

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

## **Action Plan – North Macedonia**

*February 2022*



## Table of Contents

<b>EXECUTIVE SUMMARY .....</b>	<b>4</b>
<b>1 INTRODUCTION.....</b>	<b>6</b>
1.1 CONTEXT.....	6
1.2 METHODOLOGY AND REPORT STRUCTURE.....	6
<b>2 THE ACTION PLAN .....</b>	<b>8</b>
2.1 CHALLENGES AND GAPS IDENTIFIED .....	8
2.2 UNDERLYING CAUSES AND MEANS TO ADDRESS THEM .....	11
2.2.1 EU CENTRALISED PROCEDURES CANNOT BE TRANSPOSED INTO THE NATIONAL SYSTEM BEFORE ACCESSION .....	11
2.2.2 THE CONTINUOUS EVOLUTION OF THE EUROPEAN CHEMICAL LEGISLATIVE FRAMEWORK.....	13
2.2.3 LACK OF A BUDGET FOR CHEMICAL RISK MANAGEMENT ACTIVITIES .....	15
2.2.4 LACK OF A MEMORANDUM OF UNDERSTANDING WITH SCIENTIFIC INSTITUTES AND EXTERNAL EXPERTS .....	16
2.2.5 CHEMICALS RISK MANAGEMENT IS STILL NOT HIGH ON THE AGENDA OF STAKEHOLDERS.....	18
2.3 IDENTIFIED CHALLENGES AND ASSOCIATED OBJECTIVES.....	19
2.3.1 UNDERSTAFFING OF THE MINISTRY OF HEALTH.....	19
2.3.2 LACK OF INFORMATION ON ENFORCEMENT ACTIVITIES.....	22
2.3.3 LACK OF A NATIONAL HELPDESK .....	23
2.3.4 LACK OF A COMMUNICATION STRATEGY .....	25
2.3.5 LACK OF PARTICIPATION BY THE PUBLIC AND CIVIL SOCIETY IN DECISION-MAKING PROCESSES...	27
2.3.6 LACK OF IT SYSTEM FOR SUBMITTING DOCUMENTATION TO THE DIVISION FOR CHEMICALS MANAGEMENT .....	29
2.3.7 GAPS IN IT INFRASTRUCTURE, POLICIES AND PROCEDURES.....	30
<b>3 CONCLUSIONS AND RECOMMENDATIONS .....</b>	<b>33</b>
3.1 RECOMMENDED ACTIONS AND PRIORITISATION .....	33
3.2 SIMILARITIES IN GAPS AND SHORTCOMINGS BETWEEN NORTH MACEDONIA AND POTENTIAL CANDIDATE COUNTRIES AND POTENTIAL FOR JOINT ACTIONS .....	40
<b>REFERENCES .....</b>	<b>42</b>
<b>LIST OF ABBREVIATIONS .....</b>	<b>44</b>



## List of Tables

Table 1 – Objective 1: Ensure risk assessment capacity and practical experience with e-tools.....	12
Table 2 – Objective 2: Strengthen the capacity of the MoH .....	14
Table 3 – Objective 3: Reform the budgetary system.....	15
Table 4 – Objective 4: Develop, ratify and implement an MoU .....	17
Table 5 – Objective 5: Raise the awareness of chemical risk management .....	18
Table 6 – Objective 6: Strengthening the administrative capacity of the MoH.....	21
Table 7 – Marginal labour cost of hiring DCM staff .....	21
Table 8 – Objective 7: Information on enforcement made available to the public.....	23
Table 9 – Objective 8: Establish a National Helpdesk .....	24
Table 10 – Objective 9: Develop a communication strategy.....	26
Table 11 – Objective 10: Increase stakeholder participation in public consultations and decision-making.....	28
Table 12 – Objective 11: Digitalise the submission of documentation to the DCM.....	29
Table 13 – Objective 12: Align IT infrastructure, policies and procedures with ECHA’s standards.....	31
Table 14 – Action Plan.....	35
Table 15 – Gantt chart and resource allocation .....	36
Table 16 – Risks and risk mitigation measures.....	38

## List of Figures

Figure 1 – Intervention logic.....	10
------------------------------------	----

## Executive Summary

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

*The national competent authority for the alignment of the national legislation with the EU chemical acquis is the Ministry of Health (MoH) and the Ministry of Environment and Physical Planning (MEPP). More precisely, the MoH is responsible for drafting the legislation and the establishment of a strategic framework for the management of chemicals and biocidal products, while the MEPP is responsible for the implementation of the international chemical treaties, including the Stockholm Convention, the Rotterdam Convention and the Minamata Convention, and therefore of the national legislation transposing the POPs Regulation, PIC and the Regulation (EU) 2017/852 on mercury. The Department for Chemicals within the MoH is responsible for the practical implementation and enforcement of the chemical legislation. It is composed of two divisions: the Division for Chemicals Management (DCM), responsible for the implementation, and the Division for Chemicals Inspection (DCI), responsible for the enforcement. As of June 2021, the DCM has four, and the DCI has two employees, overseen by the Head of the Department for Chemicals.*

*The assessment has identified the lack of necessary resources for the implementation and enforcement of the national legislation on chemicals and biocidal products as the main challenge. The Head of the Department for Chemicals is building the capacity of the staff, that have also benefitted from the involvement in international projects and the attendance at workshops and meetings. However, the resources dedicated to the capacity building of the staff are not sufficient, and there is a lack of expertise in the evaluation of applications for the authorisation of biocidal products.*

*North Macedonia is still developing the legislative framework, and the workload associated with this task is assumed to stay constant over the coming years. The DCM employees have to further align the national legislative framework with the EU acquis while ensuring the practical implementation of the national legislation and the provision of information to stakeholders and the general public. An official helpdesk is yet to be established. Although there is a need for additional resources, there are currently no plans to hire more people. In particular, there is the need to increase resources for the management of biocidal products. Depending on the further alignment of the national legislation to the BPR and the number of applications for the different authorisation procedures, it is estimated that the evaluation and assessment of the applications could require between five to ten FTEs per year over a period of five years. The MoH should consider the progressive hiring and training of personnel and outsourcing some tasks related to the management of biocidal products authorisations. The Ministry of Health could opt for a hybrid system of internal and external resources, with the latter provided by the academic and research institutions active in North Macedonia. Therefore, it is important that competent authorities draft and ratify a Memorandum of Understanding (MoU) with scientific institutes and external experts, which would facilitate the outsourcing of some workstreams.*

*In order to strengthen the administrative capacity and enable the implementation of other recommended actions, some underlying challenges need to be tackled first. In particular, the lack of a budget for chemical risk management needs to be addressed to ensure that adequate financial resources are available to fund new job positions within the competent authorities.*

*Furthermore, there is no official helpdesk to provide stakeholders with information on their responsibilities and obligations regarding the chemical and biocidal products legislation. In addition,*

Action Plan

*there is a low level of public awareness of chemicals and chemical safety. Therefore, the DCM should develop a communication strategy, and it is recommended that stakeholder management and other aspects of external communication form part of the job description of one of the employees of the Division, together with the assignment to helpdesk and information services.*

*It is also recommended to significantly upgrade the IT infrastructure and the IT safety policies and procedures. The competent authorities should commission an initial external IT security audit to identify needed actions to bring the existing IT system up to the standard required by the European Chemicals Agency. The availability to submit the documentation for authorisation of biocidal products electronically is also important to make the process more efficient and sustainable.*

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

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

# 1 Introduction

## 1.1 Context

This fourth part of the study presents **the recommendations stemming from the results of the comparative legal analysis of the national legislation with the EU *acquis* and from the results of the assessment of the institutional capacity and infrastructure available in North Macedonia for the implementation and enforcement of:**

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP);
- Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR);
- The recast prior informed consent (PIC) Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals; and
- Regulation (EU) No 1021/2019 on persistent organic pollutants (POPs).

## 1.2 Methodology and report structure

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

- The review of:
  - Laws, bylaws and accompanying documents;
  - The report produced by the European Commission<sup>1</sup> in assessing the progress of North Macedonia with the reforms in the framework of the accession negotiations;
- The phone interview with the Macedonian competent authorities held on 26 March 2021 and follow-up emails;
- Phone interviews with local NGOs and members of academia.

Actions have been suggested in the following areas:

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

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

All actions are broken down in subsequent sections of this report, their dependencies have been highlighted, and timelines have been suggested for their implementation. Where

---

<sup>1</sup> EC (2020): Commission Staff Working Document North Macedonia 2020 Report. Accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 2020 Communication on EU Enlargement Policy. Brussels, 6.10.2020 SWD(2020) 351 final.



#### Action Plan

applicable/relevant, the action is accompanied by a list of relevant possible actors and the estimated financial and human resources required. Finally, other important aspects are described (e.g., awareness-raising, outreach, collaboration, and communication with other stakeholders) for the successful implementation of the recommended actions.

## 2 The Action Plan

### 2.1 Challenges and gaps identified

The assessment of the degree of legal harmonisation, the institutional capacity and necessary infrastructure has identified several intertwined challenges and gaps. The work of the Ministry of Health (MoH) to align the national legislation with the EU *acquis* is still ongoing and has been challenging considering the pace of the development of the European chemical legislative framework<sup>2</sup> together with the complexities of introducing EU centralised procedures into a national system. The alignment of the legislation is a resource-intensive work, and there are other underlying issues that would be beneficial to address in order to ensure progress. The identified drivers, gaps and impacts are listed below:

#### Drivers

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

#### Gaps

The key challenges and gaps identified are:

- Lack of human resources and expertise;
  - Administrative capacities are not sufficient to undertake the full implementation of the legislation;
  - Evaluation of applications for the authorisation of biocidal products is limited;
  - A system to evaluate biocidal active substances is not aligned with BPR;
- Lack of a National Helpdesk;
- Lack of information on enforcement activities;
- Lack of a communication strategy;
- Lack of participation by the public and civil society in decision-making processes;
- Lack of IT system for submitting the documentation to Division for Chemicals Management; and
- Gaps in IT infrastructure, policies and procedures.

#### Consequences

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

- Effective implementation of the legislative framework;
- The protection of human health and the environment and the guarantee of a level playing field between North Macedonia and foreign companies;
- Stakeholder engagement and public awareness of chemicals and chemical safety; and

---

<sup>2</sup> Updates of the annexes of the REACH Regulation (new substances added to the authorisation and restriction lists, adaptations to the information requirements to better cover nanomaterials), adaptations to technical progress (ATPs) of the CLP Regulation, approvals of active substances (Biocidal Products Regulation).





