# CLP Regulation – Recent implementation and issues

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Dr. Blanca Serrano

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# CLP Regulation

## Introduction

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- **Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation)**
  - CLP = Classification, Labelling and Packaging
- Before CLP, classification and labelling (C&L) of substances and mixtures was implemented through three Directives:
  - Dangerous Substances Directive (67/548/EEC); (DSD)
  - Dangerous Preparations Directive (1999/45/EC); (DPD)
  - Safety Data Sheet Directive (91/155/EC, as amended by 2001/58/EC). (SDSD)
- Objectives have not changed: identify and communicate physicochemical, toxicological properties and ecotoxicological hazards.

- From Europe to Global: The CLP Regulation implements the United Nations (UN) Globally Harmonized System (GHS), adopted in July 2003
  - GHS aims to achieve global harmonization of the requirements of classification and labelling of substance and mixtures throught the world. To ensure their safe use, transport and handling.

- From Directives to Regulation.
  - Directive implemented through legislation adopted at Member State Level.
  - Regulation direct implementation in every Member State.

# CLP

- UN GHS is based on a building block approach.
  - Facilitate its implementation across regions (existing differences).
  - Each country selects the building blocks of GHS it will use in their different sectors (workplace, transportation, consumers).
  - Intention: to overcome the differences within sectors over time (differences between different sectors may remain)
- 3 Hazard groups in GHS: physical hazards, health hazards and environmental hazards
  - Each has several hazard classed and the classes can be further divided in categories.
- CLP contains all the GHS hazard classes but some of the hazard categories have not been taken up for consistency reason with REACH.
- CLP is hazard based and does not consider risk assessment.
- The Regulation entered into force on 20th January 2009.

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**20 January 2009: CLP Entry into force. DSD/DPD still apply.**

- 2 possibilities:
  - Classify and label only DSD/DPD for substances and mixtures.
  - Classify CLP and DSD/DPD, label either CLP or DSD/DPD for substances and mixtures.

**1 December 2010: CLP only Classification and labelling of substances.**

- Substances:
  - Classified under both CLP and the DSD
  - Labelling and packaging only CLP.
- Mixtures 2 possiblitires
  - Classify and lael only DPD
  - Classify CLP and DPD, label either CLP or DPD
- Note: Substances already labelled DSD before 1/12/2010 might remain the market until 1/12/2012

**3 January 2011 Deadline to notify C&L to the C&L inventory**

- Notification of substances only.
- Notifiers used information available to them,
- No obligation to produce new data.

**1 June 2015: DSD/DPD repealed;**

- Classification, labelling and packaging of substances and mixtures according to CLP only.
- Note: Substances already labelled DPD before 1/06/2015 might remain the market until 1/06/2017

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# CLP implementation

## Obligations and roles

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# nd roles: Manufacturers and importers

a. Classification, labelling and packaging of substances and mixtures before they can be placed on the market

b. Classify substances not placed on the market subject to registration or notification under REACH (including substances used for product and process-orientated research and development – PPORD)

c. Notify classification and labelling elements for substances placed on the market in the EU as well as substances imported in mixtures or articles to the Classification & Labelling Inventory managed by ECHA

d. Keep abreast of scientific and technical information and re-evaluate classifications when new information that may affect the classification becomes available

e. Update labels for changes in classification

f. Notify ECHA regarding new information relevant to harmonised classifications

g. Assemble and keep available all information required for classification and labelling for a period of at least 10 years after last supply.

h. Notify information to Poison Centres according to Annex VIII of CLP

# nd roles: Downstream users

a. Classification, labelling and packaging of substances and mixtures before they can be placed on the market (including in the event of a change of composition)

b. Keep abreast of scientific and technical information and re-evaluate classifications when new information that may affect the classification becomes available

c. Update labels for changes in classification

d. Notify suppliers regarding new information relevant to harmonised classifications

e. Assemble and keep available all information required for classification and labelling for a period of at least 10 years after last supply.

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# nd roles: Producers of articles

a. Conform to CLP requirements if producing and marketing an explosive article

b. Classify substances not placed on the market subject to registration or notification under REACH

c. Update labels and packaging based on new data.

# nd roles: Authorities

a. Proposals for and agreement of harmonised classifications (i.e. a CLH dossier)

b. Establishment of a national helpdesk

c. Establishment of a body or bodies (i.e. poison centres) to be responsible for receiving information on mixtures placed on the market relating to emergency health responses

d. Enforcement.

