

EU and GB CLP Updates Gill Pagliuca



CLP Revision

- Why has it changed?What is the impact of these deadlines?

Why has it changed?

2019 Chemicals Fitness Check

Evaluated effectiveness and efficiency of > 40 chemical regulations

2020 Chemicals
Strategy for
Sustainability

Target: toxic free environment, zero pollution from chemicals

2022 Commission proposal for CLP Revision



The CLP Revision – changes to classification

New measures to speed up the CLH process

- Typically takes 4-5 years at the moment to introduce new / updated harmonized classifications
- Delegated Acts to be adopted *preferably* by the end of the year following publication of RAC opinions
- In future, Commission will be able to initiate proposals; ECHA, EFSA to be able to prepare dossiers
- Grouping of substances to speed up things and avoid additional animal testing

New Hazard classes

Prioritise new hazard classes (ED, PBT, vPvB, PMT or vPvM) for harmonised classification

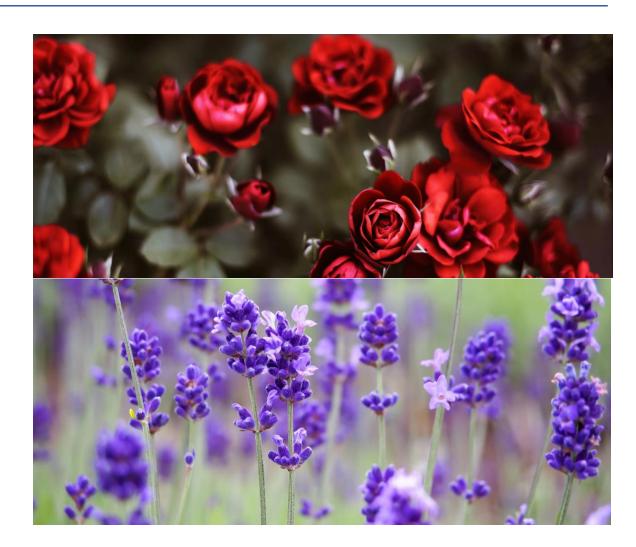
Transfer those already identified under REACH, BPR, PPP into Annex VI (by 18 months from EIF)

Mixtures containing substances classified in the new hazard classes to be classified based on component classifications, or if mixture data shows a *positive* effect not identified from components (same as currently exists for CMRs)



Classification for complex substances with **m**ore than **o**ne **c**onstituent **s**ubstance (MOCS)

- From a toxicological point of view, no different to mixtures
 - Follow mixture rules for classification
 - Aim to reduce new animal testing
 - Ensure rules applied where they contain substances of concern (CMRs, Endocrine Disrupters, Persistence, Mobility, Bioaccumulation)
- Derogation for plant extracts, not chemically modified
 - Within 5 years Commission to produce a report reviewing the scientific basis for the derogation and propose legislation if deemed to be necessary



Other classification changes

- Clarification that where harmonised classifications specify a physical form they apply only to that form, but where a form is not specified they should apply to all forms
- Acute Toxicity Estimates
 - Definition added
 - To be established for substances by manufacturers, importers and downstream users
 - Except where they have been set as part of a harmonised classification
 - Manufacturers and Importers to include ATEs in notifications to the C&L Inventory
- EUH statements listed in Annex II should apply to all mixtures if relevant, regardless of whether they
 are classified



The CLP Revision – Changes to Labelling

Explicit deadlines for updating labels (from when a new hazard evaluation is carried out or is communicated to a supplier):

- Without undue delay, and no later than 6 months where there is a more severe classification of an existing hazard, classification in a new hazard class, or new supplemental labelling requirements
- Without undue delay, and no later than 18 months for other updates
- Where the change is to a harmonized (Annex VI) classification, deadlines to remain as in the relevant ATP (typically 18 months)

Identification of hazardous components

ED, PBT/vPvB and PMT/vPvM substances to be identified on label

Supplier identified on labels must be established in the EU and acting in an industrial or professional activity

 Consumers who buy things online that may come from outside of the EU are not to be regarded as importers



