SOFT plastic, HARSH truth 2

From Regulation to reality: Have we cleared the Serbian market of restricted toxic phthalates?

ALHem Alternativa za bezbednije hemikalije | Safer Chemicals Alternative

ARNIKA

CZECH AID

TRANSITION

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Executive Summary

Safer Chemicals Alternative (ALHem) from Serbia and Arnika located in the Czech Republic analysed phthalates in everyday products as part of the project "*Youth for Healthy Serbia*". This project aims to engage young people in advocacy processes while enhancing dialogue and cooperation with decision-makers and other stakeholders. The goal is to increase young persons' participation in decision-making, particularly in health and environmental protection. To achieve this, ALHem has developed a comprehensive Program, "*Youth for a Non-Toxic Environment in Serbia,*" that encompasses education, advocacy training, and effective communication. The program's ultimate objective is to launch an advocacy initiative focused on ensuring the enforcement of regulations that restrict certain phthalates in consumer products on the Serbian market. This project received financial support from the Transition Promotion Programme of the Ministry of the Czech Republic.

As part of this project, ALHem and Arnika, in cooperation with youth representatives, will assess the effectiveness of phthalate restrictions in consumer products on the Serbian market.

This study is part of ALHem's ongoing efforts to monitor hazardous chemicals in consumer products available in Serbia. Our goal is to raise public awareness about the presence of toxic phthalates in everyday items that people regularly encounter. By highlighting these concerns, we aim to ensure that inspection controls are in line with national legislation on consumer safety regarding hazardous substances.

The primary objective of this specific study was to examine the presence of four specific phthalates in plastic products on the Serbian market: bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and diisobutyl phthalate (DIBP). Sampled products were bought in shops in Belgrade in July 2024 and laboratory testing was conducted at the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" in August 2024.

DEHP, DBP, BBP and DIBP were selected for the study because as of July 8, 2020, the EU has imposed restrictions on consumer products containing these four phthalates at concentrations exceeding 0,1%. Restricted substances are widely used plasticizers known to have toxic effects on reproduction and can disrupt hormonal systems, posing significant health risks. The restriction proposal considers cumulative effects and combined exposure from various products, highlighting the inadequately controlled risk to human health.

This restriction has been implemented in Serbian legislation, making it illegal to sell products containing these phthalates on the Serbian market since July 8, 2023. A comprehensive campaign is underway to evaluate the effectiveness of regulatory enforcement related to these restrictions.

Unfortunately, the results of the laboratory testing revealed that these phthalates were detected in 19 out of 30 samples (representing 63% of the total tested) at concentrations exceeding 0,1%, with levels ranging from 0,15% to as high as 50%. The phthalates were found in various products, including school bags, girls' bags, children's raincoats, PVC ladies' makeup bags, PVC fabric tarpaulins, bicycle cable locks, artificial leather, PVC wallpaper, self-adhesive PVC foil, car steering wheel covers, non-slip bathmats, boxing gloves, and car mats—all purchased in shops in Belgrade.

It is concerning that phthalates were found in product and that some of the sampled products are used by children and young people. Furthermore, the tested phthalates were detected in raw materials such as PVC fabric and imitation leather, which may be utilized in various applications, including indoor playgrounds, furniture, and fashion accessories, potentially leading to significant exposure.

Given that we have identified products that should not be on the market, we informed the responsible ministries, urging them to promptly withdraw from the market the products we have flagged for illegal concentrations of restricted phthalates.

It is also vital to strengthen inspections of PVC products in general use—not just at borders but throughout domestic markets. An effective inspection campaign must be implemented to ensure that products containing restricted phthalates are not allowed on the market.

During this comprehensive inspection, it is essential to communicate clearly to manufacturers, importers, distributors, and retailers that these products are prohibited. This is especially important given the large number of items made from flexible PVC plastic and the challenges of testing all these products for restricted phthalates.

We also requested that the Ministry of Health provide information on non-compliant products and the actions taken in response to the Ministry of Trade, which oversees the NEPRO system for the rapid notification of unsafe products in the Republic of Serbia. This information is essential for effective market surveillance and should be entered into the NEPRO database to ensure that it is publicly accessible to the citizens of Serbia.

Introduction

Safer Chemicals Alternatives – ALHem (Serbian NGO) and Arnika (Czech NGO) are presenting the findings of a new study aiming to monitor the actual implementation of phthalate restrictions in everyday consumer products, specifically the regulation restricting the use of phthalates (DEHP, DBP, BBP, DIBP). The provisions entered into force in the EU on July 8, 2020, and in Serbia on July 8, 2023.

In recent years, ALHem has conducted three campaigns, "The Fight to Know![1]", "CRY-GAME[2]", and "SOFT Plastic, HARSH Truth[3]", focused on testing products for phthalate content in the Serbian market. These campaigns revealed that many everyday consumer products contain phthalates, which pose risks to health and the environment. The 2020 campaign, "Soft Plastic, Harsh Truth," addressed the delayed transposition of EU regulations regarding the restriction on phthalates in everyday consumer products in Serbia. During the campaign, we discovered that one-third of the 30 tested products contained phthalates at levels exceeding allowable limits. This restriction was officially enacted in Serbia in 2022, allowing the companies a year to adapt to the new regulations. This testing aimed to evaluate the effectiveness of regulatory enforcement regarding the restriction of four phthalates (DEHP, DBP, BBP, DIBP) in everyday consumer products. Serbian legislation incorporated this restriction, which mandates that products containing these restricted phthalates cannot be sold on the Serbian market after July 8, 2023.

