

## ENKORE Cluster Deliverable

### POLICY STRATEGY FOR THE CLUSTER

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<b>Dissemination level</b>	PU
<b>Type</b>	R
<b>Delivery date</b>	31/12/2024



**Funded by  
the European Union**

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## 1. Introduction

The overall purpose of the ENKORE Policy Strategy is to outline the policy processes which ENKORE can provide input on science translation for policy and practice to maximize the impact of the five projects within the cluster. The Policy Strategy aims to increase the policy and advocacy impact of the five projects by contributing to enhanced science-based decision-making and evidence-based policy development.

The Policy Strategy describes the context in which cluster members work, provides a mapping of relevant policy processes, identifies the target audience for policy dissemination and outlines possible synergies across the five projects. The ENKORE Policy Strategy will serve as a living document for the 5-year period and will be updated if needed.

The ENKORE cluster is comprised of five projects: EDC-MASLD, ENDOMIX, HYPIEND, MERLON and NEMESIS, funded under the EU call HORIZON-HLTH-2023-ENVHLTH-02-03 (Health impacts of endocrine-disrupting chemicals: bridging science-policy gaps by addressing persistent scientific uncertainties).

The cluster will be active from 1 January 2024 until 31 December 2028, with ENDOMIX finalizing its work on 31 December 2027 but with continued contribution to some cluster activities. Within the cluster, three working groups (WG) have been established. WG1 on Science translation for policy and practice; WG2 on Data analysis/management and protection; and WG3 on Communication and Dissemination.

WG1: Science translation for policy and practice, is led by the MERLON project with the NEMESIS and HYPIEND projects as co-leads. This policy strategy is a deliverable of WG1.

The unique value of ENKORE WG1 is coordinating and harmonising the preparation of policy briefs and the policy communication activities of the projects participating in the cluster. It also works to ensure that the cluster's scientific findings are translated into policy actions where relevant. Within the ENKORE cluster, the Science to Translation Working Group (WG1) will work to gather and review relevant scientific findings related to endocrine disruptors and health from each individual project, acting as a 'one voice' platform for policy dissemination. The different activities of WG1 are outlined in this strategy, as well as possible synergies based on the policy activities of each individual project.

The ENKORE WG1 will be responsible for producing Policy Briefs during the project lifetime, alongside disseminating these briefs to relevant partners and stakeholders. Prior to publication, all draft materials will be shared with project coordinators and the European Commission for feedback and approval.

Topics covered under the cluster focus on: Endocrine disruption, public health, chemicals and policies in place in the EU to prevent exposure.

The Cluster Coordination Team will organise at least four thematic workshops of common interest. The organisation of these workshops does not exclude the possibility of organising others, if deemed necessary. The themes of the workshops will be defined in the context of the scientific strategy of the cluster and may include output from WG1.



## 2. Policy goal and main aims

The ENKORE cluster's policy goal is to inform current and future policy processes in the EU to ultimately improve the health and well-being of European populations.

We will present the most up-to-date evidence on health impacts of endocrine disruptors for uptake in different policies at EU, national and local levels, including relevant initiatives under the European Green Deal (Chemical Strategy for Sustainability, Zero Pollution Action Plan, REACH revisions, etc.), and the Environmental, Health and Research policy agendas.

The Science translation for policy and practice Working Group (WG1) aims to synthesise the findings and recommendations developed by the individual cluster projects and develop joint policy briefs and recommendations to inform EU evidence-based policies and strategic priorities.

### Specific objectives of the WG1:

- Compiling and integrating research findings of the cluster projects into clear, actionable policy recommendations
- Tracking and analysing current policy trends at the EU level
- Creating and distributing joint policy briefs and reports to inform decision-makers and the public about key findings and recommendations and advocate for the adoption and review of policies based on robust scientific evidence regarding endocrine disrupting chemicals (EDCs) generated by ENKORE

## 3. Context of the Policy Strategy

EU policymaking to protect human health and the environment has accelerated in recent years, especially since the 2019 adoption of the European Green Deal, with its holistic approach for the EU to become a sustainable climate neutral and circular economy by 2050. The Green Deal has also set a goal to better protect human health and the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment. The EU Green Deal will, among many other initiatives, be implemented through the Chemical Strategy for Sustainability, the long-term vision for the EU's chemical policy, which was presented in 2020.

