

Overview of CLP and the revision

Seminar latest trends on chemicals management in the EU

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About us

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



Topics

- What & Why classification & labelling?
- Harmonised vs self-classification
- Harmonised classification: key steps and interlinks with other processes
- The CLP revision

What & why classification & labelling



What is classification and labelling?

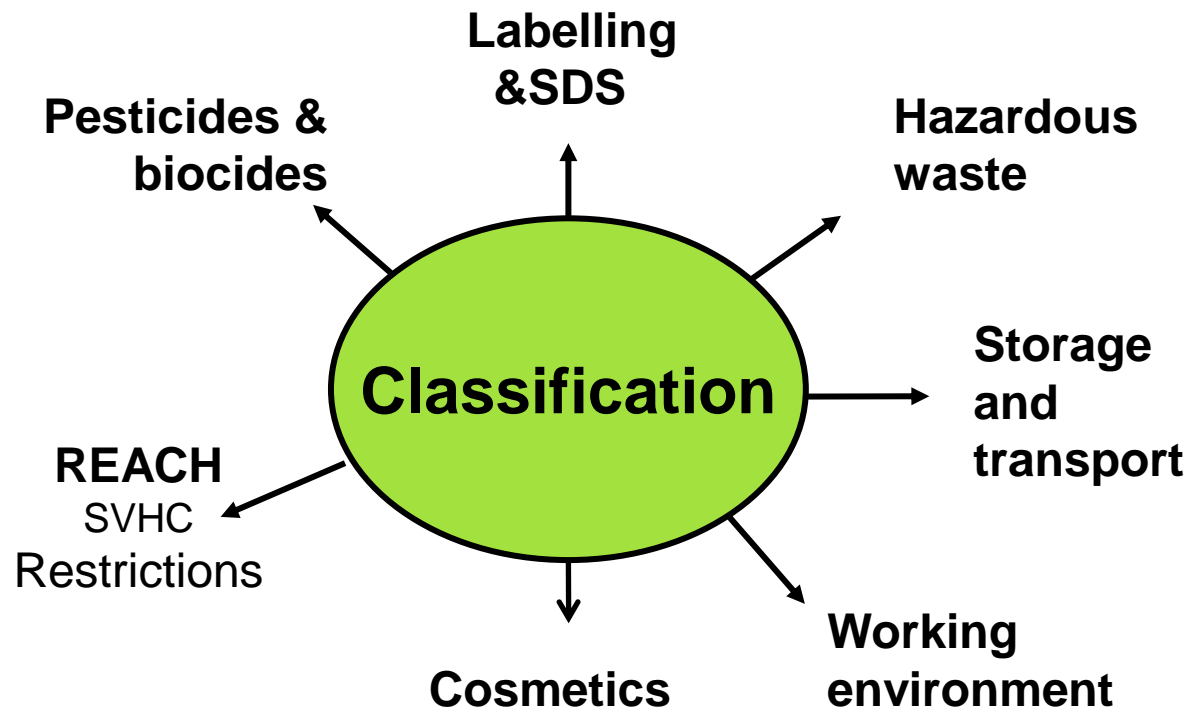
- A way to determine if a substance (or mixture) is “hazardous” to health and/or environment
- Based on **hazard, not risk**
 - Do not consider exposure or socio-economic consequences
- How to achieve it ?
 - By comparing hazard information on the substance(s) (e.g. study results) with classification criteria (Annex I, CLP)
 - By deciding on the most appropriate hazard class and category



Why classify and label?

- Worker and consumer health and safety
- Environmental protection
- Ensure correct **storage/handling/ transport**
- **Prevent consumer access** to most dangerous substances and mixtures
- Prevent **accidents** and response
- Instructions for handling and discarding **waste**

Consequences of classification



Why classify and label?

- Effective communication of identified hazards in safety data sheets (SDS) and on labels
- Hazard pictograms
 - Signal word
 - Warning (Wng), Danger (Dgr)
 - Hazard statement, e.g.
 - H200 – Unstable explosives
 - H301 – Toxic if swallowed
 - Precautionary statements, e.g.
 - P201 – Keep out of reach of children
 - P372 – Explosion risk in case of fire



ECHA's main tasks under CLP

- Processing proposals for Harmonised Classification and Labelling (CLH)
 - Adopted via the Risk Assessment Committee
- Maintaining/developing the C&L Inventory
 - Notifications on self-classifications of hazardous substances on the EU market
- Handling applications for Alternative chemical names for substances in mixtures
 - Formulators of mixtures apply for use of alternative names for hazardous substances on labels and safety data sheets

Packaging

- Material must not be susceptible to be damaged by its content
- Packaging and fastenings shall be strong and solid
- Repeated refastening of replaceable fastening must be possible without the contents escaping
- Package containing a hazardous substance / mixture supplied to the general public shall not mislead consumers.



