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Research article

SOME PROPOSALS ON REGULATION OF HIGHLY HAZARDOUS CHEMICALS IN ARTICLES

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When developing safety regulations for chemicals, the international society is constantly searching for safer analogues of highly hazardous chemicals to use as alternatives in various products. Within the Scientific Research Work under the State Program 'Provision of Chemical and Biological Safety in 2021–2024', The Russian Register of Potentially Hazardous Chemical and Biological Substances of the Federal Scientific Center of Hygiene named after F.F. Erisman of Rospotrebnadzor has developed a concept on replacement of highly hazardous chemicals in various products (food products, synthetic detergents and household chemicals, pesticides, paints and varnishes, basic chemicals) with their safer analogues. Still, we should highlight that regulation of highly hazardous chemicals in articles has not been developed sufficiently in the RF. Therefore, the purpose of the study was to provide scientific substantiation for criteria and rules for assigning chemicals in articles as prohibited and (or) restricted.

Materials this study is based on are represented by the regulatory legal acts of the Russian Federation, EEC and the EU (in particular, Decrees, Resolutions, Technical Regulations, Directives, Regulations, etc. in the field of safe management of substances of concern), as well as domestic and international databases, scientific articles and monographs containing information on the toxic properties of chemicals.

In order to develop effective measures to minimize the risk of exposure to chemicals in articles and their safe management at all stages of a life cycle, the study provides substantiation of criteria and rules for assigning chemicals in articles as prohibited and (or) restricted and proposes a mechanism for the creation of a National list of chemicals of concern in articles. When created, this List will allow monitoring of their circulation on the territory of the Russian Federation, proper waste disposal, and stimulating research work to find alternatives.

Keywords: chemical safety, regulation, highly hazardous chemicals, articles, materials, prohibition, restriction, analogues.

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Searching for alternatives and substituting highly hazardous chemicals in articles with their safer analogues is a key trend in international regulation of chemicals safety¹. In the Russian Federation, the Eurasian Economic Commission (EEC) Decision dated 21 April 2015 no. 30 'On Non-Tariff Regulation' regulates circulation of ozone depleting substances and articles containing them, hazardous wastes, crop protection chemicals and other persistent organic pollutants covered by Annexes A and B of the Stockholm Convention, narcotics, psychotropic drugs and their precursors. Apart from the aforementioned conventional chemicals regulated by the EEC documents, the Russian Federation lacks legally established mechanisms for identifying, prohibiting or restricting production and consumption of highly hazardous chemicals.

Within the Scientific Research Work under the State Program 'Provision of Chemical and Biological Safety in 2021–2024', the Russian Register of Potentially Hazardous Chemical and Biological Substances of the Federal Scientific Center of Hygiene named after F.F. Erisman of Rospotrebnadzor has developed a concept on replacement of highly hazardous chemicals in various products (food products, synthetic detergents and household chemicals, pesticides, paints and varnishes, basic chemicals) with their safer analogues. Scientific substantiation has been provided for a National List of chemicals of concern, 1480

compounds overall; 630 of them are mutagens, 320 are carcinogens, 271 are toxic for reproduction², 502 are endocrine disruptors³. Criteria have been developed to classify substances as candidates for prohibition and (or) restriction and proposals have been formulated on relevant amendments into the methodological and regulatory framework on chemical safety of the Russian Federation [1–7].

At the same time, it cannot be stated that enough attention has been paid in the RF to such important issues as regulation of highly hazardous chemicals in articles including their prohibition and (or) restriction; monitoring of such chemicals at all the stages in the article lifecycle (from raw materials to production and consumer wastes); proper waste classification and utilization considering their hazardous properties; searching for alternatives to substitute highly hazardous chemicals with their safer analogues [8, 9].

The aim of the study was to provide scientific substantiation for criteria and rules for assigning chemicals in articles as prohibited and (or) restricted.

Material and methods. Materials this study is based on are represented by the regulatory legal acts of the Russian Federation, EEC and the EU (in particular, Decrees, Resolutions, Technical Regulations, Directives, Regulations, etc. in the field of safe management of substances of concern), as well as domestic and international databases, scientific

¹ Ob Osnovakh gosudarstvennoi politiki Rossiiskoi Federatsii v oblasti obespecheniya khimicheskoi i biologicheskoi bezopasnosti na period do 2025 goda i dal'neishuyu perspektivu: Ukaz Prezidenta RF ot 11.03.2019 № 97 [On the basics of the RF state policy in the sphere of providing chemical and biological safety for the period up to 2025 and beyond: The RF President Order dated March 11, 2019 no. 97]. *Prezident Rossii: official Internet portal*. Available at: <http://www.kremlin.ru/acts/bank/44066> (July 01, 2023) (in Russian); Chemicals in products. *SAICM: Knowledge Platform of the Strategic Approach to International Chemicals Management*, 2022. Available at: <https://saicmknowledge.org> (July 03, 2023); Synthesis Report: OECD Workshop on Approaches to Support Substitution and Alternatives Assessment. Series on Risk Management no. 51. *OECD*, 2019. Available at: [https://images.chemycal.com/Media/Files/env-jm-mono\(2019\)3_synth.pdf](https://images.chemycal.com/Media/Files/env-jm-mono(2019)3_synth.pdf) (July 03, 2023).

