Action Plan - Montenegro

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

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Contents

Executive Summary

Montenegro has developed and aligned its chemicals management system with the EU regulatory framework for more than 10 years. The national legislation is harmonised to the extent possible for an EU candidate country – i.e. without transposition of procedures that are administered centrally at EU level and require EU membership. In line with the commitment to EU integration, Montenegro is making efforts to establish and implement adequate plans for the pre- and post-accession periods that would prepare both the administrative capacities and the chemicals industry for entry on the Single market.

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

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

The aim is to support Montenegro to prepare for the obligations of EU membership regarding chemical safety regulations.

The assessment identified the lack of necessary resources to implement and enforce the four Regulations as the main challenge.

Main recommendations

- *To enable the Division for Licensing and Approvals of the Agency for Nature Protection and Environment and the Administration for Inspections to fulfil their obligations and responsibilities in implementing and enforcing the four Regulations, their administrative capacities should be strengthened by allocating the necessary resources.*
- *To ensure that adequate financial resources are available to fund new job positions within the Division for Licensing and Approvals or to contract external experts for support, the revenue derived from fees and charges paid by companies applying for the authorisation of biocidal products and for the registration of substances to the Integrated e-Register should be ring-fenced and used for activities in the chemical risk management area.*
- *It is recommended that the NEPA adopts the Memorandum of Understanding with scientific institutes and external experts to facilitate the outsourcing of some workstreams and avoid overload at the DLA.*

The above measures would allow hiring of new staff and outsourcing workstreams, addressing some of the other challenges associated with insufficient administrative capacity such as the loss of expertise due to staff turnover. Avoiding work overload and ensuring competitive salaries may help in maintaining the turnover rate to natural levels.

- *The NEPA should develop an annual communication work plan. It is recommended that the organisation of communication activities is part of the job description of a new employee, who should be assigned to the provision of helpdesk and information services.*
- *It is recommended to upgrade the IT infrastructure and the IT safety policies and procedures.*

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

- *Finally, it is recommended to bring the establishment of the National Poison Centre forward, which is currently planned for 2024. This would encourage the timely transposition of Annex VIII to the CLP Regulation on harmonised information relating to emergency health response.*

Main risks

One of the main risks is that the Montenegrin competent authorities focus on "low hanging fruit", such as training and capacity building or keeping the national legislation aligned with the EU acquis, while not addressing the key issue that is at the root of many of the identified challenges: the strengthening of the administrative capacity of NEPA, which is essential to Montenegro's readiness to join the EU.

Similarities identified between Montenegro and Serbia

While Montenegro and Serbia may not be comparable from the perspective of the size of the market of chemical and biocidal products, and therefore of the administrative capacity required to fully implement and enforce the four Regulations, the two countries face similar challenges in their preparation towards accession to the EU. Both countries need to strengthen their respective administrative capacities and the underlying issues are broadly the same:

- *A moratorium on hiring civil servants was in place, although in Montenegro expired on 31 December 2020;*
- *Lack of a sustainable financing system aligned with the EU Regulations and principles;*
- *Need to ratify memorandum of understanding with scientific institutes to facilitate access to external experts.*

It is also likely that the same biocidal products are supplied in both countries, hence an enhanced collaboration may result in accelerating the authorisation process and save resources.

Montenegro could benefit from the same support received by Serbia from twinning partners in drafting a document containing recommendations for sustainable financing of biocidal products management administration. This could form the basis for a rulebook aligning the national legislation with the principles of the Biocidal Products Regulation. It is recommended that the Montenegrin authorities contact their counterparts in Serbia to explore the possibility of developing such a document.

Finally, both countries would welcome the support that ECHA or Member State competent authorities can provide in capacity building and training on risk assessment, IT security, e-tools and enforcement. There is therefore the possibility to organise the capacity building on these topics at the same time in both countries, in order to share training materials and optimise the resources allocated by ECHA or MSCAs.

1 Introduction

1.1 Context

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

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

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

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

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- Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR); and
- The recast prior informed consent (PIC) Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals.

1.2 Methodology and report structure

The report describes the identified gaps and details the actions necessary to fill them. The gap assessment draws on the information gathered through the consultation with the Montenegrin competent authorities and other national stakeholders. This has been complemented by information collected through the review of the documents and reports documenting the progress of Montenegro with the negotiations for its accession to the EU and of the National Strategy 2019-2022 on chemical management and its 2019 Action Plan implementation report.

Actions have been recommended in the following areas:

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

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

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

2 The Action Plan

2.1 Challenges and gaps identified

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

The work of the Montenegrin Authorities to align the national legislation with the EU chemical acquis has been quite successful, in particular in consideration of the continuous evolution of the European chemical legislative framework[1], and of the impossibility to introduce EU centralised procedures into the national system. The alignment of the Montenegrin legislation with the EU acquis is resource-intensive work. However, there are other underlying issues that would be beneficial to address to ensure continued progress:

Root causes

- The lack of a sustainable financial framework, due to the lack of alignment of national legislation on administrative fees with the principles of the EU Regulations;
- An expected increase of enquiries to the Helpdesk leading up to the accession and beyond;
- Lack of a Memorandum of Understanding with scientific institutes and external experts to draw on resources outside the ministry; and
- Differences between the national inventories and ECHA's inventories.

Issues and gaps

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

- **Understaffing** of the Division for Licensing and Approvals (DLA) of the Agency for Nature Protection and Environment (NEPA);
- Difficulty in resource planning, in particular for the authorisation of biocidal products;
- Lack of expertise in human health and environmental **risk assessment**;
- **Backlog** of applications for authorisation of **biocidal products**, which will need to be dealt with through the biocidal product authorisation procedures;
- High workload for existing staff;
- National Poison Centre yet to be established;
- Lack of stakeholder engagement in formal consultation on the development or amendment of rulebooks;
- Lack of capacity and alignment of existing IT infrastructure, policies and procedures with ECHA standards. In particular:
    - Lack of a non-public information management policy up to ECHA standards;
    - Lack of security awareness programme, including introduction and regular security trainings for employees;
    - Lack of teleworking security policy; and

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

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

Ultimately, all these issues could hamper the ability of Montenegrin authorities to fulfil the responsibilities and obligations in implementing and enforcing REACH, CLP, BPR and PIC Regulations.

Causes, problems, gaps and effects are further discussed in the sections below, along with the suggested remedial actions. Figure 2 presents the objective tree, with the actions to tackle the challenges and gaps identified.

When relevant, actions have been described in subsequent steps, including:

- Their dependencies;
- The identification of the body responsible for the action;
- The identification of the other relevant stakeholders who may be affected and should be involved to provide support;
- The necessary human and financial resources to implement the action;
- The suggested timeline for the action to begin and end, leading up to accession; and
- The risks and the risk-mitigation measures to support the successful implementation of the action.

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

Figure 1 – Interlinkages between causes, challenges and effects

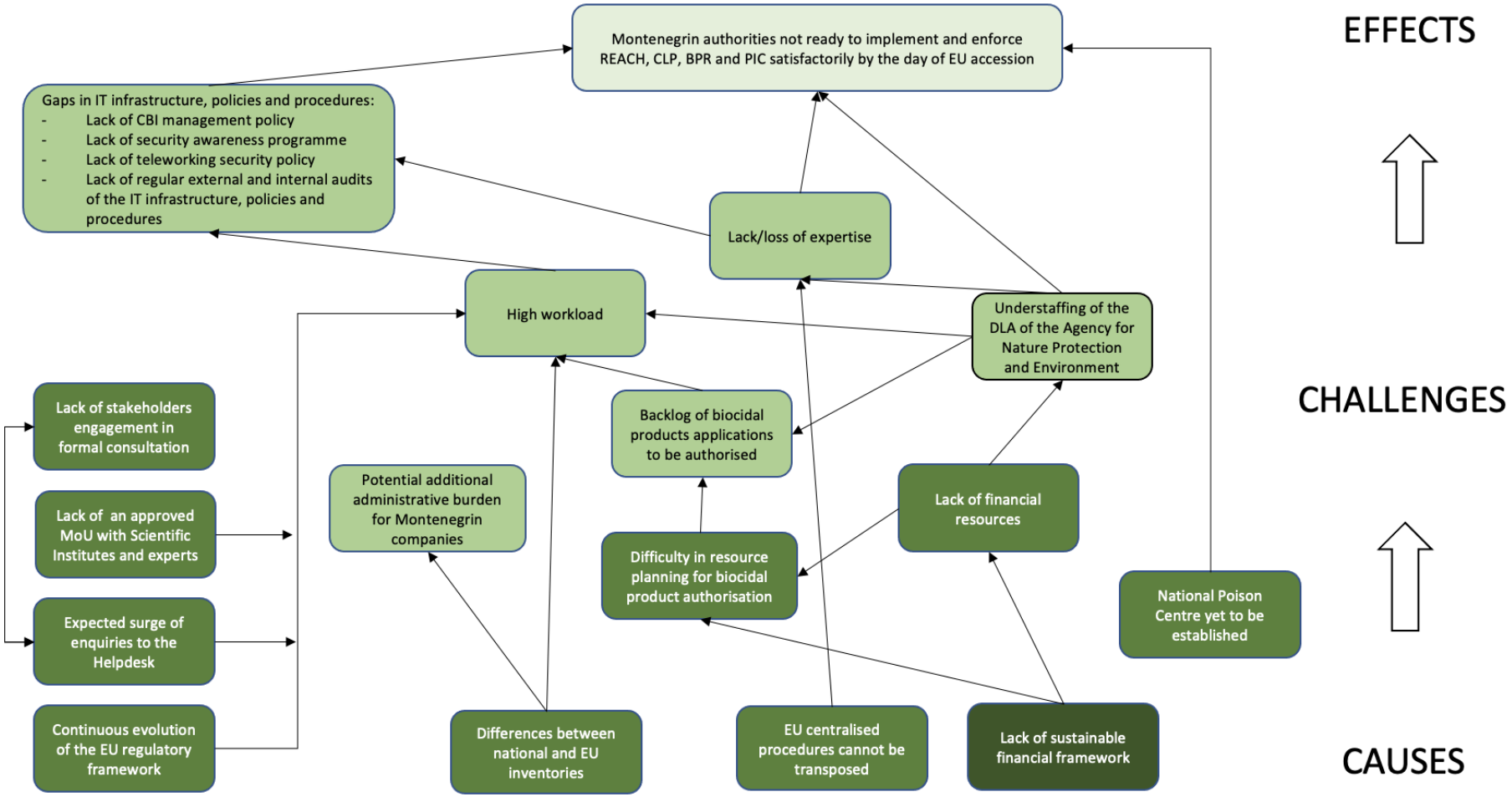
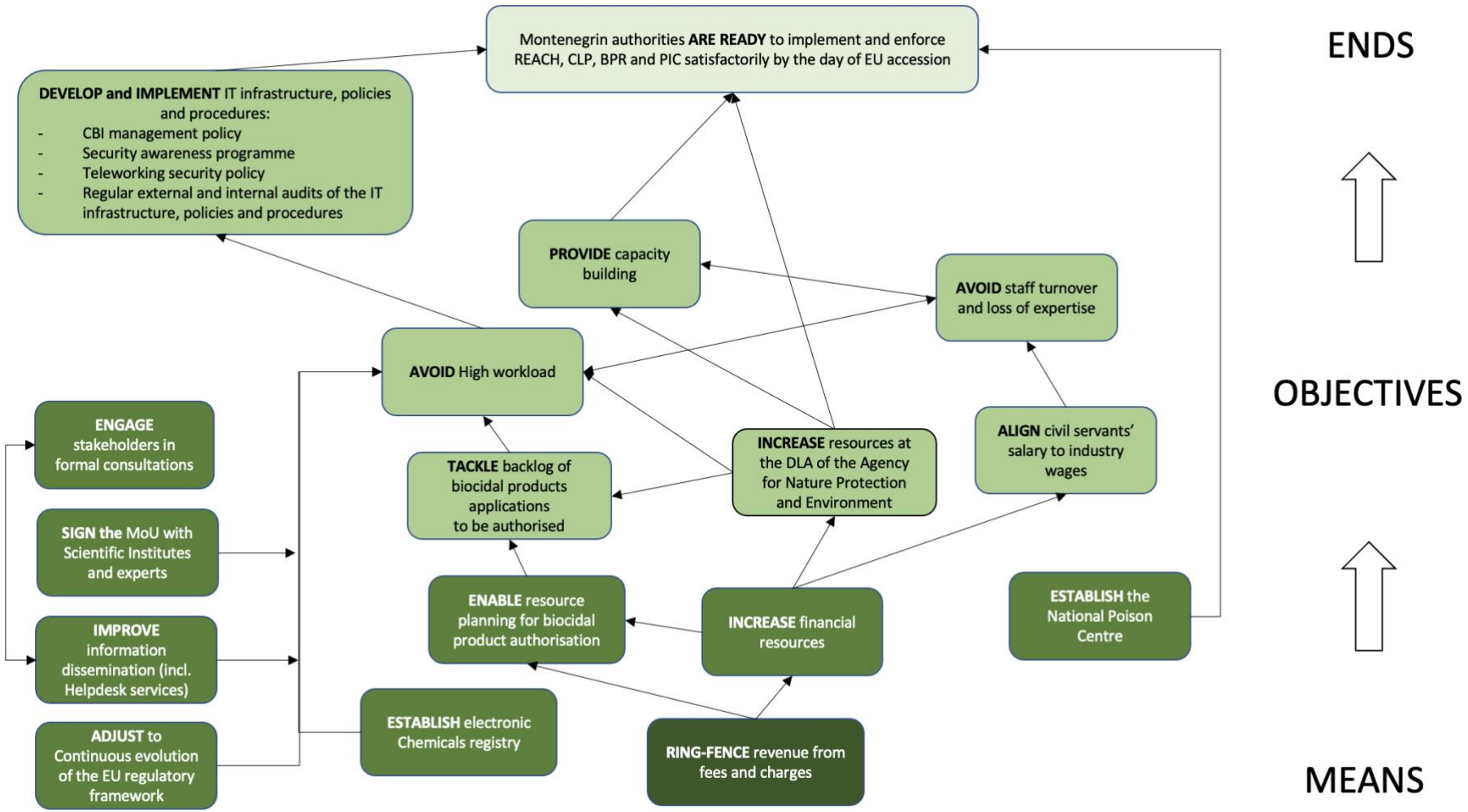


Figure 2 – Objective tree



2.2 Underlying causes and means to address them

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

2.2.1.1 Description of the challenges and dependencies

The articles of the four regulations which relate to EU centralised procedures cannot be transposed.[2] The current institutional and legislative setup focuses on strictly administrative procedures which do not necessarily require scientific expertise on risk assessment. The Montenegrin 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 staff of Division for Licensing and Approvals (DLA) of the Agency for Nature Protection and Environment (NEPA) also lack the necessary practical knowledge on how to use the ECHA e-tools such as REACH IT and IUCLID.

