

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 – Kosovo

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Executive Summary – Action Plan

Over the last decade, Kosovo has been developing its chemicals management system and has achieved some level of alignment with the EU regulatory framework. This report presents the recommendations stemming from the results of the comparative legal analysis of the national legislation with the EU acquis and the results of the assessment of the institutional capacity and infrastructure available in Kosovo for the implementation and enforcement of the five Regulations: REACH, CLP, BPR, PIC, and POPs.

The assessment has identified lack of necessary resources for implementation and enforcement of national legislation on chemicals and biocidal products as the main challenge. The national competent authority for aligning the national legislation with the EU chemical acquis is the Ministry of Environment, Spatial Planning and Infrastructure (MESPI), more precisely the Division for Waste and Chemicals (DWC) of the Department of Environmental and Water Protection. As of June 2021, the DWC employs two people in charge of the chemicals and biocidal products legislation. Kosovo is still working on the development of the legislative framework, with amendments to the laws on chemicals and biocidal products expected to be approved in 2022. The workload associated with the alignment of national legislation is assumed to stay constant over the following years and is estimated to require approximately two FTEs per year. Two additional FTEs would allow adequate implementation of the legislation and important activities such as communication with other departments, dissemination of information to the public, coordination with enforcement authorities, provision of helpdesk services and attendance to training activities.

In order to strengthen the administrative capacity and enable the implementation of recommended actions, some underlying challenges need to be tackled first. In particular, the lack of a budget for chemical risk management needs to be addressed to ensure that adequate financial resources are available to fund new job positions within the competent authorities. In parallel, it is important that competent authorities draft and ratify a Memorandum of Understanding (MoU) with scientific institutes and external experts, which would facilitate the outsourcing of certain workstreams.

There is no official helpdesk to provide stakeholders with information on their responsibilities and obligations regarding the chemical and biocidal products legislation. Furthermore, there is a low level of public awareness of chemicals and chemical safety. Therefore, the DWC should develop a communication strategy, and it is recommended that stakeholder engagement and other aspects of external communication form part of the job description of one of the employees of the Division, together with the assignment to helpdesk and information services.

It is also recommended to significantly upgrade the IT infrastructure and the IT safety policies and procedures. The competent authorities should commission an initial external IT security audit to identify needed actions to bring the existing IT system up to the standard required by the European Chemicals Agency.

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

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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 Kosovo 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).

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 document¹ produced by the European Commission in assessing the progress of Kosovo with the reforms in the framework of the accession negotiations;
- Phone interviews with Kosovo's competent authorities held on 24 March 2021 and 29 March 2021 and follow-up emails;
- Phone interviews with local NGOs and members of academia.

Actions have been suggested in the following areas:

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

In addition, the report discusses potential similarities in gaps and shortcomings between 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

¹ EC (2020): Commission Staff Working Document Kosovo 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) 356 final.

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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) are described to successfully implement the recommended actions.

2 The Action Plan

2.1 Challenges and gaps identified

The assessment of the degree of legal harmonisation, institutional capacity and necessary infrastructure has identified several intertwined challenges and gaps.

Kosovo is still developing the legislative framework, with amendments to the laws on chemicals and biocidal products expected to be approved in 2022. Kosovo chemical legislative framework is partially aligned with the PIC Regulation but not with the POPs Regulation, with requirements on the management of POPs only introduced through waste legislation. The work of the Ministry of Environment, Spatial Planning and Infrastructure (MESPI) to align the national legislation with the EU *acquis* has been challenging considering the pace of the development of the European chemical legislative framework² together with the complexities of introducing EU centralised procedures into a national system. The alignment of the legislation is resource-intensive work, and there are other underlying issues that would be beneficial to address in order to ensure progress. The identified drivers, gaps and impacts are listed below:

Drivers

- EU centralised procedures cannot be transposed into the national system before accession;
- The continuous evolution of the EU regulatory framework;
- Lack of a budget dedicated to chemical risk management activities;
- Lack of a Memorandum of Understanding with Scientific Institutes or Academia to draw on resources outside the ministry; and
- Lack of stakeholder commitment to chemical risk management.

Gaps

The key challenges and gaps identified are:

- Lack of human resources and expertise for chemicals risk assessment and the enforcement of chemical legislation;
- Lack of a National Helpdesk;
- Kosovo has not ratified the Stockholm Convention;
- New draft Law on Chemicals that transposes the EU Regulation on chemicals has not yet been approved by the new Government;
- Lack of communication strategy;
- Lack of information on enforcement activities; and
- Gaps in IT infrastructure, policies and procedures.

Consequences

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

- The protection of human health and the environment and the guarantee of a level playing field between Kosovo and national and foreign companies;
- Stakeholder engagement and public awareness of chemicals and chemical safety; and

² 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).

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- The capacity of the competent authorities in ensuring the safety of CBI and personal data.

Drivers, challenges, gaps, and consequences are discussed in the sections below, along with the recommended actions to achieve specific and general objectives. Figure 1 shows the intervention logic³ with drivers, challenges, their impact, and measures to tackle identified problems, as well as main objectives and specific objectives.

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. Kosovo is 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 national 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.

³ The intervention logic represents how an intervention such as an action, programme or measure will solve the challenge identified and how it will deliver the expected impacts.

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Figure 1 – Intervention logic

Drivers	Challenges	Impact	Specific objectives and measures	General objectives
EU centralised procedures cannot be transposed	Lack of human resources and expertise on chemicals risk assessment and the enforcement of chemical legislation	The capacity to fulfil objectives of the legislative framework is not there	Implementing additional capacity building activities	Aligning the national legislation with the EU Regulation
Continuous evolution of the EU regulatory framework	No National Implementation Plan for POPs	No full protection of human health and the environment and no level playing field between Kosovo and foreign companies	Develop a Memorandum of Understanding with scientific institutes	
	Lack of a National Helpdesk		Increase the training capacity to train more inspectors for chemical legislation enforcement	
Lack of budget dedicated to chemical risk management	Lack of a National Poison Centre	Low level of stakeholder and public awareness on chemicals and chemical safety	Establish a National Helpdesk	Bringing the capacity up to a level where the obligations laid down in the Regulations can be carried out efficiently and effectively.
	The legislation on chemicals does not fully transpose the EU Regulation		Establish a National Poison Centre	
Lack of memorandum of understanding with universities and research institutes	Lack of communication strategy	May not get access to ECHA databases and e-tools	Develop a National Implementation Plan for POPs	
		Cannot ensure safety of CBI and personal data	The development of a communication plan and closer collaboration with NGOs and other stakeholders	
Chemical risk management is not a priority for authorities and stakeholders	Gaps in IT infrastructure, policies and procedures	Cannot ensure proper enforcement	Next audits of IT systems and infrastructure to consider ECHA's SSRs	
	Lack of information on enforcement activities		Make the information on enforcement activities available to public	

2.2 Underlying causes and means to address them

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

2.2.1.1 Description of the challenges and dependencies

The articles of the five regulations, which relate to EU centralised procedures, cannot be transposed.⁴ The current institutional and legislative setup focuses on strictly administrative procedures, which do not necessarily require scientific expertise on risk assessment. Currently, the Kosovan competent authority cannot have access to the e-tools used by EU Member States' competent authorities to access and manage the information exchange with ECHA.

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

2.2.1.2 Recommended actions, action owner and other relevant stakeholders

Since 2009, ECHA activities, implemented under the Instrument for Pre-accession Assistance (IPA) and funded by the European Union, have provided capacity building and support to the implementation of the EU chemicals legislation⁵. 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.

The revised and updated Kosovo Environmental Strategy (KES) 2013-2022⁶ and the National Environment Action Plan (NEAP) 2013-2017 set the creation of a system with an improved level of health and environmental protection against the potentially harmful effects of hazardous chemicals as the main priority in the chemical sector. The key priorities in the 2013-2022 strategy include:

- Drafting legislation and harmonisation with the EU *acquis*;
- Compiling a register for banned chemicals and those with restricted use;

⁴ This is the case with:

- REACH: Article 4, REACH Articles 5-12 and 15-30, partially Art. 13 and 14, Article 32, Articles 37-39, Articles 40-54, Articles 55-66, partially Art. 68, Articles 69-73, Articles 74-120 (fees), partially Articles 121-124 and Articles 125-127, Articles 128 – 141;
- CLP: Partially Article 1 and Article 4, partially Article 24, partially Articles 25-33, Article 34, partially Article 36, Articles 37-42, partially Articles 43-47, Articles 50-60, partially Art. 61 and Art. 62;
- BPR (BPD): Partially Articles 1-3, Articles 4-11, Articles 12-16, partially Articles 17 and 19-22, Articles 18 and 23-24, Articles 25-28, partially Articles 29-31, partially Articles 32-33 and 37, Articles 34-36 and 38-40, Articles 41-46, partially Articles 47-50 and 52, Art 51, Article 54, partially Article 57, Article 58, Articles 59-64, partially Articles 65-66 and 68, Art. 67, Article 71, partially Article 73, Articles 74-79, Articles 80, 82-86 and 88-97, partially Art. 81 and Art. 87, partially Annex I, Annex IV, partially Annex V and Annex VI, Annex VII;
- PIC: Partially Art 2 and Art 4, Article 5, Article 6, partially Articles 8-14, partially Articles 18-21, Articles 21- 27, partially Article 22, Articles 29- 31, partially Annex II and Annex III, Annex IV, Annex VII.
- POPs: Article 8, Articles 10-12, partially Article 13, Articles 15-18, Article 20.

