

Workshop on substitution strategy

**Facilitating the use of registration,
classification and risk management data for
sustainable substitution**

ECHA's ongoing initiatives on information
dissemination to support substitution

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Substitution

Replacement of a chemical to deliver a similar function:

1. similar chemistry delivers similar function;
2. different chemistry delivers a similar function;
3. different design to deliver a similar function.

What are we looking for?

- Technical function and potential applications of (similar) chemicals
 - To find substitution candidates and avoid regrettable substitution
- Hazard information of (similar) chemicals
 - To avoid regrettable substitution
 - To find candidates for substitution?

What do we have?

- (i) data collected via the REACH registration and CLP notification processes
- (ii) data that has been generated and collected through the REACH and CLP processes
- (iii) tools on the basis of that information

REACH Registration and CLP notification

- Responsibility for the management of the risks of substances lies with industry:
 - Understanding of hazard properties
 - Understanding of uses throughout the supply chain
 - Ability to carry out a safety assessment and communicate the outcome
 - In registration dossier (IUCLID and CSR)
 - Throughout the supply chain(eSDS)
- Registration provisions require industry to collect and generate data (where needed):
 - Depending on the tonnage a minimum set of data requirements is defined by the REACH annexes
 - Appropriate risk management measures should be developed by industry and communicated to users down the supply chain;

Registration and Dissemination

- To ensure that industry meet these obligations in a transparent manner, industry is required to submit a dossier containing all this information to the Agency;
- All dossiers are checked for completeness, but not all are checked for compliance. Registration is not an approval process;
 - ECHA has reported several times on the lacking quality in the dossiers
- Most of the information in the dossier is published on ECHA's website

Potential use for substitution?

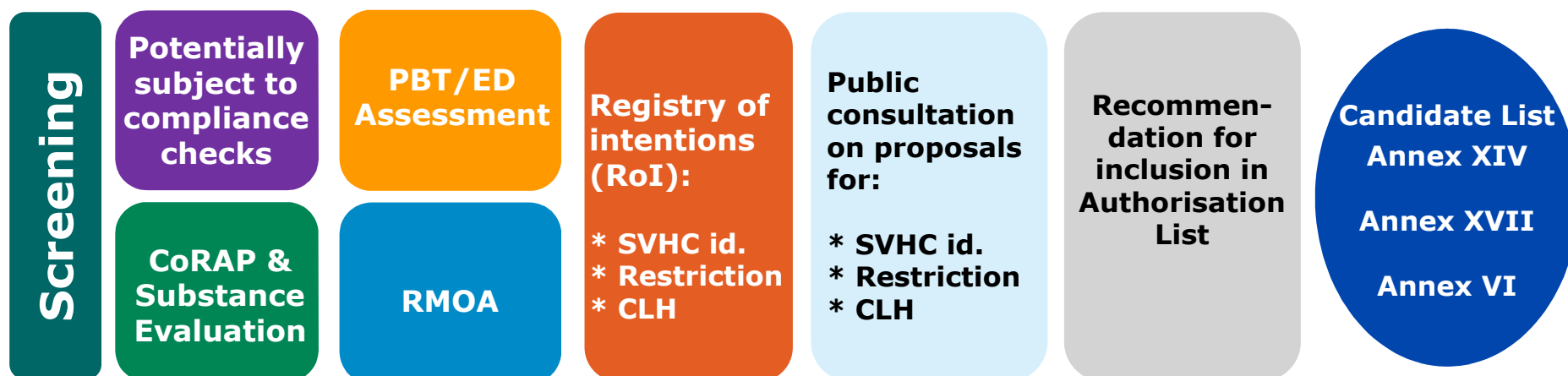
- A wealth of information, but effort is needed to make use (sense) out of it:
 - Compliance issues on hazard information
 - Quality issues on reporting of use information
 - Quite often 'over-reporting'
 - Technical function is not disseminated, but to what extent would this information be helpful?
- Generic use information is available (and searchable), but is this sufficient to inform substitution analysis?
- Hazard information is available (and searchable) in terms of studies and classification and labelling
 - How reliable are the classifications?
 - How reliable are the non-classifications?

'REACH/CLP process data': what is publicly available?

Work preceding 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**

REACH and CLP 'process' data

- Transparency of substances under (potential) scrutiny is important, e.g. predictability for industry
 - Example: <https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact>
 - > Substances to avoid?
- Outcome of regulatory work, e.g.
 - Annex VI Classification and labelling
 - Restrictions
 - > Substances to avoid
- Information generated submitted during these processes:
 - Applications for authorisation: specific use information available

Dissemination in practice

- ECHA's dissemination vision is focussed on providing an integrated view of substance information in a hierarchy:
 1. Info card
 2. Brief Profile
 3. Source data

Formaldehyde

Other names: [Regulatory process names \[3\]](#) [Trade names \[54\]](#) [IUPAC names \[19\]](#)

Substance identity ?


EC / List no.: 200-001-8

CAS no.: 50-00-0

Mol. formula: CH₂O

O=C

Hazard classification & labelling ?



Danger! According to the **harmonised classification and labelling** (ATP06) approved by the European Union, this substance is toxic if swallowed, is toxic in contact with skin, causes severe skin burns and eye damage, is toxic if inhaled, may cause cancer, is suspected of causing genetic defects and may cause an allergic skin reaction.

Additionally, the classification provided by companies to ECHA in **REACH registrations** identifies that this substance is fatal if inhaled and causes serious eye damage.

Properties of concern ?

C

Ss

Important to know ?

- Substance included in the [Community Rolling Action Plan \(CoRAP\)](#).

How to use it safely ?

- ECHA has no data from registration dossiers on the precautionary measures for using this substance.
- [Guidance on the safe use of the substance](#) provided by manufacturers and importers of this substance.

About this substance ?

This substance is manufactured and/or imported in the European Economic Area in 1 000 000+ tonnes per year.

This substance is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

Consumer Uses

This substance is used in the following products: adhesives and sealants, coating products, fillers, putties, plasters, modelling clay, inks and toners, polymers, fuels, biocides (e.g. disinfectants, pest control products), polishes and waxes, washing & cleaning products and cosmetics and personal care products. Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners), outdoor use, outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) and indoor use in long-life materials with low release rate ...



Further integration of more information is ongoing



ECHA makes the available data and information available:

- For searching and viewing
 - on the website
- For screening and integration in systems and tools:
 - via 'web-services' pilot phase for regulatory information on-going
 - a download file for the hazard data

Similarity and grouping

Similarity (hazard and uses) can help in avoiding regrettable substitution

ECHA and MS start to use grouping more and more integrated into the Regulatory processes, starting with the screening and prioritisation work

ECHA has been supporting the development of the OECD QSAR Toolbox: a toolbox to predict toxicity, including grouping and similarity functionalities. One of the prime uses by industry is the analysis of new potential products. All the relevant REACH study information is integrated.

Preventive dialogue with PPORD notifiers, in case there are indications of regrettable substitution

ECHA makes all information available on its website that can help with avoiding regrettable substitution. Information is made available also for screening and integration in systems and tools

For technical use information, the right level source information seems not be available

- Application for Authorisation as exception?

Hazard information is available, but there are different levels of robustness of the information, which needs interpretation

To avoid regrettable substitution, the OECD QSAR Toolbox is a powerful tool that has REACH data integrated

Thank you!

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