#### Action Plan

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

Drivers, challenges, gaps, and consequences are discussed in the sections below, along with the recommended actions to achieve specific and general objectives. Figure 1 shows the intervention logic<sup>3</sup> with drivers, challenges, their impact, and measures to tackle identified problems, as well as main objectives and specific objectives.

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

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

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

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

---

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

WP 4 – Action Plan

Figure 1 – Intervention logic

Drivers and external factors	Challenges		Impacts	Specific objectives and measures	General objectives
EU centralised procedures cannot be transposed	Lack of human resources and expertise	Administrative capacities are not sufficient to undertake the full implementation of the legislation	An effective implementation of the legislative framework cannot be ensured	Strengthen the capacity and expertise for the authorisation of biocidal products	Aligning the national legislation with the EU Regulation
Continuous evolution of the EU regulatory framework		Evaluation of applications for the authorisation of biocidal products is limited	No full protection of human health and the environment and no level playing field between North Macedonian and foreign companies	Develop a Memorandum of Understanding with scientific institutes	
		A system to evaluate biocidal active substances is not aligned with BPR	Cannot ensure proper enforcement	Establish a National Helpdesk	
Lack of budget dedicated to chemical risk management activities	Lack of a National Helpdesk	Low level of stakeholder and public awareness on chemicals and chemical safety	Make the information on enforcement activities available to public		
	Lack of a communication strategy		Increase stakeholder participation in public consultations and decision-making processes		
Lack of Memorandum of Understanding with universities and research institutes	Lack of information on enforcement activities	Inefficient and unsustainable application system	The development of a communication plan and closer collaboration with NGOs and other stakeholders	Bringing the capacity up to a level where the obligations laid down in the Regulations can be carried out efficiently and effectively	
	Lack of participation by the public and civil society in decision-making processes	May not get access to ECHA databases and e-tools	Digitalise the submission of documentation		
Chemical risk management is not high on the agenda of stakeholders	Lack of IT system for submitting the documentation to Division for Chemicals Management	Cannot ensure safety of CBI and personal data	Next audits of IT security to consider ECHA's SSRs		

## 2.2 Underlying causes and means to address them

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

#### 2.2.1.1 Description of the challenges and dependencies

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

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

Since 2009, ECHA activities, implemented under the Instrument for Pre-accession Assistance (IPA) and funded by the European Union, have provided capacity building and support to the implementation of the EU chemicals legislation<sup>5</sup>. In addition, to increase the impact of ECHA's general support activities (such as visits, specific training, and participation in ECHA events), the Agency has contracted an in-depth assessment of the legal and institutional capacities of Albania, Bosnia and Herzegovina, Kosovo, North Macedonia, and Turkey.

In general, DCM staff benefitted from being involved in international projects and attending workshops and meetings. Annual training programmes are developed and approved by the Ministry of Information Society and Administration but are not well-financed, and no resources for specialised training are provided. General training sessions are not frequent. The staff are encouraged to use distance learning and training by electronic means; however, no information is available on the number of staff that have undertaken such training. Specialised training on environmental issues is project-based.

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

It is recommended that **ECHA implements additional capacity building activities focusing on risk assessment**. In addition, it is also recommended that **ECHA delivers hands-on training sessions focusing on the use of the e-tools** used by EU Member States' competent authorities to

<sup>4</sup> This is the case with:

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

<sup>5</sup> The whole list of events, study visits and workshops organised by ECHA can be found at: <https://echa.europa.eu/about-us/partners-and-networks/international-cooperation/support-to-eu-external-relations-policies/activities-under-ipa/2018-2019>

Action Plan

manage the information exchange with ECHA. Although this action is a low priority, North Macedonia's competent authorities would benefit from understanding the functioning of these tools, which may help develop and improve their own procedures. This would also make data migration easier once North Macedonia joins the EU. Table 1 shows the conformity of the objective to the SMART criteria.

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

Criteria	Notes
<b>Specific</b>	It is recommended that ECHA implements additional capacity building activities focusing on risk assessment. It is recommended that ECHA delivers hands-on training sessions focusing on the use of the e-tools used by national competent authorities to manage the information exchange with ECHA.
<b>Measurable</b>	Number of civil servants and external experts trained per year.
<b>Achievable</b>	ECHA has implemented capacity-building activities in North Macedonia since 2009 and may continue supporting North Macedonia's competent authorities
<b>Relevant</b>	Capacity building will ensure a smoother EU accession.
<b>Time-bound</b>	Training on risk assessment should be prioritised and possibly start in 2022 as a yearly exercise. Hands-on training on e-tools could be organised closer to the day of accession.

### 2.2.1.3 Estimated human and financial resources required

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

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

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

It is expected that the required human resources and the cost borne by ECHA or MSCA for training North Macedonia's competent authorities' staff may be similar. However, the actual cost will depend

<sup>6</sup> Around SEK 1,500,000.

<sup>7</sup> Keml (2018): Chemicals risk management in Serbia. Annual report 2017, p.12.

<sup>8</sup> Twinning Contract number: SERBIA – IPA 2013 - ENVIRONMENT - SR 13 IB EN 03. Further development of chemicals and biocides product management in the Republic of Serbia (2015-2018), between the 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.

Action Plan

on the number of attendees (internal and/or external) and whether the training will be carried out only for North Macedonian competent authorities or as a joint action for all candidate and potential candidate countries (see Section 3.2).

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

Due to a lack of expertise in risk assessment and evaluation of applications for the authorisation of biocidal products, it is recommended to prioritise those capacity building activities, which focus on the management of applications for biocidal products. Training activities on ECHA e-tools are of a lower priority, but if these were going to be provided to other candidate and potential candidate countries, North Macedonian competent authorities would benefit from increasing their knowledge of the functioning of ECHA tools to better design their own instruments for storage, management and exchange of information.

## 2.2.2 The continuous evolution of the European chemical legislative framework

### 2.2.2.1 Description of the challenges and dependencies

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

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

The Law on Chemicals no. 145/10 and its amendments are only partially harmonised with the five Regulations. As discussed in the previous section, some centralised procedures cannot be transposed. However, there are plans to further harmonise the chemicals legislation in North Macedonia with the EU *acquis*. According to the National Program for the adoption of the *acquis*, there are plans to update the following for further alignment with REACH, CLP and PIC:

- The List of bans and restrictions of chemicals in terms of their use;
- The List of substances of very high concern;
- Amendments to the List of hazardous chemicals and products, whose export is prohibited;
- Amendments to the List of state Parties to the Rotterdam Convention requesting information on the transit of chemicals and the content of that information;
- Amendments to the Rulebook on the manner of classification, packaging and labelling of chemicals;
- Preparation of Guidelines for the preparation of a safety data sheet, arising from the Law on Chemicals, which will be harmonised with Regulation (EU) 2015/830;
- Updating of the National Action Plan for Strategic approach into International Chemical Management, which will also take into consideration harmonisation of the chemicals' legislation;

Action Plan

- There is a plan to adopt an additional Rulebook to amend the Rulebook on cases in which the PIC procedure is implemented, and the content of the Request for implementation of PIC Procedure;
- There is a plan to adopt an additional Rulebook to amend the Rulebook for the cases in which the prior notification procedure is implemented, the cases in which further implementation of the prior notification procedure is not required, the content of the export notifications and the documents submitted for the implementation of the pre-notification procedure.

In the frame of the recently approved GEF Project “Global Development, Review and Update of National Implementation Plans (NIPs) under the Stockholm Convention (SC) on Persistent Organic Pollutants (POPs)”, North Macedonia will work on the second update of the NIP on POPs. This will be an additional opportunity for the country to finalise the draft text of the Rulebook on POPs, which will be fully harmonised with the EU POPs Regulation.

Keeping North Macedonia’s legislation aligned with the EU *acquis* is a resource-intensive work. The MoH is responsible for drafting the legislation and establishing a strategic framework for the management of chemicals and biocidal products. It is also responsible for the implementation of the Law on Chemicals no. 145/10 and its amendments, including the provisions transposing REACH, CLP and BPR. Currently, the Division for Chemicals Management (DCM) within the Department for Chemicals at the MoH is responsible for checking the classification, packaging, and labelling of chemicals. In addition, the DCM maintains communication with ECHA and other international partners, mainly by attending meetings and consultations. The Division is also responsible for providing information to the general public about hazards and risks of chemicals, although currently, such a system does not exist. Finally, the DCM is responsible for establishing a National Helpdesk to provide recommendations to manufacturers, importers, distributors, downstream users and other concerned parties on their duties and responsibilities in line with the Law on Chemicals (see Section 2.3.3). Initial steps for its establishment have already been taken by the Department, but improvements and more human resources are needed to make it operational and efficient. Although there is a need for additional resources to strengthen the capacity for the approximation with the EU *acquis*, which is regularly presented by the DCM in the Strategy of the Ministry of Health, there are currently no plans to hire more people.

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

The alignment and keeping the alignment of the national legislation with the EU Regulations is a resource-intensive task, as are other tasks necessary for the adequate implementation of the national chemical laws. Currently, the DCM, which is in charge of implementing the chemical legislative framework, employs four people. All DCM employees have qualifications in either chemistry or technology. However, administrative capacities are not sufficient to undertake the full implementation of the legislation. Therefore, it is recommended that **the MoH strengthens the capacity of the DCM**. This is further discussed in Section 2.3.1. Table 2 shows the conformity of the objective to the SMART criteria.

**Table 2 – Objective 2: Strengthen the capacity of the MoH**

Criteria	Notes
Specific	The MoH strengthens the capacity of the DCM.
Measurable	Number of additional DCM staff members.
Achievable	Further discussed in Section 2.3.1.
Relevant	Additional capacity is key to overcoming many of the identified challenges.
Time-bound	It is estimated that the DCM will need around 5-10 FTEs per year over the next 10-year period dedicated to the alignment of the national legislation and implementation of administrative tasks.



### 2.2.2.3 Estimated human and financial resources required

The gap in the administrative capacity has been quantified as five to ten FTEs per year over the next five years. The necessary resources depend on a number of factors, such as the number of applications per different authorisation procedures and the time set by the legislation to evaluate different applications. The range of five to ten FTEs has been estimated by comparing North Macedonia with Malta and assuming that a similar number of biocidal products will be placed on the market (700 to 1,000). This gap in resources could be filled by hiring new employees and using external resources. In addition, both internal and external resources should receive training to strengthen their competencies and skills. Additional details are provided in Section 2.3.1.

