Concept and overview of CLP after the revision

Seminar on Chemicals Management in EU

10 March 2025

Dr. Erwin Annys
Head of Unit Support and Enforcement
European Chemicals Agency

OUR PURPOSE

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

OUR VISION

Chemical safety through science, collaboration and knowledge

Agenda

- → CLP: Implementation of GHS in the EU
- → CLP revision
- → Introductory guidance on CLP
- → Classification and Labelling Inventory

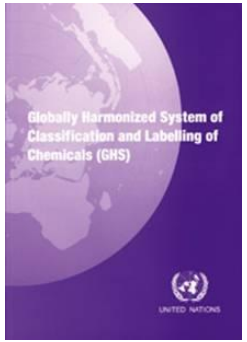
CLP: Implementation of GHS in the EU

ECHA
EUROPEAN CHEMICALS AGENCY

~~yesterday~~
NOW.
~~tomorrow~~

The CLP Regulation (EC) No 1272/2008

- Entered into force on 20 January 2009.
- Legal framework for classification & labelling in the EU
- Based on United Nations' Globally Harmonised System (GHS) – same aims
- CLP implements the UN GHS classification criteria
  ⇛ Similar legislation in a large part of the world
- Ensures a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles.



EU Implementation of GHS - History

The European Commission (EC) started in 2004 to consider implementation of GHS, for supply and use of substances and mixtures

- Aim of the EC was to maintain the current safety level

- The CLP Regulation replaced EU legislation existing at the time
  - for C&L of substances - Dir. 67/548/EEC
  - for C&L of mixtures - Dir. 1999/45/EEC

EU Implementation of GHS

- GHS very similar to previous EU legislation on C&L:
  - **hazard** based classification and labelling (intrinsic properties), not risk based.
  - similar classification criteria for substances

BUT

- Mixtures in GHS: often *lower* "generic concentration limits" than previously – more likely to trigger classification of the mixture containing a hazardous substance

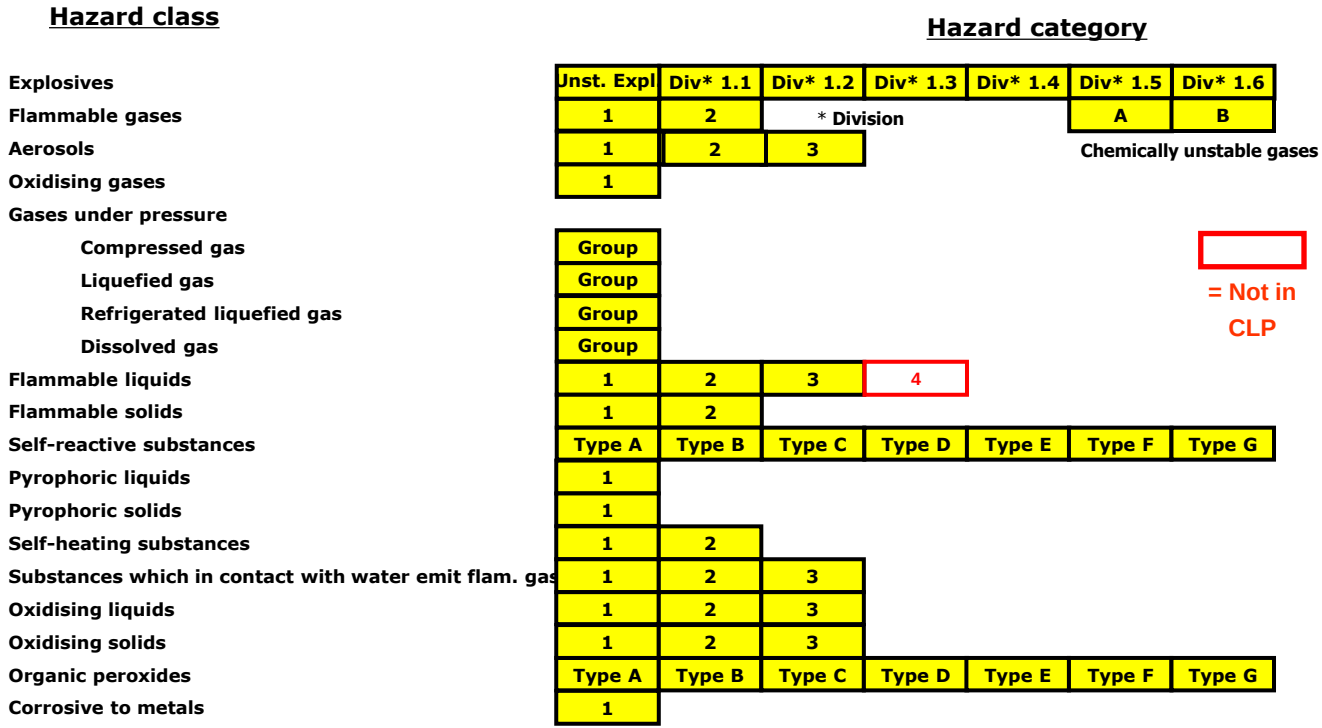
- Almost all GHS hazard categories have been implemented

- Use "building block approach" (1.1.3.1.5 in GHS)

