



# **Chemicals Management**

# Overview

The legislative framework created by the adoption of the Law on Chemicals and the Law on Biocidal Products and corresponding by-laws established a system of chemicals management according to EU principles.

The Negotiating Position for Chapter 27 envisages the drafting and adoption of the Law on the Implementation of the REACH<sup>111</sup> Regulation, as well as the Law on the Implementation of the BPR Regulation<sup>112</sup>, by the end of 2021, which would apply from the date of accession. However, these laws were not adopted in the planned period.<sup>113</sup> Drafting a new Law on Chemicals is also planned, which would retain specific provisions from the existing law, i.e. those concerning the Chemicals Register (the national chemicals registers are in principle in accordance with EU legislation), but will not contain provisions harmonized with the REACH Regulation. The Republic of Serbia will implement the REACH and BPR regulations from the date of accession, depending on the agreed adaptation periods. Serbia has requested adaptation periods for the full implementation of the REACH regulation (especially for the registration and authorization processes), as well as the CLP<sup>114</sup> and BRP regulations.

During 2021, the new Law on Biocidal Products was adopted<sup>115</sup> for the purpose of harmonizing domestic legislation with the Regulation on Biocidal Products (528/2012/EU). The Regulation could not be transposed in its entirety because, among other things, it regulates procedures that are centrally implemented by the European Chemicals Agency (ECHA) or the European Commission.

One of the key developments in the field of chemicals management is the introduction of a rule requiring that a recognition procedure must be initiated

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111 REACH – Registration, Evaluation, Authorization and Restriction of chemicals

112 BPR – Biocidal Products Regulation

113 Negotiating position of the RS for Chapter 27, Government of the Republic of Serbia, 2019

114 CLP – Classification, Labeling and Packaging

115 “Official Gazette of RS”, no. 109/2021.

for biocidal products with approval from the competent authority of an EU member state or the European Commission. Another important development is the regulation of products that have been treated with a biocidal product when they are placed on the market.

The only regulations related to chemicals management that were updated in 2021 were the List of Candidate Substances for the List of Substances of Concern and the List of Substances of Concern. On December 3, 2021, the Ministry of Environmental Protection presented the new Draft Rulebook on the Classification, Packaging, Labeling and Advertising of Chemicals and Certain Products in accordance with GHS at the Chamber of Commerce of Serbia, with the aim of harmonizing it with ATP 12, with planned changes in all six annexes to be published in early 2022. However, the planned changes have not been published as of the writing of this report. A Draft of a new amendment to the Rulebook on Restrictions/Bans on Placing on the Market and Use of Chemicals was also presented. The Draft amendment should also have been published at the beginning of 2022, with prescribed transition periods, but was not.

It is important to emphasize the necessity of adopting bans related to the content of certain phthalates in consumer goods as soon as possible, as well as banning substances classified as carcinogenic, mutagenic and/or toxic for reproduction (categories 1A or 1B) in textiles, clothing and footwear. Both bans became binding in the EU during 2020, which means that products containing them were withdrawn from the EU market. There is a risk that consumer goods containing these banned substances will spill over from the EU market into the Serbian market (where they are still allowed due to the lack of such bans).

The situation is similar regarding the banning of placing certain substances found in tattoo inks and permanent makeup on the market, which became binding in the EU on January 5, 2022.

The EU has replaced Regulation 850/2004/EC on persistent organic pollutants with Regulation 2019/1021/EU and subsequent amendments, which now need to be harmonized domestically. The action plans of the National Implementation Plan for the Stockholm Convention remained unadopted, and as of 2021, they are out of date, as they were projected until 2020.

The Negotiating Position for Chapter 27 envisaged the adoption of the Law on the Implementation of the EU Regulation on Mercury (2017/852/EU) by the end of 2021, but the Law was not adopted. Worryingly, measures related to waste containing mercury from two chlor-alkali electrolysis plants in Serbia are not included in the Waste Management Program of the Republic of Serbia for the period from 2022 to 2031. So far, no decision has been made on the ratification of the Minamata Convention on Mercury.

The development of the legislative framework must continue, both through the harmonization of regulations, taking into account new EU regulations and amendments to existing regulations, as well as by strengthening the capacities necessary for the implementation of regulations.

Prescribed administrative procedures are being implemented, but given the scope and content of the documentation required by these procedures, as well as the confidentiality of certain data, the system must be further improved, especially regarding the electronic delivery of data. The administrative and professional capacities of the Department of Chemicals, as well as inspection bodies in the control of chemicals and biocidal products, must also be increased. Administrative procedures for registration in the Chemicals Register and the Provisional List for submission of technical files for biocidal products must be made more efficient in terms of strengthening electronic protection and access to data and improving work on electronic portals. Additionally, Decisions on registration in the Chemicals Register should be adopted under an accelerated procedure for requests from previous years and requests for biocidal product effectiveness testing should be harmonized with laboratory capacities in Serbia.

A mechanism for the implementation of Article 82 of the Law on Chemicals should be established. Article 82 orders the Ministry of Environmental Protection to develop and implement projects for monitoring the placing on the market and use of chemicals, monitoring their metabolites and the path of chemicals in the environment and organisms in order to monitor the risk that chemicals may pose to human health and the environment, i.e. to ensure control over the use of substances of concern and the enforcement of restrictions and bans on the production, placing on the market and use of chemicals. This very important

measure would achieve real progress in reducing the risk posed by the most dangerous chemicals.

Due to changes to the website of the Ministry of Environmental Protection, a lot of information about the field of chemicals management is no longer available, which further reduced the transparency of the implementation of regulations. It is therefore necessary to continue to improve the Chemicals and biocidal products information desk and complete the information it contains (describe below in the implementation of regulations section of this chapter). It is also necessary to make publicly available the number of decisions issued on registration in the Chemicals Register by year, as well as data on placing chemicals on the market by hazard class as statistical data, and information on the implementation of all conventions related to chemicals management. It would be useful for the Ministry to publish data on the registration of substances of concern, and whether the risk reduction measures applied by businesses are sufficient to control the risk posed by these chemicals.

Directive 2010/63/EU on the welfare of laboratory animals has been partially transposed. In order to fully harmonize national legislation with Directive 2010/63/EC on the welfare of laboratory animals, changes to the Law on Animal Welfare are necessary. According to the Negotiating Position for Chapter 27 these changes were planned by the end of 2020. A new Rulebook on the welfare of laboratory animals should also have been adopted by the end of 2021, but was not.

