



# Scientific needs to inform regulatory decision making

## ZeroPM - Second Workshop on Prioritisation

UBA Conference Center in Dessau-Roßlau, Germany  
19-20 September 2024

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# ECHA – organisation

- EU decentralised Agency (est. 2007)
- Ca 600 staff
- 2024 budget: ca. EUR 128m
- DG GROW European Commission partner / other DGs ENV, SANTE, EMPL
- Memoranda of understanding with
  - EU agencies EFSA, EMA, ECDC, (EEA)
  - Agencies from other countries: US, Canada, Japan, Australia etc.



ISO 9001/14001 and EMAS certified

# Our mandate



Carry out technical, scientific, and administrative tasks related to the implementation of the EU's chemicals legislation and policy



Provide transparent, independent and high-quality scientific opinions and decisions, which shall serve as the basis for the drafting and adoption of Union measures



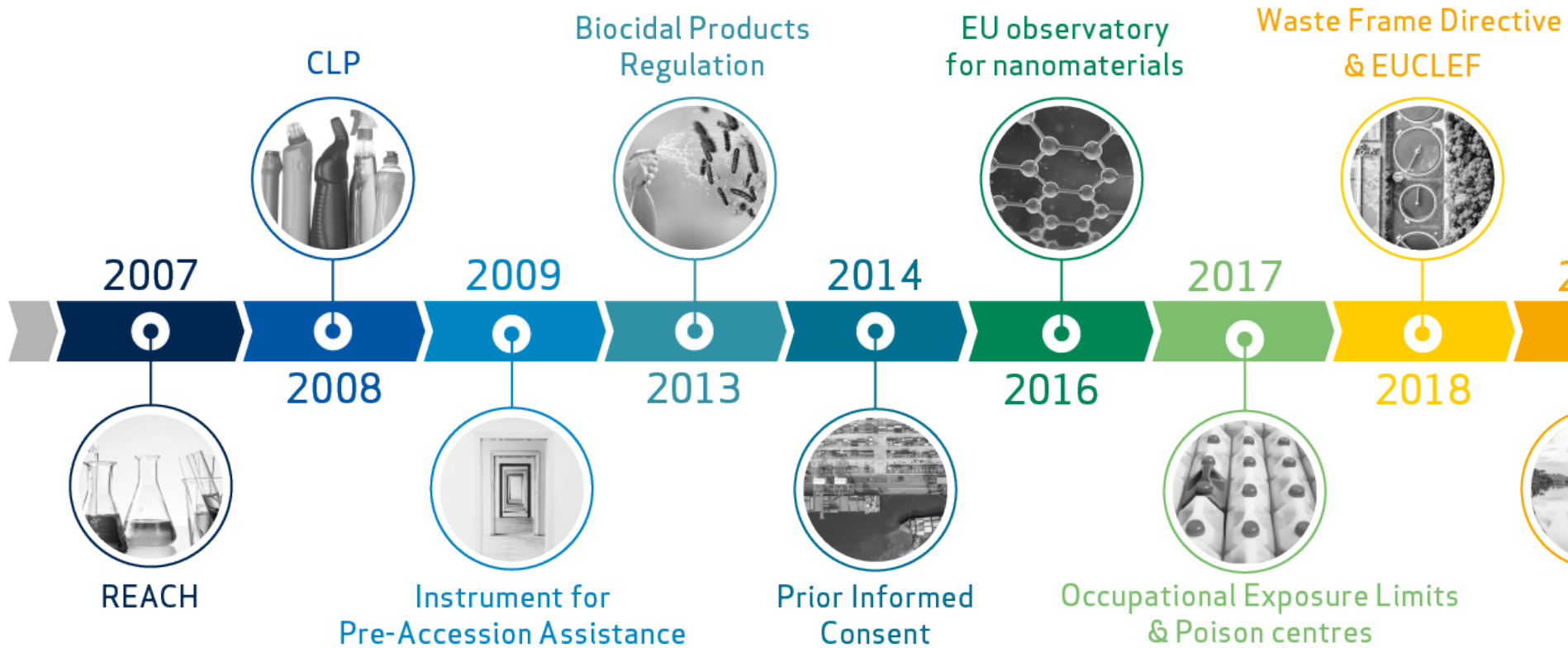
Collaborate and partner with EU bodies and Institutions, Member State authorities, as well as third countries and international organisations



