Beyond registration: what happens next

11th Stakeholders' Day

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Contents

Why REACH and registration?

Dossier quality as an asset

What we want to achieve

And where we need you

REACH in a nutshell

- ✓ Better knowledge on hazards, uses and risks
- ✓ Improved communication in the supply-chain
- ✓ Better safety and control measures
- ✓ Reducing exposures and hence negative impacts
- ✓ Substituting (gradually) hazardous substances with less hazardous ones

- ➢ Key drivers: registration, classification and labelling, supply chain communication, authorisation and restriction

Your registration dossiers are vital…

They demonstrate that:

- You know your portfolio
- All necessary information is available
- The chemical safety assessment is appropriate and convincing
- Your customers are informed adequately on how to safely use your substance

➢ Provide confidence to your clients, stakeholders and the general public, that you meet REACH and CLP information requirements

…and are watched by authorities

- Convinced by your assessment and conclusions?
- Screened to identify substances of concern
- Assessed for the need for further risk management measures, at company or EU level

What we want to achieve

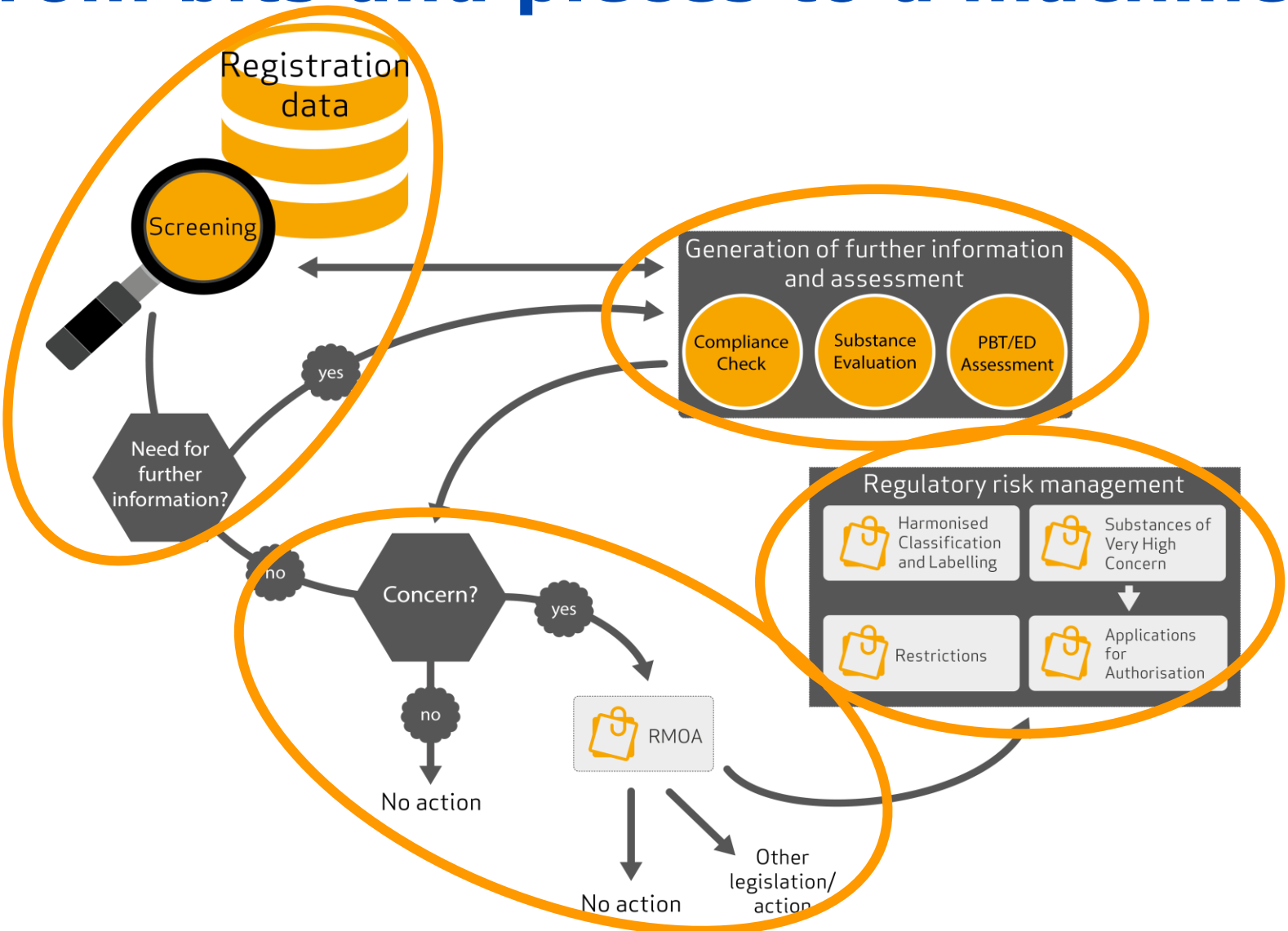
REACH(ing) the 2020 goals

2002 Johannesburg World Summit on Sustainable Development:

By 2020…chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment

REACH and CLP are the key EU instruments that help achieving this goal

From bits and pieces to a machinery



By end of 2018, we want to know for all substances above 100 tonnes

- Are they of (potential) concern?
- Do we need more (hazard) information?
- Do they need to be addressed through (the most appropriate) regulatory risk management action?