# nd roles: ECHA

a. Management of the C&L Inventory

b. Overseeing the Scientific Committee process for agreement of harmonised classifications (i.e. a CLH dossier)

c. Operation of a centralised helpdesk

d. Managing online system for handling downstream user requests relating to Article 24

e. Overseeing the Forum and its practices and projects relating to enforcement and implementation of CLP

# Encountered issues

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# cation of substances and mixtures under CLP

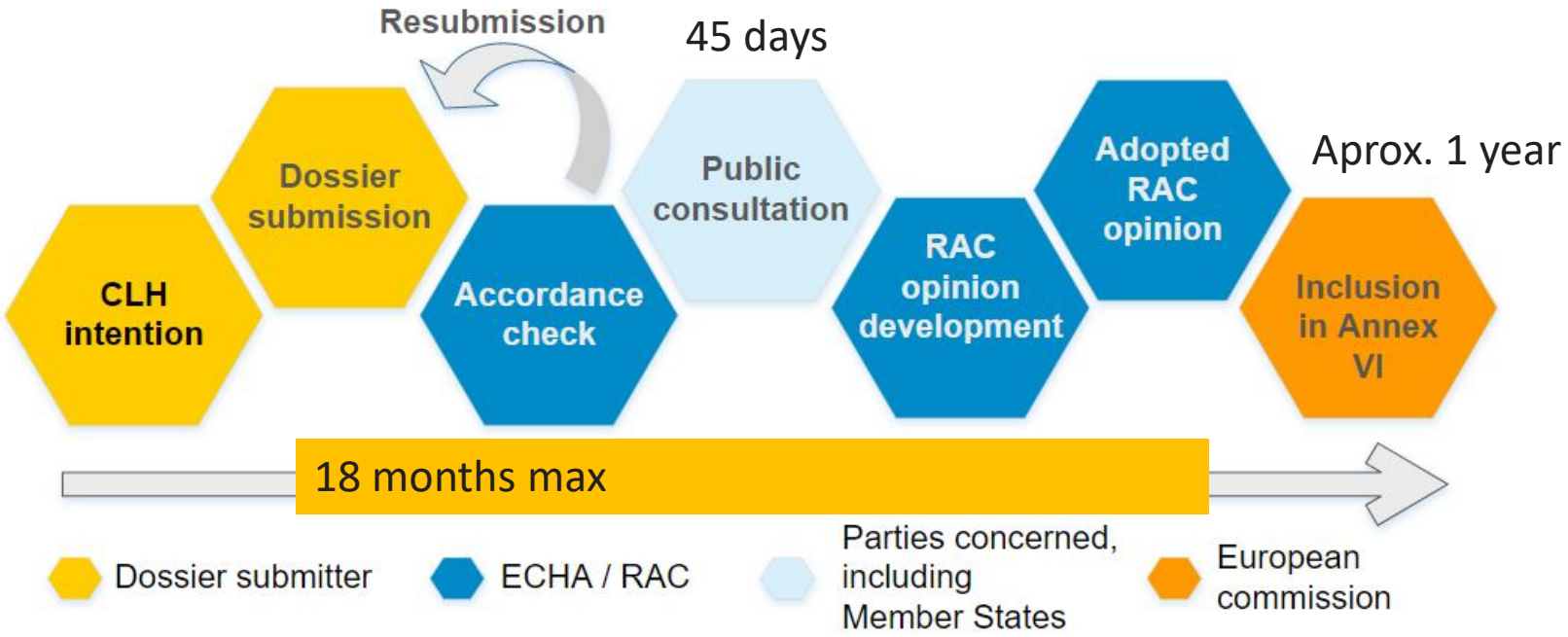
- CLP is consider a more readily system than the DSD, allowing more consistency across MS.
- Depending on the method use (testing, weight of evidence, calculation…) classifications differ.
- CLP does over classify substances/mixtures for skin corrosion and skin irritation. (Over 68.000 substances self-classified.)
  - This reduce the effectiveness of hazard classification; sends incorrect message.
  - Has effect on the reuse, recycling and circular economy.
- Reasons:
  - Lack of clarity on how to apply bridging principles to classify mixtures (e.g. Detergents). Some MS allow the use of bridging principles others do not.
  - Difficulties using classification rules to reflect bioavailability. (Metal & alloys)
  - Lack of methods to assed combination effects.