1 The Fight to Know.

2 CRY-GAME, Phthalates in plastic toys and childcare articles, 2019.

3 SOFT Plastic, HARSH Truth, 2020.

Legislation

EU Chemicals Legislation - REACH Regulation and the Serbian Law on Chemicals

The European Union's REACH Regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals took effect in 2007. Its primary objective is to safeguard human health and the environment from the dangers posed by harmful chemicals. Among other provisions, the REACH Regulation imposes prohibitions and restrictions on the production, use, and placement of specific hazardous chemicals and the products that contain them on the market (REACH Annex XVII). The restrictions under the REACH Regulation are regulatory measures designed to protect human health and the environment from unacceptable risks associated with chemicals.

Serbian legislation, particularly the Law on Chemicals (adopted in 2009) and related secondary legislation, partially aligns with REACH requirements. Serbian legislation on chemicals includes crucial provisions regarding restricted chemicals. An analysis of the alignment between domestic and EU regulations concerning bans and restrictions reveals a satisfactory level of harmonization at present. Serbian chemicals legislation also prescribes measures for managing chemical safety, classification, labeling, and packaging of chemicals, as well as regulating the import and export of controlled substances. It outlines the process for obtaining licenses and permits for their use and establishes protocols for enforcement and monitoring. Additionally, the law provides for creating an integrated chemical register containing information about chemicals available on the Serbian market.

Phthalate restrictions

The EU's REACH regulation, which restricts four specific phthalates—bis(2-ethylhexyl) phthalate (DEHP; CAS 117-81-7), dibutyl phthalate (DBP; CAS 84-74-2), diisobutyl phthalate (DIBP; CAS 84-69-5), and benzyl butyl phthalate (BBP; CAS 85-68-7)—came into effect on July 7, 2020. This regulation mandates that these substances must not exceed a concentration of 0,1% by weight, individually or in combination, in any plasticized material used in consumer products or indoor environments (Annex I part 1). Therefore, since July 2020, DEHP, DBP, DIBP, and BBP have been restricted across a wide range of products, including flooring, coated fabrics, mattresses, footwear, office supplies, and other consumer items.

Three years after the EU implemented these restrictions, Serbia adopted similar provisions through the Rulebook on Amendments to the Rulebook on Restrictions and Prohibitions on the Production, Marketing, and Use of Chemicals (Official Gazette of the RS No. 57/22) (Annex I part 1). This rulebook, specifically prohibition entry number 51, states that the restrictions will take effect starting in July 2023.

There are also three additional restriction entries in REACH and Serbian chemicals legislation related to ortho-phthalates:

- Entry 30: All phthalates with a harmonized classification as Tox. Repr. 1A or 1B are restricted from being placed on the market for consumers' supply at or above specific or generic concentration limits as substances, or as constituents of other substances or mixtures.

- Entry 52: DINP, DIDP, and DnOP are restricted in plasticized materials, toys, and childcare articles that can be placed in the mouth by children at concentrations ≥ 0,1% (w/w).

- Entry 72: diisopentyl phthalate, 1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters (C7-rich), bis(2-methoxyethyl) phthalate, dipentyl phthalate, and dihexyl phthalate shall not be

placed on the market in consumer clothing, related accessories, and other textiles that come into direct contact with the skin.

The ortho-phthalate group includes several substances that have undergone regulatory scrutiny, such as restrictions, identification as substances of very high concern (SVHC), and inclusion in the Authorization List. However, many structurally similar compounds within this group remain unregulated, including those that contain regulated phthalates as constituents in significant concentrations.

As of July 2023, Serbia banned placement of market articles containing phthalates (DEHP, BBP, DBP, and DIBP) at concentrations of 0,1% by weight or higher, individually or in combination, in any plasticized material. This restriction has been in effect in the EU since July 2020. Serbia is three years behind the EU in efforts protecting human health and the environment from exposure to these toxic chemicals.

Phthalates Production and Use

Phthalates, specifically ortho-phthalates[4], are the most used plasticizers globally with an annual consumption of 8,4 million tons[5]. In the EU, over 900 000 tonnes of plasticizers are consumed annually. Over 85% of all plasticizers consumed in Europe are used in flexible PVC applications, largely for the construction, automotive, wire, and cable sectors[6] as can be seen in figure 1. Polyvinyl chloride or PVC is the third largest-selling commodity plastic in the world after polyethylene and polypropylene, followed by polystyrene[7].

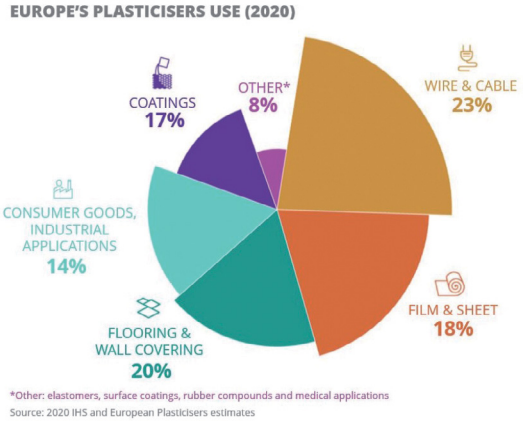

Figure 1. Use share of plasticizers in PVC applications by sector market (taken from European Plasticizers 2001, Plasticisers factsheet).

