Introduction to Common Screening

ECHA Webinar - How are substances screened and shortlisted

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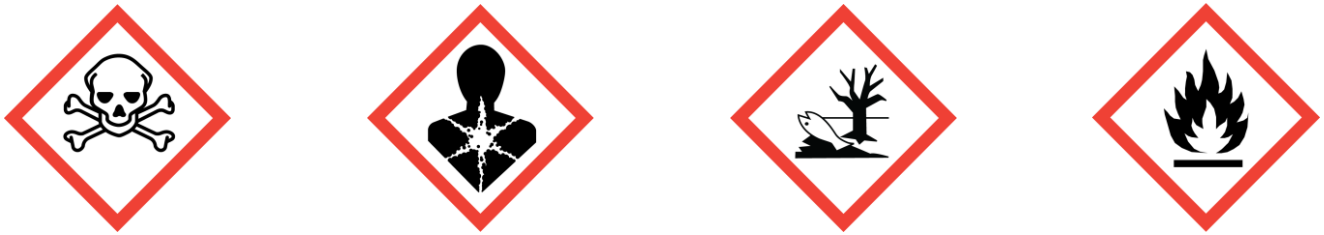
Content

- What is common screening?
  - Integrated screening of substances of concern
- How are substances selected for screening?
  - Identification and prioritisation
  - Statistics from past rounds of screening
- What happens after screening?
  - How you can follow the process for your substance

Common screening approach
- to identify substances of concern

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

… substances of concern



- **Regulatory strategy** (CCH strategy) (http://echa.europa.eu/documents/10162/21961120/mb_59_2015_update_cch_en.pdf)

Integrated screening

Use of **all available data**

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

Generation of further information

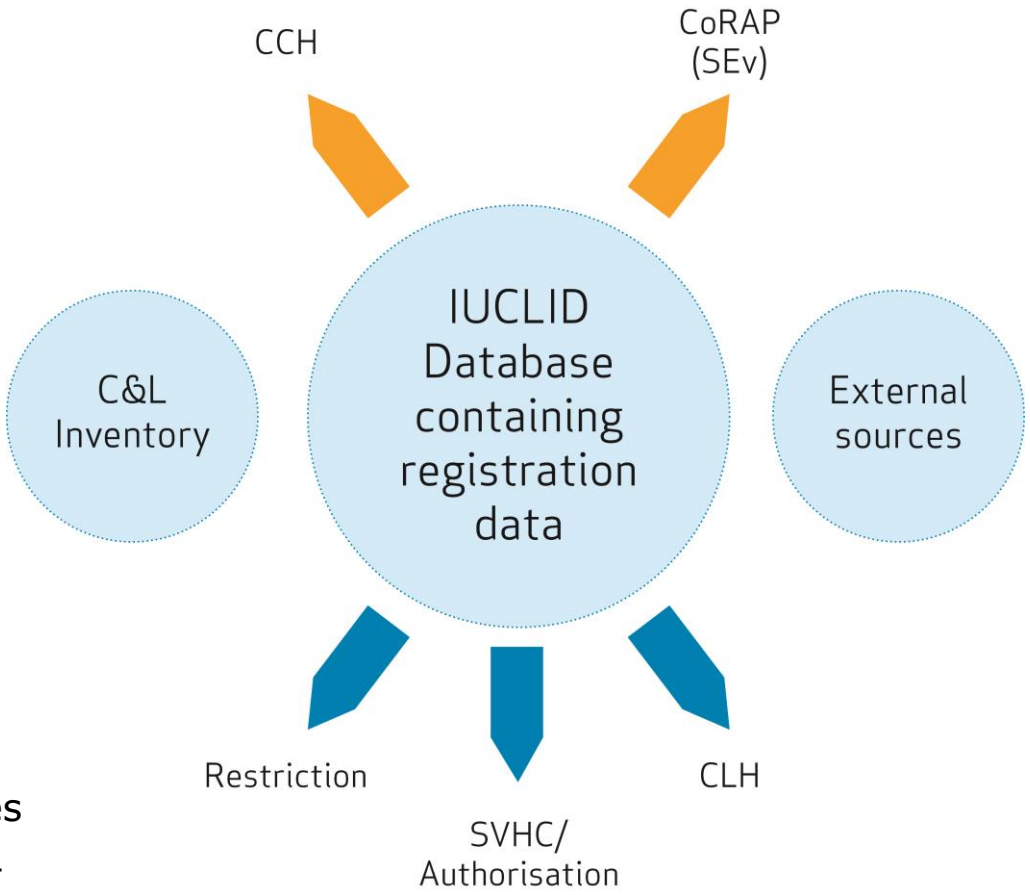
- Substance evaluation (SEv)
- Compliance check (CCH)

