Common Screening

ECHA Webinar - How are substances screened and shortlisted

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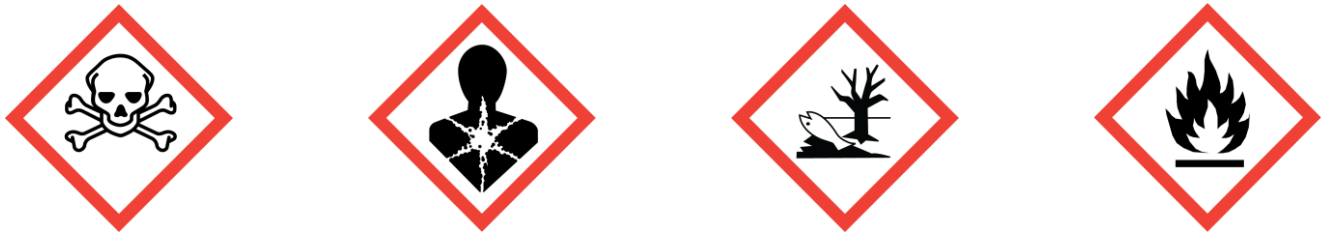
- What is common screening?
  - Integrated screening of substances of concern
- How are substances selected for screening?
  - Identification and prioritisation
- What happens after screening?
  - How you can follow the process for your substance
- Where are we now?
  - Statistics from past rounds of screening
- How can registrants influence the outcome?
  - Dossier updates

Common screening approach

Aim: Identify and prioritise those substances where regulatory action can best increase protection of human health and the environment

Substances that matter most



Integrated screening

Use of **all available data**

Allocate identified substances to the appropriate process (**if any**):

Generation of further information

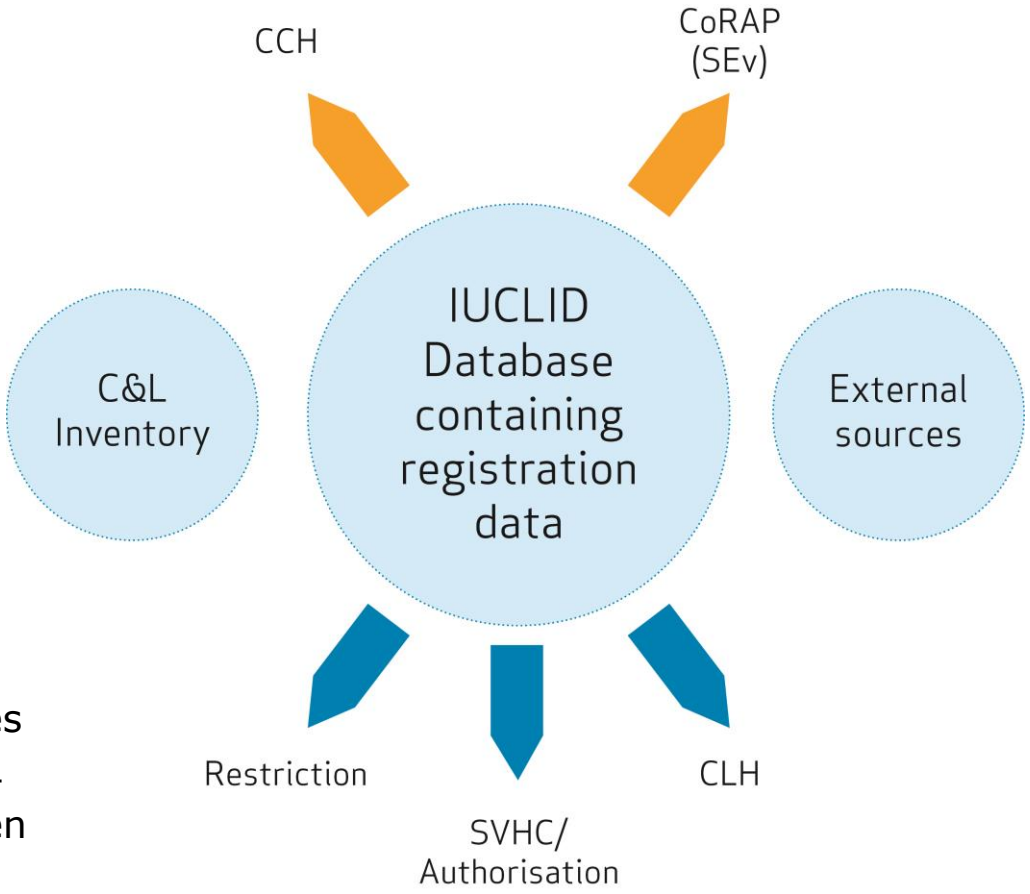
- Substance evaluation (SEv)
- Compliance check (CCH)