Ortho-phthalates are the most widely consumed plasticizers due to their high compatibility with PVC.

Ortho-phthalates are primarily used as plasticizers to add flexibility and resilience to plastic products. In addition to their main technical function as plasticizers/softeners, ortho-phthalates can have other functions, too, e.g., as solvents, binders, lubricating agents, dispersing agents, fillers, intermediates, emollients, antioxidants, process regulators, dust suppressants, and phlegmatizers.

[4] The phthalate esters family includes subgroups such as orthophthalates, isophthalates, and terephthalates, which differ in the relative position of the two carboxylates in the benzene ring, i.e., ortho, meta, or para positions, respectively.

[5] https://www.hbm4eu.eu/hbm4eu-substances/phthalates-and-hexamoll-dinch/

[6] EUROPEAN PLASTICISERS 2021. Plasticisers factsheet

[7] ECHA 2023. Investigation report on PVC and PVC additives

Ortho-phthalates are used in a variety of products, e.g., in polymers, plastic articles, plastisol, dry-blends, thermoplastics, paint/coating/inks, adhesives, rubber, lubricants/waxes/polishes, metal working fluids, curing agents, hydraulic fluids, catalysts, solvents, sealants, construction materials or cosmetics.

In the EU, there has been a transition from low molecular weight (LMW) ortho-phthalates (DIBP, DBP, BBP, DEHP), which are identified as SVHC and restricted under the REACH Regulation, to higher molecular weight (HMW) phthalates[8]. The most common types of high ortho-phthalates include di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP), and other phthalates. Figure 2 below shows the distribution of the most common plasticizers in the European market.

Although the use of phthalates as plasticizers has somewhat decreased in the European Union due to legislative measures, substances like DINP, DPHP, and DIDP continue to be produced and used in many applications. They account for just over 50% of the European plasticizers market.

However, outside the EU, low molecular weight ortho-phthalates represent approximately 35% of global consumption. These substances are predominantly produced and utilized in regions such as China, India, and other parts of Asia, as well as in the Middle East, Africa, and Latin America.

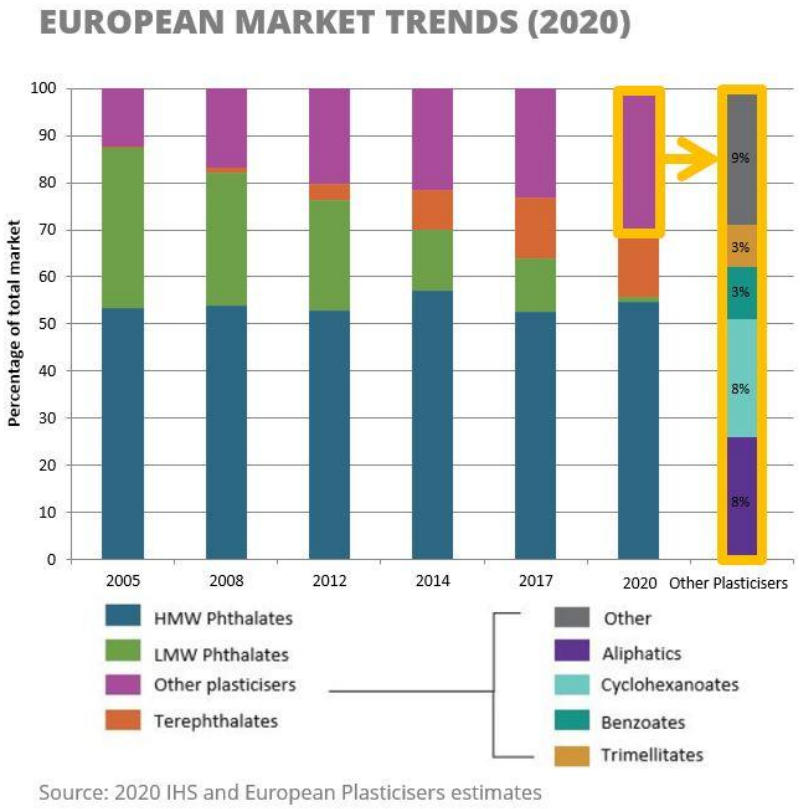

Figure 2. Distribution of most common plasticizers in the European market (taken from European Plasticizers 2001, Plasticisers factsheet)

[8] Phthalates are manufactured by reacting phthalic anhydride with alcohol(s) ranging from methanol and ethanol (C1/C2) to tridecyl alcohol (C13). Ortho-phthalates are broadly divided into two main distinct groups: low-molecular-weight and high-molecular-weight ortho-phthalates, which have different applications, classifications, and legal requirements. High-molecular-weight or high ortho-phthalates include those with 7-13 Carbon atoms in their chemical backbone, increasing their permanency and durability.

Health Risk of Phthalates

We are exposed to phthalates through food, skin, and air. Since these chemicals are not chemically bound to the materials they are added to, they can easily leach out or evaporate into the environment.

Several ortho-phthalates, such as DEHP, DBP, DIBP, and BBP, can harm fertility and affect fetal development while disrupting our hormonal system (endocrine disrupting substances[9]). Regarding male health, these substances can interfere with the development of endocrine system from young age, potentially leading to infertility in adulthood. The exposure to hormone-like substances is also held responsible for the declining fertility of men, which has been observed in Europe for decades. In addition, pregnant women and young children are among the most vulnerable groups to the effects of phthalates. Certain ortho-phthalates, including DBP, BBP, and DEHP, also pose significant environmental risks.[10]

The findings from HBM4EU[11], the largest human biomonitoring project conducted between 2017 and 2022 in the EU, revealed significant direct exposure to harmful chemicals within the EU population. This was assessed through laboratory analysis of 18 priority substances and substance groups in biological samples such as urine, blood, and hair collected from a network of EU laboratories. Notably, metabolites of phthalate breakdown were found in the urine of nearly all tested samples from children and teenagers, totaling 2880.

