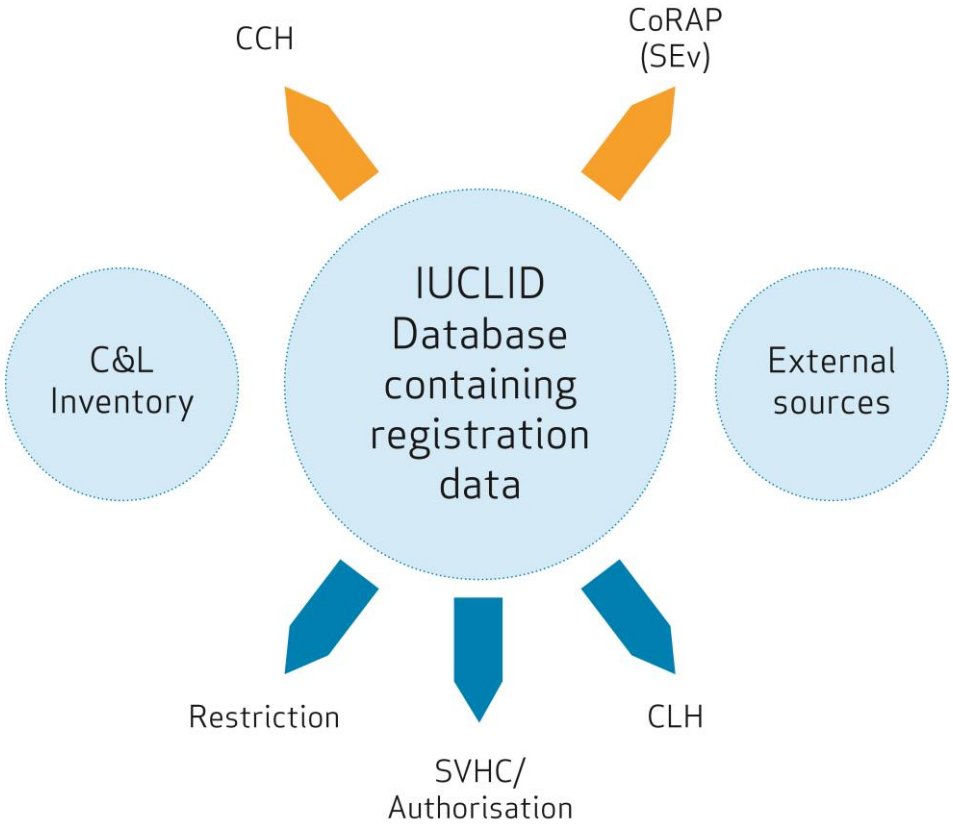
A Common Screening Approach for REACH and CLP Processes

1. Introduction

To focus the work under different REACH and CLP processes to the substances that matter most, there is a need to identify substances of potential concern. These cover substances for which further information is needed to conclude on the hazards or risks they might pose and substances for which there is a need to consider further regulatory action.

To this end ECHA has developed, in collaboration with Member State Competent Authorities, a screening approach to systematically screen the available information for substances in both REACH registration dossiers and other databases to identify substances for the following REACH and CLP processes:

- Compliance Check under **Dossier Evaluation**;
- Community Rolling Action Plan (CoRAP) under **Substance Evaluation;**
- Potential further regulatory risk management measures under the REACH and CLP Regulations i.e.:
    - **Harmonised Classification and Labelling**
    - **Authorisation**
    - **Restriction**



2. What is screening?

The term "screening" covers the identification and investigation of substance (and dossier) specific information to make a preliminary assessment on whether that substance (or dossier) should be handled via a particular REACH or CLP process.

This covers all identification/investigative work carried out before the substance (or dossier) enters into one of the processes mentioned in **Section 1** above or it is concluded that based on the information currently available no follow-up action is required at present.

The information provided in the REACH registration dossiers and C&L Inventory is the starting point for identifying potential substances of concern. Other regulatory and experimental information from external sources and predictive methods are also used.

