

Prioritisation of substances for further regulatory action

The EFSA FCM Network
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Content

- Prioritisation in ECHA's Integrated regulatory strategy
- How to prioritise?
- Role of grouping

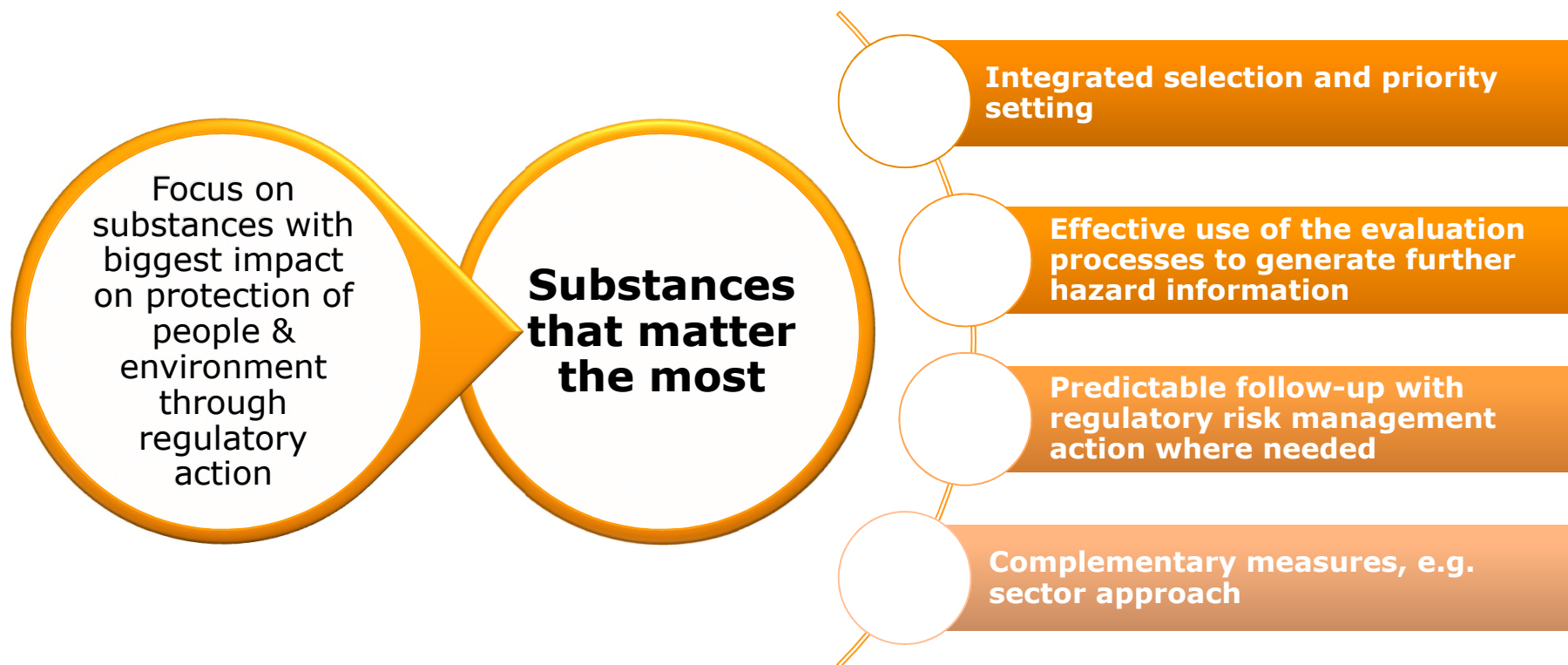
Why to prioritise

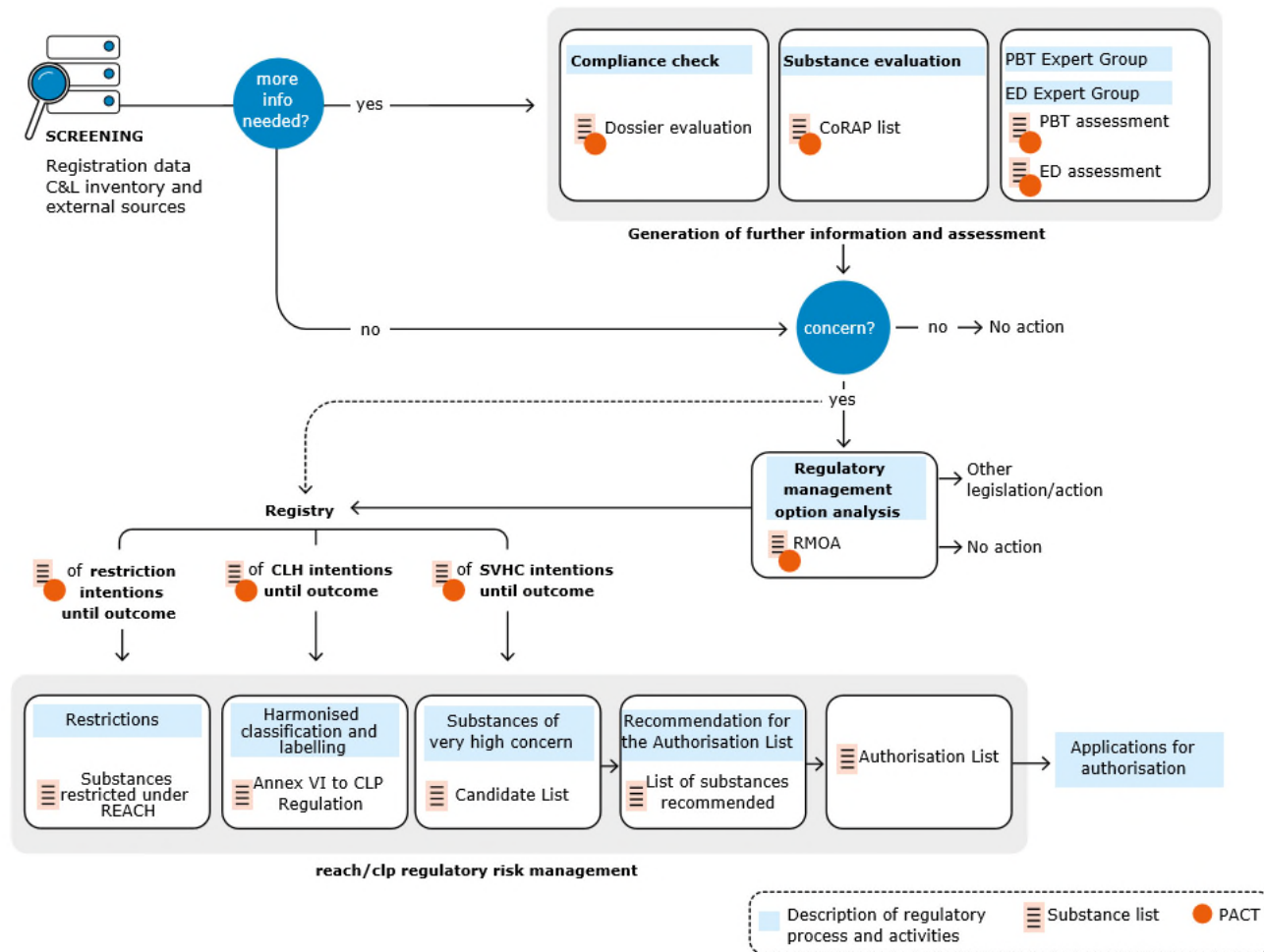
- Efficiency and effectiveness of authorities work:
focus on substances that matter first
- Predictability of authorities work:
 - for industry
 - supports aligning the work under different pieces of legislation
- Transparency

Content

- **Role of prioritisation in ECHA's Integrated regulatory strategy**
- How to prioritise?
- Role of grouping