Within the HBM4EU project to generate data for risk assessment, policy development, and evaluations, a mixture risk assessment is underway for five selected phthalates[12] (DEHP, DBP, DIBP, BBP, and DiNP). Preliminary results indicate that approximately 17% of European children and teenagers may be at risk of adverse effects from combined exposure to these five anti-androgenic phthalates. Additionally, the assessment revealed that for most European children and teenagers, the combined risks stem from multiple phthalates. These results highlight that the mixture risk for the majority of children and teenagers would likely have gone unnoticed in traditional single-substance risk assessments.

The potential release of phthalates from products is particularly concerning, as large quantities are often added to polymers to achieve desired properties. Overall, this group of substances presents a high potential for exposure among professional workers, consumers, and the environment.

Consumers may encounter phthalates in a variety of everyday items, including kitchen and bathroom products, school supplies, imitation leather furniture, flooring, vinyl wallpaper, shoe soles, electrical and electronic devices, cables, office equipment, toys, and baby products. Given

[9] Endocrine-disrupting chemicals are substances that can impair the functioning of the endocrine system by taking over the role of hormones and blocking hormone receptors, which can, in turn, affect the development and functioning of the body. The effects of endocrine-disrupting substances depend significantly on when they enter the body. They are particularly harmful if they enter the body during critical phases of life, such as pregnancy (when they can influence the development of the fetus), early childhood, and adolescence. During these critical developmental periods, it is necessary to take extraordinary measures to protect people against exposure to, and the effects of, endocrine-disrupting substances, as even minimal doses can be harmful to development.

[10] https://echa.europa.eu/hot-topics/phthalates , Candidate List of substances of very high concern for Authorisation, Annex XV restriction report proposal for a restriction substance names: four phthalates (DEHP, BBP, DBP, DIBP)

[11] HBM4EU – science and policy for a healthy future

[12] HBM4EU Substance report, Phthalates and Hexamoll® DINCH

this widespread exposure, it is crucial to remain alert regarding products containing phthalates.

In conclusion, the primary health risk associated with ortho-phthalates is their reproductive toxicity. Many of these substances have harmonized classifications for reproductive toxicity, primarily affecting development and, in many cases, fertility. They share structural similarities, differing mainly in the length and branching of their alkyl chains. Additionally, some ortho-phthalates are identified as endocrine disruptors.

Exposure levels are significant, as indicated by registration data under EU REACH. Many registered substances are widely used in high volumes, posing potential risks to human health and the environment. These substances are registered for industrial use by professionals, consumers, and in various articles.

As a result, the EU is considering further regulatory measures, such as group restrictions for additional ortho-phthalates based on their structural similarities. This is particularly important due to the cumulative and additive effects of various phthalates and the presence of shorter-chain phthalates already identified as hazardous in longer-chain compounds.

The impact of phthalates, especially in their everyday use as plasticizers in PVC, cannot be separated from assessing PVC's harmful effects, particularly in flexible forms.

Considering the risks associated with PVC production and use, the European Chemicals Agency has developed a comprehensive document[13] addressing various hazards related to its lifecycle—production, use, recycling, and disposal. The document also specifically examines the effects of flexible PVC, its impact on production, use, and the recycling industry, as well as broader environmental impact. **A key conclusion emphasizes the need to replace plasticizers with safer alternatives and explore substituting PVC with less harmful materials in certain applications.**

[13] ECHA 2023. Investigation report on PVC and PVC additives.

Results of Laboratory Testing

Methods used for sampling

Samples of simple consumer products, not categorized as toys or childcare articles, were purchased from various retailers, including both European companies and Serbian businesses.

These products were made from one or two plastic materials, mainly PVC.

In total, 30 samples were tested for phthalate content at an accredited analytical laboratory in Belgrade. Table 1 details the types of products selected for phthalate analysis.

Table 1. Types of sampled products

Article's type	Number
School supplies (school bags)	4
Clothes, footwear, accessories (girls´ bag, toilet-makeup bags, kids´ raincoats, slippers)	11
Household and recreational equipment, other (non-slip bathmat, dining table cover, inflatable swimming ring, PVC fabric tarpaulin, imitation leather fabric, boxing gloves, self-adhesive PVC foil, car mat, car steering wheel cover, stickers for decoration, wallpaper, bicycle cable lock)	15
Total	30

The products were analyzed for the **presence of four phthalates**, bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and diisobutyl phthalate (DIBP). These four phthalates were chosen because they have been the subject of broad restrictions in Serbia since July 2023 (see the section on Legislation).

The restriction on phthalates in the Serian legislation and EU REACH Regulation stipulates that articles shall not be placed on the market if they contain the phthalates that were tested in a concentration equal to or greater than 0,1% by weight (individually or in any combination of the phthalates listed in Table 2.) of the plasticized material in the article. That means if the article contains plastic parts and metal (e.g., a toilet/makeup bag with a zipper), phthalates are examined only in the plastic part of the article, and the concentration is calculated only for that plastic part.