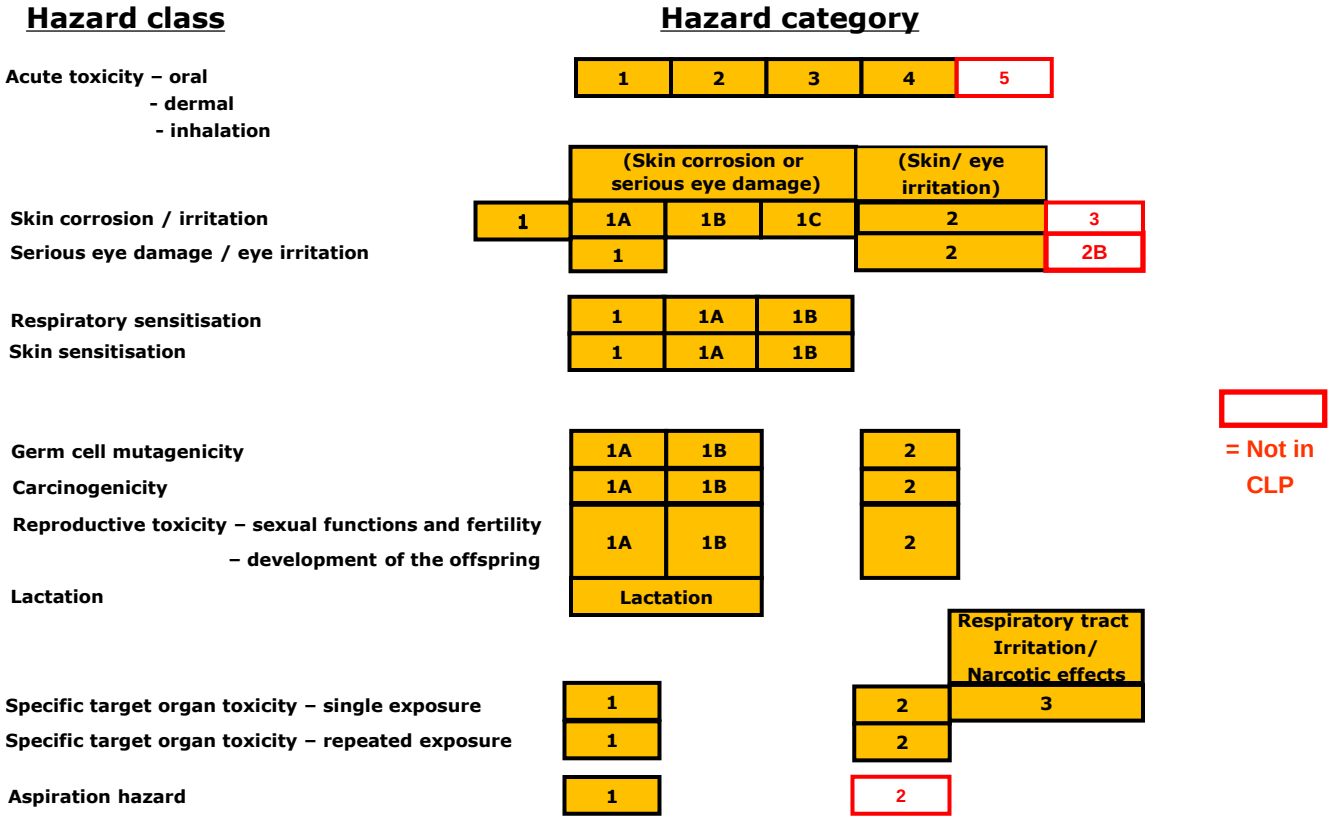
Hazard classes are grouped in CLP under the following headings:

- **Physical hazards**
- **Health hazards**
- **Environmental hazards**
- **Additional hazards**

Hazard classes and categories under CLP vs GHS - Physical hazards



Hazard classes and categories under CLP vs GHS – Health hazards



Hazard classes and categories under CLP vs GHS

- Environmental hazards
- Additional hazards

= Not in CLP

Hazardous to the Aquatic Environment

Aquatic acute	1	2	3	
Aquatic chronic	1	2	3	4

Hazardous to the ozone layer | 1

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

EU Harmonised Classification & Labelling (CLH)

Which substances should be harmonised?

- Focus 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
- Active substances in **plant protection products** (PPPs) **and biocidal products** (BPs) are normally harmonised

After the CLP revision:

- ED HH
- ED ENV
- PBT, vPvB
- PMT, vPvM

CLP Revision

A targeted revision

Adequate classification rules

- More than One Constituent Substances (MOCS), speeding up CLH process, possibility for COM to submit CLH dossier, prioritising new hazard classes

Improving hazard communication

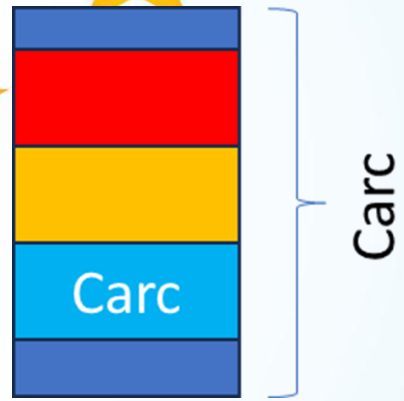
- Clear deadlines for label updates, fold-out labels, mandatory formatting requirements, introducing digital labelling, setting up rules for refill sales

Fixing gaps and unclear areas

- Introducing mandatory supplier in EU, addressing information loss for poison centres, improving and clarifying advertising rules, introducing mandatory rules for online offers

Adequate classification of chemicals (MOCS)

- Available data on known constituents shall be always evaluated (together with data on substance).
- Classification of substances for CMR, ED, Persistency, Mobility, Bioaccumulation based on the classified constituent and not on the substance data.
- Derogation for plant extracts not chemically modified => Scientific report after 5 years + legislative proposal, if necessary;
- Possibility to add (and modify) additional derogations in Annex I for other substances via delegated act.
- If a MOCS is classified due to its constituent(s), a mixture containing this MOCS is classified on the basis of the % of those constituent(s) in the mixture => same for mixtures in mixtures => % of those constituent(s).