Regulatory risk management

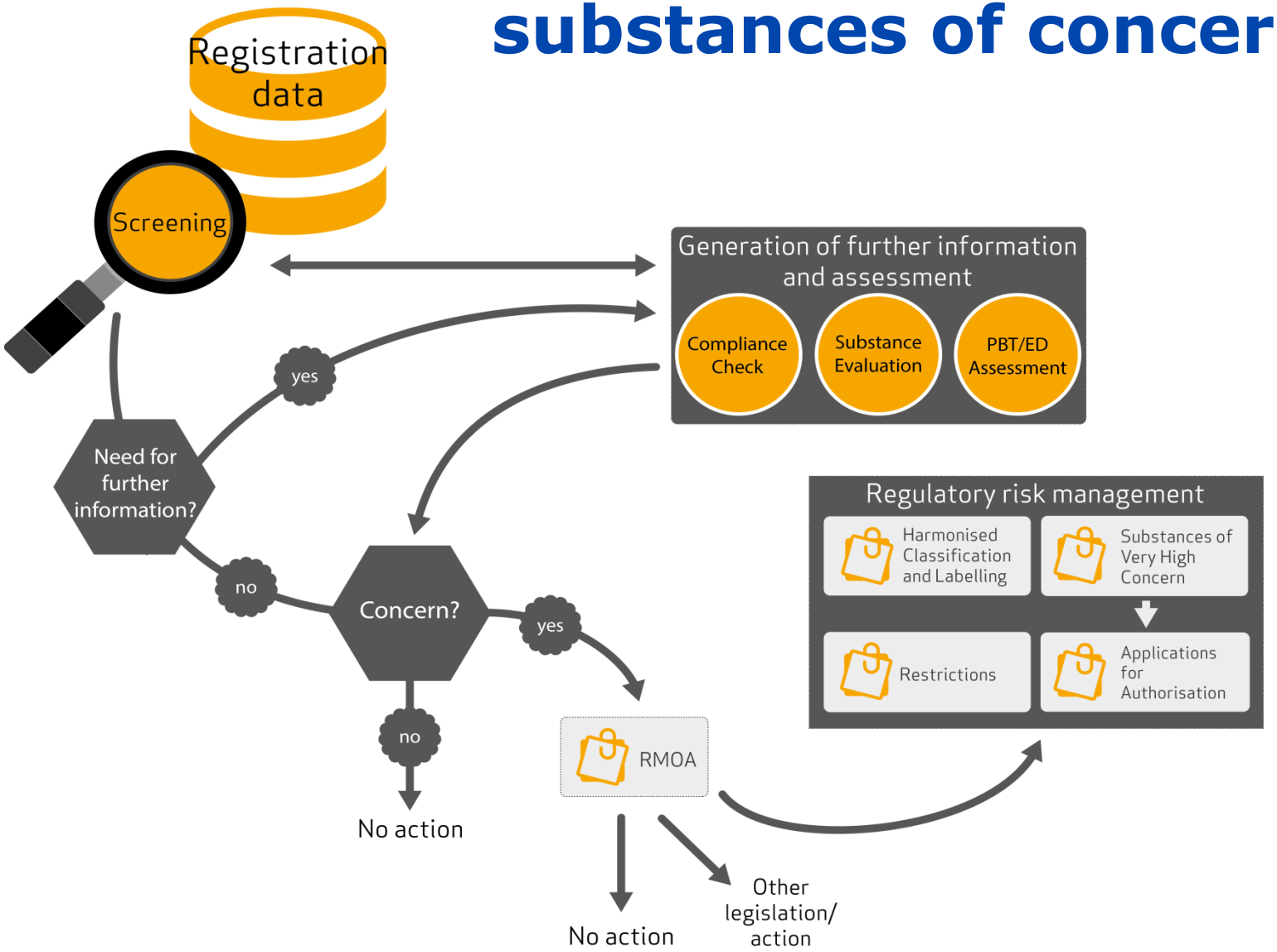
- Harmonised classification and labelling (CLH)
- Identification of SVHCs (possibly leading to Authorisation)
- Restriction