There were no significant changes in administrative capacities for professional work in this area compared to the previous period. Increased administrative capacities are required in order to implement regulations as well as for the further development of the chemicals management system. Inspection supervision of chemicals and biocidal products must also be strengthened (especially chemicals in consumer goods), both in terms of strengthening the capacities of the inspectorates themselves and increasing the number of inspections, as well as recording unsafe items that are withdrawn from the market due to chemical risk in the NEPRO database, in order to ensure that citizens are adequately informed.

Although, based on the increasing interest of consumers in sustainable ways of shopping and more frequent promotion of sustainable solutions in everyday life, it can be expected that more and more consumers will use their right to information about the content of dangerous substances in products, which is defined in Article 27 of the Law on Chemicals. The Ministry of Environmental Protection must supervise the protection of consumer rights stemming from this article. Based on a survey conducted by ALHem, as many as 80% of citizens (out of 215 surveyed) who sent a request for information about the content of dangerous substances in products did not receive it from the supplier, denying citizens their legal right.

Financial resources must be provided to strengthen the administrative and professional capacities of the Department of Chemicals at the Ministry of Environmental Protection, as well as the inspection authorities supervising the implementation of the Law on Chemicals and the new Law on Biocidal Products, so that administrative procedures can be carried out without breaking deadlines, having in mind their volume and complexity. With the opening of Cluster 4 – Green Agenda and Sustainable Connectivity in December 2021, within which Chapter 27 is located, the workload for the Department of Chemicals at the Ministry dealing with REACH and BPR regulations is increasing.

# Strategic and Legislative Framework

The legislative framework created by the adoption of the Law on Chemicals and the Law on biocidal products and the corresponding by-laws established a chemicals management system based on EU principles. The Law on Chemicals is harmonized with the REACH regulation (EC 1907/2006) to the fullest possible extent, as the REACH regulation prescribes centralized procedures which require EU membership, such as registration, evaluation and authorization procedures.<sup>116,117</sup> The Republic of Serbia requested the necessary adjustment periods for the full implementation of the REACH regulation (especially for registration and authorization processes), CLP and BRP regulations. The Negotiating Position for Chapter 27 envisaged the drafting and adoption of the Law on the Implementation of the REACH Regulation by 2021, which would apply from the date of accession, but this law has not yet been adopted. Drafting a new Law on Chemicals is also planned, which will retain specific provisions in the existing law related to the Chemicals Register (national registers of chemicals are in principle in accordance with EU legislation), but will not contain provisions harmonized with the REACH Regulation.

There was no progress in the reporting period in updating regulations on the classification and labeling of chemicals in order to adapt them in terms of technical and scientific progress. With the last update of the Rulebook on the list of classified substances<sup>118</sup> in March 2020, the list is aligned with *Adaptation to Technical Progress* – ATP 13, which has been in force in the EU since May 1,

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116 MEP 2009a. Ministry of Environmental Protection: Law on Chemicals, “Official Gazette of RS”, no. 36/2009, 88/2010, 92/2011, 93/2012 and 25/2015.

117 MEP, 2009b. Ministry of Environmental Protection, Law on Biocidal Products, “Official Gazette of RS”, no. 36/2009, 88/2010, 92/2011 and 25/2015.

118 “Official Gazette of RS”, no. 22/20.

2020, and in the Republic of Serbia since October 1, 2020.<sup>119</sup> However, ATP 14 from September 9, 2021, as well as ATP 15 from March 1, 2022, are now in force in the EU, while ATP 17 will become binding from December 17, 2022. All these ATPs apply to the List of Classified Substances (Annex VI of the CLP Regulation).

There were no new updates in the reporting period regarding the Regulation on the classification, packaging, labeling and advertising of chemicals and certain products in accordance with the GHS<sup>120</sup> which remains aligned with ATP 11. ATP 12 was published in the EU in March 2019, and has been in force since October 17, 2020.

On December 3, 2021, the Ministry of Environmental Protection presented the new Draft Rulebook on the Classification, Packaging, Labeling and Advertising of Chemicals and Certain Products in accordance with GHS at the Chamber of Commerce of Serbia, with the aim of harmonizing it with ATP 12, with planned changes in all six annexes to be published in early 2022. However, the planned changes have not been published as of the writing of this report.

The draft Rulebook envisages the following changes: a new hazard class is introduced in the physical hazards section – desensitized explosives; a new hazard category is introduced – self-igniting gasses within the hazard class *Flammable gasses*; the following are adjusted: criteria for substances and mixtures that emit flammable gasses in contact with water; general provisions for the classification of aerosol forms of mixtures; general limit concentrations.

Definitions and classification criteria for hazard classes are being improved: explosives, flammable gasses, flammable liquids, flammable solids and mixtures; acute toxicity, skin corrosion/irritation, severe eye damage/eye irritation, skin sensitization and respiratory sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity and aspiration hazard.

Some of the hazard notices and precautionary notices are being changed.

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119 MEP, 2020a. Ministry of Environmental Protection: Rulebook on the List of Classified Substances, "Official Gazette of RS", no. 22/2020.

120 "Official Gazette of RS", no. 21/19.



It is important to emphasize that the regular harmonization of these regulations is extremely important, given that delays in updating the List of Classified Substances result in the deviation of data on harmonized classified substances in Serbia and the EU. Therefore, in some cases, there are deviations in the implementation of the prescribed provisions on the classification and labeling of the same substances and mixtures when they are on the market of the EU and the Republic of Serbia, which is contrary to the basic goal of the GHS system – that chemicals are classified and labeled according to the same rules on all markets, i.e. in the same way. If these rules are not followed, difficulties arise with regard to the free circulation of imported chemicals, as well as the protection of human health and the environment.

During the reporting period, there was no update to the regulations governing restrictions and bans on the production, placing on the market and use of chemicals.

On December 3, 2021, the Ministry of Environmental Protection presented to the Chamber of Commerce of Serbia a draft amendment to the Rulebook on Bans and Restrictions on Placing on the Market and Use of Chemicals, which was planned to be published at the beginning of 2022, but had not been as of the writing of this report. The planned changes envisage the adoption of the following bans/restrictions, with prescribed transition periods: phthalates (DEHP, DBP, BBP and DIBP) in products used indoors (2018/2005/EU); carcinogenic, mutagenic and toxic-reproductive substances in clothing, textiles and footwear (2018/1513/EU); (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol, all its mono-, di – or tri-O-(alkyl) derivatives (TDFA) in mixtures for general use containing organic solvents in spray products (2019/957/EU); the use of diisocyanates as an independent substance or as a component of other substances or mixtures for industrial or professional use (2020/1149/EU), as well as the placing on the market of certain substances found in tattoo inks and permanent make-up (2020/2081/EU). The draft amendments to the Rulebook do not currently provide for the transposition of Regulation 2019/1148/EU banning/restricting explosive precursors, as well as banning/restricting lead content in shotgun pellets in and near wetlands (2021/57/EU) due to the objections of hunting associations.