### 2.2.2.4 Timeline, risks and risk mitigation measures

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

## 2.2.3 Lack of a budget for chemical risk management activities

### 2.2.3.1 Description of the challenges and dependencies

According to UNECE (2019), the expenditures on environmental issues and protection are financed by a number of different funding sources, which also depend on a particular environmental domain. The main general funding sources are the state budget and loans and grants from other countries and international financial institutions. In addition, there is no national environmental fund with a variety of earmarked revenues, and little use has been made of earmarked revenue from environmental taxes and charges.

According to the Law on Chemicals, fees for the realisation of the activities set out in Articles 8, 81, 87, 88, and 94 in relation to placing on the market biocidal products and chemicals, issuing and renewing permits for performing trade of extremely hazardous chemicals and permit for the use of extremely hazardous chemicals, and the PIC procedure are set out in the "Rulebook on the amount of funds for the realisation of activities and fees paid in the procedures conducted in accordance with the Law on Chemicals", which determines fees based on actual costs incurred. However, it is important that the fees are earmarked for chemical risk management activities, and the MoH has direct access to a dedicated budget to ensure that the competent authorities have enough financial resources for the implementation of chemicals legislation.

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

It is recommended that **the Government of North Macedonia creates a dedicated budget for chemical risk management activities by ring-fencing fees and charges paid by companies to place chemical substances and biocidal products on the market.** The dedicated budget will allow competent authorities to implement other important actions, such as strengthening the capacity of the MoH and providing the necessary training and capacity-building activities to administrative staff. Table 3 shows the conformity of the objective to the SMART criteria.

**Table 3 – Objective 3: Reform the budgetary system**

Criteria	Notes
Specific	It is recommended that the Government creates a dedicated budget for chemical risk management activities by ring-fencing fees and charges paid by companies to register their chemical substances and apply for the registration of chemicals and authorisation of biocidal products.

Action Plan

Criteria	Notes
<b>Measurable</b>	A ring-fenced budget dedicated to chemical risk management activities is created.
<b>Achievable</b>	Although achievable, the change in the budgetary system is likely to take some time.
<b>Relevant</b>	Lack of resources is one of the main challenges that needs to be resolved to implement and complete many identified actions.
<b>Time-bound</b>	It is recommended to give priority to this action in order to have a dedicated budget for the implementation of the national legislation.

### 2.2.3.3 Estimated human and financial resources required

The allocation of a budget to chemical risk management activities will not require resources at the MoH or the MEPP and instead will be a task for the Government and/or the Ministry of Finance.

### 2.2.3.4 Timeline, risks and risk mitigation measures

The implementation of the necessary changes in the budgetary system may be a lengthy process. Therefore, it is recommended that this action is given priority to allow the creation of the dedicated budget that is necessary for the implementation of the national legislation. Without the necessary financial resource, competent authorities may not be able to fulfil their responsibilities under the Law on Chemicals.

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

### 2.2.4.1 Description of the challenges and dependencies

There is a need to increase resources for the management of biocidal products. The DCM has no capacity and adequate competencies for the evaluation of applications for the authorisation of biocidal products. This gap could be filled by hiring new employees at the MoH and by using external resources. The main area of concern is the implementation of the Biocidal Products Regulation (BPR), which is resource-intensive and requires specific expertise in risk and efficacy assessment. North Macedonian authorities could consider outsourcing some of the most technical aspects to external scientific institutes through a memorandum of understanding (MoU).

Given that the capacity at the DCM will have to be built up progressively over time, support may be sought from external experts. With the right framework in place, scientific institutes and academia with expertise in chemistry, efficacy, toxicology, and ecotoxicology could play an important role in supporting the competent authority, particularly regarding risk assessment. Expertise is available in several faculties and institutes, such as the Faculty of Technology and Metallurgy and the Institute of Chemistry within the Faculty of Natural Sciences and Mathematics at the Ss. Cyril and Methodius University, or the Department of Occupational Medicine at the Faculty of Medicine.

In addition, experts from academia and scientific institutes should be trained on the technical and scientific aspects of the chemical legislation, also in consideration of staff turnover and skill decay.<sup>9</sup> Training courses could be organised for academic experts and DCM staff (see Section 2.3.1).

<sup>9</sup> The loss or decay of trained or acquired skills (or knowledge) after periods of non-use. As defined in Arthur, Bennett, Stanush, and McNelly (1998): Factors that influence skill decay and retention: a quantitative review and analysis. *Human Performance*, 11(1), 57-101.



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

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

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

Ultimately, the objective is to develop capacity and competencies, ensure the functioning of the MoU and the smooth processing of industry applications.

Table 4 shows the conformity of the objective to the SMART criteria.

**Table 4 – Objective 4: Develop, ratify and implement an MoU**

Criteria	Notes
<b>Specific</b>	It is recommended the MoH develops, ratifies and implements an MoU with the relevant scientific institutes.
<b>Measurable</b>	An MoU with external experts is ratified.
<b>Achievable</b>	The DCM is in contact with academia and the relevant scientific institutes. Experts from the entities have been trained along with DCM staff on different topics (e.g., efficacy assessment, human health and environmental risk assessment).
<b>Relevant</b>	Without the support of external experts, the North Macedonian competent authority will not be able to process all industry applications, particularly for the authorisation of biocidal products, by the day of accession.
<b>Time-bound</b>	The MoU should be functioning as soon as possible in order to relieve the workload of the DCM.

### 2.2.4.3 Estimated human and financial resources required

It is recommended that the DCM allocates at least 0.5 FTE per year in the period 2022-2024 to prepare the MoU and set up the necessary framework for a closer collaboration with academia and institutes. This is based on the work carried out by the Montenegrin competent authorities, who have been preparing an MoU over the last couple of years.

### 2.2.4.4 Timeline, risks and risk mitigation measures

It is recommended to have a functioning MoU with experts from academia, for instance, the Institute of Chemistry and the Faculty of Medicine at the Ss. Cyril and Methodius University, by the end of 2024. This would require identification of relevant parties, a survey of their competencies and needs and the definition of the scope of collaboration in the period of 2022-2024. It should be noted that, given the understaffing of the DCM, even 0.5 FTEs per year over a period of three years could be

prohibitive unless the capacity of the Division is strengthened in 2022. Moreover, the opportunity to have an MoU or implement short-term contracts depends on creating a dedicated budget. However, the risk is the lack of financial resources due to the national and global economic slowdown triggered by the ongoing COVID-19 pandemic.

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

### 2.2.5.1 Description of the challenges and dependencies

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

Furthermore, the lack of public access to environmental information, including the information on chemicals, results in low public awareness about chemical risk management and related activities. According to UNECE (2019), although there have been efforts by governmental institutions to improve communication with the public on environmental matters, in many cases, the information is given in a format that is too technical for public consumption and connection to human health and safety are not explicitly shown or explained, which limits the public's comprehension of information. In addition, the environmental information that is made available to the public is not always easily accessible because it is often kept in archives and is very time consuming and difficult to find unless the user knows the exact title of the document. Often, websites contain information that is either too general or too technical. Another factor hindering efficient access to information is the lack of awareness in civil society about the availability of environmental information and procedures to access such information (UNECE, 2019).

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

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

It is recommended that **the competent authorities raise awareness of chemical risk management among the public, civil societies, and the industry** by improving public access to information on environmental matters, including chemicals risk management. The implementation of recommendations and actions laid down in Sections 2.3.2, 2.3.3, 2.3.4 and 2.3.5 would also help raise awareness among relevant stakeholders and increase their participation in public consultations and decision-making processes. Actions include the development of communication strategy, establishment of fully functioning National Helpdesk, and publishing the information on enforcement activities for chemicals and biocidal products. The implementation of actions laid down in Sections 2.2.3 and 2.2.4 would also help strengthen the competent authorities in chemical risk management activities by creating additional resources and providing the necessary expertise for the transposition and implementation of chemicals legislation. Table 5 shows the conformity of the objective to the SMART criteria.

**Table 5 – Objective 5: Raise the awareness of chemical risk management**

Criteria	Notes
Specific	It is recommended that the competent authorities raise the awareness of chemical risk management among the public, civil societies, and the industry.

Action Plan

Criteria	Notes
<b>Measurable</b>	Improved public access to information on environmental matters and chemicals risk management. Competent authorities have the necessary resources to implement chemicals legislation. Stakeholders actively participate in public consultations. Information on enforcement activities is easily accessible to the public. MoU is in place and functioning.
<b>Achievable</b>	Actions in Sections 2.3.2, 2.3.3, 2.3.4 and 2.3.5 need to be implemented first in order to put the chemicals risk management higher on the agenda of all stakeholders.
<b>Relevant</b>	Without raising the awareness of chemical risk management among the public, the industry, civil societies and other relevant stakeholders, the North Macedonia's competent authorities may not be able to guarantee adequate enforcement of the EU Regulations.
<b>Time-bound</b>	Starting 2022 until the accession to the EU.

### 2.2.5.3 Estimated human and financial resources required

Sections 2.3.2.3, 2.3.3.3, 2.3.4.3 and 2.3.5.3 of the report describe the necessary resources for implementing actions that would help to improve the communication on and increase public awareness of chemical risk management.

### 2.2.5.4 Timeline, risks and risk mitigation measures

The timelines for implementation of related actions are presented in Sections 2.3.2.4, 2.3.3.4, 2.3.4.4 and 2.3.5.4 of the report.

## 2.3 Identified challenges and associated objectives

### 2.3.1 Understaffing of the Ministry of Health

#### 2.3.1.1 Description of the challenges and dependencies

The MoH is responsible for drafting the legislation and establishing a strategic framework for the management of chemicals and biocidal products. It is also responsible for the implementation of the Law on Chemicals no. 145/10, including the provisions transposing REACH, CLP and BPR. The MoH has the Department for Chemicals, which consists of the Division for Chemicals Management (DCM) and the Division for Chemicals Inspection (DCI) and is coordinated by one Head of the Department. The DCM employs four specialists, and the DCI employs two inspectors. However, there is a need for additional resources. According to UNECE (2019), the delayed adoption of strategic documents and a persistent lack of reporting on implementation are bottlenecks for efficient strategic planning in North Macedonia. Some policy documents are never adopted despite the significant efforts made to develop them. Preparing a national environmental action plan (NEAP), which meant to underpin the planning in the environmental field, was discontinued after the second NEAP 2006-2012. Hence, there are currently no existing strategic plans on a state level for further developing and strengthening the institutional capacity of the competent authorities, which have limited staff and inadequate resources for implementation, compliance, and enforcement of the legislation on chemicals.

