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 – Turkey

February 2022

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Executive Summary

For over a decade, Turkey has been developing its chemicals management system and has achieved a good 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 Turkey 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 Environment, Urbanisation and Climate Change (MEUCC), and its practical implementation is the responsibility of the Chemicals Management Department (CMD) within the Directorate General of Environmental Management. As of August 2021, the Department employs 16 people. The national competent authority for the alignment of the national legislation with the EU legislation on biocides is the Ministry of Health (MoH). The practical implementation is the responsibility of the General Directorate for Public Health (GDPH) and the Turkish Medicines and Medical Devices Institution. As of August 2021, GDPH employs eleven people.

The CMD employees have adequate qualifications and have built their knowledge of the legislative acquis over the years. However, Turkey has an ambitious legislative framework, mirroring the provisions of the REACH and CLP Regulations to a great extent. Therefore, the effective implementation of each mechanism requires a high number of resources. According to the self-assessment, all Units of the CMD need additional resources. The Department is currently focusing on the registration process, including the provision of support to industry to facilitate the registration of chemical substances.

The assessment identified the lack of necessary resources to implement and enforce the national legislation on chemicals and biocidal products, particularly the Regulation on Biocidal Products of Turkey, as the main challenge. In order to strengthen the administrative capacity and enable the implementation of other recommended actions, some underlying challenges need to be tackled first. Firstly, the adoption of the Memorandum of Understanding with scientific institutes and external experts would facilitate the outsourcing of some administrative tasks on risk assessment and authorisation of biocidal products and reduce the work overload of the GDPH staff. This measure would allow freeing up resources to tighten and further align the legislation on biocidal products with BPR. It would also address other challenges associated with an insufficient administrative capacity, such as the lack of expertise in risk assessment for the evaluation of applications for authorisation of biocidal products. It is also recommended that the IT system for submitting applications for active substances approval and biocidal products authorisation to the GDPH follows a format compatible with R4BP.

It is also important to develop a communication strategy, which would include the organisation of events and workshops for stakeholders, communication of the progress in developing regulatory framework, and sharing the relevant information online and via other channels. In addition, publishing the information on enforcement activities in chemical risk management would also help increase the transparency and confidence in the competent authorities on the enforcement of legislation on chemicals.

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 Turkey 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, by-laws and accompanying documents;
  - The documents produced by the European Commission[1] in assessing the progress of Turkey with the reforms in the framework of the accession negotiations;
- Phone interviews with the Turkish competent authorities held on 26 March 2021 and 28 April 2021 and follow-up emails;
- Phone interviews with local NGOs and members of academia.

Actions have been suggested in the following areas:

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

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

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

[1] EC (2020): Commission Staff Working Document Turkey 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) 355 final.

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 for the successful implementation of the recommended actions are described (e.g., awareness-raising, outreach, collaboration and communication with other stakeholders).

2 The Action Plan

2.1 Challenges and gaps identified

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

The work of the Chemicals Management Department (CMD) within the Ministry of Environment, Urbanisation and Climate Change (MEUCC) and the General Directorate for Public Health (GDPH) within 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[2] 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 to ensure progress. The identified drivers, gaps and resulting consequences are listed below:

Drivers

- EU centralised procedures cannot be transposed into the national system before accession;
- The continuous evolution of the EU regulatory framework;
- Lack of a Memorandum of Understanding with Scientific Institutes or Academia to draw on resources outside the ministry; and
- High staff turnover at the GDPH of the MoH and inefficient recruitment process.

Gaps

The key challenges and gaps identified are:

- Lack of human resources;
  - Understaffing of the Ministry of Environment, Urbanisation and Climate Change;
  - The current resources at the Ministry of Health are not sufficient for processing all submitted applications for biocidal products authorisations and implementing the national biocides legislation;
- Lack of the alignment of the Regulation on Biocidal Products of Turkey with BPR;
- Lack of expertise in risk assessment and evaluation of applications for authorisation of biocidal products;
  - It is not mandatory for the applicants to submit risk assessment information in their application dossiers;
  - A simplified procedure is followed for the authorisation of biocidal products;
- Lack of IT system for managing applications for biocidal products and active substances;
- Lack of resources for enforcement of chemical legislation;
- Lack of information on enforcement activities for chemicals; and
- Lack of communication strategy.

Consequences

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

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

- Effective implementation of the legislative framework;
- The protection of human health and the environment and the guarantee of a level playing field between Turkey and foreign companies;
- Stakeholder engagement and public awareness of chemicals and chemical safety; and
- The enforcement of legislation on chemicals and biocidal products.

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

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

- Their dependencies;
- The identification of the body responsible for the action;
- The identification of other relevant stakeholders who may be affected and should be involved to provide support. It is important to keep them informed about relevant changes and timelines;
- The necessary human and financial resources;
- The suggested timeline for 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. Turkey has an ambitious legislative framework that mirrors the provisions of the REACH and CLP Regulations to a great extent, and the effective implementation of each mechanism requires a high number of resources. Therefore, it is important for the Turkish competent authorities to increase the administrative capacity in the short term in order to have sufficient resources for full implementation and enforcement of the national legislation on chemicals and biocidal products.

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

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

Figure 1 – Intervention logic

Drivers and external factors	Problems		Consequences	Specific objectives and measures	General objectives
EU centralised procedures cannot be transposed	Lack of human resources	Understaffing of the MEUCC	An effective implementation of the legislative framework cannot be ensured	Increase administrative capacities of the competent authorities	Aligning the national legislation with the EU Regulation
		Insufficient resources at the MoH for processing applications for biocidal products and implementing the national biocides legislation		Develop a Memorandum of Understanding with scientific institutes	
Continuous evolution of the EU regulatory framework	Several gaps in the Regulation on Biocidal Products	The Regulation on Biocidal Products of Turkey is still not fully aligned with BPR	No full protection of human health and the environment and no level playing field between Turkey and foreign companies	Tightening and further developing of the legislation on biocidal products and the provision of capacity building services	
Lack of Memorandum of Understanding with universities and research institutes	Lack of expertise in risk assessment and evaluation of applications for authorisation of biocidal products	It is not mandatory for the applicants to submit risk assessment information in their application dossiers	Cannot ensure proper enforcement	Increase participation of inspectors in capacity building activities	Bringing the capacity up to a level where the obligations laid down in the Regulations can be carried out efficiently and effectively
		Simplified procedure is followed for the authorisation of biocidal products		Make the information on enforcement activities for chemicals available to the public	
	Lack of IT system for managing applications for biocidal products and active substances		Inefficient and unsustainable application system	Digitalise the management of application for biocidal products and active substances	
High staff turnover	No information on enforcement activities for chemicals		Low level of public and stakeholder awareness on chemicals and chemical safety	The development of a communication plan and closer collaboration with NGOs and other stakeholders	
	Lack of resources for enforcement of chemical legislation				
	Lack of communication strategy				

2.2 Underlying causes and means to address them

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

2.2.1.1 Description of the challenges and dependencies

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

This results in a lack of scientific capacity for risk assessment in relation to biocidal products and biocidal active substances. The competent authorities also lack the necessary practical knowledge on how to use the ECHA e-tools, such as REACH IT and R4BP.

The Turkish 11th National Development Plan (NDP) (2019-2023)[5] sets out five-year priorities and policies for Turkish institutions. In the NDP, the chemicals industry is indicated among the priority fields. Overall, the focus is on sustainable development, R&D, and efficiency in the sector. According to the NDP, the chemical industry will receive support to comply with the national legislation aligned with the EU *acquis*. The Chemicals Industry Working Group Report[6], published in 2018, provides a high-level strategy for the chemical sector according to the priorities established in the 11th NDP.

Since 2009, ECHA's 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[7]. Between December 2011 and December 2013, the CMD took part in the project "REACH Chemicals" (under IPA I). The CMD also continues to participate in the "Technical Assistance Project for Chemical Safety Assessments within the Scope of the REACH Regulation" (under IPA II), which started in November 2019 and was completed at the end of October 2021. It aims to develop and strengthen the capacities of different stakeholders, decision-makers, and relevant institutions and develop and improve the Chemical Registration System. In addition, the CMD is involved in the IPA project "Identification and remediation of sites contaminated with

[4] This is the case with:

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

[5] Source: https://sbb.gov.tr/wp-content/uploads/2020/04/KimyaSanayiiCalismaGurubuRaporu.pdf

[6] Published by the Ministry of Development in 2018. Ministry of Development has been superseded by Ministry of Industry and Technology. Report available at: https://sbb.gov.tr/wp-content/uploads/2020/04/KimyaSanayiiCalismaGurubuRaporu.pdf

[7] 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

Persistent Organic Pollutants (POPs)".[8] The project started in November 2019 and is projected to be completed by the end of 2022. It is being implemented by the United Nations Development Program (UNDP). The project has two main components: capacity building and technical assistance for contaminated site rehabilitation. Finally, the MoH has submitted a proposal for an IPA III project for the further alignment of the national legislation with the BPR and expects to start work in 2022. The proposal is going through the approval process.