This regulation must be further harmonized. The EU list currently numbers 76 entries, while the domestic regulation contains 71 restrictions/bans on the production, marketing and use of certain dangerous substances, mixtures or products. A ban on the content of certain phthalates in consumer goods must be adopted as soon as possible, as well as a ban on substances classified as carcinogenic, mutagenic and/or toxic for reproduction (categories 1A or 1B) in textiles, clothing and footwear. Both bans became binding in the EU during 2020, with products containing them being withdrawn from the EU market. There is a danger that these products will reach the market of the Republic of Serbia, as they have not yet been banned domestically. The situation is similar with the ban on placing on the market certain substances found in tattoo inks and permanent makeup, which became binding in the EU from 5 January 2022, and the planned transitional period for the Republic of Serbia is until 4 January 2023.

During 2021, the following bans which were adopted in the previous update of this regulation entered into force:

- 1.** After January 1, 2021, a ban on marketing rinse-off cosmetic products, which are regulated by regulations on cosmetic products, if the mass fraction of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) is equal to or greater than 0.1%;
- 2.** After June 1, 2021, N-methyl-2-pyrrolidone (NMP) shall not be placed on the market as a substance on its own or in mixtures in a concentration equal to or greater than 0.3 % unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets Derived No-Effect Levels (DNELs) relating to exposure of workers of 14.4 mg/m<sup>3</sup> for exposure by inhalation and 4.8 mg/kg/day for dermal exposure. NMP shall not be also manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0.3 % after June 1, 2021, unless manufacturers and downstream users take the appropriate risk management measures and provide

the appropriate operational conditions to ensure that exposure of workers is below the DNELs value.

3. After February 3, 2021, a ban on placing textile products on the market that can be assumed to be washed in water during the normal life cycle, if they contain nonylphenol or nonylphenol ethoxylate in concentrations equal to or greater than 0.1% (m/m) in that textile product or any part of the textile product;
4. After March 2, 2021, a ban on the production or marketing decabromodiphenyl ether (decaBDE) as an independent substance, or as a component of other substances or mixtures, as well as in products containing this substance in a concentration equal to or greater than 0.1% (m/m);

The EU has replaced Regulation 850/2004/EC on persistent organic pollutants with Regulation 2019/1021/EU and two subsequent amendments, which now need to be harmonized domestically. To our knowledge, the amendment of Schedule 2 of the Rulebook on Bans and Restrictions, Placing on the Market and Use of Chemicals has been prepared and was supposed to be adopted at the beginning of 2022, but at the time of writing this report it has not yet been implemented.

The List of Candidate Substances for the List of Substances of Concern has been updated<sup>121</sup> since the previous reporting period<sup>122</sup>, bringing the number of entries up to 211. However, the List has been additionally updated on several occasions in the EU (the most recent update was in January 2022). The EU List now contains 223 entries, 12 substances more than the domestic regulation. This difference limits the exercise of consumer rights to information about the presence of those 12 substances in products on the market in Serbia. The List of Substances of Concern was also updated in 2021<sup>123</sup> and is now fully harmonized with the relevant EU List.

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121 "Official Gazette of RS", no. 86/2021.

122 C27, 2020, Coalition 27 (2021): Chapter 27 in Serbia: Progress in Lockdown

123 "Official Gazette of RS", no. 86/2021.

During 2021, a new Law on Biocidal Products was adopted<sup>124</sup> in order to harmonize domestic legislation with the Regulation on Biocidal Products (528/2012/EU). However, the Regulation could not be transposed in its entirety due to the fact that, among other things, it regulates procedures that are centrally implemented by the European Chemicals Agency (ECHA) or the European Commission. In order to fully implement the EU Regulation on biocidal products, it is necessary, among other things, to have access to R4BP (the EU register for biocidal products), to create files in the IUCLID format, as well as to be able to exchange data, resolve complaints and communicate with the European Chemicals Agency (ECHA). The Republic of Serbia announced the necessary adaptation periods for the full implementation of the BPR Regulation, which concern submitting requests for the inclusion of alternative suppliers into ECHA, submitting requests for approval of biocidal products, as well as the gradual removal of non-compliant biocidal products from the market.

One of the key developments is the introduction of a rule requiring that a recognition procedure must be initiated for biocidal products with approval from the competent authority of an EU member state or the European Commission. Another important development is the regulation of placing products on the market that have been treated with a biocidal product (e.g. antibacterial socks treated with a biocidal product to prevent unpleasant odors; refrigerators treated with a biocidal product to prevent the development of mold and unpleasant odors; antibacterial dishwashing sponges). A provision was also introduced that obliges the entity placing the treated product on the market to submit data on the biocidal treatment of the product free of charge at consumers' request within 45 days. According to the Negotiating Position for Chapter 27 the drafting and adoption of the Law on the Implementation of the BPR Regulation, which would apply from the date of accession, was planned for the fourth quarter of 2021. However, this law has not yet been adopted.

The Negotiating Position for Chapter 27 envisaged the adoption of the Law on the Implementation of the EU Regulation on Mercury (2017/852/EU) by the end of 2021, but this law was not adopted. Worryingly, measures related to

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124 "Official Gazette of RS", no. 109/2021.

waste containing mercury from two chlor-alkali electrolysis plants in Serbia are not included in the Waste Management Program of the Republic of Serbia for the period from 2022 to 2031. The Minamata Convention on mercury has not yet been ratified.

In terms of administrative capacities for professional work in this area, there were no significant changes compared to the capacities in the previous period. In order to assess the necessary increase in administrative capacity in this area, the ECHA (the European Chemicals Agency) created a document entitled *Action Plan – Serbia, Assessment of the national capacity and readiness to implement and enforce REACH, CLP, BPR and PIC in Montenegro and Serbia*<sup>125</sup>. The Action Plan assesses the capacities of state authorities and gives recommendations for their improvement, which must be adopted.

