Assessment of the National Capacity and Readiness to Implement and Enforce REACH, CLP, BPR, POPs and PIC in Albania, Bosnia and Herzegovina, Kosovo, North Macedonia and Turkey

Action Plan –

Bosnia and Herzegovina

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Executive Summary

According to the Constitution of Bosnia and Herzegovina, environmental policies are the remit of two entities – the Republika Srpska and the Federation of Bosnia and Herzegovina – and a self-governing administrative unit – the Brčko District. With the support of the entities and the Brčko District, the Government of Bosnia and Herzegovina has to enable compliance with international agreements and conventions. There is no state-level legislation governing chemicals in Bosnia and Herzegovina: the legislation on chemical products and biocidal products, its implementation and enforcement are under the responsibility of the entities and the Brčko District. One of the main challenges is the need for Bosnia and Herzegovina of a countrywide strategy and harmonised approach to ensure alignment with the EU chemicals acquis at all levels of government in a consistent and comprehensive manner to minimise the administrative burden for businesses and competent authorities. A countrywide environment approximation strategy was adopted in 2017, but this needs to be supplemented by more specific chemical programmes for the entities and the Brčko District, which need to be updated and fully implemented.

This section presents the recommendations stemming from the results of the comparative legal analysis of the entities' legislation with the EU acquis and the results of the assessment of the institutional capacity and infrastructure available in both entities and the Brčko District for the implementation of REACH, CLP, BPR, PIC, and POPs.

For more than ten years, Bosnia and Herzegovina has been developing its chemicals management system to align it with the EU regulatory framework. In 2017, a working body consisting of representatives from both entities, the Brčko District and the Ministry of Civil Affairs of Bosnia and Herzegovina, was established with the aim to harmonise and mutually align entity legislation in the area of chemicals. Currently, the new Law on Chemicals in the Federation of Bosnia and Herzegovina is fully harmonised with the Law of Chemicals in the Republika Srpska, although bylaws for its full implementation are still being drafted. There are also transitional provisions in the new Law on Chemicals establishing that the old Law on Trade of Poisons from the Socialist Federal Republika Yugoslavia is applicable until the implementation of the new Law is enabled by the adoption of relevant subsidiary legislation. The Brčko District still applies a 1991 law of the Socialist Federal Republic of Yugoslavia and is currently drafting the Law on Chemicals, which will be adopted at the end of 2022. There is a Law on Biocidal Products in the Republika Srpska, but it needs further harmonisation with the BPR. There is still no Law on Biocidal Products in the FBiH, which will be drafted when the Law on Chemicals and rulebooks for its implementation are completed. In the Brčko District, there are currently no plans to draft legislation on biocides.

The Republika Srpska has achieved the most progress in chemicals management and the alignment of legislation with EU Regulations, but the assessment has identified the lack of necessary resources for the development and implementation of legislation of chemicals and biocidal products as the main challenge. The competent authorities of the Federation of Bosnia and Herzegovina need an additional employee, which is already planned for in the Ministry of Health. A specialist in chemicals and biocidal products will also be required in the Brčko District when the Law on Chemicals is adopted at the end of 2022. Therefore, a dedicated budget for chemical risk management activities should be established to ensure that adequate financial resources are available to fund new job positions within the competent authorities. In addition, the alignment of legislation on administrative fees with the EU Regulations and principles is also important and should be implemented when further developing legislation. When the dedicated budget is established, the revenue from fees and charges paid by industry applicants for the work carried out by the competent authorities should be ring-fenced for chemical risk management activities when those are collected.

It is recommended that the competent authorities start drafting Memoranda of Understanding with scientific institutes and external experts in a few years' time, which would facilitate the outsourcing of some workstreams and avoid the overloading of the relevant teams when the Law on Biocidal Products is fully aligned with the BPR, and full authorisation procedure commences. It is also recommended to establish helpdesks in both entities and the Brčko District to support and advise companies with their obligations under legislation on chemicals. Closer to the day of accession and once the legislation on chemical and biocidal products in both entities and the Brčko District is more closely aligned with the EU Regulations, one single helpdesk could be established in BiH as the first point of contact for questions related to the REACH, CLP and BPR. Furthermore, a communication strategy should also be developed in each entity and the Brčko District, and it is recommended that stakeholder management and other aspects of external communication form part of the job description of an employee allocated to helpdesk and information services. In addition, the competent authorities should conduct initial external IT security audits to identify needed actions to bring the existing IT system up to the standard required by the European Chemicals Agency.

Overall, it is of key importance that the competent authorities raise awareness of chemical risk management among the public, civil societies, and the industry, enhance public participation in decision-making processes.

Finally, Albania, Bosnia and Herzegovina, Kosovo, North Macedonia, and Turkey face similar challenges in their preparation towards accession to the EU. Significant cost savings can be achieved by the Commission, the European Chemicals Agency and/or Member State competent authorities by designing activities addressing jointly the similar gaps found in legislative alignment, financing systems of chemical risk management, collaboration with external experts, information dissemination, stakeholder engagement, IT infrastructures, information security procedures and enforcement activities.

It is recommended that all candidate and potential candidate countries apply for the funding and technical assistance available through TAIEX and IPA instruments for chemical risk management related activities while guaranteeing the allocation of adequate resources over time so that capacity-building efforts are not dissipated by understaffing and staff turnover.

1 Introduction

1.1 Context

This fourth part of the study **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 Bosnia and Herzegovina 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);
- The recast prior informed consent (PIC) Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals; and
- Regulation (EU) No 1021/2019 on persistent organic pollutants (POPs).

BiH is comprised of two entities, the Federation of Bosnia and Herzegovina (FBiH) and *Republika Srpska* (RS). The Brčko District (BD) is officially a condominium of the FBiH and RS and is effectively a self-governing administrative unit. The RS, the BD and the cantons of the FBiH all have governments, and the state-level executive power is exerted by the Council of Ministers.

The environmental legislative framework is governed by the Dayton Peace Agreement, the Stabilisation and Association Agreement with the EU, which was signed in 2008 and entered into force in 2015, and the Environmental Approximation Strategy for approximation with the EU *acquis* in the field of environmental protection. BiH adopted the latter in 2018 (Official Gazette, No 91/18), and the BiH Ministry of Foreign Trade and Economic Relations is the responsible authority for its implementation and monitoring. However, the adoption and implementation of regulations in the environmental management area is the competence of the entities (Annex IV of the Dayton Peace Agreement) and the BD. Consequently, there is no state-level legislation governing chemicals in BiH: the legislation on chemical products and biocidal products, its implementation and enforcement are under the responsibility of the entities and the BD.

In 2017, a working body consisting of representatives from the RS, the FBiH, the BD and the Ministry of Civil Affairs of BiH was established with the aim to harmonise and mutually align entity legislation in the area of chemicals.

1.2 Methodology and report structure

The report describes the identified gaps and details the actions recommended to fill them. The gap assessment draws on the information gathered through:

- The review of:
  - Laws, bylaws and accompanying documents;

- The documents produced by the European Commission in assessing the progress of Bosnia and Herzegovina with the reforms in the framework of the accession negotiations[1] and in fulfilling the 14 key priorities identified in the Commission's Opinion on BiH's membership application to the EU;[2]
- The final report about recommendations and reviews for the transposition of EU chemicals regulations (CLP-REACH) and the Biocidal Products Regulation prepared by the TAIEX Expert missions to BiH dated 2016;
- The report "Gap analysis of legal and institutional readiness for the Stockholm Convention implementation" prepared within the "Environmentally Sound Management of Persistent Organic Pollutants (POPs) in Industrial and Hazardous Waste Sectors in Bosnia and Herzegovina" project financed by Sweden and implemented by the United Nations Development Programme (UNDP) in Bosnia and Herzegovina.

- The phone interview with the competent authorities of the RS held on 15 April 2021 and follow-up emails;
- Exchange of information with the competent authorities of FBiH and BD via email;
- Phone interviews with local NGOs and members of academia.

Actions have been suggested in the following areas:

- The alignment of the legislation with five EU Regulations mentioned above;
- The capacity and competence needs at the institutional level for implementation and enforcement of legislation;
- Systems and processes for transparency and stakeholder engagement; and
- The IT infrastructure, capacity and competence.

Only scarce information is available from reports and documents on the chemical legislative frameworks and the authorities' capacities in the Federation of Bosnia and Herzegovina and the Brčko District. Information has been complemented and validated through communication with the authorities via email. Nevertheless, general recommendations were possible in several areas (training, alignment of the legislation, stakeholder engagement, etc.) for Bosnia and Herzegovina as a whole. When not possible, recommendations and actions have been tailored to each entity, given the different levels of progress in their chemical risk management and legislative frameworks.

In addition, the report discusses potential similarities in gaps and shortcomings between the candidate and potential candidate countries 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. Where applicable/relevant, the action is accompanied by a list of relevant possible actors and the estimated financial and human resources required. Finally, other important aspects (e.g., awareness-raising, outreach, collaboration, and communication with other stakeholders) for the successful implementation of the recommended actions are described.

[1] European Commission (2020): Commission Staff Working Document. Bosnia and Herzegovina 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) 350 final.

[2] European Commission (2019): Commission Staff Working Document Analytical Report Accompanying the document Communication from the Commission to the European Parliament and the Council Commission Opinion on Bosnia and Herzegovina's application for membership of the European Union (COM(2019) 261 final)

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.

The work of the Chemicals Branch (CB) at the Ministry of Health and Social Welfare (MoHSW) of the *Republika Srpska* to align the legislation with the EU *acquis* is still ongoing. The Pharmaceuticals and Chemicals Branch (PCB) at the Ministry of Health (MoH) of the Federation of Bosnia and Herzegovina is currently drafting bylaws to fully implement the new Law on Chemicals, and there are transitional provisions in this Law establishing that the old Law is applicable until the implementation of the new Law on Chemicals is enabled by the adoption of relevant subsidiary legislation. In the Brčko District, the Law on Chemicals is currently being drafted with the estimated date of adoption at the end of 2022.

The alignment of the legislation is resource-intensive work due to the pace of the development of the European chemical legislative framework,[3] the complexities of introducing EU centralised procedures into an entity level system and other underlying issues in the legislative framework that would be beneficial to address in order to ensure progress. The identified drivers, gaps and their impact are listed below:

Drivers

- The *Republika Srpska*, the Federation of Bosnia and Herzegovina and the Brčko District have their own legislative frameworks;
- EU centralised procedures cannot be transposed;
- The continuous evolution of the EU regulatory framework; and
- Lack of Memoranda of Understanding with Scientific Institutes or Academia to draw on resources outside the ministry.

Gaps

The key problems and gaps, which are mainly generated by these drivers, are:

- Lack of a budget and sustainable financial framework for chemical risk management activities;
- Lack of human resources;
- Lack of expertise in risk assessment and evaluation of applications for authorisation of biocidal products;
  - Committee on Biocidal Products in the RS is not yet functioning;
  - Simplified procedure for authorisation of biocidal products in the RS;
- Lack of official Helpdesks in all entities;
- Lack of communication strategy in all entities;
- Lack of participation in public consultations;
- Gaps in IT infrastructure, policies and procedures.

[3] 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).

Consequences

The gaps identified above impact negatively several areas, and in particular:

- The protection of human health and the environment;
- The guarantee of a level playing field between Bosnia and Herzegovina's companies and foreign companies;
- Stakeholder engagement and public awareness of chemicals and chemical safety;
- The capacity of the competent authorities in ensuring the safety of CBI and personal data; and
- The administrative burden for the industry.

Drivers, challenges, gaps, and consequences are further discussed in the sections below, along with the suggested ways forward. Figure 1 shows the intervention logic with drivers, challenges, their impact, as well as main objectives and specific objectives and measures to tackle the problems and gaps identified above.

