

## 07. CHEMICALS MANAGEMENT

### OVERVIEW

The legislative framework created by the adoption of the Law on Chemicals and the Law on Biocidal Products along with the relevant bylaws has established a modern system of chemicals management, which is significantly harmonised with the EU regulations. It is necessary however to continue with its further development, through further harmonisation; taking into account new EU regulations, as well as amendments and modifications to the existing ones, and strengthening the capacities necessary for the implementation of regulations. After a period in which the harmonisation process was partially stalled, progress was achieved in 2017, especially with regard to the updating of regulations about classification and labelling of chemicals to ensure adaptation to technical and scientific progress (ATP)<sup>90</sup>. The Biocidal Products Regulation has not yet been incorporated into national legislation.

Regarding the administrative capacities for performing professional activities in this area, there have been no significant changes in relation to the capacities in the previous period, although the new Rulebook on the systematisation of workplaces of the relevant ministry envisages a significant increase in the number of employees working in chemical and biocidal products management. Given that there is a lack of professional capacity for assessing the risk of biocidal products, the relevant authority has organised training for representatives of the scientific community in order to strengthen their capacities and later to engage them in regulatory risk assessment activities, which should be welcomed and continued in the upcoming period.

Regarding Persistent Organic Pollutants (POPs), although it was prepared in 2015, the updated National Implementation Plan (NIP) for the implementation of the Stockholm Convention on POPs by the Government of the Republic of Serbia has not yet been adopted. This made the implementation of activities from specific action plans (that are an integral part of the updated NIP) more difficult. In particular the continuation of the monitoring of POPs based on the established activities of the program for measuring the level of POPs in the environment and food, was made more difficult as was the inclusion of new POPs in the existing program.

The system of financing the management of chemicals and biocidal products does not comply with the basic principles laid down in EU regulations governing the management of chemicals, according to which the costs for regulatory procedures related to chemicals and biocidal products must be borne by economic entities that generate revenue by placing them on the market.

### LEGISLATIVE FRAMEWORK

**The legislative framework created by the adoption of the Law on Chemicals and the Law on Biocidal Products along with relevant bylaws has established a modern**

**system of chemicals management in compliance with the EU principles.** The Law on Chemicals is largely aligned with the REACH Regulation (EU 1907/2006), with the exception of provisions for the implementation of which EU membership is necessary, such as registration and authorisation procedures. **It is necessary to continue with further development of the legislative framework, not only through further harmonisation of regulations by taking into account new EU regulations, as well as through amendments and modifications of the existing ones, but also through strengthening the capacities necessary for the implementation of regulations.**

Although there has been a slowdown in the process of further harmonisation with the amendments and modifications to the relevant EU regulations adopted in the EU after 2012, (which was analysed in detail in the previous reports) some progress was made in 2017.

Regarding the updating of regulations related to the classification and labelling of chemicals in order to adjust them in terms of technical and scientific progress, there was a positive shift. Namely, in 2017, the Rulebook on classification, packaging, labelling and advertising of chemicals and certain products in accordance with the globally harmonised system of classification and labelling of the United Nations ("Official Gazette of the Republic of Serbia", No. 52/17) and the Rulebook on the List of Classified Chemicals ("Official Gazette of the Republic of Serbia", No. 50/17) have been updated, thus bringing Serbian legislation in line with the EU to the seventh ATP. However, further harmonisation needs to be established, given that these regulations are additionally updated in the EU (ATPs 8, 9 and 10), and their implementation in the EU begins at different times during 2018. We emphasise that regular harmonisation of these regulations is of great importance since the delay in updating the List of Classified Chemicals has the effect of deviation of data on harmonised chemicals in Serbia and the EU. Therefore, in some cases there is a deviation in the implementation of the prescribed provisions on the classification and labelling of the same chemicals and mixtures when they are on the EU and when they are on the Serbian market. This is contrary to the basic aim of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) which states that chemicals on all markets be classified and labelled according to the same rules, or in the same way, which may result in difficulties in the free circulation of imported chemicals, as well as greater protection of human health and the environment.