Fully integrated approach:

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



The machinery to address substances of concern



Typical screening timeline

Sept - Dec

IT Mass screening

- All registrations
- All C&L notifications
- External sources

January

Shortlist released

Letters sent to registrants

February

Substance selection

- MSCAs select substances for screening

March - July

Manual screening

- Initial concern verified/rejected
- Feedback into IT screening

How are substances selected?

Identification and prioritisation

How to find a substance of concern?

- Identify those substances which are (*potentially*) hazardous to human health or environment
  - CMR, PBT or vPvB, ED, STOT RE, Sensitisation

AND

- Prioritise them for action based on their potential for exposure to humans or release to environment
  - **High tonnage** for **wide dispersive use** within the scope of regulatory action

Identifying (potential) hazard

- Carcinogenicity, Mutagenicity, Reproductive toxicity (CMR)
- (very) Persistent, (very) Bioaccumulative and Toxic (PBT or vPvB)
- Endocrine disruptors (ED)
- Sensitisers, STOT RE toxicants

- All available data used for hazard identification
  - REACH registration dossiers
  - C&L notifications
  - External regulatory programs or lists
  - Predictive (*in silico*) methods

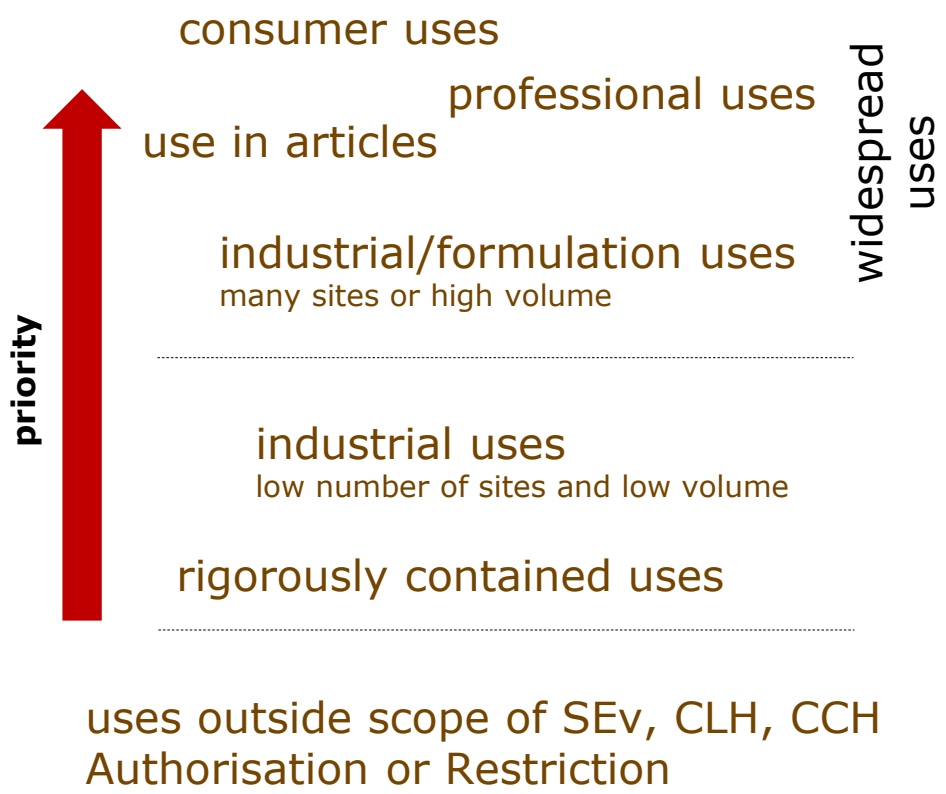
Example shortlisting criteria

- Substance is self-classified by at least one REACH registrant as **Reproductive toxicant**
- Substance has been identified by IARC as a probable **carcinogen**
- The substance is structurally similar to a known **Endocrine Disruptor** and shows positive findings in *in vitro* assays of endocrine disruption
- Studies included in registration dossiers show indications of **Persistence** and **Bioaccumulation**