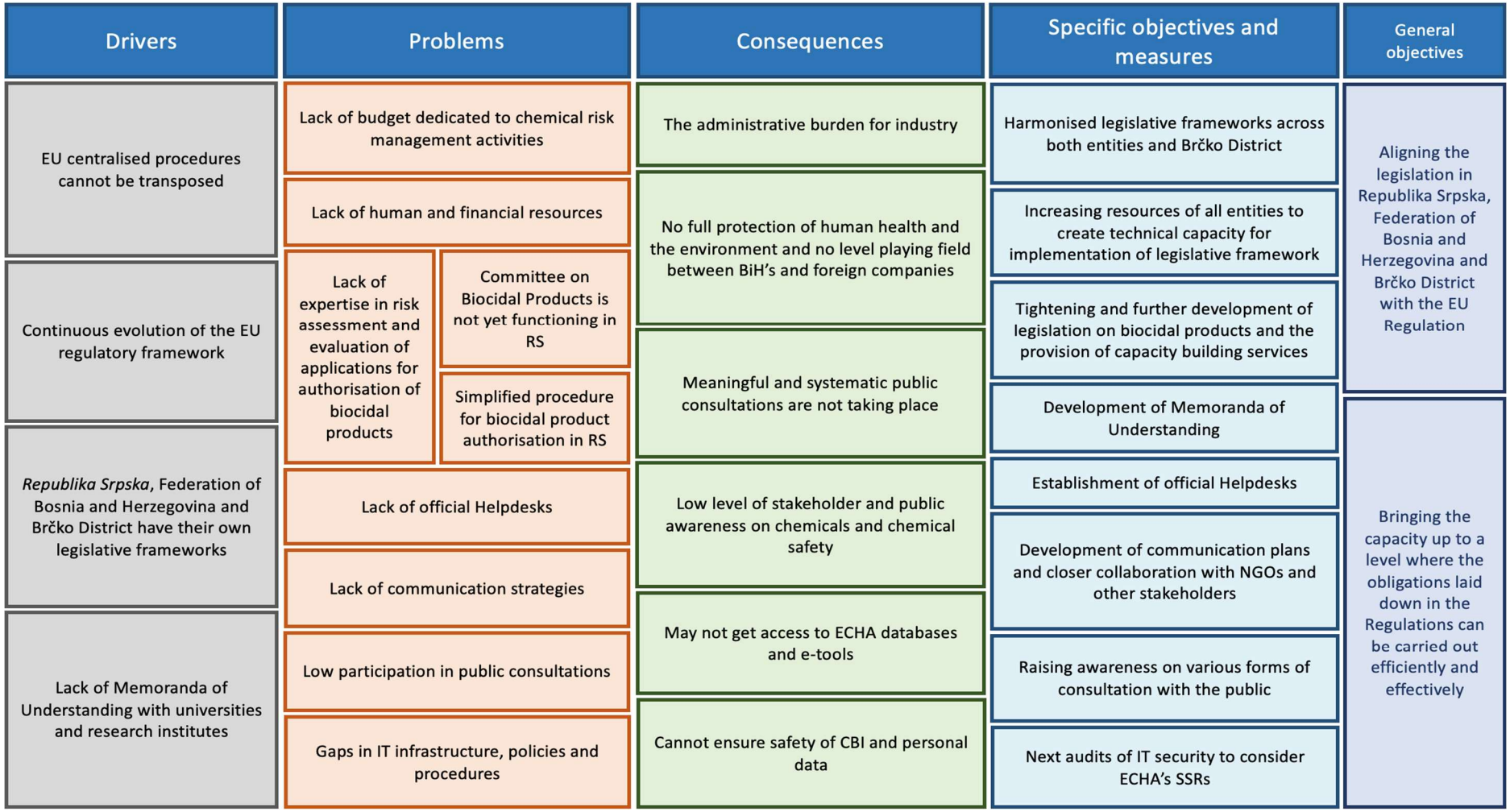
Where relevant, actions are structured in subsequent steps with descriptions including:

- Their dependencies;
- The identification of the body responsible for the action;
- The identification of the other relevant stakeholders who may be affected and should be involved to provide support. It is important to keep them informed about relevant changes and timelines;
- The necessary human and financial resources;
- The suggested timeline over the next five years; and
- The risks and the risk-mitigation measures to help ensure the successful implementation of the action.

This Action Plan considers the next five years as the timeframe for the implementation of the recommended actions. All entities in BiH are still developing the chemical legislative framework, and the necessary resources for its implementation in the medium-long term will depend on how diligently and closely the competent authorities will align the legislation with the EU *acquis*.

The final section presents an analysis of the similarities in gaps and shortcomings between candidate and potential candidate countries and discusses if and how these could be addressed by joint actions.

Figure 1 - Intervention logic



2.2 Underlying causes and means to address them

2.2.1 The *Republika Srpska*, the Federation of Bosnia and Herzegovina and the Brčko District have their own legislative frameworks

2.2.1.1 Description of the problem and dependencies

According to the Constitution of BiH, environmental policies are the remit of the *Republika Srpska*, the Federation of Bosnia and Herzegovina and the Brčko District. With the support of all entities, the Government of BiH enables compliance with international agreements and conventions.

The remit of the state-level Council of Ministers is limited to defining the basic principles for the coordination of activities and harmonisation of plans of the different authorities and institutions of the RS, the FBiH and the BD, including in the area of environmental protection and chemical risk management. There is no state-level legislation governing chemicals in BiH: the legislation on chemicals and biocidal products, its implementation and enforcement are under the responsibility of the entities and the Brčko District. In 2017, a working body consisting of representatives of the RS, the FBiH, the BD and the Ministry of Civil Affairs of BiH was established to harmonise and mutually align entities' legislations in the area of chemicals. Some activities have already been conducted, and the new Law on Chemicals in the FBiH is fully harmonised with the Law of Chemicals in the RS, although bylaws for its full implementation are yet to come. The old Law on Trade of Poisons from the Socialist Federal Republic of Yugoslavia (OG SFRY, No. 13/91 and 8/93 - correction) is being phased out due to the adoption of the new Law. Nevertheless, there are transitional provisions in the new Law on Chemicals establishing that the old Law is applicable until the implementation of the new Law is enabled by the adoption of relevant subsidiary legislation. According to UNDP (2020), the Law on Biocidal Products is being prepared; however, at the moment,[4] the priority is the drafting and adoption of the rulebooks necessary to implement the Law on Chemicals. Only then, the drafting of the Law on Biocidal Products in the FBiH will commence. The BD still applies a 1991 law of the Socialist Federal Republic of Yugoslavia, but authorities are drafting the Law on Chemicals, which is expected to be adopted at the end of 2022.

Currently, if companies of the RS want to place chemicals on the FBiH's market (or vice versa), they can register chemicals through their legal representatives (business unit or a registered partner company). In order to avoid issues experienced by companies in FBiH at the time the Law on Chemicals came into force in the RS (such as an effective ban on the placement of chemical products from the FBiH on the market of the RS), the legislative frameworks at the entity level should be fully compatible with each other. However, it is important to stress that even fully harmonised systems between the entities may still imply an administrative burden for FBiH's companies that would like to place chemical products on the RS market and vice versa.

2.2.1.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **legislative frameworks in both entities and the Brčko District in the area of chemical and biocidal products are fully harmonised**. This would create a level playing field and reduce the administrative burden for companies that wish to place their products on the BiH's market. In addition, the competent authorities of both entities and the BD could participate in

[4] December 2021.

different committees and working groups and share the information and knowledge acquired to ensure wider and more active participation. Table 1 shows the conformity of the objective to the SMART criteria.

Table 1 – Objective 1: BiH develops a single legislative framework

Criteria	Notes
Specific	It is recommended that legislative frameworks in both entities and the Brčko District in the area of chemical and biocidal products are fully harmonised.
Measurable	Legislative frameworks of all entities are aligned.
Achievable	The FBiH has already harmonised its Law on Chemicals with the Law on Chemicals in the RS.
Relevant	This is a fundamental part of the alignment of legislation to EU principles. It will ensure a level-playing field and reduce the administrative burden for all companies of BiH as well as for the competent authorities.
Time-bound	This action should be given priority.

2.2.1.3 Estimated human and financial resources required

In all entities, a significant amount of time is spent on drafting the legislation: in the RS, around 30% of the total resources (in terms of person-days) are typically spent on this task and, depending on the legislative development stage, even more; in the FBiH, approximately 20% of the total resources. The information on the resource allocation in BD is not available, but it is expected that the drafting of legislation uses a significant proportion of the available resources, given that authorities in the Brčko District are developing their Law on Chemicals.

Other candidate countries and potential candidate countries dedicate (or should dedicate) at least two full-time Equivalents (FTE) to this task and receive the support of other departments. In BiH, competent authorities of both entities and the BD allocate at least one FTE per year to this task.

2.2.1.4 Timeline, risks and risk mitigation measures

The priority should be the alignment of legislation between all entities to ensure a level playing field for all companies in BiH; however, the timeframe of this action will depend on the availability of financial and human resources in both entities and the BD, which should be ensured by a dedicated budget (see Section 2.3.1).

2.2.2 EU centralised procedures cannot be transposed into legislation before accession

2.2.2.1 Description of the challenges and dependencies

The articles of five regulations, which relate to EU centralised procedures, cannot be transposed.[5] The current institutional and legislative setup focuses on strictly administrative procedures, which do

[5] 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

not necessarily require scientific expertise on risk assessment. Currently, competent authorities at both entities and the BD cannot have access to the e-tools, such as REACH IT, R4BP and IUCLID, 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.

2.2.2.2 Recommended actions, action owner and other relevant stakeholders

Since 2009, ECHA activities implemented under the IPA instrument for Pre-accession Assistance and funded by the European Union have provided capacity building and support to the implementation of the EU chemicals legislation.[6] In addition, to increase the impact of ECHA's general support activities (such as visits, specific training, and participation in ECHA events), the Agency has contracted an in-depth assessment of the legal and institutional capacities of Albania, Bosnia and Herzegovina, Kosovo, North Macedonia, and Turkey.

It is recommended that **ECHA implements additional capacity building activities focusing on risk assessment.** At the moment, competent authorities lack the expertise and knowledge to evaluate applications for the authorisation of biocidal products. In addition, it is also recommended that **ECHA delivers hands-on training sessions focusing on the functioning of the e-tools** used by EU Member States' competent authorities to manage the information exchange with ECHA. Although this action is a low priority, BiH's competent authorities would benefit from understanding the functioning of these tools, which may help develop and improve their own procedures. Table 2 shows the conformity of the objective to the SMART criteria.

Table 2 – Objective 2: Ensure risk assessment capacity and practical experience with e-tools

Criteria	Notes
Specific	It is recommended ECHA implements additional capacity building activities focusing on risk assessment. It is recommended that ECHA delivers hands-on training sessions focusing on the functioning of the e-tools used by the competent authorities to manage the information exchange with ECHA.
Measurable	Number of civil servants and external experts trained per year.
Achievable	ECHA has implemented capacity-building activities in BiH since 2009 and may continue supporting competent authorities in the RS, the FBiH and the BD.
Relevant	Capacity building on risk assessment and e-tools will ensure a smoother EU accession.
Time-bound	Training on risk assessment should start in 2025. Hands-on training on e-tools could be organised in the following year.

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.
- POPs: Article 8, Articles 10-12, partially Article 13, Articles 15-18, Article 20.

[6] 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

2.2.2.3 Estimated human and financial resources required

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

As an indication, the Swedish Chemicals Agency spent around €150,000[7] and 150 workdays (around 0.7 FTE) carrying out training activities of Serbian Authorities staff in 2017.[8] In the context of the twinning project implemented by the Austrian and Slovenian competent authorities[9], the cost of the organisation and actual implementation of training and workshops was around €110,000. The courses, which were attended by at least two staff members from the Serbian competent authorities 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 three 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 course for at least seven 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 approximately €40,000. [10]

It is expected that the required human resources and the cost borne by ECHA or MSCA for training competent authorities' staff in BiH may be similar. However, the actual cost will depend on the number of attendees (internal and/or external) and whether the training will be carried out only for competent authorities in BiH or as a joint action for all candidate and potential candidate countries (see Section 3.2).

2.2.2.4 Timeline, risks and risk mitigation measures

It is recommended to organise capacity-building activities when the Law on Biocidal Products is fully aligned with the BPR and the competent authorities start applying a full authorisation procedure. Training the staff sooner may result in loss of knowledge and expertise gained due to skill decay and/or staff turnover. Hands-on training on e-tools can be organised in the medium-long term. However, although training activities on ECHA e-tools are of a lower priority, if these were going to be provided to other candidate and potential candidate countries, competent authorities in the RS, the FBiH and the BD would benefit from increasing their knowledge of the functioning of e-tools.

2.2.3 The continuous evolution of the European chemical legislative framework

2.2.3.1 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;

[7] Around SEK 1,500,000.

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

[9] 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.

[10] These figures cover daily allowances, travel and subsistence costs of invited experts and development of training material.

- The REACH annexes have been adapted to clarify the information requirements for nanomaterials;
- Yearly adaptations to technical progress (ATPs) of the CLP Regulation;
- Approvals of new active substances (Biocidal Products Regulation);
- New substances are added in the annexes of the PIC Regulation;
- New substances are added to the annexes of the Stockholm Convention and POPs Regulation; and
- Both the REACH and CLP Regulations are up for revision.