There is a significant delay in the process of harmonizing regulations on the methods of testing the hazardous properties of chemicals, as the regulations have not been updated since 2012.

Directive 2010/63/EU on the welfare of testing animals has been partially transposed into the legislation of the Republic of Serbia. Almost all of the most important provisions (registration of users, breeders and suppliers, approval of trials, establishment of two bodies equivalent to an animal welfare body and a national board, etc.) were already been transposed into the Law on Animal Welfare<sup>126</sup> and the Regulation on the conditions for entry into the Register of animal tests and the content and manner of keeping the Register, the training program on the welfare of testing animals, the application form for approval to conduct animal tests, the manner of care, treatment and putting-down of testing animals, as well as the content and manner of keeping records on keeping, breeding and selling of testing animals and the implementation of animal tests<sup>127</sup>. The Directorate for Veterinary Medicine at the Ministry of Agriculture, Forestry and Water Management is responsible for issuing permits

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125 Action Plan-Serbia, 2019. Action Plan – Serbia, Assessment of the national capacity and readiness to implement and enforce REACH, CLP, BPR and PIC in Montenegro and Serbia, available at: [https://echa.europa.eu/documents/10162/1459379/wp5\\_action\\_plan\\_serbia\\_en.pdf/f9a0828f-ddc8-32e5-4cef-34bb9e1c2114?t=1615544961678](https://echa.europa.eu/documents/10162/1459379/wp5_action_plan_serbia_en.pdf/f9a0828f-ddc8-32e5-4cef-34bb9e1c2114?t=1615544961678)

126 "Official Gazette of RS", number 41/09

127 "Official Gazette of RS", number 39/10

for the implementation of animal tests, the registration of all users, breeders and suppliers, maintaining the Registry of animal tests, drafting legislation and regulations, recommendations and checklists and their implementation. Two bodies prescribed in Directive 2010/63 were established: the Ethical Commission for Protecting the Welfare of Testing Animals in every scientific organization and other legal entities that perform tests, as well as the Ethical Council for the Welfare of Testing Animals. This Council is equivalent to the National Committee for the Protection of Animals Used for Scientific Purposes, which is prescribed in Article 49 of Directive 2010/63.<sup>128</sup>

For full the compliance of national legislation with Directive 2010/63/EC on the welfare of testing animals, amendments to the Law on Animal Welfare are necessary, which, according to the Negotiating Position for Chapter 27, were planned to be adopted by the end of 2020. A new Rulebook on the Welfare of Laboratory Animals must also be adopted, which was also planned to be adopted by the end of 2021. However, neither have been adopted.

The legislative framework must be further developed, both through the further harmonization of regulations, taking into account new EU regulations and amendments to existing regulations, as well as by strengthening the capacities necessary for the implementation of regulations.

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128 Government of the Republic of Serbia (2019): Negotiating position of the Republic of Serbia for the Intergovernmental Conference on the Accession of the Republic of Serbia to the European Union for Chapter 27 – Environment and Climate Change

# The Implementation of Regulations

The Department of Chemicals at the Ministry of Environmental Protection is in charge of implementing administrative procedures relating to chemicals management. Prescribed administrative procedures are being carried out, but given the volume and content of the documentation required by these procedures, as well as the confidentiality of certain data, it is necessary to continue improving the system, especially the electronic delivery of data.

## Chemicals Register

The electronic delivery of data through the electronic platform for entering chemicals into the Integral Chemicals Register (eIRH) began operating in 2019, with appropriate protection and strictly defined data access levels. There are still administrative obstacles to submitting the Application Form through the Ministry's record office, due to the continued lack of an electronic record office, which means that the signed Form must be physically submitted to the Ministry. Additionally, there are occasional technical difficulties with the portal, because the server may be overloaded, especially in March, the most intensive period for reporting chemicals to the Register.

With the introduction of electronic applications, the verification of the submitted data and decisions by the competent authority were supposed to be accelerated. The current administrative procedure – from the moment that data is submitted to the final issuance of a Decision on entering the chemical into the Register – brakes all deadlines prescribed by law and usually lasts several years on average, especially for businesses registering a large number of chemicals.

Over the previous year, the delay in issuing Decisions on registering chemicals was reduced. However, in some cases the legally prescribed deadlines are still

being missed. As highlighted in the previous Report, requests from previous years should be resolved under an accelerated procedure, by simplifying the procedure in terms of requests for supplementary documentation, given that a large number of those chemicals are no longer in circulation or have changed their classification, labeling, and very often their composition.<sup>129</sup>

The eIRH portal itself must be further developed and technically improved. Chemicals advisors should be consulted as part of this process, so that they can offer proposals and suggestions in order to facilitate the work and later review the submitted requests faster. It is necessary to harmonize the database of substances on the e-IRH portal with the Rulebook on the list of classified substances – Table 1, and harmonize the names of substances with domestic regulations.

The fees for entering chemicals into the Register should be reconsidered. Currently the ranges are too large (1-100, 100-500, etc.). For example, the fee is the same if only one chemical is registered or 99 chemicals are registered.

Strengthening the administrative capacities for registering chemicals is necessary in order to improve the work of the portal and take suggestions into account.

The number of issued decisions on registration in the Chemicals Register by year, as well as data on placing chemicals on the market by hazard class as statistical data must be made publicly available again on the website of the Ministry of Environmental Protection. In this regard, it would be useful for the Ministry to publish data on the registration of substances of concern, and information on whether the measures for risk reduction applied by businesses are sufficient to control the risk posed by these chemicals.

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## Biocidal products

As stated in the Negotiating Position for Chapter 27, the main challenges related to the implementation of the Law on Biocidal Products relate to the national approval of biocidal products, given that the instruments provided by the BPR

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129 C27, 2020, Coalition 27 (2020): Chapter 27 in Serbia: Walking in the Mist



aimed at facilitating access to information on active substances and biocidal products (e.g. negotiations on data sharing, resolution of disputes related to data sharing by the Agency, access to R4BP) are not available to the Ministry of Environmental Protection and Serbian applicants for national approval in the pre-accession period.

The functionality of the e-IRH portal must be improved with regard to biocidal products, and employ stringent IT/security standards. Considering the scope and content of the documentation required by this procedure, as well as the confidentiality of certain data, it is necessary to improve the existing data protection and strictly define the different levels of data access (to enable direct electronic submission of data for owners of confidential data, i.e. foreign manufacturers, as well as to limit the level of access for importers, while allowing chemical advisors access to all the data they need to create documentation required by domestic regulations).