2.2.1.2 Recommended actions, action owner and other relevant stakeholders

The plans for strengthening institutional structures[3] note that, in order to overcome the lack of expertise and skills in the pre-accession period, a sufficient number of civil servants and external experts[4] should be adequately trained to fulfil all tasks delegated to the competent authority of a Member State. ECHA has been active in capacity building projects in Montenegro since 2012. These activities, implemented under the Instrument for Pre-accession Assistance (IPA) and funded by the European Union, provide capacity building to support the implementation of the EU chemicals legislation and cooperation with ECHA. In addition, training courses on the risk assessment of chemical and biocidal products were held as part of a project[5] funded by the Norwegian Ministry of Foreign Affairs have funded the project and implemented by the office of the United Nations Development Programme (UNDP) in Montenegro and the Office for European Integration.

It is recommended that ECHA implements additional capacity building activities focusing on risk assessment and hands-on training sessions focusing on the functioning of the e-tools used

[2] These are:

- 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, partial Annex I, Annex IV, partially Annex V and Annex VI, Annex VII;
- PIC: Partially Art 2 and Art 4, Article 5, Article 6, partially Articles 8-14, partially Articles 18-21, Articles 21- 27, partially Article 22, Articles 29- 31, partially Annex II and Annex III, Annex IV, Annex VII.

[3] MSDT (2020): Report on the implementation of the Action Plan for the implementation of the National Chemicals Management Strategy 2019-2022. Year 2019. Izvještaj o realizaciji Akcionog plana za sprovođenje Nacionalne strategije upravljanja hemikalijama 2019-2022. godina, za 2019. godinu. Crna Gora. March 2020.

[4] The target number is set on 15 participants (between civil servants and external experts) trained on risk assessment by 2021.

[5] "Capacity building to accelerate the negotiations process with the EU".

by national competent authorities to manage the information exchange with ECHA. Table 1 shows the conformity of the objective to the SMART criteria.

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

Criteria	Notes
Specific	ECHA implements additional capacity building activities focusing on risk assessment and hands-on training sessions focusing on the functioning of the e-tools used by national competent authorities to manage the information exchange with ECHA.
Measurable	Number of civil servants and external experts trained per year
Achievable	ECHA has implemented capacity building projects in Montenegro since 2012.
Relevant	Capacity building will ensure a smoother EU accession.
Time-bound	Training on risk assessment should be prioritised and possibly start in 2021. Hands-on training on e-tools could be organised closer to the day of accession.

2.2.1.3 Estimated human and financial resources required

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

As an indication, the Swedish Chemicals Agency spent around €150,000[6] and 150 workdays (around 0.7 FTE) carrying out trainings of Serbian Authorities staff in 2017.[7] In the context of the twinning project implemented by the Austrian and Slovenian competent authorities[8], the cost of the organisation and actual implementation of trainings and workshops was around €110,000. The courses, which were attended by at least two staff members from the Serbian competent authorities per session, focused on risk assessment and risk management of biocidal products. The training was organised over a period of 20 days in Belgrade and saw the participation of 11 tutors for a total of 88 workdays (around 0.4 FTE). The preparation of the training programme and corresponding training materials required around €20,000 and two meetings in Serbia, with the participation of three experts for a total of 18 workdays (0.1 FTE).

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

2.2.1.4 Timeline, risks and risk mitigation measures

It is recommended to prioritise capacity building activities focusing on risk assessment, as risk assessors are required to tackle the backlog of applications for authorisation of biocidal products (more details are provided in Section 2.3.7). Hands-on training on e-tools can be organised closer to the day of accession, also to minimise the risk of losing trained resources because of staff turnover.

[6] Around SEK 1,500,000.

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

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

2.2.2 Continuous evolution of the European chemical legislative framework

2.2.2.1 Description of the challenges and dependencies

The European chemical legislative framework is in constant evolution:

- 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;
- Adaptations to technical progress (ATPs) of the CLP Regulation are published every year;
- New approvals of active substances (Biocidal Products Regulation); and
- New substances in the annexes of the PIC Regulation.

Montenegro has substantially aligned its legislation with the EU chemical acquis. Further alignment[9] is envisaged in relation to:

- The subsequent amendments of the annexes to the **REACH** Regulation;[10]
- The amendments of Annex I to VI of **CLP**. CLP Annex VIII on harmonised information relating to emergency health response[11] has not been transposed because Montenegro has yet to establish a National Poison Centre (further details are provided in Section 2.3.6);
- The amendments of the **BPR** annexes regarding the list of active substances approved for use in biocidal products and on the basic data and the content of the technical dossiers to be submitted for inclusion of biocidal products to the Provisional List; [12] and
- The amendments of the **PIC** annexes regarding the content of Prior Informed Consent procedure for the export of chemicals (Annexes 1, 2 and 3 and Form no. 1)[13] and the list of hazardous chemicals and products prohibited for export (Annex V).[14]

2.2.2.2 Recommended actions, action owner and other relevant stakeholders

Reaching and maintaining alignment between the national legislation and the EU regulations is a resource-intensive task, which will require further resources in the years to come. The third operational objective of the National strategy for chemicals management with Action Plan 2019-2023 (MSDT, 2019) set a target of four people by 2022[15] working at the Ministry for Ecology, Spatial Planning and Urbanism (MESPU) and seven people[16] at the Agency for Nature Protection and the Environment (NEPA).

In consideration of the competing needs for additional resources for the alignment and implementation of the legislation, it is suggested to prioritise the latter and, therefore**,** it is recommended that **the Agency for Nature Protection and Environment strengthens the capacity of the Division for Licensing and Approvals (DLA).** This is further discussed in Section 2.3.1. Table 2 shows the conformity of the objective to the SMART criteria.

[9] MSDT (2020).

[10] New substances and groups of substances added to REACH Annex XVII (Regulations 2018/675, 2018/1513, 2019/1148, 2019/0957, 2018/2005); new test methods (Regulations 2019/1390 and 2017/735) and nanoforms of substances (Regulation 2018/1881).

[11] Commission Regulation (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response.

[12] Commission Implementing Decision 2020/1036.

[13] Regulations 2018/172 and 2019/330.

[14] Regulations 2018/172 and 2019/330.

[15] As of October 2020, there are 2 employees working on aligning national legislation with the EU Regulations.

[16] As of October 2020, there are 2 employees working on chemical management.

Table 2 – Objective 2: Strengthen DLA capacity

Criteria	Notes
Specific	The Agency for Nature Protection and Environment strengthens the capacity of the Division for Licensing and Approvals.
Measurable	Number of additional DLA staff members
Achievable	Further discussed in Section ***2.3.1***
Relevant	Additional capacity is key to overcome many of the identified challenges.
Time-bound	It is estimated that as of accession to the EU the DLA will require around five FTEs dedicated to the implementation of the national legislation, supported by around seven external employees.

2.2.2.3 Estimated human and financial resources required

It is estimated that as of accession to the EU the DLA will require around five FTEs dedicated to the implementation of the national legislation, supported by around seven external employees. 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 DLA are discussed in Section 2.3.1.

2.2.3 Differences between the national inventories and ECHA's inventories

2.2.3.1 Description of the challenges and dependencies

The Agency for Nature Protection and Environment of Montenegro is the institution that hosts the chemical and biocidal product inventory and receives the information by the notifiers.

Manufacturers and importers of chemical substances, individually, in mixtures or in products, manufactured or placed on the market in quantities exceeding one tonne per calendar year need to notify information for the entry into the register maintained by the Agency no later than 31 March of each year.

The application should include:

- Information on the manufacturer or importer;
- Substance identity;
- Substance classification;
- Estimated quantity;
- A report on the testing of the physical and chemical properties of the chemicals;
- A brief description of the use of the substance in the product and the use of the product;
- Other information, at the request of the Agency.

The application needs to be accompanied by proof of registration for performing this activity in the Central Register of Business Entities,[17] a chemical dossier and the safety data sheet, if required.

The chemical dossier needs to contain the following information:

[17] Or with the competent authority of the home country for foreign legal entities.

- The trade name of the chemical and the IUPAC chemical nomenclature name as well as other chemical identification;
- The quantity of the chemical placed on the market;
- How the chemical is used;
- The chemical composition.

The administrative fee for the registration of chemicals is 2 euros.

With regard to the documentation to be submitted to the Agency for the entry in the Provisional List of Biocidal Products, the information to be provided is specified in Annex 4 of the Rulebook on the content of technical dossier for biocidal products (Official Gazette No. 5/17):

- Information on the manufacturer of the biocidal product
- Information on the applicant (biocidal product manufacturer or authorised representative)
- Indication of whether the applicant is the manufacturer, importer, authorised representative, distributor
- Information on the biocidal product:
  - Trade name
  - Place of production
  - Product type (chemical or biological biocide)
  - Formulation
  - Packaging method
  - Labelling
  - Recommended shelf life
  - Quantity to be placed on the market annually
  - Whether the biocidal product is on the EU market
- Information on the active substance(s):
  - Chemical name and trade name
  - CAS and EC numbers
  - Name and address of the manufacturer
  - Degree of purity (% w/w)
  - Concentration (minimum and maximum in percentage)
  - Classification
- Information on impurities and additives (and methods used)
- Information on surfactants
- Information on the content of any other chemical substance in the biocidal product
- Information on the efficacy
- Information on the use of the biocidal product
- Information on the classification, labelling and packaging of the biocidal products

The administrative fee for the application is 2 euros plus 40 euros at the issuing of the registration number.

With regard to biocidal products, no information on the hazards and risks is required for the inclusion on the Provisional List, beyond what is provided in the safety data sheets, because there are no resources with the necessary expertise on risk assessment. In 2019, the NEPA started with the formalisation of a cooperation agreement between the Agency and external experts and institutions for the provision of professional and technical assistance for the risk assessment of biocidal products (more details are provided in Section 2.2.7).

While the Law on Chemicals requires information (including toxicological and ecotoxicological information) on chemical substances, currently the national inventory includes chemical products (mixtures). The inventory of chemical products is kept in MS Excel and is not connected to other information systems. The inventory of biocidal products has not been established yet. The NEPA is working on the establishment of an integrated electronic chemical and biocidal product register, which should use the software application IUCLID (International Uniform ChemicaL Information Database).[18] Since its version 6, which implements the OECD Harmonised Templates, IUCLID provides a common format, for both regulatory authorities and industry, to record, store, maintain and exchange data on intrinsic and hazardous properties of chemical substances. In the European Union, IUCLID is used for REACH, CLP (including the Poison Centres Notification format specifications, and BPR. In addition, it supports the database which will contain the submitted information on Substances of Concern in articles, as such or in complex objects (Products) - SCIP. It is also being investigated to support the information requirements of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

It is expected that Montenegro will apply for IPA funding to finance the establishment of the integrated electronic chemical and biocidal product register.[19] The objective is to have the register operational by the end of 2022, at the latest. The DLA's plan for the development of the Register is, in the first phase, to ensure the proper functioning of the IT infrastructure, the adequate and safe storage of the information notified and some statistical processing of the data. In a second phase, they will test whether the system and infrastructure will enable a secure connection with the EU databases.

2.2.3.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **NEPA do not delay the establishment of the integrated e-Register of chemical and biocidal products,** which should conform with IUCLID and is currently planned by the end of 2022.[20] Following the e-Register establishment, it is recommended that **the NEPA start requesting the information necessary for the registration of chemical substances (in accordance to the Law on Chemicals)[21] and for the authorisation of biocidal products (in accordance to the Law on Biocidal Products).[22]** In addition, **it is recommended that the Montenegrin duty-holders, i.e. manufacturers and importers of chemical substances, chemical products and biocidal products, start using IUCLID to record, store, maintain and exchange the relevant information**.[23] This would facilitate the submission of the information through the IT systems of ECHA (REACH-IT, R4BP 3 and e-PIC) following Montenegro accession to the EU. It is recommended that **ECHA or Member States competent authorities organise training courses on IUCLID and, closer to the day of accession, on IT systems**. The NEPA could also link the e-Register to the Environmental Information System,[24] where statistics and reports on chemicals and chemical risk management could also be published.

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

[19] Within the IPA project IPA/2016/37896/01/ME/Environment and Climate Action, an activity was dedicated to the establishment of the integrated electronic chemical and biocidal product register. However, in agreement with the European Commission, the funds have been diverted to the response to the COVID-19 pandemic.

[20] MSDT (2020), operational objective 2.

[21] Official Gazette of Montenegro No. 51/17.

[22] Official Gazette of Montenegro No. 54/16.

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

[24] https://eis.epa.gov.me

Table 3 – Objective 3: Establish the Register of chemicals and biocidal products in accordance with ECHA/EU requirements

Criteria	Notes
Specific	The NEPA do not delay the establishment of the integrated e-Register of chemical and biocidal products. The NEPA start requesting the information necessary for the registration of chemical substances (in accordance to the Law on Chemicals) and for the authorisation of biocidal products (in accordance to the Law on Biocidal Products). The Montenegrin duty-holders, i.e. manufacturers and importers of chemical substances, chemical products and biocidal products, start using IUCLID to record, store, maintain and exchange the relevant information. ECHA or Member States competent authorities organise training courses on IUCLID and, closer to the day of accession, on IT systems.
Measurable	The integrated register is established. DLA staff and Montenegrin manufacturers and importers of chemical and biocidal products are trained on the use of IUCLID.
Achievable	Establishment of the register will be carried out with part of the new IPA III-A Technical Support project. Training materials on IUCLID is available online.
Relevant	Establishment of the register of chemicals is necessary for adequate storage and adequate statistical processing of data on chemicals on the Montenegrin market. The use of IUCLID would facilitate the submission of the information to ECHA at a later stage.
Time-bound	The e-Register shall be operational by the end of 2022.