Adequate classification of chemicals

- **Transfer** via delegated acts to Annex VI of substances identified as ED cat. 1 or PBT/vPvB in REACH, Plant Protection Products and Biocidal products regulations.
- **Procedural rules**: allowing the Commission to initiate CLH dossiers; mandates to ECHA or EFSA.
- **Grouping approach** : based on clear scientific reasoning taking into account how the available information supports the grouping and allows the properties of the substances to be reliably predicted from other substances in the group;
  - avoid animal testing on the whole group; speeding up the classification.
- **Speed-up CLH =>**The Commission shall adopt the delegated act preferably **before the end of the calendar year following the publication of the RAC opinion**.

Adequate classification of chemicals

Notification rules to ECHA's classification and labelling inventory:

- Publication of the names of the notifiers [NB! can be claimed as confidential]
- Publication of the reasons for diverging from the most severe notified C&L
- Publication of the reasons for introducing a more severe notified C&L
- Publication of the date of the latest update of the C&L
- If update of classification is needed, updates of notifications within 6 months
- Possibility for ECHA to flag to the notifiers concerned entries that in ECHA's view are incomplete, incorrect or obsolete

Improvement of hazard communication

- **Clearer rules for updating labels**
  - No later than 6 months in case of more severe classification
- **Explicit rules on refill sales**
  - Clarified labelling obligations
  - Risk management measures need to be applied and exclusion of refill for certain hazards classes
- **Introducing digital labelling**
- **Broader use of fold-out labels** for chemicals
- **Typographic and spacing rules** for the labelling of hazardous chemicals.

Improvement of hazard communication
Refill sales

- Labelling on refill stations (visible place)
- Risk mitigation measures in place:
  - Minimising the exposure
  - Preventing uncontrolled use by children
  - Assistance available
  - Reaction between substances/mixtures prevented
- Labelling of packaging (usual rules apply)

Prohibited hazards:

CMR, ED, PBT, PMT, STOT, Flammable, Acute Tox
Skin corrosion 1
Serious eye damage 1
Respiratory sensitisation
Skin sensitisation

Improvement of hazard communication

Digital labelling

- Possibility to use a digital label on a voluntary basis
- Digital label to mirror physical label =>
- Possibility to provide certain supplemental information only on a digital label
- Data carrier to be applied or printed on the physical label or on the packaging
- COM empowerment to broaden the list of elements that can be presented only digitally

Technical requirements

Information provided in one place
Free of charge
Searchable
No registration
No geoblocking
Use of widely used digital technologies

Improvement of hazard communication

Formatting requirements

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)	Minimum font-size (x-height in millimetres)
≤ 0,5 L	If possible, at least 52x74	Not smaller than 10x10 If possible, at least 16x16	1.2
≤ 3 L			1.4
≤ 50 L	At least 74x105	At least 23x23	1.8
≤ 500 L	At least 105x148	At least 32x32	2.0
> 500 L	At least 148x210	At least 46x46	2.0

- Line spacing: the distance between two lines shall be at least 120 % of the font size
- Contrast: text must be black on white background
- Typeface: single font, easily legible, without serifs
- Letter spacing: appropriate to be legible

Addressing main legal gaps

- Introducing **mandatory supplier in EU**: "*A substance or a mixture shall not be placed on the market unless a supplier, established in the Union, who shall be identified on the label, in the course of an industrial or professional activity fulfils the requirements set out in this Regulation with regard to the substances and mixtures in question*".
- Advertisements to indicate **hazard pictograms, signal word, hazard statements and EUH statements** + "***always read and follow the information on the product label***" (sale to general public).
- Advertisements shall not contain statements (**'non-toxic', 'non-harmful', 'non-polluting', 'ecological'**) that shall not appear on the label or packaging of that substance or mixture in accordance with Article 25(4).
- All labelling information shall be indicated in **online offers.**
- Introducing targeted notification obligations to poison centres in case of information loss => obligations to **notify poison centres for re-labellers, re-branders and distributors that are further distributing to another MS.**

Other provisions

- The Commission shall:
  - promote the harmonisation of the criteria for non-animal testing at UN GHS and adapt CLP **preferably within 18 months** after their inclusion in the UN GHS;
  - regularly evaluate the development of alternatives to animal testing;
  - promote the development of criteria for immunotoxicity, neurotoxicity, PBT, PMT and ED at UN GHS.

- **Enforcement**: the authorities responsible for enforcement shall follow up on complaints or reports related to non-compliance with this Regulation and verify that the corrective action referred to in Article 3(16) of Regulation 2019/1020 has been taken.

- Ammunition (Derogations from labelling requirements for special cases section 1.3 of Annex I).

CLP revision – applicability

- Entry into force: 20 days after publication in Official Journal = applicability date for provisions that are not imposing duties on stakeholders (e.g. Commission's right to submit CLH proposal).
- 18 months after entry into force: new provisions imposing duties on stakeholders (e.g. MOCS).
- 24 months after entry into force: identity of ED, PMT and PBT in mixtures on the label, font sizes and poison centres notifications. More time to adapt; also changes to ECHA IT system are necessary.
- Transitional provisions: substances and mixtures classified and labelled according to the rules applicable before entry into force and placed on the market within 18/24 months (e.g. MOCS) of entry into force: no need to re-classify, re-label or re-package for 42/48 months in total (= additional 2 years for chemicals in the supply chain).
- 'Good pupils' clause: application by stakeholders before mandatory 18/24 months possible on voluntary basis.