Table 2. Tested phthalates

	Substance	EC number	CAS number
1	Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
2	Dibutyl phthalate (DBP)	201-557-4	84-74-2
3	Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
4	Diisobutyl phthalate (DIBP)	201-553-2	84-69-5

Laboratory test methods

In August 2024, laboratory tests to determine the content of phthalates were conducted at the Institute for Public Health of Serbia "Dr. Milan Jovanovic Batut" in Belgrade. The Accreditation Body of Serbia accredits the laboratory in accordance with the SRPS ISO/IEC 17025:2017 standard. It employs an accredited methodology designed explicitly for analyzing phthalate content in various product samples, particularly those made from plastic materials.

The samples were prepared and analyzed following the Scope of Accreditation document, 01-130, outlined in the accreditation method VDM-98. This method includes the determination of softener content for the following phthalates: Butyl benzyl phthalate, Di-butyl phthalate, Di-(2-ethylhexyl) phthalate, Di-n-octyl phthalate, and Di-isononyl phthalate. The HPLC/DAD technique was utilized for testing in accordance with the CPSC-CH-C1001-09.3 Standard Operating Procedure for Phthalate Content Determination, effective April 1, 2010. This methodology is accredited for use in children's toys, plastic

materials, and articles intended for food contact, covering concentrations ranging from 0,01% to 30% (m/m).

The results of the tests are detailed in the report. Notably, the di-isodecyl phthalate (DIDP) was conducted using the same methodology as the accredited phthalates (VDM-98), although this specific phthalate is not yet accredited. For Di-isobutyl phthalate (DIBP), we utilized the HPLC method (VDM-237#) with slight modifications to the chromatographic conditions to separate Di-butyl phthalate and Di-isobutyl phthalate effectively. The sample preparation for both analyses followed the same accredited method.

Both VDM-236# and VDM-237# methods have been validated, and all relevant parameters—including selectivity, accuracy, linearity, precision, and robustness—were thoroughly checked to ensure reliable results.

Results for the phthalates that were analysed in selected products

Phthalates in concentrations above 0,1% were found in 19 of the 30 samples, i.e., 63% of the articles tested for phthalates (see Figure 3), especially the phthalate DEHP (see table in Annex II), with concentrations ranging from 0,15 to 50 %. The highest amount was found in kids´ raincoat (up to 50%). Both phthalates DBP and DIBP were found in one sample, in a bicycle lock, in concentrations of 4,7% and 23,7% respectively. Phthalate BBP was not detected in concentrations above 0,1% in any of the tested articles.

Analysed phthalates were found in:

- school bag,
- girls´ bag,
- kids´ raincoat,
- wallpaper,
- toilet/makeup bag,
- PVC fabric tarpaulin,
- imitation leather fabric,
- self-adhesive PVC foil,
- car steering wheel cover,
- boxing gloves,
- bicycle cable lock,
- car mats.

It is alarming that phthalates are found in products used by children and young people. Another important observation is that phthalates are found in raw materials such as fabrics that downstream users and consumers can use for different purposes.

Annex II includes a table with the phthalate content of the tested samples, and Annex III shows pictures of tested samples.

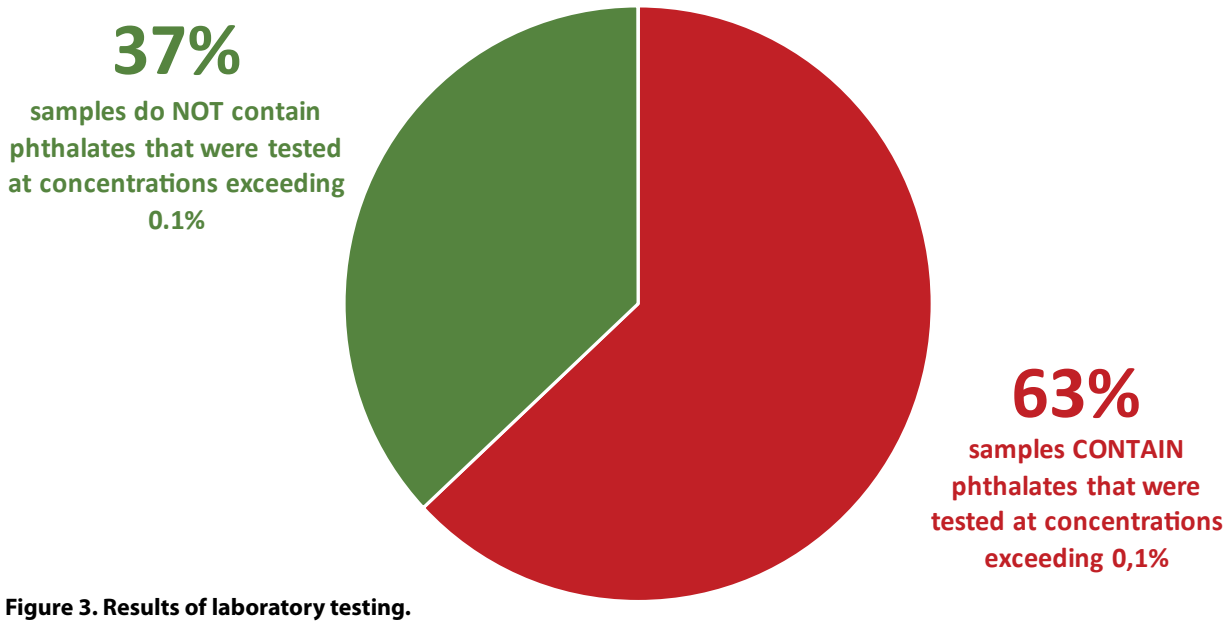

Figure 3. Results of laboratory testing.