Regulatory risk management

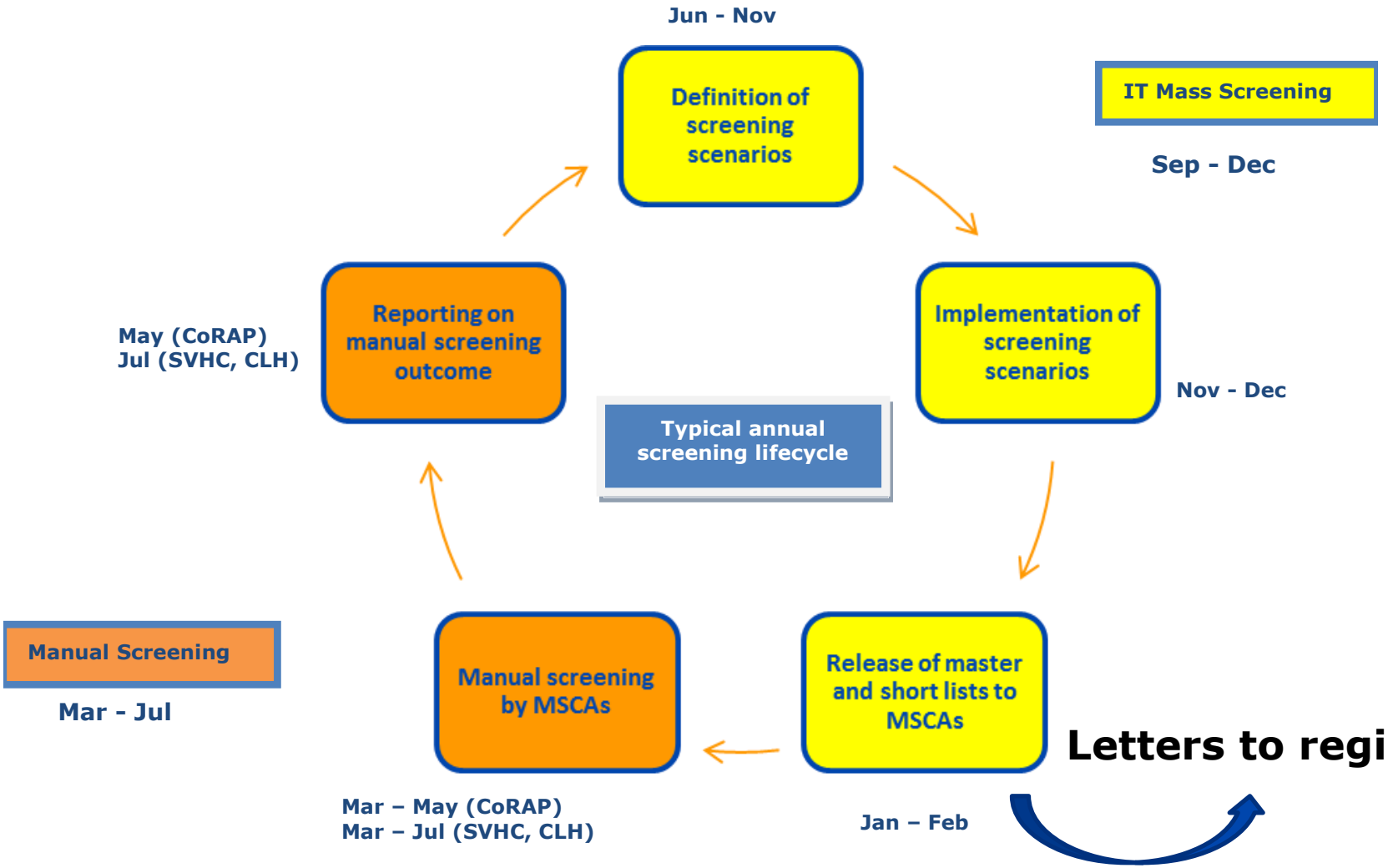
- Harmonised classification and labelling (CLH)
- Identification of SVHCs (possibly leading to Authorisation)
- Restriction