In particular, there is the need to increase resources for the management of biocidal products. The DCM has no capacity and adequate competencies for the evaluation of applications for the authorisation of biocidal products. A system to evaluate biocidal active substances for the purpose

#### Action Plan

of approval in accordance with Article 8 of the BPR has not been established yet, and the evaluation of applications for the authorisation of biocidal products is limited.

The Head of the Department for Chemicals provides training for the staff at the DCM and DCI. Also, between 2009 and 2018, ECHA invited North Macedonian authorities to many meetings on different topics and aspects of the regulations. In general, DCM staff benefitted from being involved in international projects and attending workshops and meetings. Annual training programmes are developed and approved by the Ministry of Information Society and Administration, but no resources for specialised training are provided. Specialised training on environmental issues is usually project-based. General training sessions are not frequent, and the staff are encouraged to use distance learning and training by electronic means. However, no information is available on the number of staff that have undertaken such training.

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

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

In addition, according to Article 53 of the Law on Chemicals, the MoH should maintain an Integral Register of Chemicals placed on the market, consisting of a Register of Chemicals and a Register of Biocidal Products, as well as data for plant protection for the purpose of data exchange and integrated chemicals management. According to the Law, the MoH, more precisely, the DCM is responsible for establishing and maintaining the register of chemicals and biocidal products, although the register has not been established yet. However, a national register of chemicals is not a requirement for EU Member States. In the EU, the registration of chemicals is managed by ECHA for the whole single market, and national registries add to the administrative burden for industries and competent authorities. The register of chemicals can provide useful information on chemicals on the market for North Macedonia's competent authorities; however, the establishment and maintenance may require additional resources, which could instead be used for further alignment of the national legislation with EU *acquis*. Therefore, any future plans on establishing the register of chemicals should involve a feasibility study to assess the practicality of the register.

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

It is recommended that **the MoH strengthens the administrative staff capacity for the implementation of biocides legislation**. Assuming that the number of biocidal products on the North Macedonian market is similar to the number on the Maltese market, North Macedonia's competent authorities could receive between 700 to 1,000 applications for biocidal product authorisation. Depending on the number of applications for the different authorisation procedures, the evaluation and assessment of the applications could require between **5 to 10 FTEs per year over a period of five years**. North Macedonia could opt for five additional internal employees, and five additional external experts could be trained to support and ease the competent authorities' workload when necessary. This would free up the current staff for other important tasks, such as the development of the legislative framework and the establishment of the National Helpdesk. In addition, this would also allow employees to continue participating in capacity building activities and meetings organised by ECHA and other international organisations.

In addition, it is recommended that **the competent authorities survey the needs of their staff and external experts and organise and implement training and capacity-building courses** in risk assessment and other technical and scientific areas, especially in the management of biocidal product authorisation. Training should be continuous and planned on an annual basis to keep

Action Plan

internal and external experts up to date with the evolutions in the EU. Furthermore, a capacity-building plan should be developed, involving the following, *inter alia*, aspects:

- Identification of currently available resources and gaps in expertise in the DCM;
- Planning and implementation of the provision of training (timelines);
- Provision of training to external resources, when required.

ECHA and other Member States Competent Authorities could support the increase in MoH staff capacity by implementing capacity-building projects. Therefore, the capacity-building plan should be developed in coordination with ECHA and other MSCAs, highlighting where these entities could provide additional training and support.

Table 6 shows the conformity of the objective to the SMART criteria.

**Table 6 – Objective 6: Strengthening the administrative capacity of the MoH**

Criteria	Notes
<b>Specific</b>	It is recommended that the MoH strengthens the administrative capacity in order to guarantee the adequate implementation of the EU Regulations. It is recommended that the competent authorities survey the needs of their staff and external experts and organise and implement training and capacity-building courses.
<b>Measurable</b>	Number of employees in the MoH. Number of external experts readily available for outsourced work. A capacity-building plan is developed and established, covering 2022-2026.
<b>Achievable</b>	This may require the allocation of adequate financial resources. Several Twinning projects have already been completed in North Macedonia.
<b>Relevant</b>	Without strengthening the capacity of the MoH, the North Macedonia's competent authority will not be able to transpose and implement the EU Regulations. Capacity building is necessary to overcome many challenges and ensure the implementation of the legislation on chemicals.
<b>Time-bound</b>	The capacity needs to be built over time, starting from 2022.

### 2.3.1.3 Estimated human and financial resources required

In North Macedonia, the average labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €8,000<sup>10</sup>, whereas in the professional, scientific, and technical activities sector in full-time equivalents per year is estimated to be approximately €8,500. Therefore, the additional cost of bringing the number of competent authorities' employees to the suggested five is around €120,000 over a five-year period (Table 7).

**Table 7 – Marginal labour cost of hiring DCM staff**

	2022	2023	2024	2025	2026	€ - Total
DCM Staff - FTEs	4	5	6	7	8	-
Additional FTEs	1	1	1	1	0	-
Marginal Cost	€8,000	€16,000	€24,000	€32,000	€40,000	€120,000

<sup>10</sup> Eurostat - Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016.

#### Action Plan

However, the estimated number of FTEs required to deal with the expected workload may exceed this level closer to accession and may amount to around ten (internal and external) FTEs. In this scenario, the additional cost for outsourcing all five external experts would be around €42,500 per year.<sup>11</sup> It should be noted that these costs should be covered by the applicants through fees (see Section 2.2.3.2 for more information).

Given the lack of financial resources, North Macedonia's competent authorities may need to continue relying on ECHA's and other European partners' technical and financial support on capacity-building. As discussed in Section 2.2.1, the human and financial resources for capacity building depend on several factors, for example, the number of tutors involved, the number of attendees, the number of in-person classes vs remote learning sessions, travel, accommodation, etc. Hence, the costs may vary but could be forecasted at around €100,000 per year and required 0.6 FTE.

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

The hiring of new employees should start as soon as possible and continue progressively until the required number is reached. Capacity-building activities should take place in parallel to build up competencies and expertise necessary for the implementation of the legislation on chemicals. Resources should be available for thorough training for new staff members to ensure a swift onboarding. The risk is that the resources may not be available at the MoH to implement capacity-building activities. In addition, the ongoing pandemic may restrict the possibility of organising face-to-face training, and therefore experts may need to be trained and work remotely. For this, adequate infrastructure and procedures should be established, including suitable teleworking policies (Section 2.3.7).

### 2.3.2 Lack of information on enforcement activities

#### 2.3.2.1 Description of the challenges and dependencies

There are several authorities in North Macedonia responsible for the enforcement of different aspects of the national chemical legislative framework. The Division for Chemicals Inspection employs two FTEs, who are responsible for the enforcement of chemical legislation and overseeing the planning and organisation of inspection campaigns. They are managed by the Head of the Department for Chemicals at the MoH. In addition, several Inspectorates, namely the State Environmental Inspectorate<sup>12</sup> of the MEPP, the State Labour Inspectorate of the Ministry of Labour and Social Policy, the State Market Inspectorate<sup>13</sup> of the Ministry of Economy, the State Inspectorate for Agriculture<sup>14</sup> of the Ministry of Agriculture, Forestry and Water Economy, and the State Sanitary and Health Inspectorate of the MoH also have different responsibilities under the legislative framework for chemicals.

In 2015-2016, enforcement authorities benefitted from a twinning project aiming to strengthen the administrative capacities at a central and local level for the implementation and enforcement of the environmental *acquis*. However, no information is available on the extent the guidelines and procedures have been effectively implemented. In addition, no specific information has been found on the number of inspectors working in the different inspectorates with competencies in chemical legislation nor statistics or data on inspections carried out on chemical and biocidal products.

<sup>11</sup> The estimate provided is the maximum cost per year for all recommended five external experts for biocidal products management and may differ depending on need for outsourcing the workstreams.

<sup>12</sup> [http://www.sei.gov.mk/index\\_en.asp](http://www.sei.gov.mk/index_en.asp)

<sup>13</sup> <https://www.dpi.gov.mk/index.php/en/>

<sup>14</sup> <https://diz.gov.mk/en/about-us/>



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

It is recommended that **the information on enforcement activities in chemical risk management is made available to the public** to ensure transparency and increase confidence in competent authorities on the enforcement of legislation on chemicals and biocidal products. This could be achieved by annual reporting of data and statistics on inspections and enforcement of chemicals legislation on a dedicated online platform or in annual reports. Table 8 shows the conformity of the objective to the SMART criteria.

**Table 8 – Objective 7: Information on enforcement made available to the public**

Criteria	Notes
<b>Specific</b>	It is recommended that the information on enforcement activities in chemical risk management is made available to the public.
<b>Measurable</b>	Annual reporting of data and statistics on inspections and enforcement of chemical legislation on a dedicated online platform or in annual reports.
<b>Achievable</b>	This may require the allocation of adequate financial resources. ECHA and/or MSCAs could support the enforcement authorities by sharing best practices.
<b>Relevant</b>	Publishing the information on enforcement activities will increase the public confidence in competent authorities and may increase compliance by the industry.
<b>Time-bound</b>	The establishment of working procedures should commence in 2022.

### 2.3.2.3 Estimated human and financial resources required

Recording inspections, inspection outcomes, and other statistics (e.g., size of the company inspected, type and number of non-compliances, imposed sanctions) require the establishment of working procedures, starting from identifying and agreeing on relevant indicators and data items. This initial stage could roughly require around 0.5 FTEs, involving staff at the DCI, who may be supported by other Inspectorates that have responsibilities under the Law on Chemicals.

### 2.3.2.4 Timeline, risks and risk mitigation measures

The establishment of working procedures should commence in 2022. The risk is that the DCI may not have the adequate expertise to develop working procedures. The recording of inspections focusing on certain aspects of the chemical legislation and other relevant indicators, at least at an initial stage, could be facilitated by planning the enforcement activities, i.e. an inspection campaign focusing on chemical legislation enforcement. ECHA and/or MSCAs could also support the enforcement authorities by sharing best practices.