2.2.3.3 Estimated human and financial resources required

The establishment of the electronic Chemical Register will be financed through a sub-activity of the new IPA III-A Technical Support Project.

The training of industry stakeholders on the use of IUCLID could be carried out either remotely or through courses to be organised in Podgorica. Training material on IUCLID and R4BP (including video-tutorials and webinars) is already available online on ECHA website[25]. Some of the training material could be translated and the video-tutorials and webinars could be subtitled in Montenegrin.

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

2.2.3.4 Timeline, risks and risk mitigation measures

The electronic Chemical Register shall be operational by the end of 2022. Montenegrin companies, future duty-holders of the EU regulations, should start using IUCLID as soon as possible, to familiarise themselves with the software. The Montenegrin authorities, with the support of ECHA or Member States competent authorities, could start translating the training material available on the ECHA website. This activity could be followed by the organisation and implementation of training courses, starting from 2023. The Montenegrin authorities seek to finance the establishment of the electronic

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

Chemical Register through a sub-activity of the new IPA project. The application for funding is complex and the outcome is still uncertain. This could delay the establishment of the Register.

2.2.4 Lack of a sustainable financial framework

2.2.4.1 Description of the problem and dependencies

The human resource management and planning in public administration is significantly impacted by state budget constraints. The decision of the Government of Montenegro to set up the Eco Fund was made in November 2018,[26] and in October 2019 the Statute of the Fund for Environmental Protection (the Eco Fund) was adopted. The Eco Fund was officially established in March 2020.[27] The aim of the Eco Fund is *to provide financing and technical support to projects/programmes in the field of the environment, climate change and energy*. The Eco Fund is expected to collect funds through the application of the 'polluter pays' principle. The fund is also expected to receive revenues from the state budget, fees, loans and donations, along with EU, UN and other international organisation programmes and funds.

For the Division for Licensing and Approvals of the NEPA and for the Department for Environmental Inspection to properly fulfil the responsibilities and obligations in relation to the implementation and enforcement of the EU chemicals legislation, adequate planning and allocation of financial resources are required for the **employment** of **new staff** and the provision of **training**.

2.2.4.2 Recommended actions, action owner and other relevant stakeholders

The Public Finance Management Reform Programme 2016-2020 recognised the need to implement the best EU practices along with the medium-term budgetary framework and changes to the existing procedures. Additionally, to reflect links between budgeting and government policies, the Government of Montenegro must improve programme budgeting by following international best practice.

It is recommended that **the Government of Montenegro aligns national legislation on administrative fees with the principles of the EU Regulations**.[28] 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".

The European Commission, in accordance with article 80(2) of the BPR, has issued a guidance document[29] containing recommendations for Member States' fee structures and related procedures with a view to harmonising the latter and avoiding gaps in national methods and/or fee levels. Table 4 shows the conformity of the objective to the SMART criteria. While the Rulebook on the content of the application for a biocidal product authorisation[30] already requires the applicants to bear the costs of the work of the Biocides Assessment Commission, there is the need to define the applicable fees and charges. Moreover, it is recommended that **the Government of Montenegro creates a dedicated budget for chemical risk management activities by ring-fencing fees and charges**

[26] Official Gazette of Montenegro, No. 81/18.

[27] https://www.eko-fond.me/.

[28] 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)

[29] CA-Dec12-Doc.5.1.b – Final.

[30] Official Gazette of Montenegro 17/17.

paid by companies to register their chemical substances and to apply for the authorisation of biocidal products.

Table 4 – Objective 5: Align the national legislation on administrative fees with the principles of the EU Regulations

Criteria	Notes
Specific	It is recommended that The Government of Montenegro aligns national legislation on administrative fees with the principles of the EU Regulations and ring-fences the revenue from fees and charges by the end of 2023. This is a prerequisite to start authorising biocidal products through the mutual recognition procedure. It is recommended that the MESPU analyses how these fees and charges can be introduced in the Montenegrin legal system, and in parallel, amend the Law on biocidal products depending on the rulebook on the fees payable by companies applying for the authorisation of biocidal products. It is recommended that ECHA or a MSCA support the MESPU in defining the applicable fees and charges.
Measurable	A rulebook on administrative fees is drafted and the analysis of the introduction of the fees and charges into the Montenegrin legal system is conducted.
Achievable	There is a Commission guidance document. In addition, the MESPU could contact the Serbian authorities, who have been supported to draft a similar document during the twinning project with Austria and Slovenia.
Relevant	This is a fundamental part of the alignment of the national legislation to EU principles.
Time-bound	It is recommended to give priority to this action. The target date for the adoption of the introducing fees and charges in the Montenegrin legal system should be the end of 2023.

2.2.4.3 Estimated human and financial resources required

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 action was also supported by a preparatory advisory mission. In addition, the organisation and implementation of the preparatory advisory mission to support the Serbian Ministry of Environmental Protection in developing national fees for the services that the competent authorities provides 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).

Montenegro 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 Montenegro in defining the applicable fees and charges.

Two FTEs are currently employed by the MESPU for keeping the national chemical legislation aligned with the EU acquis. **It is recommended that 0.25 FTEs are dedicated in the period 2022-2023 to drafting the rulebook on the fees payable by companies applying for the authorisation of biocidal products and for the registration of substances to the Integrated e-Register.**

2.2.4.4 Timeline, risks and risk mitigation measures

It is recommended that the MESPU prioritises the assessment of the Montenegrin legal system for the purpose of the introduction of fees and charges, the amendment of the Law on Chemicals and of the Law on Biocidal Products and the drafting of the rulebook on the fees payable by companies applying for the authorisation of biocidal products.

One risk is that, at a time of economic slowdown, there is no political will to increase the burden on companies. However, since chemical and biocidal products on the Montenegrin market need to be properly assessed and documented to ensure efficacy and safety, the shift of the financial burden for the service provided, from taxpayers to industry is important from an economic and social perspective and in line with the EU principles.

2.2.5 Expected surge of enquiries to the Helpdesk

2.2.5.1 Description of the problem and dependencies

The Helpdesk was established in 2018 and the workload is currently shared between the two employees of the DLA.[31] Information is mainly provided via email or by phone. In 2019, the Helpdesk received 60 queries by email, of which 52 on the application for the inclusion of biocidal products to the Provisional List and eight about the import of chemicals. Assuming an average of two hours to respond to one query[32], around 0.1 FTE was spent during the year on helpdesk-related activities.

It is reasonable to expect an increase in queries during the pre-accession years and during the first years after accession. Industry stakeholders will need assistance with their new registration and authorisation obligations. The public may have questions regarding the authorised uses and restricted uses of certain substances of concern. The provision of information via email or over the phone needs to be complemented by the organisation of seminars and the publication of leaflets. Finally, the employees of the national helpdesk need to continuously keep up to date with the interpretations and conclusions on certain issues provided by other Member States, ECHA or the Commission. This requires participation in HelpNet, the network of national helpdesks, which meets twice every year.

Table 5 presents a scenario where the number of queries to the Helpdesk about REACH, CLP and BPR increases over the years leading to accession, peaking in 2024-2026 and decreasing thereafter. The number of queries on other legislation, including PIC, is assumed to remain constant over this 10-year period. The national helpdesk produces three leaflets per year (requiring 15 workdays per leaflet), organises three seminars per year (requiring 10 workdays per seminar) and participates in two HelpNet meetings per year (requiring three workdays per meeting).

Table 5 – Scenario for helpdesk workload

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Number of queries	100	150	150	150	200	200	200	150	150	150	100
Workdays	25	38	38	38	50	50	50	38	38	38	25
Subtotal - FTEs	**0.1**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.2**	**0.1**
Leaflets – workdays	45	45	45	45	45	45	45	45	45	45	45
Seminars – workdays	30	30	30	30	30	30	30	30	30	30	30
HelpNet - workdays	6	6	6	6	6	6	6	6	6	6	6
Subtotal - FTEs	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Total FTEs	**0.5**	**0.5**	**0.5**	**0.5**	**0.6**	**0.6**	**0.6**	**0.5**	**0.5**	**0.5**	**0.5**

[31] During 2020 an additional person was employed on a short-term contract.

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

In this scenario, the Helpdesk would require 0.5-0.6 FTE in the coming years to deal with the number of queries for the production of written information, the organisation of seminars and information days, and the participation in ECHA HelpNet meetings.

2.2.5.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **NEPA allocates one employee at the DLA for the Helpdesk specifically to the provision of information and helpdesk services**. The job description of the new employee should include the organisation of communication activities. The helpdesk officer could also be in charge of preparing the reports to be prepared by Member States and required by the Regulations and of communicating the relevant information to the future National Poison Centre.

It is recommended that **the Helpdesk employee receive training** to stay up to date with the interpretations and conclusions on certain issues provided by other Member States, ECHA or the Commission, as well as participating in HelpNet.

Finally, it is recommended that **the DLA uploads guidelines and FAQs to the Helpdesk webpage in order to provide relevant information to the stakeholders**. Arranging other means of information provision by the Helpdesk, e.g. organising seminars and publishing leaflets, could lead to the reduction in the amount of Helpdesk enquiries. Table 6 shows the conformity of the objective to the SMART criteria.

Table 6 – Objective 6: Allocate additional FTEs to the provision of information and helpdesk services

Criteria	Notes
Specific	It is recommended that the Agency allocates at least one FTE to the provision of information and helpdesk services in the years prior to EU accession. This is to provide information to stakeholders, reporting and deal with any increase in the number of enquiries, which could be expected close to the direct entry into force of the four EU Regulations.
Measurable	The DLA employs one Helpdesk and communication officer, who would also support other DLA workstreams.
Achievable	The objective is attainable, provided the DLA's capacity is strengthened.
Relevant	The provision of information to stakeholders is a fundamental part of the obligations and responsibilities of implementing the EU chemical legislation.
Time-bound	The target date for the allocation of 1 FTE to support the provision of helpdesk and information services is 2022.

2.2.5.3 Estimated human and financial resources required

As mentioned, the workload (around 0.1 FTE per year) is currently shared between the two employees of the DLA. The hiring of a helpdesk officer would free time for the DLA employees to carry out other administrative tasks. The financial resources required are estimated and discussed in Section 2.3.1.

2.2.5.4 Timeline, risks and risk mitigation measures

According to the scenario used to estimate the Helpdesk workload, the recommended target date for the allocation of additional resources is in 2022.

The current DLA staff can further develop and enrich the information on the Helpdesk webpage (e.g. publishing Frequently Asked Questions – FAQs – or by translating the news from the ECHA portal). The development of the Helpdesk webpage has already started, and the webpage should be enriched with new information on an annual basis.

Table 7 – Timeline for strengthening helpdesk capacity

	2020	2021	2022	2023	2024	2025
Allocate resources to Helpdesk			+1 FTE			
Upload guidelines and FAQs to the Helpdesk website						

The new employee tasked with providing Helpdesk services will need training and support. Importantly, one of the regular outputs of the HelpNet is agreed replies to FAQs. These provide more detailed information concerning guidance documents, processes and methods related to the Regulations. The FAQs are published on ECHA's Questions & Answers (Q&A) support page[33] and could be translated into Montenegrin and hosted on the DLA website.

In the short term, the possibility to organise and attend training sessions may be limited by the ongoing COVID-19 pandemic, and therefore capacity-building courses may have to be organised on online platforms and attended remotely. In addition, in the event of strict lockdowns, the functioning of the DLA and of the Helpdesk could slow down, as employees won't be able to benefit from working alongside one another. Considering the medium-long time horizon, while the same restrictions may not apply, it may still be important to ensure the possibility to work remotely. Two of the long-lasting effects of the COVID-19 pandemic are expected to be the increase in virtual engagement and the enabling role of technology.[34] The DLA should therefore develop teleworking policies and procedures (see Section 2.3.10).

The main risk however is that, due to the economic crisis following the COVID-19 pandemic, it may be difficult to find the necessary resources.

2.2.6 Lack of a memorandum of understanding with scientific institutes and external experts

2.2.6.1 Description of the problem and dependencies

The gap in the administrative capacity at the DLA and MESPU has been quantified as 11 Full-Time Equivalents per year as of the planned year of the accession to the EU (2025). This gap could be filled by hiring new employees at the DLA and by using external resources. The main area of concern is the implementation of the Biocidal Products Regulation, which is resource-intensive and requires specific expertise in risk and efficacy assessment. Montenegrin authorities have identified scientific institutes with the necessary expertise and are currently preparing a memorandum of co-operation.[35]

Areas of co-operation covered by the MoU are:

- Expert assessment of data from the dossier summaries of biocidal products for authorisations issued in EU Member States and preparation of expert opinions;
- Assessment of the technical dossiers for the biocidal products' authorisation to determine impacts on human, animal and environmental health, possible effects on target organisms, efficacy and risks during use;
- Evaluation of active substances in biocidal products;
- Chemical hazard assessment (classification, labelling and packaging) and hazard communication via label and safety data sheet;

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

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

[35] Further elaboration is currently suspended as one of the parties, the Institute of Public Health, is dealing with the COVID-19 pandemic emergency.

- Risk assessment of chemicals and biocidal products, depending on whether the risk is assessed on the basis of physicochemical properties or properties that affect human health or the environment, or assessment of the effectiveness of the biocidal products;
- Evaluation of substances in accordance with the REACH Regulation;
- Preparation and submission of dossiers for the identification of substances of very high concern;
- Education and informing of target groups and professional users about environmental protection, hazards and risks of chemicals and biocidal products.

The MoU parties will cooperate through:

- Work in expert commissions for biocide assessment;
- Design, planning and implementation of projects of mutual interest;
- Joint application for project financing with domestic and international partners and donors;
- Organisation of forums, round tables, conferences;
- Development of opinions, studies and analyses, in order to further improve knowledge in the field of safe management of chemicals and biocidal products;
- Design and implementation of educational programs and media campaigns.

