



# Regulatory Mandates, Digital Tools, and SME Support

## Seminar on Chemicals: Regulatory update & practical information

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# Content

- Introduction to ECHA & its Remit
- IT Tools & Digital Infrastructure
- SME Support

# **Introduction to ECHA**



## **OUR PURPOSE**

We protect health and the environment through our work for chemical safety

## **OUR VISION**

Chemical safety through science, collaboration and knowledge

## **OUR VALUES**

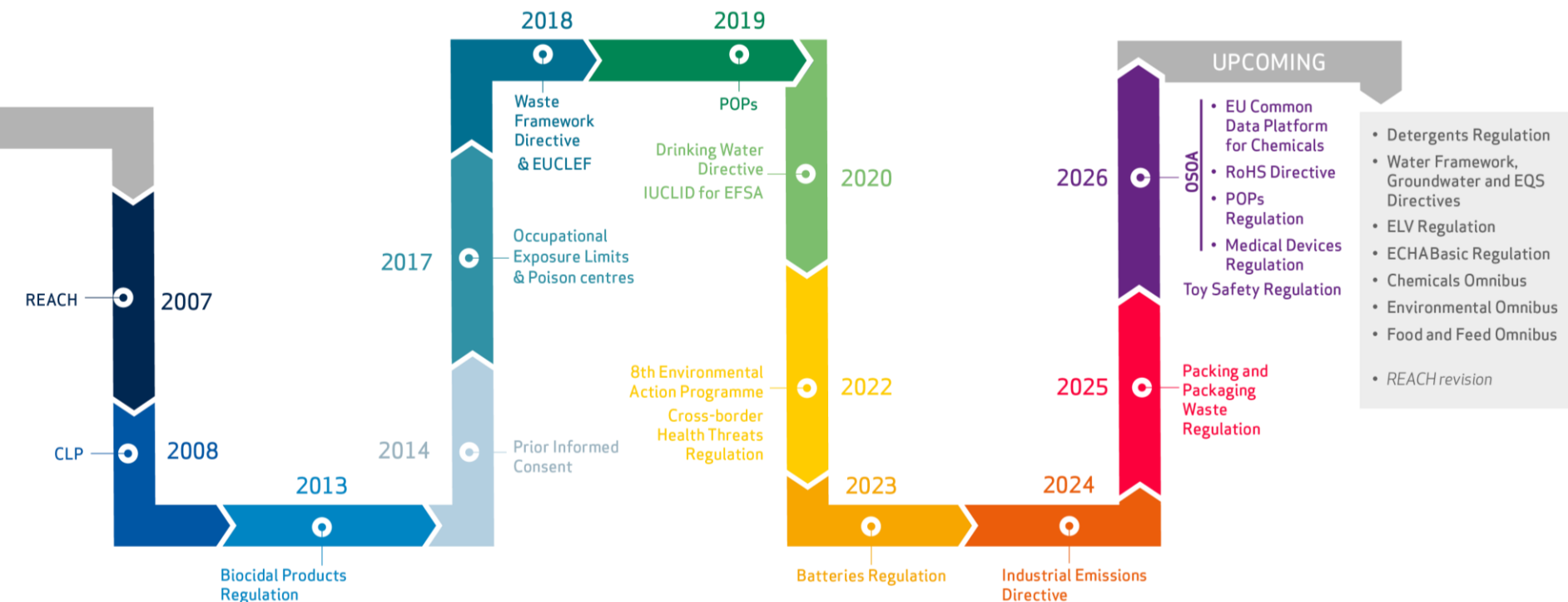
Integrity, Transparency, Collaboration, Innovation

# Our tasks

# Legislation

- REACH – registration, evaluation, authorisation and restriction
- Classification, labelling, packaging
- Biocidal products
- Prior informed consent
- Persistent organic pollutants
- Waste framework
- Drinking water
- Environmental action programme
- Cross-border health threats
- Batteries
- Industrial emissions
- Packaging and packaging waste
- Hazardous substances in electrical and electronic equipment
- Medical devices
- Common data platform on chemicals
- Toys safety
- Detergents and surfactants