Special rules on packaging

→ Child-resistant fastenings

- *Example:* mixture contains methanol $\geq 3\%$ or dichloromethane $\geq 1\%$



→ Tactile warnings



Hazard Criteria **fastenings**

Child-resistant

Tactile warnings

Acute toxicity (category 1 to 3)

Yes

Yes

Acute toxicity (category 4)

-

Yes

Flammable gases (category 1, 2)

-

Yes

**Harmonised versus
self classification**



Harmonised classification and labelling

EU harmonised classification



versus

"self-classification"



Harmonised classification and labelling

- Agreement of classification and labelling of a substance at EU-level
- **Legally binding:** obligatory to use for every manufacture, importer or downstream user of the substance within EU
- List of harmonised classifications Annex VI to CLP
 - Over 4500 entries (including many group entries)

Harmonised classification and labelling

Which substances should be harmonised?

- CLP Regulation focuses on substances which are of **most concern to human health**, i.e.:
 - Carcinogenic (C)
 - Mutagenic (M)
 - Reproductive toxicants (R)
 - Respiratory sensitisers (RS)
- Other hazard classes can be harmonised on a case-by-case basis – justification needed, but...
- Active substances in **plant protection products (PPPs)** and **biocidal products (BPs)** are harmonised

Harmonised classification and labelling

- **Who** can submit a CLH proposal to ECHA?
 - Member State Competent Authorities (MSCAs)
 - M/I/DUs can submit
 - Exception: PPP, BP, removal or revision of an existing classification / differentiation in an Annex VI entry
 - Pesticidal and biocidal active substances – only MSCAs
- **Adopted** via the **Risk Assessment Committee** (RAC)
 - Scientific committee (MSCA representatives)
 - Discusses and gives an **opinion** on the classification proposal
- **Commission** takes final **decision**
- ⇒ Inclusion in Annex VI of CLP – list of harmonised classifications



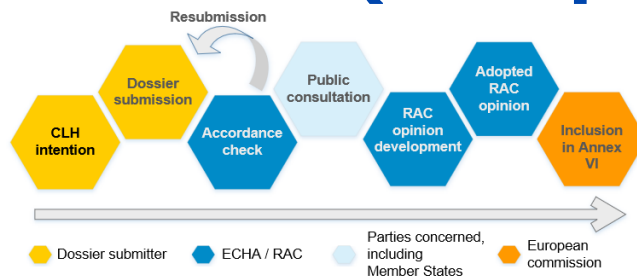
Harmonised classification and labelling

- As for substances, *mixtures* shall be classified for physical, human health and environmental hazards
- Based on test data for the **mixture as a whole** (also for physical properties)
 - Based on the use of "**bridging principles**" (some principles under discussion with MSs and Commission)
 - Based on the hazardous properties of the **individual constituents** of the mixture (concentration limits and cut offs - calculations)