It is estimated that in total seven FTEs are required to support the NEPA in all areas of co-operation mentioned above. If the scientific assessments will be largely or fully outsourced, this also implies that most of the required resources for the implementation of the EU regulations would be obtained from external parties. Therefore, it is essential that the memorandum of understanding between the Montenegrin authorities and scientific institutions is ratified in a timely manner and, subsequently, the external experts are actively and continuously engaged in supporting the DLA. Moreover, 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.[36] Training courses could be organised for both academia experts and DLA staff in, for example, future IPA and international co-operation projects (see also Section 2.3.5).

2.2.6.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **Montenegrin authorities establish long-term collaborations with scientific institutes or individual experts that could support the implementation of the four EU Regulations.**

The memorandum of understanding is currently being prepared by the NEPA. The scope of the MoU is to regulate the long-term co-operation between the Montenegrin authorities and the scientific institutes. The MoU will have to define the expected services, indicate the approximate duration of the assignments and specify the foreseen deadlines. These will have to be further detailed in specific contracts. Most likely, the MoU will have to be accompanied by non-disclosure agreements and policies and procedures for managing confidential business information will have to be described and agreed. The MoU will also have to detail penalties for the lack of quality of the services or the late delivery of the results, although it is advisable to adopt procedures for identifying problems and finding ways forward. Ultimately, the objective is to develop capacity and competences and ensure the functioning of the MoU and the smooth processing of industry applications. Table 8 shows the conformity of the objective to the SMART criteria.

[36] 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.

Table 8 – Objective 7: Establishing long-term collaborations with scientific institutes or individual experts

Criteria	Notes
Specific	It is recommended that the NEPA develop, ratify and implement a MoU with the relevant scientific institutes. The MoU should be functioning as soon as possible. In total seven external experts are recommended to be progressively engaged in providing support by 2025.
Measurable	An MoU with external experts is ratified. Number of external experts involved
Achievable	The objective is attainable by the end of 2021, provided that an agreement is reached by all parties of the memorandum of understanding.
Relevant	Support with expertise in risk assessment is particularly necessary for implementation of the BPR regulation.
Time-bound	The memorandum of understanding shall be finalised and signed by end 2021.

2.2.6.3 Estimated human and financial resources required

It is recommended that the NEPA allocates adequate resources (around 0.25 FTE) in 2021 for the finalisation of the MoU.

2.2.6.4 Timeline, risks and risk mitigation measures

The memorandum of understanding, which is currently in preparation, shall be finalised and signed by the end of 2021. To take advantage of an MoU or implement short-term contracts requires, as a prerequisite, the adoption of a dedicated budget (see Section 2.2.4). Currently, the administrative fees that would be paid by the companies in accordance with the Rulebook on the content of the technical dossier and basic data on the biocide goes to the central state budget. An additional risk is a further reduction of financial resources due to the economic slowdown triggered by the ongoing COVID-19 pandemic. According to EC (2020), early estimates foresee a 4% to 6% fall in GDP in the region. A sustainable financial framework is therefore of the uttermost importance.

2.3 Identified challenges and associated objectives

2.3.1 Understaffing of the Division for Licensing and Approvals of the Agency for Nature Protection and Environment

2.3.1.1 Description of the problem and dependencies

The third operational objective of the last report on the implementation of the Action Plan (MSDT, 2020) sets the target number of employees for the Division for Control of Industrial Pollution and Chemical Management to four, while the target for the DLA at the NEPA is seven by 2022. For the establishment of the Chemical Poison Centre (planned for 2017) within the Ministry of Health, seven new positions should have been created.

The 2019 implementation report of the National Strategy specifies that up till 2019 the Department for Environmental Inspection at the Administration for Inspection Affairs had eight environmental inspectors along with the chief inspector while five additional inspectors were planned to be hired to cover the enforcement of environmental legislation. In April 2020, the Department for Environmental Inspection still only had six inspectors, dealing with a wide range of environmental legislation.

The Public Administration Reform Strategy in Montenegro 2016-2020[37] incorporated and redefined objectives related to the downsizing of the public sector and to the improvement of personnel planning, which were earlier established in the Internal Public Sector Restructuring Plan 2013-2017. The aforementioned objectives have been included in the Public Administration Reform Strategy due to *the need for the improvement of human resources management, determining the optimal staffing level and establishing an effective system for monitoring and limiting the number of employees, as well as for measuring the quality of their work*.

In addition, the government of Montenegro has adopted the Public Administration Optimisation Plan 2018-2020 which supports the implementation of the Public Administration Reform Strategy 2016-2020. The optimisation plan, which takes into account the *efficient service delivery requirements, European accession process and state budget constraints,* also included a moratorium on employment[38]. Regardless of the moratorium, the hiring of new personnel was possible with the consent of the government cabinet. Nevertheless, despite the planned *increase* in the number of employees working on the implementation of the chemical legislation and its enforcement, the actual number of employees has *decreased* in 2020. The new government is preparing new strategies and action plans for employment and retention policies in the public administration.

In August 2020, the DLA of the Agency for Nature Protection and Environment had two employees responsible for the practical aspects of the implementation of chemical legislation. Another two employees of MESPU are responsible for aligning the national legislation with the EU *acquis on chemicals, biocides, industrial pollution and noise*.

The DLA of NEPA is currently understaffed and, if the same number of employees were maintained until the day of accession, it is highly unlikely that the division would be in a position to implement the four EU Regulations properly.

The gap in the administrative capacity has been quantified as 11 Full-Time Equivalents per year. The increase in required resources is, for the most part, driven by the need to ensure the smooth operation of the biocidal products' authorisation process. The estimate is based on the number of applications for inclusion to the Provisional List received by the Montenegrin authorities[39] and by the total number of biocidal products on the Maltese market,[40] Malta being the benchmark country, with a comparable economy and size of the chemical industry. The estimate is also based on the time required by other national competent authorities to evaluate the applications for different types of authorisation. The effective time that will be required depends on a several factors such as:

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

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

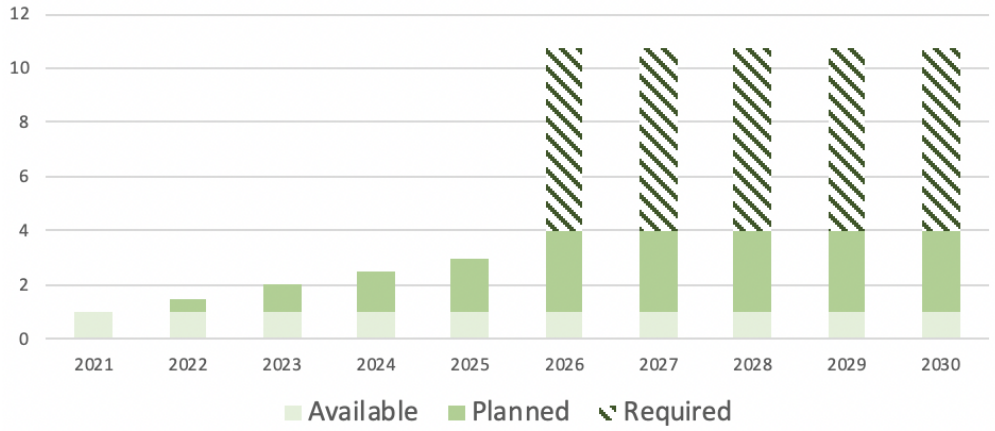
[37] Public Administration reform strategy in Montenegro 2016-2020. Issued in July 2016.

[38] Country Specific Report. Written Contribution for the 2019 Montenegro Annual Report, Chapter 15&27. Issued in 2018. Koalicija 27, Green Home, env.net. Available at: http://www.greenhome.co.me/fajlovi/greenhome/attach_fajlovi/lat/glavne-stranice/2018/12/pdf/Written_contribution_to_EU_Country_Report.pdf

[39] As of March 2019, there were 459 biocidal products in the temporary list in Montenegro.

[40] According to the Database of Registered Biocidal Products in Malta, 715 biocidal products (August 2020).

Figure 3 – Available FTEs vs planned FTEs vs necessary FTEs over the period 2021-2030 at the DLA for the management of biocidal product authorisation applications



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

- The lack of Memorandum of Understanding with academia or relevant scientific institutes (Section 2.2.6); and
- The alignment of the national legislation on administrative fees with the EU principles (Section 2.2.4).

2.3.1.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **NEPA strengthens the capacity of the DLA.** As a recommended minimum, the DLA should include: two project managers, one helpdesk support officer and one advisor responsible for PIC-related duties and for supporting the project managers in managing the work outsourced to external experts. It is important that the DLA staff has some of the expertise and capacity to carry out the assessment of the physicochemical properties and the human health and environmental risk assessment of the substances and products under evaluation, and therefore it is recommended **training and capacity building be provided to internal and external resources** in order to strengthen their competences.

The table below shows the recommended optimal mix of expertise and related competences of the internal and external resources. Montenegrin authorities have identified the scientific institutes with the necessary expertise and are currently preparing a memorandum of co-operation.

Table 9 – Recommended mix of expertise

No. of employees	Roles	Competencies
2	Head and advisor - **Department for Industrial Pollution Control and Chemicals of MESPU**	Alignment of legislation with the regulations of the EU in the fields of chemicals management and biocidal products, noise, Seveso and IED. Participation in the negotiation process with the European Union for Chapter 27. Implementation of obligations from relevant international agreements, such as Stockholm, Rotterdam and Minamata conventions. CARACAL, participation in REACH Committee and Member States Committee meetings and in seminars with industry and other stakeholders. Support in matters concerning budget and planning.
2	Project manager **(DLA)**	Responsible for detailed planning of substance evaluation, SVHC identification proposals, restriction proposals and harmonised classification and labelling proposals. He/she sets priorities and identifies critical issues,

No. of employees	Roles	Competencies
		keeps track of deadlines and used time. Develops the background documentation supporting the substance evaluation report and the proposals and communicates with ECHA and other MS competent authorities. Coordinates and takes part in checking the documentation for the biocidal product authorisation.
2	Advisor Agency of Nature and Environmental Protection **(DLA)**	PIC-related duties and issuing of licenses. Makes the evaluation of the information on the physicochemical properties of the substances under evaluation.
1	Helpdesk support **(DLA)**	Deals with the queries received, responding to the easier ones and referring more complex queries to other colleagues and coordinating the response. Produces written information and organises seminars and information days. Prepares the reports for ECHA, the Commission and other parties (international agreements). Support with PIC-related duties and issuing of licenses. Makes the evaluation of the information on the physicochemical properties of the substances under evaluation.
3	Risk assessor (human health) **(external)**	Makes the evaluation of the human health risk assessment.
3	Risk assessor (environment) **(external)**	Makes the evaluation of the risk assessment for environment.
13 (2 at the MESPU + 5 at NEPA + 6 external)	**Total**	

The European Chemicals Agency (ECHA) and other Member States competent authorities could support DLA capacity strengthening process by providing new training and by implementing new capacity building projects. Table 10 shows the conformity of the objective to the SMART criteria.

Table 10 – Objective 8: Strengthen the administrative capacity of the DLA of NEPA

Criteria	Notes
Specific	It is recommended that three employees at the DLA of the Agency for Nature Protection and Environment shall be hired progressively, leading to a total of five employees at the DLA by the year of accession to the EU (2025). It is recommended that seven external employees are engaged in biocidal product authorisation activities through the MoU to support the DLA.
Measurable	Number of employees hired annually at the DLA Number of external experts readily available for outsourced work (through an MoU)
Achievable	The National Strategy proposed similar staffing levels. Prerequisites are the lifting of the moratorium on hiring civil servants, the finalisation and adoption of an MoU and the development and adoption of a sustainable financing framework for the biocidal product authorisation.
Relevant	Understaffing is among the key problems affecting the capacity of Montenegrin authorities to implement the four EU regulations.
Time-bound	Hiring of new employees should begin immediately and be fully achieved by the year of accession to the EU (2025)

2.3.1.3 Estimated human and financial resources required

In Montenegro, the labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €10,000.[41] The additional cost of bringing the number of DLA employees to the suggested amount of five is equal to €240,000 over a ten-year period (2021-2030). As mentioned however, the estimated number of FTEs required to deal with the expected workload exceeds this level and may require seven external FTEs in the period 2026 – 2030. Overall, the total additional costs for hiring all required FTEs to reach the recommended number of FTEs would be €650,000 over a ten-year period (2021-2030). The estimated additional costs are provided in the table overleaf.

It is important to put this estimate in perspective, to highlight the importance of establishing a sustainable financing framework where the costs entailed by the competent authorities are paid for by the applicants: assuming that the Montenegrin competent authorities will receive 700 applications for biocidal product authorisation and assuming an average fee of €750 per application[42], the amount of financial resources raised by the scheme would total €525,000. Many Member States have established a system of biocidal product authorisation application fees set to cover the costs for the competent authorities for handling and evaluating applications. Fees are usually divided into a basic fee, which must always be paid for the service provided, and an additional fee which is taken out only when the conditions given apply.[43]

Table 11: Marginal cost of hiring employees

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Total
Estimated required FTEs	4	5	6	7	7	11	13	14	14	14	15	€650k
DLA and MESPU* staff (FTEs)	4	5	5	6	6	7	7	7	7	7	7	
Additional FTEs at DLA	0	1	0	1	0	1	0	0	0	0	0	
Marginal cost	€0	€10k	€10k	€20k	€20k	€30k	€30k	€30k	€30k	€30k	€30k	€240k
External FTEs	0	0	1	1	2	3	5	6	6	6	7	
Additional marginal cost	€ -	€ -	€10k	€10k	€20k	€30k	€50k	€60k	€60k	€60k	€70k	€410k

**2 FTEs at MESPU as of 2020*

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 total number of five DLA employees is reached, with the target date being the year of the accession to the EU. The year of accession is also when required resources peak, due to additional resources being required to transition from the national system to the full entry into force of the EU Regulations.

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

[42] An average fee value EU- or MS-based is not available. Fees and fee systems vary across Member States, ranging from a few hundred euros to over ten thousand euros, depending on size of the applicant and complexity (and required work) of the application. The UK Health and Safety Executive provides some illustrative examples on the total initial estimated fees for different biocidal product authorisation applications. These may range from around €400 to over €10,000 (https://www.hse.gov.uk/biocides/eu-bpr/example-fees.htm). Assuming an average fee of €3,000 in the EU and dividing by four (labour costs in Montenegro are around 20% of the EU average labour costs), the average fee in Montenegro would be €750.

