpose of:
 - Article 7(2) of REACH 'Notification of substances in articles';
 - Article 33 of REACH 'Duty to communicate information on substances in articles'.

In 2011 EU Regulation (EC) No 1907/2006 REACH amended the content of cadmium: it is prohibited to use cadmium in jewellery that is manufactured after this change, the content of cadmium in already existing jewellery must not exceed 100 mg/kg.

On April 23, 2015, the European Commission amended the Annex XVII of Regulation (EC) No 1907/2006 REACH. These changes are made to prevent the risk of multiple exposures to lead and its compounds among children, especially before the age of 36 months. It is prohibited to sell products in which the mass fraction of lead exceeds 0.05%, if during using these products as intended they may be in contact with children.

A number of countries outside of the European Union, such as Serbia, Switzerland and Turkey, have started to implement REACH-regulations or are in the process of adopting such a regulatory framework to approach a more globalized system of chemicals registration under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Some other non-EU countries have developed their own standards and regulations for jewellery alloys.

Health Canada regulates both lead content and migratable lead in jewellery that appeal primarily to children under 15 years of age. Canada has been closely monitoring the levels of cadmium in children's jewellery since requesting the industry to stop intentionally using cadmium in 2010 and the publication of a proposed regulation for these products in 2011. The overall framework for product safety is the Canada Consumer Product Safety Act (CCPSA). The specific requirements are governed by:

- Children's Jewellery Regulations (SOR / 2018-82);
- Consumer Products Containing Lead Regulations (SOR / 2018-83)/

This document regulates the use of metals in the following quantities:

- cadmium no more than 130 mg/kg;
- lead no more than 90 mg/kg [9].

In the US, jewellery products intended primarily for children aged 12 years and under are regulated by the Consumer Product Safety Improvement Act of 2008 (CPSIA). Across the nation, a host of jurisdictions regulate adult and/or children's jewellery with unique specifications. There are two American standards for jewellery. ASTM F 2923 for children's jewellery and ASTM F2999 for adult jewellery.

Jewellery for China is regulated by two mandatory standards. These are:

- GB 28480 'Adornment-Provision for limit of baneful elements';
- GB 11887 'Jewellery-Fineness precious metal alloys and designation'.

According to these standards, jewellery must not contain more than 100 mg/kg of cadmium, no more than 300 mg/kg of lead for children's jewellery and no

more than 1000 mg/kg of lead for other jewellery. The migration of nickel must not exceed 0.2 $\mu\text{g}/\text{cm}^2/\text{week}$ for post assemblies which are inserted into pierced ears and other pierced parts of the human body and 0.5 $\mu\text{g}/\text{cm}^2/\text{week}$ for other jewellery [10]. So the restrictions for cadmium and nickel are similar to those in European regulations although the limits for lead are much higher in comparison to EU and Canadian regulations.

The concern of public and the awareness of harmful effects of cadmium and lead on human health also caused the development of regulations in Brazil. In November 2013, the Brazilian National Health Surveillance Agency (ANVISA) reported that a shipment of 16 tonnes of cadmium-containing jewellery was detained at the Port of Rio de Janeiro. Although the high concentrations of cadmium found in these products did not present an imminent and significant risk to the public, the impounding led to the development and publication of legislation in 2016, to regulate the use of lead and cadmium in jewellery. Jewellery destined for Brazil is

governed by Ordinance No. 43, of January 22, 2016, which restricts the use of cadmium and lead in jewellery and came into effect on January 26, 2016.

CONCLUSIONS AND SUGGESTIONS.

Overall, it may be concluded that it is necessary to regulate the use of nickel in jewellery or at least mention its presence in the alloy in the labelling of jewellery for all age groups because of the frequent allergic reactions to this metal. The absence of cadmium and lead is mostly important for children as they are more likely to put their jewellery into their mouths. Therefore it is advisable to provide the regulations that prohibit the use of cadmium and lead in children's jewellery in order to prevent the harmful effects of constant low-level exposure of cadmium or lead that can appear throughout a whole human life. After the implementation of all the necessary regulations, it is advisable to carry out a research of their impact on the health of the population in order to prove or disprove the effectiveness of these measures.

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