OR

- Can we safely put them aside as being currently of low priority for further work?

Focussing on substances that matter

- Higher-tonnage registration dossiers with
- Important data gaps and with
- High exposure potential for:
  - Workers or
  - Consumers or
  - Environment

What do we expect from you?

Good quality registration dossiers

- Quality is improved, but more needs to be done!
- REACH requires you to update:
  - Annual and total volumes that change
  - New identified uses, uses advised against
  - New knowledge on hazard (including C&L) and risks leading to changes in your CSR

- But this is not being done consistently

Update uses/exposure information

- "Clean/clarify" the description of the supported uses and uses advised against
- Improve description of uses as an intermediate (and whether they are under SCC)
- Provide sufficient justifications (intermediate, SCC) to allow authorities to be convinced
- Map out uses with appropriate tonnage information
- Make sure you cover the whole life-cycle

Example: why updating helps

N-methylacetamide:

- Registered uses of N-methylacetamide in the scope of authorisation appeared to include formulation of mixtures at industrial sites

  → Prioritisation score; 12-15
- Updated registration dossiers clarified there appear to be no registered uses of the substance falling within the scope of authorisation

  → Prioritisation score; 1

Transparency and predictability

Addressing Chemicals of Concern

ECHA works together with the European Commission and the EU Member States for the safety of human health and the environment by identifying the needs for regulatory risk management at an EU-wide level. The Member States or ECHA (at the request of the Commission) initiate the identification of substances of very high concern and restrictions, and Industry can submit applications for authorisation. The process for harmonised classification and labelling of substances may be initiated by Member States and by manufacturers, importers or downstream users.

ECHA welcomes all members of the public to give their contributions during the different consultation phases of the authorisation, restriction and harmonised classification and labelling processes. Under the Biocidal Products Regulation, stakeholders can provide information on potential candidates for substitution.

Search for Chemicals Advanced search

I have read and I accept the legal notice

Substances of potential concern

Substances with certain hazardous properties can be of concern for human health and/or the environment. Such substances can be identified and subsequently regulated to make sure that the risks associated with these substances are properly controlled.

