Introduction to Common Screening

Webinar: how are substances shortlisted and manually screened?

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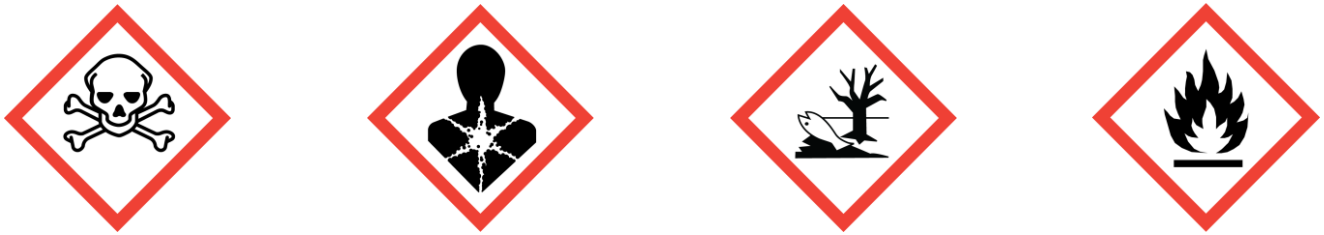
Content

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

Common screening approach

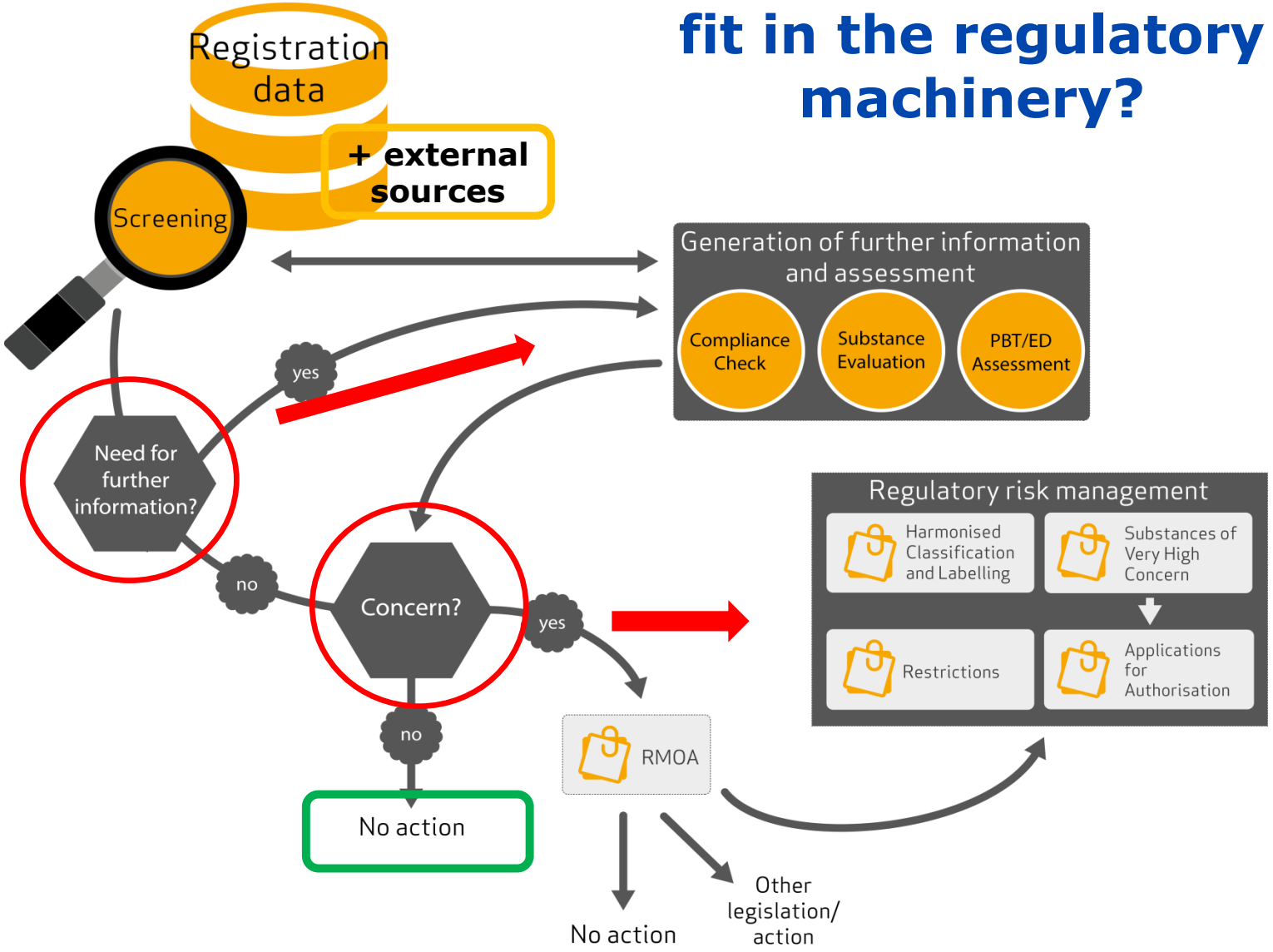
Aim: Identify and prioritise those substances where regulatory action can best increase protection of human health and the environment