² MR 1.2.0321-23. Otsenka i klassifikatsiya opasnosti reproduktivnykh toksikantov: Metodicheskie rekomendatsii, utv. rukovoditelem Federal'noi sluzhby po nadzoru v sfere zashchity prav potrebiteli i blagopoluchiya cheloveka, Glavnym gosudarstvennym sanitarnym vrachom Rossiiskoi Federatsii A.Yu. Popovoi 4 aprelya 2023 g. [Assessment and classification of substances toxic for reproduction: Methodical guidelines, approved by A.Yu. Popova, Head of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, the RF Chief Sanitary Inspector, on April 4, 2023]. Moscow, the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing, 2023, 32 p. (in Russian).

³ MR 1.2.0313-22. Otsenka i klassifikatsiya opasnosti endokrinnykh razrushitelei: Metodicheskie rekomendatsii, utv. rukovoditelem Federal'noi sluzhby po nadzoru v sfere zashchity prav potrebiteli i blagopoluchiya cheloveka, Glavnym gosudarstvennym sanitarnym vrachom Rossiiskoi Federatsii A.Yu. Popovoi 30 dekabrya 2022 g. [Assessment and classification of endocrine disruptors: Methodical guidelines, approved by A.Yu. Popova, Head of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, the RF Chief Sanitary Inspector, on December 30, 2022]. Moscow, the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing, 2022, 86 p. (in Russian).

articles and monographs containing information on the toxic properties of chemicals.

Results and discussion. According to the State Standard GOST 32419-2022 Chemical Hazard Classification. General Requirements⁴, articles are ready items that have passed through all the technological stages in production, during which they have been given a specific shape, surface, or design that determine their functional purpose to a greater extent than their chemical composition; such items are ready for private use or use in other production in a form they have been produced by their manufacturer. In Russia, requirements to safety of chemical products, including classification of their hazards and elements of information system (labeling and safety data sheet) are established by the Technical Regulations of the Eurasian Economic Union ‘On the Safety of Chemical Products’ (TR EAEU 041/2017, has not come into force yet)⁵ and the National Technical Regulations ‘On the Safety of Chemical Products’ (draft). In contrast to chemical products, articles are not regulated by the foregoing regulations. Meanwhile, many articles contain highly hazardous chemicals that can pose serious threats for human health and the environment both in short- and long-term prospect. It is noteworthy that information about such chemicals is not usually provided on labels and (or) in supporting documents and this creates certain difficulty in, for example, monitoring over circulation of highly hazardous chemicals as well as hazard classification and proper utilization of consumer waste.

In the Russian Federation, the following Technical Regulations (TR) establish safety requirements for different articles:

– TR CU 003/2011 On safety of railroad Infrastructure;

- TR CU 005/2011 On safety of package;
- TR CU 007/2011 On safety of products for children and adolescents;
- TR CU 008/2011 On safety of toys;
- TR CU 010/2011 On safety of machinery and equipment;
- TR CU 014/2011 Motorways safety;
- TR CU 017/2011 On safety of light industry products;
- TR CU 018/2011 On safety of wheeled vehicles;
- TR CU 019/2011 On safety of personal protection equipment;
- TR CU 025/2012 On safety of furniture;
- TR CU 026/2012 On safety of small vessels;
- TR CU 031/2012 On safety of agricultural and forestry tractors and trailers for them;
- TR CU 032/2013 On safety of equipment operating under excessive pressure;
- TR CU 035/2014 Technical Regulations for tobacco products;
- TR EAEU 037/2016 On restricting the use of hazardous chemicals in electric and electronic items;
- TR EAEU 038/2016 On safety of attractions;
- TR EAEU 050/2021 On safety of produces used in civil defense and protection against natural or technogenic emergencies;
- TR EAEU 052/2021 On safety of metro rolling stock.

The task was to substantiate criteria and rules for assigning chemicals in articles as prohibited and (or) restricted. To do that, the foregoing regulations were analyzed considering an article’s name, a type of a material it was made of (polymer, glass, ceramics, metal, alloy, etc.), controlled chemicals, safety requirements to articles including prohibitions and restrictions,

⁴ GOST 32419-2022. Klassifikatsiya opasnosti khimicheskoi produktsii. Obshchie trebovaniya, vved. v deistvie 01.01.2023 [Chemical Hazard Classification. General Requirements, introduced on January 01, 2023]. Moscow, Russian Standardization Institute, 2022, 40 p. (in Russian).

⁵ TR EAEU 041/2017. O bezopasnosti khimicheskoi produktsii: Tekhnicheskii reglament Evraziiskogo ekonomicheskogo soyuza, prinyat Resheniem Soveta Evraziiskoi ekonomicheskoi komissii ot 3 marta 2017 goda № 19 (ne vstupil v silu) [On the Safety of Chemical Products: the Technical Regulations of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission on March 3, 2017 no. 19 (has not come into force yet)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: <https://docs.cntd.ru/document/456065181> (July 04, 2023) (in Russian).

levels of chemicals migration into various media (air, water, a model environment, etc.).

One hundred and twenty-four chemicals were identified after requirements to chemical safety were analyzed. These chemicals are regulated by Technical Regulations of the Customs Union (TR CU) in light industry articles, articles for children and adolescents, toys, furniture, tobacco articles, personal protection equipment as well as in electric and electronic articles. Fifty of them (40.3 %) are volatile organic compounds (VOCs); 33 (26.6 %) are heavy metals and their salts. Chemicals that are subject to the strictest regulation include formaldehyde (213 indicators in TR CU), acetaldehyde (116), methanol (96), phenols (77), acetone (64), lead and its compounds (58), butanol (55), toluene (50), zinc and its compounds (45), and mercury and its compounds (37). Chemicals in articles regulated by TR CU (the first 10 positions) are given in Table 1 together with a type and category of hazards they pose according to the GHS (Globally

Harmonized System of Classification and Labelling of Chemicals).