⁵ 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>

⁶ https://mmphi.rks-gov.net/assets/cms/uploads/files/Publikimet/Strategy_for_Environment_Protection_2013-2022_English_language_62392.pdf

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- Establishing a sustainable system to improve the conditions for the protection of human health and the environment from the harmful effects of hazardous chemicals;
- Establishing a competent body as the chemical administration;
- Signing cooperation agreements with the EU and international institutions concerning hazardous chemicals;
- Creating a comprehensive plan for the direct intervention and rehabilitation measures in accidents caused by hazardous waste;
- Monitoring and establishing control over manufacturers, importers and users of hazardous chemicals; and
- Implementing awareness-raising activities targeting the citizens and industry with regards to hazardous waste.

There is a proposal for a new National Strategy for Chemicals that would also cover biocidal products. The new strategy should be finalised during 2021-2023 and cover five years. However, due to changes in the government, a new working group has to be established. In the field of chemicals, the DWC aims to draft new legislation and approximate it with EU legislation using technical support through the Technical Assistance and Information Exchange (TAIEX) and the Instruments for Pre-accession Assistance (IPA) projects (anticipating support from the European Commission through the IPA-III program regarding REACH and BPR). In particular, as indicated in the National Programme for Implementation of the Stabilisation and Association Agreement (NPISAA) 2017-2021, it was expected that the following pieces of legislation would be amended in 2021:⁷

- Law on Chemicals No. 04/L-197;
- Law No. 03/L-119 on biocidal products; and
- The Administrative Instruction MESP - No. 17/2014 on classification, labelling of hazardous chemicals.

The Draft Law on amending and supplementing the Law no. 04/L-197 on Chemicals and Draft Law for Biocide Products have been submitted to the Assembly of the Republic of Kosovo at the end of 2021 and are still under review.

In order to further align the national legislation with PIC and introduce POPs requirements in the chemical legislative framework, a new working group is expected to be established in 2022 to amend the Administrative Instruction MESP - No. 23/2015 for export, import and transit of certain hazardous chemicals (PIC-procedure) and the Administrative Instruction MESP - No.14/2017 on wastes containing POPs.

Since 2009, ECHA activities implemented under the IPA and funded by the European Union have provided capacity building and support to the implementation of the EU chemicals legislation⁸.

It is recommended that **ECHA implements additional capacity building activities, focusing on efficacy and risk assessment**. At the moment, Kosovo's competent authorities lack the expertise and knowledge to evaluate applications for authorisation of biocidal products, and MESPI only issues import permits for biocidal products authorised in the EU. It is recommended that this training is carried out in parallel to the technical assistance for the alignment of the national legislation on biocidal products with the BPR. This is important as to ensure that Kosovo's companies that may want to place biocidal products of their own formulation on the market are not prevented from doing so because of the lack of a regulatory procedure.

⁷ National Programme for Implementation of the Stabilisation and Association Agreement (NPISAA) 2017-2021. Available at: <http://mei-ks.net/repository/docs/pkzmsa20172021ang.pdf>

⁸ 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>

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Based on the assessment conducted in this study, it is also recommended that **ECHA delivers hands-on training sessions focusing on the use of e-tools** used by EU Member States' competent authorities to manage the information exchange with ECHA. Although this action is a low priority, Kosovo's competent authorities would benefit from understanding the functioning of these tools, which may help develop and improve their own procedures. This would also make the migration of data easier once Kosovo joins the EU. Table 1 shows the conformity of the objective to the SMART criteria.

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

Criteria	Notes
Specific	It is recommended ECHA implements additional capacity building activities focusing on efficacy and risk assessment. It is recommended that ECHA delivers hands-on training sessions focusing on the use of the e-tools used by national 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 Kosovo since 2009 and may continue supporting Kosovo's competent authorities.
Relevant	Capacity building will ensure a smoother EU accession.
Time-bound	Training on evaluating applications for the authorisation of biocidal products and risk assessment should be carried out in parallel to the alignment of the national legislation with BPR. Hands-on training on e-tools could be organised closer to the day of accession.

2.2.1.3 Estimated human and financial resources required

The human and financial resources that ECHA, the Member States' competent authorities or other organisations may have to allocate to fill existing needs through capacity building 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 €150,000⁹ and 150 workdays (around 0.7 FTE) carrying out training of Serbian authorities' staff in 2017.¹⁰ In the context of the twinning project implemented by the Austrian and Slovenian competent authorities¹¹, the cost of the organisation and actual implementation of training activities 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 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,

⁹ Around SEK 1,500,000.

¹⁰ Keml (2018): Chemicals risk management in Serbia. Annual report 2017, p.12.

¹¹ 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.

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etc.), with the participation of nine tutors for a total of 25 days (around 0.1 FTE), cost approximately €40,000.¹²

It is expected that the required human resources and the cost borne by ECHA or MSCA for training Kosovan competent authorities' staff 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 Kosovan competent authorities or as a joint action for all candidate and potential candidate countries (see Section 3.2).

2.2.1.4 Timeline, risks and risk mitigation measures

Kosovo's competent authorities are seeking technical assistance to align the national legislation on biocidal products with BPR through TAIEX and IPA instruments. Training of efficacy and risk assessment should be carried out in parallel, starting in 2022. The risk is that Kosovo's competent authorities do not have enough human resources to work on the legislation while attending capacity building activities. It is, therefore, important that MESPI strengthens the administrative capacity of the DCW (this is further discussed in Section 2.3.1 and Section 2.3.5). Training activities on ECHA e-tools are of lower priorities, but if these were going to be provided to other candidate and potential candidate countries, Kosovo's competent authorities would benefit from increasing their knowledge of the functioning of ECHA tools to better design their own instruments for storage, management and exchange of information.

2.2.2 The continuous evolution of the European chemical legislative framework

2.2.2.1 Description of the challenges and dependencies

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

- New substances are added to the authorisation and restriction lists every year;
- The REACH annexes have been adapted to clarify the information requirements for nanomaterials;
- Yearly adaptations to technical progress (ATPs) of the CLP Regulation;
- 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 Kosovan legislation aligned with the EU *acquis* is a resource-intensive work. The DWC employees share their time between drafting legislation and reviewing the applications for permits concerning chemicals and their import or export. Currently, most of the time (70%) of the Chemicals Officer and Biocidal Products Officer is used for drafting national legislation to approximate it with the EU legislation, respectively with the five Regulations (REACH, CLP, BPR, PIC and POPs), which have not been fully transposed yet. In order to achieve full harmonisation and transpose the REACH Regulation in its entirety, the DWC is currently working on repealing Law No. 04/L-197 on Chemicals and adopting a new law, which has already been drafted and should be adopted once the new Government and Assembly approve it. The Legal Department (LD) of the Department of Environmental Protection (DEP) supports the DWC in drafting the legislation.

¹² These figures cover daily allowances, travel and subsistence costs of invited experts and development of training material.

2.2.2.2 Recommended actions, action owner and other relevant stakeholders

The alignment and keeping the alignment of the national legislation with the EU Regulations is a resource-intensive task, as are other tasks necessary for the adequate implementation of the national chemical laws. Currently, the DWC has two employees working on chemicals legislation. Although DWC employees are supported by colleagues within the department and from other departments when drafting laws and bylaws, two additional FTEs at DWC would be beneficial considering the expected workload as new legislative requirements are implemented and enforced. Therefore, it is recommended **that the MESPI strengthens the capacity of the DWC**. This is further discussed in Section 2.3.1 and Section 2.3.5. Table 2 shows the conformity of the objective to the SMART criteria.

Table 2 – Objective 2: Strengthen the capacity of the Ministry of Environment, Spatial Planning and Infrastructure

Criteria	Notes
Specific	The MESPI strengthens the capacity of the DWC.
Measurable	Number of additional DWC staff members.
Achievable	Further discussed in Section 2.3.1 and Section 2.3.5.
Relevant	Additional capacity is key to overcoming many of the identified challenges.
Time-bound	Starting 2022 over a 5-year period.

2.2.2.3 Estimated human and financial resources required

The gap in the administrative capacity has been quantified as two FTEs per year over a five-year period. Currently, most of the time (roughly 70%)¹³ of the two DWC officers working on chemicals is dedicated to drafting laws and by-laws, leaving little time for the actual implementation of the legislation and other important activities.

Moreover, once the national legislation on biocidal products is aligned with the BPR, the DWC will need additional resources for the evaluation of applications for authorisation of biocidal products. Assuming that the number of biocidal products on the Kosovo market is similar to the number on the Maltese market, it is expected that the authorities could receive between 700 to 1,000 applications for biocidal product authorisation. Depending on the number of applications for the different authorisation procedures, the evaluation and assessment of the applications could require from **five to ten FTEs** per year in the medium-long term. Therefore, Kosovo's competent authorities should aim to build the capacity, possibly with the technical support of ECHA, EU Member States competent authorities or other relevant international organisations, DWC employees and external experts. This would allow outsourcing certain tasks when necessary. Additional details are provided in Section 2.3.1 and Section 2.3.5.