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 e-tools** used by EU Member States' competent authorities to manage the information exchange with ECHA. Although this action is a low priority, Turkish competent authorities would benefit from understanding the functioning of these tools, which may help develop and improve their own procedures. The Turkish competent authorities have developed their own versions of REACH-IT, IUCLID and Chesar, and it is very important to ensure and maintain compatibility with the EU e-tools to avoid high administrative burden for companies registering substances in both Turkey and the EU.[9] Table 1 shows the conformity of the objective to the SMART criteria.

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

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

2.2.1.3 Estimated human and financial resources required

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

As an indication, the Swedish Chemicals Agency spent around €150,000[10] and 150 workdays (around 0.7 FTE) carrying out training of Serbian Authorities staff in 2017.[11] In the context of the twinning

[8] https://open.undp.org/projects/00107003, https://kalicikirleticiler.com/en/identification-and-remediation-of-contaminated-sites-with-persistent-organic-pollutants-project/

[9] https://chemicalwatch.com/60115/cefic-flags-turkey-kkdik-reach-it-compatibility-concerns

[10] Around SEK 1,500,000.

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

project implemented by the Austrian and Slovenian competent authorities[12], the cost of the organisation and actual implementation of trainings and workshops was around €110,000. The courses, which were attended by at least two staff members from the Serbian competent authorities per session, focused on risk assessment and risk management of biocidal products. The training was organised over 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), would cost approximately €40,000.[13]

It is expected that the required human resources and the cost borne by ECHA or MSCA for training Turkish competent authorities' staff may be similar, although the training on e-tools may require fewer financial resources because the Turkish competent authorities already have experience with some tools. In addition, the actual cost will depend on the number of attendees (internal and/or external) and whether the training will be carried out only for the Turkish competent authorities or as a joint action for all candidate and potential candidate countries (see Section 3.2).

2.2.1.4 Timeline, risks and risk mitigation measures

It is recommended to prioritise those capacity building activities which focus on risk assessment because the GDPH staff do not have the right expertise for evaluating environmental and health assessment. Due to this capacity gap, it is not mandatory for the applicants to submit risk assessment information in their application dossiers.

2.2.2 The continuous evolution of the European chemical legislative framework

2.2.2.1 Description of the challenges and dependencies

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

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

[12] 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.

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

Currently, the KKDIK Regulation[14] transposes REACH, and there are 36 Turkish guidance documents for the implementation of the KKDIK, although the work on fully aligning guidelines is still ongoing. Turkish Regulation on Classification, Labelling and Packaging of Substances and Mixtures (SEA) is almost fully harmonised with the CLP Regulation. The national Regulation on POPs transposes the Regulation (EU) No 1021/2019 on persistent organic pollutants, whereas the draft national Regulation on the Export and Import of Hazardous Chemicals is in line with the Rotterdam Convention and the PIC Regulation. The law is currently in its draft version, with comments being received from other institutions and ministries. The Regulation on Biocidal Products of Turkey was initially prepared in line with Directive 98/8/EC concerning the placing of biocidal products on the market. Subsequently, for the purpose of aligning it with the BPR Regulation, amendments were made in 2011, 2014 and 2020. However, the regulation is still not fully aligned with BPR (see Section 2.3.5).

Consequently, keeping the Turkish legislation aligned with the EU *acquis* is a resource-intensive work. At the moment, the main activity of the CMD staff at the MEUCC is to fully harmonise the national legislation with the EU chemicals *acquis* while progressing with the capacity building for the implementation of the administrative tasks and the registration of chemical substances. Meanwhile, the GDPH at the MoH is responsible for the transposition of the EU legal acts to the national legislation on biocidal products and further development of the legislative framework.

2.2.2.2 Recommended actions, action owner and other relevant stakeholders

The work carried out by the CMD and the GDPH can be described as a zero-sum game, where each task competes for a limited number of resources. The alignment and keeping the alignment of the national legislation with the EU Regulations is a resource-intensive work, as are other tasks necessary for the adequate implementation of the national chemical laws. The current resources at the CMD and the GDPH are insufficient to implement all administrative tasks and process all submitted applications for biocidal products authorisation.

It is recommended that **the competent authorities strengthen the capacity of the relevant departments and further align and tighten the legislation on chemicals and biocidal products.** This is further discussed in Section 2.3.1, Section 2.3.4 and Section 2.3.5. Table 2 shows the conformity of the objective to the SMART criteria.

Table 2 – Objective 2: Strengthen the capacity of the MEUCC and the MoH and tighten the legislation

Criteria	Notes
Specific	It is recommended that the competent authorities strengthen the capacity of the relevant departments and further align and tighten the legislation on chemicals and biocidal products.
Measurable	Number of additional staff members at the CMD of the MEUCC. Number of additional staff members at the GDPH of the MoH.
Achievable	Further discussed in Section 2.3.1, Section 2.3.4 and 2.3.5.
Relevant	Additional capacity is key for overcoming many identified challenges and fully aligning the legislation on chemicals and biocidal products.
Time-bound	It is estimated that the MEUCC will require additional 3 FTEs to evaluate registration dossiers for chemical substances. It is estimated that the MoH will need around 20-30 FTEs per year dedicated to the alignment of the national legislation and implementation of administrative tasks on biocidal products.

[14] Registration, Evaluation, Permit and Permit of Chemicals Regulation on Restrictions (KKDIK) (2017). Official Gazette No. 30105, 23 June 2017. https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=23694&MevzuatTur=7&MevzuatTertip=5

2.2.2.3 Estimated human and financial resources required

The required additional human resources for the MEUCC were estimated based on the expected number of registrations for chemical substances because, currently, this is the main focus of the CMD. The MEUCC is expecting to receive 15,000 registrations before the end of the registration period in December 2023, which equals to almost 70,000 registration dossiers. The objective of the CMD is to evaluate five per cent of all dossiers received per year, for which they would require three FTEs. More details can be found in Section 2.3.1.

Currently, there are approximately 3,000 biocidal products on the Turkish market. However, it can be expected that the number could be higher in the coming years due to the biocidal products growth trend in the last couple of years. Assuming that the number of biocidal products on the Turkish market could be similar to their number on the Polish market[15] in the near future, it is expected that the Turkish authorities could receive between 7,000 and 10,000 applications for biocidal product authorisation.[16] Workload will be dependent on the timescales to process these applications. At the moment, the MoH lacks the required expertise to carry out the full evaluation of the application dossiers submitted, including the assessment of the information on the efficacy and risk. Depending on the number of applications for the different authorisation procedures, the evaluation and assessment of the applications could require between 10 to 20 additional FTEs per year over a period of five years. The gap in resources could be filled by hiring new employees and using external resources. In addition, both internal and external resources should receive training to strengthen their competencies and skills. Additional details are provided in Section 2.3.1.

2.2.2.4 Timeline, risks and risk mitigation measures

Timeline, risks and risk mitigation measures for strengthening the administrative capacity of the MEUCC and MoH and aligning the legislation on biocidal products are discussed in Section 2.3.1, Section 2.3.4 and Section 2.3.5.

2.2.3 Lack of a Memorandum of Understanding with Scientific Institutes and external experts

2.2.3.1 Description of the problem and dependencies

As of March 2021, the CMD employs 16 FTEs (6 FTEs and the Head of the Unit at the Priority Chemicals Management Unit, 4 FTEs and the Head of the Unit at the Registration and Classification of Chemicals Unit, 3 FTEs at the Risk Assessment and Control of Chemicals Unit, and the Head of the Department). At the moment, a significant proportion of the resources is allocated to the registration process, including the provision of support to the industry.

The GDPH at the Ministry of Health employs 11 FTEs, who are in charge of processing applications for the approval of active substances and the authorisation of biocidal products. Due to the lack of expertise, a simplified procedure is followed for the authorisation of biocidal products, and biocidal products used for two product types (main group 2 and main group 4) do not need authorisation. Active substances are approved if approved in the EU. Some dossiers have information on environmental and health risk assessment, but the GDPH staff do not have the right expertise to evaluate this information. Due to this capacity gap, it is not mandatory for the applicants to submit risk assessment information in their application dossiers. While the authorities recognise the need

[15] Poland has been chosen as a benchmark country for Turkey.

[16] As of May 2021, the lists of biocidal products on the Polish market totalled 7,101 products. Accessible at: http://bip.urpl.gov.pl/pl/biuletyny-i-wykazy/produkty-biobójcze

for additional resources, no information is available about plans for hiring new employees at the CMD and the GDPH.

