

# **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 – Albania**

*February 2022*

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## Executive Summary

*For ten years, Albania 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 from the results of the assessment of the institutional capacity and infrastructure available in Albania for the implementation and enforcement of the five Regulations: REACH, CLP, BPR, PIC, and POPs.*

*The assessment has identified lack of necessary staff resources to implement and enforce the five Regulations, particularly the BPR, as the main challenge. In order to strengthen the administrative capacity and enable the implementation of other recommended actions, some underlying challenges are recommended to be tackled first. These are beyond the remit of the Ministry of Tourism and Environment or the Ministry of Health and Social Protection and might be relying on policy decisions by the Government of the Republic of Albania. In particular, the lack of budget for chemical risk management needs to be addressed. The assessment found that the Office of Chemicals has adequate resources for the activities planned for the next three years. These focus on further aligning the chemical legislative framework in Albania with the EU acquis and building the competencies and skills of the current staff. However, the units at the Ministry of Health and Social Protection responsible for the authorisation of biocidal products are understaffed and are not in the position to implement the administrative tasks properly. These are resource-intensive and require specific expertise in risk and efficacy assessment. Depending on the further alignment of the national legislation with the BPR and the number of applications for different authorisation procedures, it is estimated that the evaluation and assessment of authorisation applications could require between five to ten FTEs per year over a period of five years. The Ministry of Health and Social Protection should consider the progressive hiring and training of personnel and outsourcing some tasks related to the management of biocidal products authorisations. To ensure that adequate financial resources are available to fund new job positions within the Ministry of Health and Social Protection, administrative fees and charges levied on entities applying for procedures regulated by the Law on Biocidal Products and associated rulebooks should be paid to a budget dedicated to activities in the biocidal product risk management area.*

*In synergy with the development of a Memorandum of Understanding with universities, scientific institutes and external experts, the above measure would facilitate outsourcing of some workstreams avoiding the overload of the Ministry of Health and Social Protection on the implementation of the Law on Biocidal Products and related administrative tasks.*

*Moreover, the Office of Chemicals should develop a communication strategy. It is recommended that stakeholder management and other aspects of external communication form part of the job description of one of the employees at the Office, together with the assignment to helpdesk and information services. In addition, it is recommended that the Ministry of Health and Social Protection establishes a helpdesk for the provision of information to the industry on biocidal products and appoints a dedicated member of staff for this task and communication activities. It is also important that the Ministry of Tourism and Environment strengthens a reporting and monitoring system of POPs-related duties.*

*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*

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*by the Commission, the European Chemicals Agency and/or EU Member State competent authorities by designing activities addressing jointly the similar gaps found in legislative alignment, financing systems of chemical risk management, collaboration with external experts, information dissemination, stakeholder engagement, IT infrastructures, information security procedures and enforcement activities.*

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

# 1 Introduction

## 1.1 Context

This fourth part of the study **presents the recommendations stemming from the results of the comparative legal analysis of the national legislation with the EU *acquis* and from the results of the assessment of the institutional capacity and infrastructure available in Albania 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:
  - The document produced by the European Commission<sup>1</sup> in assessing the progress of Albania with the reforms in the framework of the accession negotiations;
  - The documents produced by the Swedish Chemicals Agency (KemI) as a result of their co-operation project with the Albanian administration financed by the Swedish International Development Cooperation Agency (SIDA) "Cooperation in the environmental sector Albania – Sweden: A study of a possible new cooperation within chemicals management";
- The phone interviews with the Albanian competent authorities held on 25 March and 9 September 2021 and follow-up emails; and
- 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 of legislation;
- Systems and processes for transparency and stakeholders' engagement; and
- The IT infrastructure, capacity and competence.

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<sup>1</sup> EC (2020): Commission Staff Working Document Albania 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) 354 final.

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

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

## 2 The Action Plan

### 2.1 Challenges and gaps identified

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

The work of the Office of Chemicals, the Directorate for Policy and Strategies for the Environmental Development, and the Ministry of Health and Social Protection to align the national legislation with the EU *acquis* is still ongoing. The alignment of the legislation is resource-intensive work due to the pace of the development of the European chemical legislative framework,<sup>2</sup> the complexities of introducing EU centralised procedures into a national system and other underlying issues in the national legislative framework that would be beneficial to address in order to ensure progress. The identified drivers, gaps and their impact 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 and sustainable financial framework for 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 at the Ministry of Health and Social Protection dedicated to biocidal product risk management;
  - The national legislation on biocidal products is not fully aligned with the BPR;
- Lack of expertise in risk assessment and, in particular, evaluation of applications for authorisation of biocidal products;
  - The current national legislation on biocidal products is implemented for one product-type only;
- Lack of a fully functioning National Helpdesk;
- Lack of systematic reporting on and monitoring of the National Implementation Plan on POPs;
- Lack of a communication strategy;
- Lack of information on the extent, use and effectiveness of the public consultation feedback mechanisms;
- Lack of publicly available information on enforcement activities;
- Lack of expertise for the enforcement of chemical legislation; and

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<sup>2</sup> 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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- 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 Albanian and foreign companies;
- Stakeholder engagement and public awareness of chemicals and chemical safety;
- The capacity of the competent authorities in ensuring the safety of CBI and personal data.

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 logic<sup>3</sup> 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 other relevant stakeholders who may be affected and should be involved to provide support. It is important to keep stakeholders informed about relevant changes and timelines;
- The necessary human and financial resources;
- The suggested timeline in 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. Albania 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.

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<sup>3</sup> 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.



Figure 1 – Intervention Logic

Drivers and external factors	Problems		Consequences	Specific objectives and measures	General objectives
EU centralised procedures cannot be transposed	Lack of human resources at the Ministry of Health and Social Protection dedicated to biocidal product risk management	The national legislation on biocidal products is not fully aligned with the BPR	No full protection of human health and the environment and no level playing field between Albanian and foreign companies	Tightening and further developing of the legislation on biocidal products and the provision of capacity building services	Aligning the national legislation with the EU Regulations
Continuous evolution of the EU regulatory framework	Lack of expertise in risk assessment and evaluation of applications for authorisation of biocidal products	The current national legislation on biocidal products is implemented for one product-type only		Develop a Memorandum of Understanding with scientific institutes	
Lack of a budget and sustainable financial framework for chemical risk management activities	No information on enforcement activities and number of inspectors		Cannot ensure proper enforcement	Make information on enforcement activities available to public	
	Lack of expertise for the enforcement of chemical legislation		Low level of stakeholder and public awareness on chemicals and chemical safety	Devise plans to retain staff and prevent loss of expertise	
Lack of Memorandum of Understanding with universities and research institutes	Lack of systematic reporting on and monitoring of the National Implementation Plan on POPs		Consultations on new legislative proposals and amendments in the chemical risk management area receive low interest and participation	Helpdesks at MTE and MoHSP fully functioning and have dedicated resources	
	The National Helpdesk is not fully functioning			Strengthen the reporting and monitoring system of POPs-related duties	
Chemical risk management is still not high on the agenda of stakeholders	Lack of communication strategy		May not get access to ECHA databases and e-tools	The development of a communication plan and closer collaboration with NGOs and other stakeholders	
	No information on the extent, use and effectiveness of the public consultation feedback mechanisms			Regular reporting on how stakeholder feedback is taken into consideration	
	Gaps in IT infrastructure, policies and procedures		Cannot ensure safety of CBI and personal data	Align IT infrastructure, policies and procedures with ECHA's standards	

## 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 five regulations, which relate to EU centralised procedures, cannot be transposed.<sup>4</sup> The current institutional and legislative setup focuses on strictly administrative procedures, which do not necessarily require scientific expertise on risk assessment. Currently, the Albanian competent authorities 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 Office of Chemicals 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

According to the National Plan for European Integration (NPEI) (2021-2023), one of the priorities for chemical management in Albania is providing technical support to the Office of Chemicals to ensure its proper functioning and implementation of chemicals legislation.<sup>5</sup> Since 2009, ECHA activities implemented under the Instrument for Pre-accession Assistance (IPA) and funded by the European Union have provided capacity building and support to the implementation of the EU chemicals legislation.<sup>6</sup> 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. In addition, the project "Support for the Ministry of Tourism and the Environment for the Improvement of Chemicals Management" carried out by the Swedish Chemicals Agency (KemI) with the financial support of the Swedish International Cooperation and Development Agency (SIDA) has started in March 2019 for a period of three years. The project is contributing to raising the

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<sup>4</sup> 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.

<sup>5</sup> Assembly of the Republic of Albania (2021). Decision No. 90 On the Approval of the National Plan for European Integration 2021-2023, Pursuant to Article 100 of the Constitution, 17 February 2021. <https://qbz.gov.al/eli/fz/2021/31/c430e608-ff28-412c-9078-a9b61137ba16>

<sup>6</sup> 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>

technical and administrative capacity of the Albanian competent authorities on chemical legislation. The 2021 activity plan developed by Keml in cooperation with the Albanian authorities provides an indicative list of upcoming activities. It focuses on supporting the drafting of national legislation on chemicals and biocidal products while continuing with the capacity building of the Office of Chemicals staff and inspectors.

It is recommended that **ECHA implements additional capacity building activities focusing on risk assessment**. Based on the assessment conducted in this study, it would be beneficial to have this type of training on an annual basis to ensure that the competent authorities in Albania have the necessary expertise to implement the national legislation on chemicals and avoid skill decay. In addition, 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, Albania's competent authorities would benefit from understanding the functioning of these tools, which may help develop and improve their own procedures. Table 1 – Objective 1: Ensure risk assessment capacity and practical experience with e-tools 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
<b>Specific</b>	It is recommended that ECHA implements additional capacity building activities focusing on risk assessment. It is recommended that ECHA delivers hands-on training sessions focusing on the use of e-tools used by national competent authorities to manage the information exchange with ECHA.
<b>Measurable</b>	Number of civil servants and external experts trained per year.
<b>Achievable</b>	ECHA has implemented capacity-building activities in Albania since 2009 and may continue supporting Albania's competent authorities.
<b>Relevant</b>	Capacity building on risk assessment and e-tools will ensure a smoother EU accession.
<b>Time-bound</b>	Training on risk assessment should be prioritised and possibly start already in 2022 as an annual exercise. 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 €150,000<sup>7</sup> and 150 workdays (around 0.7 FTE) carrying out training of Serbian Authorities staff in 2017.<sup>8</sup> In the context of the twinning project implemented by the Austrian and Slovenian competent authorities<sup>9</sup>, 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

<sup>7</sup> Around SEK 1,500,000.

<sup>8</sup> KEMI (2018): Chemicals risk management in Serbia. Annual report 2017, p.12.

<sup>9</sup> 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 Office of Chemicals 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.

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, etc.), with the participation of nine tutors for a total of 25 days (around 0.1 FTE), cost approximately €40,000.<sup>10</sup>

It is expected that the required human resources and the cost borne by ECHA or MSCA for training Albanian competent authorities' staff may be similar: the actual cost will depend on the number of attendees (internal and/or external) and whether the training will be carried out only for Albanian 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

It is recommended to prioritise those capacity-building activities that focus on risk assessment. This is because there is a lack of expertise in risk assessment and evaluation of applications for the authorisation of biocidal products, and the current national legislation on biocidal products is facing challenges on proper implementation and is implemented for one product type only (see Section 2.3.6). In addition, hands-on training on e-tools can be organised closer to the day of accession.