**Harmonised
classification: key
steps and interlinks
with other processes**

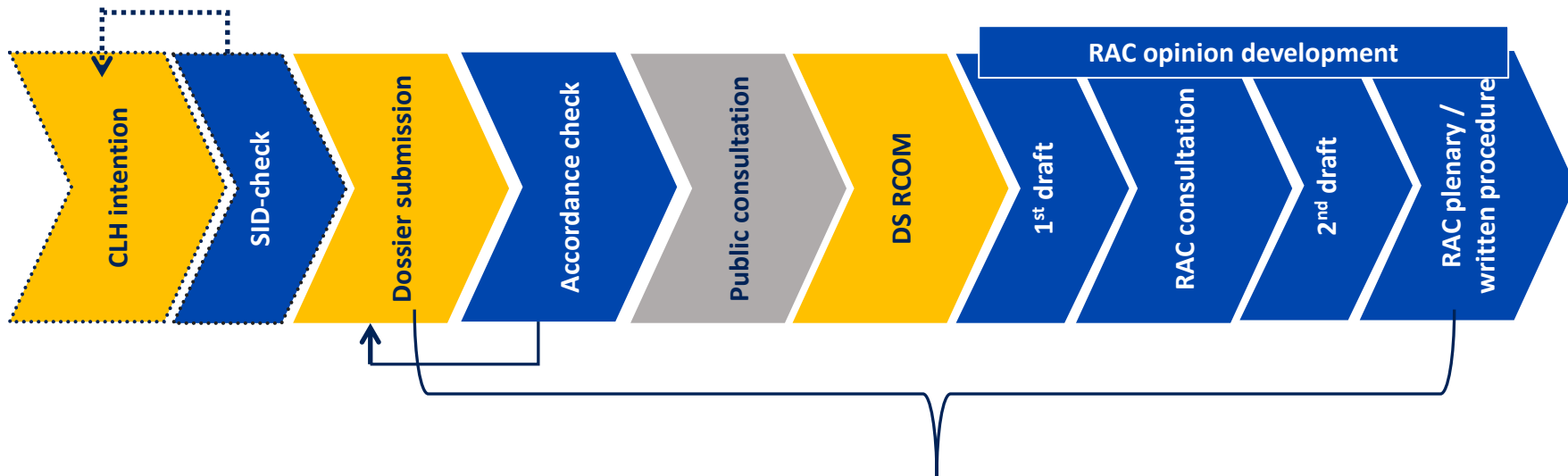


CLH process (Webpage)






- > **Intention**
- > **Dossier submission**
- > **Accordance check**
- > **Public consultation**
- > **Committee for Risk Assessment and opinion development**
- > **Adopted RAC opinion**
- > **Decision on the CLH (inclusion in Annex VI to CLP)**
- > **Re-assessment of the harmonised classification**

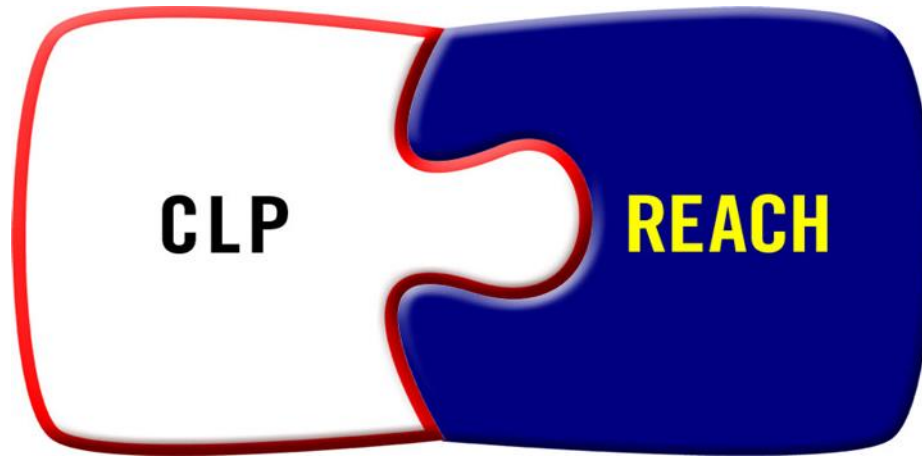
Harmonised classification and labelling - process



Max 18 months to adopt a CLH opinion (Art. 37(4) of CLP)

