

06. CHEMICALS MANAGEMENT

OVERVIEW

With the adoption of the Law on Chemicals and the Law on Biocidal Products and their bylaws, a modern system of chemicals management based on EU principles was established. To ensure the adequate functioning of the system of chemicals and biocidal products management, it is necessary to continue to update existing regulations in order to properly adapt them in line with technical and scientific progress, as well as to build appropriate administrative capacities in this area.

In the period 2009–2012, all the then relevant bylaws in the field of chemicals and biocidal products management were adopted. Administrative capacities were also established, as well as a help desk, and producers, importers and distributors were informed about prescribed obligations and timeframes for their fulfilment. Implementation of relevant legislation was initiated, including the implementation of prescribed administrative procedures within the scope of work of the then responsible authority, the Serbian Chemicals Agency.

With the adoption of amendments to the Law on Chemicals in 2012 the Serbian Chemicals Agency was abolished and all chemicals management competences, registry material, equipment and staff were taken over by the ministry then responsible for environmental protection (now the Ministry of Agriculture and Environmental Protection).

The harmonisation of national legislation with amendments to relevant EU regulations that were adopted in the EU after 2012 has noticeably slowed. This is most evident in regard to further harmonisation with the numerous and comprehensive amendments to EU Regulations on classification, labelling and packaging, as well as on testing methods for the evaluation of dangerous properties of chemicals.

There has been no significant derogation from the planned timeframes set out in the NPAA 2014-2018³⁷ for aligning regulations on bans and restrictions on the production, placing on the market and use of chemicals, or for regulations on import and export of certain dangerous chemicals and detergents, with the amendments to corresponding EU regulations. However, further harmonisation in these sub-areas *is* necessary as these regulations have been additionally updated in the EU.

37 http://www.seio.gov.rs/upload/documents/nacionalna_dokumenta/npaa/npaa_2014_2018.pdf

Harmonisation with the new Regulation EU 528/2012 on biocidal products is planned for the first quarter of 2018.

Amendments to the Law on Chemicals and the Law on Biocidal Products adopted in 2015 introduced a legal basis for prescribing taxes that provide budget revenue and for the redistribution of responsibilities of environmental protection inspectors, sanitary inspectors and trade inspectors. With regard to biocidal products, certain responsibilities were also given to veterinary inspectors. In the 2015 EC Progress Report³⁸ on Serbia, this redistribution of responsibilities was positively assessed. In addition, based on the number of inspectors who are, *inter alia*, engaged in monitoring the implementation of these laws, inspection capacities were assessed as adequate. The amendments to the laws envisage that responsible inspectorates shall establish a joint body for planning, monitoring, alignment and undertaking joint measures related to inspection. However, there is still no information available on the establishment of such a body or on the practical impact of redistributing inspection responsibilities.

The provisions of Article 27 of the Law on Chemicals were further specified and provided a basis for the transposition of a Candidate List of substances of very high concern (SVHC) into national legislation. The publication of this list in 2016 ensured the precise identification of all substances subject to the obligation of provision of information on SVHC in products.

The amendments to the Law on Biocidal Products, adopted in March 2015, provided alignment with earlier amendments to the Law on Chemicals, adopted in September 2012, in regard to the competent authority. Through this measure, two and a half years after the abolishment of the Serbian Chemicals Agency, the conditions were met to cease the provisory application of competent authority provisions of the Law on Chemicals with regard to specific competences in the field of biocidal products.

A continuous decrease of administrative capacities for performing expert work in the area of chemicals management has been noted since the 4th quarter of 2012. This topic is also discussed within the 2014 EC Progress Report³⁹ on Serbia, which points out the noted trend of decreased administrative capacities and emphasises the need to strengthen capacities in this area. Moreover, within the 2015 Post-Screening Document for Chapter 27 it was specified that administrative work is being performed by only 13 employees, one third of the human capacities in 2012.