Consequently, keeping the entities' legislation aligned with the EU *acquis* is a resource-intensive work. Both entities and the Brčko District are still working on developing the legislative frameworks, and the workload associated with this task is assumed to stay constant over the following years, in consideration of the work still to be done but also of the upcoming revisions of the regulations on chemicals and biocidal products (REACH, CLP, BPR). The competent authorities of the RS are working on further aligning the legislation on biocidal products with the BPR. The FBiH is drafting the rulebooks for the implementation of the new Law on Chemicals and still needs to draft the Law on Biocidal Products. Finally, the BD competent authorities need to draft the primary and secondary legislation for chemicals and biocidal products. The Law on Chemicals is currently being drafted in the BD and should be adopted in the 4th quarter of 2022, whereas drafting and adoption of the Law on Biocidal Products is currently not in the pipeline.

The strategic document on the adoption of the EU *acquis* in the environmental area (including chemicals management) the "Environmental Approximation Strategy of BiH"[11] (supplemented by Environmental Approximation Programmes for the Federation of Bosnia and Herzegovina[12], *Republika Srpska*[13] and Brčko District[14]) was developed in 2014. The Environmental Approximation Programmes of entities can be considered action plans for implementing the Environmental Approximation Strategy of BiH in the RS, the FBiH and the BD. The governments of the relevant entities adopted these documents in December 2016 for the RS and the FBiH and in early 2017 for the BD. According to the competent authorities of the RS, many actions in the RS have already been completed.

The Law on Chemicals in the RS also provides the development of a strategy for safe management of chemicals to implement policies efficiently and transparently in the field of safe management of chemicals and the protection of human health and the environment.

In addition, there is an ongoing project titled "Environmental Strategy and Action Plan of Bosnia and Herzegovina – ESAP 2030+"[15], which is implemented by the Swedish Environment Institute. This is a nationwide project and includes coordination between different entities. Different working groups deal with specific environmental areas, including chemicals. The Action Plan should be finalised by the end of 2022. The plan will cover the period until 2030. The Action Plan will cover different environmental issues, and legislation will be only one part of this.

Finally, there is an ongoing project with the Government of Sweden on POPs in BiH (2019-2023).[16] Partners in the project are the Ministry of Foreign Trade and Economic Relations of Bosnia and Herzegovina, the Ministry of Spatial Planning, Civil Engineering and Ecology of the *Republika Srpska*,

[11] Environmental Approximation Strategy of Bosnia and Herzegovina (OG BiH No 91/18). English version available at: http://extwprlegs1.fao.org/docs/pdf/bih200210.pdf

[12] Program of Approximation of Regulations of the Federation of Bosnia and Herzegovina with the EU *Acquis* in Environmental Area

[13] Program of Approximation of Regulations of the *Republika Srpska* with the EU *Acquis* in Environmental Protection Area

[14] Strategy for Approximation of Regulations to the EU *Acquis* in the Field of Environmental Protection of the Brčko District

[15] https://esap.ba/

[16] https://www.ba.undp.org/content/bosnia_and_herzegovina/en/home/climate-and-disaster-resilience/POPs.html

the Federal Ministry of Environment and Tourism, and the Department of Spatial Planning and Property Affairs of the Brčko District Government. The project's goal is to reduce the risk for people's health and the environment by preventing unintentional POPs (U-POPs) releases, shifting from POPs toward non-POPs chemicals in the plastic industry, and destroying POPs waste. In addition, one of the objectives of the project is the capacity-building and mainstreaming of POPs related legislation into the process of harmonisation of the BiH environmental legislation, and currently, there is an ongoing activity of drafting/amending prioritised local legislation to ensure alignment with the Stockholm Convention. Representatives of 51 institutions through four project working groups have been involved in this process. In addition, members of the working groups have been trained on various topics relevant to the implementation of the Convention in accordance with the project's training program. In addition, the Gap Analysis of Institutional and Legal Readiness to implement the Stockholm Convention[17] in BiH was produced in 2020.

2.2.3.2 Recommended actions, action owner and other relevant stakeholders

Aligning and keeping the alignment of the legislation with the EU Regulations and implementation of the chemical laws is a resource-intensive work. The CB at the MoHSW of the RS has two full-time and two part-time employees. The PCB at the MoH of the FBiH also employs three people and plans to hire one additional employee for biocidal products management in 2022, although there are some uncertainties about that. No information is available on resources in the BD, but it is known that there are no officers for chemicals in the Department of Public Health and Other Services (DPHOS).

The BiH authorities participated in IPA projects and have ongoing cooperation projects with Sweden. Through events and workshops held in the context of these projects, the authorities' staff have acquired knowledge and expertise on the implementation and enforcement of CLP, REACH, BPR, PIC and POPs Regulations. Nevertheless, there is the need to increase the resources of all entities to further align legislation on chemicals and biocidal products with the EU Regulations and between entities and the Brčko District, as well as for the implementation of administrative tasks. Due to the lack of resources, legislative requirements are not fully implemented, although with differing degrees among the entities.

It is recommended that **the competent authorities of both entities and the Brčko District further develop legislation on chemicals and biocidal products and strengthen the capacity of their relevant departments.** This is further discussed in Section 2.3.2 and Section 2.3.4. Table 3 shows the conformity of the objective to the SMART criteria.

Table 3 – Objective 3: Strengthen the capacity of the competent authorities in all entities

Criteria	Notes
Specific	It is recommended that the competent authorities of both entities and the Brčko District further develop legislation on chemicals and biocidal products and strengthen the capacity of their relevant departments.
Measurable	Legislation on chemicals and biocidal products is harmonised with EU Regulations and between entities and the Brčko District. Number of additional staff members in relevant departments.
Achievable	Further discussed in Sections 2.3.2 and 2.3.4.
Relevant	Additional capacity is key to overcoming many of the identified challenges.
Time-bound	The necessary resources at relevant departments of both entities and the Brčko District should be in place by the time of accession. However, competent authorities should ensure that the

[17] https://www.ba.undp.org/content/bosnia_and_herzegovina/en/home/library/environment_energy/POPsAnaliza.html

Criteria	Notes
	capacity to implement administrative tasks in relation to chemicals legislation is built gradually over the years before accession.

2.2.3.3 Estimated human and financial resources required

As specified in Section 2.2.1.3, other candidate countries and potential candidate countries dedicate (or should dedicate) at least two full-time equivalents to this task and receive the support of other departments. Each entity allocates at least one FTE per year to this task and should maintain this level of resources to ensure some progress with the development of legislation. However, it can be argued that the allocation to this task of one FTE per year per entity is still sub-optimal, as none of the entities has legislation partially or fully aligned with the BPR, the FBiH has just adopted the new Law on Chemicals and still has to develop bylaws, and the BD is still working on their Law on Chemicals.

2.2.3.4 Timeline, risks and risk mitigation measures

Further alignment of legislation on chemical and biocidal products in the RS, FBiH and the BD is a priority task. However, given the limited resource capacity of the entities and the Brčko District, the risk is that the legislative development may encounter further delays. Therefore, it is recommended to have more coordination and closer collaboration between the entities and the Brčko District, as well as to share the experience in developing legislation in order to mitigate the risk. In addition, strengthening the administrative capacities would also help speed up the legislative alignment process. This is further discussed in Section 2.3.2 and Section 2.3.4.

2.2.4 Lack of a Memoranda of Understanding with Scientific Institutes and external experts

2.2.4.1 Description of the problem and dependencies

There is a need to increase resources for further alignment of legislation on chemicals and biocidal products in both entities and the Brčko District and implementation of other administrative tasks. The additional administrative capacity in the MoHSW of the RS and the MoH of the FBiH has been quantified as one FTE per year per entity over the next five years. However, in the medium-long term[18], when the Law on Biocidal Products is fully aligned with the BPR, both competent authorities will require 5-10 FTEs for the management of biocidal products (see Section 2.3.2). In the BD, two employees are working on developing the chemical legislative framework. It is expected that as soon as the new Law on Chemicals is adopted, one FTE will be required to implement the legislation, also in preparation for the development and adoption of a law on biocides.

The gap in necessary resources could be filled by hiring new employees at the competent authorities and by using external resources. The implementation of the Law on Biocidal Products is resource-intensive and requires specific expertise in risk and efficacy assessment. The competent authorities could consider outsourcing some of the most technical aspects to external scientific institutes through Memoranda of Understanding (MoU).

According to Article 12 of the Law on Biocidal Products (OG RS, No. 37/09), the MoHSW of the RS has to appoint the Committee on Biocidal Products for providing professional opinions in the process of issuing authorisations. The committee should consist of seven expert members from the MoHSW and recognised experts from toxicology, veterinary medicine, pharmacy, biology, ecology.

[18] 5-10 years.

In addition, the competent authorities are expected to involve external experts from universities and research institutes. The committee is appointed, but it is not functional because its tasks are not clearly defined, and there are no sufficient funds. In addition, most of its members are experts from Serbia since the competent authority could not source local experts with suitable scientific backgrounds.

Given that the capacity at the competent authorities will have to be built up progressively over time, support should 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 authorities, particularly regarding risk assessment. There are several institutes and universities in the RS with competencies in chemistry and toxicology, such as the Institute for Protection and Ecology of the *Republika Srpska*, the Faculty of Medicine and the Faculty of Technology at the University of Banja Luka, and the Public Health Institute of the *Republika Srpska*. Nevertheless, as mentioned previously, the competent authorities experienced difficulties finding suitable experts with the right scientific background in the country.

There are also several universities and institutes in the FBiH, such as the Public Health Institute of the Federation of Bosnia and Herzegovina, the Faculty of Medicine at the University of Sarajevo, the Federal Agro-Mediterranean Institute Mostar, the Federal Institute of Agropedology, and the Federal Institute of Agriculture.

There is no information about scientific bodies with competencies in chemistry or toxicology in the Brčko District.

When MoU's are developed and ratified, experts from academia and scientific institutes should be trained on technical and scientific aspects of chemical legislation, also in consideration of staff turnover and skill decay.[19] Training courses could be organised for both academic experts and the competent authorities' staff (see also Section 2.3.4).

2.2.4.2 Recommended actions, action owner and other relevant stakeholders

It is important that **the competent authorities of both entities and the Brčko District develop, ratify, and implement the Memoranda of Understanding (MoU) with relevant scientific institutes and with a designated scientific body in the Brčko District** for rapid and long-term access to their competencies and capacities. While an agreement on such a memorandum is taking place, the competent authorities should explore the use of more agile short-term contracts on specific assignments. The scope of the MoU is to regulate the long-term cooperation between the competent authority and external experts. As a first step, the competent authorities 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 that needs strengthening in order to provide support to the relevant competent authority according to requirements and procedures determined under the BPR. Most likely, the MoU will need to be accompanied by:

- Non-disclosure agreements;
- Policies and procedures for managing Confidential Business Information (CBI);

[19] 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.

- 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 competencies, ensure the functioning of the relevant competent authorities and smooth processing of industry applications. Table 4 shows the conformity of the objective to the SMART criteria.

Table 4 – Objective 4: Develop, ratify, and implement a Memorandum of Understanding (MoU)

Criteria	Notes
Specific	It is recommended that the competent authorities of both entities and the Brčko District develop, ratify, and implement the Memoranda of Understanding (MoU) with relevant scientific institutes and with a designated scientific body in the Brčko District.
Measurable	MoU's with external experts is ratified. Number of external experts involved.
Achievable	The objective is attainable provided that all parties of MoU's reach an agreement.
Relevant	Without the support of external experts, the BiH competent authorities will not be able to process all industry applications, particularly for the authorisation of biocidal products, by the day of accession.
Time-bound	For the RS and the FBiH, starting in 2024 over three years. For the BD, when the Law on Biocidal Products is adopted (medium-long term).

2.2.4.3 Estimated human and financial resources required

The functioning of an MoU will only be relevant when the laws on biocidal products are fully aligned with the BPR, and different authorisation procedures are implemented. Therefore, the competent authorities should now focus on further development and alignment of legislation on biocidal products. When this is achieved, it is recommended that the competent authorities allocate at least 0.5 FTE per year over three years to prepare the MoU and set up the necessary framework for a closer collaboration with academia and scientific institutes. It should be noted that the competent authorities could also benefit from exchanging the information with the Montenegrin competent authorities, who have been preparing an MoU over the last couple of years.

2.2.4.4 Timeline, risks and risk mitigation measures

It is recommended to have a functioning MoU by the time the Law on Biocidal Products is fully harmonised with the BPR, which should be a medium-term objective. Therefore, the process of developing an MoU should commence in 2024-2025, or sooner if necessary. This would require the identification of relevant parties, surveying their competencies and needs and defining the scope of collaboration. There are several institutions which may have relevant knowledge and expertise. However, the competent authorities in the RS have not been able to identify suitable expertise in BiH and hence sought experts from Serbia for the Biocidal Products Commettee.[20] It should be noted that dedicating even 0.5 FTE per year over a period of 3 years could be difficult unless the capacity of the competent authorities is strengthened (Section 2.3.2). In BD, the competent authorities should develop an MoU when legislation on biocidal products is adopted, which may be a medium- to long-term plan.