With regard to updating of regulations on bans and restrictions on production, placing on the market and the use of chemicals throughout 2017, certain amendments have been adopted ("Official Gazette of the Republic of Serbia", No. 44/2017). However, further harmonisation with the amendments to Annex XVII REACH is needed, in particular the EU Regulation 2016/2235 from December 2016, which prohibits/restricts the use of bisphenol A in thermal paper at a concentration greater than or equal to 0.02%, with the beginning of application in the EU as of January the 2nd, 2020. Based on the NPAA<sup>91</sup>, these amendments are planned to enter into force in the first quarter of 2018.

90 Adaptation to Technical and scientific Progress (ATP)

91 The National Programme for the Adoption of the EU Acquis (NPAA), Third Revision (February 2018), The Ministry of European Integration.

The Republic of Serbia has transposed the EC Regulations on amendments and modifications to the EC Regulation No. 850/2004 on persistent organic pollutants (POPs) to national legislation through the adoption of the Rulebook amending the Rulebook on restrictions, banning production, placing on the market and use of chemicals ("Official Gazette of the Republic of Serbia", No. 44/17) and the Rulebook amending the Rulebook on the list of POPs, manner and procedure for POPs waste management and limit value of POPs concentrations related to disposal of waste containing POPs or contaminated with POPs ("Official Gazette of the Republic of Serbia", No. 17/17). However, it is important to note here that the Government of the Republic of Serbia has not adopted the updated National Implementation Plan (NIP) for the implementation of the Stockholm Convention on POPs yet, although it was prepared in 2015. It is consequently difficult to implement the activities defined in specific action plans that are an integral part of the updated NIP.

The List of candidate substances for the List of substances of very high concern (SVHC) was adopted in mid-2016, making it easier for consumers to exercise their rights on information on SVHC in products. However, further harmonisation needs to be continued as the list is additionally updated in the EU, most recently by adding the widely used substance Bisphenol A (BPA). The List of substances of concern was updated at the end of 2016 ("Official Gazette of the Republic of Serbia", No. 101/2016), so further harmonisation with the EU Regulation 2017/999 should be continued, since there are 43 substances on the EU list, while in Serbia there are 31. Based on the NPAA, further integration is planned for the second quarter of 2018.

There is a significant delay in the process of harmonisation of regulations relating to the methods of examining hazardous properties of chemicals; which have not been updated since 2012.

The Regulation on Biocidal Products (528/2012/EU) has not been transposed into national legislation. Since 2009, when the Law on Biocidal Products entered into force, the relevant authority has been carrying out the national procedure on the basis of which biocidal products are either placed on the market or within the procedure for the entry of a biocidal product into the Provisional List for the submission of a technical dossier. The drafting of the new Law on Biocidal Products for the purpose of harmonisation with the Biocidal Products Directive began in 2017, and the planned deadline for the adoption of the Draft Law is the fourth quarter of 2018 according to the NPAA. The adoption of the new law is planned for the second quarter of 2019. During 2017, the List of biocidal products registered in the Register of biocidal products in 2015 and 2016, as well as the Rulebook on the content of basic information on biocidal products and the active substance contained in biocidal products ("Official Gazette of the Republic of Serbia", No. 64/17) were updated.

**Regarding administrative capacities to perform expert work in this area, there have been no significant changes in relation to the capacities in the previous period.** Although the new Rulebook on the systematisation of the workplaces of the relevant ministry foresees a significant increase in the number of employees working in chemical and biocidal products management, it must be taken into consideration that the

limitation of the number of employees in state institutions is still in place, so it is not realistic to expect that there will be opportunities for significant strengthening of administrative and professional capacities within the newly formed Ministry of Environmental Protection; although this is necessary in order to reach the necessary level for the implementation of regulations.