A Eurobarometer survey from 2020 shows that people across the EU are increasingly concerned about the adverse impacts of chemicals and look to decision-makers to act. 84% of Europeans are worried about the potential personal health impacts of chemicals from everyday products, and 90% are worried about the chemicals' impact on the environment. National and EU decision-making bodies have adopted a range of measures - legislation, strategies, action plans – to address this concern and improve population health and well-being.

The Chemical Strategy for Sustainability explicitly states that exposure of humans and the environment to EDCs requires special attention. These substances are increasingly linked to diseases acting via the endocrine system and their use is on the rise, representing a serious risk to human health and wildlife, as well as creating an economic cost for society.

In the 2023 Commission communication responding to the European Citizens' Initiative (ECI) "Save cruelty-free cosmetics – Commit to a Europe without animal testing, the Commission committed to developing a roadmap towards ultimately phasing out animal testing for chemical assessments. The roadmap, which is still under development, will outline milestones and specific actions that would be prerequisites for a transition towards phasing out animal testing in the EU.

Considering the policy initiatives under the European Green Deal and the Chemical Strategy for Sustainability, results from the ENKORE projects will contribute to increased science-based decision making and evidence-based policy development in the management of endocrine disruptors.

For successful and impactful science-to-policy translation, ENKORE acknowledges the Competence Framework 'Science for Policy' that was developed by the EU's Joint Research Center (JRC). The 'Science for Policy' Competence Framework outlines the collective set of competencies (skills, knowledge and attitudes) desired for research organisations working at the science for policy interface. The continuous development of primary research competencies is outside the scope of this Framework. The Framework consists of 27 competencies divided into 5 clusters: Understanding policy, Participating in policymaking, Communicate, Engage with citizens and stakeholders, and Collaborate.

Participating in policymaking, understanding policies and communication and engaging with citizens and stakeholders are core objectives of ENKORE WG1:

- The working group will deliver 3 policy briefs and contribute to policy discussions and consultations, where relevant, throughout its activities.
- A review of relevant policies and policy processes is included as part of the policy strategy and will be updated if required. The main focus is on the EU level. The current policy landscape has implications for formulating joint recommendations for improvement.
- The working group will collaborate with the ENKORE Communication and Dissemination WG (WG3) to ensure wide reach and engagement of relevant stakeholders to influence policy making.

## 4. Relevant EU policy frameworks and process

Below is an indicative list of policy frameworks and processes which could prove relevant for the objectives of the ENKORE cluster. Without committing to engage in all these areas, the ENKORE cluster will strategize throughout the cluster's life cycle where findings and evidence would best fit and would be of most use for policy processes. In the following, we present the main policy opportunities in different policy areas: Priorities in the EU Commission policy cycle (2024-2029), Legislative reviews and revisions, Non-legislative programmes and policies, Research and International policies, Other policies.

### Main policy opportunities

#### Priorities of the EU Commission in the EU policy cycle (2024-2029)



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In the political guidelines for the 2024-2029 European Commission, European Commission President, Ursula von der Leyen, describes the new EU policy priorities for the mandate 2024-2029, which includes stepping up innovative research and work on preventive health.

## Legislative Reviews and Revisions

In addition to the overarching EU policy priorities, which are defined at the beginning of each new mandate, EU legislative developments are organised in cycles and presented in the Commission annual work plan.

The following are opportunities for ENKORE to feed into:

- Revision of the REACH Regulation: Regulation 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals entered into force in 2007. Under the EU's Chemicals Strategy for Sustainability, a revision was foreseen under the current EU mandate but has been delayed. Thus, the process will continue under the 2024-2029 cycle, which may provide opportunities for ENKORE to provide scientific evidence for the revision of relevant parts of the co-decision process, e.g. for better identification of endocrine disruptors and allocation of mixture assessment factors to prevent their health impacts and general capacity building with members of the European Parliament and Member States Competent Authorities on the valuation of health impacts of endocrine disruptors.
- Revision of sector-specific Regulations and Directives covering potential exposures to endocrine disruptors such as the Toys Directive, the Cosmetic Products Regulation and the Food Contact Materials Regulation and others, depending on the Commission annual work plans.
- The 'one substance, one assessment' legislative package aims, among others, to consolidate work in the EU agencies (ECHA, EFSA, EEA and EMA) and improve their cooperation, and to establish a common data platform on chemicals and establishing a monitoring and outlook framework on chemicals. This will ensure that new knowledge relevant for hazard and risk assessment of chemicals will be used effectively and efficiently across regulations, increasing the value of the results of the ENKORE cluster.

