REACH24H CRAC 2022 by REACH24H Consulting Group

14th Chemical Regulatory Annual Conference

Virtual Forum

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EU CLP Compliance Requirements and future update plans

European Chemicals Agency
Catherine Cornu

13 December 2022

Contents

The CLP regulation

- EU regulation on
  - Classification
  - Labelling and
  - Packaging of substances and mixtures
- Entered into force on 20 January 2009
- Based on the GHS criteria
- Ensures a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles

Main elements of CLP

- Companies to self-classify, label and package their substances and mixtures
- Classification & labelling of hazardous substances to be reported to ECHA
  - published in the C&L inventory on ECHA website
- For some legislations (e.g. pesticides, biocides) and very hazardous chemicals (e.g. CMRs) harmonised classification and labelling process

Classification and labelling of substances and mixtures

- Manufacturers, importers or downstream users (self)classify and label hazardous substances and mixtures
- Classification involves identifying the hazards of the substance or mixture and comparing the hazard information with the criteria laid down in CLP
- Hazard classes are grouped in CLP under the following headings:
  - Physical hazards
  - Health hazards
  - Environmental hazards
  - Additional hazards
- Criteria can change via adaptation to technical progress of Annex I of CLP (ATP)

Notification to the C&L inventory

- Who: Manufacturers and importers of hazardous substances
  - Group notifications possible
- How: submission of a registration or C&L notification
  - System-to-system submission of C&L notifications possible
- What:
  - Name of the notifier (and group notification members)
  - Identity of the substance
  - Classification of the substance according to the CLP criteria
  - Reason for "no classification" if the substance is not classified in a hazard class
  - Specific concentration limits or M-factors, where relevant, including a justification
  - Label elements
- Obligation on notifiers to agree/converge their C&L

The C&L inventory

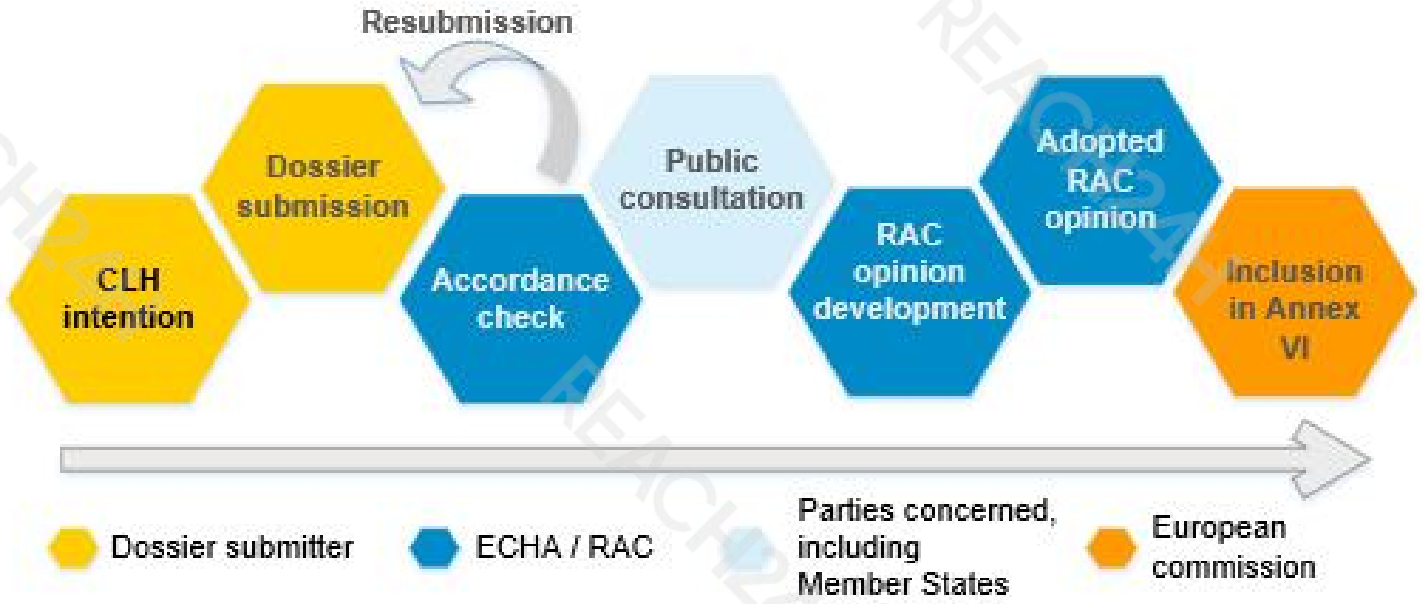
- Available on ECHA's website
  - Searchable
  - Contains ~215 000 entries
- Includes:
  - Companies' self-classifications
  - EU-wide harmonised classifications (where available)
- C&L inventory is being redesigned (launch foreseen in 2024)
  - Adaptation to CLP Regulation revision (some features launching later)
  - Improvement of the presentation of the information

Harmonisation of C&L at the EU level (CLH)

- Focus is on substances with hazard properties ‘that matter most’
  - 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 and biocides
- Companies need to assess the need to classify any hazard class that does not have a harmonised classification