## General use items

The Rulebook on Establishing the Program for Health Safety Monitoring of consumer goods for the year 2021 was entirely the same as the previous year. It planned inspection supervision of 3,394 consumer goods that may contain substances defined in the regulations on bans and restrictions from the Law on Chemicals and the Law on the Health Safety of consumer goods and corresponding by-laws, namely: materials and objects in contact with food (1,860), toys (912), and materials and objects that come into direct contact with the skin or mucous membranes during use (622). Items withdrawn from the market are publicly announced in the NEPRO system (notification system for unsafe products), which is an integral part of the market surveillance system and has the goal of providing consumers with better protection from unsafe products, while also educating all market participants and raising awareness of the importance of product safety.<sup>130, 131</sup>

Despite the extensive monitoring planned for 2021 by the Ministry of Health, only three products which were withdrawn from the market due to chemical

130 Ministry of Health, 2009. Ministry of Health, Law on General Product Safety ("Official Gazette of RS", no. 41/2009, 77/2019)

131 NEPRO. Database of unsafe products, Ministry of Trade, Tourism and Telecommunications

risk were entered into the NEPRO database in 2021. The results of the monitoring conducted for 2021 were not been published at the time of writing of this report. It is therefore impossible to determine whether a product has been withdrawn from the market or whether data about it has been entered into the NEPRO database.

The program for monitoring the health safety of consumer goods should be harmonized every year with the needs of the market and the adopted regulations, such as specific restrictions and bans on the use of chemicals, which would enable better market control. On the other hand, if the Monitoring Plan should be the same every year, then there is no need to adopt it on an annual basis.

Public access to monitoring results must be ensured.

<b>Year</b>	<b>Number of publicly available notices on unsafe products in the NEPRO database in the chemical risk category</b>	<b>The number of samples evaluated as chemically defective for the content of bisphenol A, phthalates and metals in the Public Health Institutes network*</b>
in 2021	3	ND
in 2020	2	73
in 2019	35	89
in 2018	2	26
in 2017	1	36
in 2016	2	46
in 2015	0	69

\* food dishes and utensils, food packaging (items and materials in contact with food), children's toys, items that come into direct contact with the skin or mucous membranes during use are taken into account.

**ND** no data

The Dr. Milan Jovanović Batut Institute for Public Health publishes an Annual Report on the Health Safety of consumer goods in the Republic of Serbia<sup>132</sup> every

132 Institute for Public Health of Serbia "Dr. Milan Jovanović Batut" (2021): Annual Report on the Health Safety of consumer goods in the Republic of Serbia for 2020, available at: [https://www.batut.org.rs/download/izvestaji/Zdravstvena\\_ispravnost\\_predmeta\\_opste\\_upotrebe2020.pdf](https://www.batut.org.rs/download/izvestaji/Zdravstvena_ispravnost_predmeta_opste_upotrebe2020.pdf)

year. The Report includes products from the List of restrictions/bans on the production, placing on the market and use of certain dangerous substances, mixtures or products, such as items that come into contact with food (utensils and packaging), dishes, toys and decorative items (jewelry). The last annual report was published in 2020. The published data differs from data in the NEPRO database for that year. It can therefore be concluded that the NEPRO database is still irregularly updated, thus depriving consumers of information about products containing dangerous substances.

In addition to the Ministry of Trade, Tourism and Telecommunications regularly updating the NEPRO database based on reports from the Ministry of Health's inspection, it is necessary for the Ministry of Environmental Protection to establish a mechanism for the implementation of Article 82 of the Law on Chemicals, which requires the Ministry to develop and implement projects for monitoring the marketing and use of chemicals, monitoring their metabolites and the path of chemicals in the environment and living organisms, in order to monitor the risk posed by chemicals to human health and the environment, i.e. to ensure control over the use of substances of concern and implement restrictions and bans on the production, marketing and use of chemicals.<sup>133</sup> This is a very significant measure that has not been implemented by the Ministry so far, which would enable real progress towards reducing the risk of the most dangerous chemicals.

## Chemicals info desk

The Information Desk for Chemicals and Biocidal Products of the Ministry of Environmental Protection was established in 2010, and prepares information and guidelines intended primarily for business entities placing chemicals and biocidal products on the market in the Republic of Serbia, as well as interested parties and citizens, i.e. consumers, publicly available on its website. The Chemicals Information Desk is modeled after the *help desk* of the European Chemicals Agency and is part of the *HelpNet* network of the European Chemicals Agency

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133 MEP 2009a. Ministry of Environmental Protection: Law on Chemicals, "Official Gazette of RS", no. 36/2009, 88/2010, 92/2011, 93/2012 and 25/2015.

(ECHA), and since 2016 it has been officially listed on the ECHA website.<sup>134</sup> During the creation of the new website of the Ministry of Environmental Protection in 2020, not all of the existing sub-pages, or the information contained therein, were transferred (this issue was highlighted in the previous Report). During 2021, the Chemicals Information Desk was not updated with these documents. We therefore emphasize again that it is necessary to improve the availability of information, such as:

- 1.** Guidelines and criteria for entering a biocidal product in the Provisional List, i.e. specifically, make publicly available information on the requirements/criteria for testing the effectiveness of a biocidal product by product type and its purpose. The non-transparency of this information leads to companies being asked for additional tests (that often cannot be carried out in the Republic of Serbia), which they could not have foreseen before making a decision to produce/import the item in question and preparing documentation for entry on to the Temporary List.
- 2.** Guidelines for demarcation of biocidal products. These criteria and guidelines are insisted upon in practice, but are not mentioned in the Chemicals Information Desk for biocidal products.
- 3.** Publish all the necessary guides by the European Chemicals Agency in the Serbian language, as they are used in practice and insisted upon within the curriculum and examination for chemicals advisers, as well as the administrative procedure itself.
- 4.** Establish a “Frequently Asked Questions” section about the complex documentation and criteria for implementing administrative procedures, and enable more efficient and direct communication with interested parties – improving communication with businesses and chemicals advisers, which is currently mostly based on electronic correspondence.