In particular, there is the need to increase resources for the administrative tasks related to the implementation of the national biocidal products legislation. Despite 11 FTEs at the GDPH, based on the expected number of applications for authorisation of biocidal products, an additional 10 to 20 qualified FTEs may be necessary to process the applications over a period of five years (see Section 2.3.1 for more information). The existing gap could be filled by hiring new employees at the GDPH and using external resources. In addition, the Turkish competent authorities could consider outsourcing some of the most technical aspects to external scientific institutes through a memorandum of understanding (MoU).

Article 17 of the Regulation on Biocidal Products of Turkey[17] notes that the MoH should seek assistance from universities or other institutions on issues requiring special expertise based on product type. Also, the MoH should communicate with other experts regarding risk assessment, risk management, and risk communication and make the necessary coordination on duties related to exposure and efficacy assessment.

Given that the capacity at the MoH 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.

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.[18] Training courses could be organised for both academic experts and the MoH staff (see also Section 2.3.5).

2.2.3.2 Recommended actions, action owner and other relevant stakeholders

It is important that **the competent authorities develop, ratify, and implement 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 taken place, the competent authorities should explore the use of more agile short-term contracts on specific assignments. The scope of an MoU is to regulate the long-term cooperation between the competent authorities and external experts. As a first step, the competent authorities will have to verify the availability of experts with the right profiles and survey their needs for training on the tasks they are expected to carry out and contribute to. The MoU will have to define the expected services, indicate the approximate duration of the assignments, and specify the foreseen deadlines. These may have to be further detailed in specific contracts. Importantly, the academic sector will have to determine specific areas within their scope of work that need strengthening in order to provide support to the competent authorities in accordance with requirements and procedures determined under the Regulations. Most likely, the MoU will need to be accompanied by:

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

[17] https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=13672&MevzuatTur=7&MevzuatTertip=5

[18] 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.

Ultimately, the objective is to develop capacity and competencies, ensure the functioning of the MoU and the smooth processing of industry applications. Table 3 shows the conformity of the objective to the SMART criteria.

Table 3 – Objective 3: Develop, ratify and implement a Memorandum of Understanding (MoU)

Criteria	Notes
Specific	It is recommended the competent authorities develop, ratify and implement an MoU with the relevant scientific institutes.
Measurable	An MoU with external experts is ratified. Number of external experts involved.
Achievable	The objective is attainable provided that an agreement is reached by all parties of the memorandum of understanding.
Relevant	Without the support of external experts, the Turkish competent authorities will not be able to process all industry applications, particularly for the authorisation of biocidal products, by the day of accession.
Time-bound	The MoU should be functioning as soon as possible with the target date of 2024.

2.2.3.3 Estimated human and financial resources required

It is recommended that the competent authorities allocate at least 0.5 FTE per year in the period 2022-2024 to prepare the MoU and set up the necessary framework for a closer collaboration with academia and scientific institutes. The expertise is available in the Istanbul Technical University, Hacettepe University, Ankara University, Boğaziçi University, Bilkent University, Middle East Technical University, Gazi University, Marmara University, Ege University, and Boğaziçi University.

2.2.3.4 Timeline, risks and risk mitigation measures

It is recommended to have a functioning MoU 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 2022-2024. It should be noted that given the understaffing of the MoH, dedicating even 0.5 FTE per year over a period of three years could be difficult unless the capacity of the MoH is strengthened in 2022. An additional risk is the lack of financial resources due to the economic slowdown, both national and worldwide, triggered by the ongoing COVID-19 pandemic.

2.2.4 High staff turnover

2.2.4.1 Description of the challenges and dependencies

The GDPH at the MoH has been experiencing a high staff turnover, and it is expected that there will be only seven people remaining at the GDPH in 2021 working on biocidal products. The understaffing situation has been notified, and a request for hiring additional resources submitted to the hierarchy; however, the recruitment process is not initiated immediately and is quite lengthy.

According to EC (2020), "the capacity of the Human Resources office under the Presidency needs to be strengthened to ensure central coordination of human resources management in the public sector. The civil service remuneration system is not standardised across institutions and lacks transparency. The administration lacks sufficient tools to support the professional development of civil servants. Ethics committees across line ministries and a centralised ethics board are in place, but their effectiveness remains to be strengthened".

There is a need to develop a plan to retain staff, including the provision of professional development and competitive salary.

2.2.4.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the Government of the Republic of Turkey develops and implements a plan to retain civil servants in all its administrative bodies**. The plan should *inter alia* aim to:

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

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

Table 4 – Objective 4: Implement a plan to retain civil servants

Criteria	Notes
Specific	It is recommended that the Government of the Republic of Turkey develops and implements a plan to retain civil servants in all its administrative bodies.
Measurable	Staff turnover rate.
Achievable	A strategy for retaining personnel could only be successful if the underlying causes are tackled first.
Relevant	Easing workload is necessary to avoid the current high levels of staff turnover, with associated loss of expertise and institutional memory. It is key to retain skilled workers for the adequate implementation and enforcement of all EU legislation.
Time-bound	It is recommended that, given the high risk of losing institutional memory, strengthening the capacity of the competent authorities, including measures to slow down staff turnover, should have the highest priority.

2.2.4.3 Estimated human and financial resources required

The estimated human and financial resources required for the MoH to fulfil their responsibilities and obligations in implementing and enforcing the regulation on biocidal products have been discussed in Sections 2.3.1 and 2.3.5.

In Turkey, the labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €14,000.[19] On the other hand, the labour cost per employee in the professional, scientific and technical activities sector in full-time equivalents per year is estimated to be around €16,500.

One of the most straightforward ways to retain skilled staff is to offer a higher salary, which should be at least in line with industry wages for similar expertise categories and profiles. The labour cost per employee in the professional, scientific, and technical activities sector in full-time equivalents per year is approximately 20% more costly than in the public sector. Assuming that the MoH would increase the salaries of inspectors to align them with industry wages, the marginal cost of increasing the salary of the nine environmental inspectors would be around €22,500 per year. Assuming that the MoH would also increase the salaries of the 11 employees at the GDPH, the marginal cost would

[19] https://knoema.com/lc_ncostot_r2/labour-cost-wages-and-salaries-including-apprentices-nace-rev-2?geo=1029740-turkey.

be approximately €27,500 per year. If the required additional nine employees (see Section 2.3.1) were hired with the higher starting salary, the marginal cost would be approximately €413,000 over a five-year period compared to €350,000 if the wages were kept the same.

2.2.4.4 Timeline, risks and risk mitigation measures

As for most of the recommendations, the sooner action is taken, the better. The recommended start and target year should be 2022. There is a risk that the new government may show no interest in developing a plan to retain public administration staff. In this case, the Commission should highlight the importance of ensuring the administrative capacity of the different state entities responsible for implementing and enforcing EU legislation.

2.3 Identified challenges and associated objectives

2.3.1 Understaffing of the Ministry of Environment, Urbanisation and Climate Change and the Ministry of Health

2.3.1.1 Description of the problem and dependencies

The CMD of the Directorate General of Environmental Management (DGEM) within the MEUCC is responsible for the harmonisation of the EU chemicals *acquis*. As of March 2021, the CMD consists of three units[20] overseen by the Head of the Department. The units are:

- The Priority Chemicals Management Unit, which covers work related to the implementation of relevant conventions (Stockholm, Rotterdam, Minamata). The unit has six employees and the Head of the Unit.
- The Registration and Classification of Chemicals Unit, which is working with the implementation of the CLP and REACH Regulations. It employs four employees and the Head of the Unit;
- The Risk Assessment and Control of Chemicals Unit, which handles safety data sheets. It employs three people.

The CMD employees have adequate qualifications and have built their knowledge of the legislative *acquis* over the years. The CMD staff are composed mostly of chemical and environmental engineers, chemists and biologists. There are no economists employed at the CMD who could, for example, perform socio-economic analysis. However, the use of external support is foreseen in KKDIK (Article 58): "The Ministry [MEUCC] shall conduct a risk assessment and socio-economic analysis to evaluate the risk to human health or the environment and the socio-economic impact of restriction during the restriction process. The Ministry may use the services of third parties or compose committees consisting of experts in order to conduct or help to conduct such Risk Assessments and socio-economic analysis." The CMD has an established network of contacts among the universities; however, there are no ongoing projects or an MoU with academia and scientific institutions (Section 2.2.3).