# classification

- The harmonisation of classifications and inclusions in Annex VI was one of the key cornerstones of CLP.
  - It triggers risk management in the downstream legislation.
  - CMR*, sensitisers or equivalent concern are subject to harmonised classification.
  - 3370 substances in 2009, 4537 January 2017.
- Issues found:
  - Most harmonised classification refer to plant protection products (PPP) or biocidal products (BPR).
  - Industry proposals for re-classification of substances on Annex VI do not have enough support from MS.

*CMR: Carcinogenic, mutagenic or reprotoxic.

# classification




- The dossier submitter is:
  - MS or ECHA for CMR, PBT or equivalent concern.
  - Industry for any type of substance supported by a MS.

Source ECHA

# e data

- Data requirements are consider in general adecuate.
- New test have to be carried our following GLP*, older data accepted if reliable.
- More alternative methods (non animal testing) are needed. UN GHS, OECD work toward this objective is being carried out.
- Issues found:
  - Academic sources are sometimes not taken into account because not GLP.
  - Testing cost are high, specially with the lack of enough non animal testing methods.

*GLP: Good laboratory practices.

# ion

- Communication done through:
  - Labelling
  - ECHA Classification and Labelling Inventory
  - Communication to Poison Centres (under development)

# ion: Labelling

- Objective: ensure that information or physical hazards and the (eco)tox properties is available to ensure protection during handling, transport, storage and use.
- Identified issues:
  - Pictograms are not well understood by consumers.
  - Same pictogram for different hazards (e.g. CMR/Acute toxic), causes overalarms.
  - Inflationary labelling diminishes effective hazard communication. (Habituation effect)
  - Labels contain too much information.

# on: Classification and Labelling Inventory (C&L Inventory)

- The C&L Inventory is the largest database of self- and harmonised classified substances available today.
- Issues encountered:
  - C&L notifications are not verified by ECHA
  - Notifications done with available information, resulting in (very) different classifications for the same substance.
  - In the brief profiles even clearly wrong classifications are showed.
  - Only the notifier can remove/modify a classification submitted. Since 2010 many companies have disappeared, change Legal Entity, name… Impossible to reach them.
  - No easy solution to remove the wrong classifications has been found. An implementing act allowing ECHA? to act would be needed.

# on: Poison centre reporting obligations

- Art. 45 of CLP establish the obligation to submit information for those mixtures classified as hazardous for health or physical hazards to the appointed bodies of the MS necessary for emergency response.
- COMMISSION REGULATION (EU) 2017/542 of 22 March 2017 adds Annex VII to harmonize the information that needs to be submitted.
- The creation of a centralised submission portal is still under debate.
- Information has to be sent to all MS where the mixture is placed in the market.
- Information has to be sent in the language of the MS (or if allowed in English)
- The information submitted depends on the category of use: industrial, professional, consumer.

* http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0542

# ion: Poison centers, obligation to notify

- Who:
  - Importer or Downstream User that places mixtures on the market.
- What:
  - Mixtures classified as hazardous for **human health** or **physical hazard.**
  - Excluded: Mixtures classified for environmental hazards, gases under pressure or explosives.
- When:
  - Mixtures for consumer use: January 1st 2020
  - Mixtures for professional use: January 1st 2021
  - Mixtures for industrial use: January 1st 2024
  - **Before placing in the market!**
- How:
  - Using an harmonize Poison Centre Notification (PCN) format.
- Where: 2 options
  - Directly to the appointed bodies of the Member States where the mixture is placed on the market.
  - Through the ECHA PCN portal.

# on: Poison centre existing tools

- Each mixture will be identified by a Unique Formula Identifier (UFI)
  - UFI Generator: https://ufi.echa.europa.eu/#/create

- The Poison Centres notification format and editor can be found here: https://poisoncentres.echa.europa.eu/poison-centres-notification-format

# ion: Poison Centres, Required information

- General information
  - Product identifier
  - CAS, EC number of all mixture components
  - Unique Formula Identifier (UFI)
  - Contact details of the submitter
- Hazards identification
  - Classification of  the mixture and label elements
  - Toxicological information (Section 11 of the Safety Data Sheet (SDS))

# ion: Poison Centres, Required information

- Information on mixture components
  - Components of the mixture and their concentration, even not classified as hazardous.
  - Concentrations can be expressed as exact percentages or as a range of percentages.
  - Major concern components have tighter concentration ranges than other components, they are:
    - Acute toxicity, Category 1, 2 or 3,
    - Specific target organ toxicity, single and repeated exposure, Category 1 or 2,
    - Skin corrosion, Category 1, 1A, 1B or 1C,
    - Serious eye damage, Category 1.