[20] When offering training and capacity building programmes, researchers and professionals from academia, research institutes and private consultancies could be invited to participate in order to build a larger pool of experts.

2.3 Identified challenges and associated objectives

2.3.1 Lack of sustainable financial framework and dedicated budget for chemical risk management activities

2.3.1.1 Description of the problem and dependencies

The Law on Chemicals in the RS (and therefore in the FBiH) notes that fees for the registration of chemicals should be paid in accordance with the Rulebook on the amount of fees related to chemicals ("Official Gazette of the *Republika Srpska*", No. 69/18). According to the Law, all fees paid by applicants shall be the revenue of the budget of the RS. However, although the Law on Biocidal Products foresees the payment of fees for the technical dossier assessment and authorisation issuance, which shall be the revenue of the RS, there is no Rulebook on the amounts of fees to be paid. Furthermore, as later discussed in Section 2.3.4, the assessment of technical dossiers, which is the second phase of the biocidal product authorisation process, is currently not taking place due to the lack of capacity and expertise at the MoHSW. Hence, there is a need for a dedicated budget and a sustainable financial framework to create additional resources and capacity at the MoHSW for the authorisation of biocidal products.

There is no Law on Biocidal Products in the FBiH and the BD, and the authorisation of biocidal products is not taking place. In the FBiH, the MoH is responsible for issuing decisions for the import of biocidal products (UNDP, 2020) in accordance with the Law on Trade in Poison and the Law on Transport of Hazardous Goods (OG FBiH, No. 2/92 and 13/94). When legislation on biocides is developed, adopted and aligned with the BPR, the competent authorities of the FBiH and the BD will be able to commence the authorisation process, for which the fees will need to be collected according to the law.

2.3.1.2 Recommended actions, action owner and other relevant stakeholders

As a first step, it is recommended that **both entities and the Brčko District create dedicated budgets for chemical risk management activities by ring-fencing fees and charges**. It is also recommended that **all entities align legislation on administrative fees with the principles of the EU Regulations**.[21] In particular, Article 80(3)(a) of the BPR establishes that "fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs". In accordance with Article 80(2) of the BPR, the European Commission has issued a guidance document[22] containing recommendations for Member States' fee structures and related procedures with a view of harmonising the latter and avoiding gaps in national methods and/or fee levels. The authorities may also **consider the guidance from the European Commission on fee structure when drafting the Law on Biocidal Products and relevant rulebooks**. Table 5 shows the conformity of the objective to the SMART criteria.

[21] Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products; and

Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[22] CA-Dec12-Doc.5.1.b – Final.

Table 5 – Objective 5: Reform the budgetary system

Criteria	Notes
Specific	It is recommended that both entities and the Brčko District create dedicated budgets for chemical risk management activities by ring-fencing fees and charges paid by companies. It is recommended that all entities align legislation on administrative fees with the principles of the EU Regulations.
Measurable	A ring-fenced budget dedicated to chemical risk management activities is created in each entity and the Brčko District. Relevant administrative fees are introduced and aligned with principles of the EU Regulations.
Achievable	Guidance is available at the EU and MSCA-level.
Relevant	This is a fundamental part of the alignment of legislation to EU principles.
Time-bound	Starting of the year 2022.

2.3.1.3 Estimated human and financial resources required

For illustration, in Serbia, the preparation of the document containing recommendations for sustainable financing of biocidal products management administration prepared in the context of the twinning project with Austria and Slovenia cost around €25,000 and required four meetings with the participation of three experts for a total of 19 days (0.1 FTE). The organisation and implementation of the preparatory advisory mission to support the Serbian Ministry of Environmental Protection in developing national fees for the services that the competent authorities provide with respect to procedures under the BPR, taking into consideration the EU guidance concerning the harmonised structure of fees, cost around €60,000 and required eight meetings in Serbia (involving the participation of four experts) for a total of 53 workdays (0.2 FTE).

It is expected that the required resources for completing these actions in BiH would be similar because the resources necessary to support the competent authorities in preparing these documents do not depend on the size of the chemical industry. These are potential cost estimates for any entity (MSCA or ECHA) that may support BiH with this task. Furthermore, ECHA or a Member State competent authority could support the competent authorities in defining the applicable fees and charges, which should be kept the same across both entities and the Brčko District to ensure a level-playing field for all companies in BiH.

It is estimated that 0.25 FTE in the RS and 0.25 FTE in the FBiH would be required over two years to draft the rulebook on the fees payable by companies applying for the authorisation of biocidal products.

2.3.1.4 Timeline, risks and risk mitigation measures

The establishment of a dedicated budget should be a priority in the RS, the FBiH and the BD. Nevertheless, the implementation of the necessary changes in the budgetary system may be a lengthy process. Therefore, the analysis of the legal feasibility and compatibility and the creation of the dedicated budgets should commence sooner than later.

In addition, both entities and the BD have an opportunity to align legislation on administrative fees with the EU Regulations and principles while further developing and aligning their legislation on chemicals.

2.3.2 Lack of human resources at competent authorities

2.3.2.1 Description of the problem and dependencies

The Ministry of Health and Social Welfare of the *Republika Srpska*[23] is the competent authority for the chemicals management system and for implementing regulatory procedures in relation to chemicals and biocides. The practical implementation of the legislation based on REACH, CLP, BPR, POPs (partly) and PIC is the responsibility of the Chemicals Branch of the Pharmacy Department at the MoHSW.

According to the Law on Chemicals and the Law on Biocidal Products, the CB is responsible for maintaining the Registry of Manufacturers and Importers of Chemicals, the Registry of Chemicals, and the Registry on Biocidal Products. However, a national register of chemicals is not a requirement for EU Member States. In the EU, the registration of chemicals is managed by ECHA for the whole single market, and national registries add to the administrative burden for industries and competent authorities. The register of chemicals can provide useful information on chemicals on the market for BiH's competent authorities; however, the establishment and maintenance may require additional resources, which could instead be used for further alignment of the legislation with EU *acquis* and its implementation. Therefore, the establishment and/or maintenance of the register of chemicals should be carefully considered and assessed to ascertain its practicality.

Day to day activities in the CB involve receiving submissions/notifications and checking their completeness and quality. Other activities include drafting legislation, involvement in projects, preparing opinions, and producing reports and action plans. The update of the Law on Biocidal Products (OG RS, No. 37/09) is also in the pipeline of the CB. In addition to the legal-administrative procedures related to the implementation of the laws, the CB is responsible for providing information to stakeholders. The CB is also cooperating with other ministries while drafting laws and bylaws, which are complementary to chemicals legislation. According to the RS competent authority's estimates, two-thirds of the time is spent on practical tasks required by the legislation and one-third on the development of the legislative framework, the management and coordination activities, participation in training activities and events, and aligning with the EU Regulations and Directives other than five regulations subject of this study.

The CB has two full-time employees: the Head of the Branch and one senior specialist for chemicals. There are also two part-time employees – one senior specialist for chemicals and one senior specialist for biocides. The Head of the Branch and senior specialist for biocides have master's degrees in pharmacy, whilst senior specialists for chemicals have master's degrees in engineering (chemical engineering and chemical technology). Certain legal and administrative assistance is available from two other employees at the Pharmacy Department. According to the CB, the required number of employees depend on the workflow, which can be projected by the number of requests received per month: 100 requests for chemical permits, but lower for biocides, because most biocidal products come to FBiH and do not reach RS. Nevertheless, there is the need to increase the resources of the CB to further align the legislation on biocidal products with the BPR and implement the required administrative tasks. A Committee composed of seven experts should evaluate the applications for authorisation of biocidal products submitted, but the committee is not yet functioning.

In the FBiH, the newly adopted Law on Chemicals (OG FBiH, No. 77/20) falls within the competence of the Pharmaceuticals and Chemicals Branch (PCB) at the Ministry of Health (MoH). Currently, the Branch employs three people: a Minister Assistant for Pharmacy and Chemicals, one expert advisor for pharmacy and one expert advisor for chemicals. There is also an expectation for one additional

[23] https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx

employee for biocides in 2022, although this has not been confirmed yet. Two members of staff have master's degrees in pharmacy, and one employee has a bachelor's degree in agriculture. The majority of time at the PCB is spent on replying to industry queries (50%), approximately 20% on developing the legislation, and 30% on other activities. Currently, the Branch is working on three pieces of legislation: the Rulebook on restrictions and prohibitions of chemicals, the Rulebook on the register of manufacturers and importers of chemicals, and the Rulebook on inventory of chemicals. It is important that the plan for one additional employee is implemented to ensure that the Branch has sufficient resources for drafting the Law on Biocidal Products and freeing up resources for administrative tasks and other activities, such as the establishment of a helpdesk (see Section 2.3.3) and development of a communication strategy (see Section 2.3.5). The MoH issues decisions for imports of chemicals in the FBiH. There are about 100 active importers of chemicals in the Federation, and they must have an import permit from the MoH. In the last three months, 130 permits have been issued for the import of chemicals in the FBiH. The branch spends a lot of time responding to legal entities regarding the application of the Law on Trade of Poisons, the new Law on Chemicals, and biocides, in parliament of the FBiH, participation in professional meetings, round tables, and similar.

In the BD, the Department of Physical Health and Other Services (DPHOS) still applies the Law on Trade of Poisons (OG SFRY, No. 13/91 and 8/93 - correction), which entered into force at the time of the Socialist Federal Republic of Yugoslavia. Two people have been allocated to draft the Law on Chemicals, and it is estimated that it will be adopted in the 4th quarter of 2022. However, the drafting of the Law on Biocidal Products has not commenced, and there is no estimated timeframe for its adoption. Also, there is no officer for chemicals in the department and no information on how many people are currently employed at the DPHOS.

2.3.2.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **both entities and the Brčko District strengthen their administrative staff capacities to implement legislation on chemicals and biocidal products.** Once the legislation is fully aligned with the BPR and assuming that the number of biocidal products on the BiH market is similar to the Maltese market, competent authorities could receive between 700 to 1,000 applications for authorisation of biocidal products. Depending on the number of applications for different authorisation procedures, the evaluation and assessment of the applications could require between **five to ten FTEs per year over a five-year period.** As there is no single legislative framework in BiH, businesses may need to authorise their biocidal products in each entity. For example, a company from the RS may need to obtain authorisation in the RS, the FBiH and the BD. Therefore, five to ten FTEs may be required in each entity.

No information is available on the types of industrial activities in the Brčko District and, therefore, on the biocidal product-types that may be more relevant, but it is expected that, as a minimum, the number of biocidal products on the BD market could be in the tens.[24] In the BD, the priority at the moment is to draft the Law on Chemicals, which should be fully harmonised with the Law on Chemicals in the RS and the FBiH. For this task, the DPHOS has sufficient resources (two employees). However, when the Law on Chemicals is adopted in the BD, more resources will be required for its implementation and related administrative tasks. Therefore, as a minimum, it is recommended that **the DPHOS has one officer dedicated to the implementation of the legislation on chemical and biocidal products.** Table 6 shows the conformity of the objective to the SMART criteria.

[24] It is expected that a certain number of biocidal products per product-types such as human hygiene (PT01), veterinary hygiene (PT03), food and feed area (PT04) and drinking water (PT05) will be present on the Brčko District's market. For example, there are 161 biocidal products authorised on the Maltese market for these four PTs. Source: https://echa.europa.eu/information-on-chemicals/biocidal-products

Table 6 – Objective 6: Strengthen the administrative capacity of the MoHSW

Criteria	Notes
Specific	It is recommended that both entities and the Brčko District strengthen their administrative staff capacities to implement legislation on chemicals and biocidal products. It is recommended that the DPHOS has one officer dedicated to the implementation of the legislation on chemical and biocidal products.
Measurable	Number of employees in the MoHSW of the RS and the MoH of the FBiH. Dedicated officer for chemicals and biocidal products in the BD.
Achievable	This may require the allocation of adequate financial resources. There are already plans for one additional employee at the MoH.
Relevant	Without strengthening administrative capacity, the competent authorities will not have sufficient resources to develop and align legislation on biocidal products and other administrative tasks.
Time-bound	The capacity needs to be built in 2022 in the RS and the FBiH and 2023 in the BD.