For the fulfilment of all obligations that the relevant authority will have in accordance with the new Law on Biocidal Products in the period prior to accession to the EU (or for the full implementation after accession) it is necessary to further strengthen the administrative capacities of the administration.. Considering that there is a lack of professional capacity for risk assessment of biocidal products, it is important to note that through the implementation of activities within an international project<sup>92</sup> in the area of chemicals and biocidal products management, a number of training courses have been organised for representatives of the state authorities dealing with these issues, as well as with **representatives of the professional community, with the aim of strengthening professional capacities in the scientific and academic sectors for effective implementation of legal regulations, primarily related to regulatory risk assessment.**

The plan is for the relevant authorities to benefit from the support of the scientific sector by delegating executive tasks such as substance evaluation and assessment of specific parts of dossiers for biocidal products that require specific knowledge, to scientific institutions or individual experts. **The establishment of a mechanism for improving the capacities of external experts and their engagement in regulatory risk assessment activities is needed not only for biocidal products but also for other chemicals**, since after the accession of Serbia to the European Union there is an obligation regarding the participation of the national capacities of the Member States in procedures that are implemented in a centralised way in the EU in this area. Also, a lack of expert capacities for the preparation and submission of proposals for harmonised classification and labelling of substances has been identified, since the relevant authority has not yet performed these tasks.

It is important to note that the project "Mercury Initial Assessment in the Republic of Serbia" is underway, and will be completed in the second quarter of 2018. This will provide the basis for building and further development of the necessary capacities for the implementation of the Regulation on Mercury (2017/852).

## IMPLEMENTATION OF LEGISLATION

The Department for Chemicals within the Ministry of Environmental Protection is responsible for activities related to **the implementation of administrative proceedings** in this area. Prescribed administrative proceedings are implemented, but given the scope and content of the documentation required by these proceedings, as well as the confidentiality of certain data, it is necessary to improve the implementation of

<sup>92</sup> Training courses were conducted within the IPA project "Further Development of Chemicals and Biocidal products Management in the Republic of Serbia" (ref. no. Twinning project SR 13 IB EN 03)

these proceedings through the **development of a modern electronic data submission system** with adequate protection and strictly defined levels of data access. This need has been identified within the Draft National Programme of Environmental Protection (NPEP) for the period 2015-2019 as a measure to improve the process of chemicals registration in the Chemicals Register. The same approach should be applied in the case of administrative procedures in relation to biocidal products.

**Inspection supervision** over the application of regulations governing chemicals and biocidal products is the responsibility of environmental, sanitary and market inspections as well as veterinary inspections monitoring the use of biocidal products in facilities where veterinary activities are performed. **The Law on Chemicals stipulates that relevant inspections shall establish a Joint Body for the purpose of planning, monitoring, harmonising and undertaking joint measures with regard to inspection supervision. However, there has been no information on the establishment of this body to date.**

The adoption of the new Rulebook on permits for performing business activities and/or permits for the use of particularly hazardous chemicals ("Official Gazette of the Republic of Serbia", No. 6/2017) which classified chemicals in the hazard class *skin corrosion/irritation* (subcategory 1B) as particularly hazardous chemicals caused additional problems in the implementation of this regulation in practice. First of all, there are no clear scientific criteria for the incorporation of chemicals classified into this sub-category of hazards into the 'particularly hazardous chemicals' category. Also, given that a large number of products of so-called household chemicals, primarily degreasers used to clean fatty deposits, the number of persons requiring a license to carry out business activities has increased significantly, including individual shops selling chemicals in this subcategory and hazard class. The system of issuing the relevant permits to distributors by local government has not yet come into practice to the desired extent. The new regulation on particularly hazardous chemicals does not ensure the protection of end-users (which was one of the goals of the regulation), because in the majority of cases a person using the chemical for general use is not subject to the regulation. The introduction of this measure is not based on the real danger aspect that subcategory 1b chemicals pose in practice and is not applicable to the type of product to which it is currently applied, or to the companies that have to implement it.