POLICY & LEGISLATIVE DEVELOPMENTS

The legal framework created by the adoption of the Law on Chemicals and the Law on Biocidal Products and their bylaws established a modern system of chemicals management based on EU principles. However, the development of the system of chemicals management should be continued, both through further harmonization, taking into account

38 http://www.seio.gov.rs/upload/documents/eu_dokumenta/godisnji_izvestaji_ek_o_napretku/godnji_izvestaji_15_final.pdf

39 http://www.seio.gov.rs/upload/documents/eu_dokumenta/godisnji_izvestaji_ek_o_napretku/serbia-progress-report14.pdf

new EU regulations and amendments to existing EU regulations, and through strengthening of capacities necessary for their implementation.

With regard to administrative capacities for performing tasks in this area, there has been a continuous decrease, with capacities now one third of those that existed in the 4th quarter of 2012. This issue is highlighted in the 2014 EC Progress Report on Serbia, as well as the need to strengthen capacities in this area, especially with regard to performing the most demanding tasks related to risk assessment.

Harmonization of national legislation in the period after 2012 has slowed, in particular with regard to the alignment of technical regulations (including specific lists), which must be continuously updated in order to ensure they are properly adjusted in line with scientific and technical progress, a process referred to as Adaption to Technical Progress (ATP⁴⁰). This is most evident in relation to legislation on classification, labelling and packaging of chemicals (Regulation EU No. 1272/2008-CLP Regulation, including its ATPs). Serbian CLP regulations have only been updated in line with the 3rd ATP of the EU CLP regulation, dating from 2012, whereas in the EU the 9th ATP of the CLP Regulation entered into force in mid-2016.

Given the specificity and scope of aligning these technical regulations with scientifically confirmed facts and updated knowledge, the current approach to approval and adoption of technical regulations in the field of chemicals managements has proven to be insufficient, leading to the mentioned slowing of the process of harmonization.

In regard to updating the regulation of restrictions and bans on production, placing on the market and the use of chemicals, regulation of import and export of certain dangerous chemicals and regulation of detergents, as well as transposing the lists of active substances in biocidal products, there were no significant derogations from the planned timeframes for alignment with EU regulations set out in the NPAA. However, it should be noted that further harmonization of these regulations should be continued in order to keep pace with updates to EU regulations.

Amendments to the Law on Chemicals and the Law on Biocidal Products adopted in 2015 introduced a legal basis for prescribing taxes that provide budget revenue, and for the redistribution of responsibilities between relevant inspectorates. No public consultations on the amendments to the law were organized and the laws were adopted under urgent procedure.

It should be emphasized, with a view to explaining the terms used in specifying responsibilities delegated to the sanitary inspectorate, that point 20a of Article 3 of the Law on Chemicals, which was inserted into the Law, defines chemicals and products intended for "general use" as "general use articles", within the meaning defined in a (separate) law regulating the health safety of general use articles (items such as cosmetics, toys, jewellery etc.). A definition formulated in this way, in which chemicals intended for general use are equated with articles for general use is unclear and ambiguous, and implies that chemicals intended for general use are regulated by another law, which is not the case. Definitions in Article 3 of the Law on Chemicals apply to the entire law, have been transposed

40 Adaption to Technical Progress – ATP.

from EU regulations and should not be expanded with such unclear formulations that aggravate implementation. If the intention was to clarify which chemicals and products fall under the responsibility of sanitary inspectors, such clarification should have been provided in the part of the law that specifies the responsibilities of sanitary inspectors.

A portion of the amendments to the Law on Chemicals adopted in March 2015 are positive. Namely, the provisions of Article 27 of the Law specified unambiguously that the obligation to provide information on the presence of SVHC in products applies to all substances that are candidates for substances of very high concern, and not only to substances specified in the list transposed from Annex XIV of REACH⁴¹. In addition, the legal basis for transposing the EU Candidate List, published in accordance with Article 59 of REACH, was given.

The transposition of the EU Candidate List into national legislation in mid-2016 has facilitated **the exercise of consumer rights to information on SVHCs in products**, as it provides clear identification of substances to which the obligation to provide information applies, in accordance with the provisions of Article 27 of the Law on Chemicals.

