Classification & Labelling and the work of the ECHA Risk Assessment Committee (RAC)

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FIP National Experts meeting on BPA
29 October 2012

EC 1272/2008 Classification, Labelling and Packaging (CLP) of substances and mixtures

- Provides for C&L of substances and mixtures incl. Community-wide harmonization
- Replaces Dangerous Substances Directive (DSD) 67/548/EC
- Amends parts of REACH
- Brings EU C&L practice into line with the UN Globally Harmonised System (GHS)
- Currently has two notation systems:
  - DSD notation (e.g. Repro. Cat. 2, R61) until June 2015
  - CLP notation (e.g. Repro. 1B, H360D)

- Art 36: general principles on when a substance needs to be harmonised
- Art 37: the who, what and how - (4) empowers the ECHA Committee for Risk Assessment to prepare CLH opinions
- Art 38: describes the content of opinions and decisions, accessibility of information
- Annex VI: Entries for harmonised substances with classification and labelling according to both CLP and DSD

ECHA Committees

- Member State Committee (MSC)
  - REACH: SVHC, Testing Proposals, Substance Evaluations
  - CA Representatives
- Risk Assessment Committee (RAC)
  - REACH Restrictions, Authorisations (risk & impact assessment); Classification & Labelling
  - Independent experts nominated by MS and Appointed by ECHA Management Board
- Socio-Economic Committee (SEAC)
  - REACH Restrictions, Authorisations (SEA and Alternatives)
  - Independent experts nominated by MS and Appointed by ECHA Management Board
- Forum
  - REACH Restrictions, Authorisations also has an indirect role in CLH
  - MS Representatives from Enforcement Agencies
- Biocides Committee

Endpoints subject to harmonised classification (Art 36)

- For industrial chemicals: carcinogenicity, germ cell mutagenicity, reproductive toxicity and respiratory sensitisation (CMR & RS)