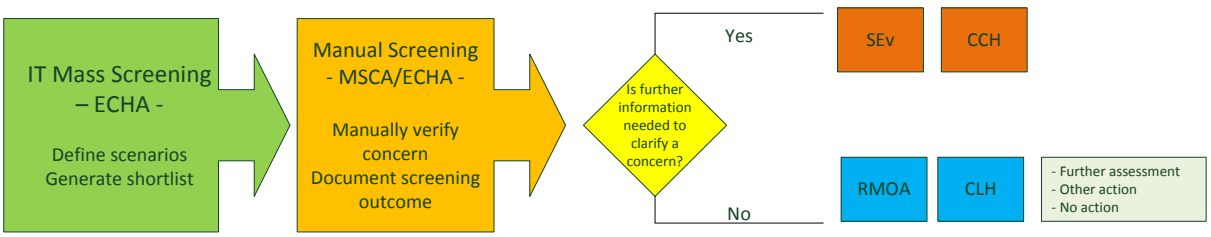
3. Why a common screening?

The REACH and CLP processes described above are all inter-linked as they all share the same aim of identifying, clarifying and managing the hazards and risks posed to human health and environment.

The ultimate goal of the common approach is to have substances with certain hazard(s) (human health, environment), exposure and ultimately risk profiles, i.e. substances which matter most[1], identified and processed via the most appropriate REACH or CLP process. This common approach is intended to ensure the swift progress of the screening activities, avoid duplication of work and minimise the risk of having the same substance being identified as suitable candidate for different processes unless there are valid reasons for that and the parallel processing is done in a co-ordinated manner.

4. Screening workflow

Due to the sheer volume of substance information available, it is resource effective to use ECHA's expertise and IT infrastructure for screening, thereby extracting and processing the relevant information automatically. However, there is a need for close collaboration with MSCAs in developing the search criteria used to identify substances in order to provide suitable candidates for manual screening that match with the priorities of MSCAs.



There are several steps involved in the screening, separated into two different phases:

[1] Please see the Safer Chemicals Strategy for more information: http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

1) IT mass screening phase and

2) manual screening phase

First, screening scenarios, specific to the REACH or CLP processes (CoRAP, SVHC and CLH), are defined in the screening definition document[2]. These screening scenarios are then translated into IT algorithms, which are then applied by ECHA's IT Tools to the REACH and CLP databases.

Manual screening is defined as a targeted, substance or dossier specific assessment of the information provided in the registration dossier(s) in relation to the search criteria applied. This manual screening is intended to scrutinise the outcome of the automated IT mass screening and to verify and better define the identified SVHC/CLH hazard profile or the risk based concerns of relevance for substance evaluation and/or compliance check. Authorities manually screen the substance from the perspective of all endpoints, where possible. The structural similarity of substances on the short list, both within the list and other substances previously assessed (e.g CoRAP candidates) is checked and substances grouped accordingly.

If a concern is identified for the substance in question, the next question the MSCAs has to answer is 'what is the most appropriate next step (REACH or CLP process) for that substance'?

The following **outcome options** of the manual screening can be selected:

- Candidate for Substance evaluation (Selection of a CoRAP Substance)
- Candidate for Further Regulatory Risk Management:
    - Risk Management Option Analysis (RMOA)
    - Proposal for Harmonised Classification and Labelling (CLH) at EU level
- Need for further assessment before the SVHC properties are confirmed and further regulatory risk management can be decided (e.g. the substance needs to be further assessed and discussed by the PBT or ED Expert Groups)
- Candidate for the compliance check (CCH) – Standard Information requirements are not fulfilled
- Need for other action (e.g. enforcement or action under other regulations)
- No need for further action.

The outcome of manual screening is recorded and used as input in subsequent screening rounds.

5. Screening timelines

ECHA and Member States/COM (via Coordination Groups (CGs) and Expert Groups (EGs)) and stakeholders (via EGs) collaborate closely in the steps to define the screening scenarios and to perform the manual screening.