[43] See for example the Danish Environmental Protection Agency's fees (https://eng.mst.dk/chemicals/biocides/authorisation-of-biocidal-products/fees-bpr/) or the Swedish Chemicals Agency fee system (https://www.kemi.se/download/18.164ad6b3172927a928969dc3/1598179553056/application-fees-biocidal-products.pdf).

In order to keep the administrative capacity at the desired level, it is important to avoid a high staff turnover (Section 2.3.4). In addition, new resources should be available for thorough training to ensure a swift onboarding (see Section 2.3.5). As already discussed, in the short term, the ongoing pandemic may restrict the possibility of organising face-to-face training and therefore experts may need to be trained and work remotely. In the medium and long term, virtual engagement and remote training is expected to have a more prominent role than in the past. For this, adequate infrastructure and procedures should be established, including suitable teleworking policies (Section 2.3.10).

2.3.2 Keeping the knowledge and competence of inspectors on EU chemical legislation up to date

2.3.2.1 Description of the problem and dependencies

Enforcement of the Law on Chemicals is a shared responsibility of environmental and sanitary inspectors from the Administration for Inspection Affairs (AIA), while veterinary and phytosanitary inspectors from the Administration for Food Safety, Veterinary and Phytosanitary Affairs (AFSVFA) and the officers of the Custom Administration oversee the import and export of chemicals. The Department for Environmental Inspection, within the Division for the Environmental and Spatial Protection of the Administration for Inspection Affairs, comprises seven inspectors who are responsible for the enforcement of the legislation of the following areas: horizontal legislation, air quality, waste management, nature protection, industrial pollution, noise, climate change and chemicals. The 2019 implementation report of the National Strategy specifies that up until 2019, the Department had eight environmental inspectors along with a chief inspector, while five additional inspectors were planned to be employed by 2022 to cover the enforcement of environmental legislation.

While the planned resources would ensure an adequate supervision of regulatory compliance, the competence and knowledge of the inspectors on the EU Regulations need to be strengthened.

2.3.2.2 Recommended actions, action owner and other relevant stakeholders

ECHA and other international cooperation partners have provided training and organised workshops and study visits to strengthen the enforcement capacity of the Montenegrin competent authorities. These experiences could be extended and replicated. It is recommended that **ECHA or an MSCA support the AIA and AFSVFA by implementing a capacity-building programme** for all inspectors with enforcement responsibilities for the four Regulations.

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

Table 12 – Objective 9: Strengthening competences of environmental inspectors

Criteria	Notes
Specific	It is recommended that competences of the inspectors with enforcement responsibilities for the four Regulations shall be strengthened prior the accession year to the EU by providing trainings and capacity building activities.
Measurable	Number of training sessions/capacity building activities held annually. Number of people attending training.
Achievable	Allocation of financial resources may be required. ECHA could provide support for increasing the competences of inspectors.
Relevant	Providing training to inspectors is essential for developing their competences which are necessary for implementation of EU Regulations.
Time-bound	The competence strengthening activities shall take place as soon as possible. The objective is to be achieved prior the year of accession to the EU.

2.3.2.3 Estimated human and financial resources required

As already discussed in Section 2.2.1, the estimation of the human and financial resources required for capacity building depends on several factors, such as number of tutors involved, number of attendees, number of in-person classes vs. number of remote learning sessions, travel, accommodation and subsistence for tutors coming from abroad, necessary IT and laboratory equipment, etc. Without a sustainable financing framework, the Montenegrin competent authorities may rely 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 estimated at around €50,000 per year for the capacity building provider (ECHA or other Member State Competent Authorities).

2.3.2.4 Timeline, risks and risk mitigation measures

It is recommended that the competence strengthening activities shall take place as soon as possible. The objective shall be achieved prior the year of accession to the EU.

The main risk is that higher than normal staff turnover could nullify the overall gain of any new appointments (further discussed in Section 2.3.4).

2.3.3 High workload

2.3.3.1 Description of the problem and dependencies

The high workload is the direct consequence of understaffing at the DLA and it is one of the causes of staff turnover. High turnover of staff leads to the loss of resources that may have been trained over the years. There are various factors that contribute to high rates of turnover and different guidelines and documents have been prepared over the years for staff retention in the public sector, most notably by the OECD.[44] OECD (2019) presents 14 principle for fit-for-purpose public service. In particular, it points to the MOA Framework:

- Motivation, which refers to both intrinsic desires and aspirations, that can be driven by leadership and management and employee engagement, and extrinsic factors such as rewards and sanctions;
- Opportunities, which should be created through organisation structure, design, worker mobility and access to knowledge and resources; and
- Abilities, which refers to the strengthen of skills and knowledge through training and recruitment.

The government of Montenegro has been working on the reform of the public sector for a number of years. The Public Administration Reform Strategy in Montenegro (2016-2020) indicates that there are significant inconsistencies and variations in salaries in the public sector. The Law on Salaries in Public Sector was first implemented in March 2016. The purpose of this law is to correct the inequalities and increase the transparency of salaries in the public sector, as well as focus on developing *a system that will be stimulating, promote rewards for the results achieved and that will take into consideration the complexity of tasks carried out within a specific position, as well the quality of their performance*. According to EC (2020), "*public sector salaries remain modest. Montenegro still needs to introduce an adequate and attractive remuneration system for civil servants and state employees, based on clear, fair and transparent criteria*."

[44] Examples are: OECD (2016): The Principles of Public Administration: A Framework for ENP Countries. Sigma Programme; OECD (2019): Recommendation of the Council on Public Service Leadership and Capability, OECD/LEGAL/0445; OECD (2001): Public Sector – An Employer of Choice? Report on the Competitive Public Employer Project by Kirsi Äijälä.

2.3.3.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **MESPU and NEPA act on the recommendations of this document as soon as possible**. In particular, the increase in resources and the implementation of an MoU with external experts would greatly help to ease the workload of current staff. Moreover, it is recommended that **the Government of Montenegro, during the preparation of the new public administration reform strategy, considers the development and implementation of a plan to retain civil servants in all its administrative bodies.** The plan should, *inter alia*, aim to:

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

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

Table 13 – Objective 10: Avoid or ease the high workload

Criteria	Notes
Specific	It is recommended that MESPU and NEPA act on the recommendations of this document as soon as possible, so to ease the high workload of current staff. It is recommended that the government of Montenegro, during the preparation of the new public administration reform strategy, considers the development and implementation of a plan to retain civil servants in all its administrative bodies.
Measurable	Number of recommended actions started and accomplished. Staff turnover rate.
Achievable	All recommended actions are achievable and in part have been already proposed either by the twinning partners or the Government of the Montenegro in national plans. The resources need to be made available. A strategy for retaining personnel could only be successful if the underlying causes are tackled first. The challenges have all been identified and documented in the Commission Staff Working Document on the progress of the negotiations in Montenegro (EC, 2020) and plans to address these challenges have already been developed by the Montenegrin authorities.
Relevant	Easing workload is necessary to avoid the current high levels of staff turnover, with associated loss of expertise and institutional memory. It is key to retain skilled workers for the adequate implementation and enforcement of all EU legislation.
Time-bound	The National Strategy for Chemicals Management has activities planned until 2023 and a new strategy will be developed in the context of the Green Agenda for the Western Balkans. These should integrate the recommended activities of this document to tackle the identified issues. A new Public Administration Reform Strategy will be developed by the new Government.

2.3.3.3 Estimated human and financial resources required

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

In Montenegro, the labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €10,000.[45] Assuming the government were to raise the salary by one quarter, the labour cost for one full-time equivalent per year would be €12,500. The additional cost of progressively hiring three additional employees at the DLA over the period 2021-2030 and of increasing the salary of the 2 employees at MESPU and of the 2 employees at the DLA would be around €300,000. It should be noted that higher salaries cannot be considered only for MESPU employees and therefore the financial resources required should be calculated on the total number of civil servants.

2.3.3.4 Timeline, risks and risk mitigation measures

Most of the recommended actions to tackle the identified challenges should start in 2021. The risk is to focus on the "low hanging fruit" such as training and capacity building or keeping the national legislation aligned with the EU *acquis*, while failing to address the key issues that are at the root of most of the identified problems: the adoption of the memorandum of understanding with scientific institutes and the funding of the policies and procedures in the environmental field. The solution to these key issues requires the political will and commitment of the new government; this is essential to Montenegro's readiness in joining the EU.

2.3.4 Lack/loss of expertise

2.3.4.1 Description of the problem and dependencies

There is a lack of expertise in the field of risk assessment, which is related to the implementation of the Biocidal Products Regulation and of the REACH Regulation. There are no skilled resources that could carry out the evaluation of chemical substances in the context of the Community rolling action plan (CoRAP) or prepare Annex XV dossiers.

New internal and external employees are expected to be hired for dealing with the authorisation of biocidal products, which requires specific expertise. DLA employees should receive adequate training (which could be offered by ECHA or other Member State competent authorities) on human health and environmental risk assessment and efficacy assessment in the years leading to accession.

2.3.4.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **MESPU and NEPA address the lack of expertise in risk assessment and other technical and scientific areas** by:

- Developing in-house expertise in risk assessment by providing the agency and the ministry staff with training on human health and environmental risk assessment;
- Providing training to external resources from the institutes which will sign the memorandum of co-operation; and
- Contracting external experts (e.g. from the scientific community) to support the different tasks requiring human health and environmental risk assessment.

A plan should be developed for in-house related activities, involving such aspects as identification of currently available resources and gaps in expertise, and the planning and implementation of provision of training (timelines).

The European Chemicals Agency and other Member State competent authorities could provide training (focused on human health and environmental risk assessment) for developing the competences of the DLA staff and of the external experts who are likely to provide technical and scientific support. The development of competences could be further

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

strengthened by the assessment and provision of comments on the work carried out by other MSCAs and ECHA. Table 14 shows the conformity of the objective to the SMART criteria.

Table 14 – Objective 12: Provide training and capacity building

Criteria	Notes
Specific	It is recommended that MESPU and NEPA survey the needs of the employees and external experts and organise and implement training and capacity building courses, with the support of ECHA and MSCAs. Training should be continuous and planned on an annual basis, to keep internal and external experts up to date with EU developments.
Measurable	A capacity building plan is established. Number of courses organised. Number of attendees.
Achievable	Short-term, the Montenegrin Authorities will still require the support and assistance of ECHA and other MSCAs for the provision of capacity building.
Relevant	Providing training to staff is essential for developing competences that are necessary for implementation of EU Regulations.
Time-bound	Continuous. The capacity building plan should be developed on a yearly basis.

2.3.4.3 Estimated human and financial resources required

As already discussed in Section 2.2.1, the estimation of the human and financial resources required for capacity building depends on several factors, such as number of tutors involved, number of attendees, number of in-person classes vs. number of remote learning sessions, travel, accommodation and subsistence for tutors coming from abroad, necessary IT and laboratory equipment, etc. Without a sustainable financing framework, the Montenegrin competent authorities are likely to have to keep relying on ECHA's and other European partners' technical and financial support on capacity building. As detailed in Section 2.2.1, depending on the scale of the training courses, costs may vary but could be around €100,000 per year.

2.3.4.4 Timeline, risks and risk mitigation measures

The survey of the needs of the MESPU and the DLA of the Agency staff members and of the external experts that are likely to provide assistance to the competent authorities has already been carried out. These are:

- For REACH, training on:
  - Preparation and submission of dossiers for the identification of substances of very high concern (Annex XV dossiers);
  - Evaluation of CoRAP substances;
  - Assessment of isolated intermediates;
  - Use of appropriate IT tools (e.g. IUCLID); and
  - Hazard assessment procedures with prescribed methods for testing the hazardous properties of chemicals.

  Montenegrin competent authorities would also benefit from attending at CARACAL meetings and meetings of the Committee for Risk Assessment (RAC) and of the Committee for Socio-economic Analysis (SEAC) with observer status;
- For CLP, training on:

- Classification, labelling and packaging of chemicals;
- Safety data sheets;
- Storage of chemicals;
- Reporting on the results of supervision and other measures taken.

- For BPR, training on:

  - Assessment of biocidal products on the basis of the technical dossier;
  - Evaluation of active substances;
  - Risk assessment of biocidal products on the basis of physicochemical properties, properties that affect human health (toxicology), properties that affect the environment (ecotoxicology);
  - Efficiency assessment, which requires specific knowledge in the field of biology of target organisms, phytomedicine and veterinary medicine;
  - Use of appropriate IT tools (R4BP);

  Montenegrin competent authorities would also benefit from attending at the meetings of the Biocidal Products Committee with observer status.

- For the enforcement of the chemical legislation, training on:

  - Control over the import and use of products containing mercury;
  - Adequate supervision on the market, import and use of paints, varnishes and other types of coatings containing volatile organic compounds;
  - Adequate supervision of the market, import and use of detergents and biocidal products;
  - Planning of inspections, check lists, instructions for inspectors, reporting in accordance with Regulation (EC) no. 648/2004 on detergents;
  - Planning of inspections, check lists, instructions for inspectors, reporting in accordance with BPR with an emphasis on border products in relation to cosmetic products, medical products - medicines and medical devices.

While the support of ECHA and other European partners is unlikely to waver over the coming years, there is the risk for the Montenegrin authorities to develop a dependency on external resources. The ring-fence of the revenue from fees and charges paid by companies for the registration of chemical substances and the application for the authorisation of biocidal products is therefore of the utmost importance. This would free financial resources to organise capacity-building and communication activities.

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

2.3.5 National Poison Centre yet to be established

2.3.5.1 Description of the problem and dependencies

There is no National Poison Centre in Montenegro. Currently the Division for Licensing and Approvals requests manufacturers and importers of chemical substances and mixtures to add the national emergency number, 124, to the safety data sheets. The Institute for Public Health

keeps a record of diagnoses of poisoning. However, the entries do not distinguish between poisonings related to chemical agents or to other factors (narcotics, alcohol, pharmaceuticals and drugs or other biological substances).

The establishment of the National Poison Centre will create a centralised system to address enquiries about potential harmful exposure to chemicals, including products, pharmaceuticals, natural toxins, pesticides and industrial chemicals. The Centre will be responsible for assessing whether a particular exposure is hazardous, and for providing the necessary information for treatment. This should ensure evidence-based, cost-effective management of poisoning and the avoidance of unnecessary or ineffective measures.