The analysis of the TR CU requirements revealed that the main criteria for chemicals in articles hazardous for human health include such indicators as mutagenic and carcinogenic effects, toxicity for reproduction, effects on the endocrine system, as well as some additional hazards including acute toxicity by inhalation or skin contact (hazard category 1 and 2), irritation of the respiratory tract, narcotic effect; impacts on target organs and (or) systems under single and (or) multiple (long-term) contacts with a chemical, respiratory and (or) skin sensitization, skin and eye damage (hazard category 1). At the same time, it is not advisable to take into account such type of hazards as acute toxicity caused by swallowing or aspiration in the case of articles due to the impossibility and (or) low probability of the process.

Figure 1 shows distribution of hazardous properties of chemicals in articles regulated by TR CU.

Table 1

Chemicals in articles regulated by TR CU (the first 10 positions)

CAS name	Number of indication in TR CU	Hazard category				Additional hazard
		M	C	R	E	
Formaldehyde 50-00-0	213	2	1A	1	2	skin (category 1B) and eye (category 1) burns, skin sensitization (category 1), after repeated / long-term inhalation exposure: the respiratory system (category 1)
Acetaldehyde 75-07-0	116	-	2	-	3	respiratory tract irritation (category 3), narcotic effect (category 3)
Methanol 67-56-1	96	-	-	2	2	under single exposure: the central nervous system, eyes (category 1)
Phenol 108-95-2	77	2	-	1	-	skin (category 1B) and eye (category 1) burns, after repeated / long-term inhalation exposure: the nervous and respiratory systems (category 2)
Acetone 67-64-1	64	-	-	2	-	respiratory tract irritation (category 3), narcotic effect (category 3)
Lead* 7439-92-1	58	-	2	1A	-	after repeated / long-term exposure: the hematopoietic and nervous systems, kidneys (category 1)
Butanol 71-36-3	55	-	-	-	-	respiratory tract irritation (category 3), narcotic effect (category 3)
Toluene 108-88-3	50	-	-	1B	2	aspiration hazard (category 1); after repeated / long-term inhalation exposure: the nervous system (category 2)
Zinc* 7440-66-6	45	-	-	-	-	eye damage (category 1), after repeated / long-term exposure: the respiratory and hematopoietic system (category 1)
Mercury* 7439-97-6	37	-	-	1	-	acute inhalation toxicity (category 1), after repeated / long-term inhalation exposure: the nervous system (category 1)

Note: *This position includes both a metal and its ion forms and classification can be different for each specific case; M is mutagen; C is carcinogen; R is toxic for reproduction; E is endocrine disruptor; hazard categories are given in accordance with the GHS classification.

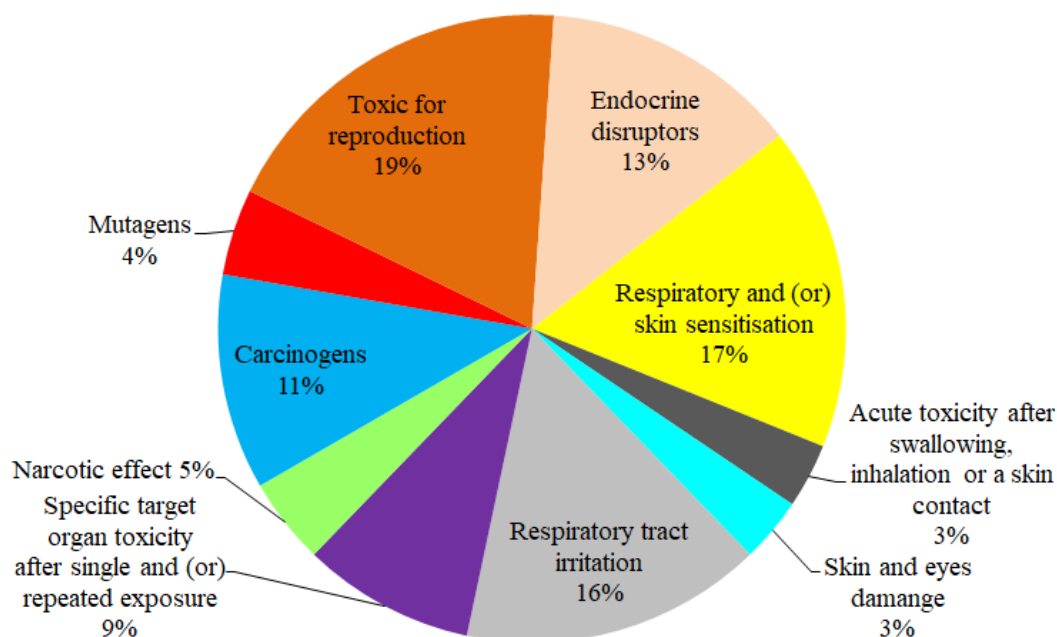


Figure 1. Distribution of hazardous properties of chemicals in articles regulated by TR CU

Major hazards posed by chemicals in articles are reproductive and developmental toxicity (19 % of the chemicals regulated by TR CU are toxic for reproduction, categories 1 and 2 according to the GHS), respiratory and (or) skin sensitization (17 %), irritation of the respiratory tract (16 %), and effects on the endocrine system (13 %).