## 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 to 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 Albanian legislation aligned with the EU *acquis* is a resource-intensive work.

The Office of Chemicals became operational in 2020. Currently, there are four full-time equivalents (FTEs) (three employees and a director) at the Office. Most of the employees have been recently hired. They have been developing their knowledge and skills in the framework of a cooperation and

<sup>10</sup> These figures cover daily allowances, travel and subsistence costs of invited experts and development of training material.

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development project financed by the Swedish International Cooperation and Development Agency (SIDA) and carried out by the Swedish Chemicals Agency (KemI). All staff of the Office of Chemicals have relevant qualifications with degrees in biology and chemistry and previous work experience as lab technicians, quality managers and environmental inspectors.

At the moment, the main activity of the Office of Chemicals staff is working with the Ministry of Tourism and Environment (MTE) on the alignment of the national legislation with the EU chemicals *acquis* and capacity building for the implementation of the administrative tasks. The Directorate for Policy and Strategies for the Environmental Development of the MTE employs five people responsible for the development of the environmental legislation. Its remit includes the alignment of the national legislation with REACH, CLP, PIC and POPs. One employee has been particularly active in drafting the national chemical legislation, and it is expected that this member of staff will keep working on the chemical legislative framework with the support of the Office of Chemicals.

The MTE is currently working on establishing the Interinstitutional Chemical Safety Committee (as required by Article 7 of the Law on Chemicals). The Committee will cover various activities in the chemicals management area and coordinate work among relevant Ministries, customs, and inspectorates. In addition, the Committee will act as an *advisory forum for policy coordination and decision-making, for the exchange of information and mutual control, without a mandate for binding decision-making*. KemI experts are providing support for the establishment of the Committee as part of the project "Improved Chemicals Management in Albania". In addition, employees of the MTE have acquired knowledge and practical experience in implementing the provisions of the national laws over several years and have participated in IPA training and workshops organised by ECHA.

The combined resources of the Directorate for Policy and Strategies for the Environmental Development and of the Office of Chemicals are considered sufficient to ensure the further alignment of the chemical product legislation and the implementation of the current administrative procedures. As the staff of the recently created Office of Chemicals acquires knowledge and skills and establish working procedures, they will be able to handle an increasing amount of workload. However, it is important that the competent authorities carefully consider the costs and benefits of establishing the register of chemicals required by Article 27 of the Law on Chemicals.

This article establishes that chemical substances manufactured and imported in Albania require registration, and it is the responsibility of the MTE to create and maintain "the electronic register of chemicals, in accordance with the standards, rules, and procedures set out in Law No. 10325, dated 23 September 2010 on the state database". The national register of chemicals has not been established yet, but the Office of Chemicals is working with KemI experts to establish the register as part of the project "Improved Chemicals Management in Albania". Firstly, a pre-study will be performed to gather information on whether there are the preconditions for the effective functioning of the register, including:

- A clear understanding of the purpose and required output from the register;
- Appropriate and adequate processes for data-reporting, collection, registering, processing of data to meet these needs;
- Institutional capacity to operate the register; and
- Awareness of the chemical industry on their obligations.

The work on the register has been slowed down by the COVID-19 pandemic. Even though the study was expected to be ready by the end of the year according to the plan of activities for 2021, it has not been conducted yet.

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 Albania'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 the EU *acquis*. Hence, the feasibility study should be used as a guide on whether the establishment of the register would not hinder the effectiveness of the competent authorities from implementing other administrative tasks.

The Ministry of Health and Social Protection (MoHSP) is responsible for the transposition of the EU legal acts to the national legislation on biocidal products. So far, the legislation on biocidal products has been implemented only for some product types (e.g. sanitisation of drinking water and insecticides) and needs revision for further alignment with the BPR. In addition, there are some ambiguities that need solving before full implementation: the DCM No. 933/2020 requires applicants to prove that the biocidal product is already authorised in the European Union according to the BPR. But the BPR provides for transitional measures, which are still valid, allowing some biocidal products to be placed on Member States' national markets without being authorised in accordance with the BPR. Moreover, article 8(4) of the Law no. 95/2015 and Chapter III of the DCM No. 933/2020 do not allow Albanian manufacturers of biocidal products to place biocidal products on the Albanian market, even if the active substance is approved in the EU unless they have received authorisation in a Member State for the same biocidal product.<sup>11</sup> Effectively, the MoHSP does not have the expertise to evaluate biocidal products produced in Albania and has therefore decided to allow only those biocidal products on the market that have been authorised in the EU.

#### 2.2.2.2 Recommended actions, action owner and other relevant stakeholders

The Office of Chemicals has adequate resources for the activities planned for the next three years. These activities focus on the practical implementation of the alignment of the chemical legislative framework in Albania with the EU *acquis* and on building the competencies and skills of recently hired staff. However, it is recommended that **the Office of Chemicals reassesses its capacity at the end of this three-year period.**

On the other hand, the MoHSP is understaffed and is not in the position to implement the administrative tasks for biocidal product authorisation fully. While the legislation established the Secretariat and the Commission for the authorisation of biocidal products, the number of staff dedicated to the implementation of the legislation on biocidal products is very limited: two to three persons on a part-time basis, including members of the Secretariat for the authorisation of biocidal products and the chairman of the Commission for the authorisation of biocidal products. The implementation of biocidal products legislation is resource-intensive and requires specific expertise in risk and efficacy assessment.

It is recommended that **the MoHSP further aligns the legislation on biocidal products with the BPR while strengthening its capacity.** This is further discussed in Section 2.3.1 and Section 2.3.6. Table 2 shows the conformity of the objective to the SMART criteria.

**Table 2 – Objective 2: Strengthen the capacity of the Ministry of Health and Social Protection**

Criteria	Notes
Specific	It is recommended that the Office for Chemicals reassess its capacity at the end of this three-year period.

<sup>11</sup> A working group has been recently set up to review the DCM on biocidal products, which has been identified to have some gaps. The group has started work to make the necessary changes.

Criteria	Notes
	It is recommended that the MoHSP further aligns the legislation on biocidal products with the BPR and strengthens in parallel its capacity.
<b>Measurable</b>	Number of additional MoHSP staff members.
<b>Achievable</b>	Further discussed in Section 2.3.1 and 2.3.6.
<b>Relevant</b>	Additional capacity is key to overcoming many of the identified challenges.
<b>Time-bound</b>	It is estimated that the MoHSP will need around 5-10 FTEs per year dedicated to the alignment of the national legislation and implementation of administrative tasks.

### 2.2.2.3 Estimated human and financial resources required

The gap in the administrative capacity has been quantified as five to ten FTEs per year over a five-years period. The necessary resources depend on several factors, such as the number of applications per authorisation procedure and the time set by the legislation to evaluate different applications. The range of five to ten FTEs has been estimated by comparing Albania with Malta and assuming that a similar number of biocidal products will be placed on the market (700 to 1,000).

The gap in resources could be filled by hiring new employees and using external resources. In addition, both internal and external resources should receive training to strengthen their competencies and skills. Additional details are provided in Section 2.3.1.

### 2.2.2.4 Timeline, risks and risk mitigation measures

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

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

### 2.2.3.1 Description of the challenge and dependencies

In accordance with the Law on Environmental Protection, the National Environment Agency (NEA) should be financed from its own resources and the state budget. However, in practice, the NEA does not have its "own resources", but the state budget funding is complemented by donor funding (grants). In 2015, the operational budget of the NEA<sup>12</sup>, excluding salaries and social security payments, was €228,332. The already limited State budget for environment and climate change was further reduced in 2019 (EC, 2020)<sup>13</sup>.

Albania does not earmark financial resources for environmental protection. Any decision about strengthening environmental taxation depends on the Government's resolve since all budgetary arrangements of ministries depend on the discretionary decision of the Ministry of Finance and Economy. Furthermore, the conditions for widening public and private environmental expenditure do not exist. Environmental taxes provide only a weak incentive for pro-environmental behaviour by individuals, organisations, and industry. Mostly, tax rates have been set without considering the impact and effects of emissions on the environment in terms of externalities or environmental damage to citizens and businesses. Environmental taxation and fiscal instruments are not subject to

<sup>13</sup> [https://ec.europa.eu/neighbourhood-enlargement/sites/default/files/albania\\_report\\_2020.pdf](https://ec.europa.eu/neighbourhood-enlargement/sites/default/files/albania_report_2020.pdf)



harmonised regulation or management at the central level, and no specific unit within the central government is vested with direct responsibility for the environmental tax system (UNECE, 2018).

As set out in Article 42 of the Law on Chemicals<sup>14</sup> on financial liabilities of the manufacturers, importers, exporters, and professional users, all relevant fees for registration of chemical substances should be paid directly to MTE. On the other hand, the financial liabilities for the application for authorisation of biocidal products are not set out in the Law on Biocidal Products. DCM No. 933/2020 requires administrative fees to be borne by the applicants and directed to the state budget. However, this may not guarantee that these funds are used to cover competent authorities' expenses for the evaluation of applications. The DCM is currently under revision, as the fee of 2,000 Albanian Leks is not sufficient to cover expenses.

### 2.2.3.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the Government of Albania aligns national legislation on administrative fees with the principles of the EU Regulations.**<sup>15</sup> In particular, Article 80(3)(a) of the BPR establishes that "fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs". In accordance with Article 80(2) of the BPR, the European Commission has issued a guidance document<sup>16</sup> containing recommendations for Member States' fee structures and related procedures with a view of harmonising the latter and avoiding gaps in national methods and/or fee levels. It is also recommended that **the Government of Albania 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: Reform the budgetary system**

Criteria	Notes
<b>Specific</b>	It is recommended that the Government of Albania 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.
<b>Measurable</b>	A ring-fenced budget dedicated to chemical risk management activities is created. Relevant administrative fees are introduced and aligned with principles of the EU Regulation.
<b>Achievable</b>	Although achievable, the reform is likely to take some time.
<b>Relevant</b>	This is a fundamental part of the alignment of the national legislation to EU principles.
<b>Time-bound</b>	It is recommended to give priority to this action in order to have aligned legislation and a dedicated budget for the implementation of the national legislation.

<sup>14</sup> <https://turizmi.gov.al/kimikate/>

<sup>15</sup> 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)

<sup>16</sup> CA-Dec12-Doc.5.1.b – Final.

### 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). 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 Albania would be similar because the resources necessary to support Albania 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 Albania with this task.

**Albania could ask Serbia to access the document containing recommendations for sustainable financing of biocidal products management administration.** ECHA or a Member State competent authority could support Albania 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 the budgetary system may be a lengthy process. Therefore, it is recommended that the budget reform is given a priority to allow for the analysis of the legal feasibility and compatibility and the creation of the dedicated budget by the day of Albania accession to the EU.

## 2.2.4 Lack of a Memorandum of Understanding with Scientific Institutes and external experts

### 2.2.4.1 Description of the challenge and dependencies

As already discussed in Section 2.2.2, the Office of Chemicals at the MTE has adequate resources for the next three years. However, the MoHSP does not have enough resources for the implementation of administrative tasks (see Section 2.3.1). The existing gap could be filled by hiring new employees at the MoHSP 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. Albanian authorities could consider outsourcing some of the most technical aspects to external scientific institutes through a memorandum of understanding (MoU).