2.3.2.3 Estimated human and financial resources required

The gap in an administrative capacity to ensure the evaluation of the applications for biocidal products' authorisation is estimated to be five to ten FTEs per year when comparing BiH with Malta and assuming that a similar number of biocidal products will be placed on the market (700 to 1,000). Due to the unique structure of the country, each entity may require this number of resources for biocidal product management. However, at the moment,[25] none of the entities has legislation fully aligned with the BPR, although the Law on Biocidal Products in the RS is harmonised with the old Biocidal Products Directive (98/8/EC) and partially aligned with the BPR. Therefore, the estimated five to ten FTEs per year will be required when the legislation on biocidal products is fully aligned with the BPR and a full authorisation procedure is applied, which may be in the medium-long term (5-10 years). In the RS, the resource may be required sooner if the legislation is fully harmonised with the short-medium term, and the competent authorities start implementing it.

In the short-medium term (next five years), the MoHSW of the RS and the MoH of the FBiH should have at least four FTEs per entity at the relevant departments to have enough recourses for further alignment of legislation with the EU *acquis* and other administrative tasks. In the BD, the DPHOS should plan for 1 FTE for chemicals and biocidal products, who could also support the drafting of legislation on biocides.

In BiH, the average labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €14,000, and in professional, scientific and technical activities – approximately €11,500.[26] Therefore, the additional cost of bringing the number of the CB's employees to the suggested minimum amount of 4 FTEs is €70,000 over a five-year period (2022-2026) (Table 7). In the FBiH, the additional cost of bringing the number of MoH employees to the suggested minimum amount of 4 FTEs is also €70,000 over a five-year period (2022-2026) (Table 8). Finally, in the BD, the additional cost for hiring one additional FTE is €56,000 over a five-year period (Table 9).

[25] December 2021.

[26] Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016.

Table 7 – Marginal labour cost of hiring staff in the RS

	2022	2023	2024	2025	2026	€ - Total
MoHSW Staff - FTEs	3	4	4	4	4	-
Additional FTEs	1	0	0	0	0	-
Marginal Cost	€14,000	€14,000	€14,000	€14,000	€14,000	€70,000[27]

Table 8 – Marginal labour cost of hiring staff in the FBiH

	2022	2023	2024	2025	2026	€ - Total
MoH Staff - FTEs	3	4	4	4	4	-
Additional FTEs	1	0	0	0	0	-
Marginal Cost	€14,000	€14,000	€14,000	€14,000	€14,000	€70,000

Table 9 – Marginal labour cost of hiring officer for chemicals for DPHOS

	2022	2023	2024	2025	2026	€ - Total
DPHOS Staff - FTEs	-	-	1	1	1	-
Additional FTEs	0	1	0	0	0	-
Marginal Cost	-	€14,000	€14,000	€14,000	€14,000	€56,000

In the medium-long term, both entities will need to increase their resources for the management of biocidal products. Additional five FTEs for this task would cost approximately €70,000 per year: however, if all five external experts are outsourced, it may add up to approximately €130,000 per year per Ministry. However, the number of required resources will depend on how many biocidal products will be placed on each entity's market.

2.3.2.4 Timeline, risks and risk mitigation measures

The hiring of additional employees should start in 2022 in the MoHSW and the MoH in order to have enough resources for further development and alignment of legislation on chemicals and biocidal products and implementation of other administrative tasks. The BD should aim to have a dedicated person for the management of chemicals and biocidal products when the Law on Chemicals is adopted.

In order to keep the administrative capacity at the desired level, it is important to avoid a high staff turnover. In addition, new resources should be available for thorough training to ensure a swift onboarding. 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 are 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 2.3.7).

[27] Rounded to the nearest 5,000.

2.3.3 There is no Helpdesk

2.3.3.1 Description of the problem and dependencies

In both entities and the Brčko District, helpdesks have not been established yet. The CB at the RS prepares instructions, guides, documents, and other information materials for the industry. Certain guidance documents, including those provided by ECHA, and other information are available on the MoHSW's webpage. Queries on legislation are sent directly to the CB staff by industry and other stakeholders via e-mail (most common way) and phone, and answers are regularly provided to stakeholders. There are no statistics on how many queries are received by the CB. Also, there is no formalised procedure or written rules on how queries should be addressed. Normally after receiving a query, a decision is made on who should address it based on responsibilities for the implementation of different parts of legislation. The query is then forwarded to the person in charge, who prepares the answer based on the applicable legislation, internal or publicly available guidelines (e.g., ECHA guidance documents) and previous answers to similar questions, if available. Usually, it takes at least a third or half workday to reply to queries. Activities on setting up a Helpdesk within the MoHSW are ongoing, but it is not foreseen to have a dedicated person responsible only for Helpdesk activities with current capacities. There are plans to have a designated email address and FAQs online.

There is no information on how many queries the competent authorities in the FBiH receive; however, approximately 50% of the time in the team is spent replying to queries from the industry. There are plans for a helpdesk but no estimated dates for its establishment.

There is no helpdesk in the BD and no plans to establish it.

2.3.3.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the RS and the FBiH establish helpdesks responsible for the provision of information on the legislation on chemicals and biocidal products and appoint members of staff to this task.** It is also recommended that **the BD establishes a helpdesk once** the Law on Chemicals is adopted. It is important to have a functioning helpdesk in the BD in order to support companies with new responsibilities and obligations under the new Law on Chemicals. The provision of information via email and telephone needs to be complemented by the organisation of seminars, the publication of leaflets and other media, including websites, social media, print media campaigns, etc. The development of a communication plan should be included in the remit of the helpdesk staff and should be part of the job description (see Section 2.3.5).

Closer to the day of EU accession, the legislation in the entities and the Brčko District should be more closely aligned with the EU Regulations and across the country. The competent authorities could therefore consider the establishment of one single helpdesk, as the first point of contact for questions related to the REACH , CLP and BPR regulations for all BiH stakeholders.

Table 10 shows the conformity of the objective to the SMART criteria.

Table 10 – Objective 7: Establish helpdesks.

Criteria	Notes
Specific	It is recommended that the MoHSW of the RS and the MoH of the FBiH establish helpdesks responsible for the provision of information on the legislation on chemicals and biocidal products and appoint members of staff to this task. It is recommended that the DPHOS establishes a helpdesk when the Law on Chemicals is adopted.

Criteria	Notes
Measurable	Helpdesks are established, and staff is appointed to the duties of helpdesk services.
Achievable	This may require the allocation of adequate financial and human resources.
Relevant	Without proper support and advice to manufacturers, importers and other users on their responsibilities and obligations under the law on chemicals and biocidal products, the competent authorities may not be able to guarantee adequate enforcement of legislation.
Time-bound	Starting from the year 2022.

2.3.3.3 Estimated human and financial resources required

Assuming that the number of queries is similar to that received by the competent authorities in Montenegro, which has been selected as a benchmark country for BiH, around 1 FTE may be necessary to deal with helpdesk-related activities in the RS and the FBiH, while for the BD, due to the limited size of the chemical industry, a lower number of resources could be factored in. As the legislation on chemical and biocidal products is still not fully aligned and harmonised across both entities and the District, it is reasonable to expect that the competent authorities in one entity could receive queries not only from the local industry but also from companies based in the other entity or the District to better understand their obligations under the entity-level legislation when placing products on the market.

It is reasonable to expect an increase in queries during the pre-accession years and the first years after accession or, in any case, upon the entry into force of new pieces of legislation introducing new requirements more in line with EU obligations. Industry stakeholders will need assistance with regard to their new obligations. In addition, the public may have questions regarding the authorised uses and restricted uses of certain substances of concern. The employees providing information and helpdesk services 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 helpdesks, which meets twice every year. Finally, the dedicated members of staff would be responsible for the development and implementation of a communication plan.

Once the legislation is more closely aligned with the EU Regulations and across the country, the establishment of one single helpdesk should be considered, which would require less resources.

2.3.3.4 Timeline, risks and risk mitigation measures

The allocation of a necessary resource for helpdesk services should be done sooner than later in the RS and the FBiH. The establishment of a helpdesk and allocation of resources in the BD will be required from 2023 when new legislation on chemicals is in place. This would allow more efficient functioning of the helpdesk and the development of the communication plan. Therefore, it is important to increase resources at the competent authorities. The risk is that financial resources to hire additional people may not be there, and the current resources may not be able to allocate time for the establishment of helpdesks and related activities.

2.3.4 Lack of expertise in risk assessment and evaluation of applications for authorisation of biocidal products

2.3.4.1 Description of the problem and dependencies

Pursuant to the Law on Biocidal Products (OG RS, No. 37/09)[28], in the RS, the MoHSW is the competent authority for the implementation of biocidal products legislation. The Law on Biocidal Products regulates the following:

- Terms and conditions for the placing on the market and use of biocidal products;
- Conditions for a risk assessment and assessment of biocidal efficacy for issuing an authorisation to place a biocidal product on the market;
- The procedure for issuing authorisations;
- Research and development;
- Classification, labelling and packaging, advertising and technical safety standards;
- Conditions for the import of biocidal products;
- Safe use;
- Authorisation for manufacture and trade of biocidal products: data availability, supervision, and other significant issues for safely placing biocidal products on the market and their use.

A biocidal product may be placed on the market and used for its intended purposes if the MoHSW issues an authorisation for placing that biocidal product on the market. The procedure for issuing an authorisation for placing biocidal products on the market is conducted in two phases: first, an applicant submits basic data regarding a biocidal product; second, the applicant submits a technical dossier for an active substance and a biocidal product. At the moment, only the first phase is applied. Biocidal products are placed on a temporary list. The first phase is detailed by the Rulebook on the Content of the Basic Data on Biocidal Product (OG RS, 32/10, 86/13, 33/17, 12/21), while the documentation for the second phase is described by Rulebook on the content of documentation for an active substance and biocidal product assessment (OG RS, No. 3/10). In the RS, a committee composed of seven experts should evaluate the applications for authorisation of biocidal products submitted. The committee has been established but is not functioning due to the lack of funds and also because its tasks are not clearly defined. The MoHSW is now focusing on aligning the legislation with the BPR and, afterwards, they will focus on implementing the second phase.

As there is no Law on Biocidal Products in the FBiH and the BD, the authorisation process is not foreseen or taking place at the moment. Currently, the MoH of the FBiH issues decisions for the import of chemicals. However, when the Law on Biocidal Products is drafted and adopted and fully aligned with the BPR, the competent authorities will need to start evaluating applications for the authorisation of biocidal products and carrying out risk assessments according to the new law.

There are currently no plans for drafting the Law on Biocidal Products in the BD.

2.3.4.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the competent authorities address the lack of expertise in risk assessment and other technical and scientific areas** by opting for a hybrid system, which would entail:

[28] Law on Biocidal Products (OG RS, No. 37/09). Available at: https://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/farmacija/hemikalije/zakoni/Documents/Law%20on%20biocidal%20products%2037-09.pdf

- Developing in-house expertise in risk assessment by providing staff with training on risk assessment for physical and chemical properties, efficacy assessment, human health, and environmental risk assessment; and
- Contracting external experts provided by the academic and research institutions active in BiH to support the different tasks requiring risk assessment for physical and chemical properties, efficacy assessment, human health, and environmental risk assessment. This can be done through the Committee on Biocidal Products, and the development of the MoU would also provide the support and expertise when necessary.

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

- In-house related activities:
  - Hire additional staff;
  - Identification of currently available resources and gaps in expertise;
  - Planning and implementation of the provision of training (timelines);
- Activities related to external resources (see Section 2.2.4):
  - Identification of external resources;
  - Identification of methods of contracting and conditions (including defining mutual obligations and responsibilities);
  - Arrangement of contracts; and
  - Provision of training to external resources, when required.

According to the Law on Civil Service in the Institutions of Bosnia and Herzegovina, a civil servant shall have a right to be encouraged and supported in advancing career and professional development through training and other means. However, the EC (2020) notes that insufficient resources are provided to civil service agencies for the training and professional development of civil servants. Also, there was no progress in establishing a coherent and fair system for performance appraisal, promotion, and training as a right of a civil servant.

It is recommended that **the competent authorities survey the needs of their staff 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.

ECHA and other Member States' competent authorities could also provide training (focused on risk assessment for physical and chemical properties, efficacy assessment, human health, and environmental risk assessment) for developing competencies of the MoHSW and the MoH staff and external experts, who are likely to provide technical and scientific support.

Table 11 shows the conformity of the objective to the SMART criteria.

Table 11 – Objective 8: Provide training and capacity building

Criteria	Notes
Specific	It is recommended that the competent authorities address the lack of expertise in risk assessment and other technical and scientific areas by opting for a hybrid system. It is recommended that the competent authorities survey the needs of their staff and external experts and organise and implement training and capacity building courses.
Measurable	Actions laid out in Section 2.2.4 are implemented. A capacity-building plan is developed and established.
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.

Criteria	Notes
Relevant	Capacity building is key for filling any gaps in competencies and maintaining current skills up to date.
Time-bound	The period 2025-2026.