Since approximately 40 % of the chemicals in articles regulated by TR CU are VOCs and are represented by, for example, monomers of polymers (vinyl acetate, methyl methacrylate, formaldehyde, chloroprene and others) or solvents (toluene, hexane, heptane, and others), it is possible to assume that VOCs levels in articles are going to decline over time of use and, consequently, hazards posed by them will also decrease. Irritation of the respiratory tract, respiratory and (or) skin sensitization, and narcotic effect are intrinsic mostly to VOCs; consequently, in long-term prospect, the greatest hazards will be posed by chemicals in articles that do not belong to VOCs and are able to produce some specific and delayed effects, including mutagenic and carcinogenic ones, reproductive toxicity, and effects on the endocrine system. Among such chemicals, it can be mentioned, for example, heavy metals and their organic compounds able to modify some properties of materials applied to manufacture articles

(photoinitiators, stabilizers, flame retardants, hardeners, accelerants, preservatives, and others). It is noteworthy that for chemical products released into circulation on the territory of the Russian Federation, the legislation requires the preparation of a safety data sheet containing information about the hazardous components of the product, as well as the classification and labeling of hazards. This allows monitoring hazardous chemicals in products at any stage in the lifecycle (from raw materials to production and consumer waste) and provides safety when dealing with them. However, when it comes down to articles, such data is not provided and this creates serious difficulties not only for proper waste disposal including possible recycling and reuse but also for studies with their focus on searching for alternatives to substitute highly hazardous chemicals in articles with their safer analogues.

At present, the list of chemicals in articles regulated by TR CU includes, in addition to VOCs and heavy metals, a few other substances used as additives to polymer materials. They include antioxidants, such vulcanization accelerants as thiazole and thiuram, tin and its compounds, polybrominated diphenyls, and diphenyl ethers. Still, a wide range of highly hazardous chemicals is practically not regulated in the RF at all and this is contrary to in-

ternational trends as regards regulation of their safety.

For example, the European list of substances in articles of very high concern for human health and the environment (so called Candidate List)⁶ currently consists of 235 positions including:

- category 1A or 1B carcinogens according to the GHS;
- category 1A or 1B mutagens according to the GHS;
- category 1A or 1B reproductive toxicants according to the GHS;
- persistent, bioaccumulative and toxic substances (PBT);
- very persistent and very bioaccumulative (vPvB);
- endocrine disruptors;
- respiratory sensitizers;
- chemicals with specific target organ toxicity after repeated exposure;
- other chemicals, for which scientific evidence is provided confirming likelihood of considerable health outcomes or effects on the environment comparable with those listed above (Article 57, REACH).

Since the chemicals from the Candidate List are considered those that might be prohibited and (or) restricted in the nearest future, a chemical having one or several of the enlisted hazard types is the necessary, but not sufficient, condition for it to be included into the Candidate List. It is also important to study a possibility whether this component could be substituted in an article with its safer alternative considering technical feasibility and assessment of involved socioeconomic risks.

All the companies operating in the EU countries that produce, import, or deliver goods (articles) onto the EU market containing chemicals from the Candidate List, that is chemicals of very high concern, in quantity exceeding 0.1 % as per an article mass, are obliged to provide information about such

goods (articles) in specific notifications submitted to the European Chemicals Agency (ECHA). This makes it possible to monitor hazardous chemicals at all the stages in the article life cycle.

The Substances of Concern In Product as such or in complex objects (Articles) database (SCIP)⁷ was created by the European Chemicals Agency in 2021. It contains data on hazardous chemicals in articles and goods distributed on the European Union market. Analysis of this database revealed chemicals that were the most frequent to be detected in articles and goods. They include lead and its compounds, boron and its compounds, ethylene thiourea, bisphenol A, siloxanes, chlorinated paraffins C₁₄-C₁₇, chromium (VI) compounds, phthalates, and ethoxylated nonylphenols (Table 2 and Figure 2). Table 2 provides the first 25 positions as per the number of notifications submitted by companies between 01 January 2021 and 01 August 2023 as well as the reason why a chemical in an article is considered of concern, the exact number of notifications, and a range of use. As for the latter, the leading place in the Candidate List belongs to additives to polymers (photoinitiators, stabilizers, and flame retardants). It is noteworthy that the European Candidate List does not include any VOCs and the emphasis is on hazards posed by chemicals in articles in the long term.

The European approach to creating groups of articles that cause concern for human health and the environment allows identifying several categories: articles made of ceramics; glass; metal; leather; paper and board; plastic and polymers; rubber and elastomers; stone, plaster, and cement; fiber include textile; wood; others (mixed materials). The chemicals included in the Candidate List are most frequently identified in articles made of metal (39 % of the submitted notifications), mixed materials (21 %), glass (11 %), rubber and elastomers (10 %), plastic and polymers (9 %) (Figure 3).

⁶ Candidate List of substances of very high concern for Authorization. ECHA: *European Chemicals Agency*. Available at: <https://echa.europa.eu/candidate-list-table> (July 03, 2023).

⁷ SCIP Database. ECHA: *European Chemicals Agency*. Available at: <https://echa.europa.eu/scip-database> (July 03, 2023).

Table 2

Chemicals in articles notified within the SCIP 2021–2023 (the first 25 positions)