[2] The Screening Definition Document is accessible at the following link:
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

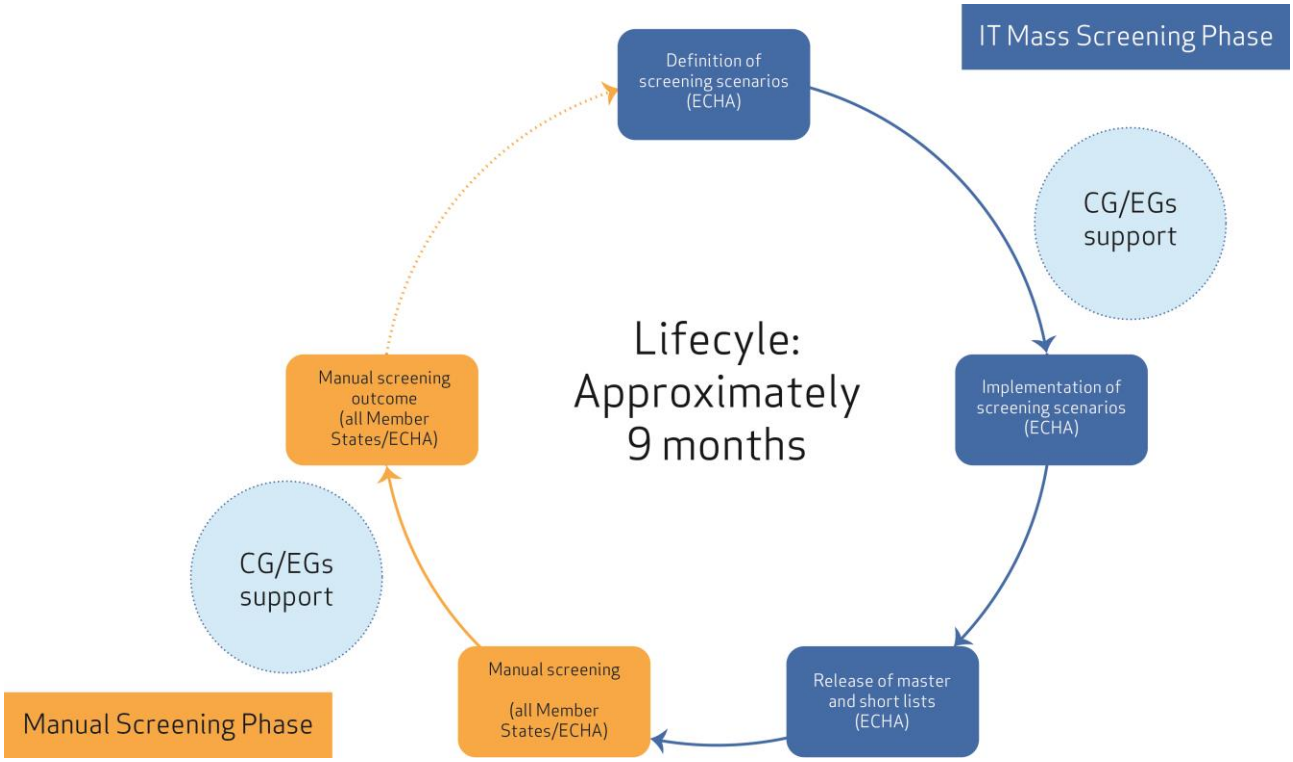


Figure 2: yearly round of screening

As illustrated in Figure 2 above, the screening workflow takes approximately 9 months to complete. The timelines associated with the screening workflow are made up of two components 1) IT mass screening phase: the time it takes to define and implement the screening scenarios to produce the master and short lists, which is typically 6 months and 2) manual screening phase, which is typically 3 months.

ECHA consults with Member States, Commission and Stakeholders to provide suggestions on how the screening methodology can be further improved with the purpose of creating a single screening result set that serves the widest possible range of concerns. The aim is to increase transparency and confidence in the screening results, by carefully documenting the search criteria. This consultation is done via the PBT and ED Expert Groups[3] and CMR and SenS Coordination Groups[4].

The general description and philosophy behind the developed scenarios is publicly available on ECHA website in the Screening Definition Document. No substance specific information is available to the public at the level of screening. Substances are shortlisted based on automated IT screening and verification needs to be done manually.

[3] Accessible at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pbt-expert-group
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/endocrine-disruptor-expert-group
[4] Accessible at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/coordination-groups