The CLP Revision – Changes to Labelling

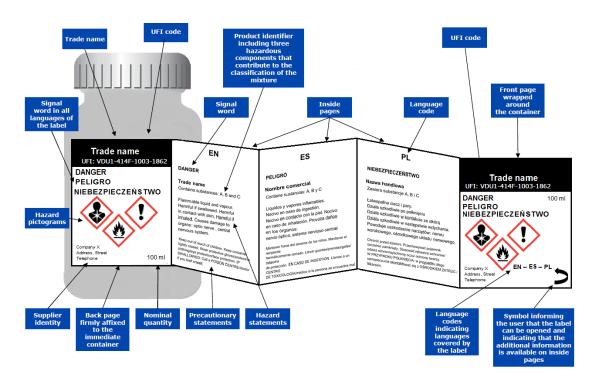
Layout

- Introduces minimum font sizes (see table)
 - Packaging < 10 ml may be smaller but must remain easily legible
- New rules on line-spacing (120% of font size)
- Text must be black on white background
- Single font, easily legible, sans serif
- Letter spacing appropriate to be legible

Capacity of the package	Dimensions of the label (in mm)	Dimensions of each pictogram (in mm)	Minimum font-size (x-height in mm)
≤ 0,5 L	If possible,	Not smaller than 10x10	1.2
≤3 L	at least 52x74	If possible, at least 16x16	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

Fold out labels

- More flexibility to use of fold-out labels on a regular basis
 - Likely to be necessary in future to accommodate increased font size, spacing, etc!
- Rules for content of front, inner and back pages of fold-out
 - Formalises what is currently in ECHA guidance



Other new/amended requirements for labelling

Ammunition

- Ammunition intended for use by defence forces need not be labelled if this would present an unacceptable security risk
- But must provide SDS (or label elements if there is no SDS)
- New derogation for ammunition that is a substance or mixture
- Can be labelled on intermediate or outer packaging

Extended provisions for very small inner packagings (e.g. writing instruments) < 10 mls (Annex I, section 1.5.2.4)

- Currently limited to R&D chemicals, extended to other products as long as they are not classified in severe health hazard classes and categories
- Intermediate/outer packaging must be fully labelled

Products supplied without packaging (Article 29(3) and Annex II, Part 5)

- Label elements to be visible on the pump for fuels directly pumped into a vehicle
- For fuels pumped into approved containers, copies of label elements to be available to attach to the container





Digital Labelling

- New framework that can be built on as technology develops
 - Initially, limited to provision of some supplemental info
- "Data carrier" (e.g. QR Code) to be accompanied by "More hazard information available online" or similar
 - Accessible for at least 10 years
 - Available within 2 clicks and without registering, passwords, etc.
 - EU data privacy requirements no tracking beyond what is absolutely necessary
 - Must be accessible by vulnerable groups
 - Label elements to be kept together
 - Must be searchable



Packaging and Advertising

Packaging

 Commission to review whether Child Resistant Fasteners should be extended to other hazard classes, particularly Eye Damage 1, within 5 years

Refill sales

- New form of sales to reduce packaging waste and achieve recycling targets
- Clarifies labelling obligations
- Sets out risk management measures to be applied in stores, etc.
- Only allowed for certain hazard classes

Advertising

- Any advertisement for a substance or a mixture classified as hazardous shall not contain statements ('non-toxic', 'nonharmful', 'non-polluting', 'ecological') that shall not appear on the label or packaging of that substance or mixture
- Advertising to show labelling info pictograms, signal words, H and EUH statements



The CLP Revision – Notifications

C & L Inventory (substances)

- Publication of
 - the names of notifiers [NB can be claimed as confidential]
 - the reasons for diverging from the most severe notified C&L
 - the reasons for introducing a more severe notified C&L
 - 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

Poison Centres (mixtures)

- Introducing targeted notification obligations to poison centres in case of information loss
- Obligations to notify poison centres for relabellers, rebranders and distributors that are further distributing to another MS



The CLP Revision – Other





Promote harmonisation of 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



Guidance updates

ECHA working on a number of updates to classification guidance

New hazard classes – expected Sep/Oct 2024

CLP 2.0 changes (MOCS, etc) – publication 2025?

Practical guide on read across – publication 2025?

Updated introduction to CLP guidance and updated Labelling guidance - Publication 2025?