Article 12 of the Law on Biocidal Products notes that the implementation of the legislation should be done through several bodies, including a Commission for the authorisation of biocidal products, which is a technical advisory body in support of the MoHSP and consists of qualified specialists in the field of environmental protection, epidemiology, microbiology, entomology, toxicology, medicine, pharmacology, chemistry, biology, veterinary medicine, agronomy, chemical engineering, as well as other fields determined by the competent authority on a case-by-case basis. The Commission for the authorisation of biocidal products is responsible for providing recommendations for the issuance or refusal of the authorisation for the placing on the market, prohibition, or

restriction of the use of biocidal products. However, it is not clear if the Commission is fully functioning.

Given that the capacity at the MoHSP and the Institute of Public Health 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. Expertise is available in several faculties, such as the Faculty of Natural Sciences at the University of Tirana, the Faculty of Agriculture and Environment, the Faculty of Food and Biotechnology, and the Faculty of Veterinary Medicine at the Agricultural University of Tirana.

In addition, experts from academia and scientific institutes should be trained on the technical and scientific aspects of the chemical legislation, also in consideration of staff turnover and skill decay.<sup>17</sup> Training courses could be organised for both academic experts and MoHSP staff (see also Section 2.3.6).

#### 2.2.4.2 Recommended actions, action owner and other relevant stakeholders

It is important that **the MoHSP 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 MoHSP should explore the use of more agile short-term contracts on specific assignments. The scope of an MoU is to regulate the long-term cooperation between the MoHSP and external experts. As a first step, the MoHSP 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 MoHSP 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.

Ultimately, the objective is to develop capacity and competencies, ensure the functioning of the MoHSP 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
<b>Specific</b>	It is recommended the MoHSP develops, ratifies, and implements an MoU with the relevant scientific institutes.
<b>Measurable</b>	An MoU with external experts is ratified. A number of external experts involved.

<sup>17</sup> The loss or decay of trained or acquired skills (or knowledge) after periods of non-use. As defined in Arthur, Bennett, Stanush, and McNelly (1998): Factors that influence skill decay and retention: a quantitative review and analysis. *Human Performance*, 11(1), 57-101.

Criteria	Notes
<b>Achievable</b>	The objective is attainable provided that an agreement is reached by all parties of the memorandum of understanding.
<b>Relevant</b>	Without the support of external experts, the Albanian competent authority will not be able to process all industry applications, particularly for the authorisation of biocidal products, by the day of accession.
<b>Time-bound</b>	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 MoHSP 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 Albania 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 Tirana, the Agricultural University of Tirana, 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 MoHSP, dedicating even 0.5 FTE per year over a period of three years could be difficult unless the capacity of the MoHSP 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 MoHSP 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

According to UNECE United Nations Economic Commission for Europe (2018), there are approximately 100 NGOs engaged in environmental issues in Albania (although the number of NGOs that have competencies, responsibilities and obligations and may contribute to the successful implementation and enforcement of the EU chemical legislative *acquis* is much lower, approximately five). The Regional Environmental Centre (REC) produces and maintains an online directory of NGOs. The systemic engagement of NGOs in environmental monitoring, decision-making and awareness-raising is weak, and the extent of public participation in the development of legislation usually depends on the topic. If the topic is very technical, for example, chemicals, attendance at the public consultation tends to be much lower than when a topic, such as protected areas, is discussed (UNECE, 2018).

Furthermore, lack of budget and sustainable financial framework for chemical risk management activities (Section 2.2.3), lack of an MoU with scientific institutions and other stakeholders (Section 2.2.4), and lack of communications strategy (Section 2.3.7) indicate that the chemical risk

management is not a priority for the Government, competent authorities and other stakeholders, and 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 chemicals 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**. The implementation of recommendations and actions laid down in Sections 2.3.2, 2.3.4, 2.3.7, and 2.3.8 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 a communication strategy, an establishment of a fully functioning helpdesk, publishing information on enforcement activities for chemicals and biocidal products and reporting of outcomes of public consultations and how stakeholder feedback impacts the decision-making processes. Table 5 shows the conformity of the objective to the SMART criteria.

**Table 5 – Objective 5: Chemicals risk management awareness raising**

Criteria	Notes
<b>Specific</b>	It is recommended that the competent authorities raise the awareness of the chemical risk management among the public, civil societies, and industry.
<b>Measurable</b>	Increased public awareness of the chemical risk management through active involvement of the public and civil society in decision-making processes and related events and workshops.
<b>Achievable</b>	Actions in Sections 2.3.2, 2.3.4, 2.3.7, and 2.3.8 need to be implemented in order to put the chemicals risk management higher on the agenda of all stakeholders.
<b>Relevant</b>	Without raising the awareness of chemical risk management among the public, industry, civil societies and other relevant stakeholders, the Albanian authorities may not be able to guarantee adequate enforcement of the EU Regulation.
<b>Time-bound</b>	Starting 2022 until the accession to the EU.

### 2.2.5.3 Estimated human and financial resources required

Sections 2.3.2.3, 2.3.4.3, 2.3.7.3 and 2.3.8.3 of the report describe the necessary resources for implementing actions that would help to improve communication on and increase public awareness of the chemical risk management.

### 2.2.5.4 Timeline, risks and risk mitigation measures

The timelines for implementation of related actions are presented in Sections 2.3.2.4, 2.3.4.4, 2.3.7.4 and 2.3.8.4 of the report.

## 2.3 Identified challenges and associated objectives

### 2.3.1 Understaffing of the Ministry of Health and Social Protection for authorisation of biocidal products

#### 2.3.1.1 Description of the challenge and dependencies

According to Law No. 95/2015 on Public Health Services and Biocidal Products (hereinafter referred to as "Law on Biocidal Products"), the Ministry of Health and Social Protection is the competent authority for biocidal products and is responsible for drafting and implementing policies in the field of public health services and biocidal products. Pursuant to Article 12 of the Law on Biocidal Products, the implementation is done through:

- The Secretariat for the authorisation of biocidal products, which is part of MoHSP;
- The Commission for the authorisation of biocidal products, which is a technical advisory body in support of the MoHSP. The Commission is responsible for providing recommendations for the issuance or refusal of the authorisation for the placing on the market of biocidal products, prohibition or restriction of the use of biocidal products; and
- The Institute of Public Health (IPH).

The number of staff dedicated to the implementation of the legislation on biocidal products is very limited. Therefore, there is the need to increase resources to implement the administrative tasks related to implementing the national legislation in line with the Biocidal Products Regulation (BPR).

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

- Lack of a budget dedicated to chemical risk management activities (2.2.3); and
- Lack of a Memorandum of Understanding with academia or relevant scientific institutes (Section 2.2.4).

#### 2.3.1.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MoHSP strengthens the administrative staff capacity for the implementation of the Law on Biocidal Products**. At the moment, national legislation refers to active substances approved in the EU and biocidal products authorised in the EU. Although this is a pragmatic approach that ensures alignment with the EU legislation while minimising the administrative and technical capacity for the evaluation of applications for authorisation, it does not provide local formulators with the opportunity to place biocidal products on the market. Once the legislation is further aligned with the BPR and assuming that the number of biocidal products on the Albanian market is similar to the number on the Maltese market, Albanian 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 between **five to ten FTEs per year over a period of five years**. In addition, the establishment of the helpdesk for the provision of support to the industry on biocidal products within the MoHSP may require **one additional FTE** (see Section 2.3.4). The MoHSP should consider the progressive hiring and training of personnel and outsourcing some tasks related to the management of biocidal products authorisations (see also 2.3.6).

As a recommended minimum, staff working on biocidal legislation should include one Chairperson for the Commission, two project managers (one Project Manager at the Secretariat and one Project

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Manager at the Institute of Public Health), three employees responsible for assessing physicochemical properties, evaluation of efficacy, the human health and environmental risk assessment of substances and products under evaluation, and one employee responsible for the provision of helpdesk and communication services, for a total of seven employees. This is estimated to be the minimum capacity necessary to implement the EU legislation on biocidal products in Albania and does not take into consideration the tasks related to other EU and national legislation included in the remit of the competent authorities. Table 6 shows the required number of FTEs and the recommended mix of expertise. Four additional external experts could be trained to support and ease the competent authorities' workload when necessary (e.g., MoHSP resources required for further alignment of the legislation, high number of applications for authorisation submitted by industry).

**Table 6 – A recommended mix of expertise**

No. of employees	Roles	Competencies
1 (internal)	Chairman of the Commission	Chairs the Commission of technical advisors on the authorisation of biocidal products.
2 (internal)	Project Manager / Regulatory coordinator	Responsible for detailed planning of evaluation of active substances and authorisation of biocidal products. The Project Manager/Regulatory coordinator sets priorities, identifies critical issues, and keeps track of deadlines and time spent on tasks/activities. Develops the background documentation supporting the substance evaluation report and the proposals and communicates with the Agency and other MS competent authorities. Participates in MSCAs meetings for the implementation of the BPR, Coordination Group, Biocidal Product Committee, Standing Committee on Biocidal Products, and Member States Committee, as well as in seminars with industry and other stakeholders. Supports in matters concerning budget and planning. Responsible for the handling of the application for authorisation of biocidal product and the administrative work through the process, coordinates the work of the experts, checks the outcome of the evaluation and compiles the documents for the biocidal product (draft the product assessment report - PAR, summary product characteristic - SPC, authorisation).
2 (1 internal, 1 external)	Chemist and efficacy assessor	Makes the evaluation of the information on the physicochemical properties of the substances under evaluation. Makes the assessment and evaluation of the efficacy to establish the benefit arising from the use of biocidal products and whether they are sufficiently effective.
2.5 (1 internal, 1.5 external)	Risk assessor (human health)	Makes the evaluation of the human health risk assessment.
2.5 (1 internal, 1.5 external)	Risk assessor (environment)	Makes the evaluation of the risk assessment for the environment.
1 internal	Helpdesk and communication services	Responsible for coordinating the provision of information on biocidal products following queries by stakeholders (helpdesk services) and other communication activities.
<b>11 = 7 (internal) + 4 (external)</b>	<b>Total</b>	

The MoHSP should also ensure the functioning of the Commission for the authorisation of biocidal products as laid out in Article 12 on the Law on Biocidal Products, which is responsible for providing recommendations to the MoHSP.

ECHA and Member States' Competent Authorities could support the increase in the MoHSP staff capacity by implementing capacity building projects. Table 7 shows the conformity of the objective to the SMART criteria.

**Table 7 – Objective 6: Strengthen the administrative capacity of the MoHSP**

Criteria	Notes
<b>Specific</b>	It is recommended that the MoHSP strengthens the administrative staff capacity for the implementation of the Law on Biocidal Products.
<b>Measurable</b>	Number of employees in the MoHSP. Number of external experts readily available for outsourced work (through the Commission and MoU).
<b>Achievable</b>	This may require the allocation of adequate financial resources.
<b>Relevant</b>	Without strengthening the capacity of the MoHSP, the Albanian competent authority will not be able to process industry applications for the authorisation of biocidal products in a reasonable amount of time.
<b>Time-bound</b>	The capacity needs to be built over time, starting from 2022.