## 2.3.3 Lack of a National Helpdesk

### 2.3.3.1 Description of the challenges and dependencies

According to Article 8 of the Law on Chemicals, the MoH should establish a helpdesk that provides advice to manufacturers, importers, distributors, prospective users and other stakeholders for their obligations and responsibilities in accordance with this law. However, the National Helpdesk has not been established yet. Initial steps for its establishment have already been taken by the Department for Chemicals, but improvements and more human resources are needed to make it operational and efficient. Nevertheless, there are plans to establish a National Helpdesk by the end of 2023.

Currently, the DCM provides information, support, and advice on regulatory topics to all stakeholders. Companies contact the DCM mostly by email, and the Division receives on average

Action Plan

two to three queries per day. It is reasonable to expect an increase in queries when new legislative requirements are implemented and brought in line with the EU *acquis*. Industry stakeholders will need assistance with regard to their new registration obligations, whereas the public may have questions regarding the authorised uses and restricted uses of certain substances of concern.

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

It is recommended that **the DCM establishes the National Helpdesk responsible for the provision of information on the national legislation on chemicals and biocidal products**. The provision of information via email and telephone needs to be complemented by the organisation of seminars, the publication of leaflets and other media, including websites, social media, print media campaigns, etc. It is also **recommended that the development of a communication plan is included in the remit of the Helpdesk staff** and should be part of the job description. This will be discussed later in Section 2.3.4. Table 9 shows the conformity of the objective to the SMART criteria.

**Table 9 – Objective 8: Establish a National Helpdesk**

Criteria	Notes
<b>Specific</b>	It is recommended that DCM establishes the National Helpdesk responsible for the provision of information on the national legislation on chemicals and biocidal products.
<b>Measurable</b>	The National Helpdesk is established.
<b>Achievable</b>	This may require the allocation of adequate financial and human resources.
<b>Relevant</b>	Without proper support and advice to manufacturers, importers and other users on their responsibilities and obligations under the law on chemicals and biocidal products, the North Macedonian competent authorities may not be able to guarantee adequate enforcement of the EU Regulations.
<b>Time-bound</b>	Starting from the year 2022.

### 2.3.3.3 Estimated human and financial resources required

Assuming that the number of queries is similar to that received by the competent authorities in Montenegro, which has been selected as a benchmark country for North Macedonia, they may have to reply to around 60 queries by email and 240 phone calls per year, although it is not expected to increase to such levels for some time. Assuming an average of half an hour to respond to one query<sup>15</sup>, around one FTE may be necessary to deal with helpdesk-related activities at the DCM. It is also reasonable to expect an increase in queries as new legislative requirements are implemented and brought in line with the EU *acquis*. In addition, once established, employees of the National Helpdesk will need to continuously keep up to date with the interpretations and conclusions on certain issues provided by other Member States, ECHA or the European Commission. This requires participation in HelpNet, the network of national helpdesks, which meets twice every year

### 2.3.3.4 Timeline, risks and risk mitigation measures

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

<sup>15</sup> Queries to the helpdesk can range from being straightforward to reply to, by pointing to relevant online materials like FAQs, or complex, requiring the input of several people and the consultation of the ECHA helpdesk or other national helpdesks via HelpNet.



of the different stakeholders, effectively invalidating the implementation of the chemical legislative framework.

## 2.3.4 Lack of a communication strategy

### 2.3.4.1 Description of the challenges and dependencies

Both the MoH and the MEPP have units for communication, public relations, and education, which should ensure the transparency and availability of environmental information to the public. EC (2020) notes that there has been some progress in improving transparency, with monitoring reports on the implementation of the Public Administration Reform Strategy being published along with data on the Government's finances. The Government is working on the development of a single-window integrated information system, which should facilitate public access to information related to environmental matters. A separate budget has been established for the public administration reform, although it has been decreased because of the reallocation of resources to economic measures to respond to the crisis ensued by the COVID-19 pandemic (EC, 2020). Activities for improving transparency and engaging a wide range of stakeholders are just at an initial stage. More efforts are required, considering the low level of public awareness of chemicals and chemical safety. The review of the work by business associations, NGOs and consumer associations showed that public awareness activities have mainly been carried out on the issue of contaminated sites across the country.

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

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

There are no ongoing regional collaboration efforts, but there has been informal communication with the chemicals departments in Slovenia and Serbia.

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

Civil society plays an essential role in the process of European integration of North Macedonia. Proactive civil society organisations are important actors in the implementation of public policies. EC (2020) notes that the environment in which civil society operates in North Macedonia has continued to improve, particularly with the implementation of the 2018-2020 Strategy and Action Plan for the Cooperation between Government and Civil Society.

It is recommended that **the DCM within MoH develops a communication plan** to address the following:

- The organisation of workshops and events, including identification and selection of topics of interest for the North Macedonian stakeholders that could be discussed during the events;

Action Plan

- Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information; and
- The organisation and dissemination of information online and by using other channels (e.g., newspapers, advertising, etc.) where appropriate:
  - The re-establishment of the official DCM webpage and establishment of the National Helpdesk and organising them by topics to facilitate access to documents and deadlines;
  - Additional information, for example, the translation of news presented on the ECHA website into Macedonian and Albanian that could be of relevance for North Macedonian companies, could also be provided on the website.

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

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

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

**Table 10 – Objective 9: Develop a communication strategy**

Criteria	Notes
<b>Specific</b>	It is recommended that the MoH develops a communication strategy to keep stakeholder engagement and increase transparency.
<b>Measurable</b>	A communication strategy is developed and implemented.
<b>Achievable</b>	The careful design of the strategy allows avoiding misuse of funding. The MoH and the DCM may not have the in-house expertise and therefore may consider outsourcing the process.
<b>Relevant</b>	Better informed stakeholders may result in a lower workload (fewer queries to the helpdesk, better quality information provided by industry in their notifications and applications, effective resource planning by the competent authority). A communication strategy improves confidence in the competent authority and increases the acceptance of the implemented policies.
<b>Time-bound</b>	It is recommended that the DCM starts drafting a communication plan for the next five years (2022-2026). This would allow earmarking the necessary resources. The plan should clearly identify the target audience, needs and optimal communication channels.

### 2.3.4.3 Estimated human and financial resources required

It is recommended that the development of a communication plan is included in the remit of the National Helpdesk staff and should be part of the job description. Currently, there are no employees allocated to the helpdesk services. Assuming that the number of queries is similar to that received by the competent authorities in Montenegro, around one FTE may be necessary to deal with helpdesk-related activities at the DCM. It is also reasonable to expect an increase in queries as new legislative requirements are implemented and brought in line with the EU *acquis*.

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

#### Action Plan

for EU chemical legislation and organise events for the divulgation of information, with the assistance of the chamber of commerce in Belgrade. The development of the communication plan was outsourced to the Faculty for Media and Communication of the University of Belgrade. The strategy included:

- The identification and engagement with key media stakeholders;
- The preparation and distribution of press materials to increase the visibility of the competent authorities;

Training for the competent authorities staff on communication tools and procedures related to media activities, crisis PR and damage control, and message development.<sup>16</sup>

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

As for capacity-building, the support of ECHA and other European partners is unlikely to waver over the coming years. However, there is the risk for North Macedonia to develop a dependency on external resources also on communication activities. The establishment of a dedicated budget is therefore of the utmost importance.

The MoH and the DCM should start planning for the resources necessary to develop the plan: survey the needs, find the optimal communication channels, implement the strategy by organising the communication activities. It is also recommended that the Helpdesk prepare annual communication work plans.

### 2.3.5 Lack of participation by the public and civil society in decision-making processes

#### 2.3.5.1 Description of the challenges and dependencies

In North Macedonia, the Law on Chemicals does not have any specific provisions on public participation in decision-making processes; however, explicit provisions for public participation are contained in Article 56(2) of the 2005 Law on Environment. The Law stipulates the principles for public participation in decision-making and the procedures for public participation in the development of legal and policy documents. In addition, the 2008 Decree on public participation during the preparation of regulations and other acts details the conditions, the form, and the procedure for public participation during the preparation of legal and policy documents in the environmental area. The Decree also specifies the types of policy documents and the form and procedure for public participation in their drafting, adoption, amendment, or revision.

According to UNECE (2019), the lack of human and financial resources hinders effective implementation of access to information, public participation, and access to justice in environmental matters, with the public, including civil society organisations, not actively participating in decision-making processes. In addition, a national integrated environmental information system to support informed decision-making and satisfy various reporting obligations is lacking. EC (2020) notes that there has been progress in improving transparency, with monitoring reports on the implementation of the Public Administration Reform Strategy published along with government finances data. The open government data portal is now operational, and the national electronic consultation system is encouraging wider participation in public consultations, although the quality control of this process needs improvement. As mentioned earlier in the report, the Government is working on the development of a single-window integrated information system, which should facilitate public access to the information related to environmental matters.

<sup>16</sup> Keml (2016): Chemical risk management in Serbia. Final report for 2008 to 2015; and Keml (2018): Chemical risk management in Serbia. Annual report 2017.

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

It is recommended that **the competent authorities implement the necessary measures to increase stakeholder participation in public consultations and decision-making processes** on chemical risk management. To achieve this, the Government and competent authorities need to raise awareness among all stakeholder groups about chemicals and the importance of the adequate implementation and enforcement of the chemical legislation to guarantee the safe use of chemical and biocidal products (see Section 2.2.5). The establishment of the National Helpdesk (see Section 2.3.3) and the development of a communication strategy (see Section 2.3.4) are important in helping to achieve this goal. The provision of information via email and telephone would need to be complemented by the organisation of seminars, workshops, and events, and using various communication channels (e.g., Internet, published leaflets, advertisement, etc.), which would reach a wider public and most likely increase participation of the public and civil society in chemicals risk management related activities. Finally, the Government should implement a national integrated environmental information system to support informed decision-making.

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

**Table 11 – Objective 10: Increase stakeholder participation in public consultations and decision-making**

Criteria	Notes
<b>Specific</b>	It is recommended that the competent authorities implement the necessary measures to increase stakeholder participation in public consultations and decision-making processes.
<b>Measurable</b>	Increase in stakeholder participation levels in public consultations on chemical risk management.
<b>Achievable</b>	The open government data portal is now operational, and the national electronic consultation system is encouraging wider participation in public consultations.
<b>Relevant</b>	UNECE (2019) notes that a national integrated environmental information system to support informed decision-making and satisfy various reporting obligations is lacking. Effective public consultations may lead to higher stakeholder engagement and more efficient implementation of the EU Regulations.
<b>Time-bound</b>	Starting in the year 2022.

