

European Chemicals Agency – who we are and what we do

SWACCS - Regulatory toxicology II

7 November 2023

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European Chemicals Agency



General about ECHA and what we do

About us

Located in Helsinki, Finland

We protect you and the environment by taking action on harmful chemicals

OUR MISSION

We work for the safe use of chemicals

OUR VISION

To be the centre of knowledge on the sustainable management of chemicals for the benefit of citizens and the environment

<https://echa.europa.eu/about-us>

https://echa.europa.eu/documents/10162/17069/this_is_echa_en.pdf/fd62ae88-bfbb-7bf4-a3c5-acd9a78e3096



We contribute to EU goals for chemical safety



Phase out most harmful chemicals in consumer products



Tackle cocktail effect



Consolidate and simplify chemical regulations



Promote alternatives to animal testing



Boost innovation and "safe by design chemicals"



Play a leading role globally

We implement EU chemicals laws



→ REACH -
registration of
chemicals



→ Classification,
labelling and
packaging



→ Biocides



→ PIC – import
and export

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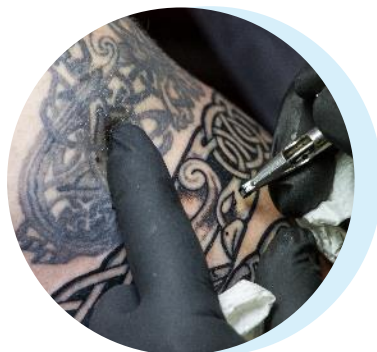
<https://echa.europa.eu/legislation>

Our other tasks under EU laws

- Chemicals in products
- Poison centres
- Nanomaterials
- Persistent organic pollutants
- Drinking water
- Exposure limits for workers (OELs)



Impacting the lives of millions of people, some examples



Protecting people

Restriction on tattoo and permanent make-up inks



Protecting the environment

Restriction on intentional uses of microplastics



Improving circular economy

Database of harmful chemicals in products

Working here

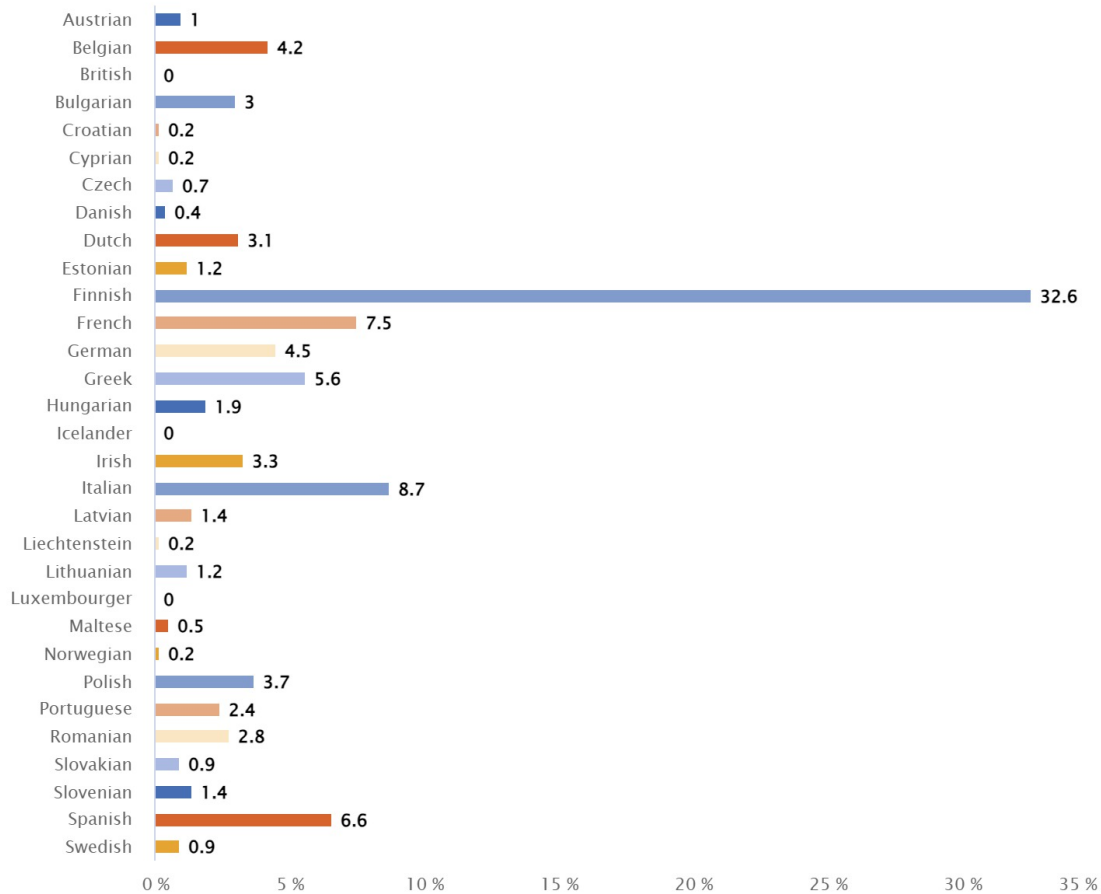


Around 600 colleagues from
28 countries

Multicultural

Multilingual

Multidisciplinary



● Percentage of staff

Examples of regulations and processes we work with

REACH Regulation (1) - registration

(REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals)