2.3.4.3 Estimated human and financial resources required

As already discussed in Section 2.2.2, the estimation of human and financial resources required for a 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 equipment, etc. Given the lack of a sustainable financing framework, the competent authorities may need to continue relying on ECHA's and other European partners' technical and financial support on capacity building. As detailed in Section 2.2.2, depending on the scale of the training courses, costs may vary but could be forecast at around €100,000 per year.

2.3.4.4 Timeline, risks and risk mitigation measures

It is recommended that capacity-building activities on risk assessment and other technical aspects are carried out towards the end of a five-year period when the MoU with scientific institutions is developed and ratified and legislation on biocidal products is fully aligned with the BPR. This will ensure that staff can apply new competencies in their day-to-day activities and will not experience skill decay. ECHA and other European partners will most likely continue supporting competent authorities in BiH over the coming years, and there is a risk for BiH to develop a dependency on external resources for capacity-building activities. Therefore, the establishment of a dedicated budget (Section 2.3.1) is of the utmost importance.

2.3.5 Lack of a communication strategy

2.3.5.1 Description of the problem and dependencies

According to EC (2020), an inclusive policy dialogue still needs to be established in BiH. In particular, there is the need for meaningful and systematic consultations with civil society. Moreover, the Council of Ministers needs to enact the 2017 charter on cooperation with civil society organisations, notably by developing regular cooperation and consultations. In addition, there are no standards for monitoring and reporting on the actions and plans of the government at both state and entity levels.

In the RS, the website of the MoHSW provides information on legislation as well as guidelines for its application. Leaflets and factsheets provided by ECHA are also available on the website. The MoHSW's representatives regularly participate in training activities and seminars organised for the industry. NGOs are invited to participate in the events organised by the MoHSW as well as in consultations on drafted laws. Some public awareness campaigns were organised in the RS, mainly during lead poisoning prevention week, and supported by the World Health Organisation.

During the public consultation for the new Law on Chemicals (2017-2018), the industry was informed about future obligations and the requirements of EU laws. Also, the MoHSW organised conferences in collaboration with the Chamber of Commerce and scientific institutions, which included presentations on future obligations and experiences of companies already registered in the EU and with substances placed on the EU market.

Currently, awareness-raising activities on environmental issues in general are being performed through the Project on Environmental Strategy Development, when stakeholders are invited to

participate in working groups and workshops. In cases of events and projects, they also contact the Chamber of Commerce. There are some NGOs working on environmental issues (e.g. nature protection, waste, etc.), however they do not possess much experience in the chemicals risk management and awareness raising field. . There were not so many public events organised in recent years. In 2009, while passing the old Law on Chemicals (Official Gazette of RS, No. 25/09), there were more events.

In 2017, the representatives of the Chamber of Commerce of the RS actively participated in the Working Group for the drafting of the Law on Chemicals and organised consultations with interested business entities. The Chamber of Commerce provides information to its members about the requirements of chemicals and biocidal products legislation on a regular basis. The Chamber organises project activities and educational events with topics related to the field of chemicals and biocides. However, the staff of the Chamber recognises that there is a significant lack of education in this area, especially in terms of comparison with the practice and regulations in the EU, and business entities need specialised training and similar events where they would get to know the regulations in more detail and more efficient ways.

In the FBiH, the Association of Employers, which is a member of the Economic and Social Council for the territory of the FBiH, informs its members daily about new regulations in BiH. Also, when giving opinions and remarks on new regulations, the Association is obliged to perform a comparative legal analysis with EU regulations. Therefore, the members of the Association are aware of EU regulations on chemicals and the obligations arising from them, or the conditions for placing chemicals on the EU market. No other information about policies and procedures to ensure transparency and stakeholder engagement are available for the FBiH.

There is no information on policies and procedures to ensure transparency and stakeholder engagement in the BD.

There is a need for all competent authorities in BiH to establish a communication strategy, including communication about working procedures and data security measures. This would ensure transparency, increase trustworthiness, and contribute to stakeholder engagement and participation in the regulatory implementation. The industry stakeholders' perception and understanding of the efficiency of the competent authorities is an important step towards ensuring regulatory compliance.

In addition, there is the need to keep BiH industry stakeholders informed about their upcoming responsibilities and duties, particularly regarding REACH registration and authorisation, CLP classification and labelling, and BPR authorisation. An effective communication strategy is essential to ensure that BiH companies are ready for the single market well before the day of BiH's accession to the EU.

Activities to improve stakeholder engagement are planned in the framework of the cooperation projects with Sweden, ECHA and other international organisations providing financial and technical support.

2.3.5.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the competent authorities in both entities and the Brčko District develop and implement communication plans**. This could address the following:

- The organisation of workshops and events, including identification and selection of topics of interest for the BiH 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 and by using other channels (e.g., newspapers, advertising, etc.) where appropriate:
  - The official competent authorities' webpages, including webpages of the helpdesks (yet to be established), could be organised by topics to facilitate access to documents and deadlines;
  - Additional information, for example, the translation of news presented on the ECHA website into Bosnian, Serbian and Croatian that could be of relevance for BiH companies, could also be provided on the websites.

The development of a communication plan can be broken down into 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 12 shows the conformity of the objective to the SMART criteria.

Table 12 – Objective 9: Develop and implement a communication strategy

Criteria	Notes
Specific	It is recommended that the competent authorities in both entities and the Brčko District develop communication plans.
Measurable	A communication strategy is developed and implemented in both entities and the Brčko District.
Achievable	The careful design of the strategy allows for avoiding misuse of funding. The competent authorities may not have the in-house expertise and therefore may consider outsourcing the process.
Relevant	Better informed stakeholders may result in a lower workload (fewer 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	Competent authorities in the RS and the FBiH should start drafting a communication plan for the next five years (2022-2026). The BD should start drafting the communication plan in 2023 for the five-year period. This would allow earmarking the necessary resources. The plan should identify the target audience, needs and optimal communication channels.

2.3.5.3 Estimated human and financial resources required

It is recommended that the development of a communication plan is included in the remit of the helpdesk staff and should be part of their job description. However, helpdesk-related activities are currently not taking place in the RS, the FBiH, and the BD. The actions for the establishment of a helpdesk are laid down in Section 2.3.3.

Given the lack of a sustainable financing framework, the competent authorities in BiH may need to continue relying on ECHA's and other international co-operation partners' technical and financial support on communication activities. Depending on the scale of these activities, costs may vary but could be estimated at around €10,000 per year. For information, in 2014, the Swedish Chemicals Agency, in the framework of its support to the Serbian competent authorities with the development of their capacity, spent around €10,000 to develop a plan to prepare Serbian industry for EU chemical legislation and organise events for the divulgation of information, with the assistance of the chamber

of commerce in Belgrade. The development of the communication plan was outsourced to the Faculty for Media and Communication of the University of Belgrade. The strategy included:

- The identification and engagement with key media stakeholders;
- The preparation and distribution of press materials to increase the visibility of the competent authorities;
- Training for the competent authorities staff on communication tools and procedures related to media activities, crisis PR and damage control, and message development.[29]

2.3.5.4 Timeline, risks and risk mitigation measures

The competent authorities should start planning for the resources necessary to develop the plan: survey the needs, find the optimal communication channels, and implement the strategy by organising the communication activities. The support of ECHA and other European partners for capacity building is unlikely to waver over the coming years. However, there is the risk for BiH to develop a dependency on external resources on communication activities. The establishment of a dedicated budget for communication strategy and activities is therefore important. This would free up financial resources to organise capacity building activities. It is also recommended that the helpdesks in both entities and the Brčko District prepare annual communication work plans.

2.3.6 Low participation in public consultations

2.3.6.1 Description of the problem and dependencies

According to UNECE (2018), Bosnia and Herzegovina is a party to the ECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention). The First National Aarhus Convention Implementation Report on Bosnia and Herzegovina was prepared in 2011. Efforts have been made by relevant environmental authorities at the state, entity, and canton levels to increase public awareness with regard to citizens' rights to environmental protection and environmental issues. The Law on Environmental Protection of the RS, the FBiH, and the BD provide individuals and organisations with the opportunity to participate in decision-making processes and include obligations for competent authorities to encourage public awareness and participation as well as facilitate access to relevant environmental information.

EC (2020) report notes that there has been no progress in improving the public's access to environmental information and its participation in decision-making processes. While the overall legal and regulatory framework for civil society in BiH is broadly in line with the EU *acquis*, meaningful and systematic consultations remain to be ensured as part of inclusive policy dialogue, and more efforts are needed to raise awareness on various forms of consultation with the public. Also, the legislation on public consultations is uneven across the country, and there is no strategic framework for cooperation with civil society. Therefore, it is key to strengthen technical capacities at all levels of the government on how to regularly use public consultations as a tool of policymaking (EC, 2020).

In the RS, according to the Guidelines for the Actions of the Republic Administrative Bodies on Public Participation and Consultations in the Drafting of Laws and Bylaws, these have to be published on the MoHSW's website for public consultation. In addition, companies from the Registry of manufacturers and importers of chemicals are regularly informed of the Ministry's activities by mailing list. Furthermore, public or expert consultations are carried out when passing new laws. However, low participation is the norm for public consultations on bylaws. According to the

[29] KemI (2016): Chemical risk management in Serbia. Final report for 2008 to 2015; and KemI (2018): Chemical risk management in Serbia. Annual report 2017.

competent authorities, the overall feedback from the stakeholders is not at a satisfactory level and strengthening their engagement is desirable.

In the FBiH, through the Economic and Social Council, the Association of Employers of the FBiH has the opportunity to participate in the drafting of new laws and amendments that are of interest to the business community, including the Law on Chemicals. The Association has lobbied for the adoption of the Law on Chemicals in the FBiH for years.

There is no information on policies and procedures to ensure stakeholder engagement in the BD.

Overall, initiatives are needed to raise awareness on public consultation activities among the public in both entities and the Brčko District and among all levels of the government.

2.3.6.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the competent authorities implement the necessary measures to increase stakeholder participation in public consultations and decision-making processes** on chemical risk management. To achieve this, the Government and competent authorities need to raise awareness among all stakeholder groups about chemicals and the importance of the adequate implementation and enforcement of the chemical legislation to guarantee the safe use of chemical and biocidal products. The establishment of the helpdesks (see Section 2.3.3) and the development of communication strategies (see Section 2.3.5) are important in helping to achieve this goal. The provision of information via email and telephone would need to be complemented by the organisation of seminars, workshops, and events, and using various communication channels (e.g., Internet, published leaflets, advertisement, etc.), which would reach a wider public and most likely increase participation of the public and civil society in chemicals risk management related activities. Table 13 shows the conformity of the objective to the SMART criteria.

Table 13 – Objective 10: Increase stakeholder participation in public consultations and decision-making

Criteria	Notes
Specific	It is recommended that the competent authorities implement the necessary measures to increase stakeholder participation in public consultations and decision-making processes.
Measurable	Increase in stakeholder participation levels in public consultations on chemical risk management.
Achievable	The overall legal and regulatory framework for civil society in BiH is already broadly in line with the EU *acquis*.
Relevant	EC (2020) report notes that there has been no progress in improving the public's access to environmental information and its participation in decision-making processes. Effective public consultations may lead to higher stakeholder engagement and more efficient implementation of legislation on chemicals and biocidal products.
Time-bound	Starting in the year 2022.

2.3.6.3 Estimated human and financial resources required

The necessary human and financial resources for the establishment of helpdesks and communication strategies that are important for raising the awareness of chemical risk management among all stakeholder groups can be found in Sections 2.3.3 and 2.3.5, respectively.

2.3.6.4 Timeline, risks and risk mitigation measures

The proposed timelines for the establishment of helpdesks and communication strategies can be found in Sections 2.3.3 and 2.3.5, respectively.

2.3.7 Gaps in IT infrastructure, policies and procedures

2.3.7.1 Description of the problem and dependencies

So far, the competent authorities have not been able to provide any specific information on the IT infrastructure and security procedures used when dealing with chemical risk management information. In the RS, all submissions are sent to the Ministry by mail (hard copies). Since all submissions to the MoHSW are sent in hard copies, printed versions of documents are kept in MoHSW's archive. Some data provided electronically (by e-mails) are stored on the personal computer (password protected) of the person in charge. The current system of submitting documentation in hard copies creates an additional administrative burden for the competent authorities, businesses, and other relevant stakeholders. There is no information about the process of submitting the information to competent authorities in the FBiH and the BD.