This campaign focused on finding the four restricted phthalates, DEHP, DBP, BBP, and DIBP, in articles; the presence of the other high-molecular-weight phthalates was not intentionally examined because the main aim of this campaign was to examine the presence of restricted phthalates in articles placed on the Serbian market.

However, alternatives to the four tested phthalates could include higher-molecular-weight phthalates, such as DINP and DIDP, which also raise certain concerns. During the testing for the four restricted phthalates, if DINP, DnOP, and DIDP were detected, the laboratory subsequently determined their concentrations. The observed concentration in these samples were 27,6% for DINP and 1,32% for DIDP, while the concentration of DNOP was 0,14%.

The levels of phthalates in soft PVC products show that the content of phthalates can reach very high levels, even up to 50% (kids' raincoat).

Limitations of the analyses in our study

This study focused on the presence of four restricted phthalates, DEHP, DBP, BBP, and DIBP, in common consumer items. The laboratory also examined the presence of phthalates restricted under entry 52 (DINP, DIDP, and DnOP), although the sampled products are not covered by entry 52. Other phthalates were not examined because the main aim of this campaign was to examine the presence of phthalates that are restricted in common consumer items placed on the Serbian market.

If the laboratory ordered to conduct the analyses for this campaign did not find the selected phthalates at significant levels in some of the products, it does not mean they are phthalate-free. It is also worth noting that unregulated phthalates can cause potential harm to human health and the environment, as demonstrated in different ECHA documents that examined risk from ortho-phthalates, such as Assessment of regulatory needs for ortho-phthalates and Annex XV Report an assessment of weather the use of ten phthalates in articles should be restricted in accordance with article 69 (2) of REACH.

Recommendations

What is needed?

Government/ responsible ministry

» The responsible inspectorate should promptly conduct an inspection of products that we have identified as being on the market with illegal concentrations of restricted phthalates. Additionally, it is crucial to strengthen inspections of PVC products in general use— not only at the borders but also within domestic markets. An effective inspection campaign should be conducted to ensure that products containing restricted phthalates are not allowed on the market. During this comprehensive inspection, it is crucial to communicate a clear message to a wide range of manufacturers, importers, distributors, and retailers that these products are not allowed to be placed on the market. Clear communication is particularly important given the vast number of items made from flexible PVC plastic and the challenges associated with testing all these products for the presence of restricted phthalates during inspections.

» The sanitary inspectorate should regularly conduct monitoring programme of consumer goods and make a report on monitoring results publicly available, which would contribute to protecting the health of our children and all people in Serbia.

» Enforce the prescribed penalties for non-compliant products on the market.

» Information about products withdrawn from the market and recalled by consumers should be effectively communicated through the NEPRO system (National Rapid Alert System for Unsafe Products) and other communication channels.

» Update the NEPRO system regularly to publish information on unsafe products related to chemical risks and enhance the database structure to make it easier for consumers to search for relevant data.

» The Ministry of Environmental Protection, responsible for chemicals management, should launch a comprehensive information campaign to inform a wide range of companies about related restrictions and regulations.

» PVC should be limited in public procurement policies, such as green public procurement, as it is a problematic plastic that requires using phthalates as plasticizers.

Companies

» Phthalates and other SVHCs in everyday products should be replaced by safer alternatives as soon as possible. Safer alternatives should be chosen based on appropriate information related to the hazardous properties of alternative substances.

» Companies shall adopt chemical policies restricting phthalates and other substances of concern from their products and materials. They shall communicate their policy toward their suppliers. Additionally, they should proactively test products and sign agreements with suppliers guaranteeing that the chemical composition of products complies with the legal requirements for chemicals. Product testing and supplier compliance is particularly relevant for large distribution chains, which must implement a robust strategy to ensure they are not selling products containing restricted chemicals. Strengthening their oversight will significantly influence supplier compliance.

» Companies should take proactive steps to stay informed about the new restrictions imposed by European and Serbian legislation to ensure proper implementation.

» It is also time to rethink the replacement of PVC in as many products as possible,

particularly those used by more sensitive groups, such as children or pregnant women.

What can consumers do?

» Avoid articles made of plastic polymers, especially PVC, since they can contain plasticizers such as phthalates. You will recognize this material according to the recycling sign, which has the number 3.

» Ventilate rooms regularly! Phthalates in toys and other household products can end up in house dust.
» Look out for products with eco-labels, such as EU Ecolabel.