# Helsinki – hub for chemical safety

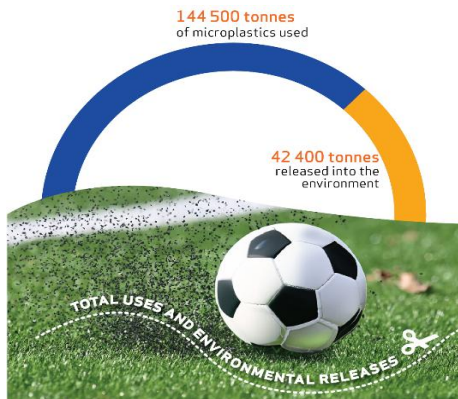
We bring together experts from EU countries and stakeholders

- 4 scientific committees
  - MSC, RAC, SEAC, BPC
- 3 expert groups
  - PBT, ED, Exposure
- Enforcement forum
- Networks of national authorities
- Independent Board of Appeal





# Highlights of our work



## 1. Microplastics

Gradual ban on intentionally added microplastics.

Prevent 500,000 tonnes of emissions over 20 years.

## 2. PFAS ("Forever Chemicals")

Major restriction proposal for over 10,000 PFAS.

Aim is to stop the accumulation of these chemicals and to protect our drinking water and prevent long-term health risks like cancer and hormonal disruption.

## 3. Tattoo Inks & Safety

Restriction of 4,000+ hazardous substances in inks.

Ensuring safer consumer products and permanent make-up.



Support

# EU Chemicals Legislation Finder (EUCLEF)



- Support with over 50 laws on chemicals
- Check which are the applicable laws and obligations.



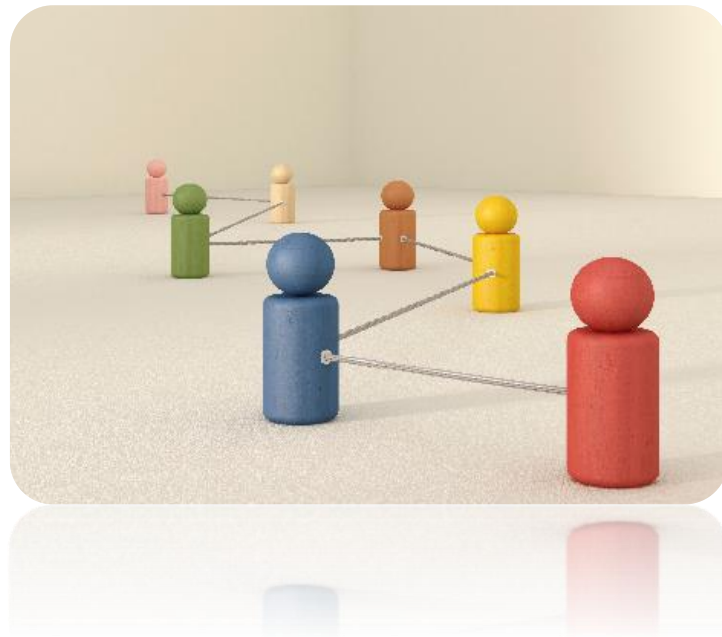
# Support at EU level

- [Your national helpdesk](#)
- [ECHA Helpdesk](#)
- [Enterprise Europe Network](#)
- [LinkedIn discussion groups](#):
  - Substitution to safer chemicals
  - EU observatory for nanomaterials
  - Poison centres
  - IUCLID
  - System-to-system submissions



# Engage with us

- Subscribe to [news](#)
- Join free [events](#)
- Give input in [consultations](#)
- Follow [substance activities](#) from first plans to final decisions
- Take part in [calls for tenders](#) to support our scientific work



# **IT Tools & Digital Infrastructure**



# Current REACH/ CLP & Biocides Submission Tools



## REACH-IT:

- Gateway for Substance Registration (REACH) & C&L Notifications (CLP).
- Manages your legal entity data and serves as the secure mailbox for official ECHA decisions.



## R4BP 3 (Register for Biocidal Products):

- Platform for all applications under BPR, including national and Union authorizations.
- Facilitates the exchange of information between applicants, ECHA, and national authorities for biocidal product approvals.

