Action Plan - Serbia

Assessment of the national capacity and readiness to implement and enforce REACH, CLP, BPR and PIC in Montenegro and Serbia

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Executive Summary

For more than 10 years, Serbia has been developing its chemicals management system to align it with the EU regulatory framework. The national legislation is harmonised to the extent possible as an EU candidate country – i.e. without those procedures that are administered centrally at EU level which would require EU membership. In line with a commitment to EU integration, Serbia is making efforts to establish and implement adequate plans for the pre- and post-accession periods that would prepare both the administrative capacities and the chemicals industry for access to the European internal market.

This report presents the recommendations stemming from the results of the comparative legal analysis of the national legislation with the EU acquis and from the results of the assessment of the institutional capacity and infrastructure available in Serbia for the implementation and enforcement of:

- *Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);*
- *Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP);*
- *Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR); and*
- *The recast prior informed consent (PIC) Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals.*

The aim of this report is to provide support to Serbia and thoroughly prepare them for their EU membership obligations regarding chemical safety regulations.

The assessment has identified the lack of necessary staff resources for the implementation and enforcement of the four Regulations as the main challenge. In order to strengthen the administrative capacity and enable the implementation of the other recommended actions, there are some underlying challenges that need to be tackled first. These are beyond the remit of the Department for Chemicals or the Ministry of Environmental Protection itself, and might be relying on policy decisions by the Government of the Republic of Serbia. In particular, the moratorium on hiring civil servants is contradicting the plans for strengthening the capacity of the public administration in the years before EU accession. The lifting or suspension of the moratorium is therefore essential to ensure that the Department for Chemicals and the Division of Chemicals for supervision and control of the Ministry of Environmental Protection are allocated the necessary resources to fulfil their obligations and responsibilities. To ensure that adequate financial resources are available to fund new job positions within the Department for Chemicals, administrative fees and charges levied on entities applying for procedures regulated by the Law on Chemicals, the Law on Biocidal Products and associated rulebooks should be paid to a budget dedicated to activities in the chemical risk management area and managed by the Ministry of Environmental Protection. Finally, the adoption of the new Draft Law on Biocidal Product enables the authorisation of biocidal products through the procedure equivalent to the BPR mutual recognition in sequence procedure.

It is recommended that these three actions are given the highest priority for implementation in 2021. In parallel, it is recommended that the Ministry of Environmental Protection drafts and ratifies a Memorandum of Understanding with scientific institutes and external experts, which would facilitate the outsourcing of some workstreams avoiding overloading the Department for Chemicals.

The above measures would allow hiring new staff and outsourcing workstreams, contributing to address some of the other challenges associated with insufficient administrative capacity such as the loss of expertise due to the high staff turnover. Avoiding work overload and ensuring competitive salaries may stabilise the turnover rate and bring it to more natural levels. It is recommended that the

Government of the Republic of Serbia develops a plan to retain the staff of the public administration entities.

The Ministry of Environmental Protection should develop a communication strategy leading up to the accession in 2025. It is recommended that stakeholder management and other aspects of external communication form part of the job description of a specific new employee together with the assignment to helpdesk and information services.

It is recommended to significantly upgrade the IT infrastructure and the IT safety policies and procedures. The Ministry of Environmental Protection should conduct an initial external IT security audit aiming at identifying needed actions to bring the existing IT system up to the standard required by the European Chemicals Agency.

One of the main risks associated with the recommended actions is that the Serbian competent authority may choose to focus on the more "low hanging fruit" recommendations, such as training, capacity building and keeping the national legislation aligned with the EU acquis, without addressing the more fundamental issue: the strengthening of the administrative capacity of the Ministry of Environmental Protection is essential to Serbia's readiness to join the EU.

While Montenegro and Serbia may not be comparable in terms of size of the market relating to chemical and biocidal products and therefore the administrative capacity required may differ, the two countries are facing many similar challenges in their preparation towards accession to the EU. Both countries need to strengthen their administrative capacities where the underlying causes are similar:

- *a moratorium on hiring civil servants is in place;*
- *lack of a sustainable financing system aligned with the EU Regulations and principles;*
- *need to ratify Memorandum of Understanding with scientific institutes to facilitate access to external experts.*

Montenegro has drafted an MoU with national research institutes; therefore, the Serbian competent authority could benefit from their experience in establishing such collaboration agreement. Montenegro and Serbia may also consider expanding the scope of the memorandum in both countries so that, if necessary, the Montenegrin authorities could access the expertise of the Serbian scientific institutes and vice versa. It is also likely that the same biocidal products are supplied in both countries, hence an enhanced collaboration may result in accelerating the authorisation process and in saving resources.

Finally, both countries would benefit from support from the European Chemicals Agency or Member State competent authorities in providing capacity building and training on risk assessment, IT security, e-tools and enforcement. Joint activities would therefore be beneficial to consider, in order to share training materials and optimise the use of resources.

1 Introduction

1.1 Context

The European Chemicals Agency (ECHA), on behalf of the European Commission (EC), is running its fifth project under the Instrument for Pre-Accession Assistance (IPA). These projects are targeted at assisting candidate countries to the European Union (EU) in preparing for the obligations of EU membership, in this context specifically regarding chemical safety regulations. They have the overall aim to equip candidate countries with the knowledge necessary to fully participate in the implementation of EU chemicals policy and in the work of ECHA.

Since 2009, ECHA has implemented four IPA projects focused on explanatory and training events for the authorities of Montenegro and Serbia. The Agency's main goal is to provide technical support to develop these countries' understanding of ECHA's regulatory activities and facilitate the alignment of their national legislations with the EU regulatory framework.

To increase the impact of ECHA's general support activities (such as visits, specific trainings and participation in ECHA events), the Agency has contracted an in-depth assessment of the legal and institutional capacities of both countries.

This report presents the recommendations stemming from the results of the comparative legal analysis of the national legislation with the EU acquis and from the results of the assessment of the institutional capacity and infrastructure available in Serbia for the implementation and enforcement of:

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP);
- Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR); and
- The recast prior informed consent (PIC) Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals.

1.2 Methodology and report structure

The report describes the identified gaps and details the actions necessary to fill them. The gap assessment draws on the information gathered through the consultation with the Serbian competent authority and other national stakeholders. This has been complemented by information collected through the review of the existing plans prepared by the Serbian authority to align the relevant legislative framework with the EU acquis, the documents produced by the Swedish Chemicals Agency as a result of their co-operation project "Chemicals risk management in Serbia" and the final report of the twinning project "Further development of chemicals and biocides products management in the Republic of Serbia" between the Ministry of Health, Chemicals Office of the Republic of Slovenia, the Austrian Environment Agency and the Ministry of Environmental Protection of the Republic of Serbia.

Actions have been suggested in the following areas:

- The alignment of the national legislation with the four EU Regulations;

- The capacity and competence needs at institutional level for implementation and enforcement;
- Systems and processes for transparency and stakeholders' engagement;
- The IT infrastructure, capacity and competence.

In addition, the report discusses potential similarities in gaps and shortcomings between Montenegro and Serbia and considers whether these could be addressed by joint actions.

All actions are broken down in subsequent sections of this report, their dependencies have been highlighted and timelines have been suggested for their implementation. Each action is accompanied by the list of relevant possible actors and the estimated financial and human resources required. Finally, other important aspects are described, (e.g. awareness raising, outreach, collaboration and communication with other stakeholders) for the successful implementation of the recommended actions.

2 The Action Plan

2.1 Challenges and gaps identified

The assessment of the degree of legal harmonisation, the institutional capacity and necessary infrastructure has identified several intertwined challenges and gaps. Figure 1 shows the interlinkages between underlying causes, challenges and effects.

The work of the Department for Chemicals to align the national legislation with the EU chemical acquis has been successful especially considering the pace of the development of the European chemical legislative framework[1] together with the complexities of introducing EU centralised procedures into a national system. The alignment of the Serbian legislation with the EU acquis is resource-intensive work. However, there are other underlying issues that would be beneficial to address to ensure progress:

Challenges

- The moratorium on hiring civil servants;
- The new Draft Law on Biocidal Products which has not yet been adopted;
- Lack of a budget dedicated to chemical risk management activities;
- Expected increase of enquiries to the Helpdesk leading up to the accession and beyond;
- Lack of a Memorandum of Understanding with Scientific Institutes or Academia to draw on resources outside the ministry; and
- Differences between the national inventories and ECHA's inventories.

Gaps

The key issues and gaps which are mainly generated by these underlying causes are:

- Understaffing of the Department for Chemicals;
  - Backlog of biocidal products on the Temporary List that require to be authorised through the BPR procedures;
  - High workload for existing staff;
- Understaffing of the Division for Chemicals of the Sector for Environmental Surveillance and Precautions at the Ministry of Environmental Protection;
- Difficulty in ensuring sustainable financing, and consequently in resource planning, for the authorisation of biocidal products;
- High staff turnover resulting in loss of expertise;
- Lack of a communication strategy and procedures, including dissemination of information about working practices such as managing confidential business information; and
- Lack of capacity and alignment of existing IT infrastructure, policies and procedures with ECHA standards. In particular:
  - Lack of a formal policy for management of non-public information;
  - Lack of a security awareness programme, including introduction and regular security trainings for DfC employees;
  - Lack of a teleworking security policy; and

[1] Updates of the annexes of the REACH Regulation (new substances added to the authorisation and restriction lists, adaptations to the information requirements to better cover nanomaterials), adaptations to technical progress (ATPs) of the CLP Regulation, approvals of active substances (Biocidal Products Regulation).

- Lack of regular external and internal audits of the IT infrastructure, policies and procedures.

These challenges and gaps may result in:

- Delays in implementing EU regulatory developments, such as the late transposition of CLP ATPs and REACH annexes amendments into Serbian law; and
- Delays in processing and responding to current industry applications, resulting in uncertainty by private entities over regulatory compliance, distrust towards the competent authority and perceived lack of transparency.

Causes, challenges, gaps and effects are further discussed in the sections below, along with the suggested ways forward. Figure 2 shows the objective tree, with the actions to tackle the challenges and gaps identified above.

Where relevant, actions are structured in subsequent steps with descriptions including:

- Their dependencies;
- The identification of the body responsible for the action;
- The identification of the other relevant stakeholders which may be affected and should be involved to provide support and should be kept informed of relevant changes and timelines;
- The necessary human and financial resources;
- The suggested timeline leading up to accession; and
- The risks, and the risk-mitigation measures to help ensure the successful implementation of the action.

The final section presents an analysis of the similarities in gaps and shortcomings between Montenegro and Serbia and discusses if and how these could be addressed by joint actions and, if so, by whom.

Figure 1 – Interlinkages between causes, challenges and effects

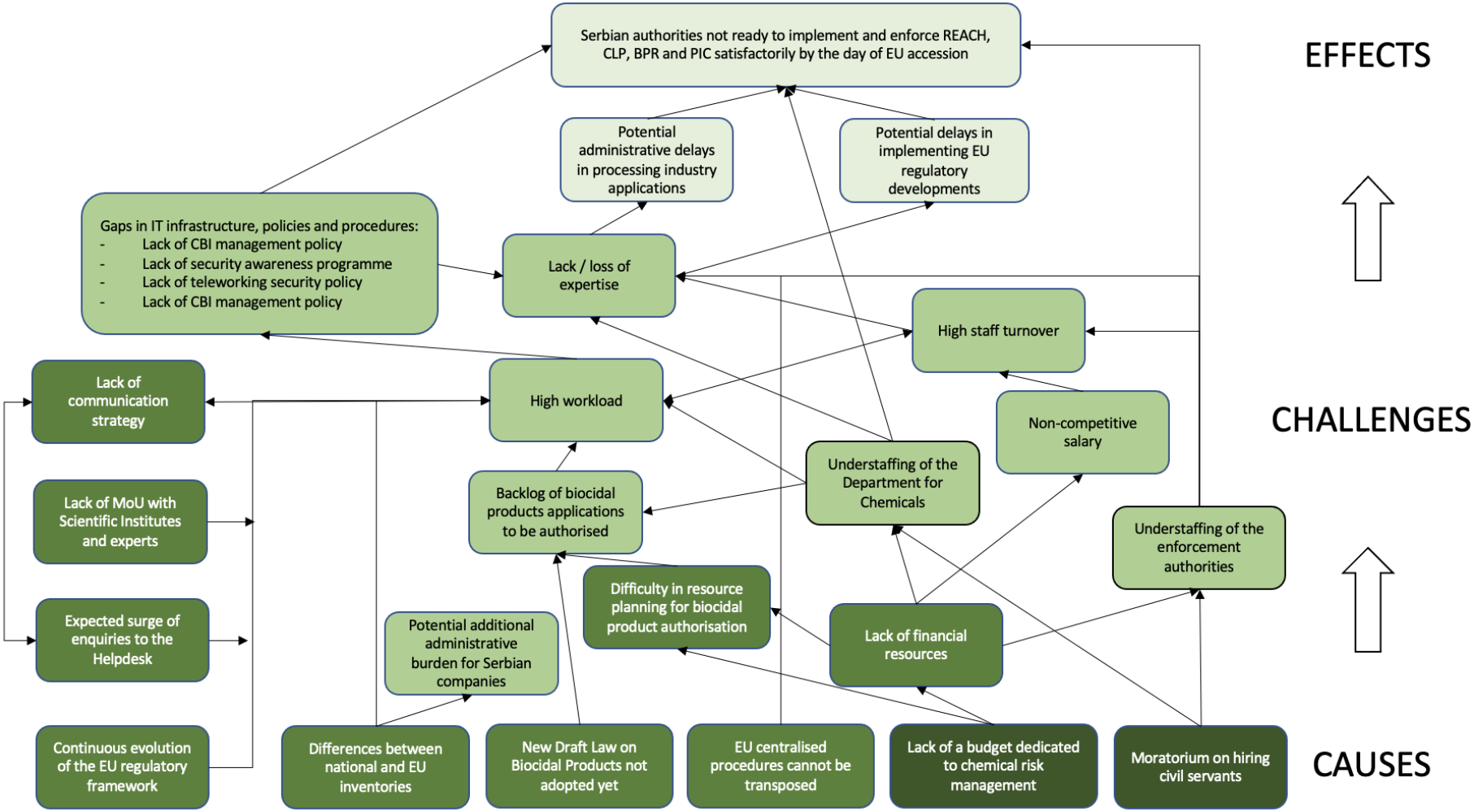
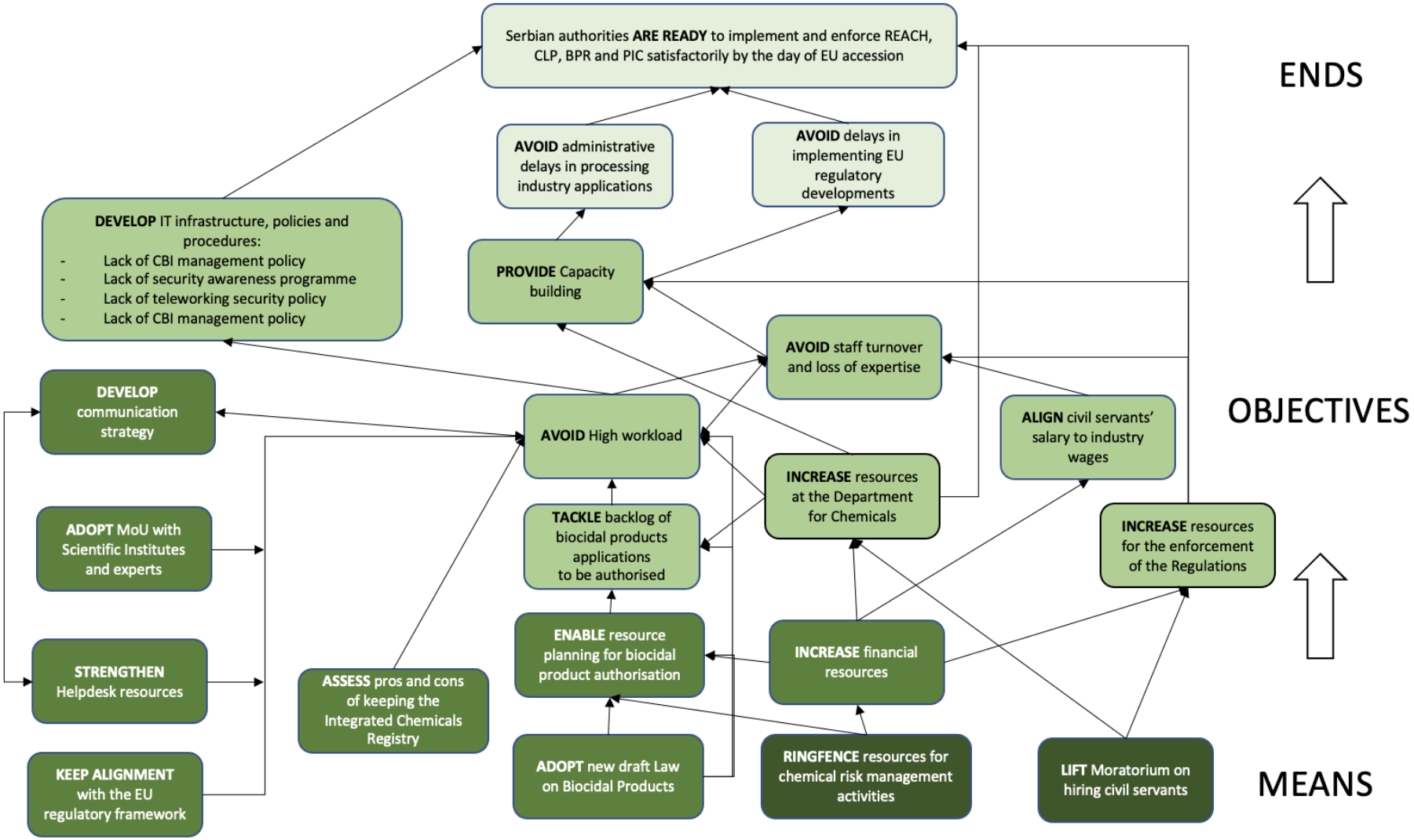


Figure 2 – Objective tree



2.2 Underlying causes and means to address them

2.2.1 EU centralised procedures cannot be transposed into the national system before accession

2.2.1.1 Description of the challenges and dependencies

The articles of the four regulations which relate to EU centralised procedures cannot be transposed.[2] The current institutional and legislative setup focuses on strictly administrative procedures which do not necessarily require scientific expertise on risk assessment. Currently, the Serbian competent authority cannot have access to the e-tools used by EU Member States' competent authorities to access and manage the information exchange with ECHA.