Turkey has an ambitious legislative framework, mirroring the provisions of the REACH and CLP Regulations to a great extent. Therefore, the effective implementation of each mechanism requires a high number of resources. **According to the self-assessment of the CMD, all Units require additional staff for fulfilling their responsibilities, and the CMD staff would benefit from more training to increase their capacity for the implementation of chemicals legislation.**

[20] https://cygm.csb.gov.tr/en/units/chemicals-management-department/2171

Currently, the CMD is focusing on the registration process, including the provision of support to the industry to facilitate the registration of chemical substances. KKDIK requires companies that manufacture or import chemical substances in quantities above one tonne per year to provide physicochemical and (eco)toxicological information. Registration started on 1 January 2021, and the final deadline for submitting registration dossiers for all tonnage substances is 31 December 2023, when dossier evaluation will commence. The Turkish authorities expect to receive information for around 15,000 chemical substances. This may imply receiving around 67,500 registration dossiers[21] over three years, equal to 22,500 registration dossiers per year. The Turkish authorities will have to evaluate dossiers, i.e. that the information required by KKDIK is available in the dossier or proposed in a testing proposal. This information is crucial for understanding whether a chemical may pose a risk to human health and the environment. It is a key task that contributes to the generation of relevant data on chemicals, ensuring that all chemicals on the market have been properly tested and are safe for use. Dossier evaluation covers two processes: compliance check and examination of testing proposals.

Based on real data on time spent on manual verification at completeness check, ECHA estimated that to process the peak workload forecasted for the 2018 REACH registration deadline of 60,000 dossiers, they would have required approximately 180 additional workforces[22]. This implies that 1 FTE can process approximately 350 registration dossiers per year. Based on this assumption, the CMD would need around 65 FTEs per year over three years to evaluate all dossiers. However, the objective of the CMD is to evaluate five per cent of all dossiers received per year, i.e. around 1,100 dossiers, for which they will require three FTEs.[23] Therefore, the additional employees should be hired already by the first half of 2023 in order to train the resources in the second half of the year and commence dossier evaluation from January 2024.

The MoH, particularly the GDPH[24] and Turkish Medicines and Medical Devices Agency (MMDA), are responsible for implementing the Regulation on Biocidal Products of Turkey. The GDPH is responsible for the evaluation, authorisation and registration of preservatives and other biocidal products, which are included in Annex V of the Biocidal Products Regulation. Among other responsibilities of the GDPH, there is support to the further development of the legislative framework and the organisation of conferences and seminars about biocidal products.

Currently, the GDPH has 11 employees working full-time on biocidal products without responsibilities in other fields. Their work usually consists of receiving hard copies of dossiers, checking the accuracy and completeness of the information, and contacting applicants to address any issues with their applications. There are also eight to nine employees in the GDPH working on the market surveillance of biocides. The current resources are not sufficient for processing all submitted applications. Due to a high staff turnover, it is expected that only seven people working on biocidal products will remain at the GDPH by the end of 2021. Therefore, there is a need to increase the number of resources for the administrative tasks related to the implementation of the national legislation for biocidal products. The gap in the administrative capacity has been quantified as 10 to 20 FTEs per year over a five-year period. 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 10 to 20 FTEs has been estimated by comparing Turkey with Poland and assuming that a similar number of biocidal products will be

[21] On 1 September 2021, ECHA registered substances database contains information on 23,376 substances from 104,384 registration dossiers, resulting in a ratio of 4.5 registration dossiers per 1 substance. Therefore: 15,000 substances x 4.5 = 67,500 registration dossiers.

[22] ECHA (2017): ECHA Programming Document 2018-2020, p. 149.

[23] The assumption is that the proportion of substances registered in different tonnage bands will be the same as in the European Union. Completeness check of registration dossiers for higher tonnages requires more resources than for lower tonnage bands.

[24] Source: https://hsgm.saglik.gov.tr/tr/

placed on the market (7,000 to 10,000). While the authorities recognise the need for additional resources, no information is available about plans for hiring new employees at the GDPH.

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 Memorandum of Understanding with academia or relevant scientific institutes (Section 2.2.3); and
- High staff turnover (Section 2.2.4).

2.3.1.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MEUCC strengthens the administrative capacity of the Registration and Classification of Chemicals Unit for evaluation of chemical substances registration dossiers** in order to have a sufficient number of resources by 2024 when the evaluation of dossiers commence.

The EU chemical legislation is currently undergoing a thorough revision that may result in significant changes in its key mechanisms and, therefore, in the number of resources required by national competent authorities to ensure implementation and enforcement. It is important to highlight that the Turkish competent authorities also carry out tasks that are the remit of ECHA in the EU context. According to the self-assessment of the CMD, there is already the need for additional resources to implement all administrative tasks. The Turkish competent authorities will have to follow the revision process closely and adapt Turkish legislation swiftly to keep it in line with the EU *acquis*. It is recommended that **the CMD carries out an assessment of the additional necessary resources in 2023 when the changes to REACH and CLP should be defined and agreed.**

In addition, it is recommended that **the MoH strengthens the administrative staff capacity for the implementation of the Regulation on Biocidal Products.** The MoH should consider the progressive hiring and training of personnel and outsourcing some tasks related to the management of biocidal products authorisations in order to have a pool of around 20 to 30 experts over the next five years at their disposal (see also 2.3.5). Table 5 shows the conformity of the objective to the SMART criteria.

Table 5 – Objective 5: Strengthen the administrative capacity of the MEUCC and the MoH

Criteria	Notes
Specific	It is recommended that the MEUCC strengthens the administrative capacity of the Registration and Classification of Chemicals Unit for evaluation of chemical substances registration dossiers. It is recommended that the CMD carries out an assessment of the additional necessary resources in 2023 when the changes to REACH and CLP should be defined and agreed. It is recommended that the MoH strengthens the administrative staff capacity for the implementation of the Regulation on Biocidal Products.
Measurable	Number of employees in the MEUCC. Number of employees in the MoH. Number of external experts readily available for outsourced work (through an MoU).
Achievable	This may require the allocation of adequate financial resources.
Relevant	Without strengthening the capacity of the MEUCC and MoH, the Turkish competent authorities will not be able to evaluate all registration dossiers and process industry applications for the authorisation of biocidal products in a reasonable amount of time.

Criteria	Notes
Time-bound	The capacity needs to be built over time, starting from 2022.

2.3.1.3 Estimated human and financial resources required

In Turkey, the average labour cost per employee in the public administration in full-time equivalents per year is estimated to be around €14,000, whereas the labour cost per employee in the professional, scientific and technical activities sector in full-time equivalents per year is estimated to be about €16,500.[25] Therefore, hiring additional three employees for the CMD at the MEUCC would be approximately €180,000 over a five-year period (Table 6). However, the CMD would benefit from additional resources in all units. Hence, the cost of hiring additional personnel may be higher in the next five years.

Table 6 – Marginal labour cost of hiring MEUCC staff

	2022	2023	2024	2025	2026	€ - Total
MEUCC Staff - FTEs	16	17	19	19	19	
Additional FTEs	1	2	-	-	-	
Marginal Cost	€14,000	€42,000	€42,000	€42,000	€42,000	€180,000[26]

The additional cost of bringing the number of employees at the MoH to the suggested minimum amount of 20 would be approximately €350,000 (considering nine additional employees to the current 11 members of staff) over a five-year period (Table 7). However, the increase in the required number of FTEs for evaluating applications would be gradual and need to be planned over a five-year period. In addition, considering the issue of high staff turnover discussed in Section 2.2.4, the required financial resources may be even higher if the salaries are aligned with the industry wages.

Table 7 – Marginal labour cost of hiring MoH staff

	2022	2023	2024	2025	2026	€ - Total
MoH Staff - FTEs	11	12	14	16	18	-
Additional FTEs	1	2	2	2	2	-
Marginal Cost	€14,000	€42,000	€70,000	€98,000	€126,000	€350,000

However, the estimated number of FTEs required to deal with the expected workload may exceed this level depending on the number of applications for biocidal product authorisation and may amount to around 30 (internal and external) FTEs. In this scenario, the additional cost for outsourcing all ten external FTEs would be €165,000 per year[27].

[25] https://knoema.com/lc_ncostot_r2/labour-cost-wages-and-salaries-including-apprentices-nace-rev-2?geo=1029740-turkey.

[26] Rounded to the nearest 5,000.

[27] The estimate provided is the maximum cost per year for all additional external FTEs and may differ depending on need for outsourcing the workstreams.

2.3.1.4 Timeline, risks and risk mitigation measures

The hiring of new employees should start as soon as possible and continue progressively until the required number is reached. In order to keep the administrative capacity at the desired level, it is important to avoid high staff turnover (Section 2.2.4). In addition, new resources should be available for thorough training to ensure a swift onboarding (see Section 2.3.5). In the short term, the ongoing pandemic may restrict the possibility of organising face-to-face training, and therefore experts may need to be trained and work remotely. In the medium and long term, virtual engagement and remote training are expected to have a more prominent role than in the past.