### 2.3.1.3 Estimated human and financial resources required

In Albania, the average labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €5,500.<sup>18</sup> Therefore, the additional cost of bringing the number of competent authorities' employees to the suggested seven (considering the existing staff and an additional one FTE for helpdesk services) is around €83,000 over a five-year period (2022-2026) (Table 8).

**Table 8 – Marginal labour cost of hiring MoHSP staff**

	2022	2023	2024	2025	2026	€ - Total
MoHSP Staff - FTEs	2	3	4	5	6	-
Additional FTEs	1	1	1	1	1	-
Marginal Cost	€5,500	€11,000	€16,500	€22,000	€27,500	€83,000 <sup>19</sup>

However, the estimated number of FTEs required to deal with the expected workload may exceed this level closer to accession and may amount to around ten (internal and external) FTEs. In this scenario, the additional cost for hiring all required FTEs and outsourcing to external experts would be around €50,000 per year.<sup>20</sup>

<sup>18</sup> Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016.

<sup>19</sup> Rounded to the nearest 5,000.

<sup>20</sup> €20,000 for MoHSP staff and €30,000 for four external FTEs per year.



The cost entailed by competent authorities is to be paid for by the applicants through fees; however, these are currently not being collected for the authorisation of biocidal products (see Section 2.2.3.2).

#### 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 minimum number of seven employees is reached. However, it should be noted that closer to the year of accession, the need for resources is expected to be higher due to additional FTEs needed to transition from the national system to the full entry into force of the EU Regulations.

In order to keep the administrative capacity at the desired level, it is important to avoid a high staff turnover. In addition, new resources should be available for thorough training to ensure a swift onboarding (see Section 2.3.6). 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 2.3.9).

### 2.3.2 No information on enforcement activities and number of inspectors

#### 2.3.2.1 Description of the challenges and dependencies

The annual inspection report provides information on the inspections carried out by all State inspectorates in Albania. The most recent annual report documenting the number of inspections carried out by the Directorate of Environmental Inspection within the State Inspectorate of Environment, Forests, Water and Tourism (SIEFW), the Directorate of Product Supervision within the State Inspectorate for Market Surveillance (SIMS), and State Health Inspectorate (SHI) was published in 2018<sup>21</sup>. Furthermore, no specific information on the number of inspectors with competencies on chemical legislation has been found, nor statistics or data on inspections carried out on chemical and biocidal products.

#### 2.3.2.2 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. It is also recommended that the inspection report is published annually as planned, as the latest report was released back in 2018, which makes the publicly available information outdated. The SHI has been publishing its inspections reports annually;<sup>22</sup> however, the enforcement activities have been limited to inspections on biocidal products used for disinfection and sanitation of drinking water.

Table 9 shows the conformity of the objective to the SMART criteria.

<sup>21</sup> Annual Inspection report 2018. Central Inspectorate. Available at: <http://www.insq.gov.al/wp-content/uploads/2016/09/Raporti-Vjetor-IQ-2018.pdf>

<sup>22</sup> Annual Inspection Report 2019. Available at: <http://ins-shendetesor.gov.al/wp-content/uploads/2020/06/Raport-2019-final.pdf>  
Annual Inspection Report 2020. Available at: <http://ins-shendetesor.gov.al/wp-content/uploads/2021/05/Raport-2020.pdf>

**Table 9 – Objective 7: Information on enforcement made available to the public**

Criteria	Notes
<b>Specific</b>	It is recommended that the information on enforcement activities in chemical risk management is made available to the public.
<b>Measurable</b>	Reports with statistics and information on enforcement activities in chemicals risk management are published annually.
<b>Achievable</b>	The reporting has already been taking place; however, limited to some biocidal product types.
<b>Relevant</b>	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.
<b>Time-bound</b>	Starting from the year 2022.

### 2.3.2.3 Estimated human and financial resources required

Inspectors are already required to store information on their enforcement activities in a database accessible by other competent authorities. 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 task is estimated to require around 0.1 to 0.3 FTEs, depending on the number of authorities that need to be involved in developing the working procedures and whether similar procedures are available for other enforcement areas.

### 2.3.2.4 Timeline, risks and risk mitigation measures

The information on enforcement activities for chemicals and biocidal products should be included in the next annual report.

## 2.3.3 Lack of expertise for the enforcement of chemical legislation

### 2.3.3.1 Description of the challenge and dependencies

Based on Law 10433/2011 on the inspection in the Republic of Albania, the Central Inspectorate coordinates training and qualification activities of inspectors. However, there is a lack of expertise among inspectors for the enforcement of the legislation on chemicals. The Central Inspectorate has published the "Training Programme for Initial and Periodical Testing of the State Inspector of the Republic of Albania" (2020)<sup>23</sup>. This programme is prepared in response to the need to provide the inspectors with the necessary knowledge and skills to perform functional tasks in the field of inspections. The programme defines the concrete needs of inspectors and what training and tests they should undertake. In addition, the SHI has published the "Training Programme for Initial Testing of the Inspector of the State Health Inspectorate" (2021). Certain aspects of inspections in the area of biocidal products are addressed in the programme. Among the topics, two modules of the programme cover biocidal products (Module 1 – Certificate documentation for the application of biocidal substances in the subject, Module 2 – Inspection of general measure: application of biocidal substances).

Regarding the training in the chemical legislation enforcement, the cooperation project with Keml foresees the capacity building of inspectors and preparation of guidance materials to support the

<sup>23</sup> <http://insq.gov.al/wp-content/uploads/2020/10/Moduli-i-trajnimite-fillestar-dhe-periodik-i-IQ-ss-3.pdf>

adequate enforcement of the chemical legislation provisions. Keml will use a train-the-trainers approach, providing training to a number of selected inspectors from different inspectorates, who will be the reference inspectors for the chemical legislation enforcement and train other peers on the supervision of the relevant provisions. In addition, the project will contribute to the development of training materials to be used in future training (in the Albanian language). As part of the project, a manual for inspection of provisions in chemical legislation will be developed in cooperation with the relevant enforcement authorities. The first two weeks' training should take place in December 2021, and three inspectors from each Inspectorate will be attending the training.

### 2.3.3.2 Recommended actions, action owner and other relevant stakeholders

Enforcement authorities will have to ensure measures to retain staff to prevent loss of the institutional memory and the experience. Therefore, it is recommended that **the competent authorities devise a plan to retain staff and avoid a high turnover of inspectors**, which could result in the loss of resources that have been trained over the years. This can be done by guaranteeing adequate salaries (in line with or above industry wages) and avoiding the overload of their resources. It is also recommended that **the capacity building approach train-the-trainer provides the necessary training to as many inspectors from different inspectorates as possible**. More trained inspectors will be able to provide training to more colleagues in a shorter period of time, and the risk of losing the trained personnel will be reduced. Table 10 shows the conformity of the objective to the SMART criteria.

**Table 10 – Objective 8: Retain staff and prevent loss of expertise**

Criteria	Notes
<b>Specific</b>	It is recommended that the competent authorities devise a plan to retain staff and avoid a high turnover of inspectors.
<b>Measurable</b>	Number of trained inspectors. Adoption of a plan to retain staff.
<b>Achievable</b>	Training activities have already been planned by both competent authorities and Keml.
<b>Relevant</b>	Without an adequate number of properly trained environmental inspectors in chemicals legislation, the Albanian authorities may not be able to guarantee adequate enforcement of the EU Regulations.
<b>Time-bound</b>	Starting from the year 2022.

### 2.3.3.3 Estimated human and financial resources required

One of the most straightforward ways to retain skilled staff is to offer a competitive salary, which should be at least in line with industry wages for similar expertise categories and profiles. The labour cost per employee in the professional, scientific, and technical activities sector in full-time equivalents per year is estimated to be around €7,500<sup>24</sup>, i.e., 36% more than in the public sector (€5,500).

Several projects already foresee the provision of capacity building activities. As already discussed in Section 2.2.1, the estimation of human and financial resources required for capacity building depends on several factors, such as number of tutors involved, number of attendees, number of in-person classes vs number of remote learning sessions, travel, accommodation, and subsistence for

<sup>24</sup> Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016.

tutors coming from abroad, necessary IT equipment, etc. Given the lack of a sustainable financing framework, the Albanian competent authority may need to continue relying on ECHA's and other European partners' technical and financial support for capacity building. As detailed in Section 2.2.1, depending on the scale of the training courses, costs may vary but could be forecasted at around €100,000 per year.

#### 2.3.3.4 Timeline, risks and risk mitigation measures

As for most of the recommendations, the sooner action is taken, the better. The recommended start and target year should be 2022 to ensure the required capacity to enforce legislation on chemicals.

### 2.3.4 The National Helpdesk is not fully functioning

#### 2.3.4.1 Description of the challenge and dependencies

The Office of Chemicals is established as a central public institution designated to provide helpdesk services in Albania, with its remit covering the provision of information on the national legislation on chemicals and biocidal products. For this purpose, the Office of Chemicals has created an official e-mail address ([info.kimikatet@akm.gov.al](mailto:info.kimikatet@akm.gov.al)), which stakeholders can use to submit queries regarding their legal obligations. In addition, a leaflet available online provides responses to generic, frequently asked questions about the national legislation<sup>25</sup>. Office of Chemicals' staff check the e-mail address on a daily basis and either reply directly or redirect queries to other competent institutions. All staff members participate in the process depending on the workload as there are no employees nominated for the provision of helpdesk services.

Albania's competent authorities have participated in multiple events organised by ECHA through IPA projects<sup>26</sup>, which also provided the platform for discussion, sharing manuals and guides on the establishment of the National Helpdesk. In addition, Keml is also providing support to the Office of Chemicals in further developing the helpdesk by sharing knowledge and practical experience on the operation of Keml's and other EU helpdesks. However, due to the high number of queries from the industry about biocidal products, Keml has recommended having two separate helpdesks, one for chemicals and one for biocidal products.

Moreover, the cooperation project will investigate the possibility to finance consultancy work in setting up a platform for receiving and replying to industry queries and will investigate the possibility of involving industry sector organisations, trade unions and other stakeholders in the communication activities.

#### 2.3.4.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the Office of Chemicals appoints a dedicated member of staff at the National Helpdesk responsible for the provision of information on the national legislation on chemicals**. The nominated employee would address queries from manufacturers, importers, other users, and any other interested parties where possible. In addition, it is recommended that **the MoHSP establishes a helpdesk for the provision of information and advice to the industry on biocidal products legislation and appoints a dedicated person**. It is also recommended that **the development of a communication plan is included in the remit of the Helpdesk staff** and forms part of the job description. This will be discussed later in Section 2.3.7. Table 11 shows the conformity of the objective to the SMART criteria.