- Additional information
  - Type(s) and size(s) of the packaging
  - Colour(s), physical state and pH
  - Product category according to the EU Product Categorisation System (In preparation by ECHA)
  - Use (consumer, professional, industrial)

# ion: Poison Centres, Challenges to industry

- Very complex regulation: New obligation in addition with the already upcoming deadlines, last registration, changes in IUCLID, REACH updates…
- Resources have to be dedicated to fulfill this new obligations: training and support will be critical
- Definitions still need to be clarify
- Knowledge of uses along the supply chain is not always possible, confidentiality, competition law…
- Timelines very tight. New IT tools and guidance will be ready shortly before the entering into force, no time to get acquainted with the system
- There are still workability issues under discussion on compositional information in some sectors (petroleum products, construction sector etc…)
- Protection of sensible data and confidentiality needs to be guaranteed by ECHA and all the appointed bodies
- Fees in some MS: creates competitivity issues

- CLP has not effectively incentivised substitution.
- The reduce use of, or exposure to hazardous substances is questionable.
- The substances used to substitute are in some cases as hazardous or more hazardous than the substance they are replacing.
  - In the future they could also be subject to substitution!
- Unintended consequences:
  - Loss or efficient active ingredients – replaces by less efficient, higher quantities are used. Costly and potentially as hazardous.
  - Impact in downstream legislation, same classification for different forms can for example affect the reuse or recycle of substances.

# sruptors

- Endocrine disruptor (ED) criteria are not define in CLP.
- ED are considered of equivalent concern.
- Different with PPP and BPR
- Commission has published already draft criteria for PPP and BPR.
- Possible modifications, unclear how to proceed.

*European Commission (2014): Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the PPP Regulation and the BPR, Roadmap published June 2014. Available at: ttp://ec.europa.eu/smartregulation/ impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf

# assessment consequences…

- CLP is hazard based, generic risk assessment is applied
  - Based on the intrinsic properties and general assumptions.
  - CMR, PBT and ED trigger automatic bans in some downstream users legislations.
  - Leads to overregulation – e.g. relevant route of exposure excluded in the products downstream, but the ban applies.
  - Might lead to “regrettable substitution”.
  - Does not take in account technical feasibility, social interest or socioeconomic reasons.
  - Impact in EU competitiveness.

# c risk assessment

- REACH is risk based, specific risk assessment is applied
  - Exposure is taken into account.
- Other legislations that take exposure into account: cosmetics, authorization process and restriction in REACH.
- More costly.

# tation and the single market

- Differences across MS in the acceptance of use of read across, bridging principles – Lack of harmonization.
- Different criteria among MS to accept harmonize classification dossier for PPP and BPR.
- Classification of PPP varies among MS.
- Different enforcement regimes for each MS.

# es on competitiveness and innovation

- Significant cost derived from the compliance with CLP, resources previously dedicated to innovation are now deviated to regulatory compliance.
- CLP applies GHS in Europe.
  - UN GHS still in revision, constant changes, transposed to CLP via adaptations to technical progress (ATP).
  - Differences in the sectoral scope of implementation across regions – Lack of harmonization.
  - Differences in labelling, hence hindering trade.

# rising from the implementation of CLP and not foreseen

- Poison centres notification issue. More costly and complicated than expected, main CLP priority for Cefic at the moment.
- The implementation of UN GHS revisions result in continues changes in the C&L requirements. Hence labels have to be change more frequently than expected with high cost deriving from that, with very little benefit.
- The ED criteria now under discussion could lead to automatic bans not foreseen 10 years ago.

# Conclusions

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# at the moment

- Overclassification of mixtures
- Divergent interpretations and implementation of certain classification rules, like bridging principles among MS
- Labels overcrowded with information – poor communication.
- Poor quality of the C&L inventory
- Continues changes lead to increase of cost (relabelling, updating SDSs…)
- Poison centres requirements not foreseen
- Classification leading to regrettable substitution

# Thank you for your attention!
# Questions?