Provide tools, advice, and support to companies, with a particular focus on SMEs, in fulfilling their duties under chemical legislation



Ensure that relevant, reliable, and objective information is available for the public and interested parties



# 8th Environmental Action Programme

Active  
A

Cross-border Health Threats Regulation

Industrial Emissions Directive

ELV Directive

RoHS Directive

M



2021

2023

1S1A



2022



Partnership for the Assessment of Risks from Chemicals

Batteries Regulation

Packaging and Packaging Waste Regulation

Toys Safety Directive

POPs Regulation

# Our purpose and vision

## OUR PURPOSE

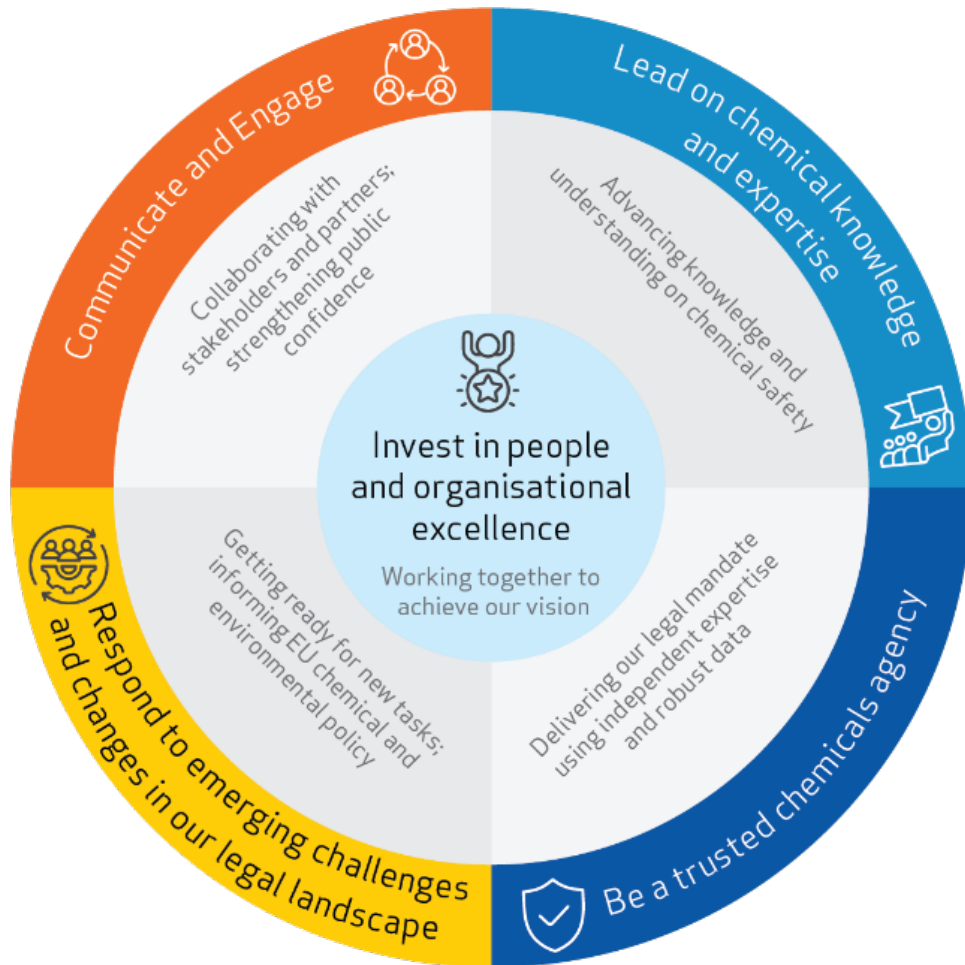
We protect health and the environment through our work for chemical safety

## OUR VISION

Chemical safety through science, collaboration and knowledge



# Our goals



## From output to input

- Formalisation of PMT
- The regulatory process
- Research needs



# Classification and Labelling (CLP)

## → History

- The Dangerous Substances Directive (DSD, 67/548/EEC) on the classification, labelling and packaging of dangerous substances
- The Globally Harmonized System of Classification and Labelling of Chemicals (GHS, first edition 2002)
- The Classification, Labelling and Packaging (CLP) Regulation (EC No 1272/2008) replaced the DSD => ECHA to manage