2.2.2.4 Timeline, risks and risk mitigation measures

Timeline, risks and risk mitigation measures for strengthening the administrative capacity of the DWC are discussed in Section 2.3.1 and Section 2.3.5.

¹³ Self-assessment of the DWC officers.

2.2.3 Lack of a budget and sustainable financial framework for chemical risk management activities

2.2.3.1 Description of the challenges and dependencies

According to EC (2020)¹⁴, insufficient funding and administrative capacity in Kosovo prevent the proper implementation of the current strategic framework. The capacity of the Kosovo Institute for Public Administration with a limited budget and ability to provide the necessary training remains weak, which continues to hamper the recruitment process and professional development of civil servants. Performance appraisals continue to have little impact on career development. This undermines the implementation of the Law on Public Officials, particularly for the recruitment, initial training and professional development of civil servants.

The lack of budget for chemicals risk management is the underlying driver for the challenges that competent authorities face when trying to align and implement the national legislation on chemicals.

The Law on Chemicals only foresees collection of fees for permits for circulation of hazardous chemicals (Article 57), which are paid to the budget of the Republic of Kosovo. However, the Law on Chemicals and the Law on Biocidal Products do not foresee any other type of fees that need to be paid for the administrative tasks carried out by the MESPI.

2.2.3.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the Government of Kosovo aligns national legislation on administrative fees with the principles of the EU Regulations**.¹⁵ 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 document¹⁶ containing recommendations for Member States' fee structures and related procedures with a view to harmonising the latter and avoiding gaps in national methods and/or fee levels. It is also recommended that **the Government of Kosovo creates a dedicated budget for chemical risk management activities by ring-fencing fees and charges paid by companies to apply for the authorisation of biocidal products**. Table 3 shows the conformity of the objective to the SMART criteria.

Table 3 – Objective 3: Create a dedicated budget for chemicals risk management

Criteria	Notes
Specific	It is recommended that the Government aligns national legislation on administrative fees with the principles of the EU Regulations. It is recommended that the Government creates a dedicated budget for chemical risk management activities by ring-fencing fees and charges paid by companies to apply for the authorisation of biocidal products.
Measurable	A ring-fenced budget dedicated to chemical risk management activities is created. Relevant administrative fees are introduced and aligned with principles of EU Regulation.

¹⁴ https://ec.europa.eu/neighbourhood-enlargement/sites/default/files/kosovo_report_2020.pdf

¹⁵ 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)

¹⁶ CA-Dec12-Doc.5.1.b – Final.

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Criteria	Notes
Achievable	Although achievable, the reform is likely to take some time.
Relevant	This is a fundamental part of the alignment of the national legislation to EU principles.
Time-bound	It is recommended to prioritise this action to have aligned legislation and a dedicated budget by the day of accession.

2.2.3.3 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). In addition, 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 Kosovo would be similar because the resources necessary to support Kosovo 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 Kosovo with this task. Furthermore, ECHA or a Member State competent authority could support Kosovo in defining the applicable fees and charges.

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

2.2.3.4 Timeline, risks and risk mitigation measures

The implementation of the necessary changes in legislation and the budgetary system may be a lengthy process. Therefore, it is recommended that the budget reform is given priority to allow for the analysis of the legal feasibility and compatibility and the creation of the dedicated budget by the day of Kosovo's accession to the EU.

2.2.4 Lack of a Memorandum of Understanding with Scientific Institutes or Academia to draw on resources outside the ministry

2.2.4.1 Description of the challenges and dependencies

Pursuant to the Law, the MESPI is responsible for keeping the register of the authorisations granted for biocidal products and all changes of the authorisations. However, currently, the MESPI does not issue authorisations, but issues import permits for biocidal products containing active substances approved or under review in the EU. The safety data sheet for each product and approved hazardous active substance are checked for this purpose, but no other information, for example, on efficacy or risk assessment, is evaluated.

According to the Law on Biocidal Products, the MESPI should cooperate with the MoH and the Ministry of Agriculture, Forestry and Rural Development (MAFRD) to appoint the Evaluation Commission for Biocidal Products constituted of professional experts in toxicology, medicine, pharmacology, pharmacy, chemistry, biology ecology, veterinary, agronomy, chemical engineering, and other relevant fields to perform certain duties in relation to the Law on Biocidal Products. However, this Commission has not been established yet.

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As of June 2021, the DWC employs two officers: one for chemicals and one for biocidal products. These officers carry out the practical implementation of the national legislation but are limited to the processing of PIC permits. It was estimated that two additional employees would be beneficial to carry out some other important tasks (Section 2.3.1). As mentioned in Section 2.2.2.3, depending on a number of factors and on the basis of comparing the biocidal product market size of Kosovo with the one in Malta, the evaluation and assessment of applications for the authorisation of biocidal products may require 5 to 10 FTEs in the medium-long term. This would also depend on when and how the national legislation is aligned with the BPR.

The gap could be filled by hiring new employees at the MESPI and using external resources. The main area of concern is the implementation of the Law on Biocidal Products, which is resource-intensive and requires specific expertise in risk and efficacy assessment. Therefore, Kosovan authorities could consider outsourcing some of the most technical aspects to external scientific institutes through a memorandum of understanding (MoU).

Given that the capacity at the MESPI will have to be built up progressively over time, support may be sought from external experts. With the right framework in place, scientific institutes and academia with expertise in chemistry, efficacy, toxicology, and ecotoxicology could play an important role in supporting the competent authority, particularly regarding risk assessment. Relevant expertise is available at the University of Priština and the University of Mitrovica and could be strengthened through capacity building activities to be carried out by ECHA, MSCA or other relevant institutions.

The possibility of outsourcing technical and scientific tasks to external experts helps mitigate the risks of staff turnover and skill decay.¹⁷ Therefore, training courses should be organised for both academic experts and the MESPI staff.

2.2.4.2 Recommended actions, action owner and other relevant stakeholders

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

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

¹⁷ 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.

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Ultimately, the objective is to develop capacity and competencies, ensure the functioning of the MESPI 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 the MESPI develops, ratifies, and implements an MoU with the relevant scientific institutes.
Measurable	An MoU with external experts is ratified. Number of external experts involved.
Achievable	The objective is attainable provided that an agreement is reached by all parties of the memorandum of understanding.
Relevant	Without the support of external experts, the Kosovan competent authority will not be able to process all industry applications, particularly for the authorisation of biocidal products, by the day of accession.
Time-bound	The MoU should be functioning as soon as possible with the target date of 2024.

2.2.4.3 Estimated human and financial resources required

It is recommended that the MESPI allocates at least 0.5 FTE per year in the period 2022-2024 to prepare the MoU and set up the necessary framework for a closer collaboration with academia and scientific institutes. It should be noted that Kosovo could also benefit from exchanging 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 with experts from academia, for instance, the University of Priština, the University of Mitrovica, by the end of 2024. This would require the identification of relevant parties, the survey of their competencies and needs and the definition of the scope of collaboration in the period 2022-2024. It should be noted that given the understaffing of the MESPI, dedicating even 0.5 FTE per year over a period of three years could be difficult unless the capacity of the MESPI is strengthened in 2022. Moreover, the opportunity of having an MoU or implementing short-term contracts depend on the creation of a dedicated budget. Completing actions in Section 2.2.3 of this report may help create and secure a dedicated budget for the MESPI on implementing biocidal product legislation, including the ratification of MoU. An additional risk is the lack of financial resources due to the economic slowdown, both national and worldwide, triggered by the ongoing COVID-19 pandemic.

2.2.5 Chemical risk management is still not high on the agenda of stakeholders

2.2.5.1 Description of the challenges and dependencies

Considering the need for further work with the alignment of the national legislation with the EU *acquis* and its adequate implementation and enforcement in combination with the few resources that are currently dedicated to the chemical risk management area indicate that the latter is not a priority for the Government or, at least, authorities may not have realised the amount of skilled resources that are necessary for this regulatory area. This may also reflect on the general awareness of other stakeholders.

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According to EC (2020), an empowered civil society is a crucial component of any democratic system and should be recognised and treated as such by public institutions. Although civil society organisations in Kosovo continue to play an important role in the democratic debate, the design and implementation of public policy, and the promotion of civil, political, economic, social and cultural rights, civil society's involvement as well as inter-institutional coordination in environmental matters remains limited in Kosovo. Furthermore, awareness-raising on environmental issues is mostly left to the international community and civil society organisations. Public consultations launched by the central government are becoming more regular but should be further improved with easier access to data and more regular feedback from public authorities. Awareness and promotion of consultation platforms are crucial in order to broaden the engagement of civil societies and citizens. Information sharing with the public is mainly carried out by Kosovo Environmental Protection Agency (KEPA), which publishes information on the official webpage. However, the information shared is not exclusively on chemicals. There is a number of NGOs, but chemicals and chemical risk management are not yet a priority. In addition, no activity has been developed to identify and contact NGOs that would deal with the field of chemicals.