This results in a lack of scientific capacity for risk assessment in relation to evaluation, authorisation, proposals for restrictions and proposals for harmonised classification and labelling, as well as in relation to biocidal products and biocidal active substances. The DfC staff also lack the necessary practical knowledge on how to use the ECHA e-tools such as REACH IT, R4BP and IUCLID.

2.2.1.2 Recommended actions, action owner and other relevant stakeholders

The existing plans for strengthening institutional structures[3] states that a sufficient number of civil servants should be adequately trained to fulfil all future tasks of a Member State post-accession. Since 2009 ECHA activities, implemented under the Instrument for Pre-accession Assistance (IPA) and funded by the European Union, have provided capacity building and support to the implementation of the EU chemicals legislation. Among the many capacity-building activities[4], the IPA 2013 twinning project SR13 IB EN 03, 'Further development of chemicals and biocidal products management in the Republic of Serbia' trained around 20 people on the assessment of physicochemical properties, toxicological and ecotoxicological aspects, efficacy, fate and behaviour and exposure assessment.

It is recommended that ECHA implements additional capacity building activities focusing on risk assessment and hands-on training sessions focusing on the functioning of the e-tools used by national competent authorities to manage the information exchange with ECHA. Table 1 shows the conformity of the objective to the SMART criteria.

[2] This is the case with:

- REACH: Article 4, REACH Articles 5-12 and 15-30, partially Art. 13 and 14, Article 32, Articles 37-39, Articles 40-54, Articles 55-66, partially Art. 68, Articles 69-73, Articles 74-120 (fees), partially Articles 121-124 and Articles 125-127, Articles 128 – 141;
- CLP: Partially Article 1 and Article 4, partially Article 24, partially Articles 25-33, Article 34, partially Article 36, Articles 37-42, partially Articles 43-47, Articles 50-60, partially Art. 61 and Art. 62;
- BPR (BPD): Partially Articles 1-3, Articles 4-11, Articles 12-16, partially Articles 17 and 19-22, Articles 18 and 23-24, Articles 25-28, partially Articles 29-31, partially Articles 32-33 and 37, Articles 34-36 and 38-40, Articles 41-46, partially Articles 47-50 and 52, Art 51, Article 54, partially Article 57, Article 58, Articles 59-64, partially Articles 65-66 and 68, Art. 67, Article 71, partially Article 73, Articles 74-79, Articles 80, 82-86 and 88-97, partially Art. 81 and Art. 87, partially Annex I, Annex IV, partially Annex V and Annex VI, Annex VII;
- PIC: Partially Art 2 and Art 4, Article 5, Article 6, partially Articles 8-14, partially Articles 18-21, Articles 21- 27, partially Article 22, Articles 29- 31, partially Annex II and Annex III, Annex IV, Annex VII.

[3] NPAA – Third revision (2018-2021), page 1201.

[4] The whole list of events, study visits and workshops organised by ECHA can be found at: https://echa.europa.eu/about-us/partners-and-networks/international-cooperation/support-to-eu-external-relations-policies/activities-under-ipa/2018-2019

Table 1 – Objective 1: Ensure risk assessment capacity and practical experience with e-tools

Criteria	Notes
Specific	ECHA implements additional capacity building activities focusing on risk assessment and hands-on training sessions focusing on the functioning of the e-tools used by national competent authorities to manage the information exchange with ECHA.
Measurable	Number of civil servants and external expert trained per year
Achievable	ECHA has implemented capacity building projects in Serbia since 2009.
Relevant	Capacity building will ensure a smoother EU accession.
Time-bound	Training on risk assessment should be prioritised and possibly start already in 2021. Hands-on training on e-tools could be organised closer to the day of accession.

2.2.1.3 Estimated human and financial resources required

The human and financial resources that ECHA, the Member States' competent authorities or any other providing organisation may have to allocate to fill existing needs through capacity building, depends on several factors. These are, for example, the number of tutors involved, the number of attendees, the number of in-person classes vs. number of remote learning sessions, travel, accommodation and subsistence for tutors coming from abroad, necessary IT and laboratory equipment, etc.

As an indication, the Swedish Chemicals Agency spent around €150,000[5] and 150 workdays (around 0.7 FTE) carrying out trainings of MEP staff in 2017[6]. In the context of the twinning project implemented by the Austrian and Slovenian competent authorities[7], the cost of the organisation and actual implementation of trainings and workshops was around €110,000. The courses, which were attended by at least two DfC staff members per session, focused on risk assessment and risk management of biocidal products. The training was organised over a period of 20 days in Belgrade and saw the participation of 11 tutors for a total of 88 workdays (around 0.4 FTE). The preparation of the training programme and corresponding training materials required around €20,000 and two meetings in Serbia, with the participation of 3 experts for a total of 18 workdays (0.1 FTE).

In the context of the same twinning project, the organisation and implementation of an eight-day training for at least seven DfC staff members on e-tools (REACH IT system, R4BP, CHESAR, IUCLID, etc.), with the participation of nine tutors for a total of 25 days (around 0.1 FTE), cost around €40,000.

2.2.1.4 Timeline, risks and risk mitigation measures

It is recommended to prioritise those capacity building activities which are focusing on risk assessment. This is because, risk assessors are needed to tackle the backlog of applications for authorisation of biocidal products (more details are provided in the sections below). The risk is, however, that once DfC staff and external experts are trained in risk assessment, they cannot use their knowledge since the new Draft Law on Biocidal Products may not be adopted yet (additional details are provided in Section 2.2.4). Also for this reason, hands-on training on e-tools can be organised closer to the day of accession.

[5] Around SEK 1,500,000.

[6] KEMI (2018): Chemicals risk management in Serbia. Annual report 2017, p.12.

[7] *Twinning Contract number: SERBIA – IPA 2013 - ENVIRONMENT - SR 13 IB EN 03.* Further development of chemicals and biocides product management in the Republic of Serbia (2015-2018), between the Chemicals Office of the Ministry of Health of the Republic of Slovenia, the Austrian Environment Agency and the Ministry of Environmental Protection of the Republic of Serbia.

2.2.2 Continuous evolution of the European chemical legislative framework

2.2.2.1 Description of the challenges and dependencies

The European chemical legislative framework is in constant evolution, e.g.:

- new substances are added to the authorisation and restriction lists every year;
- the REACH annexes have been adapted to clarify the information requirements for nanomaterials;
- yearly adaptations to technical progress (ATPs) of the CLP Regulation;
- new approvals of active substances (Biocidal Products Regulation); and
- new substances in the annexes of the PIC Regulation.

Consequently, keeping the Serbian legislation aligned with the EU acquis is a resource-intensive work. It was estimated by the Serbian authority that around 20% of the workdays of the DfC staff are today used for keeping the national legislation at the current level of alignment.

2.2.2.2 Recommended actions, action owner and other relevant stakeholders

The work carried out by the Department for Chemicals can be described as a zero-sum game, where each task competes for a limited amount of resources, i.e. the total worktime of DfC staff. The alignment, and keeping the alignment, of the national legislation with the EU regulations is a resource-intensive task, as are other tasks necessary for the adequate implementation of the national chemical laws. Currently, the Department for Chemicals is understaffed resulting in a heavy workload for DfC staff. **It is recommended that the Ministry of Environmental Protection strengthens the capacity of the Department for Chemicals.** This is further discussed in Section 2.3.1. Table 2 shows the conformity of the objective to the SMART criteria.

Table 2 – Objective 2: Strengthen DfC capacity

Criteria	Notes
Specific	The Ministry of Environmental Protection strengthens the capacity of the Department for Chemicals.
Measurable	Number of additional DfC staff members
Achievable	Further discussed in Section 2.3.1.
Relevant	Additional capacity is key to overcome many of the identified challenges.
Time-bound	It is estimated that the DfC will need around 3 FTEs per year dedicated to the alignment of the national legislation.

2.2.2.3 Estimated human and financial resources required

The Serbian authority have estimated that 3 FTEs per year in the period 2021-2025 are required to keep the alignment of the national legislation with the EU acquis.

2.2.2.4 Timeline, risks and risk mitigation measures

Timeline, risks and risk mitigation measures for strengthening the administrative capacity of the DfC are discussed in Section 2.3.1.

2.2.3 Differences between the national inventories and ECHA's inventories

2.2.3.1 Description of the challenges and dependencies

The national inventory, the so-called Register of Chemicals, was established in 2010 pursuant to Articles 39-47 of the Law on Chemicals[8]. The register includes chemicals (substances, as well as mixtures) placed on the Serbian market (i.e. manufactured or imported) in annual quantities equal to or higher than 100kg. Together with the Register for Biocidal Products and the Register of Plant Protection Products, they all form the Integrated Chemicals Registry.

The notifiers to the Register of Chemicals are manufacturers, importers or downstream users. They must submit a notification to the competent authority (i.e. the Ministry of Environmental Protection), by 31 March at the latest, for chemicals and chemical products manufactured or imported over the previous year. The notification shall contain data on the applicant (i.e. the name and address, tax identification number, type of business activity, name of the responsible person in the company and the name of the chemicals adviser, in case the obligation to have a chemicals adviser applies). A dossier for each chemical shall be submitted along with the notification and the Safety Data Sheet, in case this is prescribed. The detailed content of the chemical dossier is provided in the Rulebook on the Register of Chemicals[9]. The Rulebook also provides for the customs tariff codes of chemicals to be included in the Register of chemicals, such as the codes for category of use and forms. The chemical dossier contains general data on chemical/chemical product, the origin, the intended use, the labelling elements, data on composition and Volatile Organic Compounds (VOC) content. On a yearly basis, within the same deadline, notifiers have to submit information on the quantities of chemicals and chemical products placed on the market and any change to the information submitted in the previous years. In addition, the manufacturer, importer or downstream user of a Substance of Very High Concern (i.e. a substance listed on the national SVHC list that is transposed from Annex XIV of REACH) or mixture containing that substance, shall submit a specific dossier containing additional data: the description of the uses and risk mitigation measures, the proposed method for the systematic monitoring of use, and, if available, information on the alternative substances (name of the substances, information on the hazards or risks that these substances may pose to human health and the environment, as well as technical and socio-economic information on the feasibility of substitution).

The other parts of Integrated Chemicals Registry are:

- **The Register for Biocidal Products.** The Register for Biocidal Products[10] was launched in 2019 and comprises data on biocidal products submitted for the purpose of their inclusion into the Temporary List. The Register for Biocidal Products will be extended to cover applications for recognition of the authorisation for a biocidal product granted in line with EU procedures that will be submitted in line with the new Law on Biocidal Products. In order to apply for the inclusion of a biocidal product to the Temporary List, applicants must submit the following information[11]:
    - Identity and contact details of the applicant and whether it is a manufacturer or importer;
    - Trade name of the biocidal product and identity and country of the manufacturer of the biocidal product;
    - Product-type;
    - Type of formulation (e.g. powder, solution);
    - Data on the active substance:
        - Trade and chemical name, EC and CAS numbers;

[8] OG of RS No. 36/2009, 88/2010, 92/2011, 93/2012, 25/2015.

[9] OG of RS No. 16/2016, 6/2017, 117/2017, 7/2019, 93/2019.

[10] i.e., the e-portal for biocidal products.

[11] https://www.ekologija.gov.rs/wp-content/uploads/hemikalije/obrazac_osnovnih_informacija_final_za_sajt.docx

    - Identity and country of the manufacturer of the active substance;
    - Information whether the active substance supplier is included in Article 95 list;
    - Purity of the active substance;
  - Composition of the biocidal product (chemical substances' identities, classification and functions);
  - Intended use(s);
  - Intended user(s);
  - Mechanism of action;
  - Recommended dose, frequency and timing of application of the product;
  - Target organism(s);
  - Non-target organism(s) and items to be protected from the action of the biocidal product;
  - Efficacy data;
  - Classification, labelling, packaging of the biocidal product;
  - Information on child-resistant fastenings and tactile warning on packaging;
  - Draft label and instruction for use as well as Safety Data Sheet;
  - References and notes.

- **The Register of Plant Protection Products.** Applicants for the authorisation of placing plant protection products on the market have to notify information in line with what is required for biocidal products (see above). The DfC receives this information from the competent authority for the management of the plant protection products, which is the Plant Protection Directorate of the Ministry of Agriculture, Forestry and Water management.

The national inventories (the Registers of Chemicals, Biocidal Products and Plant Protection Products) have similarities with ECHA's inventories, but also significant differences. The national registries include a wealth of information that enables statistical analysis and inform the monitoring of chemical policies in Serbia, but do not include information on toxicity, ecotoxicity, exposure and risk assessment. The electronic submission of the data to the Integrated Chemicals Registry was enabled in 2019. The e-portal is cloud-based and is constantly being improved to enhance user-friendliness and to minimise administrative burdens for businesses. However, it does not use the software application IUCLID (International Uniform ChemicaL Information Database).[12] Since its version 6, which implements the OECD Harmonised Templates, IUCLID provides a common format, for both regulatory authorities and industry, to record, store, maintain and exchange data on intrinsic and hazardous properties of chemical substances. In the European Union, IUCLID is used for REACH, CLP (including the Poison Centres Notification format specifications), and BPR. In addition, it supports the database which will contain the submitted information on Substances of Concern in articles, as such or in complex objects (Products) - SCIP. It is also being investigated to support the information requirements of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

Following EU accession, Serbian manufacturers and importers of chemical and biocidal products will have to notify information to ECHA according to the requirements of the EU regulations. They may also have to notify information to the national inventories, if the Serbian competent authority opt to maintain this requirement in their national laws.[13] This would pose an additional administrative burden on companies, unless a common format is adopted. More importantly, three employees are currently assigned to the compilation, systematisation and analysis of the information notified to the

[12] https://iuclid6.echa.europa.eu/project-iuclid-6

[13] According to Art.89(2) of the BPR "…a Member State may continue to apply its current system or practice of making available on the market or using a given biocidal product for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product."

Integrated Chemicals Registry.[14] Given the understaffing of the Department for Chemicals (more details are provided in Section 2.3.1), revising the scope of the Integrated Chemicals Registry may free up resources, which could be allocated, for example, to support the information and helpdesk services, the preparation of PIC reports for ECHA and the European Commission or for the implementation of CLP-related tasks.

The Serbian authority consider the Integrated Chemicals Registry as a key source of intelligence for the activities of the Department for Chemicals and inspectors and argue that discontinuing the Registry would result in the loss of information used for these key activities. They have estimated that less than a third of the entities in the Register of Chemicals would have to submit registration dossiers. However, it is not clear if the information that is currently available through the Register of Chemicals may be retrieved from the classification and labelling notifications to ECHA, which are not dependent on any tonnage threshold.

2.2.3.2 Recommended actions, action owners and other relevant stakeholders

It is recommended that **the Ministry of Environmental Protection assesses the costs and benefits of keeping the Integrated Chemicals Registry**. In addition, **it is recommended that the DfC and the Serbian duty-holders, i.e. manufacturers and importers of chemical substances, chemical products and biocidal products, start using IUCLID to record, store, maintain and exchange the relevant information**.[15] This would facilitate the submission of the information through the IT systems of ECHA (REACH-IT, R4BP and e-PIC) following Serbia accession to the EU. It is recommended that **ECHA or Member States competent authorities organise training courses on IUCLID and, closer to the day of accession, on IT systems**.

Table 3 – Objective 3: Assess the advantages and disadvantages of keeping the Integrated Chemicals Registry

Criteria	Notes
Specific	The Ministry of Environmental Protection should assess the costs and benefits of keeping the Integrated Chemicals Registry. The DfC and industry stakeholders should start using IUCLID to record, store, maintain and exchange the information on the intrinsic and hazardous properties of their chemical and biocidal products. The Serbian competent authority, with the support of ECHA or Member States competent authorities, organise training courses on IUCLID.
Measurable	An impact assessment study is carried out. DfC staff and Serbian manufacturers and importers of chemical and biocidal products are trained on the use of IUCLID.
Achievable	Such assessment is not costly and could be carried out in a relatively short time. Training materials on IUCLID is available online.
Relevant	The assessment of the costs and benefits of keeping the Integrated Chemicals Registry would inform the re-organisation of resources within the DfC. The use of IUCLID would facilitate the submission of the information to ECHA at a later stage.
Time-bound	In consideration of the other challenges, the assessment of the costs and benefits of keeping the Integrated Chemicals Registry is of lower priority and could be carried out closer to the day of EU accession. The DfC and Serbian companies should start using IUCLID as soon as possible, to familiarise with the software.

[14] Information on biocidal products kept in the Register for Biocidal Products is maintained and provided by the Division for Biocidal Products Management.