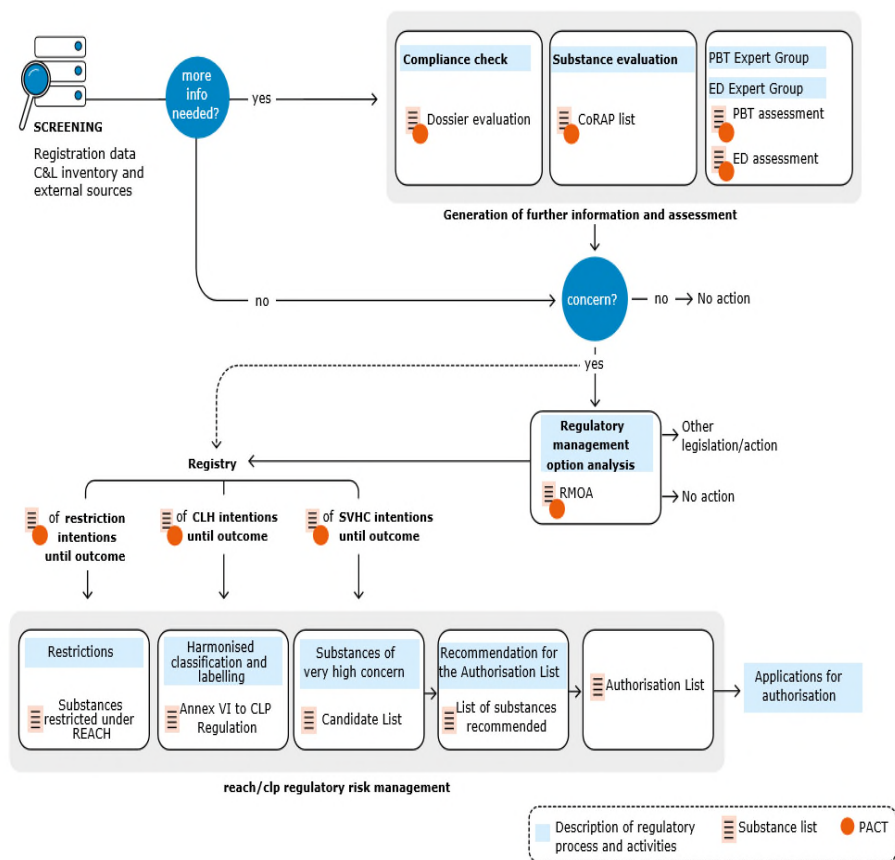
Integrated Regulatory Strategy





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

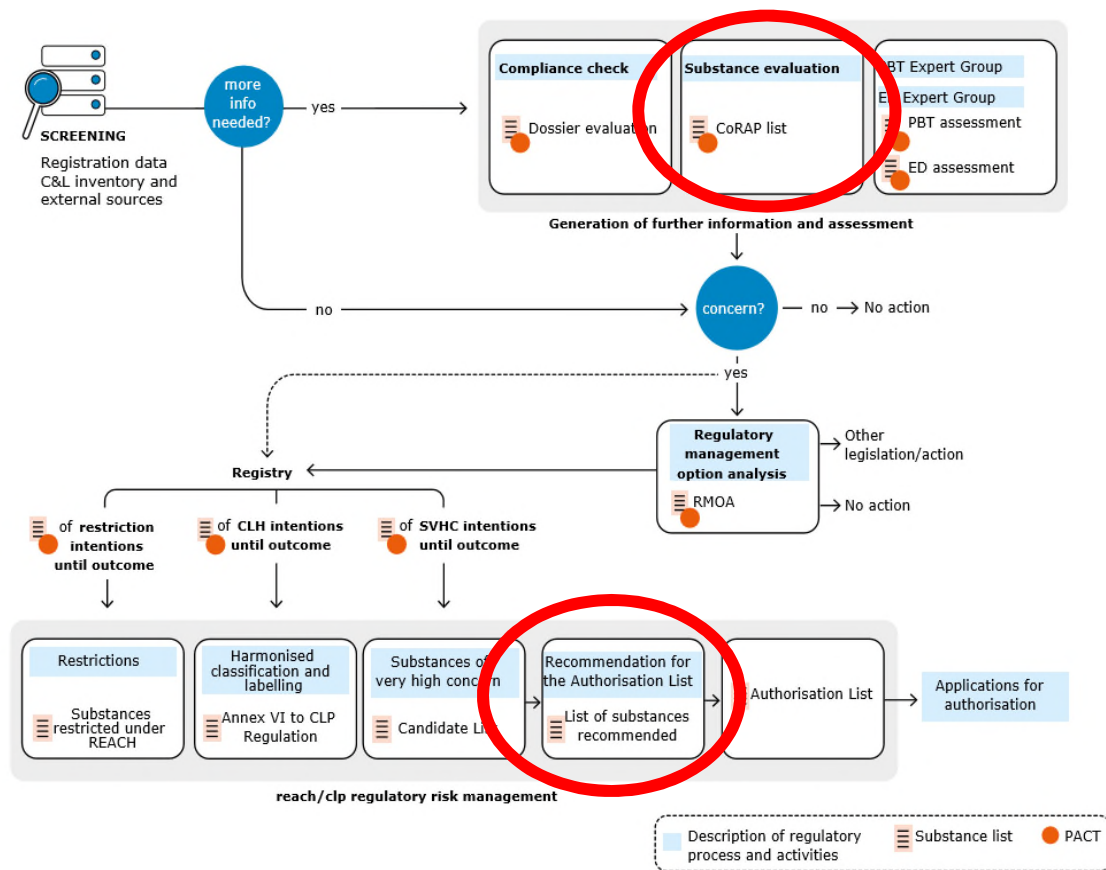
Integrated regulatory strategy - Prioritisation plays a key role



Prioritisation used to identify

- Groups of substances that require further regulatory action
- What is the optimal combination of actions
 - data generation;
 - hazard confirmation (CLH or SVHC identification) and/or
 - regulatory risk management (REACH restriction/authorisation or under other legislation)
- substances of low priority for further regulatory work at the moment

Integrated regulatory strategy - Prioritisation plays a key role



Prioritisation defined in the legislation

- Prioritisation to confirm or refute the concern (Community rolling action plan for substance evaluation)
- Prioritisation of substances of very high concern (SVHCs) from the Candidate List to the Authorisation List
- Legal text provides criteria
- ECHA has developed the practical implementation

Content

- Role of prioritisation in ECHA's Integrated regulatory strategy
- **How to prioritise?**
 - **Factors used to prioritise**
 - **Information sources**
 - **Level of the assessment**
- Role of grouping

How to prioritise?

- Factors used to prioritise

- Hazard
 - Knowledge on (severe) hazard
 - Indication of hazard
 - Lack of information on hazard
- Exposure
 - Measured or modelled exposure levels
 - Information on material and release potential
 - Information on uses
 - Not possible to exclude certain uses
- Regulatory measures already ongoing or in place
 - Under REACH/CLP
 - Under other EU legislation

- Normally a combination of factors
- The weight of the factors depend on the case

How to prioritise?

- Information sources

- Based on (readily) available information
 - Main source:
 - REACH/CLP dossiers submitted by the industry
 - Regulatory actions taken under REACH/CLP
 - Increased use of hazard data, exposure data, regulatory data outside our remit
 - Other EU legislation
 - Non-EU countries
 - Academia

Lack or low quality of information should not result in low priority for further scrutiny/action!

How to prioritise?

- Level of assessment (1/2)

Prioritisation should be fit-for-purpose, i.e. take into account the purpose of the next step and the type of work done under the next steps

- Will industry be obliged or triggered to provide further information under the next steps?
- Assessment to prioritise should normally be less detailed than what is done under the next regulatory step

How to prioritise?