## Implementation of (recently) revised legislation

With the revision of the Classification Labelling and Packaging (CLP) Regulation, four new hazard classes for identification of endocrine disruptors for human health and the environment were adopted. These hazard classes will ensure horizontal identification of endocrine disruptors relevant across all approx. 40 pieces of chemical-related legislative instruments, including REACH, the Plant Protection Products Regulation, and the Biocides Products Regulation. ENKORE is expected to significantly contribute to the implementation and development of the endocrine disruptors hazard classes by increasing our knowledge about how endocrine disruptors act and adversely affect development and functioning of biological systems and contribute to disease development, including through development and implementation of new approach methodologies (NAMs).

## Non-legislative programmes and policies



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The Chemical Strategy for Sustainability sets out an ambitious, green, long-term vision for the EU's chemicals policy with over 80 actions and indicative timing for their implementation, including for endocrine disruptors, PFAS, chemical mixtures, tackling the most harmful substances, promoting non-toxic material cycles and 'safe and sustainable by design'-chemicals.

Zero Pollution Action Plan: The plan sets out 9 flagship initiatives and 33 actions for a zero-pollution vision by 2050, including flagship 1 "Reducing health inequalities through zero pollution".

Midterm review of the EU's 8th Environment Action Programme: The programme defines the overall strategy for EU action in the field of environment for the period 2022-2030, the legally agreed common agenda for this decade. The 8th EAP sets six priority objectives for 2030 including achieving the 2030 EU climate target, enhancing adaptive capacity, the zero-pollution ambition, protecting biodiversity, tackling production and consumption.

## Research

ENKORE may provide (or derive) valuable input to (or from):

- The Horizon Europe Partnership for the assessment of Risks from Chemicals (PARC), facilitated by the SynNET programme.
- Past EU-funded projects working on endocrine disrupting chemicals and chemical risk assessment more generally (if relevant).
- The next EU research and innovation programme, in particular the work programme covering research priorities and knowledge gaps within the field of endocrine disruptors within its scope.

## International policy process

Project results and methodology development under ENKORE are relevant for several international policy processes, including:

- The OECD Environment and Health programs including the test Guideline Programme.
- Inclusion of hazard classes for endocrine disruptors in the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) under the UN.
- Revision of the state of the science on endocrine disruptors report (UNEP/WHO).
- Managing endocrine disruptors is an emerging policy issue of global concern under the Global Framework on Chemicals – For a planet free of harm from chemicals and waste. The Global Framework is an UN-based multi-stakeholder and multisectoral international agreement to implement Sustainable Development Goal 12.4 to achieve sound management of chemicals. The agreement aims to prevent, and where not possible, minimize, the adverse effects of chemicals on human health and the environment throughout its lifecycle, including from endocrine disruptors.

## National or local policies

Some of the project deliverables, such as e.g. from HYPIEND, may contribute to national or municipal decision makers developing policies or setting rules for the public procurement of food for their public canteens (including kindergartens and schools' canteens), or Kindergartens' and playrooms' managers, who design school policies that can ban use of dangerous toys etc.



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## 5. Potential Topics for Policy Briefs

Table 1 lists potential topics to include in Policy Briefs from the ENKORE cluster. The topics are presented with potential target audiences and policy processes, the information could feed into. Without committing to feed into all the listed policy processes, the ENKORE cluster will strategise throughout the cluster's life cycle to determine where its findings and evidence would best fit and would be of most use for policy processes. The list is not final nor exhaustive and remains subject to changes as the projects evolve.