The creation of the Poison Centre with the data repository on human exposure to chemicals will strengthen the competences and improve the organisational framework and procedures. This would in turn result in an enhanced service for regulators, health professionals and the general public.

According to the National Strategy on Chemicals Management 2019-2022 and the accompanying Action Plan, the Ministry of Health is tasked with establishing the National Poison Centre. The target date for this action has been pushed back to 2024. The World Health Organisation is providing support and WHO experts will prepare a report on the national capacity and the need assessment by the end of 2021. Following the publication of the report, the Ministry of Health will prepare a project proposal for the purpose of establishing the National Poison Centre, in accordance with the WHO guidelines for poison control.[46]

2.3.5.2 Recommended actions, action owner and other relevant stakeholders

The National Poison Centre should have specialist staff in emergency medicine and toxicology, the necessary databases on adequate treatment and antidotes, means to respond in case of poisoning, as well as adequate communication links with all relevant health facilities. Furthermore, because the Institute of Public Health is responsible for keeping health records and statistics, a close collaboration between the future Centre and the institute should be established, for an efficient and detailed exchange of statistics on poisoning events. Furthermore, the future Centre should exchange information on potential chemical agents that can cause poisoning on the Montenegrin market with the DLA. Therefore, it is recommended that **the Ministry of Health procures and installs technical equipment and organises adequate training for the staff of the Centre**. It is also recommended to **use the Poison Control Guidelines developed by the World Health Organisation (WHO) under the International Chemical Safety Programme, as well as the new Annex VIII of the CLP Regulation** on a harmonised approach to information collection on poison control.

2.3.5.3 Estimated human and financial resources required

The National Strategy planned for the creation of seven job positions. The study currently being carried out by the WHO experts will provide an estimate of the financial resources for the establishment of the National Poison Centre.

2.3.5.4 Timeline, risks and risk mitigation measures

The target date for the establishment of the National Poison Centre is 2024. There is a risk that the action is further delayed. In this event, the Centre may not be ready by the day of EU accession.

[46] https://www.who.int/ipcs/publications/training_poisons/guidelines_poison_control/en/

2.3.6 Number of biocidal products on the Provisional List to be authorised through the BPR procedures

2.3.6.1 Description of the problem and dependencies

The implementation of the Biocidal Products Regulation is resource-intensive for national competent authorities. Table 15 shows the estimated number of workdays necessary to complete the assessment of the information provided by the companies applying for the authorisation of biocidal products according to the different available procedures.[47]

Table 15 – Estimated workload for different biocidal product authorisation procedures – *Source: KemI's estimate*

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

Montenegrin manufacturers and importers of biocidal products must apply for inclusion of the products in the Provisional List by submitting some basic information. The DLA checks the information received and issues a decision with a deadline for the submission of a Technical Dossier with more substantial information on toxicology and ecotoxicology. The DLA has not yet started to request and assess the Technical Dossiers for the biocidal products included in the Provisional List, as there is no capacity to carry out this task at present. According to the Law on Biocidal Products, the evaluation has to be carried out by a Committee composed of seven members with expertise in toxicology, veterinary medicine, pharmacy, biology, agriculture and ecology. The Rulebook on the content of the application for a biocidal product authorisation has been amended so that applicants bear the costs of the work carried out by the Committee. However, the fees and charges go to the state rather than to a dedicated budget.

In March 2019[48], there were 459 biocidal products in the Provisional List in Montenegro (149 notifications approved in 2017 and 310 in 2018). It is reasonable to assume that, by the end of 2021, the Montenegrin competent authorities may receive a comparable number of applications for inclusion to the Provisional List. Based on the benchmarking it is expected that the Montenegrin authorities may receive around 700 applications for biocidal product authorisation. Figure 4 shows the estimated FTEs to deal with the expected workload according to the following assumptions:

- Around 10% of these 700 applications will be processed through the 'mutual recognition in sequence' procedure before 2025;
- Around 90% of the total applications will be added to the Provisional List (or its inclusion extended) until 2025, the planned year of accession of Montenegro to the European Union. From 2025:

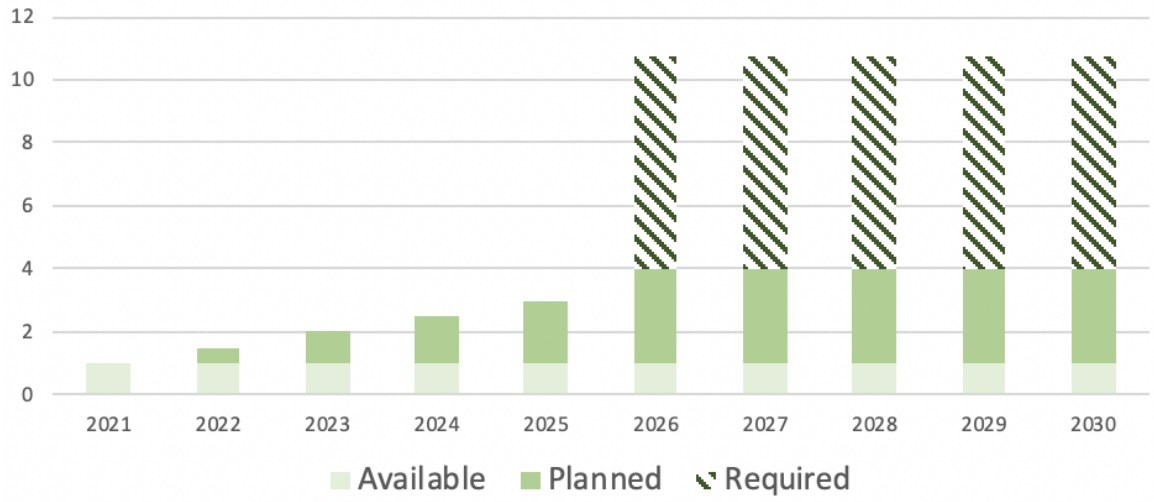
[47] Estimates by the Swedish Chemicals Agency (KemI).

[48] Publication date of the National Strategy (MSDT, 2019) reporting the number of biocidal products in the temporary list.

- Around 5% of the biocidal products still on the Provisional List will follow the procedure for the authorisation of the same biocidal products by the same or different enterprises under the same terms and conditions;
- Around 10% will apply for national authorisation, with Montenegro as reference Member State;
- Around 5% will be discontinued; and
- The remaining 80% will follow the mutual recognition procedure, as the review of active substances should be completed by 2025.

The FTEs necessary to manage the workload associated with the different procedures, assuming a period of 10 years (for example 2021-2030), adds up to an average of 6.3 FTEs per year. However, only 0.3 FTEs per year is currently dedicated to the implementation of these procedures. Assuming that one employee will be dedicated entirely to the biocidal products authorisation procedures by 2021 and that three additional employees will be progressively employed and assigned to support these procedures by 2026, the Montenegrin authorities would still require seven extra FTEs per year from 2026 onwards.

Figure 4 –Available FTEs vs planned FTEs vs necessary FTEs over the period 2021-2030 at the DLA for the management of biocidal product authorisation applications



2.3.6.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the DLA starts authorising biocidal products through the mutual recognition procedure** as soon as possible so that, by the day of EU accession, the Montenegrin authorities can manage the expected workload and can start building the capacity necessary for dealing with other types of authorisation procedures and with the approval of new active substances. It is unlikely the Montenegrin authorities will be able to process all applications for authorisation in time, even with the availability of new additional resources and the technical support of external experts. Montenegro may need some transitional measures, such as the extension of the validity of the Provisional List for biocidal products placed only on the Montenegrin market. This would still be a breach of the single market, as imported biocidal products would have to be authorised instead (there would be market distortion because due to the unlevel playing field between importers and EU companies on one side and Montenegrin manufacturers on the other) and the safety and efficacy of the biocidal products manufactured in Montenegro would still have to be assessed. Therefore, any such transitional measures need to be of the shortest duration possible and it would present a double risk:

- Market distortion; and

- Failure to meet the objectives of any negotiated transitional period.

It is recommended to develop a plan on how to manage the number of biocidal products on the Provisional List to be authorised through the BPR procedures:

- Hiring of additional resources and providing training (discussed respectively in Sections 2.3.1 and 2.2.1);
- Involving external experts for specific tasks (discussed in Section 2.2.8);
- Align the national legislation on administrative fees with the EU Regulations and principles (discussed in Section 2.2.5); and
- Starting authorising biocidal products through the mutual recognition process as soon as possible.

The competent authorities have been drafting an MoU to ease and regulate the use of the scientific community expertise in supporting the DLA with some of the tasks that will be required upon the full entry into force of the EU Regulations. These include substance evaluation and the assessment of different parts of the dossier for a biocidal product, for which specific expert knowledge is needed.[49] Another important aspect is to communicate to applicants that, according to the Biocidal Products Regulation, they are obliged to consult with the competent authorities prior to an application, if the competent authorities are to be reference Member State. This would mean that the competent authorities would be responsible for evaluating the complete documentation in the application. It is usually recommended to applicants to contact the competent authorities well in advance, preferable one year before the submission of the application. This ensures that the competent authorities can provide the support required by the applicant, but also enables the competent authorities to plan the work ahead effectively. Booking pre-submission meetings with the authorities gives the opportunity to discuss the process, the data requirements, a quotation of the fees to be paid or any other issue that is relevant to the application.

It is key to stress again that without the human and financial resources, the Montenegrin competent authorities are unlikely to be able to fulfil their responsibilities and obligations in implementing the Biocidal Products Regulation. Table 16 presents the conformity of the objective to the SMART criteria.

Table 16 – Objective 13: Develop a plan on how to manage the number of biocidal products on the Provisional List and start authorising biocidal products through the mutual recognition procedure

Criteria	Notes
Specific	It is recommended that the DLA develops a plan on how to manage the **number of biocidal products on the Provisional List** and starts authorising biocidal products through the mutual recognition procedure.
Measurable	Number of authorised biocidal products. Ratio of authorised biocidal products to not yet assessed/authorised biocidal products. Number/percentage of biocidal product applications authorised through the mutual recognition procedure.
Achievable	An MoU has already been drafted and is being refined. The DLA maintains the Temporary List and can use it to make some projections. The ultimate success of this action relies on the implementation of a sustainable financing framework and on the possibility to strengthen the administrative capacity of the DLA.
Relevant	To ensure the proper functioning of the single market and the protection of human health and the environment, biocidal products need to be authorised following one of the EU procedures.
Time-bound	Mutual recognition can already be applied for.

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

2.3.6.3 Estimated human and financial resources required

The estimated human and financial resources necessary to deal with the **number of biocidal products on the Provisional List to be authorised through the BPR procedures** has been discussed in Section 2.3.1.

2.3.6.4 Timeline, risks and risk mitigation measures

It is recommended that the DLA starts requiring the technical dossiers on the biocidal products, in order to start authorising imported biocidal products using the mutual recognition procedure. Considering the necessarily progressive build-up of the resources and competences, internal and external employees should be hired and trained before accession to the EU.

One risk is that, in consideration of the high number of resources estimated to be required to process the expected number of applications, not enough experts with the right knowledge and skills is available, at least in the short term, in Montenegro.

Another risk is underestimating the number of applications for biocidal product authorisation that will be received by the Montenegrin competent authorities and the associated workload. This would result in the Montenegrin competent authorities not being able to fulfil their obligations and responsibilities according to the BPR. The risk of overestimating the number of applications or the number of workdays necessary for each authorisation procedure can be mitigated by the use of a mix of internal and external resources. Nevertheless, early and careful planning is recommended.

2.3.7 Lack of stakeholder engagement in formal consultation on the development or amendment of rulebooks

2.3.7.1 Description of the problem and dependencies

According to the Montenegrin legislative framework, formal stakeholder consultation is carried out when drafts of new laws, rulebooks or their amendments are being developed by the authorities. However, it has been noted that stakeholder do not usually submit observations, especially regarding rulebooks and their amendments. This could be the result of the small size of the Montenegrin chemical industry or a lack of awareness about the ongoing public consultations or about the possibility to provide feedback. The National Strategy 2019-2022 acknowledges that the activities for improving transparency and engaging a wide range of stakeholders are only at an initial stage and more efforts are required, also regarding the low level of public awareness on chemicals and chemical safety.

2.3.7.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **MESPU strengthens the stakeholder engagement in formal consultations by increasing public awareness on chemical risk management**. The Montenegrin competent authorities have recently applied to participate in the capacity building programmes run by the United Nations Environment Programme on the implementation of the Basel, Rotterdam, Stockholm and Minamata Conventions. The proposed project[50] aims at increasing public awareness by producing educational material targeted to different stakeholder categories. A better-informed civil society is more likely to actively participate in policymaking.

In addition, in November 2020 MESPU has contracted six NGOs to carry out educational campaigns on chemical risk management. These activities are expected to be implemented every year.

[50] Strengthening synergies between Basel, Rotterdam, Stockholm and Minamata conventions.

Table 17 shows the conformity of the objective to the SMART criteria.

Table 17 – Objective 14: Ensuring stakeholders engagement in formal consultation on the development or amendment of rulebooks

Criteria	Notes
Specific	It is recommended that stakeholder engagement in formal consultation on the development or amendment of rulebooks is ensured by communicating with the relevant companies and informing them of upcoming regulatory measures and the possibility to participate in a public consultation. Stakeholder consultation plays an important role in involving industry in decision-making processes and engaging stakeholders in the implementation of EU regulations. Increasing public awareness may also induce higher and better participation in policymaking.
Measurable	Number of stakeholders contacted. Number of responses received from stakeholders. Stakeholders engagement rate.
Achievable	Allocation of financial resources may be required.
Relevant	Stakeholders consultation may lead to higher stakeholder engagement and more efficient implementation of EU Regulations.
Time-bound	Ideally, higher stakeholder engagement should already be ensured for the next consultation.

2.3.7.3 Estimated human and financial resources required

The IPA project IPA/2016/37896/01/ME/Environment and Climate Action "Capacity Building and Acquis related Activities for Sector Environment & Climate Action" attributed great importance to communication activities and stakeholder engagement. All primary stakeholders were consulted during the preparation of the intervention and have participated in the implementation both as direct beneficiaries and as members of the IPA project steering committee. In particular, activity 1.4 focused on public awareness, including consultation events with civil society and economic operators. It should be noted that, due to the COVID-19 pandemic, some of the activities planned within the IPA 2016 have been postponed or cancelled and the corresponding funding diverted to actions to respond to the health emergency.