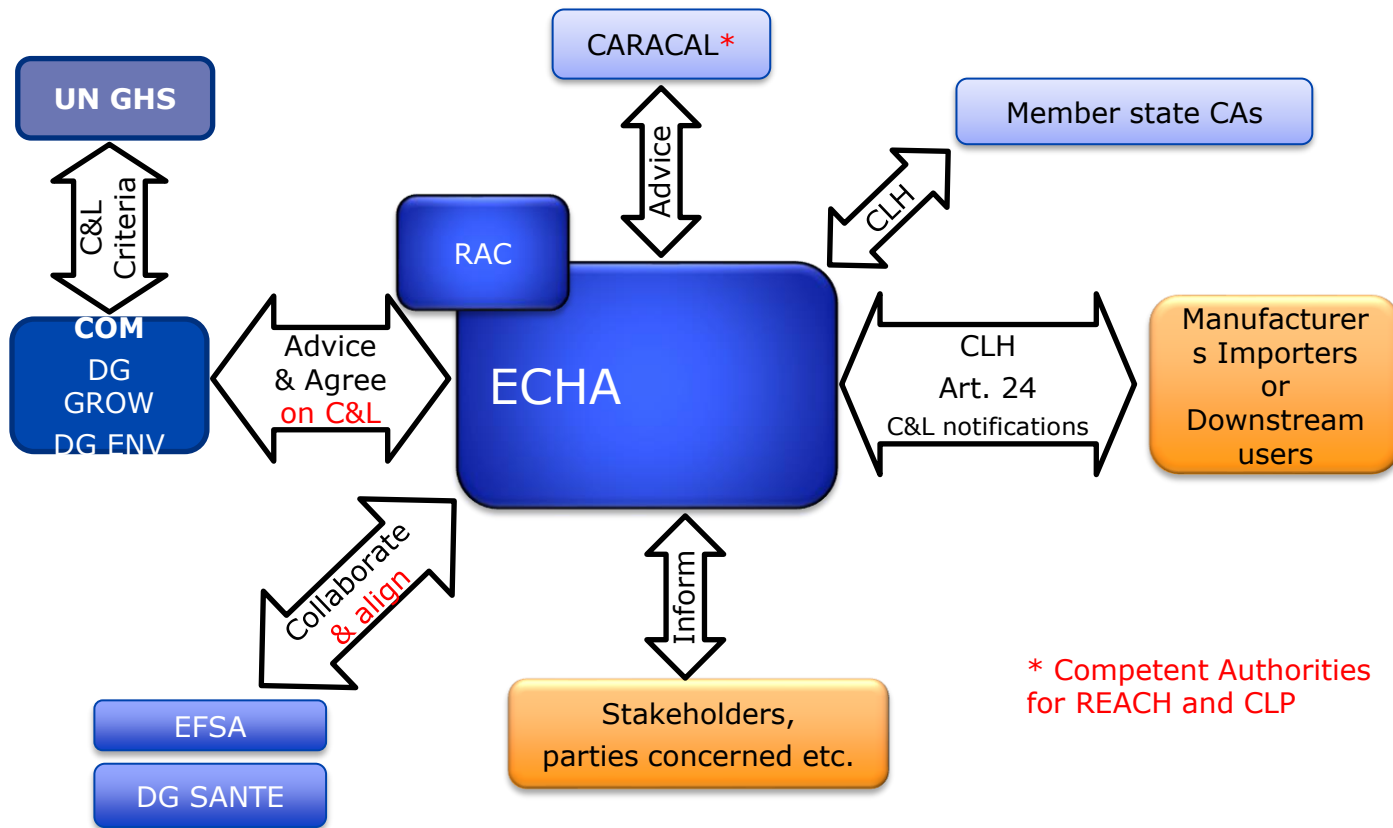
Main actors:

-  Dossier submitter (DS)
-  ECHA/RAC
-  Parties concerned



- CLP and REACH Regulations needed to be integrated/synchronised being central elements in the EU chemical policy
- Many provisions in REACH are based on classification (*What is REACH without CLP and what is CLP without REACH?*)

ECHA's network on CLP



The CLP revision



CLP Revision in 2 parts

OLP

Ordinary Legislative Procedure

(change of CLP "body" text)



Co-decision via Parliament and Council

DA

Delegated Act
(changing Annex I)



COM decision via CARACAL consultations



COM proposals for legal revisions of CLP

- a) The adopted Delegated Act (new hazards classes, C(2022)9383 final)
 - [CLP Delegated Act \(europa.eu\)](#),
- b) The proposal to change CLP regulation (COM(2022)748 final)
 - [Proposal for CLP revision \(europa.eu\)](#)

https://ec.europa.eu/commission/presscorner/detail/en/IP_22_7775

ECHA's task to prepare update of the Guidance on the Application of the CLP Criteria to include the new hazard classes

OLP

Consolidated draft
published 19.12.2022



Only 1 reading in
EP/Council?



Entry into force – earliest
June 2024



Transitional period –
18...42 months? → Jan
2026 ?



Timing?

DA

Published 19.12.2022



2-m scrutiny period by
EP/Council



Entry into force
Q2 2023



Transitional period
Substances 24 months (2
y) → **Q2 2025**
Mixtures 36 months (3 y)
→ **Q2 2026**



Reclassification
Transitional period
Substances 42 months
(3,5 y) → **Q4 2026**
Mixtures 60 months (5 y)
→ **Q2 2028**

DA (Annex I)– What's in

- Setting the new criteria for ED (HH), ED(ENV) PBT, vPvB, PMT, vPvM
 - Definitions
 - EDs Cat 1 (known/presumed) and Cat 2 (suspected)
 - PBT/vPvB – no subcategories
 - PMT/vPvM - no subcategories
 - New hazard statements (EUH)
 - Generic concentration limits/mixture classification
 - No symbol/pictogram for the new hazard classes
 - Symbol to be discussed at UN-GHS