**Table 1.** Potential topics for Policy Briefs and related relevancy to policies process.

Potential topics for Policy briefs	Target audience	Policy process, the information could feed into
<p>Findings of effects of endocrine disruptors on health aspects such as metabolism, liver disease, reproduction and hormonally controlled internal body communication pathways, including:</p> <ul style="list-style-type: none"> <li>• Impact of environmental exposure to EDCs on the metabolome, gut microbiome, epigenome, proteome, immunome and the degree of liver damage in MASLD.</li> <li>• Impact of EDCs on the immune system as target and mediator of adverse health outcomes, in particular reproductive and metabolic disorders.</li> <li>• Effects of EDCs on the hypothalamus-pituitary axis.</li> <li>• Effects of exposure to EDCs at critical life stages on human sexual development and reproductive health</li> <li>• Mechanisms and dose-dependency of metabolic disruption by EDCs and their mixtures in liver and pancreas as well as their effects on gut microbiota.</li> <li>• Effects of exposure to multiple EDCs during the life course including windows of susceptibility.</li> <li>• Effects of exposure to mixtures vs single substances.</li> </ul>	<p>EU institutions Member State authorities Relevant EU and MS regulatory agencies (EFSA, ECHA, etc.)</p> <p>OECD and other international fora</p> <p>Health communities Scientific communities Disease specific groups/affected communities, including vulnerable populations Medical professional associations</p> <p>Civil society and networks</p>	<p>Classification proposals for endocrine disruptors under the CLP Regulation.</p> <p>OECD Environment and Health programs, including the OECD test guideline programme</p> <p>Revision of the standard information requirements under REACH, PPPR and BPR.</p> <p>Input to Horizon Europe Partnership for the Assessment of Risks from Chemicals (PARC)</p> <p>Input to reducing health inequalities through zero pollution</p> <p>Input to implementation of Commission roadmap to ultimately phase out animal testing.</p> <p>Input to the PEPPER platform, which is dedicated to the pre-validation of endocrine disruptors characterization methods.</p>

<p>New methodologies to evaluate health impacts of endocrine disruptors</p>	<p>EU institutions Member State authorities Relevant EU and MS regulatory agencies (EFSA, ECHA, etc.)</p> <p>OECD and other international fora</p> <p>Health communities Scientific communities</p>	<p>Classification proposals for endocrine disruptors under the CLP Regulation.</p> <p>OECD Environment and Health programs, including the OECD test guideline programme</p> <p>Revision of the standard information requirements under REACH, PPPR and BPR.</p> <p>Revision of relevant EU Regulations assessing health effects of chemicals, incl. Cosmetic Products Regulation, Toys Regulation, Food Contact Materials Regulation, REACH, PPPR, BPR.</p> <p>Input to Horizon Europe Partnership for the Assessment of Risks from Chemicals</p> <p>Input to reducing health inequalities through zero pollution</p> <p>Input to implementation of Commission roadmap to ultimately phase out animal testing</p> <p>Input to the PEPPER platform, which is dedicated to the pre-validation of endocrine disruptors characterization methods</p>
<p>Data on exposure and co-exposure of the EU population to EDCs.</p>	<p>EU institutions (including regulatory agencies like ECHA, EFSA) Member State authorities</p> <p>Health communities Scientific communities</p> <p>Civil society and networks</p>	<p>Input to evaluation of restrictions, maximum levels etc. in place and identification of the need of new ones in relevant EU regulations, including REACH, PPPR, BPR as well as the regulations of Food Contact Materials and Food contaminants.</p>
<p>Identified research gaps in health effects of endocrine disruptors</p>	<p>Decision makers Scientific community</p>	<p>Development of the next EU Horizon programme</p>

## 6. Activities and Timeline

The ENKORE WG1 will deliver on the policy strategy with 3 cluster policy briefs and a final event (which will include a science-to-policy component). MERLON, HYPIEND and NEMESIS will lead the activities of WG1 (organising regular meetings, preparation of the deliverables) to which all project partners will actively contribute and flag policy opportunities.

WG1 will closely work with all ENKORE Working Groups with the Communication and Dissemination Working Group (led by ENDOMIX) that endeavours to harmonise communication and dissemination activities between the projects for maximum impact. The Communication and Dissemination Working group will reach key stakeholders to raise awareness of the cluster and its work within the policy, scientific and civil society communities and keep them informed on the most up-to-date findings around the health impact and methodologies for identification and regulation of endocrine disruptors.