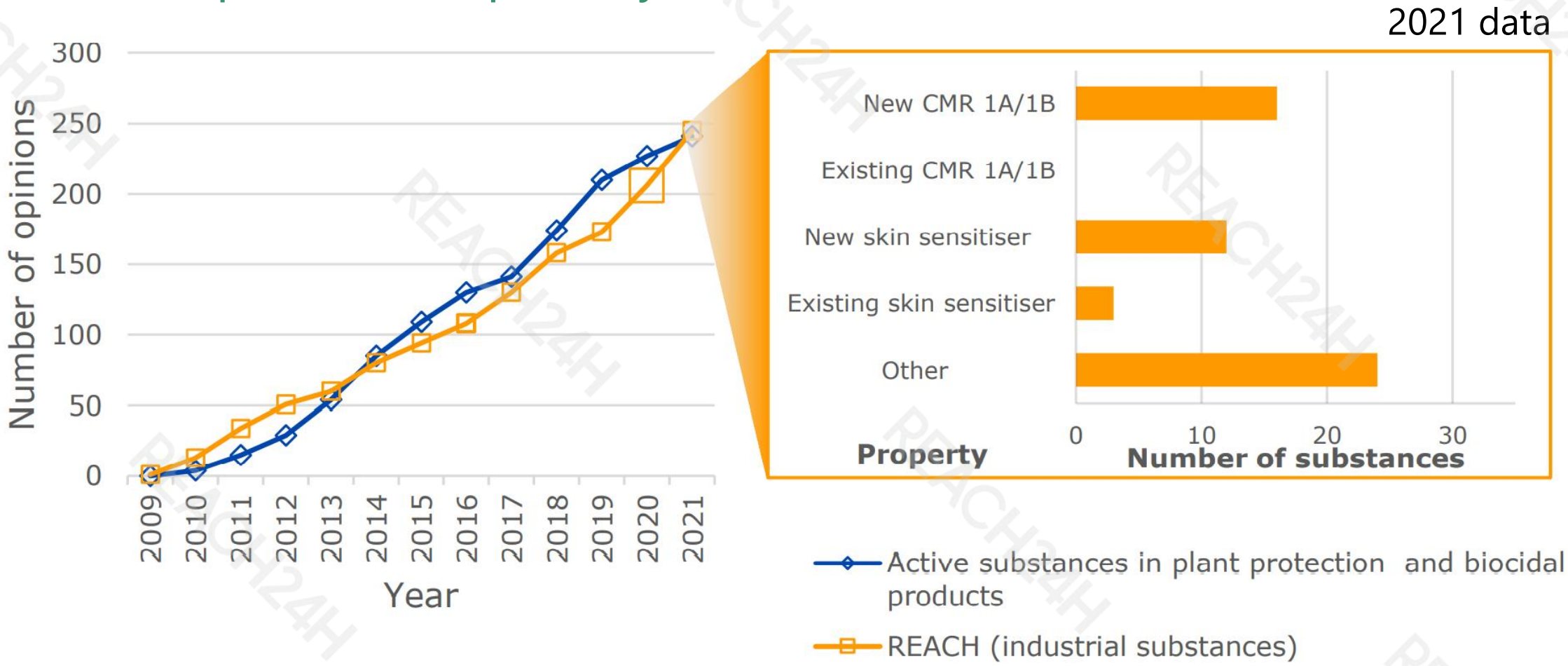
Harmonisation of C&L at the EU level (CLH)

- Member States, manufacturers, importers or downstream users can submit a CLH proposal



- Substances and their harmonised C&L are listed in Annex VI of CLP (via ATP)
- Legally binding - obligatory to be used by every manufacturer, importer and downstream user of the substance within EU

CLH opinions adopted by ECHA's RAC



- Annex VI to CLP counts over 4500 entries (including many group entries, covering about 6000 to 7000 substances)

Contents

Two-part CLP revision planned

- Change of the CLP 'body text'
  - Targeted revision
  - Via Ordinary Legislative Procedure
  - Co-decision via Parliament and Council

- Change of Annex I of CLP
  - Via Delegated Act
  - Commission decision via CARACAL consultations (Competent Authorities for the REACH and CLP Regulations)

https://ec.europa.eu/environment/chemicals/labelling/clp_revision_en.htm

Changes to Annex I of CLP

- Introduction of new hazard classes and setting new criteria
  - Endocrine disruption for human health:
    ED HH Cat 1 (known or presumed) and Cat 2 (suspected)
  - Endocrine disruption for the environment:
    ED ENV Cat 1 (known or presumed) and Cat 2 (suspected)
  - Persistent, bioaccumulative and toxic or very persistent, very bioaccumulative:
    PBT/vPvB – without subcategories
  - Persistent, mobile and toxic or very persistent, very mobile:
    PMT/vPvM – without subcategories
- Definitions
- New hazard statements (EUH)
- Generic concentration limits/mixture classification
- No symbol/pictogram for the new hazard classes

Expected timelines for entry into application of changes to Annex I

- Commission proposal by end 2022
- Entry into force Q2 2023
- Transitional period for classification and labelling of new
  - Substances: 24 months → starts Q2 2025
  - Mixtures: 36 months → starts Q2 2026
- Transitional period for reclassification and relabelling of existing
  - Substances: 42 months → starts Q4 2026
  - Mixtures: 60 months → starts Q2 2028

To be confirmed

- ECHA guidance and IUCLID update planned for May 2024

Changes to CLP 'body text' foreseen in the Chemicals Strategy

- Commission right of initiative
  - Commission can request ECHA to prepare CLH proposals
- Amend hazard categories normally prioritised for CLH
  - Add new hazard classes
- …

Expected timelines for entry into application

- Commission proposal by end 2022
- Time needed for discussion in Council and Parliament
- Entry into force earliest Q2 2024
- With 18 months transitional period →
- Entry into application earliest Q1 2026

To be confirmed

Contents

Take-home messages

- Classification and labelling is not a one-off exercise: registrations, C&L notifications and the communication in the supply chain and to consumers need to be kept up-to-date as scientific knowledge develops, the CLP is adapted to technical progress and undergoes revision
- The CLP revision will introduce new hazard classes. Prepare your strategy for getting ready to implement them for your exports to the EU
- Legislation evolves: follow ECHA on our comms channels for regular updates

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THANKS