<sup>25</sup> <http://www.akm.gov.al/assets/informacioni-i-kimikateve-per-publikim2.pdf>

<sup>26</sup> <https://echa.europa.eu/it/about-us/partners-and-networks/international-cooperation/support-to-eu-external-relations-policies/activities-under-ipa/2020-2021>

**Table 11 – Objective 9: A fully functioning National Helpdesk**

Criteria	Notes
<b>Specific</b>	It is recommended that the Office of Chemicals appoints a dedicated member of staff at the National Helpdesk responsible for the provision of information on the national legislation on chemicals. It is recommended that the MoHSP establishes a helpdesk for the provision of information and advice to the industry on biocidal products legislation and appoints a dedicated person. It is recommended that the development of a communication plan is included in the remit of the Helpdesk staff and forms part of the job description.
<b>Measurable</b>	The helpdesk at the MoHSP is established. Number of employees dedicated to the helpdesk services at the MTE and the MoHSP.
<b>Achievable</b>	The Helpdesk at the MTE is already established and has a dedicated email address.
<b>Relevant</b>	Without proper support and advice to manufacturers, importers and other users on their responsibilities and obligations under the Law on Chemicals and Law on Biocidal Products, the Albanian authorities may not be able to guarantee adequate enforcement of the EU Regulations.
<b>Time-bound</b>	Starting from the year 2022.

#### 2.3.4.3 Estimated human and financial resources required

Assuming that the number of queries is similar to that received by the competent authorities in Montenegro, which has been selected as a benchmark country for Albania, around one FTE may be needed to deal with helpdesk-related activities at the Office of Chemicals, including the development and implementation of a communication plan. Currently, the Office of Chemicals has an adequate number of employees, and one member of staff could be assigned responsibilities of the National Helpdesk. Furthermore, the establishment of the helpdesk at the MoHSP, including the helpdesk and communication activities, may require approximately one FTE depending on the further alignment of the national legislation with the BPR and the number of queries from the industry.

#### 2.3.4.4 Timeline, risks and risk mitigation measures

The establishment of a helpdesk at the MoHSP and allocation of necessary resources for helpdesk services should be prioritised and implemented in 2022. This would allow more efficient functioning of the helpdesk at both Ministries and the development of the communication plan.

### 2.3.5 Lack of systematic reporting on and monitoring of the National Implementation Plan on POPs

#### 2.3.5.1 Description of the challenge and dependencies

According to article 13 of the POPs Regulation (and in line with Article 7 of the Stockholm Convention), Member States have to monitor and report to the European Commission and ECHA on the following:

- Information on the application of the Regulation, including information on enforcement activities, infringements and penalties;
- Information compiled from the notifications of articles containing POPs, stockpiles and POPs-contaminated waste;

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- Information compiled from the release inventories;
- Information on the implementation of the National Implementation Plan (NIP);
- Information on the presence of polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) and polychlorinated biphenyls (PCB) in the environment; and
- Annual monitoring and statistical data on the actual or estimated total manufacturing and placing on the market of any POP, including relevant indicators, maps and reports.

Member States should update the report annually if new information is available and otherwise at least every three years. Albania signed the Convention in 2001, ratified it in 2004, prepared the initial NIP in 2006 and updated the NIP in 2017. The report on the review and update of the NIP<sup>27</sup> received the support of the UNEP Global Environment Facility (GEF). The key findings and recommendations were:

- Albania has no stockpiles of pesticides classified as POPs;
- There is no evaluation and monitoring of pesticide residues in the environment and POPs impurities in imported pesticides;
- Waste management of old electric and electronic equipment which may contain PCBs and PBDEs does not meet the required standards, leading to potential contamination of the surrounding environment;
- The authorities should:
  - Assess the presence of PCBs in the environment;
  - Implement appropriate measures to avoid uncontrolled waste burning and improve waste incineration, which are main contributors of unintentionally-produced POPs emissions in the environment;
  - Check and upgrade waste management measures for paper and packaging containing PFOS and textiles and polystyrene foams containing HBCD;
  - Define institutional responsibilities at a national and regional level;
  - Create a management system and strengthen technical capacity for elimination/reduction of POPs-containing waste;
  - Draft necessary by-laws;
  - Report on the presence and possible health impacts of POPs in the environment;
  - Provide the necessary funding to increase institutional capacity and implement the plan;
  - Establish a POPs unit within the MTE;
  - Organise training events and seminars.

Interinstitutional working group for POPs was created two years ago; however, it still needs to be activated.

#### 2.3.5.2 Recommended actions, action owner and other relevant stakeholders

The review and update of the NIP resulted in an action plan with associated indicators and estimated financial resources. However, there are no reports to verify the accomplishment of the recommended actions. It is recommended that **the MTE strengthens a reporting and monitoring system of POPs-related duties**. One employee of the Office of Chemicals should be tasked with overseeing the compilation of information and drafting the implementation report. Table 12 shows the conformity of the objective to the SMART criteria.

<sup>27</sup> UNEP (2017): Report – Review and update of the National Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants (POPs) in Albania. Project number: GFL-2310-2760-4E40-2202. Tirana, 2017.

**Table 12 – Objective 10: Establishment of a reporting and monitoring system of POPs-related duties**

Criteria	Notes
Specific	It is recommended that the MTE strengthens a reporting and monitoring system of POPs-related duties.
Measurable	A reporting and monitoring system is strengthened.
Achievable	Indicators for monitoring the implementation of the plan have been already suggested in the NIP, along with action owners.
Relevant	Both the POPs Regulation and the Stockholm Convention require periodic reporting on POPs-related duties.
Time-bound	The updated NIP was published in 2017, and review and update of NIPs should be carried out, as a minimum, every three years.

### 2.3.5.3 Estimated human and financial resources required

The GEF provided USD 250,000 (around €215,000) for the review and update of the NIP in Albania.<sup>28</sup> The MTE outsourced the support to the project accounting for 30 working days. It is estimated that compiling the information on the accomplishment of the updated NIP actions and drafting the implementation report would require a similar number of resources from the Office of Chemicals (around 0.1 FTEs).

### 2.3.5.4 Timeline, risks and risk mitigation measures

The review and update of the NIP by the UNEP covered the years 2017-2021. The GEF allocated:

- Around €90,000 for strengthening the institutional and regulatory capacity;
- Around €440,000 for preparation of guidelines for management and treatment of certain POPs, field studies and gradual remediation of contaminated sites and the preparation of the POPs monitoring programme; and
- Around €90,000 for raising public awareness, information dissemination, training and development.

The Office of Chemicals should allocate the resources necessary for reporting on an annual basis while requesting technical assistance for further developing and strengthening Albania's capacity to implement the obligations under the Convention and the Regulation to the Commission, Member States and/or the Agency (Article 12). The risk is that without an adequate monitoring and reporting system, the need for substantial review and update of the NIP for the period 2022-2025 could not be established, missing financial and technical support from the United Nations, the EU or EU Member States. The Office of Chemicals should therefore allocate adequate resources for annual reporting.

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

### 2.3.6.1 Description of the challenge and dependencies

There is a lack of expertise at the MoHSP in the field of risk assessment and evaluation of applications for authorisation of biocidal products. Despite the current national legislation not requiring extensive evaluation and assessment of the applications for authorisation for placing biocidal products on the

<sup>28</sup> [https://www.thegef.org/sites/default/files/council-meeting-documents/C.39.Inf\\_5\\_Guidelines\\_for\\_NIP.Final\\_1.pdf](https://www.thegef.org/sites/default/files/council-meeting-documents/C.39.Inf_5_Guidelines_for_NIP.Final_1.pdf)

Albanian market, the Secretariat and the Commission for authorisation have been able to process applications only for one product type, which is a part of a simplified authorisation procedure.

### 2.3.6.2 Recommended actions, action owner and other relevant stakeholders

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

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

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

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

According to the Law No. 152/2013 on Civil Servants<sup>29</sup>, the Albanian School of Public Administration (ASPA) "shall have the duty to provide a continuous vocational training program, which trains continuously and in issues related to the work of civil servants of all categories, as well as any other individual outside this service". The Law also states that all civil servants have a right to improve their professional skills through continuous professional training from public funds, foreign donors, or personal income.

It is recommended that **the MoHSP surveys the needs of their staff and external experts and organises and implements training and capacity building courses**. Training should be continuous and planned on an annual basis to keep internal and external experts up to date with the evolutions in the EU. The cooperation project with Keml already foresees tightening and further development of the legislation on biocidal products and provision of capacity building services and technical support to the Secretariat and the Commission. However, ECHA and other Member States' competent authorities could also provide training (focused on risk assessment for physical and chemical properties, efficacy assessment, human health, and environmental risk assessment) for developing competencies of the MoHSP staff and external experts, who are likely to provide technical and scientific support. Furthermore, the development of competencies could be further strengthened by the assessment and provision of comments on the work carried out by other MSCAs and ECHA. Table 13 shows the conformity of the objective to the SMART criteria.

<sup>29</sup> [https://www.legislationline.org/download/id/4520/file/Albania\\_civil%20service%20law%202013\\_en.pdf](https://www.legislationline.org/download/id/4520/file/Albania_civil%20service%20law%202013_en.pdf)



**Table 13 – Objective 11: Provide training and capacity building**

Criteria	Notes
<b>Specific</b>	It is recommended that the MoHSP addresses the lack of expertise in risk assessment and other technical and scientific areas by opting for a hybrid system. It is recommended that the MoHSP surveys the needs of their staff and external experts and organise and implement training and capacity building courses.
<b>Measurable</b>	Actions laid out in Section 2.2.4 are implemented. A capacity-building plan is developed and established, covering the period 2022-2026.
<b>Achievable</b>	The capacity building plan should be developed in coordination with ECHA and other MSCAs, highlighting where these entities could provide additional training and support.
<b>Relevant</b>	Capacity building is key for filling any gaps in competencies and maintaining current skills up to date.
<b>Time-bound</b>	Continuous, starting as soon as possible and following the hiring of new staff. The capacity building plan should cover the period 2022-2026.

### 2.3.6.3 Estimated human and financial resources required

The cooperation project with Keml already foresees the provision of capacity building services. As discussed in Section 2.2.1, the estimation of human and financial resources required for capacity building depends on several factors, such as number of tutors involved, number of attendees, number of in-person classes vs number of remote learning sessions, travel, accommodation, and subsistence for tutors coming from abroad, necessary IT equipment, etc. Given the lack of a sustainable financing framework, the Albanian competent authority may need to continue relying on ECHA's and other European partners' technical and financial support on capacity building. As detailed in Section 2.2.1, depending on the scale of the training courses, costs may vary but could be forecast at around €100,000 per year.

### 2.3.6.4 Timeline, risks and risk mitigation measures

ECHA and other European partners will most likely continue supporting Albania's competent authorities over the coming years, and there is a risk for Albania to develop a dependency on external resources for capacity building activities. Therefore, the establishment of a dedicated budget (Section 2.2.3) is of the utmost importance. In the short term, the ongoing COVID-19 pandemic poses an organisational and logistical challenge because training courses may need to be held remotely via webinars. ECHA has strong expertise in preparing training materials and delivering remote online courses. Even in the medium-long term, many courses could be held remotely.

## 2.3.7 Lack of a communication strategy

### 2.3.7.1 Description of the challenge and dependencies

According to EC (2020)<sup>30</sup>, the national legislation laying down the procedural norms for transparency and public participation in decision-making is in line with European standards. However, activities for improving transparency and engaging a wide range of stakeholders are just at an initial stage. More efforts are required, especially considering the low level of public awareness of chemicals and chemical safety. The review of the work by business associations, NGOs and consumer associations

<sup>30</sup> [https://ec.europa.eu/neighbourhood-enlargement/sites/default/files/albania\\_report\\_2020.pdf](https://ec.europa.eu/neighbourhood-enlargement/sites/default/files/albania_report_2020.pdf)

showed that no specific activities on this topic have been carried out, except for activities regarding the problems posed by contaminated sites across the country.