CLP Revision follow-up - implementation

- COM to assess the need to develop guidance and/or a delegated act to further specify requirements for digital labelling
- ECHA to update relevant guidance(s)
- ECHA to update IT tools, such as C&L inventory, poison centre notifications
- Transfer via delegated acts to Annex VI of substances identified as ED cat. 1 or PBT/vPvB in REACH, PPPR and BPR.

CLP Revision follow-up - review

- **5 years**: review scientific report on MOCS derogation for plant extracts, including essential oils
  - May be accompanied by legislative proposal
- **5 years**: assess the need to extend the rules for child resistant fastening and tactile warnings to other hazard classes (in particular eye damage cat. 1 for CRF)
  - If the need is justified – adoption of a delegated act

Reasons for updating CLP related guidance

→ GHS and ATP updates

→ Established RAC assessment practices

→ CLP revision

- New hazard classes
- Other CLP revision changes

Introductory Guidance on the CLP Regulation

Guidance documents subject to update

- Introductory Guidance on the CLP Regulation
- Guidance on Labelling and Packaging
- Practical guide on read across and grouping
- Guidance on Harmonised Information Relating to Health Emergency Response
- Guidance on the preparation of dossiers for harmonised classification and labelling
- Guidance on the Application of CLP Criteria
  - Part 1 - General Principles (bridging principles, MOCS)
  - Part 3 - Human Health (12th ATP, RAC experience)
  - *Parts 2, 3 and 4 recently updated (new hazard classes and physical hazards)*

Intro guidance on CLP

What is it?

Simple guidance that provides an overview of the features of the CLP Regulation

For who?

Suppliers of substances and mixtures

Producers or importers of articles who have to apply the CLP rules

Changes needed

- CLP revision based
- Minor changes only
- No PEG needed
- Delivery Q3 2025

Update of the Guidance on labelling and packaging (Version 5.0 2025)

Revised CLP outlines changes to labelling and online sales.
Delegated Regulation new hazard classes.

Update of the Guidance with PEG consultation by written procedure in line with 'Consultation procedure on guidance' (ECHA PRO-0011.12)

To make sure that needs of users of the Guidance are adequately addressed, the update covers

Digital labelling, Advertisements, Distance sales offers, Refill stations.

Changes to labels, Application of the formatting rules, Terminology.

Consultation - how? who? when?

Consultation

- PEG members (Member State Authorities, Accredited Stakeholders, COM & EFSA)
- Relevant committees (in parallel)
- Subsequently, by CARACAL

Timeline (with written procedure)

- 2024 Dec to 2025 Jan - draft for PEG consultation
- 2025 Q1 – Revised draft for consultation by relevant committees (in parallel)
- 2025 Q1 – Revised draft for consultation by CARACAL
- 2025 Q1 – Q2 - Prepare for publication and publish

CLP Read Across Practical Guide – producing updated advice

- Revised CLP emphasises use of grouping and read-across
- Need for CLP guidance

Why Practical Guide?

- In line with 'Consultation procedure on guidance' (ECHA PRO-0011.12)
- Not aiming at creating new rules or precedents
- Integrates existing guidance explaining usage under CLP
- Capture experience from already adopted RAC opinions
- Provides relatively early advice and allows easier updating

Consultation - how? who? and when?

Consultation of relevant experts and interested stakeholders via

- RAC including Industry and NGO observers; EFSA in parallel
- Subsequently, via CARACAL.

Relevant stakeholders in these fora:

- RAC, Member State authorities, EFSA, COM, Industry Associations, NGOs

Timeline (with written procedure)

- 2025 Q2 – Draft for consultation via RAC; (EFSA also)
- 2025 Q4 – Revised draft for consultation at CARACAL
- 2025 Q4 – Prepare publication

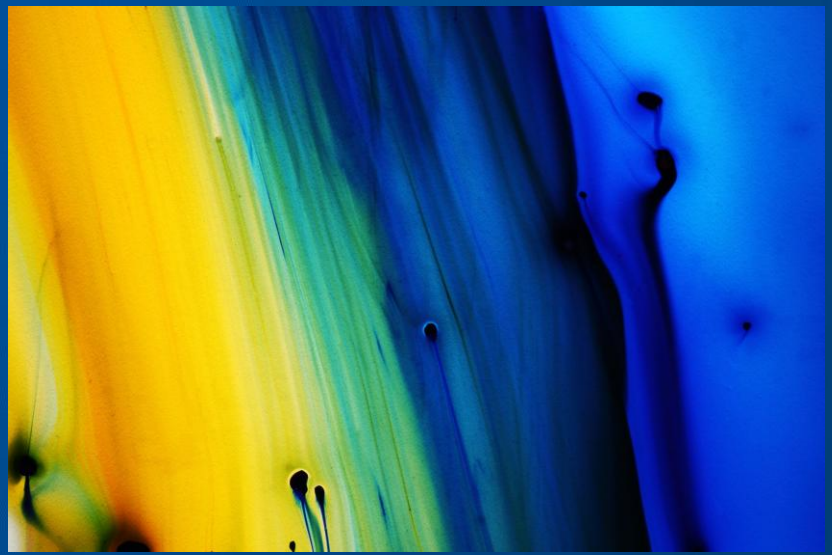
Update of the Guidance on Annex VIII

- Mostly CLP revision based and further improvements
- Consultation of relevant experts (including appointed bodies) and interested stakeholders via Forum and CARACAL (including Commission).
- Timeline (with written procedure)
  - 2025 Q1 – Draft for consultation ready
  - 2025 Q2 – Revised draft for consultation at CARACAL (also Forum)
  - 2025 Q3 – Prepare publication