Amendments to the Law on Biocidal Products of March 2015 provided alignment with Amendments to the Law on Chemicals of September 2012 ("Official Gazette of RS", No. 93/2012). Bearing in mind that the initial version of the Law on Chemicals adopted in September 2009 identified the Serbian Chemicals Agency as responsible for implementation of the law and that the Agency was abolished by Amendments to the Law on Chemicals adopted in September 2012, with all responsibilities simultaneously transferred to the ministry then responsible for environmental protection (now the Ministry of Agriculture and Environmental Protection), it has been necessary to align the legal, organizational and institutional conditions required for the proper functioning of the biocidal products management system in the Republic of Serbia. The amendments to the Law on Biocidal Products adopted in March 2015, two and a half years after the abolishment of the Serbian Chemicals Agency, eliminated the lack of alignment regarding the responsible authority for implementation of the law and provided the conditions to cease the provisory application of competent authority provisions of the Law on Chemicals with regard to specific competences in the field of biocidal products.

However, since 2013, a new Regulation on biocidal products (528/2012/EU) has been applicable in the EU and the former Directive on Biocidal Products 98/8/EC, which the Serbian Law on Biocidal Products is harmonized with, has been repealed. It is therefore necessary to align national legislation with the new EU Regulation on biocidal products. Additionally, it is necessary to create conditions for the implementation of procedures for authorizing biocidal products in line with corresponding procedures and requirements prescribed in the EU, both in terms of establishing information infrastructure to safely connect with the EU information system (R4BP) and in terms of building capacities for performing regulatory risk assessment of biocidal products.

Building capacities to conduct these highly demanding assessments and procedures, which have not been undertaken in Serbia to date, is essential. Indeed, the NAD⁴² identi-

41 Regulation (EC) No 1907/2006 - REACH

42 National priorities for international assistance for the period 2014-2017. year, with projections to 2020.

fies capacity building in this area as one of the national priorities for international assistance for the period 2014 – 2017 with projections until 2020.

The legal framework for carrying out animal testing for the purpose of gathering data on dangerous properties of chemicals and biocidal products has not been aligned with Directive 2010/63/EU on the protection of animals used for scientific purposes. The transposition of this directive into national legislation is planned for the third quarter of the 2017. It should be noted that although a legislation on good laboratory practice (GLP) has been adopted, mechanisms for issuing GLP certificates in Serbia have not yet been established, therefore no domestic laboratory can fulfil the conditions for performing testing of toxicological and ecotoxicological properties in accordance with prescribed methods of testing dangerous properties of chemicals set out in Regulation (EC) 440/2008 on testing methods. In relation to this issue, it is necessary to establish better intersectoral cooperation, as GLP falls under the responsibility of the Ministry of Health, the protection of animals fall under the responsibility of the Veterinary Directorate, while chemicals fall under the responsibility of the Ministry of Agriculture and Environmental Protection.

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 in chemicals life cycle, from production to disposal, it is of essential importance to establish adequate 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 is necessary in order to synchronize activities across different sectors and ensure safe chemicals management throughout their entire life cycle, and for the implementation of the principles set out in the Strategic Approach to International Chemicals Management (SAICM)⁴³. Article 7 of the Law on Chemicals lays down provisions on Integrated Chemicals Management, including the obligation to adopt an Integrated Chemicals Management Programme and to establish a Joint Body with the task of preparing the programme and associated action plans, as well as monitoring the implementation of the programme and action plans and coordinating activities related to safe chemicals management throughout their life cycle. To date, no information has been available about the establishment and work of the Joint Body or the adoption of the Integrated Chemicals Management Programme.

IMPLEMENTATION

The Department for Chemicals within the Ministry of Agriculture and Environmental Protection is in charge of **activities related to carrying out administrative procedures** relating to chemicals management. Administrative procedures are being implemented. However, due to the large volume and content of documentation required by procedures, as well as the confidentiality of certain data they contain, it is necessary to improve and accelerate administration procedures through **developing a modern system of electronic data submission**, with appropriate protection and strictly defined levels of data access. The need for electronic data submission was identified within the draft Action Plan for

43 Strategic Approach to International Chemicals Management - SAICM

the National Programme for Environmental Protection (NPEP) for the period 2015–2019 but only in regard to the inclusion of chemicals into the Chemicals Register. The scope of electronic data submission should be widened to include administrative procedures related to biocidal products.

