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# REACHing the Arctic

## Screening for emerging contaminants in the Arctic - Seminar on status and needs

11 October 2016

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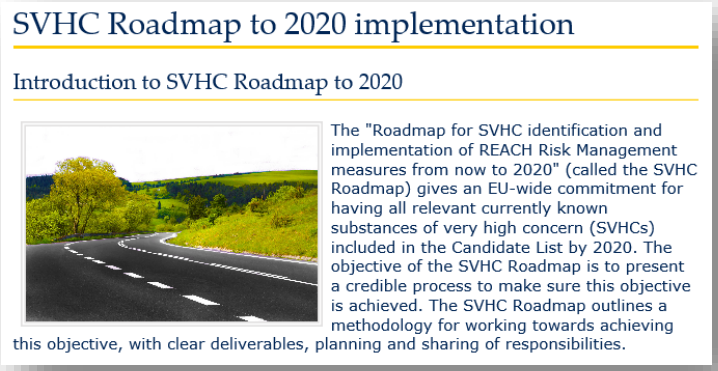
- Focusing on substances that matter
- Common screening approach
- PBT assessment
- Concluding remarks

# Focusing on substances that matter

- SVHC Roadmap 2020
- Regulatory Strategy

# EU-level agreement: SVHC Roadmap 2020

- Identify and include in the Candidate List all relevant currently known SVHCs (substances of very high concern) by the end of 2020
- Strong basis beyond 2020 to identify **substances that matter the most** and to address them timely under REACH & CLP


SVHC Roadmap to 2020 implementation

Introduction to SVHC Roadmap to 2020

The "Roadmap for SVHC identification and implementation of REACH Risk Management measures from now to 2020" (called the SVHC Roadmap) gives an EU-wide commitment for having all relevant currently known substances of very high concern (SVHCs) included in the Candidate List by 2020. The objective of the SVHC Roadmap is to present a credible process to make sure this objective is achieved. The SVHC Roadmap outlines a methodology for working towards achieving this objective, with clear deliverables, planning and sharing of responsibilities.

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# Regulatory strategy

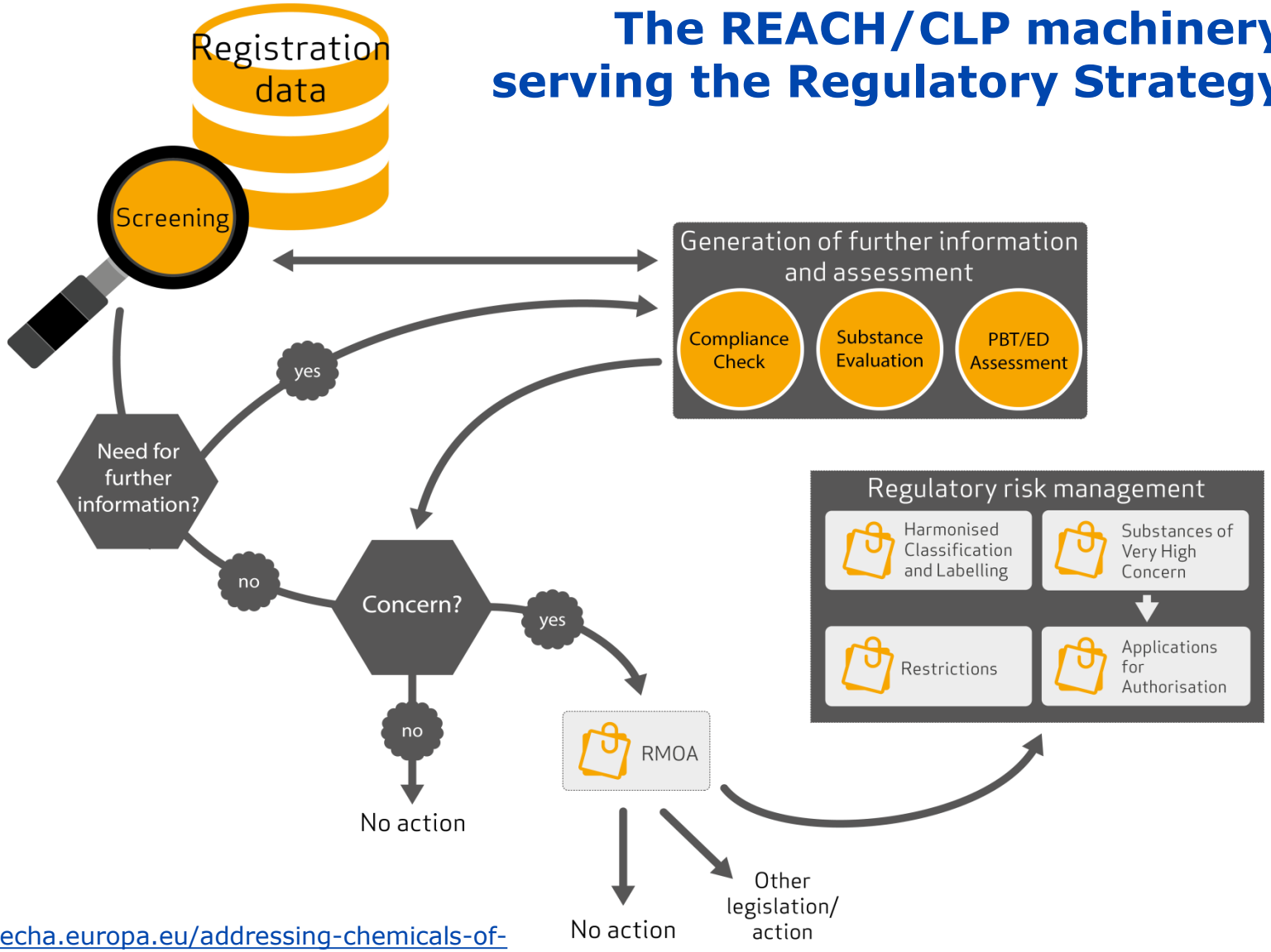
Focus on substances with biggest impact on protection of people & environment through regulatory action

