

How authorities make use of the information from registration.

Common screening to identify substances that matter

Exchange Network on Exposure Scenarios (ENES8)

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Common screening approach

- to identify substances of concern

Use of all available data

Allocate identified substances to the appropriate process:

Generation of further information

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

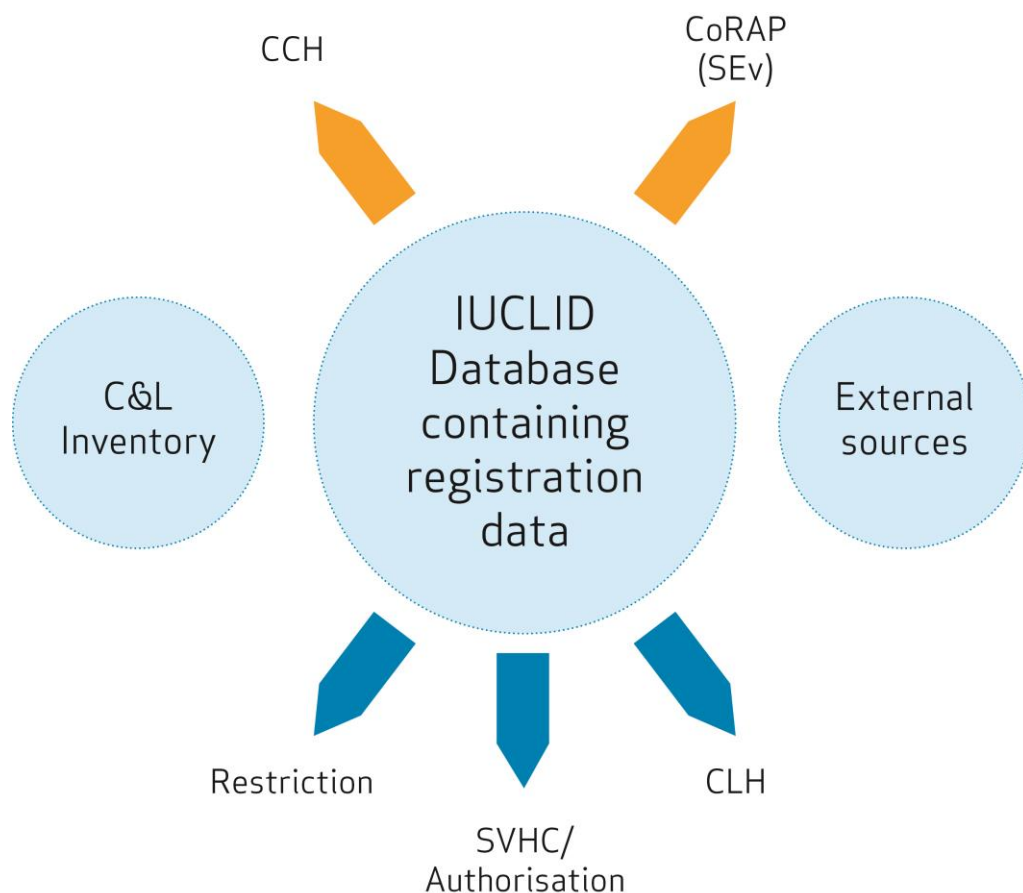
Regulatory risk management

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

The common approach from now on serves the **chemicals that matter strategy**.

Fully integrated approach:

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



Common screening approach

- to identify substances of concern

Selection of substances based on:

- Hazard information, for example:
 - P, B and T properties, Carcinogenicity, Mutagenicity, Reprotoxicity, Endocrine disruption, Sensitisation
- Use and exposure information (so called “non hazard criteria”)

The objective is to identify among the (potentially) hazardous substances those which have:

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

- In addition use of structural similarity approach to identify substances which may get focus is use increase (e.g. substances only registered as intermediates under SCC or not yet registered)

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*

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?

- 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 use in the scope of SEv, authorisation, CLH, restriction
 - Substances with no wide dispersive uses

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

How to best prepare? (1/4)

Work preceding regulatory risk management (RRM) processes

Ongoing RRM processes

Final outcome of RRM

PACT*

Screening

CoRAP +
substance
evaluation

PBT/ED
Assessment

RMOA

Dossier
intentions
(SVHC
Restriction
CLH)

Dossiers
submitted
(SVHC
Restriction
CLH)

Recommen-
dation for
inclusion
in
authorisati-
on list

Annex VI
Candidate List
Annex XIV
Annex XVII

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

Industry to prepare for public consultations

Industry to comply

Dossier Quality Important!

*PACT: Public Activities coordination tool

How to best prepare? (2/4)

Hazardous properties:

- Draw clear and traceable conclusions on the hazardous properties of your substance (including impurities and degradation products)
 - For HH: C, M, R, S properties, ED properties
 - For ENV: P,B, T and ED properties
- Be aware of the properties under scrutiny (link to ECHA website)

Screening

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

Dossier Quality Important!

How to best prepare? (3/4)

Uses and exposure information:

- “Clean/clarify” the description of the (supported) uses of your substance.
- Identify uses exempted from REACH and CLP processes
- Identify uses as an intermediate
- Identify uses under SCC
- Provide sufficient justification (intermediate, SCC) to allow authorities to be convinced
- Report tonnage information to characterise the extent of certain uses

Screening

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

Dossier Quality Important!

How to best prepare? (4/4)

Work preceding regulatory risk management (RRM) processes

PACT

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

Same considerations as for the screening stage with potentially more specific focus depending where the substance is listed e.g.

- more hazard information if listed for PBT/ED assessment,
- more uses and exposure related information is listed for RMOA

Dossier Quality Important!

To summarise....

Report and/or update information in your registration dossier, in particular

- For substances (potentially) hazardous to HH (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 ENV (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

To summarise....

- If your substance is (potentially) hazardous to the ENV (e.g. PBT) and some of the uses are professional or consumers uses or the substance enters into a subsequent service life then update either
 - The information regarding the properties of your substance (when) possible or
 - The use description and exposure assessment