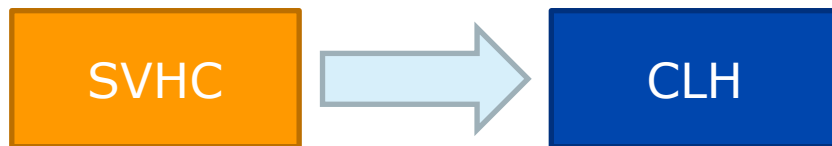
New hazard classes

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

- COM right of initiative
 - ECHA & EFSA to prepare CLH-proposals
- Obligatory Registry of Intentions (RoI)
 - MSs and IND to notify intentions
 - ECHA to publish intentions (within 1 week)
- What normally prioritised for CLH (Art 36.1)
 - Now: C, M, R, resp sens
 - Add: EDs, PBT, vPvB, PMT, vPvM
- MSCA to inform ECHA
 - Acceptance or refusion of a classification revision proposal by M, I or DU
- ATE
 - Add definition for acute toxicity estimates estimates.eu

OLP – What's in CLP (2/7)

Role of SVHC and PPP/BP ED, PBT assessments?



- COM delegated act to add existing candidate list (SVHC) substances and PPP and BP active substances identified into Annex VI of CLP
- In the future CLP route to be used: 1S1A hazard identification

OLP – What’s in CLP (3/7)

- **Changes to C&L Inventory**

- Publication of notifier names
- Reasons for divergence in self-classification
- Update of notifications within 6 m after a decision to change a classification is made

SME
benefit

Notifications submitted/updated by: 17 January 2023

> [CL Inventory](#)

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Name	EC / List no.	CAS no.	Classification	Source
α,α,α-trifluoro-p-toluoyl chloride	206-342-9	329-15-7	Skin Corr. 1B	Notified C&L
N,N-diethyl-m-anisidine	202-134-7	92-18-2	Acute Tox. 4	Notified C&L

MOCS
More than one
constituent
substance

Disclaimer
Essential oils
exemption?

• Clarification of mixture rules on MOCS

- Definition Multi-constituent substance =
“**a substance that contains more than one constituent**”
- Information on the constituents to be used for identification and examination of available information
 - Muta, carc, repro, ED HH, ED ENV
 - Biodegradation, persistence, mobility and bioaccumulation properties within Aquatic Acute/Chronic, PBT, vPvB, PMT and vPvM
- Data on the multi-constituent substance itself shall be taken into account:
 - If data demonstrates Muta, carc, repro, ED HH, ED ENV, biodegradation, persistence, mobility and bioaccumulation properties
 - Data supports the conclusions based on the relevant available info on the constituents
- Data on the multi-constituent substance itself showing absence of certain properties or less severe properties shall not override the info on the constituents.

OLP – What's in CLP (5/7)

- Online sales (distance sales)
 - Improve hazard communication and enforcement
 - Advertisement of substance/mixtures must contain:
 - hazard pictogram,
 - signal word,
 - hazard class and
 - hazard statements
 - A supplier in EU to ensure the requirements by CLP are met
i.e. consumer not becoming the importer



OLP – What's in CLP (6/7)

- Changes to labelling, on-pack label vs digital label
 - Minimum dimension of label, pictograms and font size
 - Label updates within 6 or 18 months after new evaluation
 - Broader use of fold out labels
 - Exemptions on very small packaging (< 10 ml)
 - Voluntary digital label
 - To contain info instrumental to the protection of health and environment
 - Researchable, available in less than 2 clicks
 - Sales in refillable containers
 - Chemicals with less severe hazards
 - Derogations: ammunition, ready mixed cement, fuel



OLP – What’s in CLP (7/7)

- Poison centres (PC)
 - More robust legal basis for ECHA’s role
 - ECHA to be Appointed Body
 - Confirms ECHA’s role in processing and dispatching notifications (emergency health information)
 - ECHA (and COM) may ask appointed bodies to analyse and share their PCN data for RRM purposes
 - Duty holder definition: Also distributors must notify to PCN emergency health information
 - Distributor rebranding/relabelling & supplying to another MS than the one in which the mixture was notified



Impact

- 1st route: Harmonised classification is the first step and corner stone for many risk management actions
 - Biocides a.s.(re)assessment and authorisation
 - PPP a.s.(re)assessment and authorisation
 - Authorisations and Restrictions under REACH
 - Generic restrictions (GRA)
 - A variety of other pieces of downstream legislation

- 1S1A: Even more central with the classification criteria for the new hazard classes
 - But EU needs to convince the rest of the world...GHS

Thank you

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