Further harmonisation of the regulations in the field of classification and labelling should be welcomed. However, in the implementation of regulations related to the labelling of chemicals, there was a problem regarding the changes in the text of the precautionary labels (P mark), especially in situations where the meaning of the text did not substantially change. It was the formulation that changed slightly, with a short deadline allowed to comply with these changes. This led to the non-conformity of labels on chemicals that are placed on the market to current regulations. Since the supplier is obliged to replace the existing labels with new ones within approximately three months, it represents a significant financial burden without the prior information that these costs could have been expected. The meaning of the precautionary tag itself has not substantially changed, nor was there a sufficiently long transitional pe-

riod that would have allowed for gradual and planned production of new labels when those already printed had been used. This suggests that transparency in the adoption of regulations and the predictability of costs related to the chemicals business on our market are not satisfactory and that such changes should be notified in a timely manner to business entities whose businesses can be affected. .

Although there is a dialogue between the authorities and the chemicals industry and other stakeholders, it needs to be continued in order to provide further information about their obligations regarding the application of EU regulations in the area of chemicals and biocidal products. In addition to the new legislative framework for biocidal products, it is necessary to establish adequate mechanisms for the operation of the domestic economy. Specifically, given the provisions of Article 95 of the Biocidal Products Regulation establishing the List of active substance suppliers and the fact that biocidal products containing active substances cannot be placed on the EU market if the suppliers of active substances are not listed on that list, adequate mechanisms must be established in a new legislative framework that will enable the domestic economy to prepare for such conditions when Serbia joins the EU. In addition, it is necessary to provide other conditions relating to the establishment of an information infrastructure for a secure connection with EU information systems and data protection measures. It is also essential to engage external capacities with regard to experts with adequate professional knowledge to assess the risk of biocidal products for the purpose of issuing approval by the relevant authority of the Republic of Serbia.

The current Law on Biocidal Products envisages a national procedure on the basis of which biocidal products are placed on the market, or a procedure for the entry of a biocidal product into the Provisional List for the submission of a technical dossier. Laboratory testing of the efficacy of a biocidal product in accordance with the manner in which it is used is a mandatory document to be submitted in this process. However, in Serbia, and often in the wider region, there is no laboratory capacity to test the efficacy of all types of biocidal products, especially repellents. Some EU Member States do not require efficacy studies at the national level products for those types of biocidal products where there are no harmonised testing methods. Considering that the Report on Active Substance Assessment prepared by the European Chemicals Agency contains information on the purpose and effective concentration of the active substance in a biocidal product, this data should be used for those types of biocidal products for which there are no laboratory capacities; or there are no harmonised testing methods until the necessary conditions are met. However, the current practice in Serbia is that a request for the Registration of a biocidal product is rejected by the relevant authority in the absence of laboratory testing of the biocidal product so that particular products existing on the EU market cannot be placed on the market in Serbia.

**Regarding POPs chemicals, given that the updated National Implementation Plan (NIP) for the implementation of the Stockholm Convention by the Government of the Republic of Serbia has not yet been adopted, implementation of activities from specific action plans that are an integrated part of the updated NIP has been made difficult. Particularly difficult is both the continuation of POPs monitoring based on the established activities of the program for measuring the level of POPs in the environment and food,**

**as well as the inclusion of new POPs in the existing program.** In order to establish a functional POPs monitoring system, it is necessary to improve the capacity of laboratories for measuring, especially new POPs, through accreditation of methods, procurement of laboratory equipment and training of laboratory staff. It is necessary to highlight some of the achieved results within the UNIDO/GEF project “Environmentally sound management and final disposal of PCBs in the Republic of Serbia”, above all the development of Technical Guidelines on the environmentally sound management of POPs as wastes in accordance with the guidelines of the Stockholm Convention on POPs.