[15] IUCLID latest version is available at: https://iuclid6.echa.europa.eu

2.2.3.3 Estimated human and financial resources required

The assessment of the costs and benefits of keeping the Integrated Chemicals Registry requires the comparison of the information currently collected in the national inventories with the information that could instead be retrieved from ECHA databases. If discontinuing the Integrated Chemicals Registry result in a loss of key information for the activities of the competent authority (including enforcement activities), the assessment would have to quantify (or describe qualitatively) the benefits of the additional information provided by the Registry in terms of, for example, wider regulatory oversight on companies placing chemical and biocidal products on the market. The assessment also requires the estimate of the costs of notifying the information to the registries sustained by industry, which could be collected through a survey of the notifiers and applicants. Finally, the benefits must be compared to the costs, including those incurred by the competent authority. Such an assessment could be performed internally by the DfC or outsourced to a consultancy. Indicatively, it would require no more than 10-15 workdays.[16]

The training of industry stakeholders on the use of IUCLID could be carried out either remotely or through courses to be organised in Belgrade. Training material on IUCLID (including video-tutorials and webinars) is already available online on ECHA website[17]. Some of the training material could be translated and the video-tutorials and webinars could be subtitled in Serbian.

The costs for the organisation and implementation of training courses in Belgrade would vary depending on a range of factors, such as the number of attendees, the number of days, etc. A training course on IUCLID and other IT systems used by ECHA was organised and implemented in Belgrade in the context of the twinning project with the Austrian and Slovenian authorities. The course, of the duration of eight days (four events of two days), saw the participation of five tutors for a total of 25 workdays (0.1 FTE). The cost was around €40,000.

2.2.3.4 Timeline, risks and risk mitigation measures

In consideration of the other challenges, the assessment of the costs and benefits of keeping the Integrated Chemicals Registry is of lower priority and could be carried out closer to the day of EU accession.

Serbian companies, future duty-holders of the EU regulations, should start using IUCLID as soon as possible, to familiarise with the software. The Serbian authority, with the support of ECHA or Member States competent authorities, could start translating the training material available on ECHA website. This activity could be followed by the organisation and implementation of training courses, starting from 2022.

2.2.4 Moratorium on hiring civil servants

2.2.4.1 Description of the challenges and dependencies

The most recent rulebook on the systematisation of jobs of the Ministry of Environmental Protection foresees a significant increase in the number of employees. This concerns both those working with the implementation of the chemical legislation at the Department for Chemicals and enforcement at the Division for Chemicals and Accidents of the Sector for Environmental Surveillance and Precautions. However, the administrative capacity has been reduced due to staff turnover and a moratorium on hiring new employees in state institutions. Up until 2015, Serbia employed between

[16] Two-three workdays for the scoping of the assessment and the comparison of the Integrated Chemicals Registry information with the information retrievable from ECHA databases; five workdays for preparing and launching the survey of notifiers/applicants and analyse the responses to estimate the costs; two workdays to collect information on the use of the Integrated Chemicals Registry data; two-three workdays to compare costs and benefits and draw conclusions.

[17] https://iuclid6.echa.europa.eu/videos, https://iuclid6.echa.europa.eu/training-material and https://iuclid6.echa.europa.eu/webinars

50% and 150% more people in public administration than countries of comparable size, such as Belgium, Bulgaria, Czech Republic or Hungary.[18] In 2015, Serbia agreed with the International Monetary Fund to reduce budget allocations for the salaries of public sector employees by 1.5% of gross domestic product. Therefore, the Government of Serbia passed a law[19] to reduce the number of employees by five percent over two years and losing around 70,000 jobs by the end of the downsizing process in 2018.[20] The moratorium was extended in 2019 and, in October 2020 was still in force.

According to the 2020 Communication on EU Enlargement Policy on the progress of Serbia,[21] the recent reform of the legislation on public service and human resources management "provides for merit-based recruitment and dismissal procedures". However, the report flags as an issue of increasingly serious concern the lack of transparency in, and respect for, the newly established recruitment procedure. The moratorium on hiring civil servants would allow for the creation of new positions at the DfC, provided the overall number of civil servants in the public administration was going down. However, the practice of appointing non-civil servants to "acting manager positions"[22] for six months, in combination with the possibility to convert certain categories of temporary contracts into permanent civil service contracts, may be contributing to the failure of reaching the downsizing objectives. Ultimately, this results in the impediment of strengthening the administrative capacity where necessary. Furthermore, the High Civil Service Council has limited capacity to organise the necessary competitions to replace existing acting managers at reasonable pace.

2.2.4.2 Recommended actions, action owner and other relevant stakeholders

The prerequisite for solving the understaffing of the relevant authorities, is that **the Government of the Republic of Serbia terminates or suspends the moratorium**. This is in contradiction with the plans for strengthening the capacity of the public administration in order to implement and enforce the European legislation. In turn, the opportunity for terminating or suspending the moratorium is dependent on ensuring the transparency and respect for the merit-based recruitment procedure provided for under the Serbian legislation. Table 4 shows the conformity of the objective to the SMART criteria.

Table 4 – Objective 4: Termination or suspension of the moratorium

Criteria	Notes
Specific	It is strongly recommended that the government lifts the moratorium in hiring civil servants. This is a prerequisite to tackle the understaffing situation at the DfC and the Sector for Environmental Surveillance and Precaution.
Measurable	The government should acknowledge the need for additional resources and commit to lifting the limitation on the number of civil servants. The moratorium is effectively lifted in preparation for EU accession.
Achievable	Elections were held in Serbia in 2020. The new government has to signal its political will to lift the moratorium.
Relevant	Without lifting the moratorium, it will not be possible to strengthen the capacity of the competent authority.

[18] https://www.worldbank.org/en/news/opinion/2014/04/02/serbia-state-employees-galore-but-where-is-private-sector

[19] Act of 31 July 2015 on means of determining the maximum number of public sector employees. "Official Gazette of the RS", Nos. 68/15 and 81/16-CC): https://www.ilo.org/dyn/natlex/natlex4.detail?p_lang=&p_isn=102204&p_classification=22.10

[20] https://balkaninsight.com/2015/07/28/serbia-adopting-a-law-on-cutting-public-sector/

[21] EC (2020): Commission Staff Working Document. Serbia 2020 Report. Accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 2020 Communication on EU Enlargement Policy. Brussels, 6.10.2020 SWD(2020) 352 final, pp 16-17.

[22] Acting managers are employees who are asked to assume the role of manager temporarily.

Criteria	Notes
Time-bound	The target date for such a decision should be the first quarter of 2021.

2.2.4.3 Estimated human and financial resources required

The lifting or suspension of the moratorium does not require resources in itself. However, hiring and onboarding new civil servants requires adequate funding and time, also from DfC staff (for candidate selection, interviews, training etc.). Estimates over a ten-year period and means of funding are discussed respectively in Sections 2.3.1 and 2.2.6.

2.2.4.4 Timeline, risks and risk mitigation measures

It is recommended that the termination on the limitation in staff numbers in state institutions should be decided in the first quarter of 2021. The moratorium contradicts the plans for strengthening the administrative capacity of the relevant authorities.

Lifting the moratorium is a matter of political will. However, even if a decision is taken in favour of removing the ability to increase employment numbers, hiring of new staff may be hampered by a lack of capacity for onboarding.

2.2.5 Draft Law on Biocidal Products not yet adopted

2.2.5.1 Description of the problem and dependencies

According to EC (2020)[23] and to the results of the assessment of the legal gaps in the national chemical legislation, "Serbia has a high level of alignment with the EU acquis on chemicals". It is expected that the alignment will be further improved once the new Draft Law on Biocidal Products, aiming to align the national legislation with the BPR[24] is adopted. The adoption of the new Draft Law on Biocidal Products is expected by the end of 2021.

Its adoption would allow for authorising biocidal products already approved in the EU through a recognition procedure equivalent to the mutual recognition in sequence procedure possible for biocidal products placed on the national markets of the EU Member States. This would enable DfC staff to deal with the current backlog of biocidal products included in the Temporary List (see Section 2.3.3), provided sufficient resources are available. It should be noted that the new Draft Law on Biocidal Products also regulates the placing on the market of treated articles, that are not covered by the current Law on Biocidal Products. [25]

2.2.5.2 Recommended actions, action owner and other relevant stakeholders

It is considered very important that the **Government of the Republic of Serbia adopts the new draft Law on Biocidal Products** for the purpose of alignment with the Biocidal Products Regulation. Table 5 shows the conformity of the objective to the SMART criteria.

[23] EC (2020): Commission Staff Working Document. Serbia 2020 Report. Accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 2020 Communication on EU Enlargement Policy. Brussels, 6.10.2020 SWD(2020) 352 final.

[24] As much as possible before EU accession.

[25] Koalicija 27 (2020): Walking in the Mist. Shadow Report on Chapter 27. Environment and Climate Change. Reporting period: March 2019 – February 2020. Belgrade, 2020.

Table 5 – Objective 5: Adopt the new draft Law on Biocidal Products

Criteria	Notes
Specific	The government to adopt the new Draft Law on Biocidal Products by the end of 2021. This is a prerequisite to start authorising biocidal products already approved in the EU through a recognition procedure equivalent to the BPR mutual recognition in sequence procedure.
Measurable	The government acknowledges the need for and commits to the adoption of the new law. The Law on Biocidal Products is adopted.
Achievable	Elections were held in Serbia in 2020. The new government and apparatus have just been instated and may need some time to organise and prioritise action. It is recommended that the adoption of the new Draft Law on Biocidal Products is given priority.
Relevant	Without the adoption of the new Law, it will not be possible to authorise biocidal products already approved in the EU through the recognition procedure equivalent to the BPR mutual recognition in sequence procedure. As of August 2020, the Temporary List included 2,350 biocidal products, which need to be authorised through procedures in line with EU procedures during the pre-accession period.
Time-bound	The planned date for the adoption is the last quarter of 2021 and it is recommended this is not further delayed.

2.2.5.3 Estimated human and financial resources required

The legislative process that precedes the adoption of the new Draft Law on Biocidal Products by the Serbian Parliament requires involvement of at least one in-house lawyer and of the DfC employee who was involved in drafting the legislative text.

2.2.5.4 Timeline, risks and risk mitigation measures

The adoption of the Law on Biocidal Products is envisaged for the last quarter of 2021. The drafting of the new Law on Biocidal Products was completed in 2018 and its passage was expected in 2019. There may be a risk of further delays. Such an event should be avoided by emphasising the importance of adopting the new Law on Biocidal Products and its positive effect on the readiness of Serbia to fulfil the obligations and responsibilities of joining the EU.

2.2.6 Lack of a budget dedicated to chemical risk management activities

2.2.6.1 Description of the problem and dependencies

According to EC (2020), the Green Fund of the Republic of Serbia is not yet fully operational despite its establishment in 2016 through the amendment of the Law on Environmental Protection. The Green Fund is a budgetary fund, under the direct control of the Ministry of Finance, which should finance environmental protection activities through the collection of all environmental-related taxes. Due to the lack of the required bylaws for the operation of the Green Fund that should have been established within one year of the entry into force of the amendment to the Law on Environmental Protection, the income generated by environmental fees is currently not used for environmental measures but instead diverted to other purposes. This is also the case for the administrative fees paid by companies applying for the inclusion of biocidal products in the Temporary List, meaning that they are not used to cover the costs of implementing the administrative procedures. The legal basis for the administrative fees[26] to be paid for the services that the MEP provides with respect to the procedures under the Law on Biocidal Products is given in the Law on the Budget System. According to Article 17, a fee shall be charged for a public service directly provided by the public administration. The amount of the fee is determined by applying the methodology referred to in

[26] Called "taxes" in the Serbian legislative system.

Article 17(6), which refers to the "Rulebook on the methodology and the method of determining the costs for providing of a public service". This Rulebook provides a formula which focuses on working costs i.e. the amount of time spent by a civil servants to provide the public service multiplied by the cost per unit of time plus other costs (e.g. overhead expenses).[27] The fees charged to the applicants for the different procedures regulated by the Law on Biocidal Products are calculated using the formula and specified in the rulebook "Regulation on fees, fee payers as well as payment method for placing on the market of biocidal products".[28] These fees are paid directly to the state budget managed by the Ministry of Finance and are not earmarked for the activities concerning biocidal product management. The system is therefore not fully aligned with the principles established by the European legislation. In addition, the practice by the MEP of earmarking a sub-account within the central budget does not allow for proper resource planning. Every year, the DfC has to apply for a budget to ensure the processing of the notifications and applications received. However, if the resources are not spent by the end of the year, the DfC cannot apply for the same level of funds the following year. Therefore, the DfC remains conservative in their estimate of the expected workload, applying for a limited budget to start with. The result is that the DfC may not have the budget for, for example, outsource the risk assessment of the biocidal products authorisation applications to external experts.

The DfC needs direct access to a dedicated budget for cost recovery of administrative services provided for the authorisation of biocidal products in Serbia. A ring-fenced budget, directly administered by the DfC and that cannot be redirected for other purposes, would enable a smoother and stable outsourcing of certain tasks, such as the assessment of efficacy and human health and environmental risks.

2.2.6.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the Government of the Republic of Serbia reforms the Law on the Budget System to allow for the establishment of a dedicated budget for chemical risk management activities.** Table 6 shows the conformity of the objective to the SMART criteria.

Table 6 – Objective 6: Reform the Law on the Budget System

Criteria	Notes
Specific	It is recommended that the Government of the Republic of Serbia **reforms the Law on the Budget System**. This would facilitate the authorisation of biocidal products through an equivalent procedure to the BPR mutual recognition in sequence procedure.
Measurable	A budget dedicated to chemical risk management activities is created.
Achievable	Although achievable, the reform of the Law on the Budget System is likely to take some time.
Relevant	This is a fundamental part of the alignment of the national legislation to EU principles.
Time-bound	It is recommended to give priority to this action, in order to have a dedicated budget by the day of accession.

2.2.6.3 Estimated human and financial resources required

The reform of the Law on the Budget System is likely to require an analysis of the legal compatibility of the new provisions with the national legislative system. Such analysis and the drafting of the new provisions to allow for the establishment of a dedicated budget for chemical risk management

[27] https://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/ministarstva/pravilnik/2013/14/1/reg

[28] Official Gazette of the Republic of Serbia, No 90/15. It should be noted that a new rulebook on administrative fees will be drafted in line with the new Law on Biocidal Products in order to cover services that the Serbian competent authority will provide according to procedures laid down by that Law.

activities is outside the remit of the DfC staff and is likely to be carried out by the Sector for the Control and Management of the Budget of the MEP or by the Ministry of Finance.

2.2.6.4 Timeline, risks and risk mitigation measures

The reform of the Law on the Budget System may be a lengthy process. It is recommended that the reform of the Law on the Budget System is given priority, to allow for the analysis of the legal feasibility and compatibility and for the creation of the dedicated budget by the day of Serbia accession to the EU.

2.2.7 Expected surge of enquiries to the Helpdesk

2.2.7.1 Description of the problem and dependencies

The Helpdesk was established in 2009 to assist duty-holders placing chemicals and biocidal products on the market in line with their regulatory obligations. Currently, three employees carry out Helpdesk-related tasks on a part-time basis (50% of working hours, equal to 1.5 FTE). Enquiries by industry, consumers or other stakeholders can be made by phone or email. In 2018, the Helpdesk answered around 5,000 requests, of which 4,580 were by phone and 410 by email. Around 28% (1,400) were regarding the BPR, 24% (1,200) were about the CLP Regulation, 12% (600) about REACH, 4% on detergents and 32% about other national legislation.

A substantial increase in enquiries to the Helpdesk is expected closer to the day of accession when industry stakeholders will need assistance with their new obligations. With the current resources, it is unlikely the DfC will be able to respond in a satisfactory manner and timely fashion.

The information shared via email and telephone may need to be complemented by seminars, the publication of leaflets and web-based resources. Finally, the employees of the Helpdesk need to continuously keep up to date with the interpretations and conclusions on certain issues provided by other Member States, ECHA or the Commission. This requires participation in HelpNet, the network of national BPR, CLP and REACH helpdesks, which meets at least once a year.

Table 7 presents a scenario where the number of REACH, CLP and BPR queries to the helpdesk increases over the years leading to accession, peaking in 2024-2026 and decreasing thereafter. The number of queries related to other legislations, including PIC, is assumed to remain constant over this 10-year period. The national helpdesk produces six leaflets per year (requiring 15 workdays per leaflet), organises six seminars per year (requiring 10 workdays per seminar) and participates in at least one HelpNet meetings per year (requiring three workdays per meeting).

Table 7 – Scenario for helpdesk workload

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
No. of queries on REACH, CLP and BPR	3,200	3,600	4,000	4,400	4,800	4,800	4,800	4,400	4,000	3,600	3,200
No. of queries on other legislation (including PIC)	1,800	1,800	1,800	1,800	1,800	1,800	1,800	1,800	1,800	1,800	1,800
Total number of queries	5,000	5,400	5,800	6,200	6,600	6,600	6,600	6,200	5,800	5,400	5,000
Workdays	312.5	337.5	362.5	387.5	412.5	412.5	412.5	387.5	362.5	337.5	312.5
Subtotal - FTEs	1.4	1.5	1.6	1.8	1.9	1.9	1.9	1.8	1.6	1.5	1.4
Leaflets – workdays	80	80	80	80	80	80	80	80	80	80	80
Seminars – workdays	60	60	60	60	60	60	60	60	60	60	60
HelpNet - workdays	6	6	6	6	6	6	6	6	6	6	6

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Subtotal - FTEs	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Total FTEs	2.1	2.2	2.3	2.5	2.6	2.6	2.6	2.5	2.3	2.2	2.1

In this scenario, the Helpdesk would require 1.9 FTEs, in the middle years of the decade 2021-2030, to deal with the number of queries only. Additional resources required to develop written information, translate information into Serbian from the ECHA website, organise seminars and stakeholder days and participate in ECHA HelpNet meetings are estimated to be around 0.7 FTE, with a total of 2.6 FTEs during peak years. According to estimates by the Serbian competent authority, three FTEs are required to deal with queries following the amendment of existing laws or rulebooks or the entry into force of new ones.