# The ECHA Submission Portal (PCN & ePIC)



## Poison Centres Portal (PCN):

- Allows companies (importers & downstream users) to submit harmonized data on hazardous mixtures to national poison centres for emergency health responses.
- Mandatory UFI (Unique Formula Identifier) code must be clearly displayed on the product label.
- Digitally links physical product to chemical composition and toxicological data submitted in the PCN portal.



## ePIC Portal (International Trade):

- Manages the export/import of banned or restricted chemicals (PIC Regulation).
- It streamlines the request for Reference Identification Numbers (RINs) required for customs clearance of international shipments.

# ECHA Industry Portal – the Unified Future




ECHA Industry  
Portal

## ECHA Industry Portal:

 **Fresh Launch (Jan 2026):** Priority focus on the Drinking Water Directive (DWD).

 **SME-Friendly Design:** Simplified wizard for EU Positive List substance notifications.

 **The Future Vision:** A "Single Window" to replace all current submission portals.

# IUCLID 6: The Universal Language for EU Chemical Data 1/2

- **IUCLID** (International Uniform Chemical Information Database) is the mandatory OECD-harmonized platform for capturing, storing, and submitting scientific data on chemical hazards across global jurisdictions.
  
- **One Substance, One Assessment (OSOA)**
  - IUCLID is the engine behind the OSOA framework (entered into force Jan 1, 2026).
  - Allows ECHA, EFSA, and Member States to share a single "source of truth" for chemical hazards across different laws (REACH, Biocides, Food Contact, etc.).

# IUCLID 6: The Universal Language for EU Chemical Data 2/2

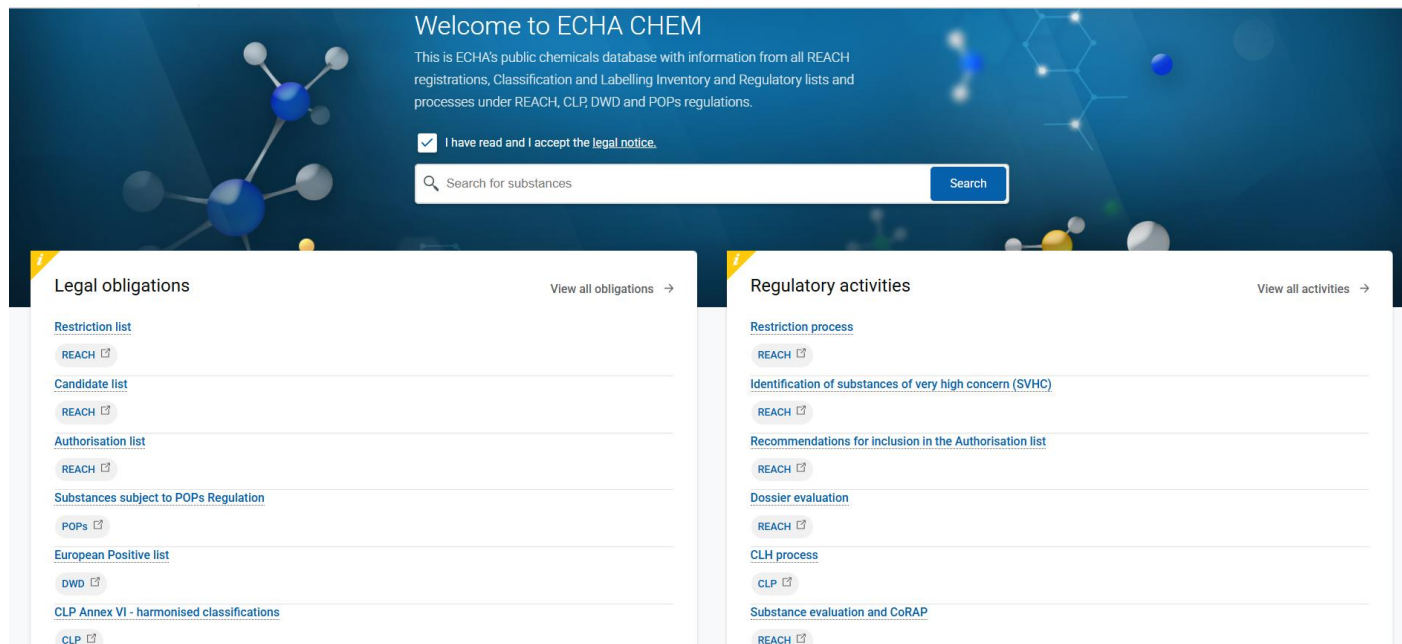
## → **Expanded Regulatory Scope (New for 2026)**