The current system for submitting documentation to the competent authorities does not conform with the Strategic Framework for Public Administration Reform (PAR) in Bosnia and Herzegovina 2018-2022[30], which lays down the main strategic objectives for public administration in BiH. The report noted that the PAR Strategy 2006-2014 was mostly focused on e-solutions for public services. The normative framework for the provision of electronic services was established by adopting the following regulations at all administrative levels: the Law on Electronic Signature, the Law on Electronic Documents, and the Law on Electronic Legal Traffic. Additionally, the RS created an e-Government portal with the most important information about services offered to citizens. As part of regulatory reform strategies in the RS and the FBiH, activities were conducted to improve the business environment and facilitate business operations by eliminating unnecessary administrative procedures. There have been several successful examples of digitalising services in the RS and the FBiH, such as the registration of businesses, the cadastre, and planned land registry reform.

Public Administration Reform Action Plan 2018 – 2022[31] states that the specific goal in the area of 'Service Delivery' is to transform the public administration into a user-oriented administration by professionally following and understanding users' needs and expectations, based on which it will improve the business processes and administrative procedures, reduce the administrative burden, provide access to services through various communication channels while ensuring high-quality service at a lower (reduced) cost.

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 competent authorities need to sign a declaration with respect to security aspects, based on the Agency's Security Model for IT systems[32]. This declaration (Unified Declaration of Commitment) and associated Standard Security Requirements (SSR) grant access to:

- The ECHA REACH-IT system;
- The IUCLID Member State database (REACH/CLP);

[30] https://parco.gov.ba/en/dokumenti/rju-dokumenti/

[31] https://parco.gov.ba/en/dokumenti/rju-dokumenti/

[32] 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.

- The Portal Dashboard which facilitates the point of access to ECHA's IT systems;
- The Register for Biocidal Products (R4BP);
- The 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 the secure electronic tool for exchanging 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.

While the RS has legislation detailing the security procedures to be followed by civil servants in managing confidential information, no specific provisions are available regarding IT procedures. According to the RS authorities, the IT infrastructure and security procedures are lacking and require strengthening, including through the establishment of formal IT security procedures, introductory and regular security training for the CB staff and the procurement of an initial external audit and regular internal audits thereafter.

No information is available on the IT infrastructure and security procedures in the FBiH and the BD, but it is assumed that in these entities, the IT framework will need revision and improvement.

2.3.7.2 Recommended actions, action owner and other relevant stakeholders

As a first step, it is recommended that **the competent authorities contract external audits of IT infrastructure, safety policies, procedures, and measures**. Furthermore, it is recommended that **the competent authorities provide training for the staff on IT security procedures and how to deal with confidential documents**. In addition, it is recommended that **the competent authorities nominate a Security Officer** within their staff members or the IT staff, 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.[33] The security officer must ensure 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.

[33] Depending on the workload of the 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.

Furthermore, 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 BiH competent authorities 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**.

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

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

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

Table 14 – Objective 11: Align IT infrastructure, policies and procedures with ECHA's standards

Criteria	Notes
Specific	It is recommended that the competent authorities contract external audits of IT infrastructure, safety policies, procedures, and measures. It is recommended that the competent authorities provide training for the staff on IT security procedures and how to deal with confidential documents. It is recommended that the competent authorities nominate a Security Officer. It is recommended to implement a new formal non-public information management policy to bring the current practices in line with ECHA's SSR. 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. It is recommended that the BiH competent authorities 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.
Measurable	IT infrastructure and security procedures are aligned with ECHA's SSR.
Achievable	Allocation of financial resources may be required.
Relevant	Without IT security policies and procedures in place, the competent authorities could not gain access to ECHA's information systems.
Time-bound	Policy and procedures need to be in place by the day of accession. The establishment of policies and procedures on the security of the information collected and managed by the competent authorities is likely to have a positive impact on the confidence of businesses towards the capacity of the BiH competent authorities.

2.3.7.3 Estimated human and financial resources required

It is recommended that the existing IT staff at the competent authorities' offices are trained on IT security policies and procedures. The organisation and implementation of training courses for IT staff and the competent authorities' staff members on IT security policies and procedures is estimated to cost around €100,000 for ECHA or MSCA. The staff from relevant competent authorities of all entities should be trained at the same time.

The cost of a new workstation, running safe and always up-to-date operating systems and antivirus software is around €500. If staff needs to be enabled to work remotely, they will need safe and

updated devices provided by the competent authorities. The total cost of updating the IT infrastructure may be around €4,600 at the MoHSW (accounting for four employees at the CB): approximately €2,300 for the workstations at the CB and €2,300 for personal devices to enable remote working unless policies allow work laptops to be used from home are implemented). A similar amount will be necessary for the MoH as there are also three employees at the PCB, and there is a plan for one additional specialist. The estimate could not be provided for the BD as there is no information on how many employees are working on chemicals legislation.

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 BiH for a total cost of €25,000.[34]

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 competent authorities earmarks around €1,000-€5,000 for the first audit.[35] The competent authorities should allocate a rolling budget for the required periodic audits.

2.3.7.4 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 competent authorities are likely to boost the confidence of businesses in the capacity and trustworthiness of the competent authorities in BiH.

There is a lack of relevant expertise among the competent authorities' staff. It is recommended that the competent authorities commission first external audits 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.

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

[35] 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 alignment of legislation on chemicals and biocidal products in the *Republika Srpska*, the Federation of Bosnia and Herzegovina and the Brčko District is of key importance to avoid administrative burden for businesses and competent authorities.

An important challenge facing the competent authorities in the RS and the FBiH is the **lack of resources** necessary to draft, align, and implement the legislation on chemicals and biocidal products. In the BD, additional resources will be required when the new Law on Chemicals is adopted in 2023. Therefore, it is recommended that **administrative capacities in both entities and the Brčko District are strengthened** in the coming years. To ensure that adequate financial resources are available to fund new job positions within the competent authorities, a dedicated budget for chemical risk management activities should be established (Section 2.3.1). In addition, all entities have an opportunity to **align legislation on administrative fees with the EU Regulations and principles** while further developing and aligning their legislation on chemicals. The revenue from fees and charges paid by industry applicants for the work carried out by the competent authorities should be **ring-fenced for chemical risk management activities** when those are collected.

Further, it is recommended that the competent authorities adopt the **Memoranda of Understanding** (MoU) with scientific institutes and external experts to facilitate the outsourcing of some workstreams and avoid overloading their teams when the full authorisation of biocidal products commence (Section 2.2.4). The drafting of the Law on Biocidal Products is currently not foreseen in the Brčko District; however, when legislation on biocidal products is adopted, and evaluation of applications for authorisation of biocidal products commences, the competent authorities would also benefit from an MoU.

The above measures would allow hiring new staff and strengthening the capacity, which would help in **drafting, tightening and further developing legislation on biocidal products,** and address some other challenges associated with an insufficient administrative capacity, such as the **lack of helpdesk services** (Section 2.3.3) and **communication strategies** (Section 2.3.5) in both entities and the Brčko District. The development and implementation of **a communication plan** should be a responsibility of a member of staff dedicated to the helpdesk services. In BD, the priority is drafting legislation, but when the new law is adopted, it is also recommended that the DPHOS establish a helpdesk.

It is also recommended that **the IT infrastructure and the IT safety policies and procedures are upgraded and aligned with ECHA's standards** (Section 2.3.7). The competent authorities should commission **initial external audits** to identify the required measures to bring the IT system up to the standards required by ECHA.

Overall, it is very important that the competent authorities **raise awareness of chemical risk management among the public, civil societies, and the industry** and implement the necessary measures to **increase stakeholder participation in public consultations and decision-making processes** on chemical risk management (Section 2.3.6).

ECHA may support the development of some of the necessary policies and procedures and provide training. ECHA and Member State competent authorities may also offer capacity building in risk assessment and enforcement.

The list of recommended actions and necessary resources for each action have been presented in Table 15. A Gantt Chart outlining a suggested resource allocation for the next five years has been developed and is presented in Table 16. In addition, the risks associated with each action and possible mitigation measures have been outlined and are summarised in Table 17.

Table 15 – Action Plan

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
1. Fully harmonise legislative frameworks across both entities and the Brčko District in the area of chemicals	!!!	2022-	MoHSW MoH DPHOS	-	-	-
2. Tighten and further develop the legislation on chemicals and biocidal products	!!!	2022-2026	MoHSW	MSCA	1 FTE	-
		2022-2026	MoH		1 FTE	-
		2022-2026	DPHOS		1 FTE	-
3. Strengthen the administrative staff capacity	!!!	2022	MoHSW	-	+1 FTEs	~€70,000 over a 5-year period
			MoH		+1 FTE	~€70,000 over a 5-year period
		2023	DPHOS		+1 FTE	~€56,000 over a 5-year period
4. Survey the needs of competent authorities' staff and external experts and organise capacity building on efficacy and risk assessment	!!	2025-2026	MoHSW MoH DPHOS	ECHA, MSCA	0.5 – 1 FTE (ECHA and/or MSCA)	~€100,000 per year over two years (ECHA and/or MSCA)
5. Align legislation on administrative fees with the principles of the EU Regulations	!!	2024-2025	MoHSW MoH	MSCA	0.25 (over a 2-year period)	~€40,000 per year (ECHA and/or MSCA)
6. Establish a budget dedicated to chemical risk management activities	!!!	2022-	MoF (RS) FMoF (FBiH)	-	-	-
		2023-	Finance Directorate of the BD			
7. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	!!!	2024-2026	MoHSW	ECHA, MSCA and/or Montenegro	1.5 FTE (over a 3-year period) – 0.5 FTE per year	-
			MoH		1.5 FTE (over a 3-year period) – 0.5 FTE per year	
8. Establish a helpdesk	!!!	2022-	MoHSW	MSCA	0.5-1 FTE	-
			MoH		0.5-1 FTE	
		2023-	DPHOS	MSCA, MoHSW, MoH	0.3 FTE	

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
9. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the BiH's 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.	!!	2022-	MoHSW	ECHA, MSCA, NGOs	0.5 FTE	€10,000 per year (ECHA and/or MSCA for the first three years)
			MoH		0.5 FTE	
		2023-	DPHOS	ECHA, MSCA, NGOs, MoHSW, MoH	0.2 FTE	
10. Increase stakeholder participation in public consultations and decision-making processes	!!!	2022-	MoHSW MoH DPHOS	-	-	-
11. Organise training courses on IUCLID	!	2022	ECHA	MSCA	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
12. Upgrade IT infrastructure	!	2022	MoHSW	-	-	~€5,000 (one-off) ~€100 per workstation (running costs: licenses, software upgrades, etc.)
			MoH			~€5,000 (one-off) ~€100 per workstation (running costs: licenses, software upgrades, etc.)
		2023	DPHOS			~€1,000 per person + ~€100 per workstation (running costs: licenses, software upgrades, etc.)
13. Provide training to the existing IT staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		2022	MoHSW MoH DPHOS		0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
14. Develop an information security policy		2023	MoHSW	ECHA		€25k (ECHA and/or MSCA)

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
15. Develop formal non-public information management policy in line with ECHA's SSR					0.1 (MoHSW) + 0.1 (MoH) + 0.1 (DPHOS) + 0.1 (ECHA and/or MSCA)	
16. Establish a security awareness programme, including introduction and regular security training for all employees.			MoH			
17. Establish a teleworking security policy			DPHOS			
18. Contract an external audit of the safety policies, procedures and measures		2022	MoHSW	-	-	€5,000 in 2022
			MoH			€5,000 in 2022
		2023	DPHOS			€5,000 in 2023
19. 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		2022-	MoHSW	-	-	€5,000 every 3 years for external audits
			MoH			€5,000 every 3 years for external audits
		2023-	DPHOS			€5,000 every 3 years for external audits
20. Hand-on training on ECHA e-tools	!	2025	ECHA	MSCA	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
Notes: DPHOS: Department of Public Health and Other Services of the BD; FMoF – Federal Ministry of Finance of the FBiH; MoF – Ministry of Finance of the RS; MoHSW – Ministry of Health and Social Welfare of the RS; MoH – Ministry of Health of the FBiH; MSCA – Member State Competent Authority;						

Table 16 – Gantt Chart and resource allocation

Action	2022	2023	2024	2025	2026
1. Fully harmonise legislative frameworks across both entities and the Brčko District in the area of chemicals	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
2. Tighten and further develop the legislation on chemicals and biocidal products	1 FTE	1 FTE	1 FTE	1 FTE	1 FTE
	1 FTE	1 FTE	1 FTE	1 FTE	1 FTE
	1 FTE	1 FTE	1 FTE	1 FTE	1 FTE
3. Strengthen the administrative staff capacity	+1 FTE €14k	€14k	€14k	€14k	€14k
	+1 FTE €14k	€14k	€14k	€14k	€14k