WG1 will flag policy opportunities to all other WG's in ENKORE's cluster yearly meetings. WG1 will keep a calendar of opportunities in the shared ENKORE drive and connect with cluster WG's via email for ad-hoc opportunities.



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The following timeline for deliverables of the ENKORE WG1 is indicative and might be updated according to actual evolution of policy opportunities arising.

Activity	Description	Audience	Expected outreach	Timing	Lead project
<b>Newsletter</b>	Cluster newsletter featuring results of cluster in 18-month intervals	<b>Policy makers;</b> Scientific Community (higher education, research); Civil Society	>100 subscribers	M18, M36, M54	HYPiEND, NEMESIS, MERLON (respectively)
<b>Policy brief</b>	Joint cluster policy briefs	<b>Policy makers;</b> Scientific Community (higher education, research); Civil Society	>1,500 general audience impressions per brief, with a focus on targeted outreach to policymakers	M24, M48, M60	MERLON, NEMESIS, MERLON (respectively)
<b>Final event</b>	Final event highlighting ENKORE achievements	<b>Policy makers;</b> Scientific Community (higher education, research); Civil Society	>100 participants	Late 2028 / Beginning of 2029	MERLON, NEMESIS

Please see the Common Communication and Dissemination Strategy for the Cluster for details on the deliverables timelines of project specific deliverables where those could be part of policy briefs for ENKORE Cluster Policy Briefs.



ENDOMIX

HYPiEND



## 7. Risk Management

Number	Risk	Mitigation Strategy
1	Lack of engagement from key stakeholders (likelihood: low, impact: high)	Partners will engage with stakeholder contacts within individual projects and as a cluster, where appropriate
2	Unexpected budget constraints (likelihood: low, impact: medium)	All partners have budgeted significant contributions to cluster activities (approx. 2% of total grant allocations), which includes the design of policy briefs and support for their joint dissemination and communication activities. Hosting meetings, workshops, and other events online can reduce costs.
3	Misalignment of messaging (likelihood: low, impact: medium)	WG1 will schedule regular meetings to review key messages for reaching policy makers and suggest appropriate updates.

## 8. Target Audience

The Cluster's WG1 main target audience are decision makers, policy makers, policy advisors, hazard and risk assessors working with endocrine disruptors, chemicals, environment and health. As a cluster, we will mainly engage with EU decision makers but also find synergies in scientific evidence and results among the five projects to communicate and engage with the UN, OECD, and at national and local levels. We will engage with our primary target audience by sharing the Cluster's Policy Briefs. Those outputs will be specifically designed with messages for EU, international, national and local level policy makers and in line with specific policy needs for which the Cluster's science is relevant.

A planned final event at the end of the cluster lifetime (late 2028 or beginning of 2029) will serve as a platform to consolidate the key messages, including new knowledge about health impacts of endocrine disruptors and methodologies for their identification and regulation for consideration and uptake in EU policy process.

Specific target groups for the Policy Strategy and Policy briefs:

Decision makers: Policy makers, policy advisors, hazard and risk assessors involved in policies on and assessment of endocrine disruptors on EU level, as well as national and local level. Decision makers may come from:

- EU institutions (European Commission including DGs ENV, GROW, SANTE, RTD, and JRC, relevant European Parliament committees such as ENVI Environment, Public Health and Food Safety, SANT Public Health),
- EU agencies (European Chemicals Agency (ECHA), European Food Safety Agency (EFSA), European Environment Agency (EEA), European Medicines Agency (EMA),
- Member State Competent Authorities on chemicals and public health

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- Non-governmental organisations (HEAL, ChemSec, ChemTrust, EEB, PAN).
- International fora and organisations: The ENKORE International Advisory Panel, WHO/IPCS, UNEP/IOMC, OECD Environment and Health programs, including the OECD test Guideline Programme.

Scientific Community (higher education, research): Research communities and other research groups working in the field of endocrine disruptors, public health and environment, including relevant partners in the “Partnership for the Assessment of Risk from Chemicals” (PARC) initiative.

Civil Society: Organizations, associations, and networks within endocrine disruptors, public health and environment.

The full communication strategy, highlighting targets, key messages and communication formats, is developed separately under ENKORE’s Communication and Dissemination Working Group. The Science translation for policy and practice WG will cooperate with this working group to ensure effective communication and engagement of policy makers.



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