Hunting for data gaps in registrations - Compliance check candidates

- The main focus is on the higher tier (Annex IX and X) human health and environment endpoints. These are:
  - genotoxicity
  - repeated-dose toxicity
  - pre-natal developmental toxicity
  - reproduction toxicity
  - carcinogenicity
  - long-term aquatic toxicity
  - biodegradation and
  - bioaccumulation.
- Those “eight super” endpoints are linked to clarification of CMR and PBT concern

Use and exposure prioritisation



Widespread uses:

- Consumer or professional uses,
- Article service life,
- Industrial/formulation at many sites

Wide dispersive uses:

- Substances with widespread uses and high potential for exposure to humans or release to environment

Sources of exposure information

- **Main sources of information**
  - Registration dossiers (IUCLID) information
    - Overall tonnage used so far but tonnage per use would be preferred
    - Information whether the use falls under REACH/CLP regulatory action as some uses may be exempted (e.g. biocides, intermediate uses exempted from authorisation)
    - Indication of widespread professional uses, consumer uses, article service life
    - Indication on the level of containment (not yet available)
    - Potential for human exposure (e.g. use of the descriptor system: defined PROCs)
  - External sources of information
    - CDR and SPIN database

Screening definition document

- Very good source of information:
  - Hazard and exposure 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

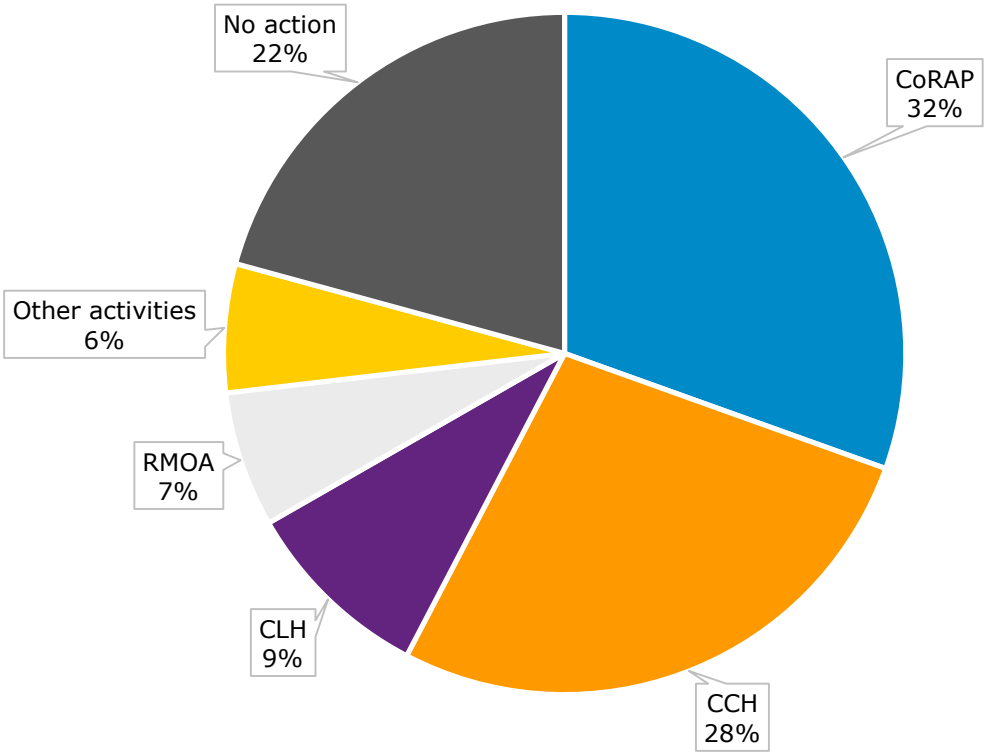
Two phases of screening

- **IT screening**
  - ~200 substances shortlisted annually
  - Selection based on screening algorithms, with minimal manual verification