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134 ECHA. European Chemicals Agency, HelpDesks, <https://echa.europa.eu/support/helpdesks>

## Consumers' right to information on the content of substances of concern in products

Article 27 of the Law on Chemicals of the Republic of Serbia prescribes that, at the request of consumers, any supplier of a product that contains a substance of concern in a concentration greater than 0.1% (m/m) is obliged to provide consumers with sufficient information, to the best of the supplier's knowledge at that time, to allow for the safe use of the product, including, at a minimum, the name of the substance in question. This article applies to products such as e.g. clothes, furniture, toys, electronic devices, etc. In the case of products such as food, medicine, cosmetics, cleaning agents or paints, this obligation applies only to materials used for packaging these products.<sup>135</sup>

In order to make it easier for consumers to request this information in accordance with the law, since December 2019, the *Scan4Chem* mobile application has been available in Serbia, through which a request for information on the content of substances of concern can be sent to the manufacturer.<sup>136</sup> About 13,000 products in Serbia have been scanned and searched using the application since December 2020, and around 3,000 requests for information about the content of substances of concern in products have been sent.

Based on the preliminary results of a survey conducted among users of the *Scan4Chem* application, two out of three citizens would not buy a product and/or would look for safer alternatives if they found out that the product contained dangerous chemicals. Around 80% of surveyed users of the application who sent a request for information about the presence of dangerous chemicals in a product stated that they received a response from the company: never, rarely or sometimes<sup>137</sup> (ALHem, 2021).

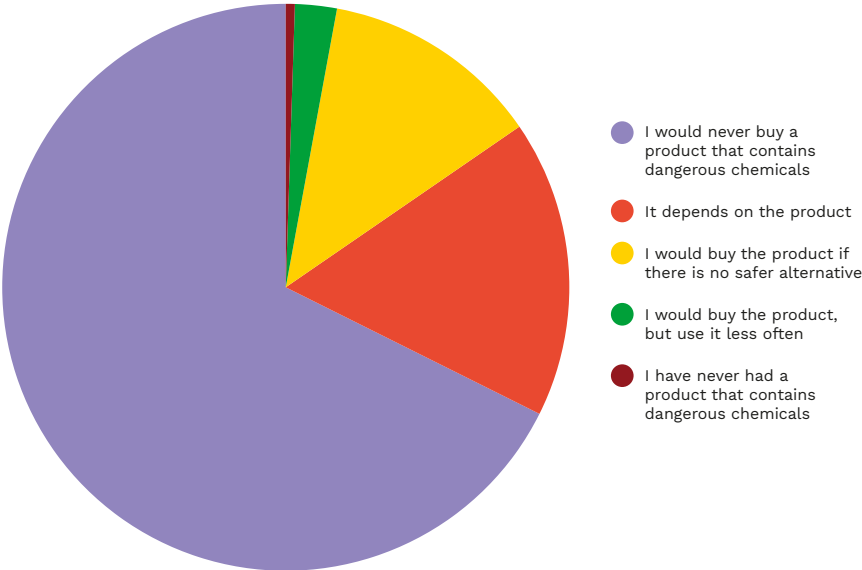
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135 MEP 2009a. Ministry of Environmental Protection: Law on Chemicals ("Official Gazette of RS", no. 36/2009, 88/2010, 92/2011, 93/2012 and 25/2015)

136 ALHem, 2019. AskReach <http://alhem.rs/ask-reach/>

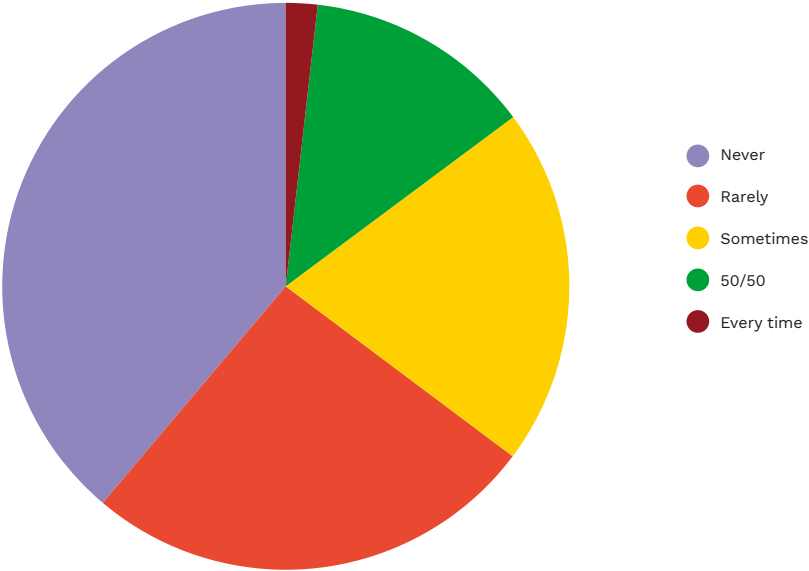
137 ALHem 2021 Final conference for the project "Realizing consumer rights to information about the presence of dangerous chemicals in products in Serbia and the countries of the Western Balkans", <https://alhem.rs/zavrсна-konferencija-projekta-ostvarivanje-prava-potrosaca-na-informaciju-o-prisustvu-opasnih-hemikalija-u-proizvodima-u-srbiji-i-zemljama-zapadnog-balkana/>

**QUESTION:** What would you do if you found out that a product you are planning to buy contains dangerous chemicals?



<b>ANSWER*</b>	<b>%</b>
I would never buy a product that contains dangerous chemicals	<b>65.4</b>
It depends on the product	<b>16.4</b>
I would buy the product if there is no safer alternative	<b>12.1</b>
I would buy the product, but use it less often	<b>2.3</b>
I have never had a product that contains dangerous chemicals	<b>0.5</b>

**QUESTION:** Based on the records from the app, how often did you receive a response from the company to a request for information about hazardous chemicals in the product?



<b>ANSWER*</b>	<b>%</b>
Never	<b>38.8</b>
Rarely	<b>25.9</b>
Sometimes	<b>20.4</b>
50/50	<b>13.0</b>
Every time	<b>1.8</b>

\* Preliminary results of the survey published by ALHem. The publication of the final results is expected in 2022.

Given the increasing interest of consumers in sustainable shopping and the increasingly frequent promotion of sustainable solutions in everyday life, it can be expected that increasing numbers of consumers will use their right to information about dangerous chemicals contained by products in the future. It is therefore important for the Ministry of Environmental Protection to supervise the implementation of Article 27 of the Law on Chemicals. However, this type of supervision has not been included in the inspectorate's annual work plan.<sup>138,139</sup> Controlling the protection of consumer rights to information about substances of concern is extremely important in order to protect the health of citizens, and given that regulations on bans/restrictions of chemicals in products are not regularly updated, this is the only way that consumers can be informed about the presence of dangerous substances in products. The condition for this is that companies fulfill their legal obligations and submit information when they receive requests.