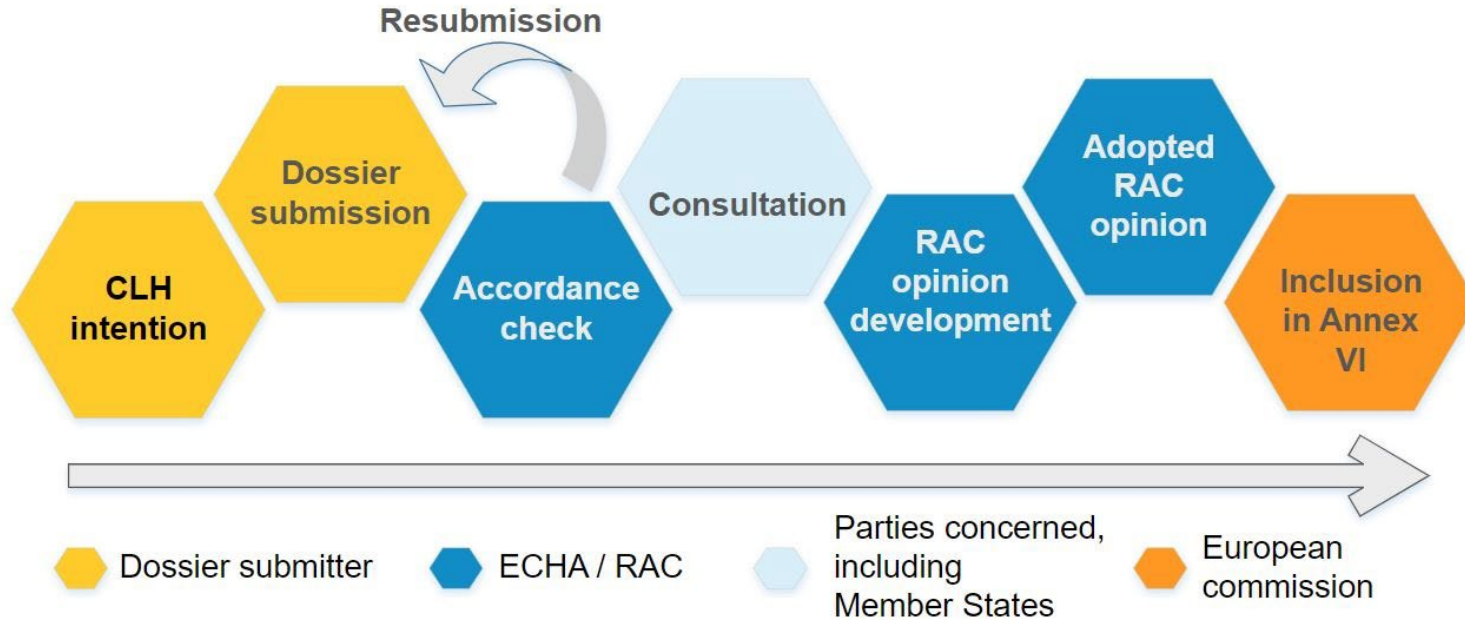
# Classification and Labelling (CLP)

- Harmonisation of hazard classification and labelling by introduction of rules for classification and labelling resulting in hazard classes, statements, pictograms,
  - ✓ Physical (e.g. explosivity, flammability, etc.), human health (e.g. mutagenicity, carcinogenicity, etc.), aquatic hazards and hazardous to the ozone layer
- CLP Annex VI contains the list of harmonised classification and labelling of hazardous substances (CLH)
- Obligations for manufacturers, producers of articles, importers, suppliers and downstream users to classify