Inspection control in regard to the implementation of a greater portion of the provisions of regulations on chemicals and biocidal products is the responsibility of the Inspectorate for Environmental Protection. The Sanitary Inspectorate is responsible for control of the implementation of regulations on bans and restrictions, placing on the market and use of chemicals and products intended for general use. In addition, the Sanitary Inspectorate is responsible for inspection of the use of biocidal products by professionals for registered activities, as well as in areas, facilities and activities that are subject to sanitary control, except for the use of biocidal products in facilities in which veterinary activities are performed. The Trade Inspectorate is responsible for control of compliance with the conditions for keeping dangerous chemicals (as well as biocidal products) in sales areas and the labelling of such areas. In 2015, the Veterinary Inspectorate took over responsibility for performing control of the use of biocidal products by professional users performing registered veterinary activities, as well as in areas, facilities and activities under veterinary control.

This redistribution of responsibilities was introduced with the amendments to the Law on Chemicals and the Law on Biocidal Products ("Official Gazette of RS", no. 25/2015) and was positively assessed in the 2015 EC Progress Report on Serbia. In addition, based on the number of inspectors who are, *inter alia*, engaged in control of the implementation of these laws, inspection capacities were assessed as adequate. The amendments to the laws envisage that responsible inspectorates shall form a joint body for planning, monitoring, alignment and undertaking joint measures related to inspection. However, to date, no information is available on the establishment of such a body. **The practical impact of this redistribution of responsibilities between various inspectorates is expected to be seen in the upcoming period, as well as the provision of information on the establishment and work of the joint body.**

FINANCING

The system of chemicals and biocidal products management is financed from the budget of the Republic of Serbia.

Taxes on biocidal products are collected in accordance with the regulation on tax height, tax payers, and the manner of payment of taxes for evaluation and verification of data on biocidal products ("Official Gazette of RS", no. 90/15).

In regard to taxes related to chemicals, at present only the minimum republic administrative tax is levied, as the necessary regulation on taxes has not yet been adopted, although the basis for it is provided for in the amendments to the Law on Chemicals of March 2015.

Given the structure and manner in which the budget system functions, data are not available on the amount of tax revenue spent on administrative procedures or the development of the chemicals and biocidal products management system.

Data is also not available on whether and to what extent part of cost of the chemicals and biocidal products management system are paid from contributions from other tax payers, i.e. those who do not generate revenue from chemicals and/or biocidal products.

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.

OTHER IMPORTANT INFORMATION

Given that the process of reducing the number of employees in state authorities is on-going, it is unrealistic to expect a significant increase in the number of employees in the Department for Chemicals within the Ministry of Agriculture and Environmental Protection or that adequate capacities to conduct regulatory risk assessment will be developed within the state administration. Therefore, in order to upgrade existing capacities for regulatory risk assessment, mechanisms for engaging external experts in chemistry, toxicology, ecotoxicology and related sciences from the scientific and academic sector should be established, and their expertise should be upgraded through trainings on regulatory activities. This should be done with the long term perspective in mind, in order to ensure that the Republic of Serbia possesses the necessary capacity to fulfil its future obligations as a Member State in terms of provision of national capacities for carrying out procedures connected to regulatory risk assessment and obligations in the EU related to chemicals and biocidal products.

RECOMMENDATIONS

Policy & Legislation

- Establish adequate dynamics of alignment with relevant amendments to EU regulations in this field, in particular with regard to adjustments to scientific and technical progress.

Implementation

- Improve existing administrative capacities for performing tasks related to chemicals management and create mechanisms and conditions for engaging external experts in order to compensate for the lack of capacities for regulatory risk assessment.
- 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, alignment and undertaking joint measures of inspectorates with responsibilities relating to chemicals and biocidal products.

- Establish better intersectoral cooperation among state authorities responsible for GLP, protection of animals and chemicals, in order to create conditions for the application of the Regulation on testing methods for the evaluation of dangerous properties of chemicals.
- Establish the Joint Body for Integrated Chemicals Management in order to provide satisfactory cooperation and coordination between all relevant sectors and ensure safe chemicals management throughout their entire life cycle.

Financing

- Prescribe 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 economic entities that generate revenue from their placement on the market.