- **Manual screening**
  - Manual verification of IT screening outcome
  - Holistic evaluation of substance
  - Determine whether further regulatory action is required
  - Not all shortlisted substances may be selected

Where are we now?

- Statistics from previous rounds



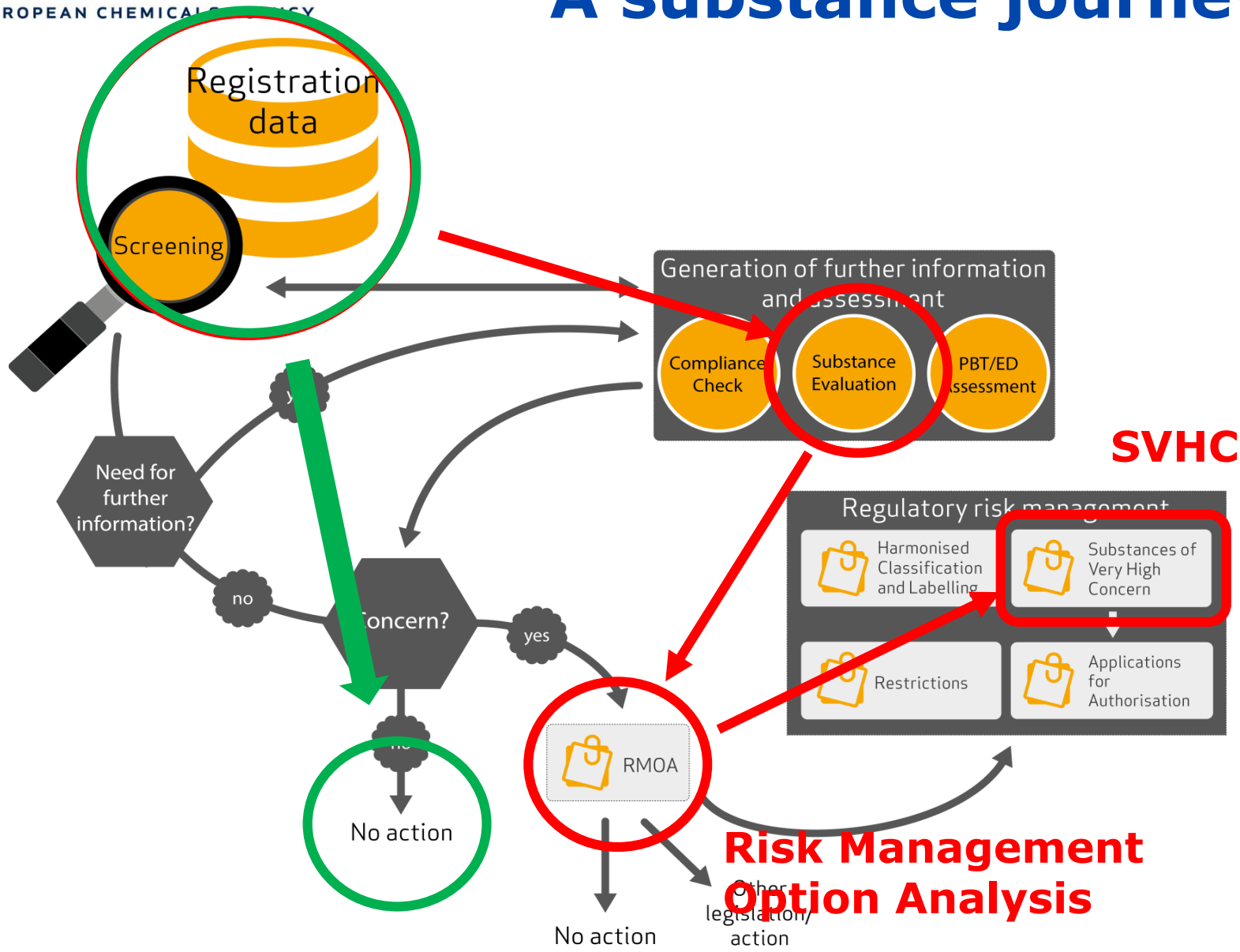
~ 600 substances manually screened in rounds 1-3