Guidance on the preparation of dossiers

- General updates to add and remove references, update practices
- Change in dossier structure
  - CLH/BR and CLH/PPP combined templates
- Adding some examples based on experience
- Significant update of the subsections on active substances due to regulatory and procedural changes
- New sub section on non-animal testing methods and defined approaches
- Considerations on dossiers for groups
- No PEG
- Written consultation via CARACAL
- Delivery Q3-Q4 2025

Changes needed – Guidance on Criteria (Part 1)



- CLP revision based
- MOCS, advice becomes rules
- Bridging principles clarifications
- Other minor changes
- No PEG - Written consultation CARACAL only
- Delivery Q3-Q4 2025

Changes needed

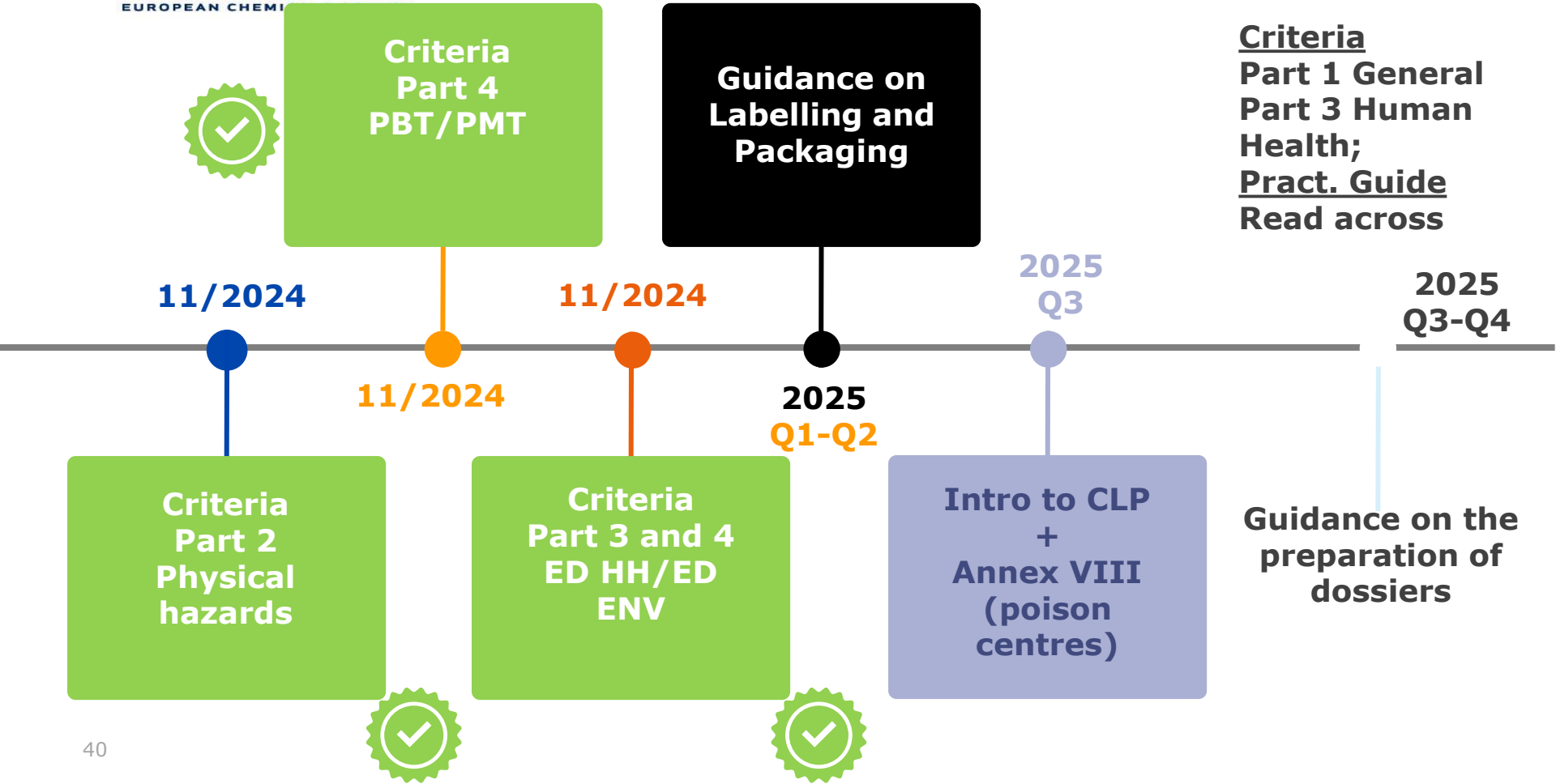
Updating to take account of RAC experiences, changes to GHS, subsequent ATPs, court cases, and CARACAL discussions

ATP 12: some revisions on acute toxicity, skin corr/irrit, eye dam, resp. sens., skin sens, muta, carc, repro, STOT SE, STOT RE

PEG input expected Q2-Q3

Delivery Q3-Q4 2025

Planned Publications Overview



Guidance on the Application of the CLP Criteria

Reference name:	*Guidance on the Application of the CLP Criteria*
Description:	This guidance is a comprehensive technical and scientific document series on the application of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP). The objective of this document series is to provide detailed guidance on the application of the CLP criteria for physical, health and environmental hazards.
	The introduction of guidance on the new hazard classes (part 3.11: Endocrine disruption HH, part 4.2 Endocrine disruption env, and part 4.3: PBT/vPvB and PMT/vPvM) in parts 3 and 4 of the CLP guidance, respectively, required that the guidance be split into its various parts for easier use. Therefore, the guidance on the application of the CLP criteria is now presented in five documents. ▪ Application of the CLP criteria guidance series overview [PDF] ▪ Part 1: General principles for classification and labelling [PDF] ▪ Part 2: Physical hazards [PDF] ▪ Part 3: Health hazards [PDF] ▪ Part 4/5: Environmental hazards and additional hazards [PDF] **Note:** It is important to consult part 1 before consulting any subsequent parts.
Additional information on the ECHA website	Read more