### 2.3.5.3 Estimated human and financial resources required

The necessary human and financial resources for the establishment of the National Helpdesk and the communication strategy can be found in Sections 2.3.3 and 2.3.4, respectively. The implementation of the national integrated information system is still ongoing, and although the budget for public administration reform has been established, it has been reduced due to the ongoing pandemic.

### 2.3.5.4 Timeline, risks and risk mitigation measures

The proposed timelines for the establishment of the National Helpdesk and the communication strategy can be found in Sections 2.3.3 and 2.3.4, respectively. The ongoing pandemic may delay the development of a single-window integrated information system due to a reduced budget.

## 2.3.6 Lack of IT system for submitting documentation to the Division for Chemicals Management

### 2.3.6.1 Description of the challenges and dependencies

The DCM used to have a website for the provision of information ([www.hemikalii.gov.mk](http://www.hemikalii.gov.mk)), but it was hacked and is currently not operational. The DCM keeps working with hard copy documentation, which may not be efficient and sustainable in the long term.

North Macedonia is working to establish a general e-government framework.<sup>17</sup> In February 2018, the Strategy for Public Administration Reform (PAR) 2018-2022<sup>18</sup> and the supporting Action Plan<sup>19</sup> were adopted in North Macedonia.<sup>20</sup> However, greater efforts by institutions and improved coordination are needed to modernise and digitise public administration. The completion of the e-government framework would enable the submission of online documentation, including notifications of chemical products and applications for authorisation of biocidal products. According to EC (2020), "preparations for a general e-government framework and services continued", and the pandemic resulted in new e-services offered by institutions. For example, individuals and businesses can now use electronic signatures in the country's new e-portal for services. Many institutions have installed equipment and software to enable the use of the interoperability system, but its use is still not widespread across the public administration.

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

It is recommended that **the submission of documentation to the DCM is digitalised** to make the process more efficient and sustainable. The DCM website [hemikalii.gov.mk](http://hemikalii.gov.mk) should be up and running by the end of 2021 (not accessible in January 2022). This creates an opportunity for the MoH to establish an online platform for the submission of documentation electronically.

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

**Table 12 – Objective 11: Digitalise the submission of documentation to the DCM**

Criteria	Notes
<b>Specific</b>	It is recommended that the submission of documentation to the DCM is digitalised.
<b>Measurable</b>	The online platform for the provision of documentation is established.
<b>Achievable</b>	The DCM used to have a website, but it was hacked. North Macedonia is already working on establishing a general e-government framework. Many institutions have already enabled the use of the interoperability system.
<b>Relevant</b>	One of the objectives of the PAR Strategy 2018-2022 includes providing services in a fast, simple, and easily accessible way.
<b>Time-bound</b>	Starting in 2022.

<sup>17</sup> EC (2020): Commission Staff Working Document. North Macedonia 2020 Report Accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 2020 Communication on EU Enlargement Policy. SWD(2020) 351 final.

<sup>18</sup> [https://mioa.gov.mk/sites/default/files/pbl\\_files/documents/strategies/par\\_strategy\\_2018-2022\\_final\\_en.pdf](https://mioa.gov.mk/sites/default/files/pbl_files/documents/strategies/par_strategy_2018-2022_final_en.pdf)

<sup>19</sup> [https://mioa.gov.mk/sites/default/files/pbl\\_files/documents/strategies/ap\\_for\\_pars\\_2018-2022\\_april2018\\_eng.pdf](https://mioa.gov.mk/sites/default/files/pbl_files/documents/strategies/ap_for_pars_2018-2022_april2018_eng.pdf)

<sup>20</sup> [https://joinup.ec.europa.eu/sites/default/files/inline-files/Digital\\_Government\\_Factsheets\\_North\\_Macedonia\\_2019.pdf](https://joinup.ec.europa.eu/sites/default/files/inline-files/Digital_Government_Factsheets_North_Macedonia_2019.pdf)

### 2.3.6.3 Estimated human and financial resources required

The MoH would require financial resources for the necessary equipment and software for the establishment of the online platform.

### 2.3.6.4 Timeline, risks and risk mitigation measures

There is a plan to switch from paper to e-forms by 2025; however, the competent authority should aim to establish such a system sooner.

## 2.3.7 Gaps in IT infrastructure, policies and procedures

### 2.3.7.1 Description of the challenges and dependencies

So far, the competent authorities have not been able to provide any specific information on the IT infrastructure and security procedures used when dealing with chemical risk management information. It should be noted that the chemicals register has not been established yet.

For the purpose of ensuring the security of the information managed by the European Chemicals Agency, before receiving remote access to ECHA's information systems, all European and national authorities need to sign a declaration with respect to security aspects, based on the Agency's Security Model for IT systems.<sup>21</sup> This declaration (Unified Declaration of Commitment) and associated Standard Security Requirements (SSR) grant access to:

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

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

The Standard Security Requirements are organised in:

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

<sup>21</sup> ECHA Management Board Decision 59/2019: Revised Decision of The Management Board on the Adoption and Scope of Application of Unified Declarations of Commitment by a Member State Competent Authority/Mandated National Institution/Designated National Authority of a Member State and the European Commission with Respect to Security Aspects for ECHA's Information Systems.





Action Plan

- Additional requirements for sharing information with external contractors.

It is expected that the physical security of the premises that will be used to access ECHA’s information systems from the day of accession may be already effectively ensured by the measures in place.<sup>22</sup> However, all other aspects will need revision and improvement, including the establishment of formal IT security procedures, introductory and regular security training for the DCM staff and the procurement of an initial external audit and regular internal audits thereafter.

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

It is recommended that, as a first step, **the North Macedonian competent authorities contract an external audit of IT infrastructure, safety policies, procedures, and measures**. Furthermore, it is recommended that **the Department for Chemicals at MoH provide training for the staff on IT security procedures and how to deal with confidential documents**. In addition, it is recommended that **the competent authority nominate a Security Officer** within their staff members or the IT staff, who will be the primary security contact point for ECHA, also in the context of any security matter related to all workstations and devices used to access the IT system.<sup>23</sup> The security officer must ensure that sufficient security training and awareness briefings are arranged. The security officer must also ensure that security is continuously promoted so that users are aware of relevant security rules and requirements, understand related security threats and risks and have a good knowledge of the meaning of their everyday actions to security.

Furthermore, it is recommended **to implement a new formal non-public information management policy to bring the current practices in line with ECHA’s SSR** to ensure safe storage, transmission, and destruction of confidential information. Importantly, it is recommended to **establish a security awareness programme, including introduction and regular security training for all employees. A teleworking security policy is also necessary to guarantee the protection of non-public information**. Finally, it is recommended that **the North Macedonian competent authorities carry out internal audits on an annual basis, validated by an external audit every three years or every time a significant change is made to the security measures**.

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

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

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

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

Criteria	Notes
<b>Specific</b>	It is recommended that the competent authorities align the IT infrastructure, policies and procedures with ECHA standards.
<b>Measurable</b>	IT infrastructure and security procedures are aligned with ECHA’s SSR’s.
<b>Achievable</b>	Allocation of financial resources may be required.
<b>Relevant</b>	Without IT security policies and procedures in place, the competent authorities could not gain access to ECHA information systems.

<sup>22</sup> Physical security refers to the measures in place at the office premises used to access ECHA’s information systems and in which local copies of non-public information downloaded from ECHA’s information systems are stored either in digital or paper format. This potentially includes related data centres.

<sup>23</sup> Depending on the workload of the IT staff, which could be significant, there may be the need to hire one person with some expertise on IT tools to be further trained to be appointed as Security Officer.

Action Plan

Criteria	Notes
Time-bound	Policy and procedures need to be in place by the day of accession. The establishment of policies and procedures on the security of the information collected and managed by the MoH and MEPP is likely to have positive impacts on the confidence of businesses towards the capacity of the North Macedonian competent authorities.

### 2.3.7.3 Estimated human and financial resources required

It is recommended that the existing IT staff at the Department of Chemicals at the MoH are trained on IT security policies and procedures. The organisation and implementation of training courses for IT staff and the competent authorities' staff members on IT security policies and procedures are estimated to cost around €100,000.

The cost of a new workstation, running safe and up-to-date operating systems and antivirus software is around €500. If staff needs to work remotely, they will need safe and updated devices provided by the competent authorities. The total cost of updating the IT infrastructure may be around €10,000 (accounting for the current four employees at the DCM and a minimum of five employees required for biocidal products authorisation): around €5000 for the workstations at the DCM and other €5000 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 North Macedonia for a total cost of €25,000.<sup>24</sup>

The cost of an external IT audit depends on several factors and, in particular, on the size and complexity of the IT environment to be audited. It is recommended the competent authorities earmarks around €1,000-€5,000 for the first audit.<sup>25</sup> The competent authorities should allocate a rolling budget for the required periodic audits.

### 2.3.7.4 Timeline, risks and risk mitigation measures

Policy and procedures need to be in place by the day of accession. However, the establishment of policies and procedures on the security of the information collected and managed by the MoH is likely to boost the confidence of businesses in the capacity and trustworthiness of the North Macedonian competent authorities.

It is recommended that the competent authorities commission first external audits by a specialised IT security consultancy, which could also provide the first classes of the security awareness programme and prepare the material for the introductory and regular IT security briefings.

<sup>24</sup> Including allowances, project management, accommodation and travel costs.

<sup>25</sup> The cost for an IT security audit may range from €5,000 to €10,000. See for example: <https://www.itgovernanceusa.com/iso27001-certification-costs/>, <https://www.getastra.com/blog/security-audit/how-much-does-an-it-security-audit-cost/>, <https://resource.optimalnetworks.com/blog/2014/11/13/cost-of-it-audit>. To account for the different price levels, these prices have been divided by 5.



## 3 Conclusions and recommendations

### 3.1 Recommended actions and prioritisation

The main challenge that North Macedonian authorities face is the lack of resources necessary to align, implement and enforce the national legislation on chemicals and biocidal products. However, in order to strengthen the administrative capacity and enable the implementation of other recommended actions (Table 14), some underlying drivers need to be addressed first. These are beyond the remit of the Division of Chemicals Management (DCM) within the Ministry of Health (MoH) and are instead actions that should be taken by the Government of the Republic of North Macedonia.