- **Drinking Water Directive (DWD):** Mandatory for "Notifications of Intention" as of Jan 5, 2026.
- **Biocides (BPR):** Mandatory for all active substance renewals starting July 1, 2026.
- **Microplastics:** New reporting format for emissions and use of synthetic polymer microparticles.

## → **Technical & Strategic Highlights (Version 9)**

- **Validation Assistant:** Critical tool to ensure dossier completeness before submission to avoid "technical fails."
- **IUCLID Cloud:** Preferred platform for SMEs; provides automated updates and secure ECHA-hosted backups.
- **Global Standard:** Based on OECD Harmonized Templates (OHTs), ensuring data is recognized internationally (e.g., Australia, New Zealand, Canada).

ECHA's public database for checking the regulatory status and hazard data of over 360,000 chemicals. Essential for identifying if your substances are subject to new restrictions or the Candidate List.



The screenshot displays the ECHA CHEM website's main interface. At the top, a dark blue banner features a molecular structure graphic on the left and the text 'Welcome to ECHA CHEM' on the right. Below the welcome text, a paragraph describes the database's scope. A checkbox with a checkmark and the text 'I have read and I accept the legal notice.' is present. A search bar with the placeholder 'Search for substances' and a blue 'Search' button is located below the checkbox. The main content area is divided into two white panels. The left panel, titled 'Legal obligations', lists several categories: 'Restriction list' (with a 'REACH' tag), 'Candidate list' (with a 'REACH' tag), 'Authorisation list' (with a 'REACH' tag), 'Substances subject to POPs Regulation' (with a 'POPs' tag), 'European Positive list' (with a 'DWD' tag), and 'CLP Annex VI - harmonised classifications' (with a 'CLP' tag). Each category has a 'View all obligations' link. The right panel, titled 'Regulatory activities', lists: 'Restriction process' (with a 'REACH' tag), 'Identification of substances of very high concern (SVHC)' (with a 'REACH' tag), 'Recommendations for inclusion in the Authorisation list' (with a 'REACH' tag), 'Dossier evaluation' (with a 'REACH' tag), 'CLH process' (with a 'CLP' tag), and 'Substance evaluation and CoRAP' (with a 'REACH' tag). Each activity has a 'View all activities' link.



# **SME Support**

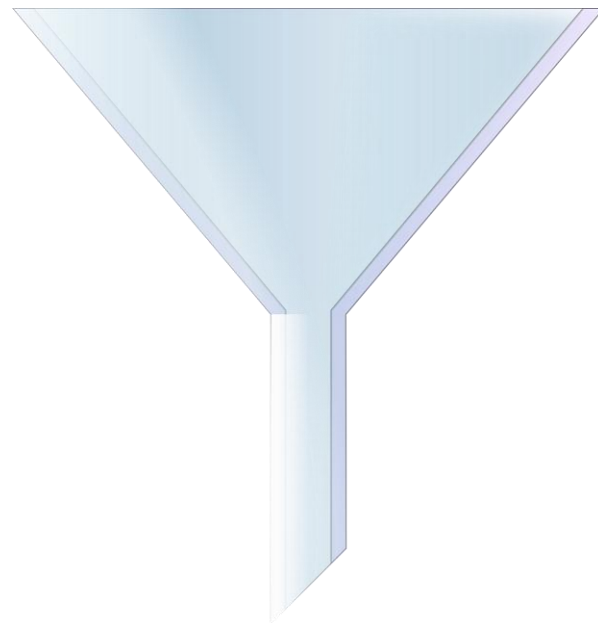
# Focus on SMEs

The focus on SMEs is a key mandate within the [ECHA Strategy 2024-2028](#). Our strategic objective is to:

- **Provide Tools and Advice:** Developing resources specifically designed for the industry's technical needs.
- **Offer Direct Support:** Ensuring companies have the guidance necessary to navigate regulatory requirements.
- **A Particular Focus on SMEs:** Prioritizing small and medium-sized enterprises to ensure they are not left behind by complex legislative changes.