Fully integrated approach:

- Optimal use of resources
- Avoids parallel processing of substances
- Ensures that the most effective regulatory option for each substance is chosen



Screening timelines



How are substances selected?

Identification and prioritisation

Shortlisting for manual screening

Two-step approach using IT screening

- Substances identified based on hazardous properties or data gaps
  - Hazardous to human health or environment

AND

- Prioritised based on uses and exposure information
  - High potential for exposure

Hazard identification

- All available data used for hazard identification
  - REACH registration dossiers
  - C&L notifications
  - External regulatory programs or lists
  - Predictive (*in silico*) methods
- IT screening to search for either indications of hazard or data gaps in hazard endpoints
- Focus on eight super endpoints
  - Human health: CMR, Sensitisation, ED
  - Environment: PBT, vPvB, ED

Use and exposure prioritisation

- Substances prioritised based on their uses and exposure potential
  - Primarily based on reported uses in REACH registration dossiers

More details later…

Two phases of screening

- IT screening results in a shortlist of substances
  - 200-300 substances annually
  - New information received, scenarios refined
- Member States select substances for further scrutiny
  - Manual verification of IT screening outcome
  - Holistic evaluation of substance
  - Determine whether further regulatory action is required
  - Feedback into IT screening to improve the process

Screening definition document

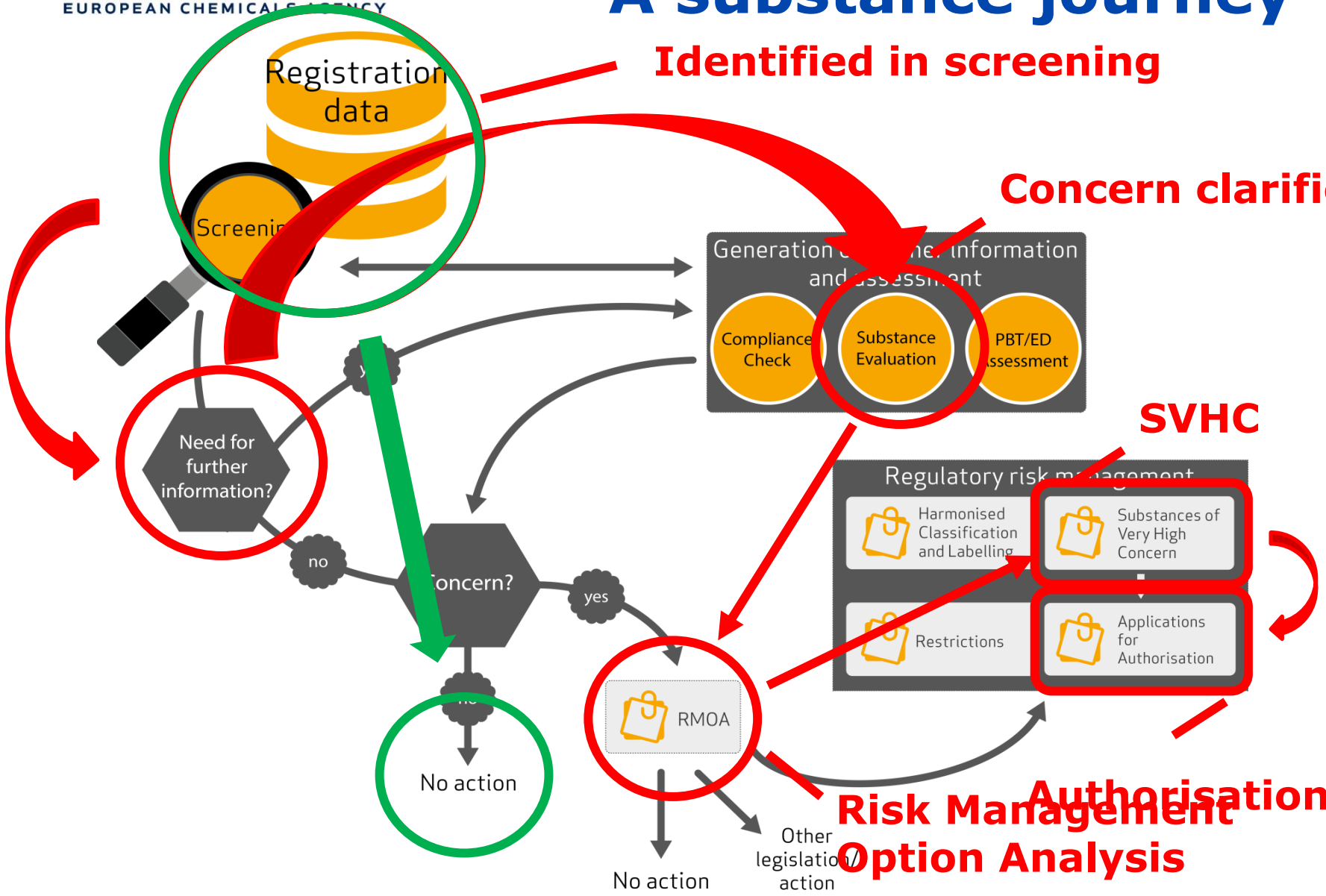
- Very good source of information:
  - Hazard and use criteria
  - Which **external sources** we use
- Updated annually, in consultation with Member States and industry stakeholders
- **Chapter 8** lists the criteria used to create the short list every year.