2.3.2 No information on enforcement activities for chemicals

2.3.2.1 Description of the problem and dependencies

Several authorities in Turkey are responsible for the enforcement of the chemical legislation. According to the KKDIK regulation, the following ministries are responsible for the inspection and enforcement of restricted and prohibited substances in the scope of Annex XVII:

- Ministry of Health (MoH);
- Ministry of Trade (MoT);
- Ministry of Agriculture and Forestry (MAF);
- Ministry of Industry and Technology (MIT);
- Ministry of Work and Social Security (MWSS);
- Ministry of Energy and Natural Resources (MENR); and
- Ministry of Environment, Urbanisation and Climate Change (MEUCC).

Within the MEUCC, the Department of EIA Monitoring and Environmental Inspection has the responsibility to prepare the inspection campaigns and coordinate the work of the provincial directorates. The GDPH at the MoH, the Provincial Directorates and the MMDA are the relevant authorities for the enforcement of the Regulation on Biocidal Products of Turkey. At the end of each year, annual plans for enforcement campaigns are made, including determining target active substances, product types, etc.

General statistics on environmental inspections are published on the MEUCC website for the Directorate General of Environmental Impact Assessment, Permit, and Inspection. In addition, the Ministry of Trade publishes the results of market surveillance of biocidal products in the National Market Surveillance Report every year. In 2018, 2019 and 2020, 59,217, 54,135, and 40,572 products were inspected on the market, respectively, of which 691, 465, and 164 were found to be non-compliant. Within the scope of the 2021 Action Plan, the Unit prepared the inspection plan for 40,000 products. As of September 2021, 24,454 products with active substances were inspected.

However, there is no specific information on inspections carried out on chemicals. Other Ministries also provide inspection reports, but the information on inspections of chemicals is lacking. In addition, no specific information has been found on the number of inspectors with competencies on chemical legislation at the central level.

2.3.2.2 Recommended actions, action owner and other relevant stakeholders

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. This could be achieved by publishing statistics on inspections and enforcement of chemicals legislation together with the

information of other environmental inspections on the MEUCC website or in annual reports by other Ministries as already done for other enforcement activities. Table 8 shows the conformity of the objective to the SMART criteria.

Table 8 – Objective 6: Information on enforcement made available to the public

Criteria	Notes
Specific	It is recommended that the information on enforcement activities in chemical risk management is made available to the public.
Measurable	Reporting of data and statistics on inspections and enforcement of chemicals legislation together with the information of other environmental inspections on the MEUCC website or in annual reports by other relevant Ministries.
Achievable	The information on inspections in relation to other environmental legislation is already published online and in reports by some Ministries.
Relevant	Publishing the information on enforcement activities will increase the public confidence in competent authorities and may increase compliance by the industry.
Time-bound	Starting from the year 2022.

2.3.2.3 Estimated human and financial resources required

Inspectors are already required to store information on their enforcement activities in a database accessible by other competent authorities. Recording inspections, inspection outcomes, and other statistics (e.g., size of the company inspected, type and number of non-compliances, imposed sanctions) require the establishment of working procedures, starting from identifying and agreeing on relevant indicators and data items. This task is estimated to require around 0.1 to 0.3 FTEs, depending on the number of authorities that need to be involved in developing the working procedures and whether similar procedures are available for other enforcement areas.

2.3.2.4 Timeline, risks and risk mitigation measures

The information on enforcement activities for chemicals should be made public sooner than later, starting from 2022.

2.3.3 Lack of resources for enforcement of chemical legislation

2.3.3.1 Description of the problem and dependencies

In accordance with the Environmental Law no. 2872 and respective by-Laws, enforcement is ensured by the Department of EIA Monitoring and Environmental Inspection of the MEUCC and by around 2,500-3,000 inspectors at 81 provincial directorates who carry out site and desktop inspections. In addition, there are 8-9 employees at the GDPH of the MoH responsible for the enforcement of biocides legislation. Inspectors conduct inspections country-wide and impose administrative penalties to facilities and natural/legal persons found non-compliant, and they can decide to suspend activity until the issues are solved. For very serious non-compliance, inspectors can also file criminal charges.

According to the self-assessment of the enforcement authorities, the enforcement of the environmental legislation in practice is quite difficult as resources are limited and inspectors are overloaded. The CMD provides capacity building for inspectors. However, the number of inspectors participating in these training courses is low.

2.3.3.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the competent authorities strengthen the capacity of inspectors working on chemical legislation**. For example, the competent authorities could consider a train-the-trainers approach, where the CMD could provide the training to a number of selected inspectors from the different directorates, who would be reference inspectors for chemical legislation enforcement and could train other peers on the supervision of the relevant provisions. It is also important for the Government to develop a plan to retain staff and avoid a high staff turnover, which could result in the loss of resources that have been trained over the years (see Section 2.2.4). Table 9 shows the conformity of the objective to the SMART criteria.

Table 9 – Objective 7: Strengthen the capacity of inspectors working on chemicals legislation

Criteria	Notes
Specific	It is recommended that the competent authorities strengthen the capacity of inspectors working on chemical legislation.
Measurable	Number of trained inspectors. Adoption of a plan to retain staff, see Section 2.2.4.
Achievable	Training activities are ongoing, but participation is low.
Relevant	Without an adequate number of properly trained environmental inspectors in chemicals legislation, the Turkish authorities may not be able to guarantee adequate enforcement of the EU Regulations.
Time-bound	Starting from the year 2022.

2.3.3.3 Estimated human and financial resources required

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

2.3.3.4 Timeline, risks and risk mitigation measures

As for most of the recommendations, the sooner action is taken, the better. The recommended start and target year should be 2022 because, without a sufficient number of properly trained environmental inspectors in chemicals legislation, the Turkish authorities may not be able to guarantee adequate enforcement of their legislation on chemicals and biocidal products.

2.3.4 Regulation on Biocidal Products is not aligned with BPR

2.3.4.1 Description of the problem and dependencies

The Regulation on Biocidal Products of Turkey (OG of TR, 31 December 2009, 27449) was originally prepared in line with the Directive 98/8/EC. Subsequently, for the purpose of alignment with the BPR Regulation, amendments were made in 2011, 2014 and 2020. However, the regulation is still not fully aligned with the BPR. The amendments introduced to the national regulation renders the content

more complicated and defined procedures less systematic. The main gaps include mutual recognition, active substances which are candidates for substitution, and comparative assessment of these.

Moreover, concepts such as nanomaterials, vulnerable groups, cumulative and synergistic effects are not prominent as in the EU Regulation, if not absent. Stakeholders, mainly SMEs, might require a significant amount of guidance for implementing the regulation, as the procedures in the national regulation are substantively different compared to the procedures in Member States. After accession, transitional measures will be needed, especially for mutual recognition, evaluation, and reporting. One of the responsibilities of the GDPH at the MoH is the further development of the legislative framework for biocidal products.

2.3.4.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the MoH fully aligns the Regulation on Biocidal Products of Turkey with the BPR.** The amendments to the regulation would need to address the main gaps that have been identified and make the regulation easier to understand by systematically defining all the procedures. Table 10 shows the conformity of the objective to the SMART criteria.

Table 10 – Objective 8: Fully align regulation on biocidal products with BPR

Criteria	Notes
Specific	It is recommended that the MoH fully aligns the Regulation on Biocidal Products of Turkey with the BPR.
Measurable	The amendments fully align the regulation on biocidal products to BPR.
Achievable	Some amendments have already been done to the current national regulation.
Relevant	The amendments to the legislation to align it with the BPR are necessary to fully transpose the EU Regulation.
Time-bound	Starting from the year 2022.

2.3.4.3 Estimated human and financial resources required

The drafting of amendments to the Regulation on Biocidal Products to approximate it with the EU legislation is the responsibility of the GDPH at the MoH as set out in the national regulation (Article 17), and the time that needs to be allocated for this task should already be included in duties of the staff within the Department.

2.3.4.4 Timeline, risks and risk mitigation measures

The MoH has submitted a proposal for an IPA III project for further alignment of the national legislation with the BPR and expects to start work in 2022. The proposal is going through the approval process.

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

2.3.5.1 Description of the problem and dependencies

The GDPH at the MoH is responsible for the registration, evaluation, and authorisation of preservatives and other biocidal products, which are included in Annex V of the BPR. Since October 2019, another institution – the MMDA – also holds some competencies on biocides. The MMDA

responsibilities cover only PT1 and PT19 (related to biocidal products usage on human skins), while all other biocidal products fall into the competency of the GDPH.