Majority require further information generation

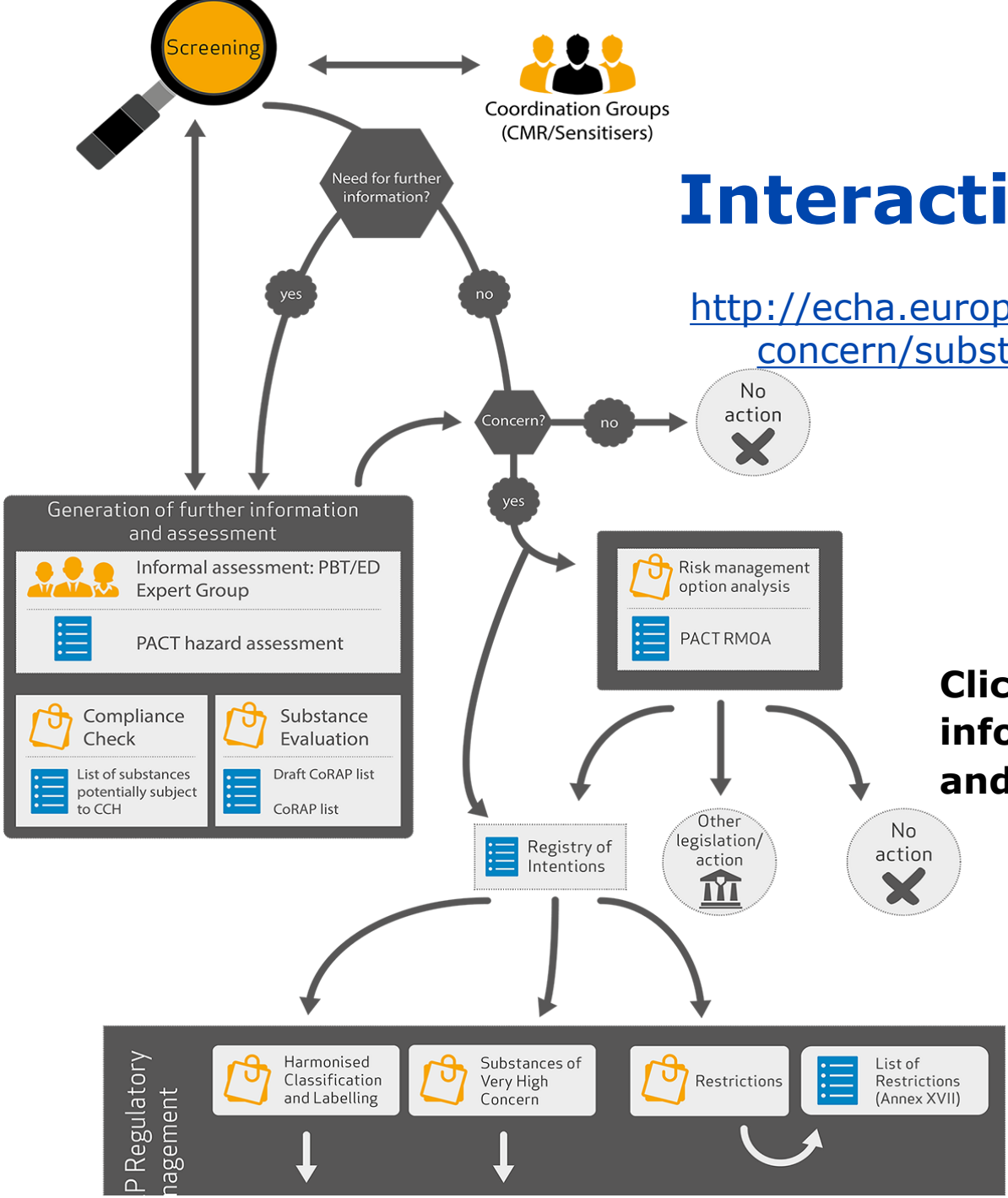
What happens next?