Currently, around 1 FTE is dedicated by the DfC to respond to the queries received by the Helpdesk. Over the past three years, an average of two events has been organised by the DfC, in collaboration with the Chamber of Commerce, or with the support of the Swedish Chemicals Agency, per year. It is recommended that at least two people will be dedicated full-time to the provision of information and helpdesk services, with the additional 0.5 FTE to be spent by other DfC staff with specific expertise to support in replying to the more complex queries received by the helpdesk.

2.2.7.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that, provided the capacity of the DfC is strengthened with new resources, **the DfC allocates at least two FTEs to the provision of information and helpdesk services**.

Table 8 – Objective 7: Allocate resources to the provision of information and helpdesk services

Criteria	Notes
Specific	It is recommended that the DfC allocates at least two FTEs to the provision of information and helpdesk services in the years prior to EU accession. This is to provide information to stakeholders and deal with any surge in the number of enquiries, which could be expected close to – and immediately following - the direct entry into force of the four EU Regulations.
Measurable	Number of FTEs allocated to the Helpdesk over time.
Achievable	The objective is attainable, provided the DfC's capacity is strengthened.
Relevant	The provision of information to stakeholders is a fundamental part of the obligations and responsibilities of implementing the EU chemical legislation.
Time-bound	The target date for allocating an additional FTE is 2022.

2.2.7.3 Estimated human and financial resources required

The recommended increase in the resources dedicated to the provision of information and helpdesk services is of 1 FTE (for a total of 2 FTEs), with the additional 0.5 FTE to be covered by other DfC staff with specific expertise for responding to the more complex queries received by the helpdesk. Financial resources are estimated and discussed in Section 2.3.1. It should be noted that according to the estimates by the Serbian competent authority, 2 FTEs may still be short for adequately respond to queries received by the Helpdesk and organise communication activities.

2.2.7.4 Timeline, risks and risk mitigation measures

According to the scenario used to estimate the Helpdesk workload, the recommended target date for the allocation of additional resources is in 2022. The current DfC staff can further develop and

enrich the information on the Helpdesk webpage (e.g. publishing Frequently Asked Questions[29] or by translating the news from the ECHA portal). The development of the Helpdesk webpage has already started, and the webpage should be enriched with new information when relevant.

Table 9 – Timeline

	2020	2021	2022	2023	2024	2025
Allocate resources to Helpdesk			+2 FTE			
Upload guidelines and FAQs to the Helpdesk website						

The allocation of additional resources to the Helpdesk is dependent on the lifting of the moratorium on hiring civil servants (and hiring additional staff to take on this work) or on a redistribution of resources within the department. The new employees tasked with providing Helpdesk services will need training and support. Importantly, one of the regular outputs of the HelpNet is agreed replies to FAQs. These provide more detailed information concerning guidance documents, processes and methods related to the Regulations. The FAQs are published on ECHA's Questions & Answers (Q&A) support page[30] and could be translated into Serbian and hosted on the DfC website.

In the short term, the possibility to organise and attend training sessions may be limited by the ongoing COVID-19 pandemic, and therefore capacity-building courses may have to be organised on online platforms and attended remotely. In addition, in the event of strict lockdowns, the functioning of the DfC and of the Helpdesk could slow down, as employees won't be able to benefit from working alongside one another. Considering the medium-long time horizon, while the same restrictions may not apply, it may still be important to ensure the possibility to work remotely. Two of the long-lasting effects of the COVID-19 pandemic are expected to be the increase in virtual engagement and the enabling role of technology.[31] The DfC should therefore develop teleworking policies and procedures (see Section 3.2.8).

2.2.8 Lack of a Memorandum of Understanding with Scientific Institutes and external experts

2.2.8.1 Description of the problem and dependencies

Due to the ongoing COVID-19 pandemic, there has been an increase in the demand and corresponding supply of disinfectants. The DfC has received a higher than expected number of applications for inclusion of biocidal products in the Temporary List, which will have to be authorised before the day of Serbia accession to the EU, to be legally on the market. The biocidal products authorised in and imported from EU Member States could be authorised in Serbia by an equivalent recognition procedure to the BPR mutual recognition in sequence procedure already before accession.[32] However, many of the biocidal products are produced and supplied by Serbian manufacturers, hence the impact on the national market is potentially significant, where these will need to be authorised through the national procedures or be discontinued. The national authorisation procedure is also resource-intensive for the competent authority, requiring around 130 workdays – significantly more than the 10 working days of the mutual recognition in sequence procedure. The estimate of the required resources is therefore highly dependent on the estimate of

[29] As of January 2021, the DfC is preparing FAQs to be published online.

[30] https://echa.europa.eu/support/qas-support/qas

[31] See for example the news piece "Poorer and smaller: Ten ways the coronavirus crisis will shape the global economy in the long term" by Martin Wolf. Available at: https://www.ft.com/content/9b0318d3-8e5b-4293-ad50-c5250e894b07

[32] Biocidal products authorised in Serbia before EU accession through recognition procedure may have to be re-authorised according to EU procedures once Serbia joins the EU. However, if the recognition procedure is equivalent to the mutual recognition in sequence procedure as established by the BPR, such re-authorisation may not require the re-evaluation of the information submitted by the applicants.

the number of applications for national authorisation of biocidal products. While a significant proportion of biocidal products on the Serbian market could be authorised following the principles of the Same Biocidal Product Regulation No 414/2013 (SBP Regulation) as amended by Regulation No 2016/1802, the resources required by the competent authority to authorise biocidal products according to the BPR procedures exceed the current and planned capacity.

Given the ongoing moratorium in hiring civil servants and in consideration of the fact that capacity would have to be built up progressively over time, support may be sought from external experts. With the right framework in place, scientific institutes and academia with expertise in chemistry, efficacy, toxicology and ecotoxicology could play an important role in supporting the competent authority, in particular with regards to risk assessment. Expertise is available in several faculties, such as Chemistry and Pharmacy and at the Institute for Chemistry, Technology and Metallurgy of the University of Belgrade. However, so far, they have not been asked to support the DfC, as risk assessment activities have not yet started.

In addition, experts from academia and scientific institutes should be trained on the technical and scientific aspects of the chemical legislation, also in consideration of staff turnover and skill decay.[33] Training courses could be organised for both academia experts and DfC staff in, for example, future IPA and international co-operation projects (see also Section 2.3.5).

2.2.8.2 Recommended actions, action owner and other relevant stakeholders

It is important that the Ministry of Environmental Protection develops, ratifies and implements a Memorandum of Understanding (MoU) with the relevant scientific institutes for a rapid and long-term access to their competences and capacities. In the meantime, while an agreement on such a memorandum is taken place, the Ministry of Environmental Protection should explore the use of more agile short-term contracts on specific assignments. The scope of a MoU is to regulate the long-term co-operation between the MEP and external experts. As a first step, the MEP will have to verify the availability of experts with the right profiles and survey their needs for training on the tasks they are expected to carry out and contribute to. The MoU will have to define the expected services, indicate the approximate duration of the assignments and specify the foreseen deadlines. These may have to be further detailed in specific contracts. Importantly, the academic sector will have to determine specific areas within their scope of work, which need strengthening, in order to provide support to the MEP in accordance with requirements and procedures determined under the Biocidal Products Regulation. Most likely, the MoU will need be accompanied by:

- Non-disclosure agreements;
- Policies and procedures for managing Confidential Business Information (CBI);
- Details on the quality control measures, remedial actions and the consequences in case of lack of quality of the services or delayed delivery of the results.

Ultimately, the objective is to develop capacity and competences, ensure the functioning of the MoU and the smooth processing of industry applications. Table 10 shows the conformity of the objective to the SMART criteria.

Table 10 – Objective 8: Develop, ratify and implement a Memorandum of Understanding (MoU)

Criteria	Notes
Specific	It is recommended the MEP develops, ratifies and implements an MoU with the relevant scientific institutes.
Measurable	An MoU with external experts is ratified.

[33] The loss or decay of trained or acquired skills (or knowledge) after periods of non-use. As defined in Arthur, Bennett, Stanush, and McNelly (1998): Factors that influence skill decay and retention: a quantitative review and analysis. Human Performance, 11(1), 57-101.

Criteria	Notes
Achievable	The DfC is in contact with academia and the relevant scientific institutes. Experts from the entities have been trained along with DfC staff on different topics (e.g. efficacy assessment, human health and environmental risk assessment).
Relevant	Without the support of external experts, the Serbian competent authority will not be able to process all industry applications, in particular for the authorisation of biocidal products, by the day of accession.
Time-bound	The MoU should be functioning as soon as possible, in order to relieve the workload of the DfC.

2.2.8.3 Estimated human and financial resources required

It is recommended that the DfC allocates at least 0.5 FTE per year in the period 2021-2023 to prepare the MoU and set up necessary framework for a closer collaboration with academia and institutes. It should be noted that Serbia could also benefit from exchanging of information with the Montenegrin competent authorities who have been preparing an MoU for the last year.

2.2.8.4 Timeline, risks and risk mitigation measures

It is recommended to have a functioning MoU by the end of 2023. This would require the identification of relevant parties, the survey of their competences and needs and the definition of the scope of collaboration in the period 2021-2023. It should be noted that, given the understaffing of the DfC, even 0.5 FTEs per year over a period of 3 years could be prohibitive, unless the capacity of the Department is strengthened in 2021. Moreover, the opportunity of having an MoU or implementing short-term contracts depend on the creation of a dedicated budget. Currently, the administrative fees paid by the companies to notify information to the Register of Chemicals or to apply for the inclusion of biocidal products to the Temporary List contribute to the central (non-ring-fenced) budget. The DfC has access to a certain amount of resources on a yearly basis which needs to be fully justified. Any unspent monetary funds may not be carried over to the following year. This functioning impedes proper planning and forecasting. Therefore, the possibility of outsourcing certain tasks depends on the reform of the Law on the Budget System (see Section 2.2.6). An additional risk is the lack of financial resources due to the economic slowdown both at national and worldwide, triggered by the ongoing COVID-19 pandemic. In 2020, the Serbian budget allocated to the implementation of environmental legislation was cut by 25%. The early planning of the necessary budget may serve to pinpoint some resources that otherwise would be diverted.

2.3 Identified challenges and associated objectives

2.3.1 Understaffing of the Department for Chemicals

2.3.1.1 Description of the problem and dependencies

As of October 2020, the capacity of the Department for Chemicals is:

- One employee in the Division for the Classification, Hazard Assessment and Hazard Communication of Chemicals and Biocidal Products, responsible of CLP-related tasks and part of the REACH-related tasks;[34]

[34] Safety data sheet, chemical safety assessment and the content of the chemical safety report, criteria for identifying Persistent, Bioaccumulative and Toxic substances (PBT) or very Persistent and very Bioaccumulative substances (vPvB) and of the Regulation on test methods.

- Three employees in the Division for Chemical Management, responsible of part of the REACH-related tasks and PIC-related tasks, including the management of the Helpdesk;
- Three employees in the Division for Integrated Chemicals Registry, responsible for compiling, systematising and analysing the information on chemical substances and biocidal products put on the Serbian market; and
- Three employees in the Division for the Biocidal Products Management, responsible for BPR-related tasks.

Overall, this sums up to a total of 10 employees, overseen and managed by one head of department.[35] The department, and the Division for Chemical Management, is also responsible for the implementation of other EU Regulations (i.e. the Detergents Regulation (EC) No 648/2004, Regulation (EU) 2017/852 on mercury, Regulation (EU) 2019/1021 on POPs and Directive 2004/42/CE on the content of VOCs in paints), other international agreements (e.g. Rotterdam Convention, Stockholm Convention, Minamata Convention and the Chemical Weapons Convention) and other national non-harmonized provisions. Over the past few years, the department staff have worked on the alignment of the national legislation with the EU acquis, a very resource-intensive task that allowed the staff to familiarise themselves with the details of the regulations. However, the Department would benefit of legal support, as none of the staff members has a specific qualification in Law.

At the same time, of working on the alignment of the national legislation DfC staff had to carry out the practical administrative tasks required for the implementation of the national chemical management legislative framework. The Division for Biocidal Products Management, in particular, is understaffed. The Law on Biocidal Products has been implemented for ten years and required so far the processing of around 3,000 applications. It should also be noted that the Division for the Classification, Hazard Assessment and Hazard Communication of Chemicals and Biocidal Products has currently one employee only, that cannot possibly cope with the range of responsibilities entrusted to the Division. In addition, given the high staff turnover rate (see Section 2.3.5), there is a risk of loss of institutional memory. Moreover, the department staff have participated in EU integration activities and in activities run by ECHA and twinning projects with other MSCAs. These activities, while necessary to develop and strengthen the competences for taking on the core administrative tasks of the EU regulations, have put an additional strain on the available resources.

Following the closure of the Serbian Chemicals Agency in September 2012, its 36 employees[36], along with all their competences, were moved to the Ministry for Environmental Protection.[37] However, by 2015 only 13 employees remained to deal with chemical and biocidal product management-related tasks.[36] In February 2018, this reduced further to 11 employees, a level of employment that was maintained up to October 2020. It should be noted that, while there are plans for strengthening the administrative capacity, the moratorium on hiring civil servants is still effectively in place. The plans for strengthening institutional structures contained in the National Programme for Adoption of the Acquis (NPAA) - Third Revision (2018-2021) foresaw additional resources for the full implementation of the regulations, including:

- Five additional staff members dedicated to CLP-related tasks, giving a total of six employees;[38]

[35] It should be noted that each Division has a coordinator.

[36] Koalicija 27 (2017): Chapter 27 in Serbia: Still under Construction. Shadow Report on Chapter 27 – Environment and Climate Change. Reporting period: September 2015 – October 2016. Belgrade, 2017, p.33.

[37] At the time named "Ministry of Energy, Development and Environmental Protection".

[38] At the time of the drafting of the NPAA (Third revision), the Division for the Hazard Assessment, Classification and Communication of Chemicals and Biocidal Products had two employees, therefore the plans foresaw four additional people (NPAA, 3rd revision, page 1195).

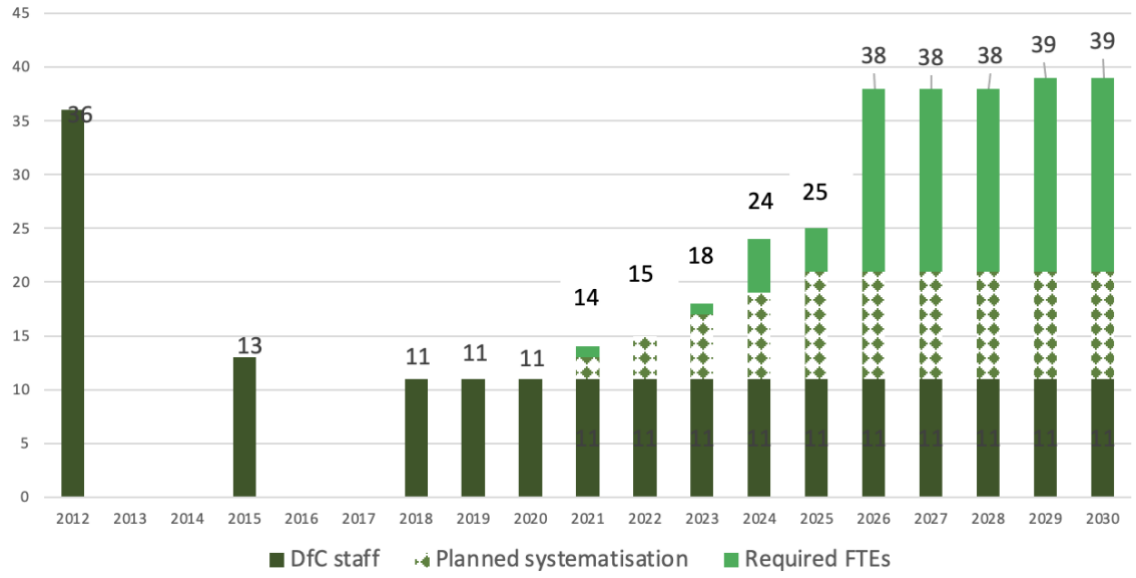
- Five additional staff members dedicated to REACH-related tasks, giving a total of seven employees;[39]
- One additional person dedicated to PIC-related tasks, through reorganisation of the Division for Chemical Management, doubling the number of employees;[40] and
- Seven additional staff members dedicated to BPR-related tasks, taking the total to ten employees. [41]

The most recent plans, outlined in the rulebook for the systematisation of the jobs at the Department for Chemicals, foresee the hiring of 10 additional employees, rather than the 18 foreseen in the NPAA. The estimated required resources in the years post accession amount to 35-40 FTEs per year. This exceeds the numbers foreseen by the NPAA (29 employees) and is nearly more than double those proposed in the rulebook for the systematisation of the jobs at the Department for Chemicals (21 employees) (Figure 3). The estimate of the required resources is driven by the number of biocidal products on the Serbian market that will need to be authorised through the BPR authorisation procedures. These amount to around 25-30 FTEs for all procedures in the years post accession (2026-2030). The estimate is based on the time required by other national competent authorities to evaluate the applications for different types of authorisation. The effective time that will be required depends on a several factors such as:

- Number of applications received;
- Type of authorisation applied for;
- Quality of the information submitted by the applicants;
- Efficiency of the internal procedures for the evaluation, etc.