# ECHA mandate under CLP/CLH

- ✓ Support Member States in developing proposals for (groups of) substances
- ✓ Process proposals for harmonised classification and labelling (CLH)
- ✓ Ensure consistent, transparent, scientifically-robust and CLP-compliant proposals (accordance check)
- ✓ Support Member States and ECHA Risk Assessment Committee (RAC)
- ✓ Technical, scientific and administrative duties during process
- ✓ Support the European Commission in the decision-making process (post RAC) but also in case of an Appeal
- ✗ We do not perform experiments/ test chemicals
- ✗ We do not select (groups of) substances for CLH
- ✗ We do not decide which classification is warranted
- ✗ We do not request generation of data
- ✗ We do not make decisions
- ✗ We do not perform risk assessment but only hazard identification

# CLH process



# Classification and Labelling (CLP)

- Commission Delegated Regulation 2023/707 amending CLP published end of March 2023
- Introduction of new hazard classes
  - ED HH and ENV (Cat 1 and 2); PBT/vPvB; **PMT/vPvM**
- As of 20 April 2023, harmonised proposals on the new hazard classes can be submitted

# New hazard classes for PMT/vPvM (and PBT/vPvB)

→ Concern due to

- ✓ absence of other relevant Regulation
- ✓ difficult to break down, difficult to reverse accumulation in living organisms, long-range transport
- ✓ possibility to enter the water cycle, including drinking water
- ✓ only partial removal from wastewater treatment process
- ✓ ongoing emissions => build-up of environmental concentrations over time
- ✓ exposure of humans and the environment
- ✓ **=> protect the water resources**

# New hazard statements

Hazard class and category code	Hazard statement code	Hazard statement
ED HH 1	EUH380	May cause endocrine disruption in humans
ED HH 2	EUH381	Suspected of causing endocrine disruption in humans
ED ENV 1	EUH430	May cause endocrine disruption in the environment
ED ENV 2	EUH431	Suspected of causing endocrine disruption in the environment
PBT	EUH440	Accumulates in living organisms including in humans
vPvB	EUH441	Strongly accumulates in living organisms including in humans
PMT	EUH450	Can cause long-lasting and diffuse contamination of water resources
vPvM	EUH451	Can cause very long-lasting and diffuse contamination of water resources

# Regulatory criteria for PMT/vPvM substances

<b>Persistence</b>	<b>P criteria</b>	<b>vP criteria</b>
<b>Medium</b>	<b>Half-day (days)</b>	<b>Half-day (days)</b>
Water (marine)	>60	>60
Water (fresh /estuarine)	>40	>60
Sediment (marine)	>80	>180
Sediment (fresh/estuarine)	>120	>180
Soil	>120	>180

<b>Mobility</b>	<b>M criteria</b>	<b>vM criteria</b>
LogKoc (soil, sludge or sediment)	<3	<2

<b>Toxicity</b>	<b>T criteria</b>	
	<b>Exposure duration</b>	<b>Value (mg/L)</b>
Ecotoxicity	Chronic NOEC or EC <sub>10</sub>	<0.01
	<b>Endpoint</b>	<b>Category</b>
Mammalian toxicity	Carcinogenic	Category 1A or 1B
	Germ cell mutagenic	Category 1A or 1B
	Toxic for reproduction	Category 1A, 1B or 2
	Specific target organ toxicity after repeated exposure	Category 1 or 2
	Endocrine disruption	Category 1

Same as in REACH, Annex XIII

**! NEW !**

# Regulatory criteria for Mobility (M)

**Annex I: 4.4.2.1.2.** A substance shall be considered to fulfil the mobility criterion (M) when the log  $K_{OC}$  is less than 3. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log  $K_{OC}$  value for pH between 4 and 9 is less than 3.

**Annex I: 4.4.2.2.2.** A substance shall be considered to fulfil the 'very mobile' criterion (vM) when the log  $K_{OC}$  is less than 2. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log  $K_{OC}$  value for pH between 4 and 9 is less than 2.

*"The  $K_{OC}$  value [...] reflects the ability of a substance to be adsorbed on the organic fraction of solid environmental compartments such as soil, sludge and sediment, and is therefore inversely related to the substances' potential of entering into ground water".*

# Information to be considered

**Commission Delegated Regulation (EU) 2023/707, Annex I: 4.4.2.3.2.** The following information shall be considered for the assessment of M or vM properties:

(a) results from adsorption/desorption testing;

(b) other information, such as information from leaching, modelling or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

**Annex I: 4.4.2.4.2.** In applying the WoE determination, the following information, in addition to the information referred to in Sections ... 4.4.2.3.2 ... shall be considered as part of the scientific assessment of the information relevant for the ... M, vM ... properties:

...(b) Information relevant for the M or vM properties:

(i) Organic carbon to water partition coefficient ( $K_{OC}$ ) estimated by well-developed and reliable (Q)SAR models;

(ii) Other information, provided that its suitability and reliability can be reasonably demonstrated.