- Registration of chemicals^{1,2} by companies (*more details in link)
 - Relevant and available data (physicochemical, toxicological and ecotoxicological + information on use, exposure, risk management measures)
- The companies should identify and manage risks linked to their substances
- Demonstrate to ECHA how their substances can be safely used
- Communicate to users how they should handle risks from the substances (e.g., workers, consumers)
- If the risks cannot be managed => the use of the substance can be restricted through various processes
- Aim is to substitute the most hazardous substances with less dangerous ones

*<https://echa.europa.eu/regulations/reach/understanding-reach>

¹ chemical = substance throughout the presentation; ² In principle, REACH applies to all chemical substances; not only used in industrial processes but also in our day-to-day lives, e.g., in cleaning products, paints, articles (clothes, furniture and electrical appliances etc.) => has an impact on most companies across the EU

REACH Regulation (2) – data generation

- Certain tests are required to be performed under REACH
- Which tests depends e.g., on how many tonnes of the substance is put on the market per year (by companies in joint registration)
- Usually performed according to OECD test guidelines and GLP (Good Laboratory Practise)
- Adaptions / waivers to avoid testing may be claimed (weight of evidence, grouping of substances, read across etc.)

<https://echa.europa.eu/regulations/reach/registration/information-requirements>

How to avoid unnecessary testing: <https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals>

OECD Test guidelines for testing of chemicals (1)

- Collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories to assess the safety of chemicals
- These tests are primarily used in regulatory safety testing
- Industrial chemicals, pesticides, personal care products, etc.
- Accepted internationally as standard methods for safety testing
 - enhance the validity and international acceptance of test data
 - make the best use of available resources in both governments and industry
 - avoid the unnecessary use of laboratory animals
 - minimise non-tariff trade barriers

OECD Test guidelines for testing of chemicals (2)

- Physicochemical hazards (e.g., explosive properties)
- Human health hazards
- Environmental hazards
- Other tests

<https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm>

https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_72d77764-en

Good Laboratory Practise (GLP)

- Quality control system to ensure the generation of high quality and reliable test data
- Conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, reported and retained (or archived)
- GLP is followed by test facilities carrying out studies for the purposes of assessing the health and environmental safety of chemicals and chemical (to be submitted to authorities)

<https://www.oecd.org/chemicalsafety/testing/overview-of-good-laboratory-practice.htm>

Classification and labelling (1)

- Based on the **Classification Labelling and Packaging (CLP) Regulation**
- Evaluation of substances based on their hazardous properties
- The hazard of a substance is the potential for that substance to cause harm
- CLP includes criteria for when a substance should be considered hazardous; e.g., toxic to reproduction, carcinogenic or acutely toxic
- Where the nature and severity of an identified hazard meets the classification criteria => a substance should be classified and labelled accordingly
- Mixtures in which the substances are included should also be classified and labelled if the substance is present above a certain concentration (stipulated in CLP Regulation)



Classification and labelling (2) – self-classification

- Companies have to classify and label their hazardous substances and mixtures
- Companies must communicate the identified hazards of their substances or mixtures to other actors in the supply chain, including consumers.
- Ensure high level of protection of human health and the environment
- Self-classification is done by companies themselves, evaluating the data of the substance from e.g., animal studies or environmental studies, comparing with the criteria in CLP and concluding on the appropriate classification
- To be included in the registration dossier

<https://echa.europa.eu/regulations/clp/classification>

<https://echa.europa.eu/regulations/clp/cl-inventory/notification-to-the-cl-inventory>

<https://echa.europa.eu/information-on-chemicals/cl-inventory-database>



Classification and labelling (3) - harmonised

Harmonised classification and labelling (CLH)

- For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity and respiratory sensitisers)* => harmonised classification and labelling should be implemented
- EU companies should follow CLH and classify their substances accordingly (no self-classification for those hazards)
- The process for harmonised classification also involves **EU member state competent authorities**, **Risk assessment committee** (with representative from EU member states) and the **European Commission** + consultation with possibility to provide comments (companies, stakeholders, member states, individuals, organisations etc.)
- **Cooperation** with e.g., European Food Safety Agency (EFSA) in certain cases where the substance is included in both agencies' processes; plant protection products

<https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling>

¹⁸
* and for other chemicals on a case-by-case basis

Classification and Labelling (4) - labelling



Labelling

- Hazard communication to users on the classification
- **Hazard pictogram** = an image on a label with a warning symbol that gives information about the damage a particular substance or mixture can cause to our health or to the environment.
- **Hazard statement**: E.g., Causes serious eye irritation, May harm the unborn child
- Gives information to users how they should handle the substance (or mixture), e.g., if they need personal protection equipment (gloves, goggles, overall, etc.)