… substances of concern



- **Integrated Regulatory strategy** (https://echa.europa.eu/documents/10162/22837330/mb_44_2016_regulatory_strategy_en.pdf/)

Where does screening fit in the regulatory machinery?



Fully integrated approach:

- Optimal use of resources
- Avoids parallel processing of substances and duplication of work
- Ensures that the most effective regulatory option for each substance is chosen
- Ensures related substances are handled consistently

Typical screening timeline

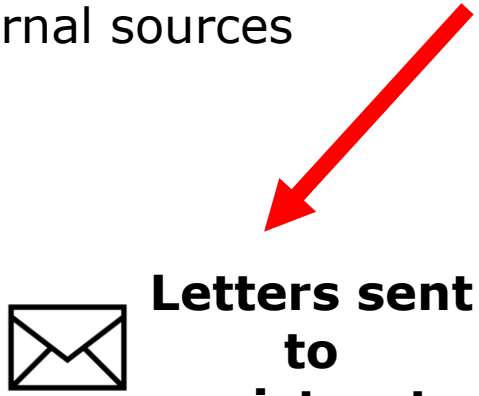
Sept - Dec

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

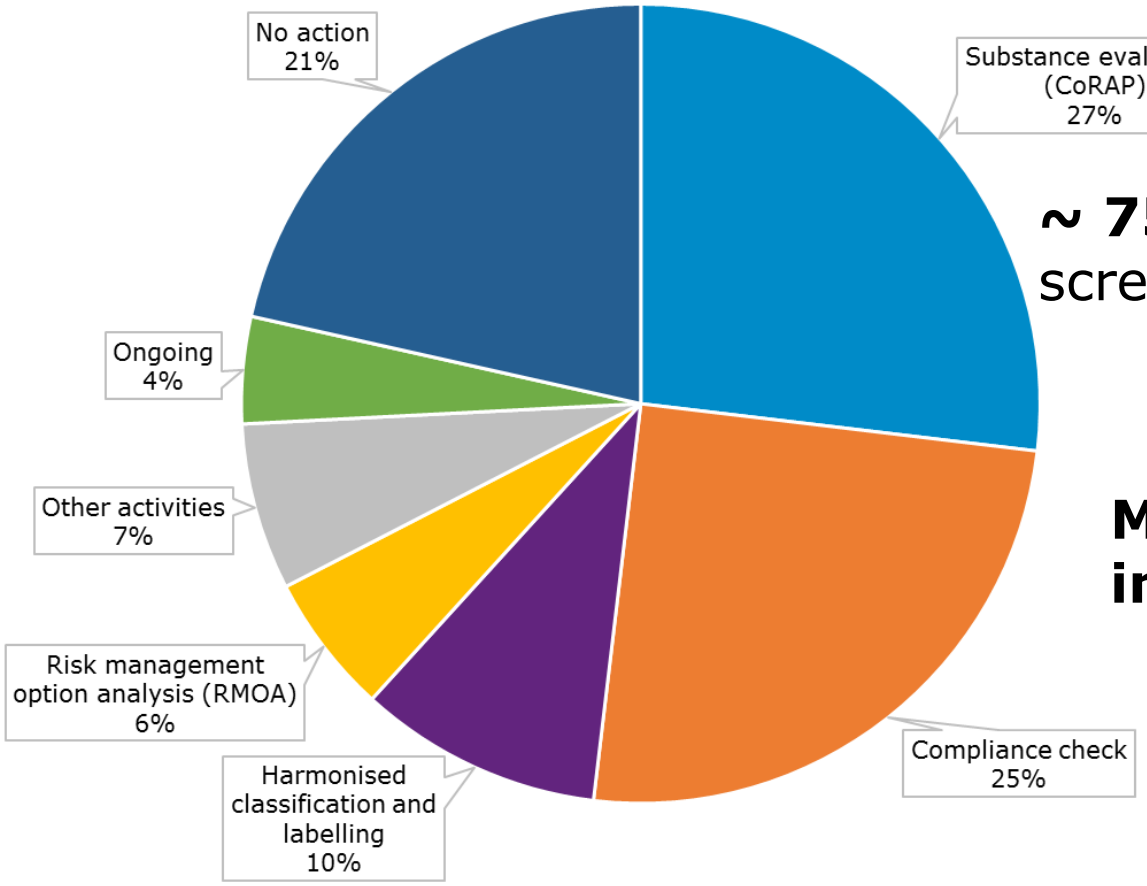
Feb - May

Manual screening

- Initial concern verified/rejected
- Feedback into IT screening

Where are we now?

- Statistics from previous rounds



~ 750 substances manually screened in rounds 1-4

Majority require further information generation

How are substances shortlisted?

Two phases of screening

- **IT screening (ECHA)**
  - ~200 substances shortlisted annually (some in groups)
  - Selection largely IT-based, with minimal manual verification

- **Manual screening (MSCAs)**
  - Manual verification of IT screening outcome
  - Holistic evaluation of substance/group