The required amount of resources may therefore vary but it is expected to exceed the resources available to the DfC significantly.

Figure 3 – Understaffing of the Department of Chemicals



[39] At the time of the drafting of the NPAA (Third revision), there were two employees in charge of the implementation of REACH, therefore the plans foresaw five additional people (NPAA, 3rd revision, page 1196).

[40] NPAA (3rd revision), page 1198.

[41] At the time of the drafting of the NPAA (Third revision), there were three employees in charge of the implementation of BPR-related tasks, therefore the plans foresaw seven additional people (NPAA, 3rd revision, page 1199).

There are two ways to address this challenge: hiring new employees or outsourcing work to external experts. However, these proposed ways forward could only be implemented if some of the underlying issues first are addressed and solved. These are:

- The moratorium on hiring civil servants (Section 2.2.4);
- The lack of Memorandum of Understanding with academia or relevant scientific institutes (Section 2.2.8);
- The adoption of the new Draft Law on Biocidal Products (Section 2.2.5); and
- The reform of the Law on the Budget System (Section 2.2.6).

2.3.1.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MEP strengthens the administrative staff capacity of the DfC.** As a recommended minimum, DfC staff should include: one head of the department, 10 project managers, two helpdesk officers and nine employees responsible to carry out the assessment of the physicochemical properties, evaluation of efficacy, the human health and environmental risk assessment of the substances and products under evaluation, for a total of 22 employees. This is estimated to be the minimum capacity necessary to implement the four EU Regulations in Serbia and does not take into consideration the tasks related to other EU and national legislation included in the remit of the DfC. Table 11 shows the required number of FTEs and the recommended mix of expertise.

Table 11 – Recommended mix of expertise

No. of employees	Roles	Competencies
1 (internal)	Head of department	Coordination of the department
10 (internal)	Project Manager / Regulatory coordinator	Responsible for detailed planning of substance evaluation, SVHC identification proposals, restriction proposals and harmonised classification and labelling proposals. He/she sets priorities and identifies critical issues, keeps track of deadlines and time spent on tasks/activities. Develops the background documentation supporting the substance evaluation report and the proposals and communicates with the agency and other MS competent authorities. Participates in meetings of CARACAL, REACH Committee, MSCAs for the implementation of the BPR, Coordination Group, Biocidal Product Committee, Standing Committee on Biocidal Products, DNA meetings for PIC and Member States Committee as well as in seminars with industry and other stakeholders. Supports in matters concerning budget and planning. Responsible for the handling of the application for authorisation of biocidal product and the administrative work through the process, coordinates the work of the experts, checks the outcome of the evaluation and compiles the documents for the biocidal product (draft the product assessment report - PAR, summary product characteristic - SPC, authorisation). Responsible for handling the explicit consent requests and other PIC-related duties.

No. of employees	Roles	Competencies
2 (internal)	Helpdesk support	Deals with the queries received, responding to the simpler queries and referring more complex queries to other colleagues and coordinating the response. Produces written information and organises seminars and information days.
9 (3 internal, 6 external)	Chemist and efficacy assessor	Makes the evaluation of the information on the physicochemical properties of the substances under evaluation. Makes the assessment and evaluation of the efficacy to establish the benefit arising from the use of biocidal products and whether they are sufficiently effective.
9 (3 internal, 6 external)	Risk assessor (human health)	Makes the evaluation of the human health risk assessment.
9 (3 internal, 6 external)	Risk assessor (environment)	Makes the evaluation of the risk assessment for environment.
40 = 22 (internal) + 18 (external)	**Total**	

The suggested build-up of resources would bring the number of employees at the DfC to 60% of the level of employment of the Serbian Chemicals Agency at the time of its closure in 2012. This is not very dissimilar from the numbers foreseen by the NPAA (29 employees) or the rulebook for the systematisation of the jobs at the Department for Chemicals (21 employees).

As a complementary measure, the Serbian competent authority must seek the support of the scientific institutes and universities present in Serbia and establish a budget dedicated to chemical risk management activities.

The European Chemicals Agency (ECHA) and other Member States Competent Authorities could support the increase in DfC staff capacity by implementing capacity-building projects. The University of Belgrade and other scientific institutes must participate and remain involved in capacity building to better support the Serbian authority. Table 12 shows the conformity of the objective to the SMART criteria.

Table 12 – Objective 9: Strengthen the administrative capacity of the DfC

Criteria	Notes
Specific	It is recommended the MEP strengthens the administrative capacity of the DfC in order to guarantee the adequate implementation of the EU Regulations.
Measurable	Number of employees in the DfC Number of external experts readily available for outsourced work (through an MoU) Adoption of a plan to retain staff
Achievable	The NPAA and the most recent systematisation of jobs propose similar staffing levels. Prerequisite is the lifting of the moratorium on hiring civil servants, the development and adoption of an MoU and the establishment of a budget dedicated to chemical risk management activities.
Relevant	Without strengthening the capacity of the DfC, the Serbian competent authority will not be able to process all industry applications, in particular for the authorisation of biocidal

Criteria	Notes
	products, in a reasonable amount of time, that already is expected to exceed the year of accession.
Time-bound	The capacity needs to be built over time, starting from 2021.

2.3.1.3 Estimated human and financial resources required

In Serbia, the average labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €10,000.[42] The additional cost of bringing the number of DfC employees to the suggested amount of 22 is equal to €900,000 over a ten-year period (2021-2030).

As mentioned however, the estimated number of FTEs required to deal with the expected workload exceeds this level and may amount to around 40 (internal or external) FTEs in the period 2026 – 2030. In this scenario, the additional cost of hiring all required FTEs would be around €1.8 million over a ten-year period (2021-2030).

It is important to put this estimate in perspective, as the costs entailed by the competent authority are paid for by the applicants.[43]

Table 13: Marginal cost of hiring 11 additional employees or all missing FTEs

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Total
Estimated required FTEs	11	14	15	18	24	25	38	38	38	39	39	€1.8M
DfC staff (FTEs)	11	14	16	18	20	22	22	22	22	22	22	
Additional DfC FTEs	0	3	2	2	2	2	0	0	0	0	0	
Marginal cost	€0	€30k	€50k	€70k	€90k	€110k	€110k	€110k	€110k	€110k	€110k	€900k
Additional required FTEs	0	0	0	0	4	3	16	16	16	17	17	
Additional marginal cost	€ -	€ -	€ -	€0	€40k	€30k	€160k	€160k	€160k	€170k	€170k	€900k

2.3.1.4 Timeline, risks and risk mitigation measures

The strengthening of staff capacity at the DfC, both via hiring new employees or contracting external experts, should start as soon as possible. As already highlighted, some underlying issues need to be tackled first and may result in further delays. It should be noted that the National Programme for the Adoption of the Acquis for the period 2018-2021 which was prepared and published in 2018 by the Serbian Ministry of European Integration, foresaw many of this study's recommended actions, including:

- Assessment of the existing administrative staff capacities;
- Assessment of the possibility of redistribution of jobs;
- Increase in the number of employees;
- Preparation of the Development Plan of the competent authority that will cover issues such as current administrative capacities and duties;

[42] Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016 [LC_NCOST_R2] - Public administration and defence; compulsory social security.

[43] In line with Regulation on fees, fee payers as well as payment method for placing on the market of biocidal products („Official Gazette of the RS", No 90/15), the fee to be paid for the application for national authorisation amounts to ~ €8,500 and for the recognition of authorisation granted in line with EU procedures ~ €2,500.

- Further capacity building activities; and
- Exploration of different cooperation models with the scientific sector with the aim of identifying the best option for Serbia.

However, as of February 2021, not much progress has taken place. The risk is that, due to the ongoing COVID-19 pandemic, any action is further delayed and that the required resources are diverted. It is therefore very important, for all parties concerned, to underline that without the necessary resources, the Serbian competent authority would not be in the position to fulfil its responsibilities and obligations in implementing the regulations as an EU Member State post 2025.

Finally, the strengthening of the capacity of the DfC should be accompanied by initiatives to avoid a high staff turnover (further discussed in Section 2.3.5) and by a thorough training effort to ensure a swift onboarding (see Section 2.3.6). Because of the high number of additional FTEs needed, it is important to ensure these are trained, kept up-to-date and involved in the work processes. As already discussed, in the short term, the ongoing pandemic may restrict the possibility of organising face-to-face training and therefore experts may need to be trained and work remotely. In the medium and long term, virtual engagement and remote training is expected to have a more prominent role than in the past. For this, adequate infrastructure and procedures should be established, including suitable teleworking policies (Section 2.3.8).

2.3.2 Insufficient number of inspectors

2.3.2.1 Description of the problem and dependencies

The Department for Accidents and Chemicals of the Sector for Environmental Surveillance and Precautions at the Ministry of Environmental Protection is organised in two divisions: the Division for Chemicals and the Division for Accidents. The Division for Chemicals, according to the most recent planning, should employee 6 inspectors. Currently it only employs two environmental inspectors. While these are sometimes assisted by inspectors from the Division for Accidents, also this division is understaffed: currently it employs 5 inspectors only, against the 12 planned. Additional resources are required to ensure an effective and efficient supervision, as also recognised by the National Plan.

In addition, the enforcement authorities have been characterised by a high staff turnover, including retirements which have not been replaced by new recruits and workers leaving for better-paid jobs in the private sector. The loss of trained staff may result in loss of institutional memory,[44] i.e. their knowledge may not be passed on to new colleagues or been successfully institutionalised.

Article 12 of the Law on Inspection requires the establishment of a joint body, the Coordination Committee, which would be responsible for monitoring the coordination of the inspectorates, as well as harmonising inspection plans and the work of inspectorates, is stipulated by the Law on Inspection (Article 12).

A key contributing factor to the persistent situation is – again - the moratorium on hiring civil servants. A prerequisite for solving the identified gap is therefore the termination or suspension of this moratorium. In 2019, the Government of the Republic of Serbia adopted a three-year action plan for the employment of inspectors in different divisions, but as of November 2020, this had yet to benefit the Department for Accidents and Chemicals.

2.3.2.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MEP strengthens the capacity of the Sector for Environmental Surveillance and Precautions by hiring at least four new environmental inspectors at the Division for Chemicals**, to bring the number to the level planned in the NPAA. The MEP should

[44] See also EC (2020), p.16.

provide training on REACH, CLP, PIC and BPR to the inspectors. ECHA and other international cooperation partners have provided training and organised workshops and study visits to strengthen the enforcement capacity of the Serbian competent authority. These experiences could be extended and replicated, but the Serbian authority should guarantee the allocation of adequate resources.

Finally, it is recommended that **the Serbian authority develop a plan to ensure increased possibilities in retaining their staff**. This is usually done by guaranteeing salaries in line or above industry wages and by avoiding overloading of their resources (further discussed in Section 2.3.5).

Finally, it is recommended that **ECHA or an MSCA support the MEP by implementing a capacity-building programme** for environmental inspectors and the other inspectors with enforcement responsibilities for the four Regulation.

Table 14 shows the conformity of the objective to the SMART criteria.

Table 14 – Objective 7: Strengthen the capacity of the enforcement authorities

Criteria	Notes
Specific	It is recommended that the MEP should strengthen the capacity of the Sector for Environmental Surveillance and Precautions by hiring four new environmental inspectors at the Division for Chemicals. The MEP should provide training, with support from ECHA and other MSCAs. Finally, it is recommended the Serbian authorities develop a plan to retain their staff.
Measurable	Number of new inspectors Number of trained inspectors Adoption of a plan to retain staff
Achievable	The objective is achievable and has been proposed in the NPAA. The prerequisite is the lifting of the moratorium on hiring civil servants and the allocation of adequate financial resources.
Relevant	Without a higher number of environmental inspectors at the Division of Chemicals, the Serbian authorities may not be able to guarantee the adequate enforcement of the EU Regulations.
Time-bound	Starting date: 2021; target date: 2025.

2.3.2.3 Estimated human and financial resources required

In Serbia, the average labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €10,000.[45] Assuming the MEP starts hiring inspectors in 2021 until reaching the target number of 6 inspectors for the Division for Chemicals (NPAA) - as in the scenario presented in Table 15 -, the additional cost in the period 2021-2030 would be around €340,000.

Table 15 – Marginal cost of hiring 11 new inspectors

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Total
Division of Chemicals	2	3	4	5	6	6	6	6	6	6	6	-
Additional inspectors	0	1	1	1	1	0	0	0	0	0	0	4
Marginal cost	€0	€10k	€20k	€30k	€40k	€40k	€40k	€40k	€40k	€40k	€40k	€340k

Finally, as detailed in Section 2.2.1, depending on the scale of the capacity building programme, costs may vary but could preventively set to be around €100,000 per year.

[45] Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016 [LC_NCOST_R2] - Public administration and defence; compulsory social security.

2.3.2.4 Timeline, risks and risk mitigation measures

The target number of environmental inspectors of the NPAA should be met by 2025. Training should start with the appointment of new environmental inspectors.

The main risk is that high staff turnover could nullify the overall gain of any new appointments. The Division of Chemicals is at high risk of losing institutional memory, as there are only two inspectors left. While rules and procedures are codified, the practical application of those rules and procedures can only be taught by the inspectors themselves. Mitigation measures for staff turnover are discussed in Section 2.3.5.

2.3.3 Increasing backlog of biocidal products on the Temporary List to be authorised through the BPR procedures

2.3.3.1 Description of the problem and dependencies

The authorisation of biocidal products is a resource-intensive task for the national competent authorities. Table 16 shows the estimated number of workdays necessary to complete the assessment of the information provided by the companies applying for the authorisation of biocidal products according to the different available procedures.

Table 16 – Estimated workload for different biocidal product authorisation procedures – *Source: KemI's estimate*

Procedure	Workdays
National authorisation as reference MS	130
Renewal national authorisation as reference MS	130
Mutual recognition	10
Simplified authorisation	10
Union authorisation / Authorisation of BP family	140
Same biocidal product authorisation	3
Amendment of existing authorisation, derogation according to art. 55	1
Inclusion / extension of inclusion in the Serbian Temporary List	0.5

Serbian manufacturers and importers of biocidal products can apply for inclusion of the products on the Temporary List by submitting basic information on a biocidal product and the active substance(s). The DfC checks the information received and issues a decision with a deadline for submission of both an application for authorisation and of a technical dossier for the biocidal product with more substantial information on toxicology and ecotoxicology. However, as of October 2020, the DfC had not yet started to request the technical dossiers for the biocidal products included in the Temporary List, instead postponing the deadlines in the decisions.

A high number of biocidal products are currently on the Temporary List and more are expected. Around 2,500 applications were expected to be included in the Temporary List by the end of 2020, and the DfC expects to receive around 200 applications per year in the next 3-5 years, based on the annual number of past applications. Because of the coronavirus pandemic, there has been a surge in the demand for biocidal products, which in Serbia has been satisfied mostly by domestic manufacturers. These biocidal products will eventually have to be either authorised through the BPR authorisation procedures or discontinued/removed from the market.

In addition, the adoption of the new Draft Law on Biocidal Products is envisaged for the last quarter of 2021. This has partially transposed the rules for the mutual recognition in sequence procedure laid down by the BPR, but the DfC cannot start authorising the imported biocidal products which are

eligible for this procedure, even if there were enough available resources, because the law has not yet been adopted.[46]

Finally, as already discussed, the functioning of the central budget and the budget earmarked for the DfC do not allow for efficient and flexible resource planning.

2.3.3.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the DfC starts authorising biocidal products through the procedure equivalent to the BPR mutual recognition in sequence procedure** as soon as the new Law on Biocidal Products enters into force. This would allow the Serbian competent authority to start building the capacity necessary to deal with other types of authorisation procedures and with the approval of new active substances.

It is recommended to **develop a plan on how to manage the backlog**:

- Hire of additional resources and provide training (discussed respectively in Sections 2.3.1 and 2.2.1);
- Adopt an MoU with relevant scientific institutes (discussed in Section 2.2.8);
- Establish a budget dedicated to chemical risk management activities (discussed in Section 2.2.6); and
- Start authorising biocidal products through the procedure equivalent to the BPR mutual recognition in sequence procedure as soon as possible.

The competent authority has been planning to use the support of the scientific community in carrying out some of the tasks that will be required of them upon the full entry into force of the EU Regulations. These include the assessment of different parts of the dossier for a biocidal product, for which specific expert knowledge is needed.[47] Another important aspect is to communicate to applicants that, according to the Biocidal Products Regulation, they are obliged to consult with the competent authority prior to an application, if the competent authority is to be reference Member State. This would mean that the competent authority would be responsible for evaluating the complete documentation in the application. It is usually recommended to applicants to contact the competent authority well in advance, preferably one year before the submission of the application. This ensures that the competent authority can provide the support required by the applicant, but also enables the competent authority to plan the work ahead effectively. Booking pre-submission meetings with the authority gives the opportunity to discuss the process, the data requirements, a quotation of the fees to be paid or any other issue that is relevant to the application.

It is key to stress again that without the human and financial resources, the Serbian competent authority will not be in a position to realistically fulfil their responsibilities and obligations in implementing the Biocidal Products Regulation. Table 17 shows the conformity of the objective to the SMART criteria.