To ensure that adequate financial resources are available to fund new job positions and provide the capacity building activities within the competent authorities or contract external experts for support, it is essential that **the revenue from fees and charges** paid by industry applicants for the work carried out by the competent authority is **ring-fenced for chemicals risk management activities** (Section 17.2.3). Further, it is recommended that the competent authorities adopt the **Memorandum of Understanding** with scientific institutes and external experts to facilitate outsourcing some workstreams and avoid overload at the MoH (Section 17.2.4). It is recommended that these actions are given priority and are implemented as soon as possible.

A dedicated budget would allow hiring new people and strengthening the capacity of administrative staff (Section 17.3.1), which would help to **tighten and further develop the legislation on chemicals and biocidal products** and address some other challenges associated with an insufficient administrative capacity, such as the lack of expertise for evaluating applications for authorisation of biocidal products and the **establishment of the National Helpdesk** (Section 17.3.3). In addition, the DCM should **develop a communication strategy**, which could be a responsibility of a member of staff dedicated to the National Helpdesk services (Section 17.3.4).

The competent authorities should address **the lack of expertise in risk assessment** and other technical and scientific areas by providing staff with training and capacity building activities on the management of biocidal products authorisation. ECHA may support the development of some of the necessary policies and procedures and provide training. ECHA and Member State competent authorities may also offer capacity building in risk assessment and enforcement.

It is recommended **that the information on enforcement activities in chemicals risk management** is made available to the public to ensure transparency and increase confidence in competent authorities on the enforcement of legislation on chemicals and biocidal products (Section 17.3.2). In addition, the availability to submit the documentation for the registration of chemicals and authorisation of biocidal products electronically is important to make the process more efficient and sustainable (17.3.6). Finally, it is recommended that **the IT infrastructure and the IT safety policies and procedures are upgraded and aligned with ECHA's standards** (Section 17.3.7). The MoH should commission an initial external audit to identify the required measures to bring the IT system up to the standards required by ECHA.

Overall, it is important that the competent authorities **raise awareness of chemical risk management among the public, civil societies, and the industry** (Section 17.2.5) and implement the necessary measures to **increase stakeholder participation in public consultations and decision-making processes** on chemical risk management (Section 17.3.5).

Action Plan

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

Action Plan

Table 14 – Action Plan

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
1. Strengthen the capacity of MoH	!!!	2022-2026	Gov MoH		5-10 FTEs	~€40,000 - ~€80,000 per year
2. Survey the needs of MoH staff and external experts and organise capacity-building activities	!!	2022-2023	MoH ECHA	MSCA	0.5 – 1 FTE (ECHA and/or MSCA)	~€100,000 per year over two years (ECHA and/or MSCA)
3. Establish a budget dedicated to chemical risk management activities	!!!	2022-2023	Gov	-	-	-
4. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	!!	2022-2024	MoH	ECHA, MSCA and/or Montenegro	1.5 FTE (over a 3-year period) – 0.5 FTE per year	-
5. Report on chemical legislation enforcement activities	!!	2022-	MoH	Inspectorates	0.5 FTE	-
6. Establish the National Helpdesk	!!!	2022-	MoH	ECHA, MSCA	1 FTE per year	-
7. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the North Macedonian stakeholders that could be discussed during the events; - Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information; - The organisation and dissemination of information online; - Allocation of resources for a multiannual plan; - Survey of the needs and topics of interest; - Identification of the communication channels; and - Implementation of the communication plan.	!!	2022-	MoH	MEPP, ECHA, MSCA, MCoC, NGOs	0.5 FTE	€10,000 per year (ECHA and/or MSCA) or €10,000 per year (North Macedonia's CAs)
8. Implement measures to increase stakeholder participation in public consultations and decision-making processes	!!!	2022-	MoH Gov	-	-	-
9. Digitalise submission of documentation	!	2022-	MoH		-	-

Action Plan

Recommended actions	Criticality	Action start - end	Action owner	Support	Required resources	
					Human	Financial
10. Organise training courses on IUCLID	!	2022	ECHA	MoH, MSCA	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
11. Upgrade IT infrastructure	!	2022	MoH	-	-	€10,500 (one-off) ~€100 per workstation (running costs: licenses, software upgrades, etc.)
12. Provide training to the existing IT staff within the MoH on IT safety and security policies and procedures. Nominate one user administrator and one security officer.		2022	ECHA	MoH	0.1 FTE (ECHA and/or MSCA)	€50,000 (ECHA and/or MSCA)
13. Develop an information security policy		2023	MoH	ECHA	0.1 (MoH) + 0.1 (ECHA and/or MSCA)	€25k (ECHA and/or MSCA)
14. Develop formal non-public information management policy in line with ECHA's SSR		2023	MoH	ECHA		
15. Establish a security awareness programme, including introduction and regular security training for all employees.		2023	MoH	ECHA		
16. Establish a teleworking security policy		2023	MoH	ECHA		
17. Contract an external audit of the safety policies, procedures and measures		2022	MoH	-		
18. 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-	MoH	-	-	€5,000 every 3 years for external audits
19. Raise stakeholder awareness on chemicals risk management			MoH Gov	MEPP	-	-
20. Hand-on training on ECHA e-tools	!	2025	ECHA	MSCA and MoH	0.1 FTE (ECHA and/or MSCA)	€40,000 (ECHA and/or MSCA)

MCoC: Macedonian Chamber of Commerce; Gov: Government of the Republic of North Macedonia; MEPP: Ministry of Environment and Physical Planning; MoH: Ministry of Health; MSCA: Member State Competent Authorities

Table 15 – Gantt chart and resource allocation

Action	2022	2023	2024	2025	2026
1. Strengthen the capacity of MoH	+1 FTEs €8k	+1 FTEs €16k	+1 FTEs €24k	+1 FTEs €32k	+1 FTEs €40k
2. Survey the needs of MoH staff and external experts and organise capacity-building activities	0.5 FTE €100k	0.5 FTE €100k			
3. Establish a budget dedicated to chemical risk management activities	-	-			
4. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	0.5 FTE	0.5 FTE	0.5 FTE		

Action Plan

Action	2022	2023	2024	2025	2026
5. Report on chemical legislation enforcement activities	0.5 FTE	-	-	-	-
6. Establish the National Helpdesk	1 FTE	0.5 FTE	0.5 FTE	0.5 FTE	0.5 FTE
7. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the North Macedonian stakeholders that could be discussed during the events; - Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information; - The organisation and dissemination of information online; - Allocation of resources for a multiannual plan; - Survey of the needs and topics of interest; - Identification of the communication channels; and - Implementation of the communication plan.	0.5 FTE €10k (ECHA or MSCA)	0.5 FTE €10k (ECHA or MSCA)	0.5 FTE €10k (ECHA or MSCA)	0.5 FTE €10k (MoH)	0.5 FTE €10k (MoH)
8. Implement measures to increase stakeholder participation in public consultations and decision-making processes	-	-	-	-	-
9. Digitalise submission of documentation	-	-	-	-	-
10. Organise training courses on IUCLID	0.1 FTE €50k				
11. Upgrade IT infrastructure	€10k				
12. Provide training to the existing IT staff within the MoH on IT safety and security policies and procedures. Nominate one user administrator and one security officer.	0.1 FTE €50k				
13. Develop an information security policy		0.1 (MoH) + 0.1 (ECHA and/or MSCA) €25k			
14. Develop formal non-public information management policy in line with ECHA's SSR					
15. Establish a security awareness programme, including introduction and regular security training for all employees.					
16. Establish a teleworking security policy					
17. Contract an external audit of the safety policies, procedures and measures	€1k-€5k			€1k-€5k	
18. 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	-	-	-	-	-
19. Raise stakeholder awareness on chemicals risk management	-	-	-	-	-
20. Hand-on training on ECHA e-tools				0.1 FTE €50k	
<b>Totals</b>					
ECHA or MSCA	~1 FTEs €200-€210k	~0.5 FTE €100k-€135k	-	0.1 FTE €50k	-

Action Plan

Action	2022	2023	2024	2025	2026
MoH	2.5 FTEs (+1 FTE) <sup>26</sup> €19k-24k	~1.5 FTEs (+1 FTE) €16k	1.5 FTEs (+1 FTE) €24k	1 FTE (+1 FTE) €43k-€47k	1 FTE (+1 FTE) €50k

Table 16 – Risks and risk mitigation measures

Action	Risk	Risk Mitigation Measures
1. Strengthen the capacity of MoH	The government does not agree and may not fund the necessary resource increase.	The Commission and ECHA note that without the administrative capacity for implementing the Regulations, North Macedonia would not be deemed ready to fulfil EU obligations and responsibilities. Actions: 3. Establish a budget dedicated to chemical risk management activities
2. Survey the needs of MoH staff and external experts and organise capacity-building activities	Lack of resources COVID-19 pandemic The MoU is not ratified on time	Support of ECHA or MSCA Remote learning Actions: 4. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities
3. Establish a budget dedicated to chemical risk management activities	Lack of resources	Fees are collected from applicants according to the Law on Chemicals and relevant Rulebook
4. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	Lack of resources	Actions: 1. Strengthen the capacity of MoH 3. Establish a budget dedicated to chemical risk management activities
5. Report on chemical legislation enforcement activities	DCI may not have the adequate expertise to develop working procedures No exchange of information between relevant departments and Ministries	An inspection campaign focusing on chemical legislation enforcement ECHA and/or MSCAs could support the enforcement authorities by sharing best practices
6. Establish the National Helpdesk	Lack of resources	Support of ECHA or MSCA Apply for TAIEX, IPA Actions: 1. Strengthen the capacity of MoH
7. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the North Macedonian stakeholders that could be discussed during the events;	Lack of resources  Lack of expertise.	Communication activities part of the job description for the person responsible for the Helpdesk ECHA or MSCA support. Actions: 1. Strengthen the capacity of MoH

<sup>26</sup> 2.5 FTEs are required for recommended actions plus 1 additional FTE to increase the capacity of the MoH.