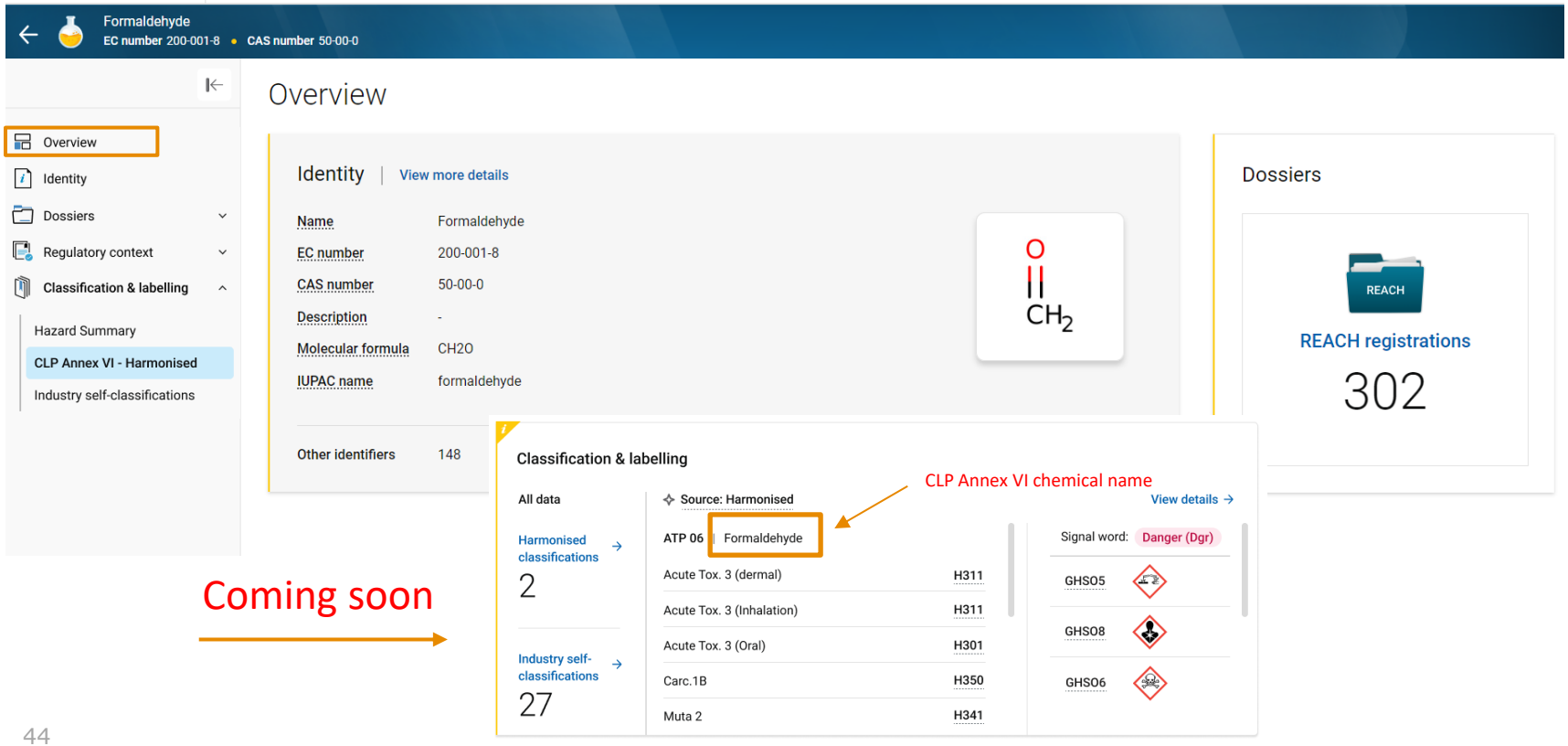
Classification and Labelling Inventory

New C&L Inventory: design principles

- → Redesign addresses the known shortcomings of the C&L Inventory.
- → Aim is to provide the information in an understandable, useful and easy-to-access manner:
  - The display will emphasise where classifications are **aligned**, rather than highlight divergences.
  - The **origin** of the classifications will be more transparent.
- → Stakeholder engagement throughout the design and development.