Establishing a database on substances of concern in products, similar to the SCIP database (*Substances of Concern in articles as such or in complex objects (Products)*) by the European Chemicals Agency, should be considered in order to provide recyclers and consumers with better information about the content of hazardous substances in products.

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## Projects of the Ministry

In mid-December 2021, the Specific Implementation Plans for the REACH Regulation and the Biocidal Products Regulation (BPR) were presented. The Plans were developed with the support of the European Union within the Project "EU for a better environment – Development of a framework for harmonization with EU legislation in the field of air, chemicals and horizontal issues (EAS3 project)". During the two years of project implementation, EU experts, together with representatives of the Ministry of Environmental Protection, worked on assessing legislative and institutional deficiencies and deficiencies in the implementation of regulations, as well as measures and activities to eliminate

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138 MEP, 2019. Ministry of Environmental Protection (2019): Environmental Protection Inspection Plan for 2020

139 MEP, 2020b. Ministry of Environmental Protection (2020): Environmental Protection Inspection Plan for 2021



these deficiencies. An assessment of the costs for their implementation was also carried out. Representatives of industrial associations also participated in the Working Group. However, civil society organizations were not invited to join the Working Group. For the implementation of these regulations, the public must be provided with better information, businesses must be provided with education and professional development, and the level of expert knowledge must be raised. Civil society organizations can certainly contribute here.

The Republic of Serbia harmonized national legislation with the POPs Regulation, but the National Implementation Plan (NIP) for the implementation of the Stockholm Convention, which was updated in 2015, has not yet been adopted. Given that the NIP Action Plan covers the period until 2020, it can be considered outdated, and the specific action plans that are an integral part of the improved NIP within this document must be updated. It is unclear why the improved NIP was not adopted, given that it defines clear goals, measures and activities for reducing exposure to POPs chemicals. By ratifying the Convention, the Republic of Serbia assumed the prescribed obligations and has harmonized domestic regulations with EU regulations, so that it can establish adequate control over these substances. The adoption of the improved NIP document would open up opportunities for using funds such as the GEF fund (*Global Environment Facility*), which provides significant funding for implementing the Convention for developing countries and countries in transition.

The Stockholm Convention also regulates emissions of so-called unintentional POPs compounds (polychlorinated dibenzodioxins and furans and other compounds) which, among other things, are released during open waste incineration. In Serbia, there has been a significant increase in the number of fires at landfills, some of which have covered large areas. It is therefore necessary to apply preventive measures to control the outbreak of these fires. Additionally, it is necessary to establish adequate monitoring of the content of dioxins in soil, as well as in food that comes from raising animals near landfills where fires occur.

It is important to emphasize that consumer products can contain POPs chemicals and end up in municipal landfills. Due to the persistence of these

substances, as well as their toxicity and bioaccumulation, they pass into various environmental media. The transfer of perfluorinated compounds from waste to water should also be taken into account, especially in unsanitary and illegal landfills where there is no leachate treatment, but also from sanitary landfills where the treatment of these waters is not carried out in a way that removes these substances.

It is also important to mention the phenomenon of outdoor burning of cables in order to remove insulation from copper wires. It should be borne in mind that emissions of unintentional POPs during such burning are huge and that it is necessary to revise the regulations for punishing these actions and implement appropriate public information campaigns to prevent the outdoor burning of cables.

Within the project "Initial Assessment of Capacities for the Implementation of the Minamata Convention on Mercury in the Republic of Serbia", which was carried out by the Ministry of Environmental Protection, with the technical support of the UN Development Program and the financial support of the Global Fund for Environmental Protection, the National Inventory of Mercury Emissions for Republic of Serbia was compiled, as well as the Report on the Capacity Assessment for the Implementation of the Minamata Convention, which the Republic of Serbia signed in 2014. The report on the state of mercury in Serbia represents an important step towards the ratification of the Minamata Convention and the adoption of measures to successfully solve the problem of mercury. However, although the final report within the project was completed in 2018, it is not publicly available. So far, no decision has been made on the ratification of the Minamata Convention, although the expert team and the expert service of the Ministry of Environmental Protection have recommended that it should be ratified. Here too, it is unclear why the Republic of Serbia did not ratify this convention, given that it ratified the Protocol on Heavy Metals with the UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP), that certain provisions of the EU regulation on mercury have already been adopted, and that there is a clear plan in the Negotiating Position for Chapter 27 for full harmonization of mercury regulations. The ratification of the Minamata Convention would open up the opportunity to

access funds to solve the mercury problem, which is especially relevant given that the Republic of Serbia had two chlor-alkali electrolysis plants, which are significant sources of mercury. Funds for the implementation of these conventions are also provided for the reduction of mercury emissions (as well as POPs compounds) from coal-fired thermal power plants.

The project "Strengthening synergy in the implementation of the Basel, Rotterdam, Stockholm and Minamata Conventions in the Republic of Serbia", implemented by the Ministry of Environmental Protection in cooperation with UNDP, financed by funds from the special trust fund of UNEP, has been completed. Several drafts of public policy documents were prepared, which have not yet been adopted, nor are the drafts of those documents publicly available. As part of the project, a new BRSM web portal (<https://brsm.ekologija.gov.rs>) was established, which was primarily intended for internal communication and the exchange of official data for reporting in accordance with the requirements of the BRSM Conventions between competent state authorities. To our knowledge, the portal is not yet operational.

It should be emphasized that information regarding the implementation of all conventions under the jurisdiction of the Ministry of Environmental Protection must be made publicly available.

# Financing

There have been no significant changes to the financing of chemicals and biocidal products management since the in previous Report.

The chemical and biocidal product management system is financed from the budget of the Republic of Serbia. The Ministry of Environmental Protection opened a dedicated sub-account for paying state administrative fees for chemicals and biocidal products. However, due to the structure and functioning of the budget system, there is no data available about revenue generated from fees for providing administrative services, or whether and how much of the costs for these services were paid from other sources of tax income, i.e. from taxes not related to chemicals and/or biocidal products. This is not in accordance with the basic principles established by REACH and the Biocidal Products Regulation (BPR), as well as the accompanying implemented EU regulations that regulate fees, according to which costs related to regulatory procedures regarding chemicals and biocidal products must be borne by businesses that profit by putting them into circulation. In this sense, the new Law on Biocidal Products, adopted in 2021, did not adopt the system of fees according to the EU model, because it is not in accordance with the domestic system regulating the collection of fees. This should to be changed as soon as possible. Given that the funds generated from fees would be used, among other things, for assessing hazard levels, exposure and risk of biocidal products (which is not part of the usual administrative procedure), all citizens of Serbia would benefit, as this would protect human health and the environment.