› More

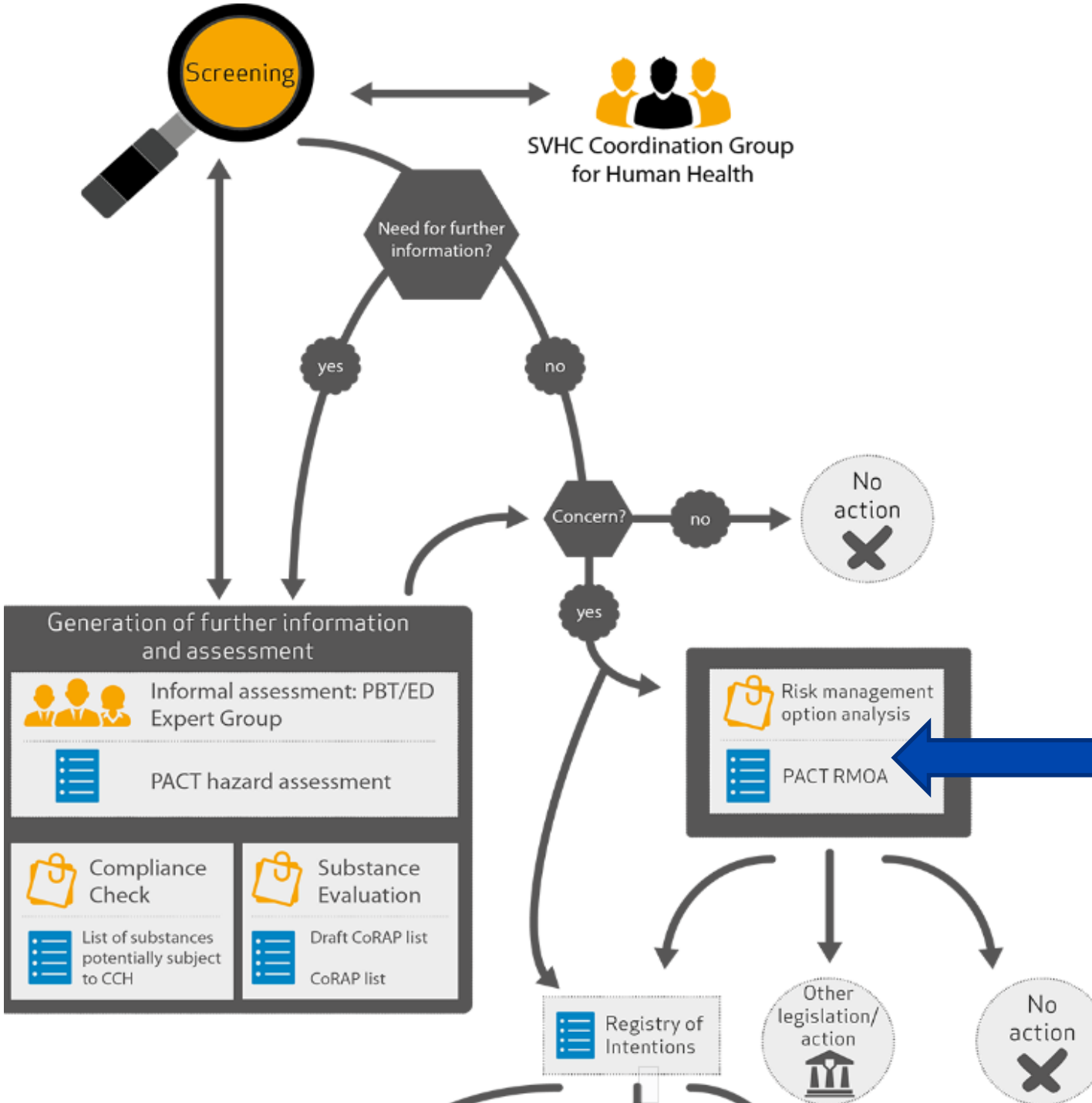
Registry of Intentions

The notifications of intention to submit a dossier to ECHA related to the risk management processes under the REACH (SVHCs and restrictions) and CLP (CLH) regulations are included in the respective Registry of Intentions.

› More

Biocidal Products Regulation

Under the Biocidal Products Regulation, the evaluating Member State Competent Authority may identify an active substance as a potential candidate for substitution. Following the identification, a public consultation is launched. Products containing substances on the list will need to undergo a comparative assessment which will be taken into account for their authorisation.



PACT – RMOA and hazard assessment activities

The Public Activities Coordination Tool (PACT) lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative and toxic/very persistent and very bioaccumulative) properties or endocrine disruptor properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013.

Please read the information on status and purpose of PACT to learn more concerning this matter.

› **Further information**

Disclaimer: The information and views set out in the PACT table and in the RMOA and hazard assessment outcome documents are those of the evaluating authority and do not necessarily reflect the position or opinion of the other Member States or ECHA. Neither ECHA nor the evaluating authority nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the documents are without prejudice to any formal regulatory activities that ECHA or the Member States may initiate at a later stage. RMOAs, hazard assessments and their outcomes are compiled on the basis of information available by the date of the publication of the document.

Further information

- Status and purpose of PACT
- Substance evaluation - CoRAP
- Glossary - PACT technical details [PDF]

Showing 1 - 50 of 332 results. Items per Page 50 Page 1 of 7 |< First < Previous Next > Last

Name	EC Number	CAS Number	Authority	Activity	Latest update	Scope	Outcome	
(-)-pin-2(10)-ene	242-060-2	18172-67-3	Greece	RMOA	07/08/2015	Sensitiser	Under development	Detail
(1-methyl-1,2-ethanediyl)bis[oxy (methyl-2,1-ethanediyl)] diacrylate	256-032-2	42978-66-5	Sweden	RMOA	06/03/2015	Sensitiser	Under development	Detail
(±)-1,7,7-trimethyl-3-[(4-methylphenyl) methylene]bicyclo[2.2.1]heptan-2-one (4-Methylbenzylidenecamphor)	253-242-6	36861-47-9	Germany	RMOA	10/07/2015	ED	Appropriate to initiate regulatory risk management	Detail

Innovation needs predictability

- Authorities to indicate the substances they think are of concern, leading to:
  - Further scrutiny (e.g. compliance check)
  - Risk management option analysis
  - Possible future regulatory action

    (listing on Candidate and Authorisation lists, restrictions, harmonised classification and labelling)
- Helps companies to be proactive:
  - Update your registration dossiers
  - If needed, collect information that can support the RMOA
  - Consider possible long-term consequences and substitution and innovation needs

Take home messages

- Registration is not the end, it’s the beginning!
- Authorities take your registration dossiers very serious
- They form the basis for prioritisation, de-prioritisation, RMOA and possible further actions
- Good quality dossiers are a REACH obligation but should be mostly in the interest of industry
- They are fundamental to demonstrating corporate social responsibility!

Thank you!

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