**Given that the legislation on chemicals covers only one phase of the life cycle of chemicals, i.e. placing on the market and use of chemicals, and that there are other phases of the chemicals’ life cycle, from production to disposal, it is of essential importance to establish cooperation and coordination between departments in charge of implementing regulations on chemicals and other relevant sectors, primarily in the field of environmental protection.** This cooperation and coordination are necessary given the need for the synchronization of activities that are within the competences of different sectors to ensure adequate management of chemicals throughout their entire life cycle and for implementation of the principles of the Strategic Approach to International Chemicals Management (SAICM)<sup>93</sup>. **To date, no information is available concerning the establishment and the work of the Joint Body or the adoption of the Integrated Chemicals Management Programme, which is envisaged by the Law on Chemicals (Article 7).**

In 2017, the civil society organisation “Safer Chemicals Alternative”, a member of Coalition 27, conducted a study of the content of the hazardous chemical Bisphenol A in thermal paper and published a report in the **“Toxic Cash Receipts” campaign**<sup>94</sup>. Laboratory tests of samples of thermal paper (fiscal receipts, banking slips, etc.) were carried out at the Institute of Public Health of Serbia “Dr Milan Jovanović Batut”. They tested the presence of the substance Bisphenol A in the samples from the majority of distributors and importers in the Republic of Serbia, as well as large retail chains. The results showed that almost **all fiscal receipts in Serbia contain the dangerous substance Bisphenol A, which received great attention in the media.** Bisphenol A is a substance that has been proven to have a harmful effect on fertility; it interferes with the endocrine system, causes allergic reactions to the skin and irritation of the respiratory organs, and leads to severe eye damage. This chemical is used in the production of thermal paper as a chemical solution for dye. It is not chemically bound to the paper, so in contact with the skin, it migrates into the skin and is absorbed<sup>95</sup>.

Exactly because of that, in December 2016, the European Commission issued a regulation banning, or limiting the use of Bisphenol A in thermal paper<sup>96</sup>, primarily in order to reduce health risks for people who are exposed to BPA from fiscal receipts on

93 Strategic Approach to International Chemicals Management – SAICM

94 Safer Chemicals Alternative ALHem 2017. Toxic Cash Receipts – Testing for Presence of Bisphenol A in thermal paper, plastic and cardboard food packaging.

95 JRC EC 2010. Updated European Union risk assessment report, 4,4'-isopropylidenediphenol (Bisphenol-A): environment addendum of February 2008 – Study.

96 Commission Regulation (EU) 2016/2235 on 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Bisphenol A. Journal of the European Union, Regulation 2016/2235, Dec 2016.

a daily basis, such as employees at cash registers in retail chains, especially pregnant women. This decision will be applied in the EU as of January the 2nd, 2020. **So far, the Republic of Serbia has not transposed this regulation into domestic legislation, but the update of the relevant regulation, based on the NPAA, was announced for March 2018.** In addition, Bisphenol A has been listed on the Candidate List of substances of very high concern in the European Union since January last year; as it has been proven that it can potentially affect fertility and interfere with the endocrine system<sup>97</sup>.

For the second year in succession (in 2017 and 2018), the Government of the Republic of Serbia is organising a prize game “Take an account and win” in which it is necessary for the participants to collect and send a certain number of fiscal cash receipts in order to win some of the awards. Bearing in mind all that has been mentioned above, **the implementation of the prize game increases the risk of Bisphenol A, since citizens have extended contact with fiscal cash receipts by keeping their receipts and later counting and placing them in envelopes, thereby multiplying their exposure and therefore the risk.**