There is a need for the Albanian 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 Albanian 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 Albanian companies are ready for the single market well before the day of Albania's accession to the EU.

Finally, the publication of information on enforcement activities in chemical risk management would ensure transparency, increase confidence in competent authorities and boost compliance with regulatory requirements.

#### 2.3.7.2 Recommended actions, action owner and other relevant stakeholders

Civil society plays an essential role in the process of European integration of Albania. Proactive civil society organisations are important actors in the implementation of public policies. However, EC (2020) notes that the current legal environment in Albania does not favour financing of civil society organisations, which may result in a narrower focus on chemicals and chemical safety in these organisations' activities.

It is recommended that **the competent authorities develop and implement a communication plan** for the next five years (2022-2026). This could address the following:

- The organisation of workshops and events, including identification and selection of topics of interest for the Albanian 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:
  - Official MTE and MoHSP webpages, including webpages of relevant helpdesks, 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 that could be relevant for Albanian companies, could also be provided on websites.

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

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

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

**Table 14 – Objective 12: Develop a communication strategy**

Criteria	Notes
<b>Specific</b>	It is recommended that the competent authorities develop and implement a communication strategy to keep stakeholder engagement and increase transparency.
<b>Measurable</b>	A communication strategy is developed and implemented.
<b>Achievable</b>	The careful design of the strategy allows for avoiding misuse of funding. The MTE and the MoHSP may not have the in-house expertise and therefore may consider outsourcing the process. It should be noted that the cooperation project with Keml will investigate the possibility of involving industry sector organisations, trade unions and other stakeholders in the communication activities. In addition, it foresees stakeholder engagement and public awareness-raising activities.
<b>Relevant</b>	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.
<b>Time-bound</b>	It is recommended that the competent authorities start drafting a communication plan for the next five years (2022-2026). This would allow earmarking necessary resources. The plan should clearly identify the target audience, needs and optimal communication channels.

### 2.3.7.3 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 a part of the job description. Currently, there are no employees allocated to the helpdesk services at the MTE, and all staff are involved in the process depending on the workload. However, it is recommended to appoint a dedicated member of staff to the duties of the helpdesk. This is discussed in more detail in Section 2.3.4 of the report.

Given the lack of a sustainable financing framework, the Albanian 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.<sup>31</sup>

<sup>31</sup> Keml (2016): Chemical risk management in Serbia. Final report for 2008 to 2015; and Keml (2018): Chemical risk management in Serbia. Annual report 2017.

#### 2.3.7.4 Timeline, risks and risk mitigation measures

The MTE and the MoHSP should start planning for the resources necessary to develop the plan: survey the needs, find the optimal communication channels, and implement the strategy by organising the communication activities. The support of ECHA and other European partners for capacity building is unlikely to waver over the coming years. However, there is the risk for Albania 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.

Communication activities and cooperation with stakeholders such as the EDEN Centre<sup>32</sup> have already been established by MTE, for example, on the development of the first report on the monitoring of the EU approximation and negotiation processes for Chapter 27<sup>33</sup>. Such initiatives should be reiterated and strengthened in the future. It is also recommended that staff at both helpdesks collaborate in preparing annual communication work plans.

### 2.3.8 No information on the extent, use and effectiveness of the public consultation feedback mechanisms

#### 2.3.8.1 Description of the challenge and dependencies

Law No. 146/2014 for Notification and Public Consultation<sup>34</sup> (hereinafter referred to as "Law on Public Consultation") regulates "the notification process and public consultation on draft laws, draft national and local strategic documents as well and policies of high public interest". It sets out the procedural rules to guarantee transparency and public participation in policymaking and decision-making by the public bodies in Albania. As required by the Law on Public Consultation, the MTE needs to publish drafts of new laws and by-laws on the web page for public consultation, giving the industry and other stakeholders some time to comment on the legal acts. However, comments are rarely submitted during these public consultation periods. The Law also requires reporting on how feedback received from civil society organisations is taken into consideration.

According to UNECE (2018), comments received at public consultations should be addressed by the team working on the legislation, and they are required to summarise how the comments were dealt with in the report for the Prime Minister's Office. In addition, in 2016 (DCM No. 653 dated 14.09.2016), amendments were introduced to the Regulation of the Council of Ministers to require that all draft legislation submitted to the Council of Ministers by public institutions include a summary of public comments and how they were addressed or not as part of the accompanying information (UNECE, 2018).

To foster stakeholder engagement, the MTE has created steering committees and has invited the Chamber of Commerce and other parties to participate in them. The authorities have also established two websites to facilitate the access to information and the participation of the public in the decision-making process:

- The National Agency for Information Society (NAIS), based on Law no. 119/2014 "On the right to information" and Law no. 146/2014 "On notification and public consultation", built the system, which serves as a place of consultation between citizens and decision-making institutions in Albania and can be accessed on <https://www.konsultimipublik.gov.al/>.

<sup>32</sup> <http://www.eden-al.org/index.php/al/>

<sup>33</sup> [http://www.eden-al.org/images/Publikime/GREEN27\\_The\\_Alternative\\_view\\_of\\_environmental\\_progress.pdf](http://www.eden-al.org/images/Publikime/GREEN27_The_Alternative_view_of_environmental_progress.pdf)

<sup>34</sup> [http://partnersalbania.org/wp-content/uploads/2016/01/Ligj\\_nr.146\\_2014\\_Per\\_njoftimin\\_dhe\\_konsultimin\\_publik-1.pdf](http://partnersalbania.org/wp-content/uploads/2016/01/Ligj_nr.146_2014_Per_njoftimin_dhe_konsultimin_publik-1.pdf)

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- The portal to request information from the authorities has been established (<https://www.pyetshtetin.al/home/>). It is a joint initiative of the Information and Data Protection Commissioner (IDP) and the Open Society Foundation for Albania. This portal aims to help all citizens easily find public information drafted by all public authorities pursuant to Law 119/2014 "On the right to information" and provides the possibility to track the process and complain if the information provided is not adequate or satisfactory.

The Information and Data Protection Commissioner is the institution responsible for monitoring the practical implementation of Law no. 119/2014 "On the right to information" by authorities.

Although the formal procedures to ensure access and transparency of information are in place, stakeholders reported that the process could be improved. It is often not clear how the feedback provided by the public is considered in the decision-making process, and there is no information on the extent, use and effectiveness of the feedback mechanisms. This results in low interest and participation in consultations on new legislative proposals and amendments in the chemical risk management area.

The 2021 activity plan developed by Keml in cooperation with the Albanian authorities foresees some stakeholder engagement and public awareness-raising activities.

### 2.3.8.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the National Agency for Information Society implements regular reporting on how feedback received from stakeholders is taken into consideration** as laid out in Law on Public Consultation. The latest National Plan for European Integration (NPEI) 2021-2023 indicates the need to improve the public participation and consultation process in decision making, especially at a local level. However, despite the plan recognising the need to increase the state budget for Environment and Climate Change, it had been further reduced in 2019.

The information on the use, extent and effectiveness of the public consultation stakeholder feedback could be regularly published on <https://www.konsultimipublik.gov.al/>, established by NAIS to facilitate the possibility for the participation of the public in the decision-making process. Table 15 shows the conformity of the objective to the SMART criteria.

**Table 15 – Objective 13: Regular reporting on stakeholder feedback**

Criteria	Notes
<b>Specific</b>	It is recommended that the National Agency for Information Society implements regular reporting on how feedback received from stakeholders is taken into consideration as laid out in Law on Public Consultation.
<b>Measurable</b>	The way the feedback in public consultations is used is available online, preferably on the NAIS website established to facilitate access to information and the public's participation in the decision-making process.
<b>Achievable</b>	The online platform that could be used for regular reporting is already established. Allocation of financial resources may be required.
<b>Relevant</b>	The NPEI 2021-2023 indicates the need to improve the public participation and consultation process in decision-making. Effective public consultations may lead to higher stakeholder engagement and more efficient implementation of the EU Regulation.
<b>Time-bound</b>	Starting from the year 2022.

### 2.3.8.3 Estimated human and financial resources required

As recommended, the reporting of the use of public consultations feedback could be published on the NAIS website. Hence, the financial and human resources necessary for the establishment of a new reporting platform could be avoided. Nevertheless, the reporting of such information would require resources at the MTE and NAIS, which would likely depend on the number of public consultations, their scope, the number of comments from participants, and other factors. However, according to amendments to the Regulation of the Council of Ministers, all draft legislation submitted to the Council of Ministers by public institutions must include a summary of public comments and how they were addressed; hence the resources required for this task should have already been foreseen by competent authorities.

### 2.3.8.4 Timeline, risks and risk mitigation measures

It is recommended that the reporting of how the feedback from stakeholders is taken into consideration during public consultations starts as soon as possible as required by the Law on Public Consultations in order to improve public participation in decision-making processes and raise stakeholder and public awareness on chemical risk management.

## 2.3.9 Gaps in IT infrastructure, policies and procedures

### 2.3.9.1 Description of the challenge and dependencies

So far, the competent authorities have not been able to provide any specific information on the IT infrastructure and security procedures necessary to deal with information on chemical risk management need to be developed.

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<sup>35</sup>. This declaration (Unified Declaration of Commitment) and associated Standard Security Requirements (SSR) grant access to:

- The ECHA REACH-IT system;
- The IUCLID<sup>36</sup> 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 UCLID Member State database (BPR); and
- The Interact Portal, Platform for Authorities (REACH/CLP).

A slightly modified version of the declaration and the SSR apply to grant access to the ECHA Poison Centre Notification searchable database (PCN Database) and the secure electronic tool for exchanging information called eDelivery. Access to ECHA's Information Systems is only allowed when the organisation complies with the standard security requirements and the additional requirements for teleworking and information sharing with contractors. The declaration requires the competent authorities to seek regular external or internal audits of the respective security requirements, and a

<sup>35</sup> ECHA Management Board Decision 59/2019: Revised Decision of The Management Board on the Adoption and Scope of Application of Unified Declarations of Commitment by a Member State Competent Authority/Mandated National Institution/Designated National Authority of a Member State and the European Commission with Respect to Security Aspects for ECHA's Information Systems.

<sup>36</sup> 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/>)

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 MTE has an IT department dealing with system and network security, and it is expected that the physical security of the premises that will be used to access ECHA's information systems from the day of accession may be already effectively ensured by the measures in place.<sup>37</sup> Moreover, the Office of Chemicals will receive support from the Agency for Security of Information. At the moment, the Office of Chemicals staff has no training on IT security procedures and how to deal with confidential documents. However, the Office of Chemicals is working with the Agency for Security of Information on preparing security procedures.

Albania is progressing with work on the digital agenda strategy and e-government services. In particular, the Law on cybersecurity is partially aligned with the EU Directive on the security of network and information systems. In addition, Albania has established a list of critical information infrastructures and the necessary implementing legislation. In 2019, the National Authority for Electronic Certification and Cyber Security (NAECCS) drafted a national cybersecurity strategy that still needs to be adopted (EC, 2020).