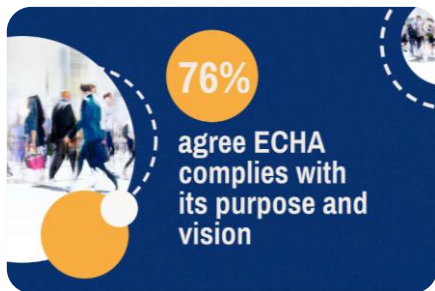
## The Goal

- To empower industry and SMEs in particular, to successfully fulfill their duties under chemical legislation.

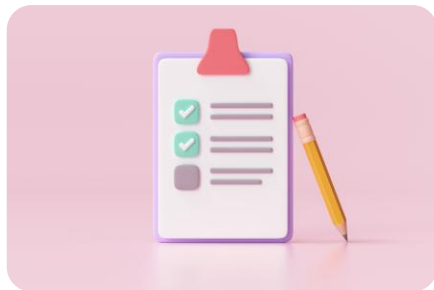


# Listen to SMEs' needs

Analyse SME  
response to  
Stakeholders survey



Surveys to find  
SMEs in new tasks



**Focus group** of  
SMEs and SME  
representatives



Gather specific  
feedback as actions  
are implemented



# Map and promote good practices



ECHA's activities  
supporting SMEs



Member states' activities  
supporting SMEs



Participation of ECHA staff  
in own language to national  
events for SMEs



Share good practices  
and work together  
with peer Agencies



# Engage through targeted initiatives

Help SMEs navigate the ECHA website



Create videos on key SME duties



Continue to promote EUCLEF



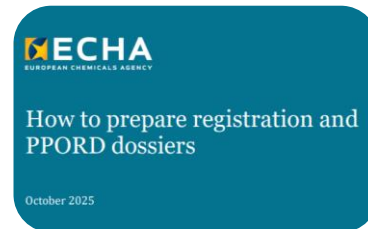
Expand the SME support hub



Information package for the new SME verification (2027)



Promote the PPORD exemption from registration



## Small and medium-sized enterprises (SMEs)

### Getting started

Manufacturer

Importer

Only representative

Distributor

User of chemicals

REACH and CLP for non-EU companies

Biocides for non-EU companies

Trader in hazardous chemicals

Biocides supplier or user

Exemptions?

Finding help

Inventory of national support materials

### Reduced fees for SMEs under REACH and CLP

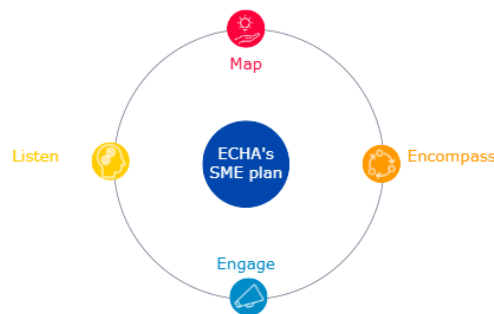
Reduced fees for SMEs under BPR

## SME Hub

ECHA is committed to supporting Small and Medium-size enterprises (SME). Our SME action plan is structured around four strategic pillars:

- **Listen**, to establish SME-specific needs and preferences,
- **Map**, to identify and promote good practices,
- **Engage**, to organise targeted interactions and simplify messages and tools, and
- **Encompass**, to 'think SMEs' throughout our activities.

This action plan is **iterative and responsive**. We will continue to refine our approach based on the feedback we receive from SMEs and stakeholders.



Companies of all sizes play a vital role in ensuring the safety of chemicals on the EU market, protecting people and the environment.