Action	2022	2023	2024	2025	2026
		+1 €14k	€14k	€14k	€14k
4. Survey the needs of competent authorities' staff and external experts and organise capacity building on efficacy and risk assessment				0.5 FTE €100k	0.5 FTE €100k
5. Align legislation on administrative fees with the principles of the EU Regulations			0.25 FTE	0.25 FTE	
			0.25 FTE	0.25 FTE	
			€40k	€40k	
6. Establish a budget dedicated to chemical risk management activities	-	-	-	-	-
	-	-	-	-	-
		-	-	-	-
7. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities			0.5 FTE	0.5 FTE	0.5 FTE
			0.5 FTE	0.5 FTE	0.5 FTE
8. Establish a helpdesk	0.5 FTE	0.5 FTE	0.5 FTE	0.5 FTE	0.5 FTE
	0.5 FTE	0.5 FTE	0.5 FTE	0.5 FTE	0.5 FTE
		0.3 FTE	0.3 FTE	0.3 FTE	0.3 FTE
9. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the BiH's 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.	0.5 FTE	0.5 FTE	0.5 FTE	0.5 FTE €10k	0.5 FTE €10k
	0.5 FTE	0.5 FTE	0.5 FTE	0.5 FTE €10k	0.5 FTE €10k
		0.2 FTE	0.2 FTE	0.2 FTE €10k	0.2 FTE €10k
	€10k (ECHA or MSCA)	€10k (ECHA or MSCA)	€10k (ECHA or MSCA)		
10. Increase stakeholder participation in public consultations and decision-making processes	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
11. Organise training courses on IUCLID	0.1 FTE €50k				
12. Upgrade IT infrastructure	~€5k				
	~€5k				
		?			
13. Provide training to the existing IT staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer	0.1 FTE €50k				
14. Develop an information security policy		0.1 (MoHSW) +			
15. Develop formal non-public information management policy in line with ECHA's SSR					

Action	2022	2023	2024	2025	2026
16. Establish a security awareness programme, including introduction and regular security training for all employees.		0.1 (MoH) + 0.1 (DPHOS) + 0.1 (ECHA and/or MSCA) €25k (ECHA and/or MSCA)			
17. Establish a teleworking security policy					
18. Contract an external audit of the safety policies, procedures and measures	€5k				
	€5k				
		€5k			
19. 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	-
		-	-	€5k	-
			-	-	€5k
20. Hand-on training on ECHA e-tools					0.1 FTE €50k
Totals					
ECHA or MSCA	0.2 FTE €140k-150k	~0.5 FTE ~€170k-180k	0.5 FTE €100k-110k	0.1 FTE €50k	-
MoHSW of the RS	~3 FTEs (+1 FTE)[36] ~€25k	~3 FTEs (+1 FTE) ~€15k	2.5 FTE (+1 FTE) ~€15k	1 FTE (+1 FTE) ~€30k	1 FTE (+2 FTE) ~€25k
MoH of the FBiH	~2 FTE (+1 FTE) ~€25k	~2 FTE ~€15k	2.5 FTE ~€15k	2.5 FTE ~€30k	2.5 FTE ~€25k
DPHOS of the BD	1 FTE	~1.5 FTEs (+1 FTE) ~€20k	1.5 FTEs ~€15k	1.5 FTEs ~€25k	1.5 FTEs €30k

Table 17 – Risks and Risk mitigation measures

Action	Risk	Risk Mitigation Measures
1. Fully harmonise legislative frameworks across both entities and the Brčko District in the area of chemicals	Lack of resources Delays	Coordination and cooperation between all parties and sharing the experience and good practice.

[36] ~3 FTEs are required for recommended actions plus 1 additional FTE to increase the capacity of the MoHSW.

Action	Risk	Risk Mitigation Measures
		Actions: 2. Tighten and further develop the legislation on chemicals and biocidal products 3. Strengthen the administrative staff capacity 6. Establish a budget dedicated to chemical risk management activities
2. Tighten and further develop the legislation on chemicals and biocidal products	Delays	Increase resources of the competent authorities
3. Strengthen the administrative staff capacity	The government of the relevant entity may not agree and fund the necessary resource increase	Actions: 6. Establish a budget dedicated to chemical risk management activities
4. Survey the needs of competent authorities' staff and external experts and organise capacity building on efficacy and risk assessment	Lack of resources COVID-19 pandemic The alignment of the entity level legislation is further delayed, and therefore the trained experts cannot apply the new competencies The MoU is not ratified on time	Actions: 2. Tighten and further develop the legislation on chemicals and biocidal products 3. Strengthen the administrative staff capacity 6. Establish a budget dedicated to chemical risk management activities
5. Align legislation on administrative fees with the principles of the EU Regulations	Delays	The Commission and ECHA stress the importance of aligning the legislation with the EU Regulations
6. Establish a budget dedicated to chemical risk management activities	Lack of resources	Action: 5. Align legislation on administrative fees with the principles of the EU Regulations
7. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	Lack of resources	Action: 5. Align legislation on administrative fees with the principles of the EU Regulations 6. Establish a budget dedicated to chemical risk management activities
8. Establish a helpdesk	Lack of resources	Develop and formalise procedures for helpdesk services and communication strategy Nominate person responsible for these tasks
9. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the BiH's 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;	Lack of resources Lack of expertise	Communication activities are part of the job description for the person responsible for the helpdesk ECHA or MSCA support Actions: 3. Strengthen the administrative staff capacity 5. Align legislation on administrative fees with the principles of the EU Regulations 6. Establish a budget dedicated to chemical risk management activities

Action	Risk	Risk Mitigation Measures
- Survey of the needs and topics of interest; - Identification of the communication channels; and - Implementation of the communication plan.		
10. Increase stakeholder participation in public consultations and decision-making processes	Lack of resources	Actions: 3. Strengthen the administrative staff capacity 5. Align legislation on administrative fees with the principles of the EU Regulations 6. Establish a budget dedicated to chemical risk management activities
11. Organise training courses on IUCLID	Lack of resources COVID-19 pandemic	Support of ECHA or MSCA Remote learning
12. 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 competent authorities should ensure the resources for upgrading and keeping up to date the IT infrastructure The Commission and ECHA stress the importance of ensuring the strictest respect to the SSR
13. Provide training to the existing IT staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer		
14. Develop an information security policy		
15. Develop formal non-public information management policy in line with ECHA's SSR		
16. Establish a security awareness programme, including introduction and regular security training for all employees		
17. Establish a teleworking security policy		
18. Contract an external audit of the safety policies, procedures and measures		
19. 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		
20. Hand-on training on ECHA e-tools	High staff turnover	All members of staff need to be trained to avoid loss of expertise in case of staff leaving

3.2 Similarities in gaps and shortcomings between candidate and potential candidate countries and potential for joint actions

The chemical industries of Albania, Bosnia and Herzegovina, Kosovo and North Macedonia are comparable in size, and the competent authorities require similar administrative capacities to further align their national legislation with the EU *acquis*. Resources have been focused on the development of the legislative frameworks while maintaining their functional implementation. Turkey has a larger chemical industry and has developed an ambitious legislative framework mirroring the requirements of the EU *acquis* to a great extent. Higher degrees of approximation to the EU Regulations require additional resources for implementation and enforcement.

In their preparation towards accession to the EU, the competent authorities of these countries face similar challenges:

- All countries still have to fully align their national or entity level legislation with the BPR;
- All countries are establishing or foresee the establishment of registers of chemicals;
- All countries need strengthening of their respective administrative capacities for dealing with biocidal products, with similar underlying issues:
  - The need to develop sustainable financing systems aligned with the EU Regulations and principles and the need for ring-fencing the fees collected for chemical risk management activities by the authorities;
  - The need to ratify Memorandum of Understanding with scientific institutes to facilitate access to external experts to speed up regulatory processes and avoid bottlenecks;
- All countries need to improve their transparency and stakeholder engagement procedures, including:
  - Increasing collaboration with civil society organisations, chambers of commerce, industry associations and other stakeholders for raising public awareness on chemical risks;
  - Publication of information on enforcement activities;
  - Publication of information on participation in public consultations and follow-ups;
- Albania, Bosnia and Herzegovina, Kosovo and North Macedonia need to strengthen their administrative capacities for the enforcement of the legislation;
- Albania, Bosnia and Herzegovina, Kosovo and North Macedonia have to establish suitable IT infrastructures and adequate information security procedures, whereas Turkey has already developed a sophisticated IT infrastructure coupled with certified security procedures, which need to be expanded to cover the management of information on biocidal products.

These similarities in gaps and challenges provide the opportunity to achieve significant cost savings by designing actions that could be implemented simultaneously (for example, in remote) or country by country but sharing the same material and resources. Importantly, the results of twinning projects, technical support provision and capacity building activities by EU Member States and the European Chemicals Agency testify to the efficacy of these instruments. It is therefore recommended that:

- All five countries apply for the funding and technical assistance available through TAIEX and IPA instruments for chemical risk management related activities. It is important to stress that the chemical *acquis*, while not being more or less important of other environmental legislative areas, does require a significant amount of resources for its implementation and

enforcement. All beneficiaries should ensure the allocation of adequate resources over time so that capacity-building efforts are not dissipated by understaffing and staff turnover;

- ECHA and/or other Member State competent authorities provide training and capacity building in the following areas:
  - Evaluation of applications for authorisation of biocidal products, in particular on efficacy and human health and environmental risk assessment;
  - Use and functioning of ECHA e-tools for information storage, management and sharing;
  - Information security procedures;
  - Enforcement best practices;
  - Dissemination of information, development of a communication strategy and helpdesk best practices.

Participation in seminars and workshops organised by ECHA, the Commission or MSCAs for all candidate and potential candidate countries provide the opportunity to the competent authorities of these countries to share experiences and ideas in an informal setting. In addition, they could also be invited to share their experiences and best practices on the different topics covered by the common activities (e.g., communication, IT, enforcement, collaboration with external partners, etc.).

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List of abbreviations

Acronym	Full name
ASOs	Accredited Stakeholder Organisations
BAM	Bosnia-Herzegovina Convertible Mark
BD	Brčko District
BiH	Bosnia and Herzegovina
BPC	Biocidal Product Committee
BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
CARACAL	Competent authorities for REACH and CLP
CBI	Confidential Business Information
CB	Chemicals Branch within the Ministry of Health and Social Welfare of the *Republika Srpska*
CEFTA	Central European Free Trade Agreement
CLH	Harmonised classification and labelling
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, mutagenic, or toxic for reproduction
CoRAP	Community Rolling Action Plan
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNA	Designated National Authority
DPHOS	Department of Public Health and Other Services
EC	European Commission
ECHA	European Chemicals Agency
ECRAN	Environment and Climate Regional Accession Network
EQALM	European Association for Clinical Chemistry and Laboratory Medicine
ESAP	Environmental Strategy and Action Plan
ESC	Economic and Social Council
EU	European Union
FBiH	Federation of Bosnia and Herzegovina
FTE	Full-Time Equivalent
GDP	Gross Domestic Product
GEF	Global Environment Facility

Acronym	Full name
GLP	Good Laboratory Practice
IPA	Instrument for Pre-Accession Assistance
IT	Information Technology
IUCLID	International Uniform ChemicaL Information Database
KemI	Swedish Chemicals Agency
MoH	Ministry of Health of the Federation of Bosnia and Herzegovina
MoHSW	Ministry of Health and Social Welfare of the *Republika Srpska*
MoU	Memorandum of Understanding
MS	Member State
MSCA	Member State Competent Authority
NGO	Non-Governmental Organisation
NIP	National Implementation Plan
NPAA	National programme for the adoption of the EU *acquis*
OG	Official Gazette
PAR	Public Administration Report
PBT/ VPVB	Persistent, Bioaccumulative and Toxic Chemicals/ Very Persistent, very Bioaccumulative
PCB	Pharmaceuticals and Chemicals Branch within the Ministry of Health of the Federation of Bosnia and Herzegovina
PCN	Poison Centre Notification
PIC	Prior Informed Consent Regulation
POP	Persistent Organic Pollutant
PT	Product Types
R4BP	Register for Biocidal Products
RAC	Committee for Risk Assessment of ECHA
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RS	*Republika Srpska*
SAA	Stabilisation and Association Agreement
SAICM	Strategic Approach to International Chemicals Management
SCBP	Standing Committee on Biocidal Products
SEAC	Socio-Economic Analysis Committee
SDS	Safety Data Sheet
SEI	Stockholm Environment Institute

Acronym	Full name
SIDA	Swedish International Development Agency
SPC	Summary of the product characteristics
SSR	Standard Safety Requirement
SVHC	Substances of Very High Concern
TAIEX	Technical Assistance and Information Exchange instrument of the European Commission
UNDP	United Nations Development Programme
WHO	World Health Organisation

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