### 2.3.9.2 Recommended actions, action owner and other relevant stakeholders

As a first step, it is recommended that **the Albanian competent authorities contract an external audit of IT infrastructure, safety policies, procedures, and measures**. Furthermore, it is recommended that **the Office of Chemicals and the MoHSP provide training for the staff on IT security procedures and how to deal with confidential documents**. In addition, it is recommended that **the competent authorities nominate a Security Officer** within their staff members or the IT staff, who will be the primary security contact point for ECHA, also in the context of any security matter related to all workstations and devices used to access the IT system.<sup>38</sup> The security officer must make sure that sufficient security training and awareness briefings are arranged. The security officer must also ensure that security is continuously promoted so that users are aware of relevant security rules and requirements, understand related security threats and risks and have a good knowledge of the meaning of their everyday actions to security.

Furthermore, it is recommended to **implement a new formal non-public information management policy to bring the current practices in line with ECHA's SSR**. This is to ensure the safe storage, transmission, and destruction of confidential information. Importantly, it is

<sup>37</sup> 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.

<sup>38</sup> 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.

recommended to **establish a security awareness programme, including introduction and regular security training for all employees. A teleworking security policy is also necessary to guarantee the protection of non-public information.** Finally, it is recommended that **the Albanian competent authorities carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures.**

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

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

Table 16 shows the conformity of the objective to the SMART criteria.

**Table 16 – Objective 14: Align IT infrastructure, policies and procedures with ECHA's standards**

Criteria	Notes
<b>Specific</b>	It is recommended that the MTE aligns the IT infrastructure, policies and procedures with ECHA's standards.
<b>Measurable</b>	IT infrastructure and security procedures are aligned with ECHA's SSR.
<b>Achievable</b>	Allocation of financial resources may be required.
<b>Relevant</b>	Without IT security policies and procedures in place, the Office of Chemicals could not gain access to ECHA's information systems.
<b>Time-bound</b>	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 Office of Chemicals and the MoHSP are likely to have positive impacts on the confidence of businesses towards the capacity of the Albanian competent authorities.

### 2.3.9.3 Estimated human and financial resources required

It is recommended that the existing IT staff at the Office of Chemicals and MoHSP 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 €10,000 (accounting for four employees at the Office of Chemicals and a minimum of six employees at MoHSP): approximately €5,000 for the workstations at the Office of Chemicals and MoHSP and other €5,000 for personal devices to enable remote working unless policies allowing work laptops to be used from home are implemented).

The provision of assistance by ECHA or one MSCA on the preparation of a formal non-public information management policy, a security awareness programme and a teleworking security policy may entail around 20 workdays (0.1 FTEs) and four meetings in Albania for a total cost of €25,000.<sup>39</sup>

<sup>39</sup> Including allowances, project management, accommodation and travel costs.



The cost of an external IT audit depends on a number of factors and, in particular, on the size and complexity of the IT environment to be audited. It is recommended the competent authorities earmark around €1,000-€5,000 for the first audit.<sup>40</sup> The competent authorities should allocate a rolling budget for the required periodic audits.

#### **2.3.9.4 Timeline, risks and risk mitigation measures**

Policy and procedures need to be in place by the day of accession. However, the establishment of policies and procedures about the security of the information collected and managed by the Office of Chemicals and the MoHSP is likely to boost the confidence of businesses in the capacity and trustworthiness of the Albanian competent authorities.

There is a lack of relevant expertise among the MTE and MoHSP staff. Therefore, it is recommended that the competent authorities commission first external audits by a specialised IT security consultancy, which could also provide the first classes of the security awareness programme and prepare the material for the introductory and regular IT security briefings.

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<sup>40</sup> The cost for an IT security audit may range from €5,000 to €10,000. See for example: <https://www.itgovernanceusa.com/iso27001-certification-costs>, <https://www.getastra.com/blog/security-audit/how-much-does-an-it-security-audit-cost/>, <https://resource.optimalnetworks.com/blog/2014/11/13/cost-of-it-audit>. To account for the different price levels, these prices have been divided by 5.

## 3 Conclusions and recommendations

### 3.1 Recommended actions and prioritisation

The main challenge facing Albanian authorities is the lack of resources necessary to implement and enforce the national legislation on chemicals and biocidal products. However, in order to strengthen the administrative capacity and enable the implementation of recommended actions (Table 17), some underlying drivers need to be addressed first. These are beyond the remit of the Office of Chemicals within the Ministry of Tourism and Environment and the Ministry of Health and Social Protection and are instead actions that should be taken by the Government of the Republic of Albania.

A **dedicated budget for chemical risk management** activities needs to be established to ensure that adequate financial resources are available to fund new job positions within the MTE and the MoHSP or contract external experts for support. Therefore, the **national legislation on administrative fees should be aligned with the EU Regulations and principles**, and the revenue from fees paid by industry applicants for the work carried out by the competent authorities **ring-fenced for chemical 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 the outsourcing of some workstreams (e.g. efficacy, human health and environmental risk assessment) and avoid overload at the MoHSP (Section 16.2.4). It is recommended that these actions are given priority and are implemented as soon as possible.

The above measures would allow hiring new staff, strengthening the capacity of administrative staff, and outsourcing some workstreams, which would help to **tighten and further develop the legislation on biocidal products** and address some other challenges associated with an insufficient administrative capacity, such as the lack of expertise in risk assessment and evaluation of applications for authorisation of biocidal products (Section 16.3.6) or lack of expertise for the enforcement of chemical legislation (Section 16.3.3). It is recommended that the competent authorities develop and implement a **plan to retain staff**, avoid work overload and ensure adequate salaries to prevent a high staff turnover of staff.

The **Office of Chemicals should dedicate staff to National Helpdesk services**. In addition, it is recommended that the **MoHSP establishes a separate helpdesk** for the provision of information and advice to the industry on biocidal products and appoints a dedicated person to this task (Section 16.3.4). It is also important to develop and implement a **communication strategy**, which should form a part of a job description of members of staff dedicated to the helpdesk services. In addition, it is recommended that the **MTE strengthens a reporting and monitoring system of POPs-related duties** (Section 16.3.5).

Finally, it is recommended that **the IT infrastructure and the IT safety policies and procedures are upgraded and aligned with ECHA's standards** (Section 16.3.9). The MTE and the MoHSP should commission an initial external audit to identify the required measures to bring the IT system up to the standards required by ECHA.

ECHA may support the development of some of the necessary policies and procedures and provide training. ECHA and Member States' competent authorities may also offer capacity building in risk assessment and enforcement. Keml is already supporting the Albanian competent authorities in capacity building, stakeholder engagement, and public awareness-raising activities. In addition, it is recommended that **the National Agency for Information Society implements regular reporting**

**on how feedback received from stakeholders is taken into consideration** as laid out in the Law on Public Consultation to increase the transparency of competent authorities and enhance public participation in decision-making processes (Section 16.3.8). Publishing **the information on enforcement activities in chemicals risk management** may also help increase the transparency and confidence in competent authorities on the enforcement of legislation on chemicals and biocidal products (16.3.2).

Overall, it is very 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 18. Furthermore, the risks associated with each action and possible mitigation measures have been outlined and are summarised in Table 19.



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Table 17 – Action Plan

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
1. Tighten and further develop the legislation on biocidal products	!!!	2022-2023	MoHSP	MSCA	1 FTE	-
2. Strengthen the technical capacities of MoHSP	!!!	2022-2025	Gov	Institute of Public Health	5-10 FTEs	~€15,000 per year
			MoHSP			
3. Survey the needs of MoHSP staff and external experts and organise capacity building on efficacy and risk assessment	!!	2022-2023	MoHSP	MTE, NEA, Institute of Public Health	0.5 – 1 FTE (ECHA and/or MSCA)	~€100,000 per year over two years (ECHA and/or MSCA)
			ECHA			
4. Align national legislation on administrative fees with the principles of the EU Regulations	!!	2022-2023	MoHSP	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	!!!	2022-2023	Ministry of Finance with MTE and MoHSP	-	-	-
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	MoHSP	ECHA, MSCA and/or Montenegro	1.5 FTE (over a 3-year period) – 0.5 FTE per year	-
7. Report on chemical legislation enforcement activities	!!	2022-	NEA	Inspectorates	-	-
8. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants; - Promote the implementation of MoU with scientific institutes to outsource certain workstreams; - Promptly adopt the legislation enabling the better functioning of its institutions; and - Continuously build up capacity	!	2022	Gov	-	-	-
9. Capacity building on enforcement	!!!	2022 and 2025	ECHA or MSCA	Inspectorates	-	~€50,000 per year over two years (ECHA and/or MSCA)
10. Appoint resources to the helpdesk at MTE	!!!	2022-	MTE	MSCA	1 FTE	-
11. Establish a Helpdesk at MoHSP and appoint necessary resources	!!!	2022-	MoHSP	MSCA	0.5-1 FTE	-

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Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
12. Strengthening the reporting and monitoring system of POPs-related duties	!!	2022-	MTE	GEF, MSCA, ECHA	~0.1 FTE	-
13. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Albanian stakeholders that could be discussed during the events; - Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information The organisation and dissemination of information online - Allocation of resources for a multiannual plan; - Survey of the needs and topics of interest; - Identification of the communication channels; and - Implementation of the communication plan.	!!	2022-	NEA	ECHA, MSCA, CoC, NGOs	0.5 FTE	€10,000 per year (ECHA and/or MSCA)
14. Report on how feedback received from stakeholders is taken into consideration	!!!	2022-	National Agency for Information Society	-	-	-
15. Organise training courses on IUCLID	!	2022	ECHA	MTE, MSCA, CoC	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
16. Upgrade IT infrastructure	!	2022	NEA	ASI	-	€10,500 (one-off) ~€100 per workstation (running costs: licenses, software upgrades, etc.)
17. Provide training to the existing IT staff within the NEA and MOHSP staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		2022	ECHA	ASI, NEA	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
18. Develop an information security policy		2023	NEA	ASI, ECHA	0.1 (NEA) + 0.1 (ECHA and/or MSCA)	€25k (ECHA and/or MSCA)
19. Develop formal non-public information management policy in line with ECHA's SSR		2023	NEA	ASI, ECHA		
20. Establish a security awareness programme, including introduction and regular security training for all employees.		2023	NEA	ASI, ECHA		
21. Establish a teleworking security policy		2023	NEA	ASI, ECHA		

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Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
22. Contract an external audit of the safety policies, procedures and measures		2022	NEA		-	€5,000 in 2022
23. Carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures		2022-	NEA		-	€5,000 every 3 years for external audits
24. Hand-on training on ECHA e-tools	!	2025	ECHA	MSCA, MoHSP, MTE	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)

Notes:  
 ASI: Agency for Security of Information; CoC: Chamber of Commerce; Gov: Government of the Republic of Albania; MTE: Ministry of Tourism and Environment; MoHSP: Ministry of Health and Social Protection; MSCA: Member State Competent Authorities; NEA: National Environment Agency