It is recommended that MESPU allocates additional resources for enhancing communication with the stakeholders and ensuring their engagement in formal consultations.

2.3.7.4 Timeline, risks and risk mitigation measures

Communication activities and cooperation with stakeholders such as the Chamber of Commerce have already been established, for example in the Strategy for Chemical Management 2019-2022. Such initiatives should be reiterated and strengthened in the new Strategy for Chemical Management to be developed for 2023 onwards. The new Strategy could also recommend that the Helpdesk prepare annual communication work plans.

2.3.8 Lack of communication on working procedures and procedures to manage confidential business information

2.3.8.1 Description of the problem and dependencies

There is a need for Montenegrin authorities to establish communication on working procedures and procedures to manage confidential business information. This would ensure transparency and

increase the trustworthiness of the authorities in relation to working procedures and on the data-security measures implemented, contributing to stakeholder engagement.

In addition, there is the need to keep Montenegrin industry stakeholders informed about their upcoming responsibilities and duties, in particular with regard to REACH registration and authorisation, CLP classification and labelling, and BPR authorisation. With regard to the 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 helpdesk service is essential to ensure that Montenegrin companies are ready for the single market well in advance of the day of accession to the EU.

2.3.8.2 Recommended actions, action owner and other relevant stakeholders

Civil society plays an essential role in the process of European integration of Montenegro. Proactive civil society organisations are important actors in the implementation of public policies. An example is the role played by the non-governmental organisations grouped under the name of Koalicija27 on the negotiation process, with the publishing of shadow reports on the status and progress on Chapter 27, 'Environment and Climate Change'.[51]

It is recommended that **the Helpdesk develops and implements an annual work plan**. This could address the following:

- Organisation of **workshops and events**, including identification and selection of topics of interest for the Montenegrin stakeholders that could be discussed during the events;
- **Communication of information** on the progress in establishing an effective **regulatory framework**, including information on the measures to ensure the confidentiality of non-public information; and
- The organisation and dissemination of **information online**:
  - The content on the DLA website, including the webpage of the Helpdesk, 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 Montenegrin that could be of relevance for companies, could also be provided on the website.
  - The Helpdesk's webpage could have a Frequently Asked Questions (FAQ) section, which could assist companies and the public.

NEPA should focus on the information needs of companies. For example, on the basis of the lessons learnt from other national competent authorities, arranging mandatory pre-submission meetings with applicants reduces the number of poor-quality biocidal product authorisation applications. Table 18 shows the conformity of the objective to the SMART criteria.

Table 18 – Objective 15: Development and implementation of communication strategy

Criteria	Notes
Specific	It is recommended that the Helpdesk develops and implements annual work plans on communication activities, including communication on working procedures and procedures to manage confidential business information. This would ensure transparency and increase the trustworthiness of the authorities in relation to working procedures, contributing to stakeholder engagement and participation in regulatory implementation.
Measurable	A communication strategy is developed and implemented. Number of organised activities.

[51] See for example: Koalicija 27 (2020): Progress of Montenegro 2020: Long travel to the EU. Shadow report of the Coalition 27 for the Chapter 27 – Environment and Climate Change. Available at: http://koalicija27.me/wp-content/uploads/2020/10/Contribution-report_Montenegro-2020.pdf

Criteria	Notes
	Number of actors involved. Content of relevant information provided online.
Achievable	The careful design of the strategy avoids the misuse of funding. MESPU and DLA may not have the in-house expertise and therefore may consider outsourcing the process.
Relevant	Better informed stakeholders may result in a lower workload (less queries to the helpdesk, better quality information provided by industry in their notifications and applications). A communication strategy improves confidence in the competent authorities and increases the acceptance of the implemented policies.
Time-bound	Annual work plans. This would allow earmarking the necessary resources. The plan should clearly identify target audience, needs and optimal communication channels.

2.3.8.3 Estimated human and financial resources required

The Montenegrin Authorities, in collaboration with ECHA, European partners and local NGOs have implemented a series of events over the past years. It is recommended that the development of a Helpdesk work plan is included in the remit of the Helpdesk staff and should be part of the job description.

Given the lack of a sustainable financing framework, the Montenegrin competent authorities may rely on ECHA and other European partners' technical and financial support on communication activities (see Section 2.3.7). It should be noted however that MESPU, in cooperation with the Ministry of Public Administration, has developed a funding plan to support NGOs in implementing educational campaigns on the safe management of chemicals and on Persistent Organic Pollutants (POPs), to be carried out between 2021 and 2022. In addition, as already mentioned, in November 2020 the Ministry has commissioned six NGO to conduct educational campaigns in the field of safe management of chemicals during 2021. This kind of activities should be implemented every year.

Depending on the scale of the communication activities, costs for ECHA or MSCAs may vary but could be forecast at around €50,000 per year. If costs were instead borne by NEPA, considering the difference in price levels, around €10,000 could be allocated by the Montenegrin authorities for communication activities.

2.3.8.4 Timeline, risks and risk mitigation measures

As for capacity-building, the support of ECHA and other European partners is unlikely to waver over the coming years. However, it is important that adequate funding is ensured by ring-fencing the revenue from fees and charges paid by industry applicants for the work carried out by the competent authorities, which could also be used for capacity building and communication activities. As already mentioned, there is the need to assess how the Montenegrin legislative system could be amended to create a dedicated budget for chemical risk management activities.

In the short term, means of disseminating information are likely to be disrupted by the ongoing COVID-19 pandemic. The DLA should explore opportunities for organising webinars. ECHA has years of experience in organising and running webinars, issuing newsletters and providing remote classes and could therefore provide advice and support with these activities.

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

2.3.9.1 Description of the problem and dependencies

Information managed by ECHA must remain secure.

Before receiving remote access to ECHA's information systems, all European and national authorities need to sign a declaration confirming they have taken appropriate security precautions, based on the Agency's Security Model for IT systems.[52] This declaration ('Unified Declaration of Commitment') and satisfying the associated Standard Security Requirements (SSR) grant access to:

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

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

The Standard Security Requirements cover:

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

While the physical security of the Montenegrin authorities' premises that will be used to access ECHA's information systems from the day of accession already seems to be effectively ensured by the measures in place, all other aspects need revision and improvement.

The workstations used by the DLA staff run malware prevention software, but the antivirus signatures are not regularly updated, and the antivirus is not monitored. The network is protected from malicious emails by the antivirus and anti-spam systems provided by the private telecommunication operator and provider.

Points to address

- There are no security rules to control the use of removable drives/storage.
- There is no formal patch-management process to remediate security vulnerabilities.
- Security updates are not regularly installed on the workstations' systems

[52] 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.

- Normal users without privileged access rights can install non-authorised applications without restriction.
- Users do not have individual user accounts
- One single account is shared between the users.
- Access to the workstations is not protected by authentication mechanisms
- There is no password policy.
- Security events are not recorded, monitored or analysed.
- NEPA has only two IT experts, and they have not been trained in IT security. There are no formal archiving practices for the storage of non-public information.
- There is no control and record of non-temporary local copies.
- Archived information is not securely deleted once the justification for storage is expired.
- Personal or non-formal archives of non-public information are permitted,
- Storage devices are not encrypted nor are the transmissions over a public network.
- Non-public information in paper format can be taken out (though when in NEPA premises, they are stored in locked cabinets).
- There is no process to verify the level of protection of non-public information once this has been transferred for legal or administrative proceedings. Teleworking is allowed, but no teleworking security policy is in place.
- The traffic between the client device and the office network is not protected by encryption. No internal or external audits are carried out on the safety procedures and measures.

NEPA staff have received some introductory training on IUCLID, but employees do not report to be confident in this area, as they lack hands-on training and daily use of the tool. They have not yet been introduced to all other IT tools used for managing and exchanging information with ECHA (REACH-IT, Chesar, EUSES, SPC, R4BP, ePIC).

2.3.9.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **NEPA upgrades the IT infrastructure of the DLA and ensures compliance with the requirements of ECHA's IT security policies** in order to be able to access ECHA's information systems and tools. The following policies and procedures related to IT infrastructure should be developed and implemented:

- CBI management policy;
- Security awareness programme; and
- Teleworking security policy.

The current practices of information management should be aligned with ECHA's Standard Safety Requirement (SSR). In addition, the first external and further regular internal and external audits of IT policies must be carried out:

- An initial external audit of the safety policies, procedures and measures in place should be carried out to identify the gaps and measures to be implemented;
- Internal audits should be carried out annually; and
- External audits should be carried out every three years or every time a significant change is made to the security measures.

It is recommended that ECHA and MSCAs provide support, training and capacity building on all IT aspects.

Table 19 shows the conformity of the objective to the SMART criteria.

Table 19 – Objective 16: Ensuring compliance with the requirements of ECHA's IT security policies

Criteria	Notes
Specific	It is recommended that NEPA upgrades the IT infrastructure and ensures compliance with the requirements of ECHA's IT security policies by developing and implementing CBI management policy, security awareness programme and teleworking security policy. The first external and regular internal and external audits shall be carried out. ECHA and MSCAs could provide support, training and capacity building.
Measurable	The IT infrastructure is upgraded. The new safety policy is implemented. Human resources are allocated to IT security, either by hiring additional employees with the right profile or by providing training and capacity building to the existing IT staff. A new formal non-public information management policy is implemented. A security awareness programme, including introduction and regular security trainings for all employees is established. A teleworking security policy is implemented. External and internal audits are regularly implemented.
Achievable	ECHA has offered support.
Relevant	Without IT security policies and procedures in place, the DLA cannot gain access to ECHA information systems.
Time-bound	Policies 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 DLA are likely to have positive impacts on the confidence of businesses regarding the Montenegrin competent authorities.

2.3.9.3 Estimated human and financial resources required

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

The organisation and implementation of training courses for IT staff and DLA staff members on IT security policies and procedures is estimated to cost around €100,000 in the period 2021-2025.

The cost to ensure workstations are secure, with updated operating systems and antivirus software, would be around €500 per workstation. If the staff needs to be enabled to work remotely, they would need safe and updated devices provided NEPA. The total cost of updating the IT infrastructure may be around €5,000 (accounting for five employees at the DLA: around €2,500 for the workstations at the DLA, and other €2,500 for personal devices to enable remote working, unless policies allowing work laptops to be used from home are implemented).

The provision of assistance by ECHA or one MSCA on the preparation of a formal non-public information management policy, a security awareness programme and a teleworking security policy may entail around 20 workdays (0.1 FTEs) and four meetings in Podgorica for a total cost of €25,000.[53]

[53] 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 NEPA earmarks around €1,000-€5,000 for the first audit.[54] NEPA should also 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 DLA are likely to boost confidence of businesses in the trustworthiness of the Montenegrin competent authorities. Table 20 shows the suggested timeline for the development of the IT infrastructure and the establishment of IT policies and procedures.

Table 20 – Timeline for the development of IT infrastructure and the establishment of IT policies and procedures

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Development and implementation of CBI management policy											
Development and implementation of security awareness programme											
Development and implementation of a teleworking security policy											
Carrying out first external audit and plan for regular internal and external audits		EA	IA	IA	EA	IA	IA	EA	IA	IA	EA

DLA staff lack expertise in IT security. ECHA has offered assistance and support. However, it is recommended that NEPA commissions a first external audit to 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.

[54] 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 Montenegrin authorities is the lack of resources necessary to implement and enforce the four Regulations.

However, in order to strengthen the administrative capacity and enable the implementation of the other recommended actions (Table 21), there are some underlying challenges that need to be addressed first. These are beyond the remit of the Division for Licensing and Approvals of the Agency for Nature Protection and Environment or of Ministry for Ecology, Spatial Planning and Urbanism itself and are instead actions that should be taken by the Government of Montenegro.

To ensure that adequate financial resources are available to fund new job positions within the DLA or to contract external experts for support, the **national legislation on administrative fees should be aligned with the EU Regulations and principles and the revenue from fees and charges paid by industry applicants for the work carried out by the competent authorities ring-fenced for chemical risk management activities** (Section 2.2.5).

Further, it is recommended that NEPA adopts the **Memorandum of Understanding** with scientific institutes and external experts to facilitate the **outsourcing of some workstreams** and avoid overload at the DLA (Section 2.2.7).

It is recommended that these two actions are given priority and are implemented as soon as possible (Table 22).

The above measures would allow the hiring of new staff and outsourcing of workstreams, helping to address some of the other challenges associated with an insufficient administrative capacity, such as the loss of expertise (Section 2.3.5) due to high staff turnover (Section 2.3.4). Avoiding work overload and ensuring adequate salaries may stabilise the turnover rate and bring it to more natural levels. It is recommended that the Government of Montenegro, during the preparation of the new public administration reform strategy, considers the development and implementation of a **plan to retain the staff** of the public administration entities.

NEPA should **develop an annual Helpdesk work plan** (Section 2.3.9):

- It is recommended that the organisation of communication activities forms part of the job description of a new employee who should be assigned to the provision of helpdesk and information services.
- Finally, it is recommended that **the IT infrastructure** and the **IT safety policies and procedures be upgraded** (Section 2.3.10). NEPA should commission an initial external audit, to identify the required measures to bring the IT system up to the standard required by ECHA.

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

The risks associated with each action and possible mitigation measures have been outlined and are summarised in Table 23. One of the main risks is that the Montenegrin competent authorities focus on "low hanging fruit", such as training and capacity building or keeping the national legislation aligned with the EU acquis, while failing to address the key issue at the root of most of the identified

challenges. **Strengthening the administrative capacity of NEPA is essential to Montenegro's readiness** to join the EU.