Table 17 – Objective 8: Develop a plan on how to manage the backlog and start authorising biocidal products through the procedure equivalent to the BPR mutual recognition in sequence procedure

Criteria	Notes
Specific	It is recommended that the DfC starts authorising biocidal products through the recognition procedure equivalent to the BPR mutual recognition in sequence procedure. It is recommended that the Government of Serbia and the relevant ministries address the underlying causes and provide the necessary human and financial resources.

[46] The current Law on Biocidal Products also envisages procedure for recognition of authorisations granted by the EU MSCA. However, this procedure is in line with the Biocidal Products Directive, not the BPR. The data requirements prescribed by the national legislation do not follow the BPR requirements for applications for the mutual recognition procedure in sequence.

[47] NPAA – Third revision (2018-2021), page 1202.

Criteria	Notes
Measurable	Number of authorised biocidal products Rate between authorised biocidal products and not yet assessed / authorised biocidal products
Achievable	The resources and capabilities are significant and still lacking. The capacity of dealing with the backlog of applications in time for EU accession is uncertain and indeed there is the significant risk that may not be dealt with in time.
Relevant	To ensure the proper functioning of the single market and the protection of human health and the environment, biocidal products need to be authorised following one of the EU procedures.
Time-bound	If the new Law on Biocidal Products is effectively adopted in the last quarter of 2021, the DfC should start authorising imported biocidal products using the recognition procedure equivalent to the BPR mutual recognition in sequence procedure from the second half of 2022 and be fully functioning on biocidal product authorisation by 2026.

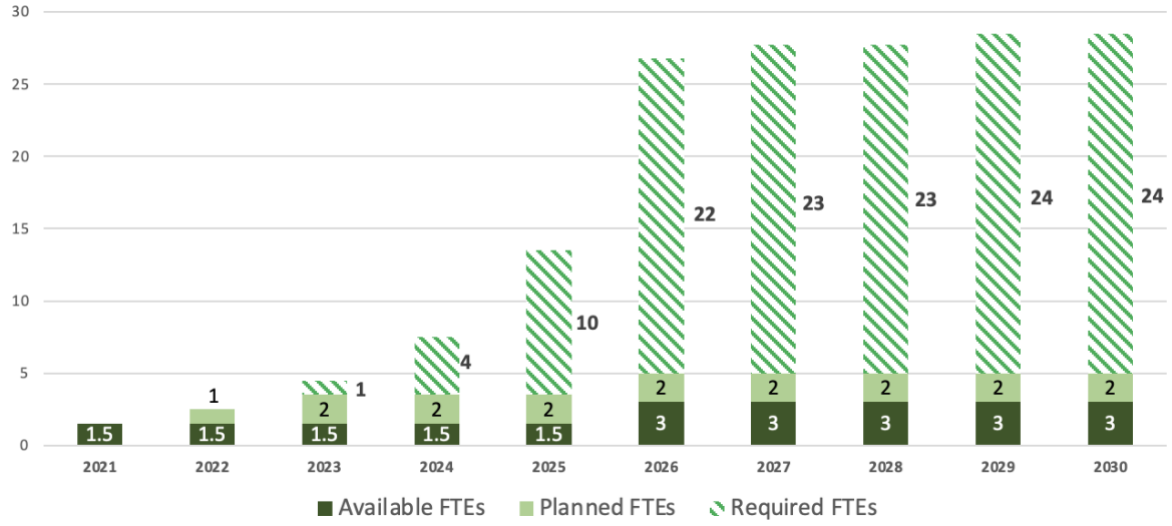
2.3.3.3 Estimated human and financial resources required

The estimated human and financial resources necessary to deal with the backlog of biocidal product authorisation applications have been discussed in Section 2.3.1.

2.3.3.4 Timeline, risks and risk mitigation measures

It is recommended to effectively adopt the new Law on Biocidal Products in the last quarter of 2021, or earlier if possible. The establishment of a dedicated budget for processing applications deriving from the payment of the fees by applicants, would enable allocation of the necessary resources, both internally and externally through the MoU. Considering the necessarily progressive build-up of the resources and competences, the DfC and the MoU should be fully functioning on biocidal product authorisation by 2026 (Figure 4).

Figure 4 – Available FTEs vs planned FTEs vs necessary FTEs over the period 2021-2030 at the Division for Biocidal Products Management – over a period of 10 years



One risk is that, in consideration of the high number of resources estimated to be required to process the expected number of applications, not enough experts with the right knowledge and skills is available, at least in the short term, in Serbia. In the context of the twinning project with Austria and Slovenia, a comprehensive course on risk assessment and risk management of biocidal products was carried out from December 2016 to December 2017. Over the one-year-long course, 13 missions

were implemented, during which the tutors covered different sections, such as chemistry and analytics of biocidal products, efficacy of biocidal products, human health and environmental risk assessment of biocidal products. Of the 32 participants from the scientific sector, 19 undertook a final test and received a certificate in at least one different section of regulatory risk assessment and risk management of biocidal products. It should be noted that there may be even a wider pool of expertise in risk assessment: 81 risk assessors were trained in the context of the Twinning Project "further Capacity building in the area of Plant Protection Products and Pesticide Residues"[48] on technical equivalence, environmental fate, eco-toxicology, toxicology, operator exposure, residue and consumer risk assessment.[49]

Another risk is underestimating the number of applications for biocidal product authorisation that will be received by the Serbian competent authority and therefore the associated workload. The opposite risk - i.e. the overestimation of the number of applications or the number of workdays necessary for each authorisation procedure - can be mitigated by using a mix of internal and external resources. Nevertheless, early and careful planning is recommended.

2.3.4 High workload

2.3.4.1 Description of the problem and dependencies

The high workload is the direct consequence of the understaffing situation at the DfC. The personnel have been doing a great job in keeping the national legislation aligned as much as possible with the constant evolution of the European legislative framework.

The high workload, together with less-competitive salaries than in the private sector, is one of the causes of a high staff turnover.

2.3.4.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MEP acts on the recommendations of this document as soon as possible**. In particular, the increase in resources and the implementation of an MoU with external experts would greatly help in easing the workload on the current staff. It is important to note that external experts could support the MEP in processing the applications for biocidal products authorisations, in particular in carrying out risk assessment when the BPR enters into force. In addition, external experts could participate in the BPC WGs meetings and other technical meetings on behalf of the Serbian competent authority. However, in order to facilitate implementation of the tasks carried out by the DfC daily and reduce the workload of the current staff, it is necessary to increase in-house capacities as soon as possible. Easing the workload on the current staff would not be possible without hiring new civil servants.

Table 18 shows the conformity of the objective to the SMART criteria.

Table 18 – Objective 9: Avoid or ease the high workload

Criteria	Notes
Specific	It is recommended that the MEP acts on the recommendations of this document as soon as possible, to ease the high workload on current staff.
Measurable	Number of recommended actions started and accomplished
Achievable	All recommended actions are achievable and in part have been already proposed and suggested either by the twinning partners or the Government of the Republic of Serbia in national plans. The resources need to be made available, in particular by establishing a dedicated budget.

[48] SR 13 IB AG 02

[49] NPAA – Third revision (2018-2021), page 630.

Criteria	Notes
Relevant	Avoiding / easing the workload is necessary to address the current high levels of staff turnover, with associated loss of expertise and institutional memory.
Time-bound	The start date is 2021, with the development of a strategy, based on the present document, to tackle the identified issues.

2.3.4.3 Estimated human and financial resources required

The estimated human and financial resources required for the DfC to be able to fulfil its responsibilities and obligations in implementing the regulations have been discussed in Section 2.3.1.

2.3.4.4 Timeline, risks and risk mitigation measures

The start date is 2021, with the development of a strategy, based on the present document, to tackle the identified issues. The risk is that focus is placed on "low hanging fruit", such as training and capacity-building or keeping the national legislation aligned with the EU acquis, while failing to address the key issues that are at the root of most of the identified challenges: the moratorium on hiring civil servants, the absence of a dedicated budget managed or easily accessible by the MEP and the adoption of the new Law on Biocidal Products that would allow starting to process biocidal product authorisation applications through the procedure equivalent to the BPR mutual recognition in sequence procedure. The solution to these three key challenges requires the political will and commitment of the new government, but it is essential to Serbia's readiness for joining the EU.

2.3.5 High staff turnover

2.3.5.1 Description of the problem and dependencies

The Serbian competent authority have been characterised by a high turnover in the staff allocated to the implementation and enforcement of the chemical legislation. This has resulted in the loss of resources that have been trained over several years.

The abolishment of the Serbian Chemicals Agency has been followed by a high turnover of staff, the loss of expertise and a decrease in the financial resources available for the implementation and enforcement of the legislation. The understaffing situation and the high workload, along with salaries that are not in line with the competences of the workers, are all contributing factors to the high staff turnover. The turnover of staff has even affected the Serbian negotiating team, as noted by EC (2020): "adequate human and financial resources will need to be allocated across all institutions involved so Serbia can meet its objectives as regards EU accession negotiations".

2.3.5.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the Government of the Republic of Serbia develops and implements a plan to retain civil servants in all its administrative bodies**. The plan should *inter alia* aim to:

- Guarantee adequate salaries (in line with or above industry levels);
- Prevent work overload by hiring sufficient new civil servants;
- Promote the implementation of MoU with scientific institutes to outsource certain workstreams;
- Promptly adopt legislation enabling the better functioning of its institutions; and
- Continuously build up capacity, including training.

The law on the salary system for civil servants was reformed in 2016 and introduced the principle of equal pay for equal work for all public sector employees (EC, 2020). However, its implementation has been delayed and its now expected in 2021. There are other things that can be done to favour staff

retention beyond offering higher salaries and benefits packages and avoiding work overload. For example, regular meetings between employees and management about work procedures and how to improve them has the twofold effect of increasing efficiency and making the employees feel part of the decision-making process. Ideally, employees should have clear paths of advancement. However, according to EC (2020), the practice of recruiting senior civil servants through less than transparent procedures is still an issue. Table 19 shows the conformity of the objective to the SMART criteria.

Table 19 – Objective 10: Implement a plan to retain civil servants

Criteria	Notes
Specific	It is recommended that the Government of the Republic of Serbia develops and implements a plan to retain civil servants in all its administrative bodies.
Measurable	Staff turnover rate
Achievable	A strategy for retaining personnel could only be successful if the underlying causes are tackled first. The challenges have all been identified and documented in the Commission Staff Working Document on the progress of the negotiations in Serbia (EC, 2020) and plans to address these challenges have already been developed by the Serbian authorities.
Relevant	It is key to retain skilled workers for the adequate implementation and enforcement of all EU legislation.
Time-bound	It is recommended that, given the high risk of losing institutional memory, strengthening the capacity of both the DfC and the Division of Chemicals for control and supervision, including measures to slow down staff turnover, should have the highest priority.

2.3.5.3 Estimated human and financial resources required

The estimated human and financial resources required for the DfC and for the Division of Chemicals for control and supervision to be able to fulfil their responsibilities and obligations in implementing and enforcing the regulations have been discussed in Section 2.3.1 and 2.3.2.

In Serbia, the labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €10,000.[50] The labour cost per employee in the professional, scientific and technical activities sector in full-time equivalents per year is estimated to be around €15,000.[51]

One of the most straight-forward ways to retain skilled staff is to offer a higher salary, which should be at least in line with industry wages for similar expertise categories and profiles. The labour cost per employee in the professional, scientific and technical activities sector in full-time equivalents per year is estimated to be around €15,000[52], i.e. 50% more costly than in the public sector. Assuming that the MEP would increase the salaries of inspectors to align them with industry wages, the marginal cost of progressively hiring 4 additional inspectors over the period 2021-2030 and of increasing the salary of the 2 environmental inspectors would be around €510,000. Assuming that the MEP would also increase the salaries of the 11 DfC employees, the marginal cost would be around €550,000 over the period 2021-2030 (around €50,000 per year). If the recommended 11 new employees were hired with higher starting salaries, the marginal cost over the period 2021-2030 would be around €1.35 million (around €130,000 per year) rather than €900,000.

[50] Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016 [LC_NCOST_R2] - Public administration and defence; compulsory social security.

[51] Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016 [LC_NCOST_R2] - Professional, scientific and technical activities.

[52] Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016 [LC_NCOST_R2] - Professional, scientific and technical activities.

It should be noted that higher salaries cannot be considered only for the MEP employees and therefore the financial resources required should be calculated on the total number of civil servants. EC (2020) notes that the implementation of the law on the salary system in the public sector, which was approved in 2016, is severely delayed and has been postponed to 2021.

2.3.5.4 Timeline, risks and risk mitigation measures

As for most of the recommendations, the sooner action is taken the better. The recommended start and target year should be 2021. There is a risk that the new government may show no interest in developing a plan to retain public administration staff. In this case, the Commission should highlight the importance of ensuring the administrative capacity of the different state entities responsible for implementing and enforcing EU legislation.

2.3.6 Lack/loss of expertise

2.3.6.1 Description of the problem and dependencies

There is a lack of expertise in the field of risk assessment, which is especially related to the implementation of the Biocidal Products Regulation.

Training on risk assessment and risk management, including socio-economic analysis, assessment of physicochemical properties of biocidal products, efficacy evaluation, assessment of toxicological and ecotoxicological parameters and exposure assessment, was provided to the DfC staff and a pool of external experts as part of the IPA projects. However, given staff turnover, the delays in adopting the new Draft Law on Biocidal Products and issues around the budget for processing the applications, some trained staff has been lost and the trained external experts have not been asked to support the DfC and apply their newly acquired competences, with the risk of not fully completing the learning process and of the new knowledge to become obsolete. This, in turn, increase the risk that trained staff leave, because of work overload and uncompetitive remuneration.

The loss of expertise is directly linked to the problem of high staff turnover observed in all public institutions in Serbia (Section 2.3.5). The lack of expertise instead can be addressed by commissioning and providing training and capacity building and by outsourcing certain workstreams to external experts, thereby reducing the direct workload burden on DfC staff.

2.3.6.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the Ministry of Environmental Protection addresses the lack of expertise in risk assessment and other technical and scientific areas** by:

- Developing in-house expertise in risk assessment by providing DfC staff with training on risk assessment for physical and chemical properties, efficacy assessment, human health and environmental risk assessment; and
- Contracting external experts to support the different tasks requiring risk assessment for physical and chemical properties, efficacy assessment, human health and environmental risk assessment.

A plan should be developed, involving the following, *inter alia*, aspects:

- In-house related activities:
  - Hire additional staff;
  - Identification of current available resources and gaps in expertise;
  - Planning and implementation of provision of training (timelines);
- Activities related to external resources (see Section 2.2.8):
  - Identification of external resources;

- Identification of methods of contracting and conditions (incl. defining mutual obligations and responsibilities);
- Arrangement of contracts; and
- Provision of training to external resources, when required.

A right and duty of civil servants to professional development is exercised in accordance with the provisions of the Law on Civil Servants.[53] Professional development is a right and duty of civil servants to acquire knowledge and skills, i.e. the ability to perform tasks of the workplace, in accordance with the needs of the state authority. In doing so, the manager is obliged to provide professional training for the civil servant, for the execution of the work in accordance with the training programmes established by this law.

The European Chemicals Agency and other Member State Competent Authorities could provide training (focused on risk assessment for physical and chemical properties, efficacy assessment, human health and environmental risk assessment) for developing the competences of the DfC staff and of the external experts who are likely to provide technical and scientific support. The development of competences could be further strengthened by the assessment and provision of comments on the work carried out by other MSCAs and ECHA. Table 20 shows the conformity of the objective to the SMART criteria.

Table 20 – Objective 11: Provide training and capacity building

Criteria	Notes
Specific	It is recommended that the MEP surveys the needs of the DfC and external experts and organise and implement training and capacity-building courses. Training should be continuous and planned on an annual basis, to keep internal and external experts up to date with the evolutions in the EU.
Measurable	A capacity-building plan is developed and established, covering the period 2021-2025.
Achievable	The capacity-building plan should be developed in coordination with ECHA and other MSCAs, highlighting where these entities could provide additional training and support.
Relevant	Capacity-building is key for filling any gaps in competences and maintaining current skills up to date.
Time-bound	Continuous, starting as soon as possible and following the hiring of new staff. The capacity building plan should cover the period 2021-2025.

2.3.6.3 Estimated human and financial resources required

The head of the Department for Chemicals, in coordination with the colleagues within the department and the support of the Swedish Chemicals Agency, has already allocated time to identify the areas where further training and capacity-building would be beneficial. As already discussed in Section 2.2.1, the estimation of the human and financial resources required for capacity-building depends on several factors, such as number of tutors involved, number of attendees, number of in-person classes vs. number of remote learning sessions, travel, accommodation and subsistence for tutors coming from abroad, necessary IT and laboratory equipment, etc. Given the lack of a sustainable financing framework, the Serbian competent authority are likely to have to keep relying on ECHA's and other European partners' technical and financial support on capacity-building. As detailed in Section 2.2.1, depending on the scale of the training courses, costs may vary but could be forecast at around €100,000 per year.

[53] Official Gazette of the RS, Nos. 79/05, 81/05 – corr, 83/05 – corr, 64/07, 67/07 – corr, 116/08, 104/09 and 99/14.

2.3.6.4 Timeline, risks and risk mitigation measures

While the support of ECHA and other European partners is unlikely to waver over the coming years, there is the risk for Serbia to develop a dependency on external resources. The establishment of a dedicated budget is therefore of the utmost importance. This would free financial resources to organise capacity-building and communication activities.

In the short term, the ongoing COVID-19 pandemic poses an organisational and logistical challenge, as the courses cannot be attended in person, but need to be held remotely via webinars. ECHA has strong expertise in preparing training materials for and delivering remote online courses. Even in the medium-long term, many courses could be held remotely. However local resources in Serbia may lack full capability to benefit from such arrangement. There is therefore the need for the Serbian stakeholders to invest on better IT equipment.