Therefore, further work is required to raise awareness on the importance of the adequate implementation and enforcement of the chemical legislation to guarantee the safe use of chemical and biocidal products.

2.2.5.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the competent authorities raise awareness of chemical risk management among the public, civil societies, and the industry, but also among other governmental bodies, such as the Ministry of Finance**. The implementation of recommendations and actions laid down in Sections 2.3.4, 2.3.5 and 2.3.6 may help raise awareness among the public, industry, civil society, and other relevant stakeholders and increase their participation in public consultations and decision-making processes. Actions include the development of communication strategy, establishment of a fully functioning National Helpdesk, and publishing the information on enforcement activities for chemicals and biocidal products. The implementation of actions laid down in Sections 2.2.3 and 2.2.4 would also help strengthen the competent authorities in chemical risk management activities by creating additional resources and providing the necessary expertise for the transposition and implementation of chemicals legislation. Raising awareness on the necessary resources for the adequate implementation and enforcement of chemical legislation among other governmental bodies could be implemented, for example, through the annual reports on chemicals that MESPI should prepare and integrate into the report on the state of the environment to be approved by the Government of the Republic of Kosovo (article 14 of the Law on Chemicals). Table 5 shows the conformity of the objective to the SMART criteria.

Table 5 – Objective 5: Chemicals risk management awareness raising

Criteria	Notes
Specific	It is recommended that the competent authorities raise the awareness of chemical risk management among the public, civil societies, industry and other governmental bodies.
Measurable	Increased public awareness of chemical risk management through active involvement of the public and civil society in decision-making processes and related events and workshops.
Achievable	Actions in Sections 2.3.4, 2.3.5, and 2.3.6 need to be implemented in order to put the chemicals risk management higher on the agenda of all stakeholders.
Relevant	Without raising the awareness of chemical risk management among the public, the industry, civil societies, and other relevant stakeholders, the Kosovan authorities may not be able to guarantee adequate enforcement of the EU Regulations.

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Criteria	Notes
Time-bound	Starting 2022 until the accession to the EU.

2.2.5.3 Estimated human and financial resources required

Sections 2.3.4.3, 2.3.5.3, and 2.3.6.3 of the report describe the necessary resources for implementing actions that would help to improve communication on and increase public awareness of chemical risk management.

2.2.5.4 Timeline, risks and risk mitigation measures

The timelines for implementation of related actions are presented in Sections 2.3.4.4, 2.3.5.4, and 2.3.6.4 of the report.

2.3 Identified challenges and associated objectives

2.3.1 Understaffing of the Ministry of Environment, Spatial Planning and Infrastructure

2.3.1.1 Description of the challenge and dependencies

As of June 2021, the DWC employs two full-time equivalents: one FTE on chemicals and one FTE on biocidal products, and, currently, there are no plans to hire additional resources for the DWC. Most of the officers' time¹⁸ has been used for drafting legislation to approximate it with the EU Regulations, with the remaining time used for processing PIC permits and a variety of other tasks. According to the National Programme for Implementation of the Stabilisation and Association Agreement (NPISAA) 2017-2021¹⁹, a lack of administrative capacity is an obstacle for implementing a system for authorising biocidal products in Kosovo.

Furthermore, Article 42 of the Law on Chemicals sets out that chemicals produced, imported or placed on the market in Kosovo shall be registered in the general register of chemicals. According to Article 5 and Article 20 of the Law on Biocidal Products, the competent authorities have to establish and maintain registers of approved and not-approved active substances and authorised biocidal products. The MESPI is responsible for keeping the general register of chemicals in electronic form and as hard copies. The general register has not been established yet, although there is a plan to establish it during 2022. 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 Kosovo's competent authorities; however, the establishment and maintenance may require additional resources, which could instead be used for further alignment of the national legislation with EU *acquis*. Therefore, any future plans on establishing the register of chemicals should involve a feasibility study to assess the practicality of the register.

Finally, according to Article 76 of the Law on Chemicals, Kosovo National Institute for Public Health and the Food and Veterinary Agency (FVA) are the poison control centres responsible for collecting data on chemical poisonings. The poison centres need to submit the collected data to the MESPI to

¹⁸ Roughly estimated in 70% of overall time (self- assessment).

¹⁹ National Programme for Implementation of the Stabilisation and Association Agreement (NPISAA) 2017-2021. Available at: <http://mei-ks.net/repository/docs/pkzmsa20172021ang.pdf>

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maintain control over the harmful effects of chemical substances and mixtures on human health and the environment. However, such data is currently not being transferred, and no line for joint communication between the poison control centres and the DWC has been created.

2.3.1.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MESPI strengthens the administrative staff capacity of the DWC**. Kosovo is still developing the legislative framework, with amendments to the laws on chemicals and biocidal products expected to be approved by the end of 2021. The workload associated with the further alignment of national legislation is assumed to stay constant over the following years and is estimated to require approximately two FTEs per year. DWC officers are supported by colleagues within the department and from other departments when drafting laws and bylaws. However, **two additional FTEs** would allow dedicating more time to the actual implementation of the legislation and other important activities, such as communication with other departments, dissemination of information to the public, coordination with enforcement authorities, provision of helpdesk services, development and implementation of an MoU, attendance to training activities, participation in international bodies and so on. This would also allow speeding up the development of the legislative framework and the establishment of the National Helpdesk and associated lines and procedures for communication and the exchange of information with the poison control centres.

With time, employees could also start coordinating the evaluation of the information provided in the applications for the authorisation of biocidal products in collaboration with the research and scientific community in Kosovo (Section 2.2.4). Assuming that the number of biocidal products on the Kosovo market is similar to the number on the Maltese market, it is expected that the authorities could receive between 700 to 1,000 applications for biocidal product authorisation. Depending on the number of applications for the different authorisation procedures, the evaluation and assessment of the applications could require from **five to ten FTEs** per year over a period of five years.

It is also recommended that **the MESPI surveys the needs of DWC staff and external experts and organise capacity building on efficacy and risk assessment**. ECHA and other Member States Competent Authorities could support the strengthening of the DWC administrative capacity by implementing capacity building activities. Table 6 shows the conformity of the objective to the SMART criteria.

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

Criteria	Notes
Specific	It is recommended that the MESPI strengthens the administrative staff capacity of the DWC. It is also recommended that the MESPI surveys the needs of DWC staff and external experts and organise capacity building on efficacy and risk assessment.
Measurable	Number of employees at the DWC.
Achievable	This may require the allocation of adequate financial resources.
Relevant	Understaffing is one of the key problems affecting the capacity of Kosovan authorities to implement the EU regulations on chemicals.
Time-bound	The capacity needs to be built over time, starting from 2022.

2.3.1.3 Estimated human and financial resources required

In Kosovo, the average labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €8,000, and in professional, scientific and technical activities –

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approximately €6,000.²⁰ Therefore, the additional cost of bringing the number of DWC employees to the suggested four FTEs would amount to €70,000 over five years (Table 7). While the priority is the alignment of the national legislation with the BPR, in the medium-long term, the DWC will need additional resources for the evaluation of applications for authorisation of biocidal products. The required additional five-ten FTEs (five internal/five external) for this task would cost approximately €40,000-€70,000 per year.²¹

Table 7 – Marginal labour cost of hiring MESPI staff

	2022	2023	2024	2025	2026	€ - Total
MESPI Staff - FTEs	2	3	4	4	4	-
Additional FTEs	1	1	0	0	0	-
Marginal Cost	€8,000	€16,000	€16,000	€16,000	€16,000	€70,000 ²²

It should be noted that these costs should be covered by the applicants through fees (see Section 2.2.3.2 for more information).

2.3.1.4 Timeline, risks and risk mitigation measures

The hiring of new employees should start as soon as possible and continue progressively until the required number is reached. In order to keep the administrative capacity at the desired level, it is important to avoid high staff turnover. In addition, 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).

2.3.2 No National Implementation Plan for POPs

2.3.2.1 Description of the challenges and dependencies

Due to the unsolved issue of international recognition of Kosovo as a sovereign state, Kosovo is not a party to the Rotterdam Convention or the Stockholm Convention. However, the national legislation has been partially aligned with both the PIC and POPs Regulation. Administrative Instruction No. 23/2015 “for export, import and transit of certain hazardous chemicals, PIC procedure” transposes the PIC Regulation, with the exception of minor amendments and the penalties to be applied (Article 22), which are still to be defined. On the other hand, Administrative Instruction No.14/2017 “on wastes containing material persistent organic pollution” only partially transposes the POPs Regulation: Annex II (Part A and Part B), Annex III, and Annex V (Part A) are not transposed, whereas Article 14, Article 19, Annex I (Part A and Part B) Annex IV and Annex V (Part B) are only partially transposed. No National Implementation Plan (NIP) for POPs has been developed yet.

²⁰ <https://ask.rks-gov.net/media/6098/wage-level-in-kosovo-2020.pdf>

²¹ The estimate provided is the maximum cost per year for all additional FTEs for biocidal products management and may differ depending on need for outsourcing the workstreams.

²² Rounded to the nearest 5,000.