No.	Name	CAS No.	The reason for inclusion into the Candidate List	Number of notifications*	Range of use
1.	Lead and its compounds	7439-92-1 and others	Toxic for reproduction	9852535	Electric and electronic equipment, vehicles, batteries and accumulators
2.	Boron and its compounds	7440-42-8 and others	Toxic for reproduction	1716812	Articles made of stone, plaster, cement, glass, ceramics, plastic, leather, textiles, electric and electronic equipment, construction materials
3.	Imidazolidine-2-thione (ethylene thiourea)	96-45-7	Toxic for reproduction	1228390	Accelerator of neoprene rubber vulcanization
4.	4,4'-Isopropylidenediphenol (bisphenol A)	80-05-7	Toxic for reproduction, endocrine disruptor	1102646	Manufacture of plastic, polycarbonate plastic, epoxy resins; electric and electronic equipment, thermal paper
5.	Decamethylcyclotetrasiloxane	541-02-6	PBT; vPvB	1085887	Used in manufacture of plastic articles and rubber articles
6.	Octamethylcyclotetrasiloxane	556-67-2	PBT; vPvB	1073677	Used in manufacture of plastic articles and rubber articles
7.	2-Methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	Toxic for reproduction	852311	Photoinitiator of polymerization
8.	Tris (nonylphenyl) phosphite	26523-78-4, 3050-88-2, 31631-13-7, 106599-06-8 and others	Endocrine disruptor	822419	Plastic and rubber manufacture; food contact packaging
9.	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.16,9.02,13.05,10] octadeca-7,15-dien ("Dechlorane plus" TM)	13560-89-9	vPvB	764317	Flame retardants for thermoplastic materials
10.	2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	Toxic for reproduction	749979	Photoinitiator of polymerization, pigmentation of US-hardened systems, photoresistors, print plates
11.	1,1'-Azobiscarboxamide	123-77-3	Respiratory sensitizing properties	748211	Foaming agents, manufacture of textile articles, plastic, rubber, construction materials
12.	1,2-Dimethoxyethane	110-71-4	Toxic for reproduction	686611	Electric and electronic equipment, batteries
13.	2-Methylimidazole	693-98-1	Toxic for reproduction	686337	Epoxy resin hardener
14.	6,6'-Di-tert-butyl-2,2'-methylendi-p-cresol	119-47-1	Toxic for reproduction	683227	Antioxidant, manufacture of rubber, oil articles, fiber, varnishes and paints
15.	Chlorinated paraffins C ₁₄ -C ₁₇	85535-85-9	PBT; vPvB	672779	Electric and electronic equipment
16.	Dodecamethylcyclotetrasiloxane	540-97-6	PBT; vPvB	616328	Articles made of rubber and plastic
17.	1,3,5-Tris(oxirane-2-methyl)-1,3,5-triazin-2,4,6-(1H,3H,5H)-trion	2451-62-9	Mutagen	598114	Polyether powder paints hardener
18.	2-Ethylhexyl-2-[[{(2-ethylhexyl)oxi]-2-oxoethyl} sulfanyl] dioctylstannil]sulfanyl]acetate	15571-58-1	Toxic for reproduction	577018	Thermal stabilizer of polyvinylchloride in food package
19.	Dicyclohexyl phthalate	84-61-7	Toxic for reproduction, endocrine disruptor	574011	Articles made of polyvinylchloride, rubber, plastic; textiles, electric and electronic equipment, vehicles
20.	Chromium (VI) compounds	1333-82-0, 24613-89-6 and others	Mutagen, carcinogen	484806	Electric and electronic equipment, vehicles
21.	Ethoxylated nonylphenol	-	Endocrine disruptor	473720	Non-ionic surfactant, textiles, leather articles, metal processing
22.	Bis(2-ethylhexyl)phthalate	117-81-7	Toxic for reproduction, endocrine disruptor	455496	Plasticizer, manufacture of plastic and rubber, vehicles, textiles, electric and electronic equipment, construction materials, batteries and accumulators
23.	Bis(2-(2-methoxyethoxy)ethyl)ether	143-24-8	Toxic for reproduction	442439	Electric and electronic equipment
24.	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol	79-94-7	Carcinogen	404195	Flame retardants for resins and polymer materials
25.	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride	552-30-7	Respiratory sensitizing properties	382426	Epoxy resin hardener and inhibitor in PVC-pastes used in linoleum manufacture; electric and electronic equipment, vehicles

Note: * EU companies have submitted 10,592,895 notifications between January 01, 2021 and August 01, 2023; PBT means persistent, bioaccumulative and toxic substances; vPvB means very persistent and very bioaccumulative.