http://echa.europa.eu/documents/10162/19126370/screening_definition_document_en.pdf

What happens next?

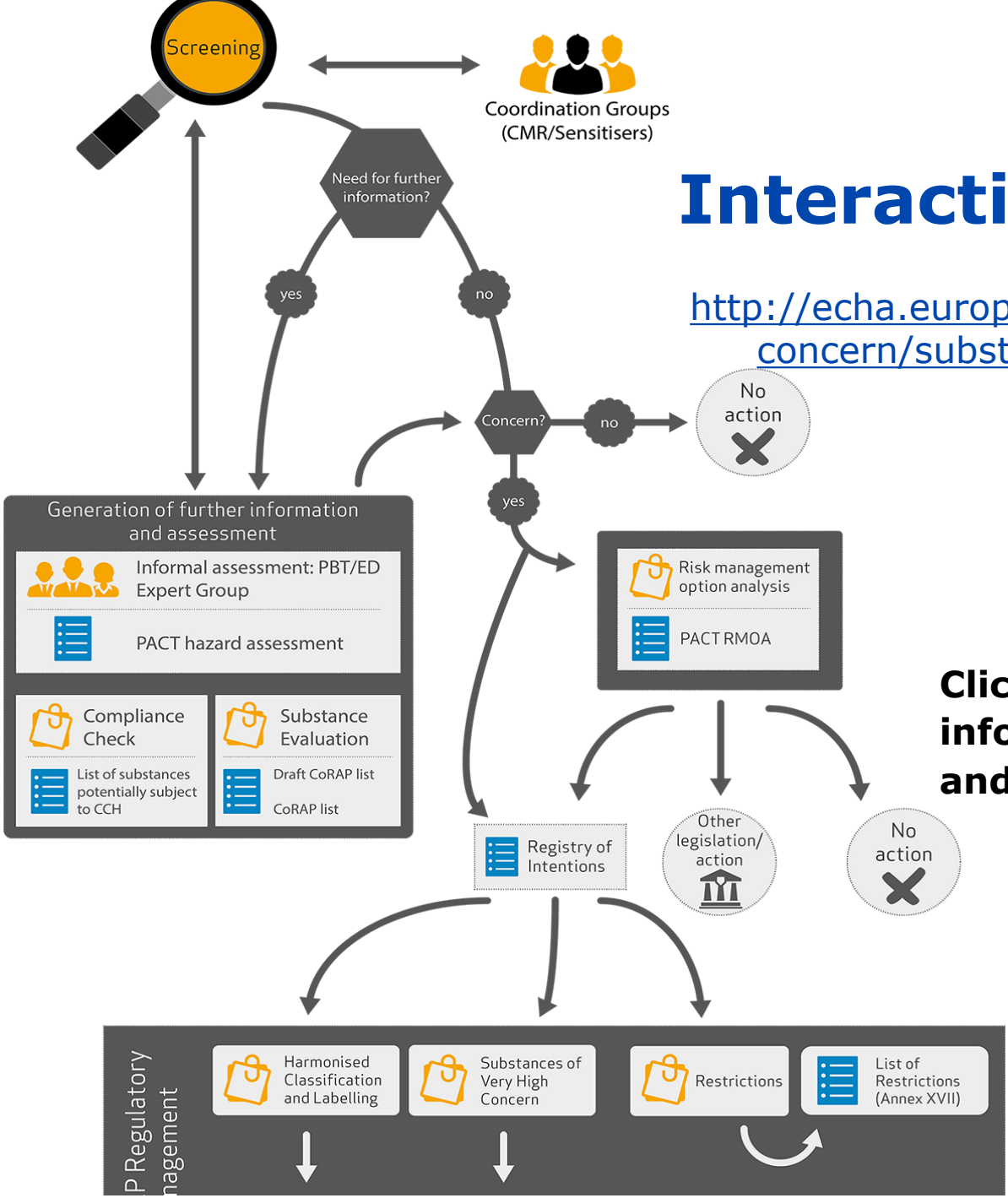
How to follow the process for your substance