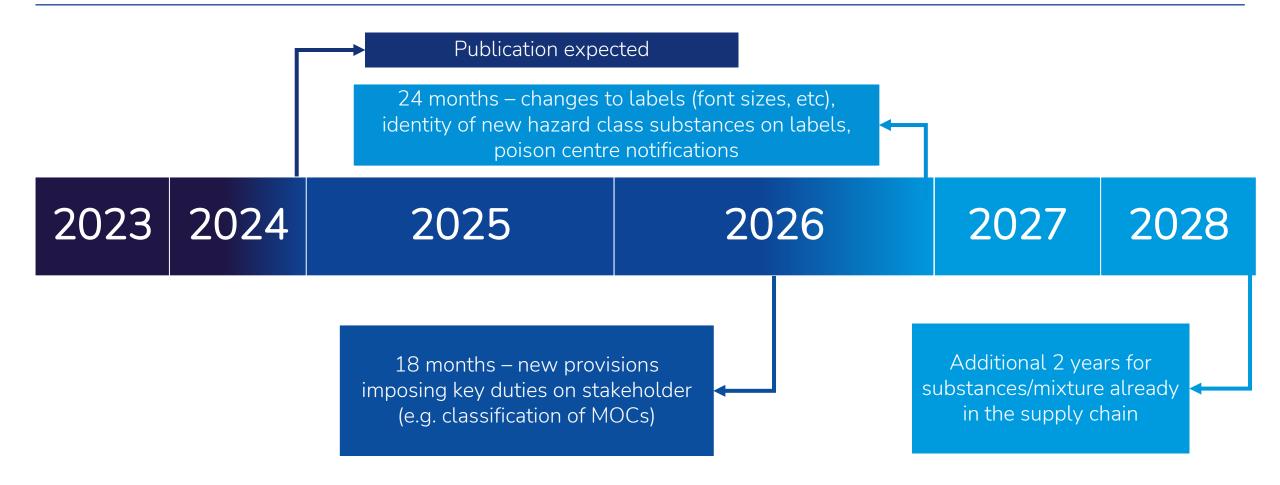
IT tools update

Updated in May to include new hazard classes

C&L Inventory to be added to ECHA CHEM – Autumn 2024



CLP Revision – Provisional Timetable



N.B. Updates to guidance and to ECHA IT systems also needed



Legal Text

- Background to the proposal https://www.europarl.europa.eu/legislative-train/theme-a-european-green-deal/file-revision-of-the-rules-on-classification-labelling-and-packaging-of-chemicals
- Latest version of the legal text (Corrigendum of the text agreed at the European Parliament in April 2024)
 https://www.europarl.europa.eu/meetdocs/2024_2029/plmrep/COMMITTEES/ENVI/DV/2024/09-04/2022_0432_COR01_EN.pdf
- Next steps:
 - Agreement of the Council of Ministers
 - Publication in the EU Official Journal Dec 2024/Jan 2025?



Other EU Changes

Updates to Annex VI

GHS Updates

Other EU Changes

Annex VI updates

Regulation	Changes	EIF/Application date
21 st ATP (EU) 2024/197	28 new entries, 24 revised entries	EIF 25 January 2024 Applies 1 September 2025
22 nd ATP	27 new entries, 16 revised entries, 1 entry deleted	<u>Draft regulation adopted</u> , Publication expected Q4 2024 Application date approximately 18 months after publication (Q2 2026)
23 rd ATP	Provisionally 26 new entries, 14 revised entries	Work begun Publication target mid 2025?? Application date approximately 18 months after publication

- Plans to update CLP to GHS Revisions 8-10
 - Draft text in development
 - Next steps consultation and finalisation of text
 - Aim to adopt Q1 2025, publication Q2 2025, Transition to end of 2026





GB Changes

Updates to GB MCL

Future changes?

GB Changes

• The GB MCL has been updated several times in the last 12 months:

GB MCL Version	Changes	Entry into Force Date	Final Compliance Deadline
Version 2.0	1 st update: 98 new & revised classifications included	20 October 2023	20 April 2025
Version 4.0	2 nd update: 25 new substances included	2 March 2024	2 September 2025
Version 5.0	Updated to correct legal omission, giving effect to 88 substances included in the 14 th and 15 th ATPs. 2 substances were deleted (titanium dioxide and granulated copper).	26 June 2024	26 June 2024

• Future updates to the GB MCL will be drawn from the Agency Opinions published in https://www.hse.gov.uk/chemical-classification/assets/docs/publication-template.xlsx



GB Future Developments

- HSE starting a review of CLP, BPR and PIC Regulations under powers given in the Retained EU Law Act 2023
 - Original transfer from EU to GB law did not allow any changes in provisions
 - New powers give opportunity to make changes until 23 June 2026
- For CLP looking at measures such as
 - notification (by manufacturers and importers)
 - re-labelling
 - · label formatting
 - chemicals under pressure
 - explosives not in transport configuration
 - 'Keep out of reach of children' pictogram
 - precautionary statements

Look out for further information and consultations later this year/early next year!







Thank you