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

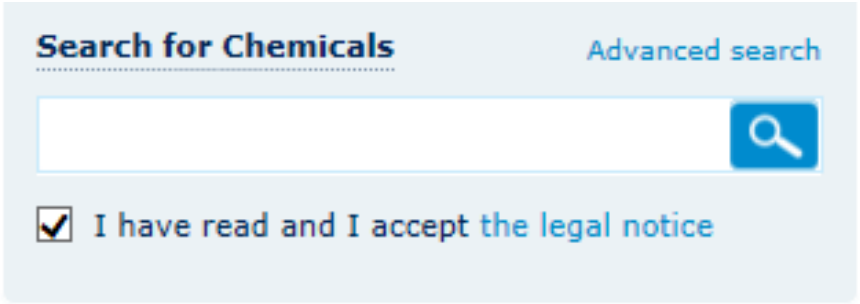
Was your substance shortlisted?

- The shortlist is not published
  - IT process with potential false positives and might cause unwarranted blacklisting
  - 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

One stop search for all ECHA information on a substance



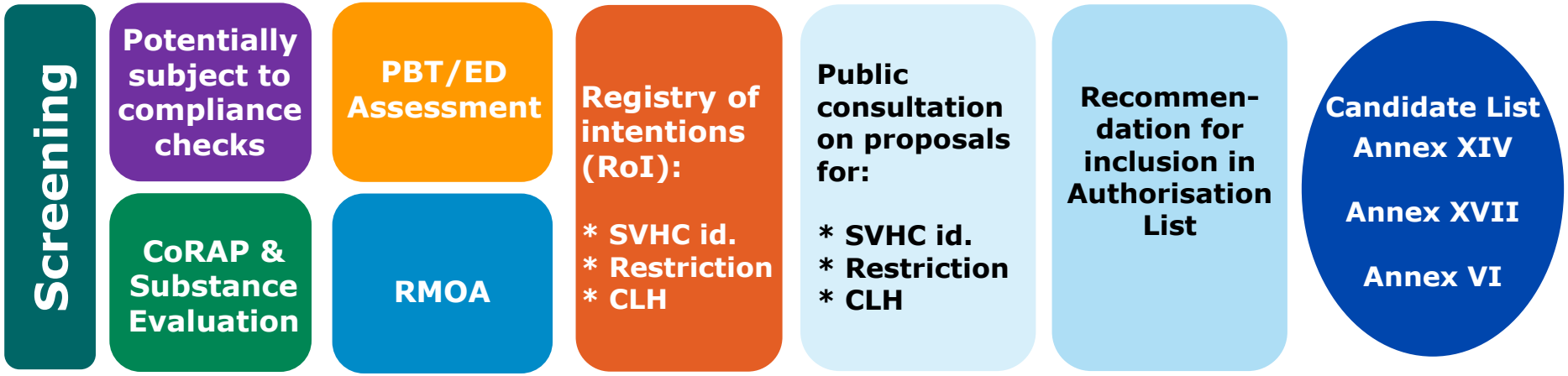
- Search box on ECHA front page
  - Advanced search available
- Leads to Infocards and Brief Profiles
  - Easy to see whether the substance is under a regulatory process, e.g.
    - **PACT** (RMOA, further assessment)
    - **CoRAP** (SEv)
    - **Registry of intentions** (CLH, SVHC, Restrictions)

When can you influence the process?

Work preceeding regulatory risk management (RRM) processes

Ongoing 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**

Conclusions

- Two phases of screening – IT and manual
- Two aspects to a concern – hazard and exposure

- Screening is just the first cog in the ECHA machinery

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