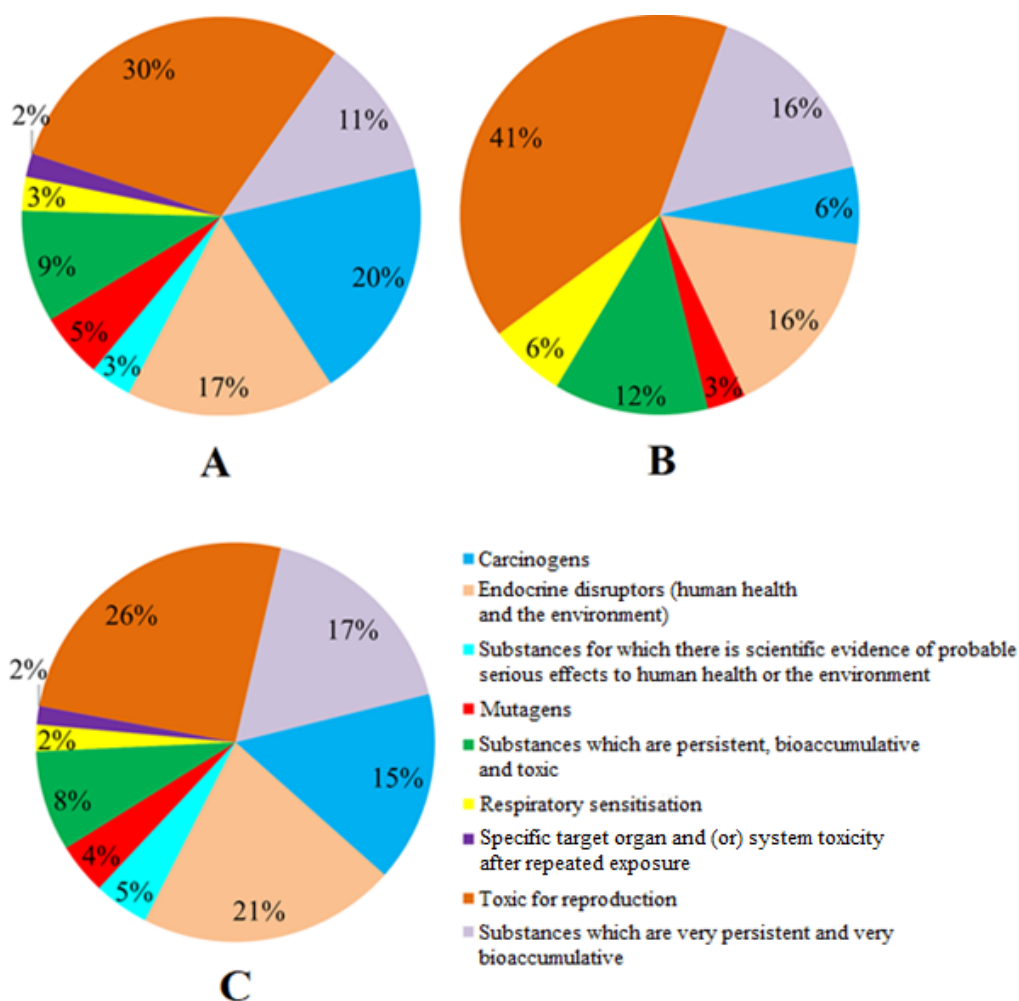


Figure 2. Distribution of hazardous properties of chemicals in articles subject to notification being submitted to SCIP considering all the notifications submitted between 01 January 2021 and 01 August 2023 (A), considering the most frequent 25 (B); included into the Candidate List (C)

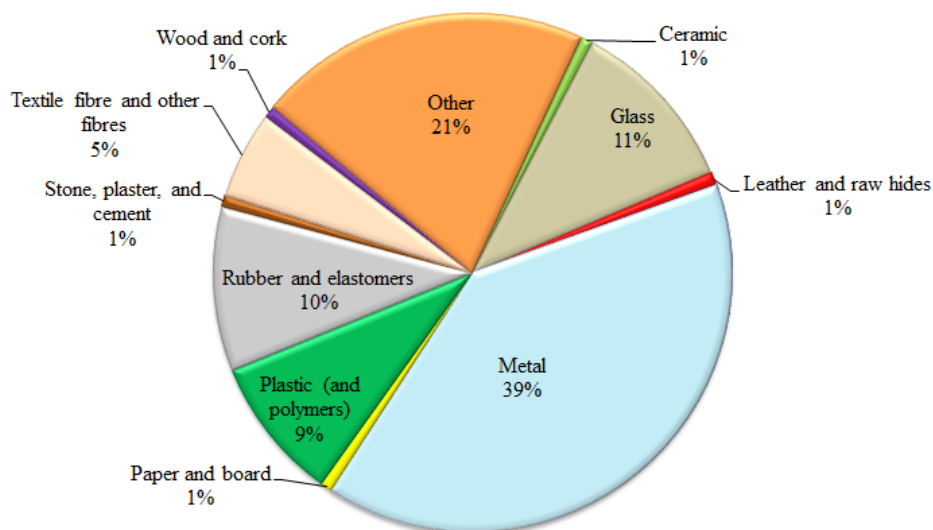


Figure 3. Distribution of notifications on chemicals from the Candidate List as per categories (groups) of articles

The analysis of distribution of hazardous properties of chemicals included in the Candidate List and chemicals in articles notified to the SCIP showed that the main types of hazards are reproductive toxicity (26–30 % of chemicals have this type of hazard), carcinogenicity (15–20 %), endocrine disrupting (17–21 %), very persistent and highly bioaccumulative (11–17 %).

In order to develop effective measures to minimize the risk of exposure to chemicals in articles and its safe management at all stages of the life cycle, including prohibition and (or) restriction, proper waste disposal, stimulating research to find alternatives, as well as creating a transparent mechanism that allows the chemical to be classified as prohibited and (or) restricted, it is considerable to create and maintain a National List of chemicals of concern in articles.

Such a List should include both substances that have acute (e.g., VOCs) and delayed effects. The European approach to creating a Candidate List, which excludes VOCs from consideration, is inapplicable in the Russian Federation, because VOCs are:

- highly hazardous chemicals (for example, formaldehyde is a mutagen category 2, carcinogen – 1A, toxic for reproduction – 1, endocrine disruptor – 2; benzene is mutagen – 1B, carcinogen – 1A, toxic for reproduction – 1; vinyl chloride is carcinogen – 1A, endocrine disruptor – 2, toxic for reproduction – 2);

- widely used in synthesis of polymer materials of articles most people come in contact with;

- pollute the environment by migrating into ambient air and water. This is becoming an acute problem especially for sensitive population groups (for example, formaldehyde migrates into ambient air from construction materials).

It is necessary not only to control VOCs levels in articles and check whether they comply with TR CU requirements but also to search for ways to decrease these levels and (or) to substitute VOCs in articles with safer alternatives.