2.3.7 Lack of a communication strategy, including communication about working procedures and procedures to manage confidential business information

2.3.7.1 Description of the problem and dependencies

The Serbian authority have relied on the support of ECHA, Sweden and other IPA and international co-operation partners for communication activities and stakeholder engagement. There is a need for Serbian authority to establish a communication strategy, including communication about working procedures and procedures to manage confidential business information. This would ensure transparency and provide trustworthiness of the authorities in relation to working procedures, contributing to stakeholder engagement and participation in regulatory implementation. In addition, the DfC should be fully transparent on its working procedures and on the data-security measures implemented. The perception and understanding of industry stakeholders of the efficiency of the competent authorities is an important step towards ensuring regulatory compliance.

In addition, there is the need to keep Serbian industry stakeholders informed about their upcoming responsibilities and duties, in particular with regard to REACH registration and authorisation, CLP classification and labelling and BPR authorisation. With regard to the last, duty-holders should be made aware of their obligation to contact the competent authorities in advance of applying for biocidal product authorisation. An effective communication strategy is essential to ensure that Serbian companies are ready for the single market well before the day of Serbia accession to the EU.

2.3.7.2 Recommended actions, action owner and other relevant stakeholders

Civil society plays an essential role in the process of European integration of the Republic of Serbia. Proactive civil society organisations are important actors in the implementation of public policies. An example is the role played by the non-governmental organisations grouped under the name of Koalicija 27 on the negotiation process, with the annual publishing of shadow reports on the status and progress on Chapter 27, 'Environment and Climate Change'.

It is recommended that **the DfC develops a communication plan**. This could address the following:

- Organisation of **workshops and events**, including identification and selection of topics of interest for the Serbian stakeholders that could be discussed during the events;
- **Communication of information** on the progress in establishing an effective **regulatory framework**, including information on the measures to ensure the confidentiality of non-public information; and
- The organisation and dissemination of **information online**:

- The content on DfC website, including the webpage of the Helpdesk, is already organised by topics to facilitate access to documents and deadlines. The content should be continuously updated;
- Additional information, for example the translation of news presented on the ECHA website into Serbian that could be of relevance for Serbian companies, could also be provided on the website;[54]
- The Helpdesk's webpage could have a Frequently Asked Questions (FAQ) section, which could assist companies and the public.[55]

The development of a communication plan can be broken down in four steps:

- Allocation of resources for a multiannual plan;
- Survey of the needs and topics of interest;
- Identification of the communication channels; and
- Implementation of the communication plan.

Table 21 shows the conformity of the objective to the SMART criteria.

Table 21 – Objective 12: Develop a communication strategy

Criteria	Notes
Specific	It is recommended that the MEP develops a communication strategy to keep stakeholder engagement and increase transparency.
Measurable	A communication strategy is developed and implemented.
Achievable	The careful design of the strategy allows for avoiding misuse of funding. The MEP and the DfC may not have the in-house expertise and therefore may consider outsourcing the process. It should be noted however that the Serbian competent authority have been supported by Sweden in developing a communication strategy and ECHA in implementing communication activities.
Relevant	Better informed stakeholders may result in a lower workload (less queries to the helpdesk, better quality information provided by industry in their notifications and applications, effective resource planning by the competent authority). A communication strategy improves confidence in the competent authority and increases the acceptance of the implemented policies.
Time-bound	It is recommended that the DfC starts drafting a communication plan for the next five years (2021-2025). This would allow earmarking the necessary resources. The plan should clearly identify: target audience, needs and optimal communication channels.

2.3.7.3 Estimated human and financial resources required

The MEP, in particular the DfC staff, in collaboration with ECHA, European partners, the Chamber of Commerce and local NGOs have implemented a series of events over the past years. It is recommended that the development of a communication plan is included in the remit of the Helpdesk staff and should be part of the job description. As discussed, three FTEs should be dedicated to delivering Helpdesk services.

Given the lack of a sustainable financing framework, the Serbian competent authority is likely to have to keep relying on ECHA's and other European partners' technical and financial support on communication activities. Depending on the scale of these activities, costs may vary but could be estimated at around €50,000 per year. If costs were instead borne by the MEP, considering the

[54] Currently, as part of their training, chemical advisers are familiarised with ECHA webpages, to facilitate them in finding information that could help them in their future work.

[55] FAQs are currently in development.

difference in price levels, around €10,000 could be allocated by the Serbian authority for communication activities.

2.3.7.4 Timeline, risks and risk mitigation measures

As for capacity-building, the support of ECHA and other European partners is unlikely to waver over the coming years. However, there is the risk for Serbia to develop a dependency on external resources also on communication activities. The establishment of a dedicated budget is therefore of the utmost importance. This would free financial resources to organise capacity building and communication activities. The MEP and the DfC should start planning for the resources necessary to develop the plan: survey the needs, finding the optimal communication channels, implement the strategy by organising the communication activities (Table 22).

Table 22 – Recommended timeline

	2020	2021	2022	2023	2024	2025
Action 10 Development of a communication plan						
10.1 Allocate resources for a multiannual plan						
10.2 Survey needs and topics of interest						
10.3 Identify communication channels and format						
10.4 Communication plan implementation						

According to the NPAA, communication activities have been planned for the period 2018-2021, in order to raise awareness and readiness of the private sector to enter the single market. "Companies, and particularly SMEs, will be encouraged to understand their roles and obligations, not only for their fulfilment, but also making strategic choices related to the sustainability of their product portfolio" (NPAA, 2018). Beyond the chemical industry actors, other target groups are industry associations and consultants, which will offer technical support to companies for certain procedures and applications. Ensuring the participation of the Chamber of Commerce guarantees that all relevant actors are informed of the communication activities and can choose to attend or join events of interest to them.

The dissemination of the information was planned through the organisation of information seminars, workshops and stakeholder days. These are likely to have been disrupted by the ongoing COVID-19 pandemic. Nevertheless, communication activities should not stop and the MEP and the DfC should explore the opportunity to organise webinars instead. ECHA has years of experience in organising and running webinars, issuing newsletters and providing remote classes and could therefore provide advice and support with these activities.

2.3.8 IT infrastructure, policies and procedures not aligned with ECHA standards

2.3.8.1 Description of the problem and dependencies

The Department for Chemicals recently made operational the electronic platform for the registration of chemicals (January 2019) and for biocidal products (April 2019) in the Integrated Registry of Chemicals. Nevertheless, there is the need to improve data protection and define different levels of data access.

For the purpose of ensuring the security of the information managed by the European Chemicals Agency, before receiving remote access to ECHA's information systems, all European and national authorities need to sign a declaration with respect to security aspects, based on the Agency's Security

Model for IT systems.[56] This declaration (Unified Declaration of Commitment) and associated Standard Security Requirements (SSR) grant access to:

- The ECHA REACH-IT system;
- The ECHA IUCLID Member State database (REACH/CLP);
- The Portal Dashboard which facilitates the point of access to ECHA's IT systems;
- The Register for Biocidal Products (R4BP);
- The ECHA IUCLID Member State database (BPR); and
- The Interact Portal, Platform for Authorities (REACH/CLP).

A slightly modified version of the declaration and the SSR apply for granting access to the ECHA Poison Centre Notification searchable database (PCN Database) and to the secure electronic tool for exchange of information called eDelivery. Access to ECHA's Information Systems is only allowed when the organisation complies with the standard security requirements and the additional requirements for teleworking and information sharing with contractors. The declaration requires the competent authorities to seek regular external or internal audits of the respective security requirements and a full scope audit must be conducted every three years. New organisations must conduct a first full-scope audit to demonstrate all the required security controls and measures are in place.

The Standard Security Requirements are organised in:

- General security requirements;
- Physical security;
- Security requirements for the organisation's IT systems;
- Security requirements for protecting local copies;
- Identity and access management;
- Security awareness;
- Additional teleworking requirements; and
- Additional requirements for sharing information with external contractors.

The physical security of the premises that will be used to access ECHA's information systems from the day of accession is already effectively ensured by the measures in place at the MEP. The arrangements in place for the workstations, the internal network and the WiFi network seem adequate too. However, there is a lack of:

- A formal policy for managing non-public information;
- A teleworking security policy;
- A security awareness programme, including introduction and regular security trainings for DfC employees; and
- Regular external and internal audits of the IT infrastructure, policies and procedures.

There is a lack of formal non-public information management policy ensuring safe storage, transmission and destruction of confidential information. MEP employees follow formal archiving practices, but there is no control and record of all non-temporary local copies. Information is not securely deleted when there is no more justification (for example, there is no regulatory obligation to keep the information as evidence that a regulatory task has been performed). Personal and other non-formal archives are permitted, and local copies of non-public information are not encrypted.

[56] ECHA Management Board Decision 59/2019: Revised Decision of The Management Board on the Adoption and Scope of Application of Unified Declarations of Commitment by a Member State Competent Authority/Mandated National Institution/Designated National Authority of a Member State and the European Commission with Respect to Security Aspects for ECHA's Information Systems.

Non-public information can be stored outside the organisation's protected IT environment even when there is not a clear justification and encryption is not normally used. Indeed, neither portable storage devices with non-public information nor non-public information transmitted over a public network are encrypted. However, documents with non-public information in paper format cannot be taken out without a formal need for particular regulatory tasks or enforcement activities and they are usually stored in locked cabinets. Non-public information in paper format is not disposed of or shredded in a secure manner when it is no longer needed. When non-public information is transmitted for legal or administrative proceedings, there is no verification that confidentiality is secured at least at the same level of protection. It should be noted that the information stored in the Integrated Chemicals Registry can only be accessed by the staff of the Division for the Integrated Chemicals Registry and the Division for Biocidal Products Management and it is shared with other authorities only by written request. The MEP does not have enough resources to deal with the detection of intrusions and unusual activities, which include recording logs of security relevant events, protecting logs from unauthorised tampering, monitoring and analysis of security events and the determining of remediation actions.

There is no security-awareness programme and no introduction or regular security training of the employees; there is no teleworking security policy in place; employees can use personal devices to connect to the office network, but the internet traffic between the client device and the office network is protected by encryption through a VPN connection. There is a security policy regulating how to share information with external contractors. At the moment, policies, procedures and safety measures are not audited, but annual audits have been planned.

2.3.8.2 Recommended actions, action owner and other relevant stakeholders

It is recommended **the MEP upgrades the IT infrastructure of the DfC**, with new workstations running safe and up-to-date operating systems and antivirus software.

Additional security procedures are required to mitigate the risk of malware infection posed by the use of mass memory devices. This new safety policy has already been established in the MEP, but it still needs to be implemented. It is recommended that **the MEP implements the new safety policy**. In order to guarantee extra protection against unauthorised access, workstations' screens could lock automatically after a period of inactivity. It is recommended that **the MEP provides training for the existing IT staff (2 FTEs) on IT security policy and procedures, including the detection of intrusions and unusual activities**. **One should be nominated as user administrator**, in charge of coordinating the identity and access right management tasks. In addition, it is recommended that **the DfC nominates a Security Officer** within the DfC staff members or the IT staff of the MEP, who will be the primary security contact point for ECHA also in the context of any security matter related to all workstations and devices used to access the IT system.[57] The security officer must make sure that sufficient security training and awareness briefings are arranged. The security officer must also ensure that security is continuously promoted so that users are aware of relevant security rules and requirements, understand related security threats and risks, and have a good knowledge of the meaning of their everyday actions to security. It is recommended **to implement a new formal non-public information management policy, to bring the current practices in line with ECHA's SSR**; this is to ensure the safe storage, transmission and destruction of confidential information. Importantly, it is recommended to **establish a security awareness programme, including introduction and regular security training for all employees**. **A teleworking security policy is also necessary to guarantee the protection of non-public information**. Finally, it is recommended that **the Serbian competent authority contract an external audit of the safety policies, procedures and measures and carry out internal audits on an annual basis, validated**

[57] Depending on the workload of the MEP's IT staff, which could be significant, there may be the need to hire one person with some expertise on IT tools to be further trained to be appointed as Security Officer.

by an external audit every three years or every time a significant change is made to the security measures.

Importantly, ECHA requires security measures for accessing ECHA's information systems:

- A new formal non-public information management policy should to be developed and implemented; and
- The current practices of information management should be aligned with ECHA's Standard Safety Requirement (SSR).

Table 23 shows the conformity of the objective to the SMART criteria. ECHA has offered assistance and support to the MEP and the DfC in carrying out a first assessment of all the gaps against the list of requirements.

Table 23 – Objective 13: Align IT infrastructure, policies and procedures with ECHA standards

Criteria	Notes
Specific	It is recommended that the MEP aligns the IT infrastructure, policies and procedures with ECHA standards.
Measurable	The IT infrastructure including workstations is updated. The new safety policy is implemented. Human resources are allocated to IT security, either by hiring additional employees with the right profile or by providing training and capacity building to the existing IT staff within the MEP. One user administrator is nominated. One security officer is nominated. A new formal non-public information management policy is implemented. A security-awareness programme, including introduction and regular security trainings for all employees is established. A teleworking security policy is implemented. External and internal audits are regularly implemented.
Achievable	ECHA has offered support.
Relevant	Without IT security policies and procedures in place, the DfC could not gain access to ECHA information systems.
Time-bound	Policy and procedures need to be in place by the day of accession. The establishment of policies and procedures about the security of the information collected and managed by the DfC are likely to have positive impacts on the confidence of businesses towards the capacity of the Serbian competent authority.

2.3.8.3 Estimated human and financial resources required

It is recommended the existing IT staff at the MEP is trained on IT security policies and procedures.

The organisation and implementation of training courses for IT staff and the DfC staff members on IT security policies and procedures is estimated to cost around €100,000.

The cost of a new workstation, running safe and always up-to-date operating systems and antivirus software is around €500. If DfC staff needs to be enabled to work remotely, they would need safe and updated devices provided by the MEP. The total cost of updating the IT infrastructure may be around €25,000 (accounting for the recommended 22 employees at the DfC: around €12,500 for the workstations at the MEP and other €12,500 for personal devices to enable remote working, unless policies allowing work laptops to be used from home are implemented).

The provision of assistance by ECHA or one MSCA on the preparation of a formal non-public information management policy, a security awareness programme and a teleworking security policy may entail around 20 workdays (0.1 FTEs) and four meetings in Belgrade for a total cost of €25,000.[58]

The cost of an external IT audit depends on a number of factors and in particular on the size and complexity of the IT environment to be audited. It is recommended the MEP earmarks around €1,000-€5,000 for the first audit.[59] The MEP should allocate a rolling budget for the required periodic audits.

2.3.8.4 Timeline, risks and risk mitigation measures

Policy and procedures need to be in place by the day of accession. However, the establishment of policies and procedures about the security of the information collected and managed by the DfC are likely to boost confidence of businesses in the capacity and trustworthiness of the Serbian competent authority. It should be noted that the NPAA published in 2018 planned to establish the necessary infrastructure and procedures during the period 2018-2021, in order to provide secure links to the European Chemicals Agency and establish a safe system of work in compliance with the data protection requirements. Table 24 shows the suggested timeline for the development of the IT infrastructure and the establishment of IT policies and procedures.

Table 24 – Suggested timeline for the establishment of IT infrastructure, policies and procedures

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Action 11: Development and implementation of CBI management policy											
Action 12: Development and implementation of security awareness programme											
Action 13: Development and implementation of teleworking security policy											
Action 14: Carry out first external audit and plan for regular internal and external audits		EA	IA	IA	EA	IA	IA	EA	IA	IA	EA

There is a lack of relevant expertise among the MEP and DfC staff. ECHA has offered assistance and support. However, it is recommended that the MEP commissions a first external audit by a specialised IT security consultancy, which could also provide the first classes of the security awareness programme and prepare the material for the introductory and regular IT security briefings.

[58] Including allowances, project management, accommodation and travel costs.

[59] The cost for an IT security audit may range from €5,000 to €10,000. See for example: https://www.itgovernanceusa.com/iso27001-certification-costs, https://www.getastra.com/blog/security-audit/how-much-does-an-it-security-audit-cost/, https://resource.optimalnetworks.com/blog/2014/11/13/cost-of-it-audit. To account for the different price levels, these prices have been divided by 5.

3 Conclusions and recommendations

3.1 Recommended actions and prioritisation

The assessment of the degree of legal harmonisation and of the institutional capacity and needed infrastructure has identified the **lack of necessary resources** to implement and enforce the four Regulations as the main challenge. However, in order to strengthen the administrative capacity and enable the implementation of the other recommended actions (Table 25), there are some underlying challenges that need to be tackled first. These are beyond the remit of the Department for Chemicals or the Ministry of Environmental Protection itself, and are instead actions that should be taken by the Government of the Republic of Serbia.

In particular, the moratorium on hiring civil servants is in contradiction with the plans for strengthening the capacity of the public administration. **The lifting or suspension of the moratorium is therefore essential to ensure that the Department for Chemicals and the Division of Chemicals for supervision and control of the Ministry of Environmental Protection are allocated the necessary resources to fulfil their obligations and responsibilities in implementing and enforcing the four Regulations** more details in Section 2.2.4).

To ensure that adequate financial resources are available to fund new job positions within the DfC or to contract external experts for support, a budget dedicated to chemical risk management activities should be established (Section 2.2.6).

The adoption of the new Draft Law on Biocidal Products would allow starting to authorise some biocidal products through the procedure equivalent to the BPR mutual recognition in sequence procedure (Section 2.2.5). It is recommended that these three actions are given the highest priority and are implemented in 2021 (Table 26).