  - Determine whether further regulatory action is required

➢ Not all shortlisted substances/groups may be selected

What constitutes a concern?

- **(suspected) Hazardous properties**
  - CMR, PBT or vPvB, ED, STOT RE, Sensitisation

AND

- Potential for **exposure** to humans or release to environment
  - **High tonnage** for **wide dispersive use** within the scope of regulatory action

Changing ways

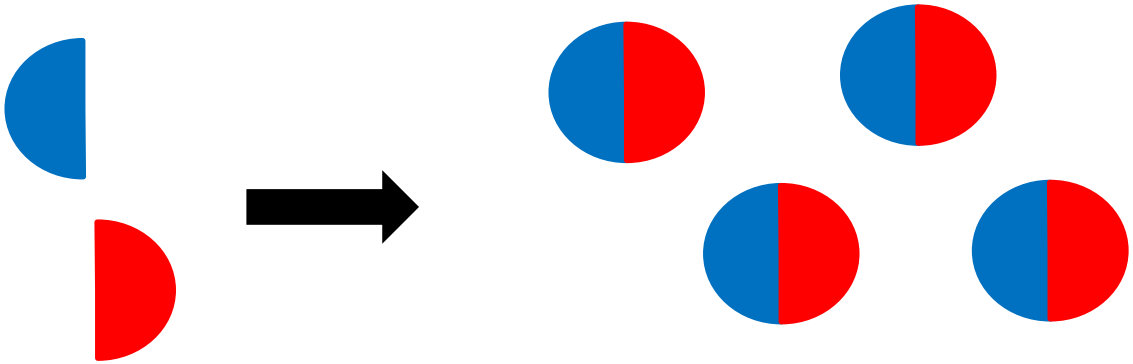
Individuals vs groups

Same substance

Old way

Hazard

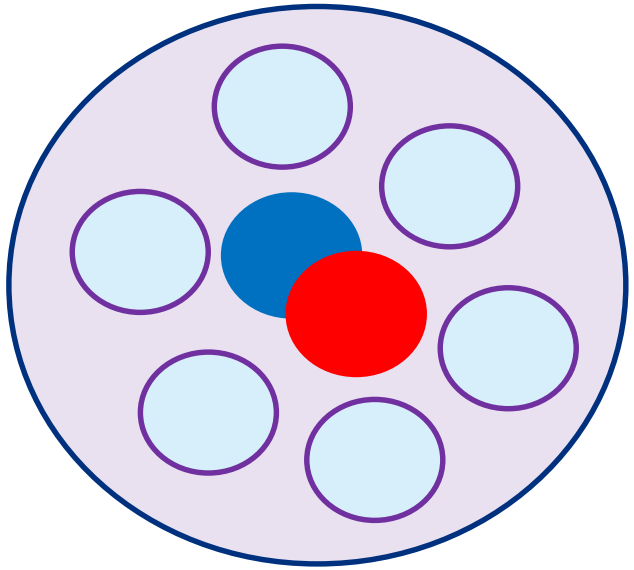
Exposure



New way

Hazard

Exposure



Same OR related substance

Round 5 shortlisting

- Group seeds:
  - Substances listed in CoRAP or already under **substance evaluation** or which have been concluded with follow up actions
    - Suspected hazardous properties AND potential for exposure
  - Substances on the **Candidate List** of Substances of very high concern
    - Potential for substitution
  - Substances identified as of concern by non-EU authorities and external bodies. (e.g. US EPA, IARC) and with high potential for exposure
  - Substances meeting national priorities of Member States
- Still some individual substances included