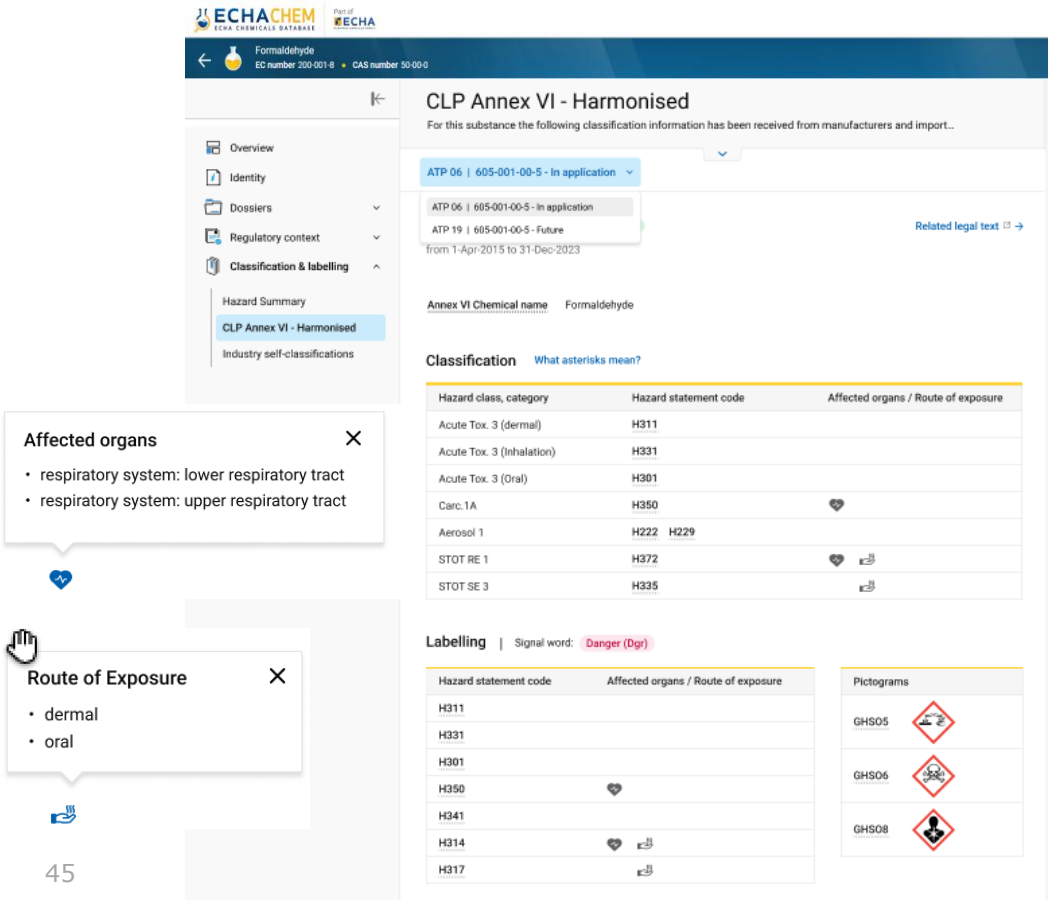
Substance dashboard with C&L data

UX design not final



Harmonised classification

UX design not final



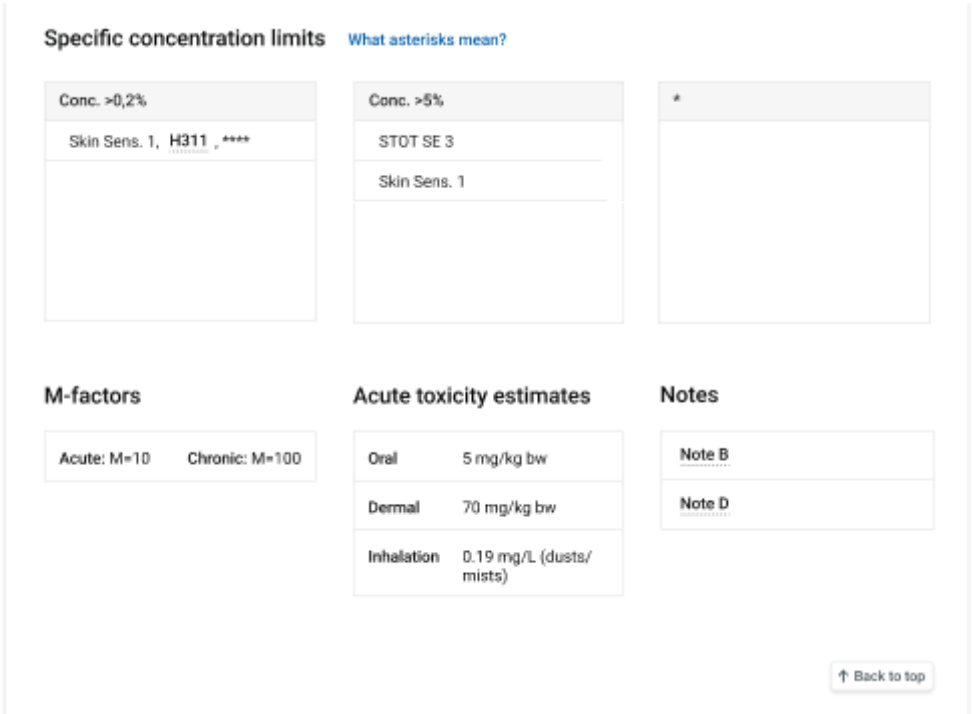
→ Same core information displayed as before

→ Improved context data e.g. ATP entry into application

→ Different harmonisations due to state/form shown in separate tabs

Harmonised classification

UX design not final



Specific concentration limits What asterisks mean?