# Guidance development on the application of the CLP criteria

→ Current CLP Guidance includes:

- ❑ Physical hazards
- ❑ Health hazards
- ❑ Aquatic hazards
- ❑ Hazards to ozone layer



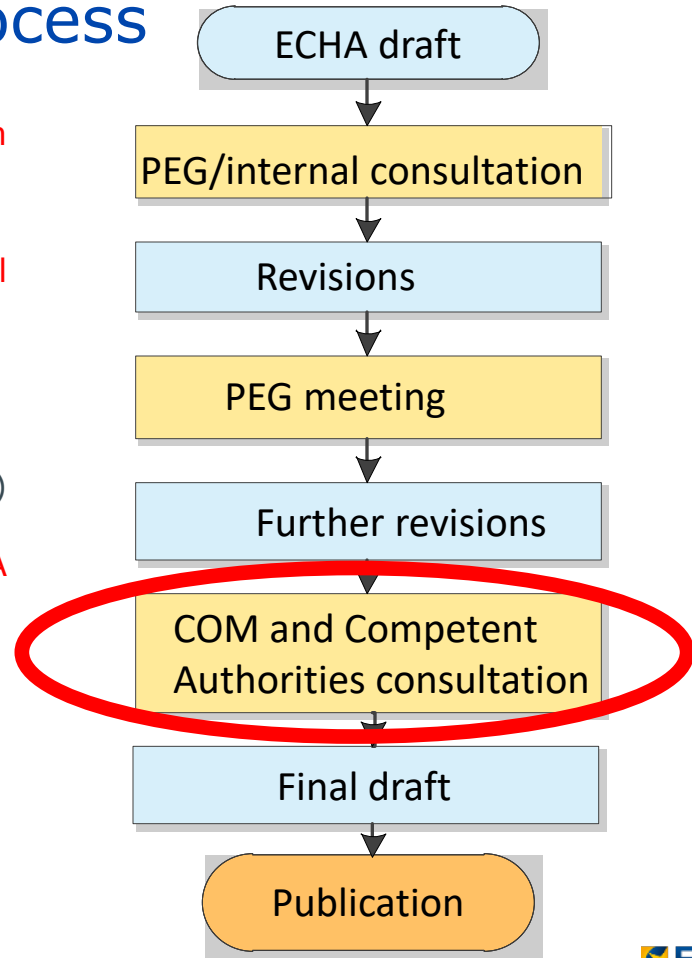
→ Guidance on the application of the **NEW** CLP criteria:

- ❑ PBT/vPvB; PMT/vPvM
- ❑ ED Human Health and Environment (Category 1 and 2)



# CLP Guidance development process

- 12/2022: Establishment of internal **ECHA drafting team** and project co-ordinator
- Spring 2023: First discussions with **independent external experts**
- May 2023: **Ad-hoc PBT expert group**
- June 2023: Establishment of Partner Expert Group (PEG)
- September 2023: **Consultation with PEG and ECHA Committees**
- December 2023: **PEG meeting** (online)
- March 2024: **Revised draft to PEG**
- June 2024: **Consultation with CARACAL**
- Autumn 2024: Publication



# Status and next steps of the guidance development

- Next steps (tentative timelines):
  - CARACAL consultation (June-September 2024)
  - Publication (Autumn 2024)
- Follow the status of the CLP Guidance development:

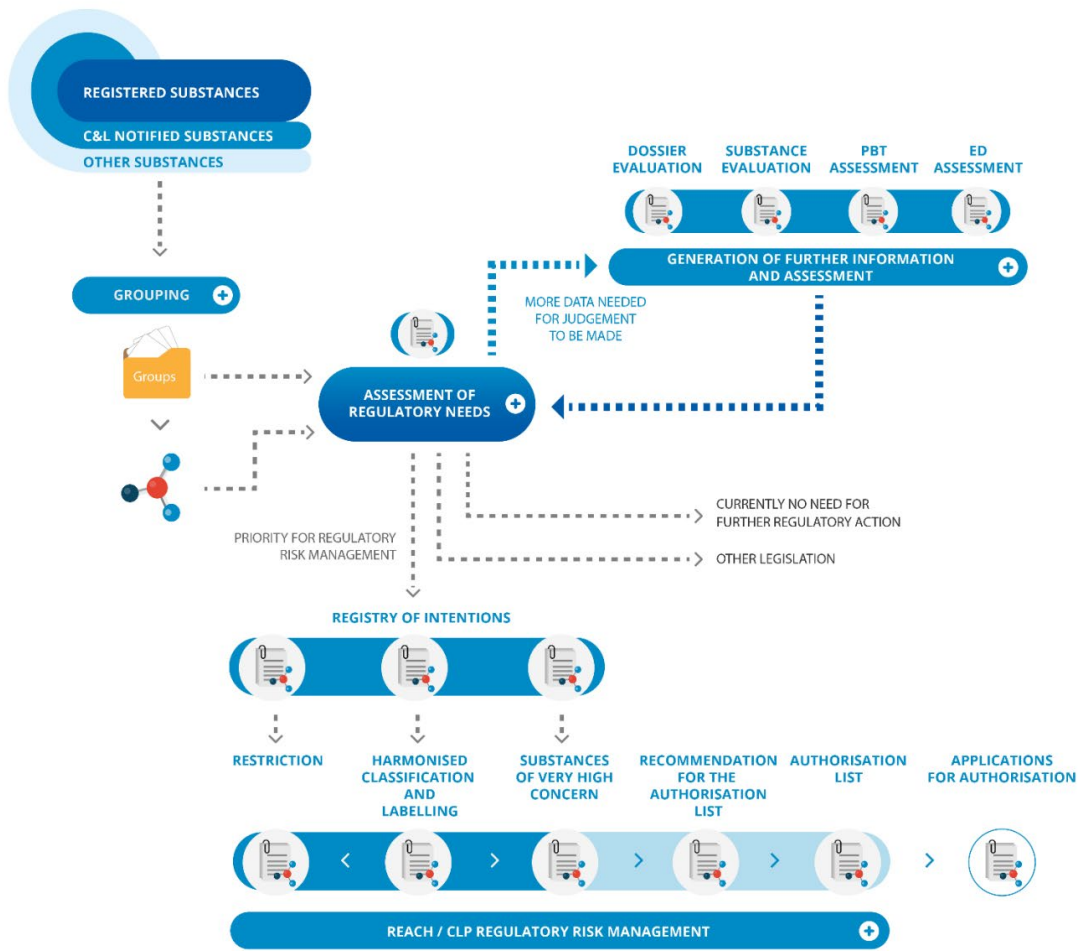
<https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-clp>

- Process of first cases (2024)
- Several MS intentions already logged

# Role of Classification and Labelling

- Purpose and scope: ensure a high level of protection of human health and the environment, as well as the free movement of substances, mixtures and articles
- Role
  - CLP sets the legal standard for hazard classification which as such functions as input to (regulatory) risk management measures
  - Biocides and pesticide substances, as well as REACH priority substances receive a Harmonised Classification, other substances require self-classification

**Figure 1: REACH and CLP machinery serving ECHA's Integrated Regulatory Strategy<sup>7</sup>**



# Regulatory Research Needs

# Implementing EU Regulation: where science makes a difference

- We implement **law**, using science to make the argumentation
- Key is to identify and characterise **hazardous** properties and **exposure** leading to **risks** for humans and the environment
- Required in order to set appropriate risk management actions (e.g. Classification and Labelling, Authorisations, Restrictions, Occupational exposure limits) in order to manage safe uses of substances

*We need the further development of models, methodologies, data*

# Drivers for regulatory science



## ECHA – Strategy Statement 2024-2028

- Lead on chemical knowledge and expertise
- Promote development and use of alternative methods for the assessment of hazards and risks of chemicals



## Chemical Strategy for Sustainability (CSS)

- Addressing chemical pollution in the environment
- Provide protection against most harmful chemicals
- Shift away from Animal Testing
- Data availability



## Legal Requirements

- Changes in Regulations e.g. new hazard classes in CLP Regulation (ED, PMT/vPvM, PBT/vPvB) and new information requirements
- Discussion on emerging hazards (e.g. neurotoxicity, immunotoxicity...)