Candidates for inclusion in the National List of chemicals of concern in articles are

chemicals classified in accordance with the GHS:

- carcinogens (hazard categories 1 and 2);
- mutagens (hazard categories 1 and 2);
- toxic for reproduction (hazard categories 1 and 2);
- endocrine disruptors (hazard categories 1 and 2);
- acutely toxic by inhalation and skin contact (hazard categories 1 and 2);
- skin and eye damage (hazard category 1);
- respiratory and (or) skin sensitization (hazard category 1);
- chemicals with specific target organ and (or) system toxicity after single and (or) repeated (long-term) exposure (including those able to produce narcotic effect and irritating the respiratory tract);
- acute (hazard category 1) and chronic (hazard categories 1 and 2) toxicity for aquatic biota [10]; as well as chemicals, which are
 - persistent, bioaccumulative and toxic substances
 - very persistent and very bioaccumulative.

Chemicals classified as carcinogens, mutagens, toxic for reproduction, and endocrine disruptors of hazard categories 1 and 2 according to the GHS are included into the National List of chemicals of concern that consists of 1480 positions. Of them, 630 chemicals are mutagens; 320 are carcinogens; 271 are toxic for reproduction; 502 are endocrine disruptors (12 chemicals have all four effects and 29 chemicals have three of them). Comparison of the National List of chemicals of concern with the RF Inventory List of Chemicals obtained as part of the inventory and posted on the State Industry Information Website (as of July 2023) showed that 1295 items (87.5 %) are circulating in the Russian Federation.

In addition to evaluating and classifying hazards for human health and the environment, the following points are to be considered prior to including a chemical into the National List of chemicals of concern in articles:

- risk of exposure,
- a number of person in contact,
- production volumes,
- application area,

– migration from articles into ambient air and water,

– method of disposal (recycling),

– possibility to substitute a chemical with its safer alternatives considering the international experience in the sphere.

Some alternatives have already been developed or (are) being developed now for many chemicals enlisted in international conventions (Stockholm and Rotterdam Conventions) as well as for chemicals from the European Candidate List. These alternatives consider an application area for a specific chemical (Table 3) [11, 12].

The creation of a National List of chemicals of concern in articles will make it possible to organize monitoring of their circulation on the territory of the Russian Federation. Within implementation of the National Technical Regulations ‘On the Safety of Chemical Products’ permissive registration might be introduced for such chemicals. In addition, with the involvement of manufacturers, it is possible to form a database ‘Substances in articles’, which will facilitate establishing the composition of

consumption and production waste as well as their proper classification and disposal.

An ultimate decision on assigning a chemical in an article as prohibited and (or) restricted should be based on an expert report issued with the participation of representatives from Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, the RF Ministry of Health, the RF Ministry of Industry and Trade, the RF Ministry of Natural Resources and Environment, the RF Ministry of Agriculture, and the RF Ministry of Economic Development. The report should cover the following points:

– assessment and classification of hazards and risks of exposure to a chemical for human health and the environment;

– substantiation of its permissible levels in an article, levels of its migration into ambient air and water;

– information about alternatives including safer chemical analogues, technological alternatives, a possibility to apply organizational measures as a substitute for a hazardous chemical;

Table 3

Some examples of substituting hazardous chemicals in articles [13–20]

№	Name	Substitute (alternative)
1	Lead and its compounds	– magnesium and aluminum hydrates in manufacturing rubber and plastic articles, – synthetic hydrotalcit as thermal stabilizer in PVC manufacture
2	Bisphenol A	– polyamide in children bottles made of transparent hard plastic; – so-polymer of dimethyl terephthalate, cyclohexanedimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutandiol in bottles for drinks; – a mixture based on vegetable oil and resin as an inner surface of a package
3	Di(2-ethylhexyl)phthalate	– diisononyl adipate, acetyltirbutylcitrate, diisononyl cyclohexane 1,2-dicarboxilate, di(2-ethylhexyl)terephthalate, phenyl ethers of C ₁₀ -C ₁₈ -alkyl-substituted sulfonic acids as plasticizers in toys and childcare items; – copolymer of ethene-1-acetene to substitute a basis of PVC carpet and phthalate plasticizer; – dimethyl siloxane and methyl hydrosiloxane in plastisol printing and textile manufacturing
4	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol	– aluminum hydroxide, melamine polyphosphate, aluminum salt of diethyl phosphine acid, boehmite
5	Perfluorooctanesulfonic acid	– paraffins in textiles and carpets; siloxanes modified with alpha-olefin; polyurethanes modified with fatty acids

- assessment of alternatives;
- assessment of socioeconomic risks associated with prohibition and (or) restriction of a chemical;
- an overall conclusion whether a chemical can be assigned as prohibited and (or) restricted.

Conclusion. Upon completion of the present study, the following results have been achieved. The criteria and rules for assigning chemical substances in articles as prohibited and (or) restricted have been substantiated;

a mechanism has been proposed for the creation of a National List of chemicals of concern in article. When created, this List will allow monitoring of their circulation on the territory of the Russian Federation, proper waste disposal, and stimulating research work to find alternatives.