2.3.2.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MESPI develops a National Implementation Plan (NIP) for POPs** to fully transpose the POPs Regulation. The NIP should include action plans on measures to identify, characterise and minimise, with a view to eliminating where feasible as soon as possible, the total releases of substances listed in Annex III to the POPs Regulation as recorded in the inventories. The NIP should also have information on measures to promote the development and use of alternative substances, mixtures, articles, and processes to prevent the formation and release of substances listed in Annex III. **It is also recommended that the Commission, EU Member States and/or other international organisations provide technical and financial assistance to Kosovo for the development of the NIP**, in accordance with article 12 of the POPs Regulation and articles 12 and 13 of the Stockholm Convention. Table 8 shows the conformity of the objective to the SMART criteria.

Table 8 – Objective 7: The NIP for POPs Regulation

Criteria	Notes
Specific	It is recommended that the MESPI develops a National Implementation Plan (NIP) for POPs to fully transpose the POP Regulation. It is recommended that the Commission EU Member States and/or other international organisations provide technical and financial assistance to Kosovo for the development of the NIP.
Measurable	Kosovo has a National Implementation Plan as a result of the action. Financial and technical resources allocated to support Kosovo by the Commission, EU Member States and/or other international organisations
Achievable	The POPs Regulation is already partially transposed. UNEP GEF and EU MS have supported other countries in the past.
Relevant	A NIP is required by the POPs Regulation.
Time-bound	NIP to be developed over 2022.

2.3.2.3 Estimated human and financial resources required

For information, in 2004, for the preparation of the National Implementation Plan in Albania, the Global Environmental Facility (GEF) through the UNDP offered financial support for USD 347,000 (around €300,000), and the Albanian Government contributed USD 31,400 (approximately €25,000).²³ In 2001, the GEF financed the preparation of the National Implementation Plan in North Macedonia for USD 497,000 (around €440,000). Based on the similarities in the size of the chemical industry in these countries but also of the common industrial historical legacy, it is expected that the preparation of the National Implementation Plan in Kosovo may require resources in the same magnitude, ranging between €300,000 and €500,000.²⁴ However, the actual amount will depend on a number of factors, such as the existence of a coordinating and organisational mechanism and the availability of information on past use of POPs, known POPs stockpiles and contaminated sites.

²³ UNDP (2006): National Implementation Plan for Reduction and Disposal of Persistent Organic Pollutants. Tirana, December 2006.

²⁴ <https://www.thegef.org/project/enabling-activities-facilitate-early-action-implementation-stockholm-convention-13>

2.3.2.4 Timeline, risks and risk mitigation measures

The NIP is key to understanding the situation in Kosovo with regard to POPs contamination, presence of stockpiles, need for site remediation, etc. Therefore, it is important to develop the NIP with priority. However, Kosovo may not have the financial and technical resources necessary for this task and should therefore be supported by the Commission, EU Member States and/or other international organisations.

2.3.3 National legislation on chemical and biocidal products is only partially aligned with EU regulations

2.3.3.1 Description of the problem and dependencies

According to NPISAA (2017),²⁵ Kosovo's legislation is still in an initial stage of transposing the EU legislation concerning the registration, evaluation, authorisation, and restriction of chemicals (REACH), and Law No. 04/L-197 on Chemicals only partially transposes the regulation in question.

The Law on Chemicals and the Administrative Instruction no. 17/2014 on classification, labelling and packaging of hazardous chemicals partially transpose Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures.

Law no. 03/L-119 on Biocidal Products transposed Directive no. 98/8/EC on Biocidal Products, but it should be repealed to align with Regulation on Biocidal Products no. 528/2012/EU.

In order to achieve full harmonisation and transpose the REACH Regulation in its entirety, the DWC is currently working on repealing Law No. 04/L-197 on Chemicals and adopting a new law, which has already been drafted and should be adopted once the new Government and the Assembly approve it. The NPISAA for the period 2017-2021 indicated that also Law No. 03/L-119 on biocidal products and the Administrative Instruction (AI) MESP - No. 17/2014 on classification, labelling of hazardous chemicals were due to be amended by the end of 2021, and a new working group should have started work on further alignment with PIC and POPs by amending the AI MESP - No. 23/2015 for export, import and transit of certain hazardous chemicals (PIC procedure) as well as the AI MESP - No.14/2017 on wastes containing POPs. The DWC applied for the technical support available through TAIEX and IPA instruments to approximate national legislation with the EU regulations.

2.3.3.2 Recommended actions, action owner and other relevant stakeholders

The new draft Law on Chemicals is due for the scrutiny and approval of the government of Kosovo. **It is recommended that the DWC now focuses on amending** the national legislation to further align with CLP, PIC, POPs and, in particular, BPR. **It is recommended that the Commission, ECHA and/or EU Member State competent authorities provide technical support to Kosovo.** Table 9 shows the conformity of the objective to the SMART criteria.

Table 9 – Objective 8: Further align national legislation with EU regulations

Criteria	Notes
Specific	Competent authorities amend the Law on Biocidal Products, the AI on classification, labelling of hazardous chemicals, the AI for export, import and transit of certain hazardous chemicals, PIC procedure, and the AI on wastes containing POPs. The government adopts the new draft Law on Chemicals.

²⁵ National Programme for Implementation of the Stabilisation and Association Agreement (NPISAA) 2017 – 2021. Available at: <http://mei-ks.net/repository/docs/pkzmsa20172021ang.pdf>

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Criteria	Notes
	The Commission, ECHA and/or EU Member State competent authorities provide technical support to Kosovo.
Measurable	The new Law on Chemicals is approved and adopted. The Law on Biocidal Products, the AI on classification, labelling of hazardous chemicals, the AI for export, import and transit of certain hazardous chemicals (PIC procedure), and the AI on wastes containing POPs are amended and adopted.
Achievable	The new Law on Chemicals is already drafted and waiting for approval from the new Government. The NPISAA 2017-2021 indicates that the legislation should be amended in 2021.
Relevant	The adoption of a new draft Law on Chemicals and amendments to other relevant legislation is necessary to fully transpose the EU Regulation.
Time-bound	It is recommended that the new Law on Chemicals is adopted without further delays. The new NPISAA for the period 2022-2025 should provide a new timeline for the development, drafting and adoption of all other new legislation.

2.3.3.3 Estimated human and financial resources required

The legislative process that precedes the adoption of the new draft Law on Chemicals by the Kosovan Parliament requires the involvement of at least one in-house lawyer and the DWC employee who was involved in drafting the legislative text. The drafting of amendments to the Law on Biocidal Products, the AI on classification, labelling of hazardous chemicals, the AI for export, import and transit of certain hazardous chemicals (PIC procedure), and the AI on wastes containing POPs is also the responsibility of the DWC. As mentioned, the two DWC officers spend most of their time (roughly 70%) on drafting national legislation. In consideration of the expected work on the further approximation with the EU *acquis*, the two DWC staff working on chemicals should be working full-time on this task and should therefore be supported by two new colleagues, that could ensure the implementation of administrative and other important tasks.

2.3.3.4 Timeline, risks and risk mitigation measures

The new draft Law on Chemicals still needs to be approved by the new Government. It is recommended that the new law is adopted without further delays. The new NPISAA for the period 2022-2025 should provide a new timeline for the development, drafting and adoption of all other new legislation. The risk is that the administrative capacity of the DWC is not strengthened as a matter of priority, having knock-on effects on the timely development of the new law on biocidal products and the necessary amendments of other administrative instructions. Kosovo's competent authorities intend to apply for technical support through TAIEX and IPA but should guarantee the availability of an adequate number of human resources at the DWC.

2.3.4 No information on enforcement activities

2.3.4.1 Description of the problem and dependencies

Different inspectorates from different Ministries are involved in the enforcement of chemicals and biocidal products legislation. The Department for Environmental Inspection, Nature, Water, Construction and Spatial Planning (DI) of MESPI, and more precisely the Environmental Inspection, Nature and Water Protection Division, is responsible for the inspection of the implementation of environmental protection laws and bylaws, including the Law on Chemicals (Article 79) and the Law on Biocidal Products (Article 54). The DI has 20 employees responsible for the enforcement of environmental legislation. One environmental inspector at the central level has expertise in chemical

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legislation. For the enforcement of chemical legislation, environmental inspectors are supported by sanitary and phytosanitary inspectors.

The statistics regarding enforcement activities in Kosovo are limited. The Phytosanitary Inspectorate publishes a weekly report and annual reports of official control activities.²⁶ The Environmental Inspectorate prepares and publishes annual reports, but the website is currently under reconstruction. Nevertheless, the report is usually general, and inspections on chemicals and other enforcement activities focusing on chemical legislation are not specified.

2.3.4.2 Recommended actions, action owner and other relevant stakeholders

It is recommended **that the information on enforcement activities in chemical risk management is made available to the public** to ensure transparency and increase confidence in competent authorities on the enforcement of legislation on chemicals and biocidal products. This can be done by including the information on chemical inspections in an annual report by the Environmental Inspectorate to be published online. Table 10 shows the conformity of the objective to the SMART criteria.