There are two main implementing tasks that should be carried out: active substance approval and biocidal products authorisation. For the authorisation of biocidal products, there are different procedures based on the list of the active substances, which are:

- The licensing of biocidal products containing new active substances, or active substances listed in List-I (active substances allowed to be used in biocidal products);
- The registration of low-risk biocidal products containing new active substances, or active substances listed in List-IA (low-risk active substances); and
- Licensing of biocidal products containing active substances not listed in List-I or List-IA in terms of relevant product type.

Before starting these procedures, a pre-application is required. It should be noted that low-risk biocidal products require registration but not a license.

Currently, there is no mutual recognition procedure for biocidal products authorisation in Turkey. All biocidal products have to be authorised before selling them on the Turkish market. For any biocidal product to be authorised, the applicant has to provide a hard copy of the dossier of their product. The dossier includes information on physical and chemical properties of the biocidal product and active substance, its efficacy and toxicity. GDPH staff assess the information in dossiers and can issue an authorisation, with the exception for some biocidal products included in the Biocidal Product Inventory[28] (main group 2 – preservatives and main group 4 – other biocidal products: antifouling products and embalming fluids and preservative fluids), which can be sold in Turkey without authorisation until the end of 2023. Active substances are allowed on the Turkish market if they are approved in the EU or in the Review Program but not yet approved. Some of the dossiers have information on environmental and health risk assessment. However, at the moment, GDPH staff lack the required expertise to carry out the full evaluation of the application dossiers submitted, including the assessment of the information on the efficacy and risk. Due to this capacity gap, it is not mandatory for the applicants to submit risk assessment information in their application dossiers. In order to receive authorisation for placing a biocidal product on the Turkish market, the applicant has to provide samples of the biocidal product. The GDPH orders analyses of efficacy, toxicity, and chemical/physical properties, which are carried out in approved laboratories.

2.3.5.2 Recommended actions, action owner and other relevant stakeholders

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

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

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

- In-house related activities:
  - Hire additional staff;

[28]https://hsgm.saglik.gov.tr/depo/birimler/cevre-sagligi/4-biyo-ab-uygulama/Envanter_Kaydi_Yapilan_Urunler/Envanter_Kaydi_Yapilan_Urunler_-_20211022.pdf

- Identification of currently available resources and gaps in expertise;
- Planning and implementation of the provision of training (timelines);

- Activities related to external resources (see Section 2.2.3):
  - Identification of external resources;
  - Identification of methods of contracting and conditions (including defining mutual obligations and responsibilities);
  - Arrangement of contracts; and
  - Provision of training to external resources, when required.

It is recommended that **the MoH surveys the needs of their staff and external experts and organises and implements training and capacity building courses.** Training should be continuous and planned on an annual basis to keep internal and external experts up to date with the evolutions in the EU. ECHA and other Member States' competent authorities could also provide training (focused on risk assessment for physical and chemical properties, efficacy assessment, human health, and environmental risk assessment) for developing competencies of the MoH staff and external experts, who are likely to provide technical and scientific support. The development of competencies could be further strengthened by the assessment and provision of comments on the work carried out by other MSCAs and ECHA. Table 11 shows the conformity of the objective to the SMART criteria.

Table 11 – Objective 9: Address the lack of expertise in risk assessment and provide capacity building

Criteria	Notes
Specific	It is recommended that the MoH addresses the lack of expertise in risk assessment and other technical and scientific areas by opting for a hybrid system. It is recommended that the MoH surveys the needs of their staff and external experts and organise and implement training and capacity building courses.
Measurable	Actions laid out in Section 2.2.3 are implemented. A capacity-building plan is developed and established, covering 2022-2026.
Achievable	The capacity building plan should be developed in coordination with ECHA and other MSCAs, highlighting where these entities could provide additional training and support.
Relevant	Capacity building is key for filling any gaps in competencies and maintaining current skills up to date.
Time-bound	Continuous, starting as soon as possible and following the hiring of new staff. The capacity building plan should cover the period 2022-2026.

2.3.5.3 Estimated human and financial resources required

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

2.3.5.4 Timeline, risks and risk mitigation measures

ECHA and other European partners will most likely continue supporting the Turkey's competent authorities over the coming years, and there is the risk for Turkey to develop a dependency on external resources for capacity building activities. In the short term, the ongoing COVID-19 pandemic

poses an organisational and logistical challenge because training courses may need to be held remotely via webinars. ECHA has strong expertise in preparing training materials and delivering remote online courses. Even in the medium-long term, many courses could be held remotely.

2.3.6 Lack of a communication strategy

2.3.6.1 Description of the problem and dependencies

The Regulation on Principles and Procedures for Preparation of Legislation 2005/9986[29] regulates the procedures and principles regarding the preparation of draft texts of laws, decrees, and other regulatory acts to be prepared by the Ministries, related institutions, and organisations. According to this regulation, all draft laws have to be presented to the relevant stakeholders, including ministries, public institutions and organisations, relevant local administrations, universities, trade unions, professional organisations, NGOs, and also the General Secretariat for European Union regarding drafts prepared within the framework of harmonisation with the EU *acquis*. Drafts of public interest may be submitted to the public by the responsible ministry through the internet, press or broadcast before the draft is submitted to the Presidency. Article 7 of the Regulation sets out the rules for the Ministries and stakeholders to express their opinion on the drafts. While the Regulation foresees formal public consultation, EC (2020)[30] notes that systematic and inclusive mechanisms for consulting a wide spectrum of civil society organisations, notably on new legislation and policies, still need to be in place.

In the framework of international cooperation projects, the CMD has carried out information dissemination activities and hosted training activities and seminars to strengthen knowledge of industry regarding chemicals legislation. However, 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.

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

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

In addition, there is the need to keep Turkish industry stakeholders informed about their 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. As noted by ECHA (2017)[31], it is "more cost-effective to support companies while they are preparing their dossiers rather than asking for updating the dossier after the initial submission." Turkish authorities are investing resources to provide advice and assistance to the industry to support businesses in fulfilling their legal obligations. This requires reactive support upon receiving a request and the organisation of webinars and training events for industry stakeholders.

[29] https://www.resmigazete.gov.tr/eskiler/2006/02/20060217-4.htm

[30] EC (2020): Commission Staff Working Document. Turkey 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.

[31] ECHA (2017): ECHA Programming Document 2018-2020, p. 40

Overall, an effective communication strategy is essential to ensure that Turkish companies are ready for the single market well before the day of Turkey's accession to the EU.

2.3.6.2 Recommended actions, action owner and other relevant stakeholders

Civil society plays an essential role in the process of European integration of Turkey. Proactive civil society organisations are important actors in the implementation of public policies. However, EC (2020) notes that civil society is under continuous pressure, and their space to operate freely has continued to diminish in Turkey. Administrative difficulties for national and international non-governmental NGOs continue to hamper civil society activities, and organisations remain excluded from genuine legislative consultation processes.

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

- The organisation of workshops and events, including identification and selection of topics of interest for the Turkish stakeholders that could be discussed during the events;
- Communication of information on the progress in establishing an effective regulatory framework, including information on the measures to ensure the confidentiality of non-public information; and
- The organisation and dissemination of information online and by using other channels (e.g., newspapers, advertising, etc.) where appropriate:
  - The official MEUCC webpage, including the webpage of the Helpdesk, could be organised by topics to facilitate access to documents and deadlines;
  - Additional information, for example, the translation of news presented on the ECHA website into Turkish that could be relevant for Turkish 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 12 shows the conformity of the objective to the SMART criteria.

Table 12 – Objective 10: Develop a communication strategy

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

2.3.6.3 Estimated human and financial resources required

It is recommended that the development of a communication plan is included in the remit of the Helpdesk staff and should be a part of the job description. However, there are no employees allocated to the helpdesk services at the moment, and staff are involved in the process depending on the workload. Currently, the team receives around ten queries per week via Helpdesk, 25 via phone, and 15 through the Chemicals Registration System, which is a total of 50 queries. Assuming an average of half an hour to respond to one query[32], it requires 0.6 FTE per year for this task, which may also increase with time considering the increasing number of queries closer to regulatory deadlines. It would therefore be beneficial to have an assigned full-time employee for the helpdesk activities, who would also be responsible for the development and the implementation of the communication strategy.