Annex I – Restrictions on phthalates in the European Union and Serbia

Part 1. Restriction of phthalates (entries 51 and 52) in the European Union – Extract from Annex XVII to REACH Regulation on the Registration, Evaluation, Authorisation, and restriction of CHemicals – Restrictions on the manufacturing, placing on the market, and use of certain dangerous substances, mixtures, and articles

Entry No.	Name of the substance, group of substances or mixtures, CAS number and EC number	Restrictions
51.	Bis(2-ethylhexyl) phthalate (DEHP) CAS No.: 117-81-7 EC No.: 204-211-0 Dibutyl phthalate (DBP) CAS No.: 84-74-2 EC No.: 201-557-4 Benzyl butyl phthalate (BBP) CAS No.: 85-68-7 EC No.: 201-622-7 Diisobutyl phthalate (DIBP) CAS No.: 84-69-5 EC No.: 201-553-2	**1.** Shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1% by weight of the plasticised material, in toys and childcare articles. **2.** Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1% by weight of the plasticised material. In addition, DIBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1% by weight of the plasticised material. **3.** Shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1% by weight of the plasticised material in the article. **4.** Paragraph 3 shall not apply to: a. articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin; b. aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft;

		c. motor vehicles within the scope of Directive 2007/46/EC, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles; d. articles placed on the market before 7 July 2020; e. measuring devices for laboratory use, or parts thereof; f. materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011 (*1); g. medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof; h. electrical and electronic equipment within the scope of Directive 2011/65/EU; i. the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC; j. toys and childcare articles covered by paragraphs 1 or 2. **5.** For the purposes of paragraphs 1, 2, 3 and 4(a), a. 'plasticised material' means any of the following homogeneous materials: — polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, — any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, — surface coatings, non-slip coatings, finishes, decals, printed designs, — adhesives, sealants, paints, and inks. b. 'prolonged contact with human skin' means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day. c. 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children, or sucking on the part of children. **6.** For the purposes of paragraph 4(b), 'aircraft' means one of the following: a. a civil aircraft produced in accordance with a type certificate issued under Regulation (EC) No 216/2008 or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation, signed on December 7, 1944 , in Chicago; b. a military aircraft.
52.	Phthalates a) Di- isononyl phthalate, DINP CAS no. 28553-12-0 and 68515-48-0, EC no. 249-079-5 and 271-090-9 b) Di-isodecyl phthalate, DIDP CAS no. 26761-40-0 and 68515-49-1, EC no. 247-977-1 and 271-091-4 v) Di-n-octyl phthalate, DNOP CAS no. 117-84-0, EC no. 204-214-7	**1.** Shall not be used as substances or in mixtures, in concentrations greater than 0,1% by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children. **2.** Such toys and childcare articles containing these phthalates in a concentration greater than 0,1% by weight of the plasticised material shall not be placed on the market. **3.** (3. Regulation (EU) No 326/2015: paragraph 3 is deleted.) **4.** For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children, or sucking on the part of children.

Part 2. Restrictions on phthalates (entries 51 and 52) in Serbia – Extracted from Part 1, Annex 1 of the *Rulebook on restrictions and bans on the production, placement on the market, and use of chemicals* (Official Gazette of RS, no. 90/13, 25/15, 2/16, 44/2017, 36/18, 9/2020, 57/2022 i 29/2024)

Entry No.	Name of the substance, group of substances, or mixtures, CAS number and EC number	Restrictions
51.	Bis(2-ethylhexyl) phthalate (DEHP) CAS No.: 117-81-7 EC No.: 204-211-0 Dibutyl phthalate (DBP) CAS No.: 84-74-2 EC No.: 201-557-4 Benzyl butyl phthalate (BBP) CAS No.: 85-68-7 EC No.: 201-622-7 Diisobutyl phthalate (DIBP) CAS No.: 84-69-5 EC No.: 201-553-2	**1.** The use as substances or in mixtures, individually or in any combination of the phthalates listed in entry 51, in a concentration equal to or greater than 0,1% by weight of the plasticised material, in toys and childcare articles is banned. **2.** Placement on the market of toys or childcare articles that contain, individually or in any combination DEHP, DBP i BBP, in a concentration equal to or greater than 0,1% by weight of the plasticised material is banned. After 7 July 2023 placement on the market of toys or childcare articles that contain DIBP, individually or in any combination DEHP, DBP i BBP, in a concentration equal to or greater than 0,1% by weight of the plasticised material is banned. **3.** After 7 July 2023 placement on the market of articles that contain individually or in any combination of the phthalates under entry 51, in a concentration equal to or greater than 0,1% by weight of the plasticised material in the article is banned. **4.** Point 3 shall not apply to: a) articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin; b) aircraft, placed on the market before 7 January 2026, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft; v) motor vehicles, placed on the market before 7 January 2026, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles; g) articles placed on the market before 7 July 2023; d) measuring devices for laboratory use, or parts thereof; đ) materials and articles intended to come into contact with food; e) medical devices; ž) electrical and electronic equipment; z) the immediate packaging of medicinal products; i) toys and childcare articles covered by point 1 or 2. "Plasticised material" means any of the following homogeneous materials: — polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, — any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings,

		— Surface coatings, non-slip coatings, finishes, decals, printed designs, — adhesives, sealants, paints, and inks. "Prolonged contact with human skin" means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day. "Childcare article" shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children, or sucking on the part of children.
52.	Phthalates a) Di- isononyl phthalate, DINP CAS no. 28553-12-0 and 68515-48-0, EC no. 249-079-5 and 271-090-9 b) Di-isodecyl phthalate, DIDP CAS no. 26761-40-0 and 68515-49-1, EC no. 247-977-1 and 271-091-4 v) Di-n-octyl phthalate, DNOP CAS no. 117-84-0, EC no. 204-214-7	**1.** The use of these substances or mixtures containing them in toys and baby care products that children can put in their mouth in concentrations exceeding 0,1% (m/m) of plasticised material is banned. **2.** Placement on the market of toys and baby care products containing more than 0,1% (m/m) of these phthalates is banned. **3.** A baby care product means any product that eases sleep, relaxes, maintains hygiene, or is used for the feeding or breastfeeding of infants.