Table 10 – Objective 9: Information on enforcement made available to the public

Criteria	Notes
Specific	It is recommended that the information on enforcement activities in chemical risk management is made available to the public.
Measurable	Annual reporting of data and statistics on inspections and enforcement of chemicals legislation.
Achievable	The weekly and annual inspection reports are already being published by the Phytosanitary Inspectorate.
Relevant	Publishing the information on enforcement of legislation on chemicals and biocidal products will increase the public confidence in competent authorities and may increase compliance by the industry.
Time-bound	The information on enforcement activities should be included in the next annual report.

2.3.4.3 Estimated human and financial resources required

Recording inspections, inspection outcomes, and other statistics (e.g., size of the company inspected, type and number of non-compliances, imposed sanctions) require the establishment of working procedures, starting from identifying and agreeing on relevant indicators and data items. This initial stage could roughly require around 0.5 FTEs, involving staff of the Environmental, Sanitary and Phytosanitary Inspectorates.

2.3.4.4 Timeline, risks and risk mitigation measures

The information on enforcement activities for chemicals and biocidal products should be included in the next annual report by the Environmental Inspectorate. The risk is that the Environmental Inspectorate may not have the adequate expertise to develop working procedures. The recording of inspections focusing on certain aspects of the chemical legislation and other relevant indicators, at least at an initial stage, could be facilitated by planning the enforcement activities, i.e. an inspection campaign focusing on chemical legislation enforcement. ECHA and/or MSCAs could also support the enforcement authorities by sharing best practices.

²⁶ <https://auvk.rks-gov.net/sq/fitosanitar>

2.3.5 There is no National Helpdesk

2.3.5.1 Description of the problem and dependencies

According to Article 16 of the Law on Chemicals, MESPI should establish a helpdesk for the provision of information to stakeholders on responsibilities and obligations deriving from the Law on Chemicals. However, the helpdesk has not been established yet. The Law on Biocidal Products does not have any requirements for establishing a helpdesk, but it should be repealed by a new Law aligned with the BPR.

Currently, the public and industry stakeholders submit their queries to the information office of the MESPI, which forward them to the DWC. Competent authorities receive around five queries per year, possibly because of the lack of awareness of the responsibilities of duty-holders. It is reasonable to expect an increase in queries when new legislative requirements are implemented and brought in line with the EU *acquis*. Industry stakeholders will need assistance with regard to their new registration obligations, whereas the public may have questions regarding the authorised uses and restricted uses of certain substances of concern.

2.3.5.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MESPI establishes the National Helpdesk responsible for the provision of information on the national legislation on chemicals and biocidal products**. 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. It is also important to **align the Law on Biocidal Products with the BPR to include the provision of information and helpdesk services on biocidal products**. It is also recommended that **the development of a communication plan is included in the remit of the Helpdesk staff** and should be part of the job description (see Section 2.3.6). Table 11 shows the conformity of the objective to the SMART criteria.

Table 11 – Objective 10: Establish the National Helpdesk

Criteria	Notes
Specific	It is recommended that MESPI establishes the National Helpdesk responsible for the provision of information on the national legislation on chemicals and biocidal products.
Measurable	The National Helpdesk is established.
Achievable	This may require the allocation of adequate financial 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 Kosovan authorities may not be able to guarantee adequate enforcement of the EU Regulations.
Time-bound	Starting from the year 2022.

2.3.5.3 Estimated human and financial resources required

Assuming that the DWC will receive a number of queries similar to that received by the competent authorities in Montenegro, which has been selected as a benchmark country for Kosovo, the team may have to reply to around 60 queries by email and 240 phone calls per year, although it is not expected to increase to such levels for some time. Assuming an average of half an hour to respond

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to one query²⁷, around one FTE may be necessary to deal with helpdesk-related activities. In addition, once established, employees of the National Helpdesk will need to continuously keep up to date with the interpretations and conclusions on certain issues provided by other Member States, ECHA or the European Commission. This requires participation in HelpNet, the network of national helpdesks, which meets twice every year.

The required financial resources are already accounted for the overall strengthening of the administrative capacity of the DWC.

2.3.5.4 Timeline, risks and risk mitigation measures

The allocation of necessary resources for the National Helpdesk should be done sooner than later. This would allow more efficient functioning of the Helpdesk and the development of a communication plan. The risk is that the further alignment of the national legislation with the EU regulations is not accompanied by the communication of the new duties and responsibilities of the different stakeholders, effectively invalidating the implementation of the chemical legislative framework.

2.3.6 Lack of a communication strategy

2.3.6.1 Description of the challenges and dependencies

In Kosovo, there is an ongoing engagement and information sharing process between the competent authorities and representatives of industry and civil society into working groups. Also, there is an active collaboration with American, German and Italian Chambers of Commerce and with working groups, including representatives from the Ministry of Industry, Entrepreneurship and Trade (MIET) and the Ministry of Health (MoH). Information sharing with the public is mainly carried out by KEPA, which publishes information on their official webpage, although the information shared is not exclusively on chemicals. Information to businesses and other stakeholders is provided through emailing lists. Several meetings and workshops have been held to inform stakeholders and industry on current regulatory requirements and functioning of REACH and CLP; however, they received limited participation. No activity has taken place to identify and involve NGOs that would deal with the field of chemicals. Initiatives regarding stakeholder engagement and communication remain very limited and are mostly carried out within the scope of projects funded by ECHA and EU MSCAs.

There is a need for the Kosovan competent authorities 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 Kosovan industry stakeholders informed about their upcoming responsibilities and duties, particularly regarding REACH registration and authorisation, CLP classification and labelling and BPR authorisation. With regard to the latter, duty-holders should be made aware of their obligation to contact the competent authorities in advance of applying for biocidal product authorisation. An effective communication strategy is essential to ensure that Kosovan companies are ready for the single market well before the day of Kosovo's accession to the EU.

²⁷ Queries to the helpdesk can range from being straightforward to reply to, by pointing to relevant online materials like FAQs, or complex, requiring the input of several people and the consultation of the ECHA helpdesk or other national helpdesks via HelpNet.

2.3.6.2 Recommended actions, action owner and other relevant stakeholders

Civil society plays an essential role in the process of European integration of Kosovo. Proactive civil society organisations are important actors in the implementation of public policies. According to EC (2020), the environment in which civil society operates in Kosovo continues to improve, and the government authorities continue to make efforts to increase the ability of civil society to contribute to policy development, although further efforts are required to enhance the transparency of public funding for civil society organisation.

It is recommended that **the DWC develops a communication plan** to address the following:

- The organisation of workshops and events, including identification and selection of topics of interest for the Kosovan 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 MESPI webpage, including the webpage of the Helpdesk when 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 Albanian and Serbian that could be relevant for Kosovan companies, could also be provided on the website.

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.

The DWC has just started collaborating with the Slovenian government and its competent authorities. There is also a memorandum of collaboration established in the area of environment, not just on chemicals, with the University of Priština and other private universities. Such initiatives should be reiterated and strengthened in the future.

Table 12 shows the conformity of the objective to the SMART criteria.

Table 12 – Objective 11: Develop a communication strategy

Criteria	Notes
Specific	It is recommended that the DWC develops a communication strategy to keep stakeholder engagement and increase transparency.
Measurable	A communication strategy is developed and implemented.
Achievable	The careful design of the strategy allows for avoiding misuse of funding. The MESPI and the DWC 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.

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Criteria	Notes
Time-bound	It is recommended that the DWC starts drafting a communication plan for the next five years (2022-2026). This would allow earmarking the necessary resources. The plan should clearly identify the target audience, needs and optimal communication channels.

2.3.6.3 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 the job description. Currently, there are no employees allocated to the helpdesk services. This is discussed in more detail in Section 2.3.4.

Given the lack of a sustainable financing framework, the Kosovan competent authorities 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.²⁸

2.3.6.4 Timeline, risks and risk mitigation measures

The MESPI and the DWC should start planning for the resources necessary to develop the plan: survey the needs, find the optimal communication channels, implement the strategy by organising the communication activities. It is also recommended that the Helpdesk prepare an annual communication work plan. 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 Kosovo to develop a dependency on external resources for 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.

2.3.7 Gaps in IT infrastructure, policies and procedures

2.3.7.1 Description of the problem and dependencies

For the purpose of ensuring the security of the information managed by the European Chemicals Agency, before receiving remote access to ECHA's information systems, all European and national authorities need to sign a declaration with respect to security aspects, based on the Agency's Security Model for IT systems.²⁹ This declaration (Unified Declaration of Commitment) and associated Standard Security Requirements (SSR) grant access to:

²⁸ Keml (2016): Chemical risk management in Serbia. Final report for 2008 to 2015; and Keml (2018): Chemical risk management in Serbia. Annual report 2017.

²⁹ 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

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- The ECHA REACH-IT system;
- The IUCLID³⁰ Member State database (REACH/CLP);
- The Portal Dashboard which facilitates the point of access to ECHA's IT systems;
- The Register for Biocidal Products (R4BP);
- The 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 an organisation complies with the standard security requirements and the additional requirements for teleworking and information sharing with contractors. The declaration requires the competent authorities to seek regular external or internal audits of the respective security requirements, and a full scope audit must be conducted every three years. New organisations must conduct a first full-scope audit to demonstrate all the required security controls and measures are in place.