Screening definition document

- Good source of information:
  - **Grouping** methodology
  - **Shortlisting** criteria
  - Which **external sources** we use

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

What happens next?

How to follow the process for your substance

Was your substance shortlisted?

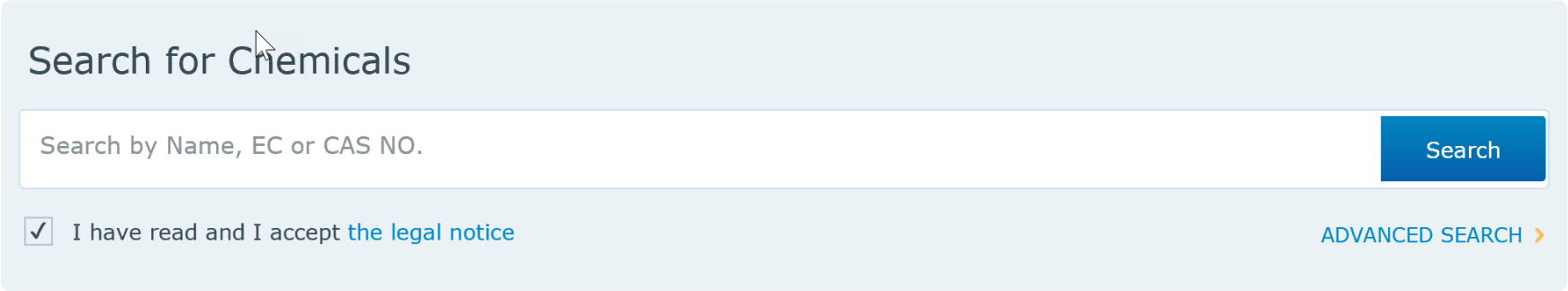
- The shortlist is not published
  - IT process with potential false positives and might cause unwarranted blacklisting
  - Statistics reported in SVHC Roadmap annual report
- But whenever regulatory action is started on a substance…