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References

1. Tickner J.A., Schifano J.N., Blake A., Rudisill C., Mulvihill M.J. Advancing safer alternatives through functional substitution. *Environ. Sci. Technol.*, 2015, vol. 49, no. 2, pp. 742–749. DOI: 10.1021/es503328m
2. Khamidulina Kh.Kh., Proskurina A.S., Tarasova E.V. Development and implementation of a concept for the replacement of highly hazardous substances with safe chemical alternatives. *Meditsina truda i promyshlennaya ekologiya*, 2022, vol. 62, no. 11, pp. 733–739. DOI: 10.31089/1026-9428-2022-62-11-733-739 (in Russian).
3. Khamidulina Kh.Kh., Tarasova E.V., Nazarenko A.K., Rabikova D.N., Proskurina A.S. Proposals for improving the methodic and regulatory framework of the Russian Federation in the field of chemical safety. *Toksikologicheskii vestnik*, 2023, vol. 31, no. 4, pp. 214–225. DOI: 10.47470/0869-7922-2023-31-4-214-225 (in Russian).
4. Dutta S., Sengupta P., Bagchi S., Chhikara B.S., Pavlík A., Sláma P., Roychoudhury S. Reproductive toxicity of combined effects of endocrine disruptors on human reproduction. *Front. Cell. Dev. Biol.*, 2023, vol. 11, pp. 1162015. DOI: 10.3389/fcell.2023.1162015
5. Kabir E.R., Rahman M.S., Rahman I. A review on endocrine disruptors and their possible impacts on human health. *Environ. Toxicol. Pharmacol.*, 2015, vol. 40, no. 1, pp. 241–258. DOI: 10.1016/j.etap.2015.06.009
6. Assessment and classification of the danger of endocrine disruptors. *Toksikologicheskii vestnik*, 2023, vol. 31, no. 2, pp. 135–138. DOI: 10.47470/0869-7922-2023-31-2-135-138 (in Russian).
7. Filippone A., Rossi C., Rossi M.M., Di Micco A., Maggiore C., Forcina L., Natale M., Constantini L. [et al.]. Endocrine Disruptors in Food, Estrobolome and Breast Cancer. *J. Clin. Med.*, 2023, vol. 12, no. 9, pp. 3158. DOI: 10.3390/jcm12093158
8. Zhang J., Qin Q., Li G., Tseng C.-H. Sustainable municipal waste management strategies through life cycle assessment method: A review. *J. Environ. Manage.*, 2021, vol. 287, pp. 112238. DOI: 10.1016/j.jenvman.2021.112238
9. Lalit D., Adyasha D., Sitikantha M. Municipal Solid Waste Model Development through Binary Coding. *Ecology Environment and Conservation*, 2022. DOI: 10.53550/EEC.2022.v28i03.069
10. Sifakis S., Androutsopoulos V.P., Tsatsakis A.M., Spandidos D.A. Human exposure to endocrine disrupting chemicals: effects on the male and female reproductive systems. *Environ. Toxicol. Pharmacol.*, 2017, vol. 51, pp. 56–70. DOI: 10.1016/j.etap.2017.02.024
11. Zaitseva N.V., May I.V., Kiryanov D.A., Goryaev D.V., Kleyn S.V. Social and hygienic monitoring today: state and prospects in conjunction with the risk-based supervision. *Health Risk Analysis*, 2016, no. 4, pp. 4–16. DOI: 10.21668/health.risk/2016.4.01.eng
12. Jacobs M.M., Malloy T.F., Tickner J.A., Edwards S. Alternatives Assessment Frameworks: Research Needs for the Informed Substitution of Hazardous Chemicals. *Environ. Health Perspect.*, 2016, vol. 124, no. 3, pp. 265–280. DOI: 10.1289/ehp.1409581
13. Karthikeyan B.S., Ravichandran J., Mohanraj K., Vivek-Ananth R.P., Samal A. A curated knowledgebase on endocrine disrupting chemicals and their biological systems-level perturbations. *Science of the Total Environment*, 2019, no. 692, pp. 281–296. DOI: 10.1016/j.scitotenv.2019.07.225

14. Antonsson A.B. Substitution of dangerous chemicals – the solution to problems with chemical health hazards in the work environment? *Am. Ind. Hyg. Assoc. J.*, 1995, vol. 56, no. 4, pp. 394–397. DOI: 10.1080/15428119591017024
15. Lissner L., Romano D. Substitution for hazardous chemicals on an international level – the approach of the European project “SUBSPORT”. *New Solut.*, 2011, vol. 21, no. 3, pp. 477–497. DOI: 10.2190/NS.21.3.1
16. Lofstedt R. The substitution principle in chemical regulation: A constructive critique. *Journal of Risk Research*, 2014, vol. 17, no. 5. DOI: 10.1080/13669877.2013.841733
17. Malloy T., Blake A., Linkov I., Sinsheimer P. Decisions, Science, and Values: Crafting Regulatory Alternatives Analysis. *Risk Anal.*, 2015, vol. 35, no. 12, pp. 2137–2151. DOI: 10.1111/risa.12466
18. Oguzcan S., Dvarioniene J., Tugnoli A., Kruopiene J. Environmental impact assessment model for substitution of hazardous substances by using life cycle approach. *Environ. Pollut.*, 2019, vol. 254, pt A, pp. 112945. DOI: 10.1016/j.envpol.2019.07.113
19. Syeda S.R., Khan E.A., Padungwatanaroj O., Kuprasertwong N., Tula A.K. A perspective on hazardous chemical substitution in consumer products. *Current Opinion in Chemical Engineering*, 2022, vol. 36, pp. 100748. DOI: 10.1016/j.coche.2021.100748
20. Soeteman-Hernández L.G., Hogendoorn E.A., Bakker J., Van Broekhuizen F.A., Palmen N.G.M., Bruinen De Bruin Y., Kooi M., Sijm D.T.H.M., Traas T.P. An approach to identify, prioritise and provide regulatory follow-up actions for new or emerging risks of chemicals for workers, consumers and the environment. *International Journal of Risk Assessment and Management*, 2018, vol. 21, no. 3, pp. 248–269. DOI: 10.1504/IJRAM.2018.093763

Khamidulina Kh.Kh., Tarasova E.V., Nazarenko A.K., Rabikova D.N., Proskurina A.S., Zamkova I.V. Some proposals on regulation of highly hazardous chemicals in articles. Health Risk Analysis, 2023, no. 3, pp. 17–28. DOI: 10.21668/health.risk/2023.3.02.eng

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