Conc. >0,2%	Conc. >5%	*
Skin Sens. 1, H311 , ****	STOT SE 3	
	Skin Sens. 1	

M-factors

Acute: M=10	Chronic: M=100

Acute toxicity estimates

Oral	5 mg/kg bw
Dermal	70 mg/kg bw
Inhalation	0.19 mg/L (dusts/ mists)

Notes

Note B
Note D

↑ Back to top

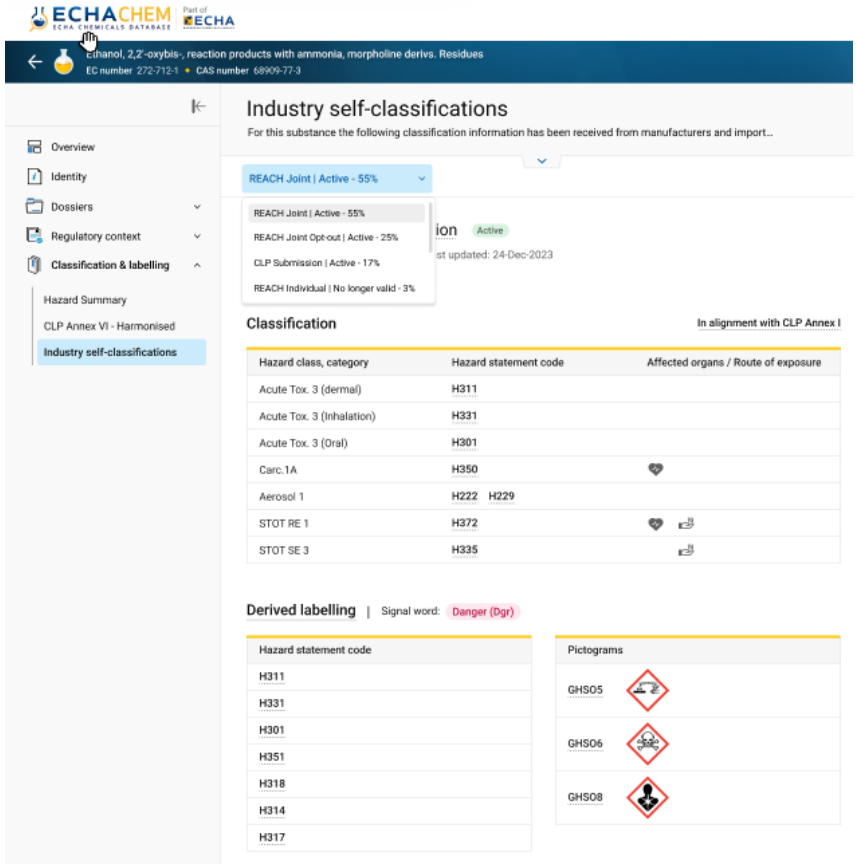
→ More granular data, improved user experience through clear structure

Current C&L Inventory

Specific Concentration limits, M-Factors, Acute Toxicity Estimates (ATE)	Notes
Eye Dam. 1; H318: 3 % ≤ C < 5 % Eye Irrit. 2; H319: 0,3 % ≤ C < 3 % STOT SE 3; H335: C ≥ 3 % Skin Corr. 1B; H314: C ≥ 5 % Skin Irrit. 2; H315: 1 % ≤ C < 5 % M=10	Note B

Industry self-classification

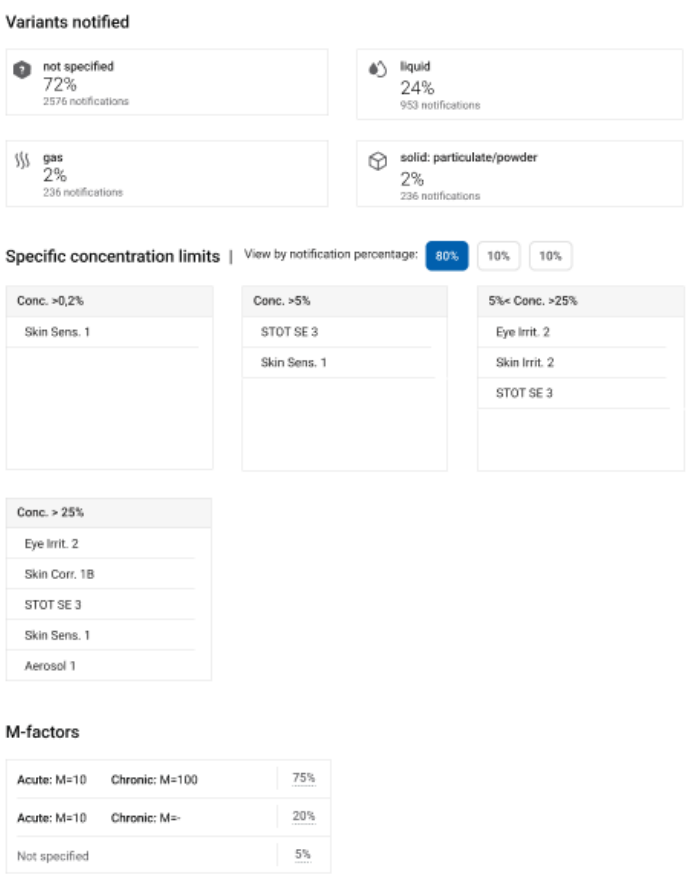
UX design not final



- → Promote alignment in the data
- → Tabs based on classification information
- → Improved context data e.g. last updated, % of notifications, source data
- → Derived labelling based on principles set out in CLP Regulation

Industry self-classification

UX design not final



→ Additional classification elements presented statistically in % of notification counts

Benefits

New approach

~ 380 000 distinct classifications

Only classification differences

Legally correct labelling (derived as per CLP Annex I)

Highlights classification alignment

Today

~ 680 000 classifications

All differences considered

Including labelling differences

Hides classification alignment

SAME source data – SAME substances

C&L Inventory: Future enhancements

- → The first version will allow visual browsing of the data. Next year, we will focus on making the C&L inventory available for download/API access.
  - We will gather feedback from stakeholders, especially authorities who use C&L data.
- → C&L inventory is built on a new data management approach, utilising cloud-based data products to provide data in a more structured format.
- → Following the CLP revision, the new inventory will start making available notifier names as of mid-2026.

Thank you

erwin.annys@echa.europa.eu

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