The Standard Security Requirements are organised in:

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

The IT infrastructure and security procedures at the MESPI partially meet the ECHA Standard Security Requirements (SSR), and the IT systems are audited on a regular basis. The physical security of the premises³¹ that will be used to access ECHA's information systems from the day of accession is already effectively ensured by the measures in place at the governmental building, where the MESPI is located. Although there are IT security measures and procedures in place, certain aspects will need revision and improvement, including the establishment of formal IT security procedures, introductory and regular security training for DWC staff, and the security awareness programme.

2.3.7.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the next audit of IT systems and infrastructure considers ECHA's SSRs**. In addition, it is recommended that **the MESPI 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.³² The security officer must ensure that sufficient security training and awareness briefings are arranged.

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.

³⁰ IUCLID plays a central role in the IT environments of all organisations that manage scientific data on chemicals in a regulatory context, for example under the OECD HPV, EU Biocides, and EU REACH (<https://iuclid6.echa.europa.eu/>)

³¹ Physical security refers to the measures in place at the office premises used to access ECHA's information systems and in which local copies of non-public information downloaded from ECHA's information systems are stored either in digital or paper format. This potentially includes related data centres.

³² 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.

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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. 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** 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**.

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 13 shows the conformity of the objective to the SMART criteria.

Table 13 – Objective 12: Align IT infrastructure, policies and procedures with ECHA's standards

Criteria	Notes
Specific	It is recommended that the MESPI aligns the IT infrastructure, policies and procedures with ECHA's standards.
Measurable	IT infrastructure and security procedures are aligned with ECHA's SSR's.
Achievable	Allocation of financial resources may be required.
Relevant	Without IT security policies and procedures in place, the DWC could not gain access to ECHA information systems.
Time-bound	Policy and procedures need to be in place by the day of accession. The establishment of policies and procedures on the security of the information collected and managed by the DWC are likely to have positive impacts on the confidence of businesses towards the capacity of the Kosovo competent authority.

2.3.7.3 Estimated human and financial resources required

It is recommended that the existing IT staff at the DWC is 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 are estimated to cost around €100,000.

The cost of a new workstation, running safe and up-to-date operating systems and antivirus software is around €500. If staff needs 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 (accounting for 4 employees at the DWC): approximately €2,300 for the workstations at the DWC and other €2,300 for personal devices to enable remote working unless policies allowing work laptops to be used from home are implemented).

The provision of assistance by ECHA or one MSCA on the preparation of a formal non-public information management policy and a security awareness programme and a teleworking security policy may entail around 20 workdays (0.1 FTEs) and four meetings in Kosovo for a total cost of €25,000.³³

³³ Including allowances, project management, accommodation, and travel costs.

2.3.7.4 Timeline, risks and risk mitigation measures

Policy and procedures need to be aligned with ECHA's SSRs by the day of accession. However, the establishment of policies and procedures about the security of the information collected and managed by the DWC is likely to boost the confidence of businesses in the capacity and trustworthiness of the Kosovan competent authorities.

It is recommended that the specialised IT security consultancy, which carries out external audits, provide the first classes of the security awareness programme and prepare the material for the introductory and regular IT security briefings.

3 Conclusions and recommendations

3.1 Recommended actions and prioritisation

The main challenge that the Kosovan authorities are facing is the lack of resources necessary to align, implement and enforce the national legislation on chemicals and biocidal products. However, in order to strengthen the administrative capacity and enable the implementation of other recommended actions (Table 14), some underlying drivers need to be addressed first. These are beyond the remit of the DWC within the MESPI and are instead actions that should be taken by the Government of the Republic of Kosovo.

To ensure that adequate financial resources are available to fund new job positions within the MESPI or contract external experts for support, the **national legislation on administrative fees should be aligned with the EU Regulations and principles**, and **the revenue** from fees and charges paid by industry applicants for the work carried out by the competent authority **ring-fenced for chemicals risk management activities** (Section 16.2.3). Further, it is recommended that the competent authorities adopt the **Memorandum of Understanding** with scientific institutes and external experts to facilitate outsourcing some workstreams (e.g. efficacy, human health and environmental risk assessment) and avoid the overload of the MESPI (Section 16.2.4). It is recommended that these actions are given priority and are implemented as soon as possible.

A dedicated budget would allow hiring new people and strengthening the capacity of administrative staff, which would help to **tighten and further develop the legislation on chemicals and biocidal products** and address some other challenges associated with an insufficient administrative capacity, such as the lack of **a National Helpdesk** (Section 16.3.5). In addition, the DWC should **develop a communication strategy**, which could be a responsibility of a member of staff dedicated to the National Helpdesk services (Section 16.3.6).

Furthermore, it is recommended that **the DWC now focuses on amending the national legislation** to further align it with CLP, PIC, POPs and, in particular, BPR. It is also recommended that the Commission, ECHA and/or EU Member State competent authorities provide technical support to Kosovo. At the same time, it is necessary for the MESPI to develop a **National Implementation Plan for POPs** to fully transpose the POPs Regulation.

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

It is recommended that **the information on enforcement activities** in chemicals risk management is made available to the public to ensure transparency and increase confidence in competent authorities on the enforcement of legislation on chemicals and biocidal products (Section 16.3.4).

Finally, it is recommended that **the next audit of IT systems and infrastructure considers ECHA's standards** (Section 16.3.7).

Overall, it is important that the competent authorities **raise awareness of chemical risk management** among the public, civil societies, and industry (Section 16.2.5).

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

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Table 14 – Action Plan

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
1. Strengthen the capacity of DWC	!!!	2022	Gov MESPI	-	2 FTEs in the short term 5-10 FTEs in the medium-long term	~€16,000 pa (short term) ~€40,000-€70,000 pa (medium-long term)
2. Reassess capacity needs of DWC	!	2025	MESPI	MSCA	-	-
3. Survey the needs of DWC staff and external experts and organise capacity building on efficacy and risk assessment	!!	2022-2023	MESPI ECHA	MSCA	0.5 – 1 FTE (ECHA and/or MSCA)	~€100,000 per year over two years (ECHA and/or MSCA)
4. Align national legislation on administrative fees with the principles of the EU Regulations	!!	2022-2023	MESPI	MSCA	0.25 (over a 2-year period)	~€40,000 per year (ECHA and/or MSCA)
5. Establish a budget dedicated to chemical risk management activities	!!	2023-2024	Gov	-	-	-
6. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	!!	2022-2024	MESPI	ECHA, MSCA and/or Montenegro	1.5 FTE (over a 3-year period) – 0.5 FTE per year	-
7. Develop a National Implementation Plan for POPs	!!!	2022-2024	MESPI	UNDP GEF or other donor	1 FTE (one-off)	~€325,000 one-off (€300k GEF or other donor and €25k Kosovo Gov.)
8. Tighten and further develop the legislation on chemical and biocidal products	!!!	2022-2023	MESPI	MSCA (TAIEX and/or IPA)	-	-
9. Report on chemical legislation enforcement activities	!!	2022-	DI (MESPI)	Sanitary and phytosanitary inspectors	-	-
10. Establish the National Helpdesk	!!!	2022-	MESPI	ECHA and/or MSCA	1 FTE per year	-
11. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Kosovan stakeholders that could be discussed during the events;	!!	2022-	MESPI	ECHA, MSCA, CoC, NGOs	0.5 FTE	€50,000 per year ECHA and/or MSCA €10,000 Kosovo authorities

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Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
<ul style="list-style-type: none"> - 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. 						
12. Upgrade IT infrastructure	!	2023	DWC (MESPI)	-	-	€5,000 (one-off) ~€100 per workstation (running costs: licenses, software upgrades, etc.)
13. Provide training to DWC staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		2023	ECHA	MESPI	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
14. Develop an information security policy		2023	DWC (MESPI)	ECHA	0.1 (DWC) + 0.1 (ECHA and/or MSCA)	€25k (ECHA and/or MSCA)
15. Develop formal non-public information management policy in line with ECHA's SSR		2023	DWC (MESPI)	ECHA		
16. Establish a security awareness programme, including introduction and regular security training for all employees.		2023	DWC (MESPI)	ECHA		
17. Establish a teleworking security policy		2023	DWC (MESPI)	ECHA		
18. Contract an external audit of the safety policies, procedures and measures		2022	DWC (MESPI)		-	€5,000 in 2022
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		2023-	DWC (MESPI)		-	€5,000 every 3 years for external audits
20. Hand-on training on ECHA e-tools	!	2025	ECHA	MESPI	0.1 FTE (ECHA and/or MSCA)	€40,000 (ECHA and/or MSCA)
<p>Notes: MESPI: Ministry of Environment, Spatial Planning and Infrastructure; DWC: Division for Waste and Chemicals; Gov: Government of Kosovo; DI: Department for Environmental, Nature, Water, Construction and Spatial Planning Inspection; MSCA: Member State Competent Authorities</p>						

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Table 15 – Gantt chart and resource allocation