In EU Member States, costs of communication activities vary depending on the scale (number of events, media channels used for disseminating informative material, etc.) but could be estimated at around €10,000 per year. For information, in 2014, the Swedish Chemicals Agency, in the framework of its support to the Serbian competent authorities with the development of their capacity, spent around €10,000 to develop a plan to prepare Serbian industry for EU chemical legislation and organise events for the divulgation of information, with the assistance of the chamber of commerce in Belgrade. The development of the communication plan was outsourced to the Faculty for Media and Communication of the University of Belgrade. The strategy included:

- The identification and engagement with key media stakeholders;
- The preparation and distribution of press materials to increase the visibility of the competent authorities;
- Training for the competent authorities staff on communication tools and procedures related to media activities, crisis PR and damage control, and message development.[33]

2.3.6.4 Timeline, risks and risk mitigation measures

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

2.3.7 No IT system for managing applications for biocidal products and active substances

2.3.7.1 Description of the problem and dependencies

The MoH has an online system[34] through which notifications, such as licence and permit applications, registering, inspections, implementations required by different regulations, can be made. However,

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

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

[34] https://cevsis.saglik.gov.tr/

there is no IT system for managing applications for the approval of active substances and authorisation of biocidal products. The development of the IT system has been planned, and two options were initially considered: to use the existing National Chemicals Registration System (KKS) system used by the Ministry of Environment, Urbanisation and Climate Change or to develop a separate system in the GDPH for the submission of dossiers for active substances and biocidal products. The second option has been chosen, and, currently, the IT system is developing, which will be similar to KKS and should be running before 2023.

2.3.7.2 Recommended actions, action owner and other relevant stakeholders

It is recommended that **the IT system for applications for active substances and biocidal products to the GDPH follows a format compatible with R4BP**. This would facilitate the submission of the information through the IT systems of ECHA following Turkey's accession to the EU. Turkey has already developed other e-tools similar to those used by ECHA and MSCAs to manage information. Table 13 shows the conformity of the objective to the SMART criteria.

Table 13 – Objective 11: Digitalise the submission of documentation to the CMD

Criteria	Notes
Specific	It is recommended that the IT system for applications for active substances and biocidal products to the GDPH follows the format compatible with R4BP.
Measurable	The IT system for the provision of documentation is established.
Achievable	Turkey has already developed e-tools similar to those used by ECHA and MSCAs.
Relevant	The online system would enable a more efficient and sustainable way for managing applications.
Time-bound	Starting in 2023.

2.3.7.3 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. In addition, the training on the e-tool R4BP would also be required to ensure that the competent authority has the necessary knowledge and competencies to establish such a tool. Therefore, training may be required, which has already been discussed in Section 2.2.1.

2.3.7.4 Timeline, risks and risk mitigation measures

The planning of the IT system has already commenced and should be finalised by the end of 2023. The risk is the lack of resources that may prevent the development of the IT system and the lack of knowledge of the R4BP e-tool. Hence, the support from ECHA or MSCA throughout the process would be beneficial.

3 Conclusions and recommendations

3.1 Recommended actions and prioritisation

The main challenge facing Turkish authorities is the lack of resources necessary to implement and enforce the national legislation on chemicals and biocidal products. However, in order to strengthen the administrative capacity and enable the implementation of other recommended actions (Table 14), some underlying drivers need to be addressed.

Firstly, the adoption of the **Memorandum of Understanding** with scientific institutes and external experts (Section 2.2.3) to facilitate the outsourcing of some workstreams would allow avoiding an overload of the General Directorate for Public Health at the Ministry of Health, responsible for the implementation of the Regulation on Biocidal Products. In addition, **the plan to retain staff** in all administrative bodies and avoid high staff turnover (Section 2.2.4) is also necessary in order to reduce the risk of losing trained and experienced staff and institutional memory. It is recommended that these actions are given priority and are implemented as soon as possible.

The above measures would allow strengthening the capacity of administrative staff (Section 16.3.1) and outsourcing some workstreams, which would help to **tighten and further develop the legislation on biocidal products to fully align it with the BPR** (Section 2.3.4) and address some other challenges associated with an insufficient administrative capacity, for example, the lack of expertise in risk assessment and evaluation of applications for authorisation of biocidal products (Section 2.3.5). In addition, it is also essential to strengthen the capacity of the Chemicals Management Department at the Ministry of Environment, Urbanisation and Climate Change (Section 2.3.1) and the inspectors working on chemicals legislation (2.3.3).

Furthermore, the availability to submit the application for the authorisation of biocidal products and the approval of active substances **via IT system and in a format compatible to R4BP** is recommended to make the application process more efficient and sustainable and to facilitate the submission of the information through the IT systems of ECHA once Turkey joins the EU (2.3.7).

The development of **a communication strategy** (Section 2.3.6) and publishing **the information on enforcement activities** in chemical risk management would help increase the transparency, stakeholder engagement, and confidence in competent authorities on the enforcement of legislation on chemicals (2.3.2).

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

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. Tighten and further develop the legislation on biocidal products	!!!	2022-2023	MoH	MSCA	1 FTE	-
2. Strengthen the capacity of MEUCC	!!!	2022-2023	Gov MEUCC	-	3 FTEs	~€42,000
3. Carry out an assessment of the necessary additional resources at CMD	!!	2023	MEUCC	-	-	-
4. Strengthen the capacity of MoH	!!!	2022-2025	Gov MoH	-	20-30 FTEs	~€126,000 - ~€266,000 per year
5. Survey the needs of MoH staff and external experts and organise capacity building on efficacy and risk assessment	!!	2022-2023	MoH ECHA	MEUCC, MMDA	0.5 – 1 FTE (ECHA and/or MSCA)	~€100,000 per year over two years (ECHA and/or MSCA)
6. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	!!	2022-2024	MoH	MEUCC, ECHA, MSCA and/or Montenegro	1.5 FTE (over a 3-year period) – 0.5 FTE per year	-
7. Report on chemical legislation enforcement activities	!!	2022-	MEUCC	MoH, other relevant Ministries, Provincial Directorates	0.1-0.3 FTE	-
8. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants; - Promote the implementation of MoU with scientific institutes to outsource certain workstreams; - Promptly adopt the legislation enabling the better functioning of its institutions; and - Continuously build up capacity	!	2022	Gov	-	-	-
9. Capacity building on enforcement	!!!	2022-2025	ECHA or MSCA	MEUCC, MoH, MoT, MAF, MIT, MWSS, MENR, Provincial Directorates	0.5 – 1 FTE (ECHA and/or MSCA)	~€50,000 per year over two years (ECHA and/or MSCA)

Action Plan

Recommended actions	Criticality	Action start – end	Action owner	Support	Required resources	
					Human	Financial
10. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Turkish 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-	MEUCC	MoH, ECHA, MSCA, TCMA NGOs	0.5 FTE	€10,000 per year (ECHA and/or MSCA); €10,000 per year (Turkish CA's)
11. IT system for management of applications for active substances and biocidal products to follow the format compatible with R4BP	!!	2022-2024	MoH	MEUCC, ECHA	-	-
12. Hand-on training on ECHA e-tools	!	2025	ECHA	MSCA and MEUCC	0.1 FTE (ECHA and/or MSCA)	€40,000 (ECHA and/or MSCA)

Notes:
Gov: Government of the Republic of Turkey; MoT: Ministry of Trade; MENR: Ministry of Energy and Natural Resources; MAF: Ministry of Agriculture and Forestry; MEUCC: Ministry of Environment, Urbanisation and Climate Change; MoH: Ministry of Health; MSCA: Member State Competent Authority; MIT: Ministry of Industry and Technology; MWSS: Ministry of Work and Social Security; TCMA: Turkish Chemical Manufacturers Association

Table 15 – Gantt chart and resource allocation

Action	2022	2023	2024	2025	2026
1. Tighten and further develop the legislation on biocidal products	0.5 FTE	0.5 FTE			
2. Strengthen the capacity of MEUCC	+1 FTE €14k	+2 FTEs €42k	- €42k	- €42k	- €42k
3. Carry out an assessment of the necessary additional resources at CMD		-			
4. Strengthen the capacity of MoH	+1 FTE €14k	+2 FTEs €42k	+2 FTEs €70k	+2 FTEs €98k	+2 FTEs €126k
5. Survey the needs of MoH staff and external experts and organise capacity building on efficacy and risk assessment	0.5 FTE €100k	0.5 FTE €100k			

Action Plan

Action	2022	2023	2024	2025	2026
6. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	0.5 FTE	0.5 FTE	0.5 FTE		
7. Report on chemical legislation enforcement activities	0.1-0.3 FTE	-	-	-	-
8. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants; - Promote the implementation of MoU with scientific institutes to outsource certain workstreams; - Promptly adopt the legislation enabling the better functioning of its institutions; and - Continuously build up capacity	-				
9. Capacity building on enforcement	0.5 FTE €50k			0.5 FTE €50k	
10. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Turkish 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 (MEUCC)	0.5 FTE €10k (MEUCC)
11. IT system for management of applications for active substances and biocidal products to follow the format compatible with R4BP	-	-	-	-	-
12. Hand-on training on ECHA e-tools				0.1 FTE €40k	
Totals					
ECHA or MSCA	0.5 FTEs ~€150k	0.5 FTE ~€100k	- €0-10k	~0.5 FTE €90k	
MoH	1 FTE (+1 FTE)[35] €14k	1 FTE (+2 FTEs) €42k	0.5 FTE (+2 FTEs) €70k	+2 FTEs €98k	+2 FTEs €126k
MEUCC	~1 FTE (+1 FTE)[36] €14k	0.5 FTE (+2 FTEs) €42k	0.5 FTE €42k	0.5 FTE €52k	0.5 FTE €52k

[35] 1 FTE is required for recommended actions plus 1 additional FTE to increase the capacity of the MoH.