<https://chemicalsinourlife.echa.europa.eu/understand-the-labels>

<https://echa.europa.eu/regulations/clp/labelling>

<https://echa.europa.eu/regulations/clp/clp-pictograms>

Classification and Labelling (5) -how data is used in CLH process

- Data from registration dossiers must be used in the CLH process (stipulated in the CLP Regulation)
- Other data can be used for example:
 - Animal studies not according to OECD test guidelines
 - Publications
 - In vitro data
 - Epidemiological data
 - Studies assessing effects on environment
 - Studies evaluating a mechanism of action for the substance
 - Other relevant studies

Research and development chemicals, obligations under REACH and CLP

<https://echa.europa.eu/regulations/reach/registration/research-and-development>

<https://echa.europa.eu/regulations/clp/cl-inventory/notification-to-the-cl-inventory>

Example of substances 'hot topics' (1) - bisphenols

For example bisphenol A:

- Now regulated through several EU processes due to effects e.g., on reproduction and the endocrine system
 - re-usable plastic tableware and bottles for drinks
 - sports equipment
 - CDs and DVDs
 - to coat the insides of water pipes as well as food and drink cans
 - baby bottles
 - flooring, car body coatings and in adhesives
 - thermal paper, receipts, inks, textiles, paper or in board

<https://echa.europa.eu/hot-topics/bisphenols>

Example of substances 'hot topics' (2) - phthalates

Phthalates

- Wide variety of uses, from consumer to industrial products
- Commonly used as softeners to make plastics, such as PVC, more flexible and durable
- Also found in, e.g., paints, rubber materials, wires and cables, flooring, packaging, food contact materials, medical devices and sports equipment
- Due to their wide use, they can be found almost everywhere in our environment
- Not all phthalates have been thoroughly studied or evaluated
- Evidence that some of them are harmful to our health as they can e.g., cause effects on reproduction, interfere with our hormonal systems and cause allergies => the use of certain phthalates is already regulated both in Europe and globally

Example of substances 'hot topics' (3) - microplastics

Microplastics

- Small pieces of plastics (typically smaller than 5mm)
- Unintentionally formed when larger pieces of plastic, like car tyres or synthetic textiles, wear and tear (ca. 176000 tonnes per year released into the environment)
- Deliberately manufactured and added to products for specific purposes, such as exfoliating beads in facial or body scrubs (ca. 42000 tonnes per year released into the environment)
- Once in the environment, microplastics do not biodegrade => accumulate in animals, including fish and shellfish => also consumed as food by humans
- Exposure to microplastics in laboratory studies has been linked to a range of negative effects on health and environment
- Through ECHA processes, the European Commission recently adopted a restriction on the use of microplastics, for example a ban on loose glitter and microbeads

<https://echa.europa.eu/hot-topics/microplastics>

Example of substances 'hot topics' (4) – further examples

- Tattoo inks: <https://echa.europa.eu/hot-topics/tattoo-inks>
- Lead in shot, bullets and fishing weights: <https://echa.europa.eu/hot-topics/lead-in-shot-bullets-and-fishing-weights>
- More 'hot topics': <https://echa.europa.eu/hot-topics>

EU institutions / bodies / agencies – learn more

- European Commission
- European Parliament
- Council of the European Union
- Other EU agencies

<https://euagencies.eu/>

<https://echa.europa.eu/about-us/partners-and-networks/eu-bodies/commission>



Working with us

- International working environment – colleagues from EU/EEA countries
- Interesting tasks and inspiring work environment
- Meaningful work – making a difference
- Cooperation with EU member states, EU commission, other EU agencies etc.
- International cooperation (OECD, awareness raising in countries outside EU etc.)
- Must be a national of an EU Member State or of the European Economic Area (Norway, Iceland, Liechtenstein)
- Other eligibility criteria:
<https://echa.europa.eu/about-us/jobs/eligibility-criteria>
- Open positions:
<https://echa.europa.eu/about-us/jobs/open-positions>
- What we offer:
<https://echa.europa.eu/about-us/jobs/what-we-offer>

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