Action	2022	2023	2024	2025	2026
1. Strengthen the capacity of DWC	+1 FTEs €8k	+1 FTE €16k			
2. Reassess capacity needs of DWC				-	
3. Survey the needs of DWC staff and external experts and organise capacity building on efficacy and risk assessment	0.5 FTE €100k			0.5 FTE €100k	
4. Align national legislation on administrative fees with the principles of the EU Regulations	0.25 FTE €40k (ECHA and/or MSCA)	0.25 FTE €40k (ECHA and/or MSCA)			
5. Establish a budget dedicated to chemical risk management activities		-	-		
6. 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		
7. Develop a National Implementation Plan for POPs	0.3 FTE ~€100k (GEF or other donor and €10k Kosovo Gov.)	0.3 FTE ~€100k (GEF or other donor and €10k Kosovo Gov.)	0.3 FTE ~€100k (GEF or other donor and €10k Kosovo Gov.)		
8. Tighten and further develop the legislation on chemical and biocidal products	€50k			€50k	
9 Report on chemical legislation enforcement activities	-	-	-	-	-
10. Establish the National Helpdesk	1 FTE-	0.5 FTE	0.5 FTE	0.5 FTE	0.5 FTE
11. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Kosovan 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 €10k (ECHA or MSCA)	0.5 FTE €10k (ECHA or MSCA)	0.5 FTE €10k (MESPI)	0.5 FTE €10k (MESPI)
12. Upgrade IT infrastructure		€5k			
13. Provide training to the DWC staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		0.1 FTEs €50k			
14. Develop an information security policy					
15. Develop formal non-public information management policy in line with ECHA's SSR					

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Action	2022	2023	2024	2025	2026
16. Establish a security awareness programme, including introduction and regular security training for all employees.		0.1 (DWC) + 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				
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	-
20. Hand-on training on ECHA e-tools				0.1 FTE and €50k	
Totals					
ECHA, MSCA, GEF or other donor	0.5 FTEs €150k-190k	1 FTEs ~€50k-€130k	- €0-10k	0.1 FTEs €200k	
MESPI	~2 FTEs (+1 FTE) ³⁴ €23k	~2 FTEs (+1 FTE) €31k	~2 FTEs €10k	1 FTEs €15k	1 FTEs €10k

Table 16 – Risks and risk mitigation measures

Action	Risk	Risk Mitigation Measures
1. Strengthen the capacity of DWC	The government does not agree and may not fund the necessary resource increase.	The Commission and ECHA note that without the administrative capacity for implementing the Regulations, Kosovo would not be deemed ready to fulfil EU obligations and responsibilities.
2. Reassess capacity needs of DWC	-	-
3. Survey the needs of DWC staff and external experts and organise capacity building on efficacy and risk assessment	Lack of resources COVID-19 pandemic The alignment of the national legislation on biocidal products is further delayed, and therefore the trained experts cannot apply the new competences	Support of ECHA or MSCA Remote learning Action: 1. Strengthen the capacity of DWC 6. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities 8. Tighten and further develop the legislation on biocidal products
4. Align national legislation on administrative fees with the principles of the EU Regulations	Delays	The Commission and ECHA stress the importance of aligning the national legislation with the EU Regulations
5. Establish a budget dedicated to chemical risk management activities	Lack of resources	Action:

³⁴ 2 FTEs are required for recommended actions plus 1 additional FTE to increase the capacity of the DWC.

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Action	Risk	Risk Mitigation Measures
		4. Align national legislation on administrative fees with the principles of the EU Regulations
6. 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	<p>Actions:</p> <p>1. Strengthen the capacity of DWC</p> <p>4. Align national legislation on administrative fees with the principles of the EU Regulations</p> <p>5. Establish a budget dedicated to chemical risk management activities</p>
7. Develop a National Implementation Plan for POPs	Lack of financial and technical resources	<p>Support by the Commission, EU Member States and/or other international organisations.</p> <p>Actions:</p> <p>1. Strengthen the capacity of DWC</p>
8. Tighten and further develop the legislation on chemical and biocidal products	The administrative capacity of the DWC is not strengthened	<p>Apply for technical support through TAIEX and IPA</p> <p>Action:</p> <p>1. Strengthen the capacity of DWC</p>
9. Report on chemical legislation enforcement activities	<p>Environmental Inspectorate may not have the adequate expertise to develop working procedures</p> <p>No exchange of information between the relevant departments</p>	<p>An inspection campaign focusing on chemical legislation enforcement</p> <p>ECHA and/or MSCAs could support the enforcement authorities by sharing best practices</p> <p>The Phytosanitary Inspectorate have established working procedures as they publish enforcement statistics</p>
10. Establish the National Helpdesk	<p>Lack of resources</p> <p>Further alignment of the national legislation with the EU regulations is not accompanied by the communication of new duties and responsibilities of different stakeholders</p>	<p>Support of ECHA or MSCA</p> <p>Apply for TAIEX, IPA</p> <p>Communication strategy to include actions on effective communication on any changes in the national legislation to relevant stakeholders</p> <p>Action:</p> <p>1. Strengthen the capacity of DWC</p>
<p>11. Development and implementation of a communication plan:</p> <ul style="list-style-type: none"> - Organisation of workshops and events, including identification and selection of topics of interest for the Kosovan 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 <p>The organisation and dissemination of information online</p> <ul style="list-style-type: none"> - Allocation of resources for a multiannual plan; - Survey of the needs and topics of interest; 	<p>Lack of resources</p> <p>Lack of expertise</p>	<p>Communication activities part of the job description for the person responsible for the Helpdesk</p> <p>ECHA or MSCA support</p> <p>Apply for TAIEX, IPA</p> <p>Action:</p> <p>1. Strengthen the capacity of DWC</p> <p>10. Establish the National Helpdesk</p>

Action Plan

Action	Risk	Risk Mitigation Measures
- Identification of the communication channels; and - Implementation of the communication plan.		
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 MESPI 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 DWC 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		

3.2 Similarities in gaps and shortcomings between Kosovo and other 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 legislation with the BPR;
- 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:

Action Plan

- 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 national 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
AIS	Agency for Information Services
ASOs	Accredited Stakeholder Organisations
BPC	Biocidal Product Committee
BPR	Biocidal Products Regulation
BP	Biocidal Product
CARACAL	Competent authorities for REACH and CLP
CBI	Confidential Business Information
CG	Coordination group
CLH	Harmonised classification and labelling
CLP	Classification, Labelling and Packaging
CoRAP	Community Rolling Action Plan
COSME	Competitiveness of Enterprises and Small and Medium-sized Enterprises
CSOs	Civil Society Organisations
DEP	Department of Environmental Protection
DEWP	Department of Environmental and Water Protection
DI	Department for Environmental, Nature, Water, Construction and Spatial Planning Inspection
DWC	Division for Waste and Chemicals
EEA	European Environmental Agency
EC	European Commission
ECHA	European Chemicals Agency
EIONET	European Environment Information and Observation Network
ENWCPIID	Environment, Nature, Water, Construction and Planning Inspection Department
EPWD	Environmental Protection and Water Department
EU	European Union
FSHM	Faculty of Mathematical Natural Sciences
FVA	Food and Veterinary Agency
FTE	Full-time employee
GDP	Gross Domestic Product
GEF	Global Environmental Facility

Acronym	Full name
GLP	Good Laboratory Practice
GoK	Government of Kosovo
HWMs	Hazardous Waste Materials
IPA	Instrument for Pre-Accession Assistance
IT	Information Technology
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
KCC	Kosovo Chamber of Commerce
KemI	Swedish Chemicals Agency
KEPA	Kosovo Environmental Protection Agency
KES	Kosovo Environmental Strategy
KFOR	Kosovo Forces
KSF	Kosovo Security Force
LD	Legal Department at DEP
MAFRD	Ministry of Agriculture, Forestry and Rural Development
MEE	Ministry of Economy and Environment
MEI	Ministry of European Integration
MESP	Ministry of Environment, Spatial Planning
MESPI	Ministry of Environment, Spatial Planning and Infrastructure
MIET	Ministry of Industry, Entrepreneurship and Trade
MoH	Ministry of Health
MoU	Memorandum of Understanding
MS	Member State
MSCA	Member State Competent Authority
MSW	Municipal solid waste
NACE	Nomenclature of Economic Activities
NEAP	National Environment Action Plan
NIoPH	National Institute of Public Health
NGO	Non-Governmental Organisation
NIP	National Implementation Plan
NPISAA	National Programme for Implementation of the Stabilisation and Association Agreement

Acronym	Full name
PCN	Poison centre notifications
PIC	Prior Informed Consent Regulation
POP	Persistent Organic Pollutant
R4BP	Register for Biocidal Products
RAC	Committee for Risk Assessment
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REC	Regional Environmental Centre
RETF	Restriction Efficiency Task Force
SAA	Stabilisation and Association Agreement
SDS	Safety Data Sheets
SIDA	Swedish International Development Cooperation Agency
SSR	Standard Security Requirements
SVHC	Substance of Very High Concern
TAIEX	Technical Assistance and Information Exchange
UBT	University for Business and Technology
UMIB	University of Mitrovica 'Isa Boletini'
UNEP	United Nations Environment Programme



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