- Level of assessment (2/2)

- IT based screening and prioritisation
 - Can cover high number of substances and make use of high amount of information as long as it is sufficiently structured
 - Assessment based on algorithms: false positives and negatives
- Manual screening
 - To verify the outcome of the IT screening
 - Can cover less substances
 - Reduces the number of false positives/negatives
- More detailed assessment of hazard or exposure
 - Only where the level of work at and consequences of the next step justifies the effort

Content

- Role of prioritisation in ECHA's Integrated regulatory strategy
- How to prioritise?
- **Role of grouping**

Grouping

- High number of substances; limited resources
- Grouping used to
 - Bring consistency in how related substances are treated
 - Target the right substance at the right time
 - Use of all information may allow faster action – despite data gaps
 - Increased predictability of authorities' actions
 - Support informed substitutions, or avoid regrettable substitutions

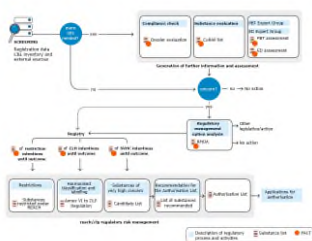
Forming groups for regulatory scrutiny

- First step is to identify a single substance or a set of related substances that will act as “seed”
- Structural similarity: We have built an elaborate machinery that allows identifying all other substances that are related to the seed(s) through *associations* of various types
- We cover registered and C&L notified substances and also substances not on the EU market
- Putative group members that are algorithmically identified are *manually* screened for their suitability for inclusion into the group;
- further refinement of the group based on further information and assessment; regulatory measures can be on the whole or part of the group or per substance

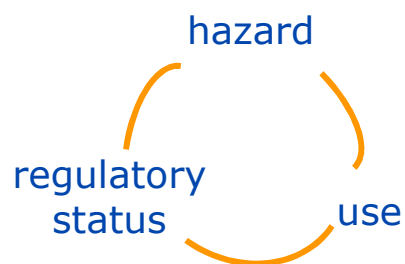
Grouping and prioritisation

- Selection of seeds
 - Known and potential CMRs, PBTs, EDs
 - Function, e.g. flame retardants
 - Use, e.g. in plastics
- Progressing with
 - Chemically related groups;
 - Groups with the same function; and/or
 - Groups relevant for certain industrial sector

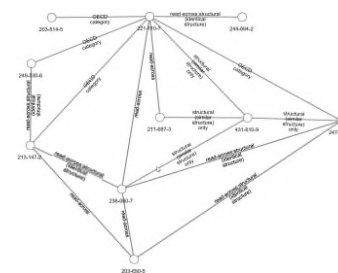
Summary



Integration of processes



Prioritisation



Grouping

- Speed up the work
- Increase efficiency and effectiveness
- Enhance consistency
- Enable predictability and transparency of authorities work

Thank you!

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More information

- Integrated Regulatory Strategy
 - <https://www.echa.europa.eu/substances-of-potential-concern>
- Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)
 - Prioritisation Approach:
 - https://www.echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8
 - https://echa.europa.eu/documents/10162/13640/recom_general_prio_approach_implementation_examples_en.pdf/61b242f5-0ef8-45d6-abe2-1d1f3e00fdd9
- Prioritisation of substances for substance evaluation (Community rolling action plan, CoRAP)
 - <https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan>

We know which substances are used

Tonnage	Registrations	Substances
1 000 tonnes and more	19 930	2 195
100 - 1 000 tonnes per year	12 706	3 419
10 - 100 tonnes per year	12 672	4 019
0 - 10 tonnes per year	16 108	5 649
Intermediate	13 447	6 563
Complete (unique substances)	89 751	21 470

>2 million

Study summaries on properties and effects of chemicals

147 000

Substances classified with GHS

22 000

Substances registered under REACH

1 800

Dossiers for HPV chemicals checked for compliance

580

Risk management proposals

201

Substances of Very High Concern

Tests requested under Compliance check in 2018