## Advances in Science

- Ambition to further develop animal free methodologies
- Partnership for the Assessment of Risks from Chemicals (PARC)

# Partnership for the Assessment of Risks from Chemicals

- ECHA is **co-leader in** “Priority setting”, (WP2 “common Policy agenda”)
- **~80** projects ongoing (anno 2024)
- ECHA is involved in the review of **~ 40** projects. Our role is to assess the regulatory relevance
- End of 2023, ECHA starting to engage more closely with some projects (**~ 27**) of high relevance for our mandate. (e.g.: regular catch-up, potential webinar on specific topics (new hazard classes),...)



200 institutions, 28 countries,  
including three European  
Agencies



7 years



€400 million  
(50% EU, 50%  
Member States)

PARC website: [eu-parc.eu](http://eu-parc.eu)



# Key Areas of Regulatory Challenge

Provide protection against most harmful chemicals

Shift away from Animal Testing

Addressing chemical pollution in the environment

Improved availability on chemical data



- PARC was the trigger to initiate internal prioritisation of science areas where we face biggest challenges
- Based on the structure of the Commission's Chemical strategy for Sustainability (CSS; Part of the Green Deal)
- In 2023, first ECHA attempt to illustrate what would be beneficial in terms of research and why
- In 2024, the second publication was released, regular updates planned
- ECHA website : [Link](#)
- Webinar 18/06/2024: [Link](#)

# Addressing chemical pollution in the environment

## → Bioaccumulation

- Development of non-vertebrate methods to predict the bioaccumulation potential of surfactants, ionisable substances and organometals
- Improved bioaccumulation assessment for air-breathing organisms,
- Improve the assessment for secondary poisoning and man via environment specially for mixtures
- Development of new methods and assessment approaches to evaluate the bioaccumulation potential of super hydrophobic substances
- How to improve assessment of secondary poisoning and man via environment?

## → Monitoring

- Development of approaches based on monitoring field data enabling persistence, long-range environmental transport and/or bioaccumulation assessment.
- Case study 1: Environmental monitoring data for linear and cyclic siloxanes

## → Expanding protection of biodiversity by use of NAMs

## → Data generation for assessing the sensitivity of non-bee pollinators (NBP) to biocidal active substances



# Call for tenders ECHA/2024/OP/0004

- Aim:  
*Scientific and technical support work related to hazard assessment and identification, including regulatory support of work on Classification and Labelling, Dossier and Substance Evaluation, POPs, Drinking Water Directive and potential future tasks under certain water protection directives (Water Framework Directive; Ground Water Directive, EQS Directive)*
- 4 Lots:
  - LOT 1 - **Human Health** expertise with special attention on reproductive toxicity (including developmental neuro- and immunotoxicity), neurotoxicity and immunotoxicity (72 months)
  - LOT 2 - **Ecotoxicology**, environmental fate and environmental exposure assessment (72 months)
  - LOT 3 - **Endocrine disruption** analysis for environmental and human health (72 months)
  - LOT 4 - Scientific and technical support for **ECHA regulatory processes** (48 months)

# ZeroPM Project: Prevention–Prioritisation-Removal

- Regulators (COM/ECHA) a bridge between Academia and Industry
- CLH process/ECHA a bridge between science and regulatory actions
- Synergies with Integrated Projects such as ZeroPM in
  - ✓ generating and compiling relevant hazard information (WP6, throughout)
  - ✓ identification and grouping of priority substances (WP5)
  - ✓ establishing safer alternatives (WP2) => minimise risk management actions
  - ✓ risk communication (WP2, WP4)
  - ✓ development of novel assessment tools (WP5, WP6)
  - ✓ support in an expert level





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ECHA is here to contribute but even more to listen and learn...

... wishing you (and us!) a fruitful and inspiring discussion!

# Thank you

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# Interested to know more?

→ Scan our QR code: Key Areas of Regulatory Challenge