ECHA Dissemination site

https://echa.europa.eu/

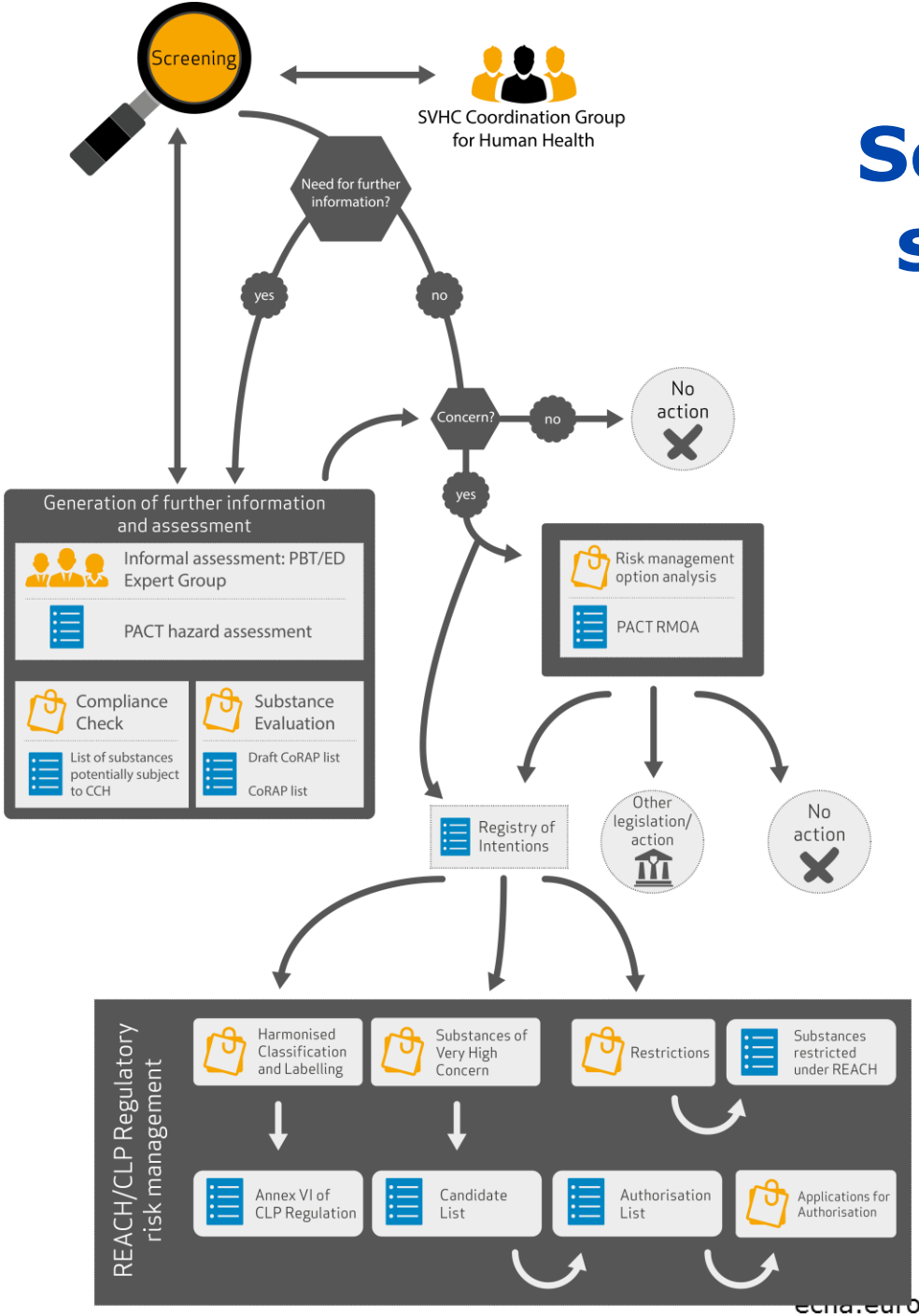
ECHA Dissemination site

One stop shop 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)

Screening is the first step in the process



Interactive flowchart

https://echa.europa.eu/substances-of-potential-concern

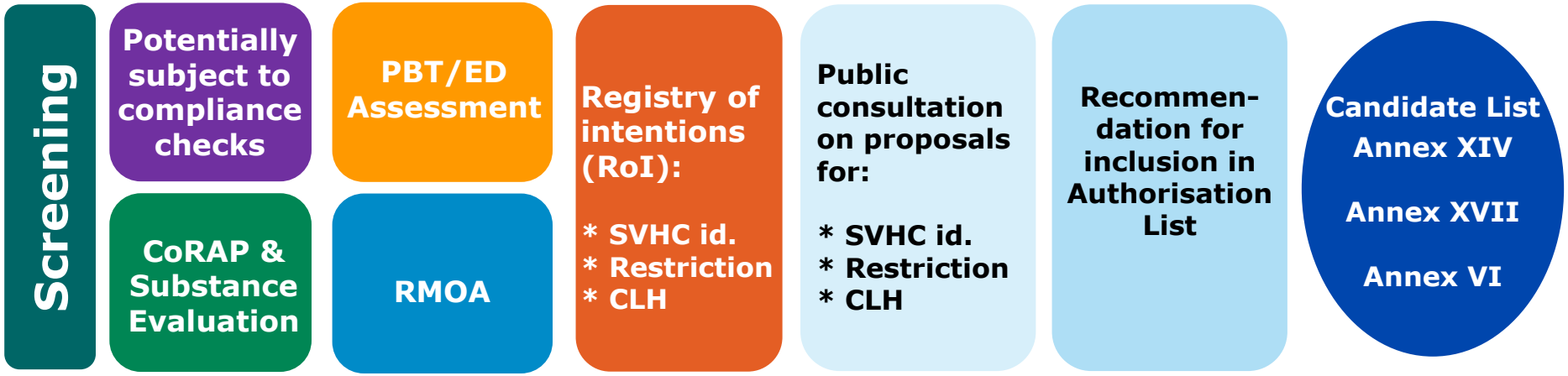
Click around to get more information on the processes and the substances involved

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**

Key messages

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

- Screening is just the first step in the process

- Follow our website and make sure you contribute where you can

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