A substance journey



Interactive flowchart

http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern



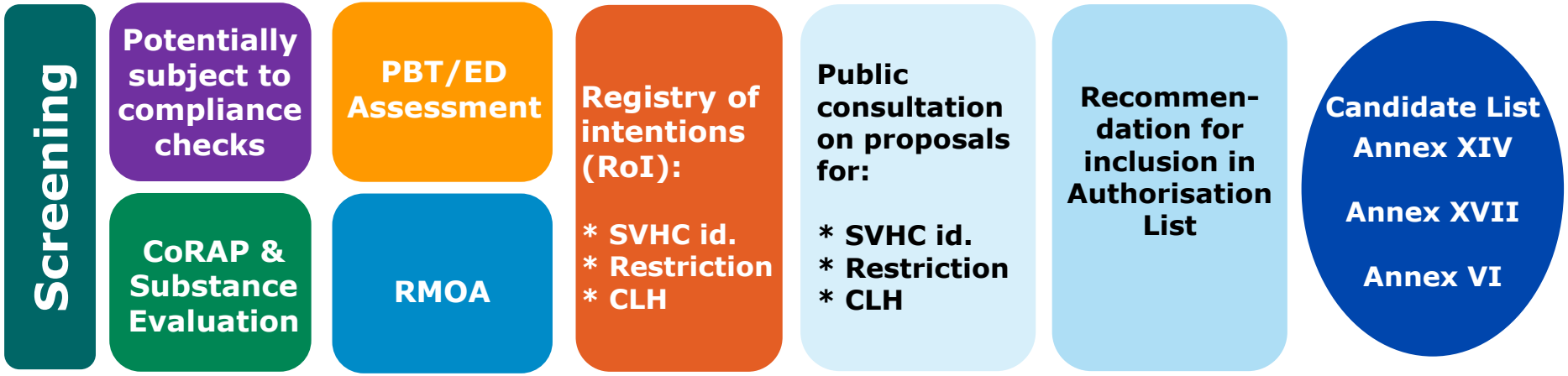
Click around to get more information on the processes and the substances involved

What can you do to influence the process?