Table 18 – Gantt chart and resource allocation

Action	2022	2023	2024	2025	2026
1. Tighten and further develop the legislation on biocidal products	0.5 FTE	0.5 FTE			
2. Strengthen the technical capacities of MoHSP	+1 FTE €5k	+1 FTE €10k	+1 FTE €15k	+1 FTEs €20k	+1 FTE €25k
3. Survey the needs of MoHSP 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	0.25 FTE €40k			
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. Report on chemical legislation enforcement activities	-	-	-	-	-
8. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants; - Promote the implementation of MoU with scientific institutes to outsource certain workstreams; - Promptly adopt the legislation enabling the better functioning of its institutions; and - Continuously build up capacity	-				
9. Capacity building on enforcement	€50k			€50k	
10. Appoint resources to the helpdesk at MTE	1 FTE	1 FTE	1 FTE	1 FTE	1 FTE
11. Establish a helpdesk at MoHSP and appoint necessary resources	1 FTE	1 FTE	1 FTE	1 FTE	1 FTE



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Action	2022	2023	2024	2025	2026
12. Strengthening the reporting and monitoring system of POPs-related duties	0.1 FTE	0.1 FTE	0.1 FTE	0.1 FTE	0.1 FTE
13. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Albanian 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 (ECHA or MSCA)	0.5 FTE €10k NEA	0.5 FTE €10k (NEA)
14. Report on how feedback received from stakeholders is taken into consideration	-	-	-	-	-
15. Organise training courses on IUCLID	0.1 FTE €50k				
16. Upgrade IT infrastructure	€10k				
17. Provide training to the existing IT staff within the NEA and MOHSP staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.	0.1 FTE €50k				
18. Develop an information security policy		0.1 (NEA) + 0.1 (ECHA and/or MSCA)			
19. Develop formal non-public information management policy in line with ECHA's SSR					
20. Establish a security awareness programme, including introduction and regular security training for all employees.					
21. Establish a teleworking security policy		€25k (ECHA and/or MSCA)			
22. Contract an external audit of the safety policies, procedures and measures	€5,000				
23. 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		€5,000			€5,000
24. Hand-on training on ECHA e-tools				0.1 FTE €50k	
<b>Totals</b>					
ECHA or MSCA	0.7 FTEs ~€300k	1 FTE ~€150k	-	0.1 FTE €100k	
MoHSP	~2 FTEs (+1 FTE) <sup>41</sup>	~2 FTEs (+1 FTE)	1.5 FTEs (+1 FTE)	1 FTE (+1 FTEs)	1 FTE (+1 FTE)

<sup>41</sup> ~2 FTEs are required for recommended actions plus 1 additional FTE to increase the capacity of the MoHSP.

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Action	2022	2023	2024	2025	2026
	€5k	€10k	€15k	€20k	€25k
NEA/MTE	~1.5 FTEs €25k (€10k by ECHA or MSCA)	~1.5 FTE €40k (€35k ECHA or MSCA)	~1.5 FTE €10k (ECHA or MSCA)	~1.5 FTE €10k NEA	~1.5 FTE €15k (NEA)

**Table 19 – Risks and risk mitigation measures**

Action	Risk	Risk Mitigation Measures
1. Tighten and further develop the legislation on biocidal products	Delays	The Commission and ECHA stress the importance of aligning the national legislation with the BPR
2. Strengthen the technical capacities of MoHSP	The government does not agree and may not fund the necessary resource increase.	The Commission and ECHA note that Albania would not be deemed ready to fulfil EU obligations and responsibilities without the administrative capacity for implementing the Regulations.
3. Survey the needs of MoHSP 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 The MoU is not ratified on time High staff turnover	Support of ECHA or MSCA Remote learning Actions: 1. Tighten and further develop the legislation on biocidal products 6. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities
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: 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	Action: 4. Align national legislation on administrative fees with the principles of the EU Regulations
7. Report on chemical legislation enforcement activities	No exchange of information between the relevant departments	A central digital system to exchange information is in place
8. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants;	Lack of resources	Albania should progress with Public Administration Reform and advance preparations to adopt a salary policy for civil servants.





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Action	Risk	Risk Mitigation Measures
<ul style="list-style-type: none"> <li>- Promote the implementation of MoU with scientific institutes to outsource certain workstreams;</li> <li>- Promptly adopt the legislation enabling the better functioning of its institutions; and</li> <li>- Continuously build up capacity</li> </ul>		
9. Capacity building on enforcement	Lack of resources Loss of expertise because of high staff turnover	Support of ECHA or MSCA Actions: 8. Develop a plan to retain staff
10. Appoint resources to the helpdesk at MTE	Lack of resources	Develop and formalise procedures for helpdesk services and communication strategy Nominate person responsible for these tasks
11. Establish a helpdesk at MoHSP and appoint necessary resources	Lack of resources	Develop and formalise procedures for helpdesk services and communication strategy Nominate person responsible for these tasks
12. Strengthening the reporting and monitoring system of POPs-related duties	Lack of resources	Develop and formalise procedures on reporting every year Nominate person responsible for this action
13. Development and implementation of a communication plan: <ul style="list-style-type: none"> <li>- Organisation of workshops and events, including identification and selection of topics of interest for the Albanian stakeholders that could be discussed during the events;</li> <li>- 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</li> <li>- The organisation and dissemination of information online;</li> <li>- Allocation of resources for a multiannual plan;</li> <li>- Survey of the needs and topics of interest;</li> <li>- Identification of the communication channels; and</li> <li>- Implementation of the communication plan.</li> </ul>	Lack of resources  Lack of expertise	Actions: 4. Align national legislation on administrative fees with the principles of the EU Regulations Communication activities are part of the job description for the person responsible for the helpdesk ECHA or MSCA support.
14. Report on how feedback received from stakeholders is taken into consideration	Delays	The Commission stresses the importance of the transparency of the decision-making process and stakeholder engagement.
15. Organise training courses on IUCLID	Lack of resources COVID-19 pandemic Loss of expertise because of high staff turnover	Support of ECHA or MSCA Remote learning Actions: 8. Develop a plan to retain staff
16. Upgrade IT infrastructure	Lack of resources	



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Action	Risk	Risk Mitigation Measures
17. Provide training to the existing IT staff within the NEA and MoHSP staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.	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 MTE 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.
18. Develop an information security policy		
19. Develop formal non-public information management policy in line with ECHA's SSR		
20. Establish a security awareness programme, including introduction and regular security training for all employees.		
21. Establish a teleworking security policy		
22. Contract an external audit of the safety policies, procedures and measures		
23. 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		
24. Hand-on training on ECHA e-tools		

### 3.2 Similarities in gaps and shortcomings between Albania and other 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, online) 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;

Action Plan

- ECHA and/or other Member State competent authorities provide training and capacity building in the following areas:
  - Evaluation of applications for authorisation of biocidal products, in particular on efficacy and human health and environmental risk assessment;
  - Use and functioning of ECHA e-tools for information storage, management and sharing;
  - Information security procedures;
  - Enforcement best practices;
  - Dissemination of information, development of a communication strategy and 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
<b>ASI</b>	Agency for Security of Information
<b>ASO</b>	Accredited Stakeholder Organisation
<b>ASPA</b>	Albanian School of Public Administration
<b>ATPs</b>	Adaptations to technical progress
<b>BPD</b>	Biocidal Products Directive
<b>BP</b>	Biocidal Product
<b>BPC</b>	Biocidal Product Committee
<b>BPR</b>	Biocidal Products Regulation
<b>CARACAL</b>	Competent authorities for REACH and CLP
<b>CBI</b>	Confidential Business Information
<b>CG</b>	Coordination group
<b>CLH</b>	Harmonised classification and labelling
<b>CLP</b>	Classification, Labelling and Packaging
<b>CoRAP</b>	Community Rolling Action Plan
<b>DCM</b>	Decision of the Council of Ministers
<b>DPS</b>	Directorate of Product Supervision
<b>DPSED</b>	Directorate for Policy and Strategies for the Environmental Development
<b>EC</b>	European Commission
<b>ECAT</b>	Environmental Centre for Administration and Technology
<b>ECHA</b>	European Chemicals Agency
<b>ECRAN</b>	Environment and Climate Regional Accession Network
<b>EDEN</b>	Environmental center for Development Education and Networking)
<b>e-PIC</b>	Prior Informed Consent IT System
<b>EU</b>	European Union
<b>FTE</b>	Full-time equivalent
<b>GCD</b>	General Customs Directorate
<b>GDP</b>	Gross Domestic Product
<b>GEF</b>	Global Environment Facility of UNEP



Acronym	Full name
<b>GLP</b>	Good Laboratory Practice
<b>HBCD</b>	Hexabromocyclododecane
<b>IPEN</b>	International Pollutants Elimination Network
<b>IPA</b>	Instrument for Pre-Accession Assistance
<b>IPH</b>	Institute of Public Health
<b>ISHMT</b>	State Inspectorate of Market Surveillance
<b>IT</b>	Information Technology
<b>IUCLID</b>	International Uniform Chemical Information Database
<b>KemI</b>	Swedish Chemicals Agency
<b>LDA</b>	Local Democracy Agency-Albania
<b>MFE</b>	Ministry of Finance and the Economy
<b>MIE</b>	Ministry of Infrastructure and Energy
<b>MoHSP</b>	Ministry of Health and Social Protection
<b>MoU</b>	Memorandum of Understanding
<b>MTE</b>	Ministry of Tourism and Environment
<b>MS</b>	Member State
<b>MSCA</b>	Member State Competent Authority
<b>MSDS</b>	Documentation with safety data
<b>NADMD</b>	National Agency for Drugs and Medical Devices
<b>NAECCS</b>	National Authority for Electronic Certification and Cyber Security
<b>NAIS</b>	National Agency for Information Society
<b>NBC</b>	National Business Centre
<b>NEA</b>	National Environment Agency
<b>NGO</b>	Non-Governmental Organisation
<b>NIP</b>	National Implementation Plan
<b>NPEI</b>	National Plan for European Integration
<b>NSDI</b>	National Strategy for Development and Integration
<b>PBDEs</b>	Polybrominated diphenyl ethers
<b>PCB</b>	Polychlorinated Biphenyl
<b>PCN</b>	Poison Centre Notification
<b>PFOS</b>	Perfluorooctane sulfonate
<b>PIC</b>	Prior Informed Consent Regulation

Acronym	Full name
<b>POP</b>	Persistent Organic Pollutant
<b>RAC</b>	Committee for Risk Assessment
<b>R4BP</b>	Register for Biocidal Products
<b>REACH</b>	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>REC</b>	Regional Environmental Centre
<b>RETF</b>	Restriction Efficiency Task Force
<b>SCBP</b>	Standing Committee on Biocidal Products
<b>SDS</b>	Safety Data Sheets
<b>SEAC</b>	Socio-Economic Analysis Committee
<b>SHI</b>	State Health Inspectorate
<b>SIDA</b>	Swedish International Development Cooperation Agency
<b>SIEFWT</b>	State Inspectorate of Environment, Forest, Water and Tourism
<b>SIMS</b>	State Inspectorate for Market Surveillance
<b>SPC</b>	Summary Product Characteristic
<b>SSR</b>	Standard Safety Requirement
<b>SVHC</b>	Substance of Very High Concern
<b>TAIEX</b>	Technical Assistance and Information Exchange instrument of the European Commission
<b>UHCMT</b>	Clinical Toxicology Service of the University Hospital Centre Mother Teresa
<b>UN</b>	United Nations
<b>UNECE</b>	United Nations Economic Commission for Europe
<b>WB</b>	Western Balkans



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