[36] ~1 FTE is required for recommended actions plus 1 additional FTE to increase the capacity of the MEUCC.

Table 16 – Risks and risk mitigation measures

Action	Risk	Risk Mitigation Measures
1. Tighten and further develop the legislation on biocidal products	Delays	The Commission and ECHA stress the importance of aligning the national legislation with the BPR Actions: 4. Strengthen the capacity of MoH 6. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities
2. Strengthen the capacity of MEUCC	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, Turkey would not be deemed ready to fulfil EU obligations and responsibilities
3. Carry out an assessment of the necessary additional resources at CMD	-	-
4. 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, Turkey would not be deemed ready to fulfil EU obligations and responsibilities.
5. Survey the needs of MoH staff and external experts and organise capacity building on efficacy and risk assessment	Lack of resources COVID-19 pandemic The alignment of the national legislation on biocidal products is further delayed, and therefore the trained experts cannot apply the new competencies The MoU is not ratified on time High staff turnover	Support of ECHA or MSCA Remote learning Actions: 1. Tighten and further develop the legislation on biocidal products 4. Strengthen the capacity of MoH 6. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities
6. Develop, ratify and implement an MoU with the relevant scientific institutes for rapid and long-term access to their competencies and capabilities	Lack of resources	Actions: 2. Strengthen the capacity of MEUCC 4. Strengthen the capacity of MoH 8. Develop a plan to retain staff
7. Report on chemical legislation enforcement activities	No exchange of information between the relevant departments	A central digital system to exchange information is in place
8. Develop a plan to retain staff: - Guarantee competitive salaries (in line with or above industry levels); - Prevent work overload by hiring new civil servants; - Promote the implementation of MoU with scientific institutes to outsource certain workstreams; - Promptly adopt the legislation enabling the better functioning of its institutions; and - Continuously build up capacity	Lack of resources The new government may show no interest in developing a plan to retain public administration staff	The Commission should highlight the importance of ensuring the administrative capacity of the different state entities responsible for implementing and enforcing EU legislation

Action Plan

Action	Risk	Risk Mitigation Measures
9. Capacity building on enforcement	Lack of resources Loss of expertise because of high staff turnover	Support of ECHA or MSCA Actions: 8. Develop a plan to retain staff
10. Development and implementation of a communication plan: - Organisation of workshops and events, including identification and selection of topics of interest for the Turkish 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.	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: 2. Strengthen the capacity of MEUCC
11. IT system for management of applications for active substances and biocidal products to follow the format compatible with R4BP	Lack of resources Lack of experience Delays	Support from ECHA and MSCAs Actions: 12. Hand-on training on ECHA e-tools
12. Hand-on training on ECHA e-tools	High staff turnover	8. Develop a plan to retain staff

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

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

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

- All countries still have to fully align their national legislation with the BPR;
- All countries need strengthening of their respective administrative capacities for dealing with biocidal products, with similar underlying issues:
  - The need to develop sustainable financing systems aligned with the EU Regulations and principles and the need for ring-fencing the fees collected for chemical risk management activities by the authorities;
  - The need to ratify Memorandum of Understanding with scientific institutes to facilitate access to external experts to speed up regulatory processes and avoid bottlenecks;
- All countries need to improve their transparency and stakeholder engagement procedures, including:
  - Increasing collaboration with civil society organisations, chambers of commerce, industry associations and other stakeholders for raising public awareness on chemical risks;
  - Publication of information on enforcement activities;
  - Publication of information on participation in public consultations and follow-ups;

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

- All five countries apply for the funding and technical assistance available through TAIEX and IPA instruments for chemical risk management related activities. It is important to stress that the chemical *acquis*, while not being more or less important of other environmental legislative areas, does require a significant amount of resources for its implementation and enforcement. All beneficiaries should ensure the allocation of adequate resources over time so that capacity-building efforts are not dissipated by understaffing and staff turnover;
- ECHA and/or other Member State competent authorities provide training and capacity building in the following areas:
  - Evaluation of applications for authorisation of biocidal products, in particular on efficacy and human health and environmental risk assessment;
  - Use and functioning of ECHA e-tools for information storage, management and sharing;
  - Information security procedures;
  - Enforcement best practices;

- Dissemination of information, development of a communication strategy and national helpdesk best practices.

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

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List of Abbreviations

Acronym	Full name
ATPs	Adaptations to technical progress
BOSAD	Association of Paint Industry
BPC	Biocidal Product Committee
BPD	Biocidal Product Directive
BPR	Biocidal Products Regulation
CARACAL	Competent authorities for REACH and CLP
CBI	Confidential Business Information
CEFIC	European Chemical Industry Council
CEN	European Committee for Standardisation
CLH	Classification and Labelling
CLP	Classification, Labelling and Packaging
CLRTAP	Convention on Long-Range Transboundary Air Pollution
CMD	Chemicals Management Department
CMR	Carcinogenic, mutagenic, or toxic for reproduction
CoRAP	Community Rolling Action Plan
DDoS	Distributed denial-of-service
DGEM	Directorate General of Environmental Management
DGGIS	Directorate General for Geographic Information Systems
EC	European Commission
ECHA	European Chemicals Agency
EIA	Environmental Impact Assessment
EU	European Union
GDP	Gross Domestic Product
GDPH	General Directorate for Public Health
GLP	Good Laboratory Practice
HCF	Helsinki Chemicals Forum
HEAL	Health and Environment Alliance
ICOC	Istanbul Chamber of Commerce
IEIS	Pharmaceutical Manufacturers Association of Turkey
IKMIB	Istanbul Chemicals and Chemical Products Exporters' Association
İMMİB	Istanbul Mineral and Metals Exporters Associations

Acronym	Full name
IPA	Instrument for Pre-Accession Assistance
IPS	Intrusion prevention system
IT	Information Technology
IUCLID	International Uniform Chemical Information Database
KemI	Swedish Chemicals Agency
KIPLAS	Turkey Chemicals Petroleum Tire and Plastic Industries Employers Union
KKDIK	The Turkish Law on Registration, Evaluation, Authorisation and Restriction of Chemicals
KKS	National Registration System for Chemicals
KOSGEB	Small and Medium Enterprises Development Organisation
KTSD	Association of Cosmetics and Cleaning Products Industrialists
LISoT	Legislation Information System of Turkey
MMDA	Medicines and Medical Devices Agency
MAF	Ministry of Agriculture and Forestry
MENR	Ministry of Energy and Natural Resources
MEUCC	Ministry of Environment, Urbanisation and Climate Change
MIT	Ministry of Industry and Technology
MoAF	Ministry of Agriculture and Forestry
MoEU	Ministry of Environment and Urbanisation (note that the name was changed in 2021 to Ministry of Environment, Urbanisation and Climate Change)
MoH	Ministry of Health
MoT	Ministry of Trade
MoU	Memorandum of Understanding
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
MSDS	Material Safety Data Sheet
MWSS	Ministry of Work and Social Security
NAC	Network access control
NDP	National Development Plan
NGO	Non-Governmental Organisation
NIP	National Implementation Plan
OG	Official Gazette
PAM	Privileged access management

Acronym	Full name
PCB	Polychlorinated biphenyls
PCT	Polycyclohexylenedimethylene terephthalate
PIC	Prior Informed Consent Regulation
POP	Persistent Organic Pollutant
R4BP	Register for Biocidal Products
RAC	Risk Assessment Committee
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SCBP	Standing Committee on Biocidal Products
SDS	Safety Data Sheets
SEA	Turkish Regulation on Classification, Labelling and Packaging of Substances and Mixtures
SEAC	Socio-Economic Analysis Committee
SME	Small and Medium-sized Enterprise
SPC	Summary of the product characteristics
SSR	Standard Security Requirements
SVHC	Substances of very high concern
TAIEX	Technical Assistance and Information Exchange
TCMA	Turkish Chemical Manufacturers Association
TEMA	Turkish Foundation for Combating Erosion, Afforestation and Conservation of Natural Assets
TKSD	Turkish Chemical Manufacturers Association
TOBB	Union of Chambers and Commodity Exchanges of Turkey
TUBİTAK	Scientific and Technological Research Council of Turkey
UÇES	EU Integrated Approximation Strategy
UNDP	United Nations Development Program
UZEM	National Poison Centre

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