Although public procurement is covered in Chapter 5, it should be emphasized here that green public procurement is an important economic instrument that can contribute to economic development while reducing environmental impact throughout a product's life cycle. For certain groups of products, the EU criteria for green public procurement requires that information on the presence of substances of concern (e.g. in IT equipment, furniture) is provided,

while for other products, such as cleaning agents, paints and varnishes, the absence of substances of concern are a condition to meet the green procurement criteria. The application of green public procurement in the public sector could contribute to better communication about dangerous substances in products, and thus to reducing risks to human health and the environment. During 2021, the Ministry of Environmental Protection started drafting the document "Program for the Circular Economy with Action Plan 2022-2024", which is the first public policy document on the circular economy in Serbia. The document clearly recognizes green public procurement, and defines a goal, measures and activities. The first planned measure is defining priority groups of goods, services and works for including green criteria in public procurement procedures in Serbia, which was proposed in 2019 by ALHem as part of an initiative submitted to the Ministry of Environmental Protection together with 20 CSOs in Serbia, which we consider a positive outcome of civil society advocacy. ALHem, as an interested party, actively participated in the process of public consultations, held at the end of October 2021, as well as in the public discussion held in January 2022, and submitted suggestions for amending and/or supplementing the Program. The effective establishment of a green public procurement system in the Republic of Serbia would be of great importance for creating a sustainable economy, encouraging the circular economy and innovation, and increasing the quality of life of all citizens in Serbia.

# Recommendations



## Strategic and Legislative Framework

1. Harmonize national regulations with relevant amendments to EU regulations in this sector.
2. Ratify the Minamata Convention on Mercury.
3. Update and adopt the NIP for the implementation of the Stockholm Convention on POPs.
4. Adopt a strategic document and action plan to strengthen synergies in the implementation of the Basel, Rotterdam, Stockholm and Minamata Conventions.
5. Adopt the Law on the Implementation of the REACH Regulation.
6. Adopt the Law on the Implementation of the BPR Regulation.



## The Implementation of Regulations

7. Strengthen administrative and professional capacities for chemicals and biocidal products management, especially for entering chemicals and biocidal products in the Register, as well as managing biocidal products, due to the introduction of a new procedure for the recognition of EU legislation resulting from the new Law on Biocidal Products.
8. Resolve active requests for entering chemicals into the Chemicals Register from previous years by simplifying the procedure in terms of requests to supplement documentation.

- 9.** Given the scope and content of the documentation required by the procedure for registering biocidal products in the eIRH, as well as the confidentiality of certain data, improve existing protection and strictly define different levels of data access.
- 10.** Establish a joint body for integrated chemicals management in order to establish satisfactory cooperation and coordination between all relevant sectors and ensure safe management of chemicals throughout their life cycle, i.e. the adoption and implementation of the Integrated Chemicals Management Program. The joint body should include representatives of the competent state bodies in the field of chemicals management and representatives of industry, science and research, and civil society organizations.
- 11.** Strengthen inspections of chemicals and biocidal products.
- 12.** Strengthen inspection supervision over the application of the Law on Consumer Goods.
- 13.** Improve information available on the Chemicals Helpdesk, including: guidelines and criteria for entering a biocidal product in the Provisional List, guides that are in practice applied, and frequently asked questions.
- 14.** Make data from the Chemicals Register about the number of reported chemicals by hazard class available on the website of the Ministry of Environmental Protection again.
- 15.** Establish supervision over the implementation of Article 27 of the Law on Chemicals and protect consumer rights.
- 16.** Regularly update the NEPRO database.
- 17.** Make information on the implementation of all conventions related to chemicals management publicly available on the website of the Ministry of Environmental Protection.

- 18.** Prioritize products, services and works that fit the criteria for green public procurement in public procurement procedures in Serbia and regulate the percentage of the total number of public procurements carried out for each priority group that should be in line with green procurement criteria.
- 19.** Establish a mechanism for the implementation of Article 82 of the Law on Chemicals, which orders the Ministry of Environmental Protection to develop and implement projects for monitoring the marketing and use of chemicals, monitoring their metabolites and the path of chemicals in the environment and living organisms.
- 20.** Include criteria for green public procurement in public procurement procedures in Serbia.



## Financing

- 21.** Change the domestic system governing the collection of fees and charges by implementing the EU model of financing the chemicals and biocidal product management system, in order to ensure that fees related to regulatory procedures for chemicals and biocidal products are borne by the businesses generating income by putting these chemicals and products on the market.





# CHEMICALS MANAGEMENT

The "Dr Milan Jovanović Batut" Public Health Institute publishes an annual report on the Health Safety of Consumer Goods in the Republic of Serbia. **THE REPORT ALSO CONTAINS THE NUMBER OF ITEMS FOUND TO BE CHEMICALLY DEFECTIVE** in terms of bisphenol A, phthalate and metals content.

Items that have been withdrawn from the market are **PUBLICLY LISTED ON THE NEPRO SYSTEM** (the unsafe product information system), which is part of the market oversight system with the goal of providing consumers with better protection from unsafe products.

**IN 2021, ONLY THREE PRODUCTS WERE ENTERED INTO THE NEPRO DATABASE.**

Number of publicly available notifications on **unsafe products** in the NEPRO database, in the chemical risk category

3  
2  
35  
2  
1  
2  
0



Number of samples rated as **chemically defective** in terms of bisphenol A, phthalate and metals content within the Public Health Institute network\*

No data

73  
89  
26  
36  
46  
69

\* Dishes and food utensils, food packaging (items and materials in contact with food), children's toys, items making direct contact with the skin or mucous membranes while used)

## ARE CONSUMERS APPROPRIATELY INFORMED ON CHEMICALLY UNSAFE PRODUCTS ON THE MARKET IN THE REPUBLIC OF SERBIA?

A comparison of the results from the Institute's Report and the number of NEPRO entries **INDICATES THAT THE NEPRO DATABASE IS NOT KEPT UP-TO-DATE**, thus withholding information on products that contain dangerous substances from consumers.