Work <u>preceeding</u> regulatory risk management (RRM) processes

<u>Ongoing</u> RRM processes

Final outcome of RRM



Industry to:
- ensure that registration and other REACH/CLP dossiers are **up-to-date**
- **plan** their business approach

Industry/Third parties: to **prepare for public consultations**

Industry to **comply**

for Industry and authorities' benefit

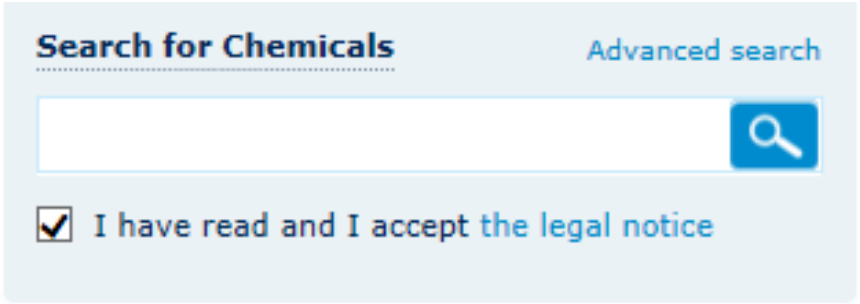
So, your substance was shortlisted…

- The shortlist is not published
  - IT process with potential false positives and might cause unwarranted blacklisting
- The outcome of manual screening is not published
  - Statistics reported in SVHC Roadmap annual report
- But there is hope….
  - When regulatory action is started on a substance

ECHA Dissemination site

ECHA Dissemination site

A one-stop shop for your substance information needs

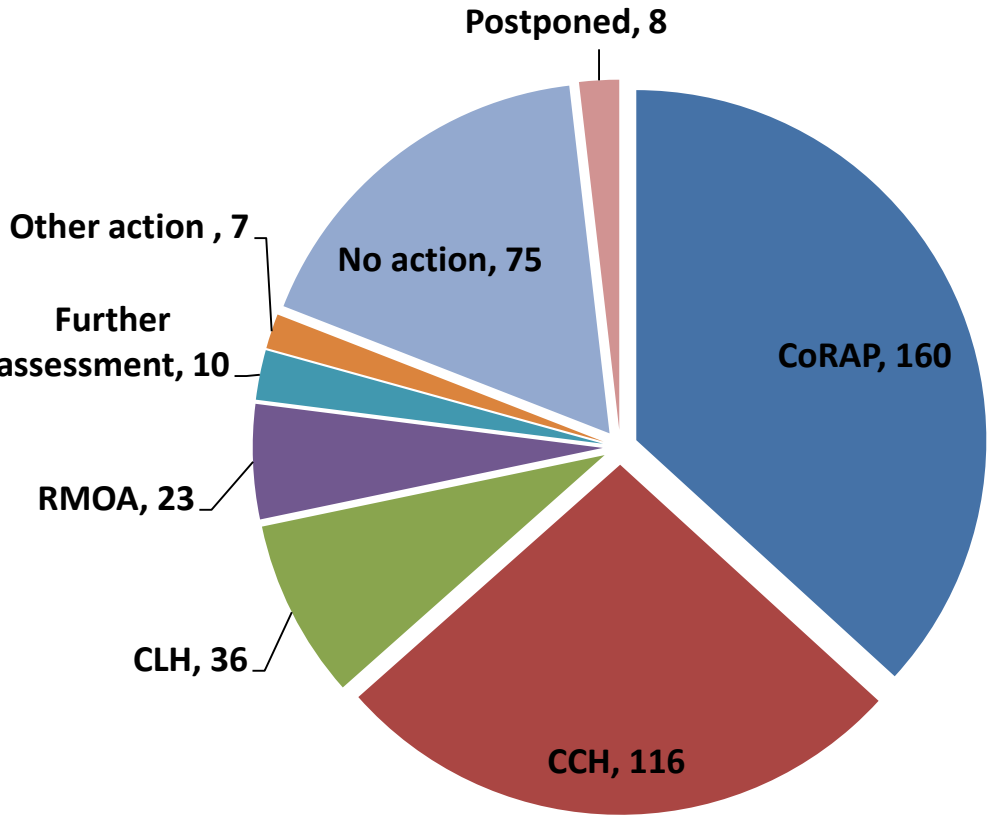


- Search box on ECHA front page
  - Advanced search available
- Leads to Infocards and Brief Profiles
  - Easy to see whether the substance is under a regulatory process, e.g.
    - **PACT** (RMOA, further assessment)
    - **CoRAP** (SEv)
    - **Registry of intentions** (CLH, SVHC, Restrictions)

Where are we now?