Annex II – Table with phthalate content in tested samples

SAMPLE ID	Name and description of the product	Lab results (phthalates %)			
		BBP	DBP	DEHP	DIBP
ALH- 01	**PVC fabric tarpaulin**	<0,01	<0,01	**25,95 ± 2,91**	<0,01
ALH-02	**Imitation leather fabric**	<0,01	<0,01	**19,86 ± 2,2**	<0,01
ALH-03	**Non-slip bathmat**	<0,01	**0,02**	<0,01	<0,01
ALH-04	**Bicycle cable lock**	<0,01	**4,73 ± 0,57**	**0,02**	**23,67 ± 2,86**
ALH-05	**Toilet/makeup bag**	<0,01	<0,01	<0,01	<0,01
ALH-06	**Tablecloth**	<0,01	<0,01	<0,01	<0,01
ALH-07	**Woman's slippers**	<0,01	<0,01	**0,03**	<0,01
ALH-08	**Toilet/makeup bag**	<0,01	<0,01	**22,81 ± 2,55 purple handle** **17,31 ± 1,94 transparent part**	<0,01
ALH-09	**Toilet/makeup bag**	<0,01	<0,01	**13,60 ±1 ,52 handle** **42,74 ± 4,79 transparent part**	<0,01
ALH-10	**Toilet/makeup bag**	<0,01	<0,01	**31,48 ± 3,53**	<0,01
ALH-11	**Self-adhesive PVC foil**	<0,01	<0,01	**0,34 ± 0,04**	<0,01
ALH-12	**Wallpaper**	<0,01	<0,01	**1,71 ± 0,13**	<0,01
ALH-13	**Stickers for decoration**	<0,01	<0,01	**0,04**	<0,01
ALH-14	**Car steering wheel cover**	<0,01	<0,01	**0,20 ± 0,02**	<0,01
ALH-15	**Car mat**	<0,01	<0,01	**3,21 ± 0,36**	<0,01
ALH-16	**Toilet/makeup bag**	<0,01	<0,01	**22,00 ± 2,46**	<0,01
ALH-17	**Toilet/makeup bag**	<0,01	<0,01	**0,15 ± 0,02**	<0,01
ALH-18	**Toilet/makeup bag**[a]	<0,01	<0,01	**21,49 ± 2,40**	<0,01
ALH-19	**Inflammable ring for swimming**	<0,01	<0,01	0,01	<0,01

ALH-20	**Kids´ raincoat**[b]	<0,01	<0,01	**50,47 ± 5,65** (Packaging bag) **46,61 ± 5,22** (sleeve, back of the raincoat) **24,20 ± 2,27** (button, transparent part)	<0,01
ALH-21	**Girls´ bag**	<0,01	**0,03** (fins, scale) **0,08** (sides of the beg)	**3,33 ± 0,37** (fins, scale) **0,48 ± 0,05** (sides of the beg)	<0,01
ALH-22	**Girls´ bag**	<0,01	**0,05** (ear, imitation leather pink colour)	**23,29 ± 2,60** (ear, imitation leather pink colour) **0,05** (fabric)	<0,01
ALH-23	**Boxing gloves**	<0,01	**0,02**	**0,02**	<0,01
ALH-24	**Non-slip bathmat**	<0,01	<0,01	**27,86 ± 3,12**	<0,01
ALH-25	**Imitation leather fabric**	<0,01	<0,01	<0,01	<0,01
ALH-26	**Boxing gloves**	<0,01	<0,01	**0,97 ± 0,10**	<0,01
ALH-27	**School backpack**	<0,01	<0,01	**0,02**	<0,01
ALH-28	**School backpack**	<0,01	<0,01	<0,01	<0,01
ALH-29	**School backpack**	<0,01	<0,01	0,04	<0,01
ALH-30	**School backpack**[c]	<0,01	<0,01	**4,24 ± 0,47** (pocket, sides of the beg)	<0,01

[a] In this samples is found DnOP 0,14% ± 0,02

[b] In this samples is found DINP 0,75% ± 0,19 (fins, scale) and 27,60 % ± 7,06 (sides of the beg)

[c] In this samples is found DINP 12,52% ± 3,20 (pocket, sides of the beg) and DIDP 12,32% ± 0,16 (pocket, sides of the beg)

ANNEX III – Tested articles

ALH 01- PVC fabric tarpaulin

ALH 02- Artificial leather fabric

ALH 03-Non-slip bathmap

ALH 04- Bicycle cable lock

ALH 05- Toilet/makeup bag

ALH 06- Tablecloth

ALH 07- Women's slipers

ALH 08- Toilet/makeup bag

ALH 09- Toilet/makeup bag

ALH 10- Toilet/makeup bag

ALH 11- Self-adhesive PVC foil

ALH 12- Wallpaper

ALH 13- Stickers for decoration

ALH 14- Car wheel cover

ALH 15- Car mat

ALH 16- Toilet/makeup bag

ALH 17- Toilet/makeup bag

ALH 18- Toilet/makeup bag

ALH 19- Inflammable ring for swiming

ALH 20- Kids' raincoat

ALH 21- Girls' bag

ALH 22- Girls' bag

ALH 23- Boxing gloves

ALH 24- Non-slip bathmat

ALH 25- Imitation leather fabric

ALH 26- Boxing gloves

ALH 27- School backpack

ALH 28- School backpack

ALH 29- School backpack

ALH 30- School backpack

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