Table 21 – Action Plan

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
1. Carry out an assessment of how to introduce fees and charges and create a dedicated budget for chemical risk management	!!!	4nd Q of 2021	MESPU	MSCA	0.25 FTE	
2. Align national legislation on administrative fees with the principles of the EU Regulations Action cannot start before actions no. 1 complete.	!!!	1st Q 2022 – 4nd Q 2022	MESPU	ECHA / MSCA /		
3. Draft a rulebook on the fees payable by companies applying for the authorisation of biocidal products and for the notification of information to the Chemicals Registry	!!!	4nd Q 2023 –	MESPU	ECHA / MSCA	0.25 FTE	-
4. Request technical dossiers on biocidal products to start authorisation through mutual recognition	!!!	4th Q 2021 / 1st Q 2022	NEPA	-	-	-
5. Adopt and implement the MoU with the relevant scientific institutes for long-term access to their competences and capabilities	!!!	4th Q 2021	NEPA		0.25 FTE	-
6. Strengthen the capacity of the DLA	!!!	continuously	NEPA	-	Additional 4 FTEs	Around €30k per year in the period 2021-2030
7. Start authorising biocidal products through the mutual recognition procedure Action cannot start before action no. 4 is complete and would benefit of actions no. 3, 5 and 6.	!!!	2022	DLA)	External experts through the MoU		For external experts: Around €40k per year in the period 2021-2030
8. Capacity building on risk assessment and other topics	!!!	2021-2022	ECHA	MSCA and MESPU / AIA	0.5 – 1 FTE (ECHA and/or MSCA)	~€75,000 per year over two years (ECHA and/or MSCA)
9. Capacity building of inspectors Action cannot start before actions no. 1, 2 and 3 are complete.	!	2023 and 2025	ECHA MESPU / AIA		-	~€50,000 per year over two years (ECHA and/or MSCA)
10. Organise training courses on IUCLID and R4BP	!	2021-2022	ECHA	MESPU (DLA), MSCA, CoC	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
11. Start using IUCLID to record, store, maintain and exchange the relevant information Action would benefit of action no. 10	!!!	2022	DLA		-	-
			Montenegrin manufacturers and importers of chemical substances, chemical products		-	-

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
			and biocidal products			
12. Allocate resources to the provision of information and helpdesk services	!	2021-	NEPA		1 additional FTE per year (see Action no. 6)	-
13. Development and implementation of a helpdesk working plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Serbian stakeholders that could be discussed during the events; - Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information The organisation and dissemination of information online	!	2022-2025	DLA	ECHA, MSCA, CoC, NGO	0.5 FTE	€50,000 per year
14. Establish National Poison Centre	!!!	2024	MH	WHO	7 FTEs	-
15. Upgrade IT infrastructure	!!!	2023	NEPA		-	€8,000 (one-off) ~€100 per workstation (running costs: licenses, software upgrades, etc.)
16. Provide training to the existing IT staff within the DLA staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		2021-2023	ECHA	DLA	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
17. Implement new safety policy		2023	DLA	ECHA	0.1 (DLA) + 0.1 (ECHA and/or MSCA)	€25k (ECHA and/or MSCA)
18. Implement a new formal non-public information management policy in line with ECHA's SSR		2023	DLA	ECHA		
19. Establish a security awareness programme, including introduction and regular security trainings for all employees.		2023		ECHA		
20. Establish a teleworking security policy		2023	DLA	ECHA		
21. Contract an external audit of the safety policies, procedures and measures		2023	NEPA		-	€5,000 in 2021

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
22. Carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures		2022	NEPA	ECHA	-	€5,000 every 3 years for external audits
23. Hand-on training on ECHA e-tools	!	2025	ECHA	MSCA and MESPU	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
Notes: CoC: Chamber of Commerce; MESPU: Ministry for Ecology, Spatial Planning and Urbanism; DLA: Division for Licensing and Approvals MH: Ministry of Health; AIA: Administration for Inspection Affairs; WHO: World Health Organisation						

Table 22 – Gantt Chart and resource allocation

Action	2021	2022	2023	2024	2025
1. Carry out an assessment of how to introduce fees and charges and create a dedicated budget for chemical risk management	0.25 FTE				
2. Align national legislation on administrative fees with the principles of the EU Regulations					
3. Draft a rulebook on the fees payable by companies applying for the authorisation of biocidal products and for the notification of information to the Chemicals Registry			0.25		
4. Request technical dossiers on biocidal products to start authorisation through mutual recognition		-	-	-	-
5. Adopt and implement the MoU with the relevant scientific institutes for long-term access to their competences and capabilities	0.25 FTE				
6. Strengthen the capacity of the DLA	-	+1 FTE €10k	- €10k	+1 FTE €20k	+1 FTEs €30k
7. Start authorising biocidal products through the mutual recognition procedure		+1 FTE (external) €10k	+1 FTE (external) €20k	+2 FTEs (external) €40k	+3 FTEs (external) €70k
8. Capacity building on risk assessment and other topics	0.25 – 0.5 FTE €35k-40k	0.25 – 0.5 FTE €35k-40k			
9. Capacity building of inspectors			~€50k		~€50k
10. Organise training courses on IUCLID	0.1 FTE €50k 0.1 FTE				
11. Start using IUCLID to record, store, maintain and exchange the relevant information					
12. Allocate resources to the provision of information and helpdesk services		+1 FTEs €10k	€10k	€10k	€10k
13. Development and implementation of a helpdesk communication work plan:	-	€50k	€50k	€50k	€50k

Action	2021	2022	2023	2024	2025
- Organisation of workshops and events, including identification and selection of topics of interest for the 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 - Organisation and dissemination of information online					
14. Establish National Poison Centre				+7 FTEs €70k	€70k
15. Upgrade IT infrastructure	€8,000	€800	€800	€800	€800
16. Provide training to the existing IT staff within the DLA staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.	~0.05 FTE ~€15,000	~0.05 FTE ~€15,000	~0.05 FTE ~€15,000		
17. Implement new safety policy	~0.05 FTE	~0.05 FTE	~0.05 FTE		
18. Implement a new formal non-public information management policy in line with ECHA's SSR					
19. Establish a security awareness programme, including introduction and regular security trainings for all employees.	~0.05 FTE ~€8,000	~0.05 FTE ~€8,000	~0.05 FTE ~€8,000		
20. Establish a teleworking security policy					
21. Contract an external audit of the safety policies, procedures and measures		€5k			
22. Carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures					€5k
23. Hand-on training on ECHA e-tools					0.1 FTE (ECHA and/or MSCA) €50k
Totals					
ECHA or MSCA	~0.4 –0.8 FTEs ~€115k	~0.4 FTE €60k	~0.1 FTE ~€75k		0.1 FTE (ECHA and/or MSCA) ~€100k
MESPU / DLA / AIA	0.65 FTE €8k	~3 FTEs ~€85k	~1.3 FTE €90k	+3 FTEs €120k	+4 FTEs €160k
MH	-	-	-	+7 FTEs €70k	€70k

Table 23 – Risks and Risk mitigation measures

Action	Risk	Risk Mitigation Measures
1. Carry out an assessment of how to introduce fees and charges and create a dedicated budget for chemical risk management	Requires collaboration with other ministries.	Start the dialogue with other ministries as soon as possible, highlighting the importance of establishing a dedicated budget for chemical risk management.
2. Align national legislation on administrative fees with the principles of the EU Regulations	Because of the pandemic, no political will to increase the burden on companies.	The Commission and ECHA stress the importance of creating a sustainable funding system and highlight the fairness of shifting the burden from taxpayers to companies generating an income from commercialising chemical and biocidal products.
3. Draft a rulebook on the fees payable by companies applying for the authorisation of biocidal products and for the notification of information to the Chemicals Registry	No expertise available.	Ask support of ECHA / MSCA / Serbia.
4. Request technical dossiers on biocidal products to start authorisation through mutual recognition	Delays in establishing the inventory and in building the necessary expertise	ECHA provides training on risk assessment.
5. Adopt and implement the MoU with the relevant scientific institutes for long-term access to their competences and capabilities	Lack of resources also due to the ongoing COVID-19 pandemic	Create a dedicated budget for chemical risk management
6. Strengthen the capacity of the DLA	The Montenegrin government may not fund the necessary resource increase.	The Commission and ECHA note that without the administrative capacity for implementing the Regulations, Montenegro would be deemed not ready to fulfil EU obligations and responsibilities.
7. Start authorising biocidal products through the mutual recognition procedure	Lack of expertise Insufficient number of risk assessors because of lack of resources	Capacity building on risk assessment. The government of the Republic of Montenegro aligns national legislation on administrative fees with the principles of the EU Regulations, strengthen the capacity of the DLA and adopt the MoU.
8. Capacity building on risk assessment	Lack of resources COVID-19 pandemic The adoption of the MoU is further delayed Staff turnover	Support of ECHA or MSCA Remote learning Actions: 3. Align national legislation on administrative fees with the principles of the EU Regulations 5. Adopt and implement the MoU with the relevant scientific institutes for a rapid and long-term access to their competences and capabilities 7. Start authorising biocidal products through the mutual recognition procedure
9. Capacity building of inspectors	Lack of resources COVID-19 pandemic Staff turnover	Support of ECHA or MSCA Remote learning 3. Align national legislation on administrative fees with the principles of the EU Regulations
10. Organise training courses on IUCLID	Lack of resources COVID-19 pandemic	Support of ECHA or MSCA Remote learning

Action	Risk	Risk Mitigation Measures
	Lack of training material in Montenegrin	The DLA or MESPU translate the training material available online. Actions: 6. Strengthen the capacity of the DLA
11. Start using IUCLID to record, store, maintain and exchange the relevant information	Lack of resources COVID-19 pandemic	Support of ECHA or MSCA Remote learning Actions: 6. Strengthen the capacity of the DLA
12. Allocate resources to the provision of information and helpdesk services	Lack of resources.	Actions: 3. Align national legislation on administrative fees with the principles of the EU Regulations 6. Strengthen the capacity of the DLA
13. Development and implementation of a Helpdesk work plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Serbian stakeholders that could be discussed during the events; - Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information - Organisation and dissemination of information online	Lack of resources. Lack of expertise.	Actions: 6. Strengthen the capacity of the DLA Communication activities part of the job description for 1 FTE to be hired for the helpdesk. ECHA or MSCA support.
14. Establish National Poison Centre	Lack of resources. Lack of expertise. Further delays.	Support of the WHO. The Ministry of Health prioritises the establishment of the National Poison Centre and guarantees the allocation of sufficient resources.
15. Upgrade IT infrastructure	Lack of resources. Lack of expertise. Data leaks and disclosure of CBI.	ECHA will support the development of the relevant policies and procedures and the training of staff. NEPA 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.
16. Provide training to the existing IT staff within the DLA staff on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		
17. Implement new safety policy		
18. Implement a new formal non-public information management policy in line with ECHA's SSR		
19. Establish a security awareness programme, including introduction and regular security trainings for all employees.		
20. Establish a teleworking security policy		
21. Contract an external audit of the safety policies, procedures and measures		
22. Carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures		
23. Hand-on training on ECHA e-tools	Staff turnover	Action: 6. Strengthen the capacity of the DLA to ease workload and minimise staff turnover

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

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

Both countries need strengthening of their respective administrative capacities and the underlying issues are broadly the same:

- in both countries a moratorium on hiring civil servants was in place, although in Montenegro expired on 31 December 2020;
- both countries need to develop a sustainable financing system aligned with the EU Regulations and principles;
- both countries have still to ratify memoranda of understanding with scientific institutes to facilitate access to external experts.

However, Montenegro has already drafted an **MoU** and is currently in process of refining it.

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

Montenegro could also benefit from the support received by Serbia from twinning partners in drafting a document containing recommendations for **sustainable financing** of biocidal products management administration, following an assessment of how to better integrate these changes in the Montenegrin legislative system. Both countries should assess the possibility of creating a dedicated budget for chemical risk management. It is recommended that the **Montenegrin authorities contact their counterparts in Serbia** to explore potential synergies and mutually beneficial collaboration. Finally, both countries would welcome the support that ECHA or Member State competent authorities can provide in capacity building and training on risk assessment, IT security, e-tools and enforcement.

There may therefore be the possibility to organise capacity building on these topics at the same time in both countries, in order to share training materials and optimise the resources allocated by ECHA or MSCAs.

Additional joint actions could focus on:

- Sharing best practices with regard helpdesk services and information provided online (FAQs);
- Sharing criteria and guidance on quality standards for biocidal products authorisation applications and refusals, to allow for better resource planning and to tackle the number of biocidal products on the Provisional List to be authorised through the BPR procedures;
- Providing harmonised guidance for controls and training for inspectors;
- Exchanging inspectors between competent authorities;

- Sharing experience and expertise in developing communication work plans and engaging stakeholders; and
- Jointly organised workshops and events.

ECHA could provide capacity building jointly to both countries in two areas:

- Efficacy and risk assessment of biocidal products;
- IT infrastructure, policies and procedures.

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5 Annexes

5.1 List of abbreviations

Acronym	Full name
AIA	Administration for Inspection Affairs
AFSVFA	Administration for Food Safety, Veterinary and Phytosanitary Affairs
BPC	Biocidal Product Committee
BPR	Biocidal Products Regulation
CARACAL	Competent authorities for REACH and CLP
Cefic	European Chemical Industry Council
CG	Coordination Group
CLH	Harmonised classification and labelling
CLP	Classification, Labelling and Packaging
CoRAP	Community Rolling Action Plan
DNA	Designated National Authority
DLA	Division for Licensing and Approvals of the Agency for Nature Protection and Environment
EC	European Commission
ECHA	European Chemicals Agency
EEB	European Environmental Bureau
EU	European Union
FTE	Full-Time Equivalent
IPA	Instrument for Pre-Accession Assistance
IT	Information Technology
IUCLID	International Uniform ChemicaL Information Database
MS	Member State
MSCA	Member State Competent Authority
MSDT	Ministry of Sustainable Development and Tourism
MESPU	Ministry for Ecology, Spatial Planning and Urbanism
NEPA	Nature and Environment Protection Agency
NGO	Non-Governmental Organisation
NPCC	National Poison Control Centre
OECD	Organisation for Economic Co-operation and Development

Acronym	Full name
PCN	Poison Centre Notification
PIC	Prior Informed Consent Regulation
R4BP	Register for Biocidal Products
RAC	Risk Assessment Committee
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SCBP	Standing Committee on Biocidal Products
SEAC	Socio-Economic Analysis Committee
SME	Small and Medium-sized Enterprise
SSR	Standard Safety Requirement
SVHC	Substances of Very High Concern
WP	Work Package

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