In parallel, it is recommended that the Ministry of Environmental Protection drafts and ratifies a **Memorandum of Understanding with scientific institutes and external experts** (Section 2.2.8), which would facilitate the outsourcing of some workstreams to avoid overload at the DfC.

The above measures would allow hiring new staff and outsourcing workstreams, contributing to address some of the other challenges associated with insufficient administrative capacity, such as the loss of expertise (Section 2.3.6) due to high staff turnover (Section 2.3.5). Avoiding work overload (Section 2.3.4) and ensuring higher salaries would help stabilise the turnover rate and bring it to more natural levels. It is recommended that the Government of the Republic of Serbia develops a **plan to retain the staff of the public administration entities**.

The MEP should develop a **communication strategy** for the next five years (Section 2.3.7) and it is recommended that the organisation of communication activities is part of the job description of a new employee who should be assigned to the provision of helpdesk and information services.

Finally, it is recommended to **upgrade the IT infrastructure and the IT safety policies and procedures** (Section 2.3.8). The MEP should commission an initial external audit, to identify the required measures to bring the IT system up to the standard required by ECHA. ECHA is available to support the development of some of the necessary policies and procedures and to provide training. ECHA and Member State competent authorities may also offer capacity-building in risk-assessment and enforcement.

The risks associated with each action and possible mitigation measures have been discussed and are summarised in Table 27. One of the main risks is that the Serbian competent authority focuses on "low hanging fruit", such as training and capacity-building or keeping the national legislation aligned

with the EU acquis, while not addressing the key issue that is at the roots of most of the identified challenges: the strengthening of the administrative capacity of the MEP is essential to Serbia's readiness in joining the EU.

Table 25 – Action Plan

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
1. Lift or suspend moratorium on hiring civil servants	!!!	2021	Gov	-	-	-
2. Establish a budget dedicated to chemical risk management activities.	!!!	1st Q 2021 – 2nd Q 2021	Gov	-	-	-
3. Adopt the new Draft Law on Biocidal Products	!!!	2021	Gov	-	-	-
4. Develop, ratify and implement an MoU with the relevant scientific institutes for a rapid and long-term access to their competences and capabilities	!!!	2021-2023	MEP	ECHA, MSCA and/or Montenegro	1.5 FTE	-
5. Strengthen the capacity of the DfC Action cannot start before actions no. 1, 2 and 3 are complete.	!!!	2021-2025	Gov MEP	-	Additional 11 FTEs	€90k - €135k per year
6. Start authorising biocidal products through the recognition procedure equivalent to the BPR mutual recognition in sequence procedure Action cannot start before action no. 4 is complete and would benefit of actions no. 2, 3, 4 and 5.	!!!	2022	MEP (DfC)	External experts through the MoU		For external experts: €40k in 2024 €70k in 2025
7. Strengthen the capacity of the Sector for Environmental Surveillance and Precautions (environmental inspectors) Action cannot start before actions no. 1 is complete.	!!!	2021-2025	Gov MEP		Additional 4 environmental inspectors	€40k - €60k per year
8. Capacity building on risk assessment	!	2021-2022	ECHA	MSCA and MEP	0.5 – 1 FTE (ECHA and/or MSCA)	~€75,000 per year over two years (ECHA and/or MSCA)
9. Capacity building on enforcement	!	2023 and 2025	ECHA or MSCA			~€50,000 per year over two years (ECHA and/or MSCA)
10. Organise training courses on IUCLID	!	2021	ECHA	MEP (DfC), MSCA, CoC	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
11. Start using IUCLID to record, store, maintain and exchange the relevant information Action would benefit of action no. 10	!!!	2021-	DfC		-	-
			Serbian manufacturers and importers of chemical substances, chemical products and biocidal products,		-	-
12. Allocate resources to the provision of information and helpdesk services Action cannot start before action no. 5 is complete.	!	2022	MEP		2 additional FTEs	-

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
13. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants; - Promote the implementation of MoU with scientific institutes to outsource certain workstreams; - Promptly adopt the legislation enabling the better functioning of its institutions; and - Continuously build up capacity	!!	2021-	Gov	-	-	DfC: additional €150k per year Environmental inspectors: additional €60k per year
14. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Serbian stakeholders that could be discussed during the events; - Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information The organisation and dissemination of information online - Allocation of resources for a multiannual plan; - Survey of the needs and topics of interest; - Identification of the communication channels; and - Implementation of the communication plan.	!	2021-	MEP (DfC)	ECHA, MSCA, CoC, NGO	0.5 FTE	€50,000 per year
15. Upgrade IT infrastructure	!!!	2021	MEP		-	€12,500 (one-off) ~€100 per workstation (running costs: licenses, software upgrades, etc.)
16. Provide training to the existing IT staff within the MEP and the DfC staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		2021	ECHA	DfC	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
17. Implement new safety policy		2021	DfC	ECHA	0.1 (DfC) + 0.1 (ECHA and/or MSCA)	€25k (ECHA and/or MSCA)
18. Implement a new formal non-public information management policy in line with ECHA's SSR		2021	DfC	ECHA		
19. Establish a security awareness programme, including introduction and regular security trainings for all employees.		2021		ECHA		

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
20. Establish a teleworking security policy		2021	DfC	ECHA		
21. Contract an external audit of the safety policies, procedures and measures		2021	MEP		-	€5,000 in 2021
22. Carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures		2021-	MEP		-	€5,000 every 3 years for external audits
23. Hand-on training on ECHA e-tools	!	2025	ECHA	MSCA and MEP	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
24. Impact assessment of keeping the Integrated Chemicals Registry		2024	MEP	-		€5k -10k in 2024

Notes:
CoC: Chamber of Commerce; Gov: Government of the Republic of Serbia; MA: Ministry of Agriculture; MEP: Ministry of Environmental Protection; MH: Ministry of Health; MSCA: Member State Competent Authorities; MTTT: Ministry of Trade, Tourism and Telecommunications

Table 26 – Gantt Chart and resource allocation

Action	2021	2022	2023	2024	2025
1. Lift or suspend moratorium on hiring civil servants	-				
2. Establish a budget dedicated to chemical risk management activities	0.5 FTE				
3. Adopt the new Draft Law on Biocidal Products	-				
4. Develop, ratify and implement an MoU with the relevant scientific institutes for a rapid and long-term access to their competences and capabilities	0.5 FTE				
5. Strengthen the capacity of the DfC	3 FTEs €30k	2 FTEs €50k	2 FTEs €70k	2 FTEs €90k	2 FTEs €110k
6. Start authorising biocidal products through the recognition procedure equivalent to the BPR mutual recognition in sequence procedure			€10k	€60k	€70k
7. Strengthen the capacity of the Sector for Environmental Surveillance and Precautions (environmental inspectors)	1 FTE €10k	1 FTE €20k	1 FTE €30k	1 FTE €40k	- €40k
8. Capacity building on risk assessment	0.25 – 0.5 FTE €35k-40k	0.25 – 0.5 FTE €35k-40k			
9. Capacity building on enforcement			~€50k		~€50k
10. Organise training courses on IUCLID	0.1 FTE €50k				
11. Start using IUCLID to record, store, maintain and exchange the relevant information					

Action	2021	2022	2023	2024	2025
12. Allocate resources to the provision of information and helpdesk services Action cannot start before action no. 5 is complete.					
13. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants; - Promote the implementation of MoU with scientific institutes to outsource certain workstreams; - Promptly adopt the legislation enabling the better functioning of its institutions; and - Continuously build up capacity					
14. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Serbian stakeholders that could be discussed during the events; - Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information The organisation and dissemination of information online - Allocation of resources for a multiannual plan; - Survey of the needs and topics of interest; - Identification of the communication channels; and - Implementation of the communication plan.	€50k	€50k	€50k	€50k	€50k
15. Upgrade IT infrastructure	€12,500	€2,200	€2,200	€2,200	€2,200
16. Provide training to the existing IT staff within the MEP and the DfC staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.	0.1 FTE €50,000				
17. Implement new safety policy	0.1 (DfC) + 0.1 (ECHA and/or MSCA) €25k (ECHA and/or MSCA)				
18. Implement a new formal non-public information management policy in line with ECHA's SSR					
19. Establish a security awareness programme, including introduction and regular security trainings for all employees.					
20. Establish a teleworking security policy					
21. Contract an external audit of the safety policies, procedures and measures	€5k				
22. Carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures				€5k	
23. Hand-on training on ECHA e-tools					0.1 FTE (ECHA and/or MSCA) €50k
24. Impact assessment of keeping the Integrated Chemicals Registry				€5k-10k	
Totals					
ECHA or MSCA	0.6 – 0.8 FTEs €200k	0.25 – 0.5 FTE €35k-40k	~€50k		0.1 FTE (ECHA

Action	2021	2022	2023	2024	2025
					and/or MSCA) ~€100k
Government of the Republic of Serbia	5 FTEs €50k	5 FTEs €100k	4 FTEs €140k	5 FTEs €190k	3 FTEs €210k
MEP	1.2 FTEs €70k	€50k	€60k	€125k	€170k

Table 27 – Risks and Risk mitigation measures

Action	Risk	Risk Mitigation Measures
1. Lift or suspend moratorium on hiring civil servants	Lack of resources due to the economic crisis caused by ongoing COVID-19 pandemic.	The creation of new job positions in state institutions may be one of the expansionary measures to counteract the economic slowdown.
2. Establish a budget dedicated to chemical risk management activities	The reform of the Law on the Budget system may be a lengthy process	The reform of the Law on the Budget system. Prioritised the assessment of the legal feasibility.
3. Adopt the new Draft Law on Biocidal Products	Further delays	The Commission and ECHA stress the importance of adopting the new Draft Law on Biocidal Products.
4. Develop, ratify and implement an MoU with the relevant scientific institutes for a rapid and long-term access to their competences and capabilities	Lack of resources due to the ongoing COVID-19 pandemic	Action: 2. Establish a budget dedicated to chemical risk management activities
5. Strengthen the capacity of the DfC	The Serbian government does not agree and may not fund the necessary resource increase.	The Commission and ECHA note that without the administrative capacity for implementing the Regulations, Serbia would be deemed not ready to fulfil EU obligations and responsibilities.
6. Start authorising biocidal products through the recognition procedure equivalent to the BPR mutual recognition in sequence procedure	Lack of expertise Adoption of the new Draft Law on Biocidal Products further delayed Insufficient number of risk assessors because of lack of resources	Capacity building on risk assessment. The Commission and ECHA stress the importance of adopting the new Draft Law on Biocidal Products. Establish a budget dedicated to chemical risk management activities, strengthen the capacity of the DfC and adopt an MoU.
7. Strengthen the capacity of the Sector for Environmental Surveillance and Precautions (environmental inspectors)	The Serbian government does not agree and may not fund the necessary resource increase.	The Commission and ECHA note that without the administrative capacity for enforcing the Regulations Serbia would be deemed not ready to fulfil EU obligations and responsibilities.
8. Capacity building on risk assessment	Lack of resources COVID-19 pandemic The adoption of new Draft Law on Biocidal Products is further delayed, and therefore the trained experts cannot apply the new competences	Support of ECHA or MSCA Remote learning Actions: 3. Adopt the new Draft Law on Biocidal Products

Action	Risk	Risk Mitigation Measures
	The MoU is not ratified by the adoption of the new Draft Law on Biocidal Products High staff turnover	4. Develop, ratify and implement an MoU with the relevant scientific institutes for a rapid and long-term access to their competences and capabilities 6. Start authorising biocidal products through the recognition procedure equivalent to the BPR mutual recognition in sequence procedure 14. Develop a plan to retain staff
9. Capacity building on enforcement	Lack of resources COVID-19 pandemic Loss of expertise because of high staff turnover	Support of ECHA or MSCA Remote learning Actions: 5. Strengthen the capacity of the DfC
10. Organise training courses on IUCLID	Lack of resources COVID-19 pandemic Loss of expertise because of high staff turnover	Support of ECHA or MSCA Remote learning Actions: 5. Strengthen the capacity of the DfC
11. Start using IUCLID to record, store, maintain and exchange the relevant information	Lack of expertise	Training material available online Action: 10. Organise training courses on IUCLID (by ECHA or MSCA)
12. Allocate resources to the provision of information and helpdesk services Action cannot start before action no. 6 is complete.	Lack of resources.	Action no. 6: Strengthen the capacity of the DfC
13. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants; - Promote the implementation of MoU with scientific institutes to outsource certain workstreams; - Promptly adopt the legislation enabling the better functioning of its institutions; and - Continuously build up capacity	Lack of resources.	The government of Serbia implements the 2016 law on the salary system in the public sector
14. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Serbian stakeholders that could be discussed during the events; - Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information The organisation and dissemination of information online - Allocation of resources for a multiannual plan; - Survey of the needs and topics of interest; - Identification of the communication channels; and	Lack of resources. Lack of expertise.	Actions: 2. Establish a budget dedicated to chemical risk management activities The task should be part of the job description for 1 FTE to be hired for the heldesk. ECHA or MSCA support.

Action	Risk	Risk Mitigation Measures
- Implementation of the communication plan.		
15. Upgrade IT infrastructure	Lack of resources. Lack of expertise. Data leaks and disclosure of CBI.	ECHA will support the development of the relevant policies and procedures and the training of staff. The MEP should ensure the resources for upgrading and keeping up to date the the IT infrastructure. The Commission and ECHA stress the importance of ensuring the strictest respect to the SSR.
16. Provide training to the existing IT staff within the MEP and the DfC staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		
17. Implement new safety policy		
18. Implement a new formal non-public information management policy in line with ECHA's SSR		
19. Establish a security awareness programme, including introduction and regular security trainings for all employees.		
20. Establish a teleworking security policy		
21. Contract an external audit of the safety policies, procedures and measures		
22. Carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures		
23. Hand-on training on ECHA e-tools	High staff turnover	13. Develop a plan to retain staff
24. Impact assessment of keeping the Integrated Chemicals Registry	Administrative burden on companies for notifying information to ECHA and the national inventories. Administrative burden on the DfC of keeping the national inventories.	The impact assessment should support the DfC in making an informed decision.

3.2 Similarities in gaps and shortcomings between Montenegro and Serbia and potential for joint actions

While Montenegro and Serbia may not be comparable from the perspective of the size of the market of chemical and biocidal products, and therefore of the administrative capacity required to fully implement and enforce the four Regulations, the two countries face similar challenges in their preparation towards accession to the EU.

Both countries need strengthening of their respective administrative capacities and the underlying issues are broadly the same: in both countries a moratorium on hiring civil servants is in place; both countries need to develop a sustainable financing system aligned with the EU Regulations and principles; both countries have still to ratify Memorandum of Understanding with scientific institutes to facilitate access to external experts. However, Montenegro has already drafted an MoU and is currently in the process of refining it. The Serbian competent authority could therefore benefit from the recent experience of the Montenegrin authorities in brokering such a collaboration agreement.

- It is recommended that the Serbian competent authority contact their Montenegrin counterparts to explore the possibility of exchanging information on the process.

As many of the Montenegrin experts working in the institutes that are part of the memorandum have been trained in Serbia, there is even the possibility to expand the scope of the memorandum in both countries so that, if necessary, the Montenegrin authorities could access the expertise of the Serbian scientific institutes and vice versa. It is also likely that some of the biocidal products placed on the Montenegrin market may be the same of those placed on the Serbian market, and therefore an enhanced collaboration between the competent authorities and supporting scientific institutes of the two countries may result in speeding up the authorisation process and, importantly, in saving resources.

Montenegro, conversely, could benefit from the support received by Serbia from twinning partners in drafting a document containing recommendations for sustainable financing of biocidal products management administration. This could be used as the basis for a rulebook aligning the national legislation with the principles of the Biocidal Products Regulation.

- It is recommended that the Montenegrin authorities contact their counterparts in Serbia to explore the possibility of accessing such a document.

Finally, both countries would welcome the support that ECHA or Member State competent authorities can provide in capacity building and training on risk assessment, IT security, e-tools and enforcement.

- There is therefore the possibility to organise capacity-building on these topics at the same time in both countries or also include other candidate countries and potential candidates, in order to share training materials and optimise the resources allocated by ECHA or MSCAs.

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5 Annexes

5.1 List of abbreviations

Acronym	Full name
BPC	Biocidal Product Committee
BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
CARACAL	Competent authorities for REACH and CLP
Cefic	European Chemical Industry Council
CG	Coordination Group
CLH	Harmonised classification and labelling
CLP	Classification, Labelling and Packaging
CoRAP	Community Rolling Action Plan
DfC	Department for Chemicals
DNA	Designated National Authority
EC	European Commission
ECHA	European Chemicals Agency
EEB	European Environmental Bureau
EU	European Union
FTE	Full-Time Equivalent
IPA	Instrument for Pre-Accession Assistance
IT	Information Technology
IUCLID	International Uniform ChemicaL Information Database
MEP	Ministry of Environmental Protection
MS	Member State
MSCA	Member State Competent Authority
NGO	Non-Governmental Organisation
NPAA	National Programme for Adoption of the Acquis
NPCC	National Poison Control Centre
PAR	Product Assessment Report
PCN	Poison Centre Notification
PIC	Prior Informed Consent Regulation
R4BP	Register for Biocidal Products

Acronym	Full name
RAC	Risk Assessment Committee
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RSD	Serbian Dinar
SCBP	Standing Committee on Biocidal Products
SEAC	Socio-Economic Analysis Committee
SME	Small and Medium-sized Enterprise
SPC	Summary Product Characteristic
SSR	Standard Safety Requirement
SVHC	Substances of Very High Concern
VOC	Volatile Organic Compounds
WP	Work Package

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