## Virtual assistant

- ☐ I have read and agree to the [Terms and Conditions](#) on using the virtual assistant

Launch

### SEE ALSO

- [ECHA CHEM database](#)
- [EU Chemicals Legislation Finder](#)
- [Chemical Safety in your business](#) [PDF]
- [ECHA's YouTube channel](#)
- [Factsheets](#)



## SME webinar: Do you need to register under REACH?

Online | 22/10/2025 | 11:00 - 17:00

Times are in EEST, GMT +3

Add to calendar

Are you unsure whether your products need to be registered under REACH? This webinar will guide you through the key factors that determine registration obligations.

We will explain:

- How to determine if your product is a substance, a mixture or an article.
- Thresholds and exemptions.
- Which of the different actors in the supply chain have registration obligations.
- The option to notify a product and process orientated research and development (PPORD) instead of registering.
- What to do next.

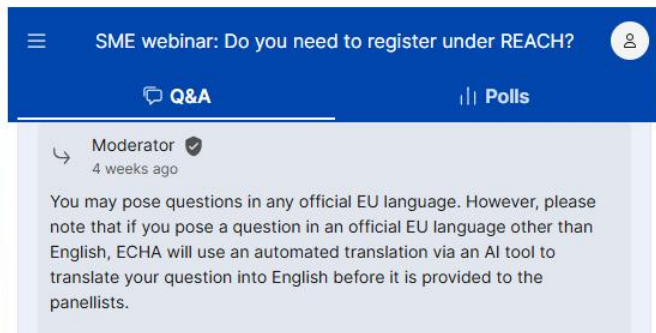
The first part of the webinar consists of presentations until approximately 12:30 (EEST, GMT+3). After this, the event will be kept open until 17:00 (EEST, GMT+3) to reply to your questions.



Watch the webinar



Join the Q&A



# Encompass – *Think* SMEs

SMEs systematically involved in stakeholders' groups and IT tools development



SME-friendly processes and support material 'from the beginning' for new tasks



SME-friendly public consultations and calls for evidence

ECHA

## Have your say in our consultations

Contribute to chemical safety in the EU by submitting your input on our topical consultations and calls for evidence.

Our open consultations and calls for evidence with deadlines for comments in January and February include:

- Testing proposals;
- Proposals for harmonised classification and labelling;
- Potential candidates for substitution and on derogations conditions of biocidal products; and
- Occupational exposure limits.

# Visit our SME hub

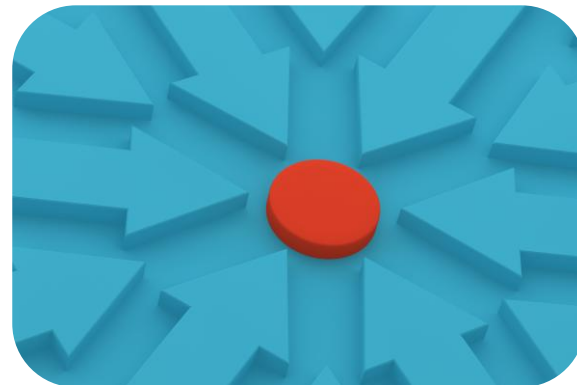
- Support tools and resources from ECHA and national authorities
- Multilingual virtual assistant



# Get involved!

## **SME focus group**

- Share what matters to SMEs
- Influence the action plan and actions
- Provide feedback on implemented actions/documents



- Present case study in webinar/videos
- First webinar on REACH registration and promotion of PPORD
  - Suggest next topics

# Help Us Shape the SME Hub

1. Review & Refine	2. Expand Our Reach	3. Get Direct Support
Test the SME Hub: Is the content practical for your daily operations?	Connect Us: Help us reach national associations and new sectors.	Share Your Voice: Tell us what support tools your business actually needs.



Email your insights **[sme@echa.europa.eu](mailto:sme@echa.europa.eu)**

# Thank you

[audreyanne.anastasi@echa.europa.eu](mailto:audreyanne.anastasi@echa.europa.eu)

## Connect with us

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