Although all members of Coalition 27 support the strengthening of tax culture in order to reduce the shadow economy in the Republic of Serbia, it is unacceptable that such a campaign is carried out to the detriment of citizens’ health, as there are other measures that would be as equally successful and without harmful effects on human health. These measures could include: strengthening of inspection supervision, more efficient sanctioning of non-compliance with regulations in this area, improvement of business environment, and introduction of incentives for the economy. In addition, it is necessary to draw attention to **the dangerous practice of recycling this paper**, because this procedure is another way of introducing this dangerous chemical into the body, through food which has been in contact with recycled paper packaging used for food packaging (boxes for confectionery products, pizza boxes). The Law on Environmental Protection rests on the **principle of prevention and precaution**, which means that **each activity must be planned and implemented in such a way as to**, among other things, **represent the least risk to the environment and human health.** The implementation of the “Take an account and win” prize game in a situation where there is no ban on the use of Bisphenol A in thermal paper in the Republic of Serbia sits at odds with these principles.

## FINANCING

Given that the financial aspect of chemicals and biocidal products management has been thoroughly analysed in previous reports, we note that there have been no changes since then. **The system of chemicals and biocidal products management is financed from the budget of the Republic of Serbia.** Given the structure and the manner in which the budget system functions, there are no available data on the amount of tax revenue spent on administrative procedures or the development of

97 ECHA, European Chemicals Agency. Candidate list of substances of very high concern for Authorization, published in accordance with Article 59(10) of the REACH Regulation: inclusions of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV ED/30/2017, ED/01/2017, ED/01/2018.

the chemicals and biocidal products management system. Also, it is not known **if a part of the costs of the chemicals and biocidal products management system is paid for from contributions from other taxpayers, i.e. those who do not generate revenue from chemicals and/or biocidal products, and if this is the case, to what amount.** This is not in accordance with the basic principles set out in REACH and the EU Regulation of biocidal products, or the accompanying EU implementing regulations on fees (Regulation (EC) No. 340/2008 and Regulation (EU) No. 564/2013), according to which the costs of regulatory procedures related to chemicals and biocidal products should be borne by economic entities that generate revenue from their placing on the market.

## RECOMMENDATIONS

### *Legislative framework*

- Establish adequate dynamics for harmonisation with relevant amendments to EU regulations in this field.
- Adopt a new Law on Biocidal Products harmonised with EU Regulation 528/2012 on biocidal products to the extent to which it is possible due to centralised procedures at the EU level.
- Amend the Rulebook on permits for performing business activities, that is, on permits for the use of particularly hazardous chemicals: delist the hazard class skin corrosion/irritation (subcategory 1B) from the criteria for particularly hazardous chemicals. When the Law on Chemicals is next amended, we suggest the provisions about particularly hazardous chemicals be removed (they do not exist even in the EU), taking into account the existence of other risk control measures for hazardous chemicals that have been implemented in practice for some time.

### *Implementation of Legislation*

- Continue improving existing administrative and professional capacities in this area and create mechanisms and conditions for engaging external experts in order to compensate for the current lack of capacity for regulatory risk assessment activities.
- The Government of the Republic of Serbia needs to adopt the updated NIP for the implementation of the Stockholm Convention on POPs as soon as possible in order to implement the activities defined in specific action plans, primarily the activities related to monitoring POPs in the environment and food.
- Improve implementation of administrative procedures through establishing

information infrastructure for electronic data submission, with appropriate protection and levels of data access.

- Establish a Joint Body for planning, monitoring, harmonising and undertaking joint measures of different inspectorates in charge of control and monitoring of chemicals and biocidal products.
- Establish a Joint Body for Integrated Chemicals Management in order to provide satisfactory cooperation and coordination between all relevant sectors and ensure safe chemical management throughout their entire life cycle, that is, adopt and start implementation of the Integrated Chemicals Management Programme.

### *Financing*

- Determine fees for administrative procedures related to chemicals and establish financial mechanisms to ensure that costs of regulatory procedures related to chemicals and biocidal products are borne by business entities that generate revenue from their placement on the market.