Statistics from past screening rounds

Outcome of screening Rounds 1 and 2



- 426 substances manually verified in rounds 1 and 2
  - 82% found to require follow-up action
  - Majority require further information generation

Third round of common screening

- About **300** substances shortlisted for round 3
- Letters sent to some **2400** registrants
- Member states expected to select around **200** for further scrutiny
  - The remaining ones are still priority candidates for compliance check

How registrants can influence the screening by updating their dossier

Common screening approach

- to identify substances of concern

- Selection of substances based on a combination of **(potential) hazard** information and **use and exposure information**

- **Priority** is given to those substances having:

  A high tonnage for wide dispersive uses within the scope of substance evaluation, CLH, authorisation, restriction

- What does that mean?

Definition of wide dispersive use

- **Wide dispersive:**
  - *widespread* (used at many sites, by many users) and
  - *potential for release to environment* and/or *potential for human exposure*

- See also R12 Guidance

Definition of widespread use

- **Wide spread use:**
  - use by professionals, consumers; subsequent service life
  - use at industrial sites, unless low tonnage and/or low number of sites

Potential for release/potential for human exposure

- **Potential for release to environment**
  - Potential for a substance to be released from a use into one of the environmental compartments
  - By definition a substance that is fully contained will have no (or very low) potential for release to the environment

- **Potential for human exposure**
  - Potential for a substance that its use leads to exposure of humans (workers, consumers)
  - By definition a substance that is fully contained will have no (or very low) potential for human exposure

What does it mean for screening? (1/2)

- A substance (potentially) hazardous with high tonnage for wide dispersive uses within the scope of substance evaluation, CLH, authorisation or restriction will be prioritised for further work

- But also that the following (potentially) hazardous substances will be parked for the time being (low priority)
  - Substances with no uses in the scope of SEv, authorisation, CLH, restriction
  - Substances with no wide dispersive uses

- Note that for some specific hazard scenarios we have started to prioritise substances being only widespread.

What does it mean for screening? (2/2)

- Current implementation IT screening
  - Prioritisation for Human Health related hazard
    - Widespread uses: at least one professional, consumer use or article service life
    - Potential for exposure: presence for widespread uses of PROCs
  - Prioritisation for Environmental hazards
    - Widespread uses only due to limitation of the current IUCLID structure
  - Use of external source of information to support information in registration dossiers
- Manual screening verification
  - Possibility to consider additional information provided in both IUCLID and CSR

Current (mass) screening approach

- At present, no use-specific tonnage information available
- Potentially relatively high number of false positives and negatives
- E.g. two substances with similar overall tonnage

Substance A:

- Several intermediate uses, high tonnage
- One wide dispersive use, small tonnage

Substance B:

- One intermediate use, low tonnage
- Several wide dispersive uses, high tonnage

→ **Same priority** as no specific information on tonnage

Improvements foreseen with new IUCLID fields

- Better identification of uses exempted (e.g. intermediates, biocide, fuel)
- Better identification of uses limited to a small number of industrial sites (and thus not considered widespread use)
- Better identification of uses with/without potential for release/exposure:
  - Possibility to claim strictly controlled conditions (SCC) and to describe these condition to enable verification
  - Use of information on the estimated total releases going to the environment for ranking among substances
- Apply use-specific tonnage (when available) in the ranking in order to park substances with high tonnage:
  - For uses not in scope of SEv/authorisation/CLH/restriction…
  - For non wide dispersive uses

To summarise

Report and/or update information in your registration dossier on tonnage, use and exposure information, in particular

- For substances (potentially) hazardous to human health (e.g. CMR, S, ED) and
  - With most of the use exempted from REACH and CLP processes (e.g. intermediates) and/or
  - With most of the use taking place under strictly controlled conditions and/or
  - With most of the use taking place in a limited number of industrial sites
- For substances (potentially) hazardous to the environment (PBT, ED) and
  - With most of the use exempted from REACH and CLP processes (e.g. intermediates) and/or
  - For which most of the use takes place under strictly controlled conditions

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