Action Plan

Action	Risk	Risk Mitigation Measures
<ul style="list-style-type: none"> <li>- Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information</li> <li>The organisation and dissemination of information online</li> <li>- Allocation of resources for a multiannual plan;</li> <li>- Survey of the needs and topics of interest;</li> <li>- Identification of the communication channels; and</li> <li>- Implementation of the communication plan.</li> </ul>		<ul style="list-style-type: none"> <li>3. Establish a budget dedicated to chemical risk management activities</li> <li>6. Establish the National Helpdesk</li> </ul>
8. Implement measures to increase stakeholder participation in public consultations and decision-making processes	Delays	Support by ECHA, MSCA Actions: 1. Strengthen the capacity of MoH
9. Digitalise submission of documentation	Lack of resources Delays	Use of an existing platform (hemikalii.gov.mk)
10. Organise training courses on IUCLID	Lack of resources COVID-19 pandemic Loss of expertise due to high staff turnover	Support of ECHA or MSCA Remote learning
11. Upgrade IT infrastructure	Lack of resources	ECHA may support the development of the relevant policies and procedures and the training of staff. The MoH 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.
12. Provide training to the existing IT staff within the MoH on IT safety and security policies and procedures. Nominate one user administrator and one security officer.	Lack of expertise Data leaks and disclosure of CBI	
13. Develop an information security policy		
14. Develop formal non-public information management policy in line with ECHA's SSR		
15. Establish a security awareness programme, including introduction and regular security training for all employees.		
16. Establish a teleworking security policy		
17. Contract an external audit of the safety policies, procedures and measures		
18. 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		
19. Raise stakeholder awareness on chemicals risk management	Lack of resources	Support by ECHA, MSCA
20. Hand-on training on ECHA e-tools	-	-

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

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

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

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

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

- All five countries apply for the funding and technical assistance available through TAIEX and IPA instruments for chemical risk management related activities. It is important to stress that the chemical *acquis*, while not being more or less important of other environmental legislative areas, does require a significant amount of resources for its implementation and enforcement. All beneficiaries should ensure the allocation of adequate resources over time so that capacity-building efforts are not dissipated by understaffing and staff turnover;



Action Plan

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

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



## References

Amec Foster Wheeler et al (2016). Assessment of the current substance evaluation process under REACH, Final report. Available at:

[https://echa.europa.eu/documents/10162/13628/sev\\_survey\\_2015\\_en.pdf/b1532056-a551-4d25-aa6e-d29998713685](https://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf/b1532056-a551-4d25-aa6e-d29998713685) [Accessed on: 18/05/2021]

Assembly of the Republic of Macedonia (2010). Law on Chemicals no. 145/10. Official Gazette of RM, No. 145, 5 November 2010. Available at: <http://zdravstvo.gov.mk/wp-content/uploads/2015/10/1-ZAKON-ZA-HEMIKALII-145.10.pdf> [Accessed on: 24/02/2022]

EC (2020). Commission Staff Working Document North Macedonia 2020 Report. Accompanying the communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 2020 Communication on EU Enlargement Policy. Brussels, 6.10.2020 SWD(2020) 351 final.

EC (2019). Digital Government Factsheet 2019 Republic of North Macedonia. Available at: [https://joinup.ec.europa.eu/sites/default/files/inline-files/Digital Government Factsheets North Macedonia 2019.pdf](https://joinup.ec.europa.eu/sites/default/files/inline-files/Digital%20Government%20Factsheets%20North%20Macedonia%202019.pdf) [Accessed on: 24/02/2022]

European Parliament and Council of the European Union (2019). Regulation No. 1021/2019 of the European Parliament and of the Council on persistent organic pollutants (POPs), 20 June 2019. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1021&from=en> [Accessed on: 18/11/2021]

European Parliament and Council of the European Union (2012). Regulation No. 528/2012 of the European Parliament and of the Council concerning the making available on the Market and Use of Biocidal Products (BPR), 22 May 2012. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016DC0151&qid=1621337598833> [Accessed on: 18/11/2021]

European Parliament and Council of the European Union (2012). Regulation No. 649/2012 of the European Parliament and of the Council concerning the Export and Import of Hazardous Chemical, 4 July 2012. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0649&qid=1621338649715&from=EN> [Accessed on: 18/11/2021]

European Parliament and Council of the European Union (2008). Regulation No. 1272/2008 of the European Union and of the Council on Classification, Labelling and Packaging of Substances and Mixtures (CLP), 16 December 2008. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&qid=1621337330332&from=EN> [Accessed on: 18/11/2021]

European Parliament and Council of the European Union (2006). Regulation No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 18 December 2006. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&from=EN> [Accessed on: 18/11/2021]

Milieu (2016). Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting. Report prepared for the European Commission DG Environment. Available at: [https://ec.europa.eu/environment/chemicals/reach/pdf/final\\_report\\_2016.pdf](https://ec.europa.eu/environment/chemicals/reach/pdf/final_report_2016.pdf) [Accessed on: 28/07/2021]

UNECE (2019): North Macedonia. Environmental Performance Reviews. Third Review. ECE/CEP/186. United Nations, Geneva, 2019. Available at: <https://www.moepp.gov.mk/wp-content/uploads/2017/03/ECE.CEP.186.Eng.pdf> [Accessed on: 28/11/2021]

## Websites

European Chemical Agency. <https://echa.europa.eu/>

Statistical office of the European Union. <https://ec.europa.eu/eurostat>

Swedish Chemical Agency. <https://www.kemi.se>

World Bank. <https://www.worldbank.org/en/home>

Information on Multilateral Environmental Agreements. <https://www.informea.org/en>

Ministry of Health, North Macedonia. <http://zdravstvo.gov.mk/>

Ministry of Environment and Physical Planning, North Macedonia. <https://www.moepp.gov.mk/>

Ministry of Foreign Affairs. North Macedonia. <https://mfa.gov.mk/en>

Ministry of Information Society and Administration. <https://mioa.gov.mk/?q=en>

State Statistical Office of the Republic of Macedonia. <https://www.stat.gov.mk/>

State Environmental Inspectorate, North Macedonia. <http://www.sei.gov.mk/>

State Market Inspectorate, North Macedonia. <https://www.dpi.gov.mk/>

State Inspectorate for Agriculture, North Macedonia. <https://diz.gov.mk/>

EXIM North Macedonia (electronic system used by 16 institutions that have competencies in the field of foreign trade operations). <http://www.exim.gov.mk/EILWeb/startPage.jsf>

University Clinic of Toxicology in Skopje. <https://toxicocenter.com.mk/>



## List of Abbreviations

Acronym	Full name
<b>ASOs</b>	Accredited Stakeholder Organisations
<b>ATPs</b>	Adaptations to technical progress
<b>BPC</b>	Biocidal Product Committee
<b>BPR</b>	Biocidal Products Regulation
<b>BP</b>	Biocidal Product
<b>CARACAL</b>	Competent authorities for REACH and CLP
<b>CBI</b>	Confidential Business Information
<b>CG</b>	Coordination group
<b>CLH</b>	Harmonised classification and labelling
<b>CLP</b>	Classification, Labelling and Packaging
<b>CoRAP</b>	Community Rolling Action Plan
<b>DCI</b>	Division of Chemicals Inspection
<b>DCM</b>	Division of Chemicals Management
<b>EC</b>	European Commission
<b>ECHA</b>	European Chemicals Agency
<b>EINECS</b>	European Inventory of Existing Commercial Chemical Substances
<b>ELINCS</b>	European List of Notified Chemical Substances
<b>e-PIC</b>	Prior Informed Consent IT System
<b>EU</b>	European Union
<b>FTE</b>	Full-time employee
<b>FYR</b>	Former Yugoslav Republic
<b>FYROM</b>	Former Yugoslav Republic of Macedonia
<b>GDP</b>	Gross Domestic Product
<b>GLP</b>	Good Laboratory Practice
<b>HCF</b>	Helsinki Chemicals Forum
<b>IPA</b>	Instrument for Pre-Accession Assistance
<b>IT</b>	Information Technology
<b>IUCLID</b>	International Uniform Chemical Information Database
<b>KemI</b>	Swedish Chemicals Agency
<b>MEPP</b>	Ministry of Environment and Physical Planning
<b>MES</b>	Macedonian Ecological Society

Acronym	Full name
<b>MoH</b>	Ministry of Health
<b>MoU</b>	Memorandum of Understanding
<b>MS</b>	Member State
<b>MSC</b>	Member State Committee
<b>MSCA</b>	Member State Competent Authority
<b>MSDS</b>	Material Safety Data Sheet
<b>NAPs</b>	National Action Plans
<b>NEAP</b>	National Environmental Action Plan
<b>NGO</b>	Non-Governmental Organisation
<b>NIP</b>	National Implementation Plan
<b>NPAA</b>	National Programme for Adoption of the Acquis Communautaire
<b>NSSD</b>	National Strategy for Sustainable Development
<b>OG</b>	Official Gazette
<b>OXO</b>	Association for Education, Communication and Consulting
<b>PCB</b>	Polychlorinated biphenyls
<b>PCN</b>	Poison centre notifications
<b>PIC</b>	Prior Informed Consent Regulation
<b>POP</b>	Persistent Organic Pollutant
<b>PVC</b>	Polyvinyl chloride
<b>R4BP</b>	Register for Biocidal Products
<b>RAC</b>	Committee for Risk Assessment
<b>REACH</b>	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>REC</b>	Regional Environmental Centre
<b>SAICM</b>	Strategic Approach to International Chemicals Management
<b>SC</b>	Stockholm Convention
<b>SCBP</b>	Standing Committee on Biocidal Products
<b>SDS</b>	Safety Data Sheets
<b>SEAC</b>	Socio-Economic Analysis Committee
<b>SIDA</b>	Swedish International Development & Cooperation Agency
<b>SME</b>	Small and medium-sized enterprise
<b>SPC</b>	Summary of the product characteristics
<b>SSR</b>	Standard Security Requirements

Acronym	Full name
<b>SVHC</b>	Substance of Very High Concern
<b>TAIEX</b>	Technical Assistance and Information Exchange
<b>UN</b>	United Nations
<b>UNECE</b>	United Nations Economic Commission for Europe
<b>UNIDO</b>	United Nations Industrial Development Organisation



Valdani Vicari & Associati

---

**BRUSSELS**

Avenue des Arts 10-11  
1210 Bruxelles  
Phone: +32 476771187  
[www.vva.it/economics-policy/](http://www.vva.it/economics-policy/)

---

---

**MILAN**

Palazzo Stampa di Soncino – Via Torino, 61  
20123 Milano  
Phone: +39 02 727331  
[www.vva.it](http://www.vva.it)

---

**RPA**  
Europe

Phone: +39.347 777 5763

<https://www.rpa-europe.eu/>