- For BP/PPP: usually all endpoints

Physical hazards
Health hazards
Environmental hazards
Additional EU hazard

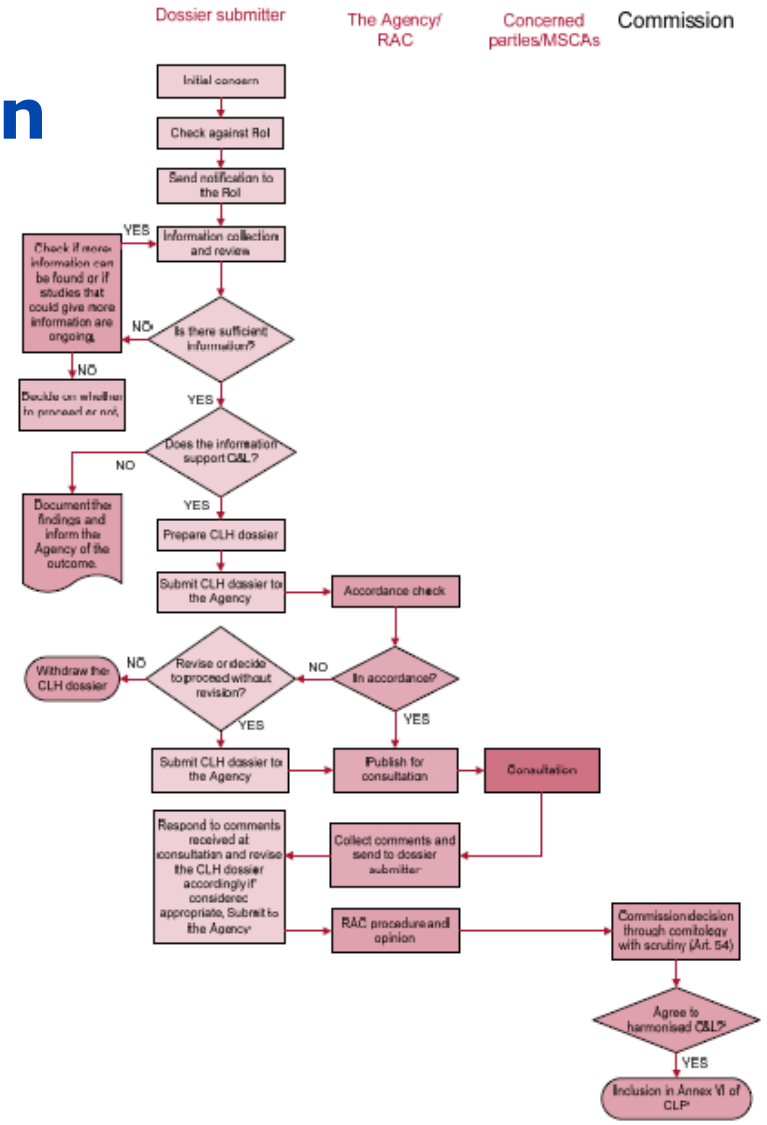
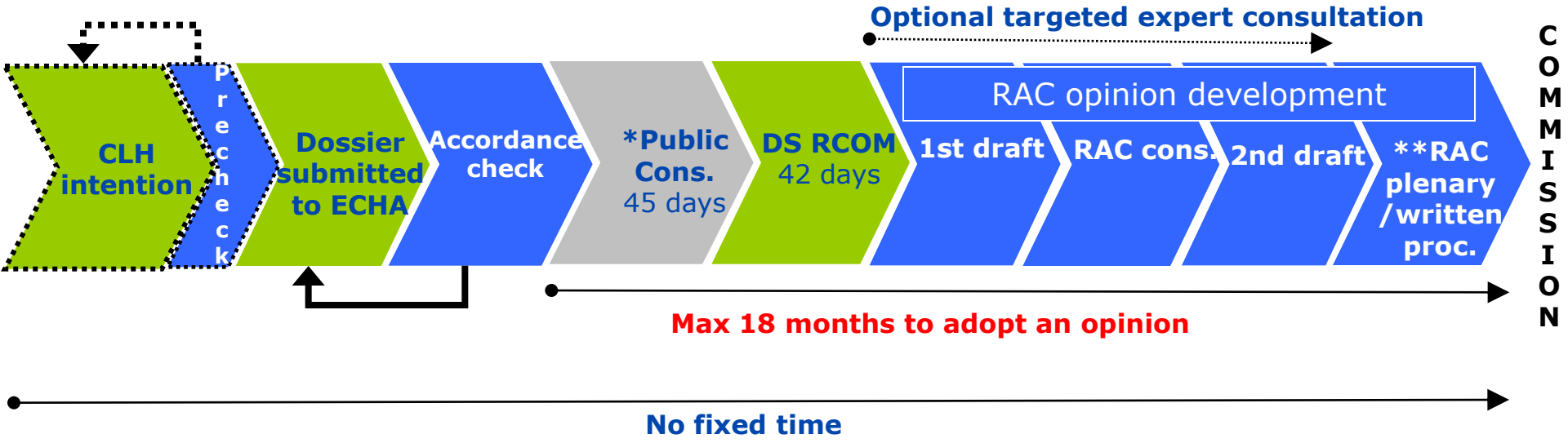


Figure 1: Overview of the preparation and further processing of a CLH dossier

CLH process overview

Main actors

- Dossier submitter (DS)
- ECHA/RAC
- Parties Concerned including MSs



* The Public consultation is launched only for dossiers that are in **accordance with CLP legal requirements and CLP/DSD C&L criteria**

** The adoption of the opinion may require **more than one** plenary discussion

Actors and roles in CLH

- **Dossier submitter**: Prepares a dossier and initiates the CLH process
- **Committee for Risk Assessment (RAC) and its Rapporteurs**
  - Independent experts (currently 39) nominated by MS but appointed by the ECHA Management Board
  - Examines the proposals for CLH and provides an opinion on the proposed harmonised classification of substances to the Commission
- **Parties concerned:** Provide comments during the Public Consultation (MSCAs, Industry, NGO's etc.)
- **ECHA-secretariat**: manages the CLH process; provides technical, administrative and scientific support (through a Scientific Dossier Manager, SDM) to RAC and the Rapporteurs
- **Commission:** observes RAC; after an opinion has been adopted, decides whether the CLH of the substance should be included in Annex VI of the CLP Regulation

Accordance check (ACCH)

- ECHA performs an accordance check of the dossier, RAC Rapporteurs provides their observations
- The CLH report is a stand-alone document for RAC to develop an opinion on CLH
- Accordance Check letter + annexes issued to the DS
- If the CLH dossier is not in accordance, ECHA provides suggestions to fulfill the legal requirements

Public consultation (PC) and follow-up

- Critical to adequate information gathering for the opinion
- Preferred point of stakeholder involvement
- Lasts 45 days
- Launched by an ECHA press release
- DS and MS may use the opportunity to comment
- Rapporteur responds to collected comments via the RCOM table
- Initiation of the opinion development process by ECHA and RAC
- Issue identification by the SDM - screens the PC comments and DS's reponses - discusses with the rapporteurs
- The optional targeted expert consultation including parties concerned may be initiated