**Substances that matter the most!**

CMRs (cat 1A/1B), sensitisers, endocrine disruptors & substances with specific target organ toxicity

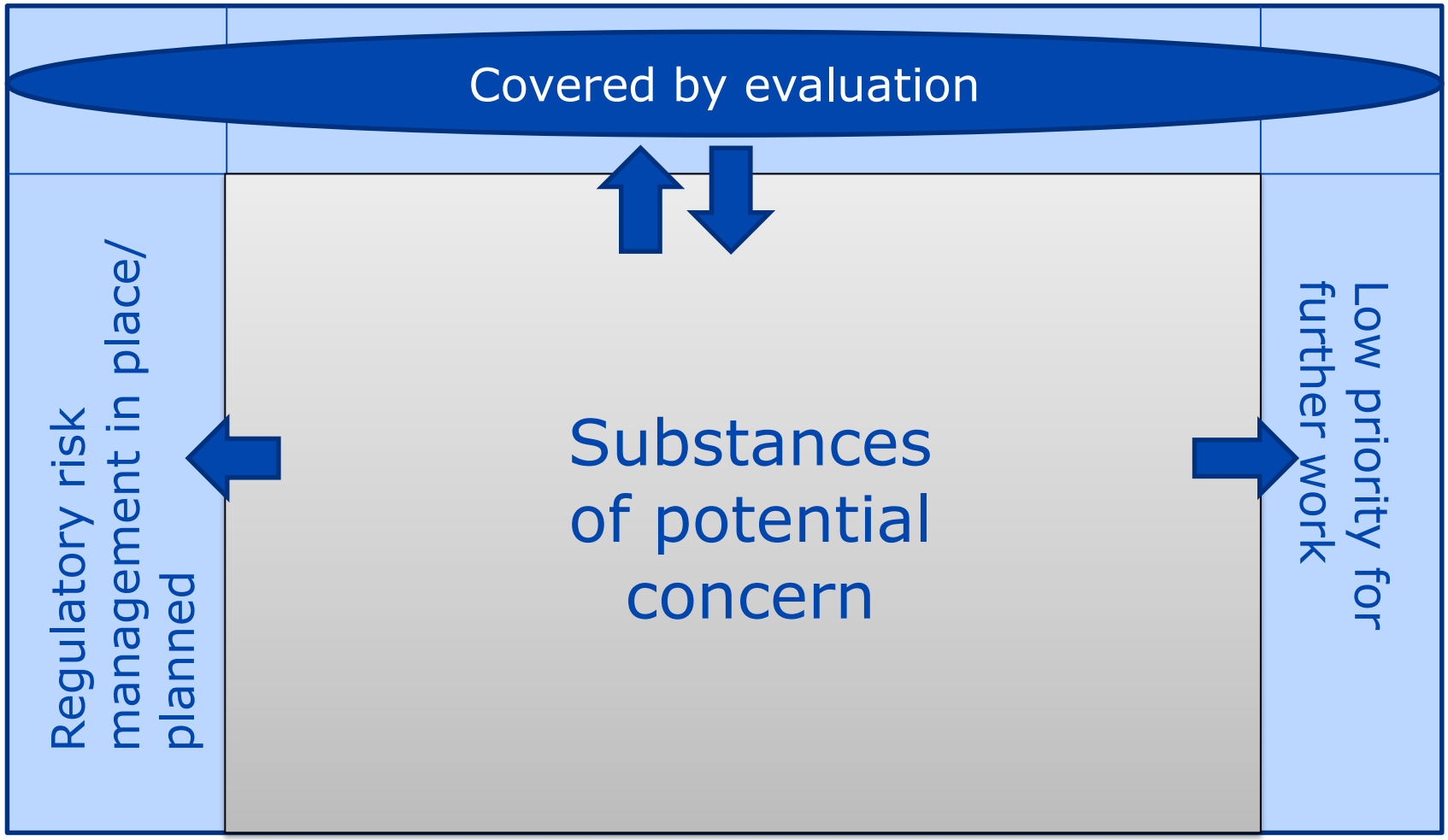
PBTs, vPvBs & endocrine disruptors

# The REACH/CLP machinery serving the Regulatory Strategy

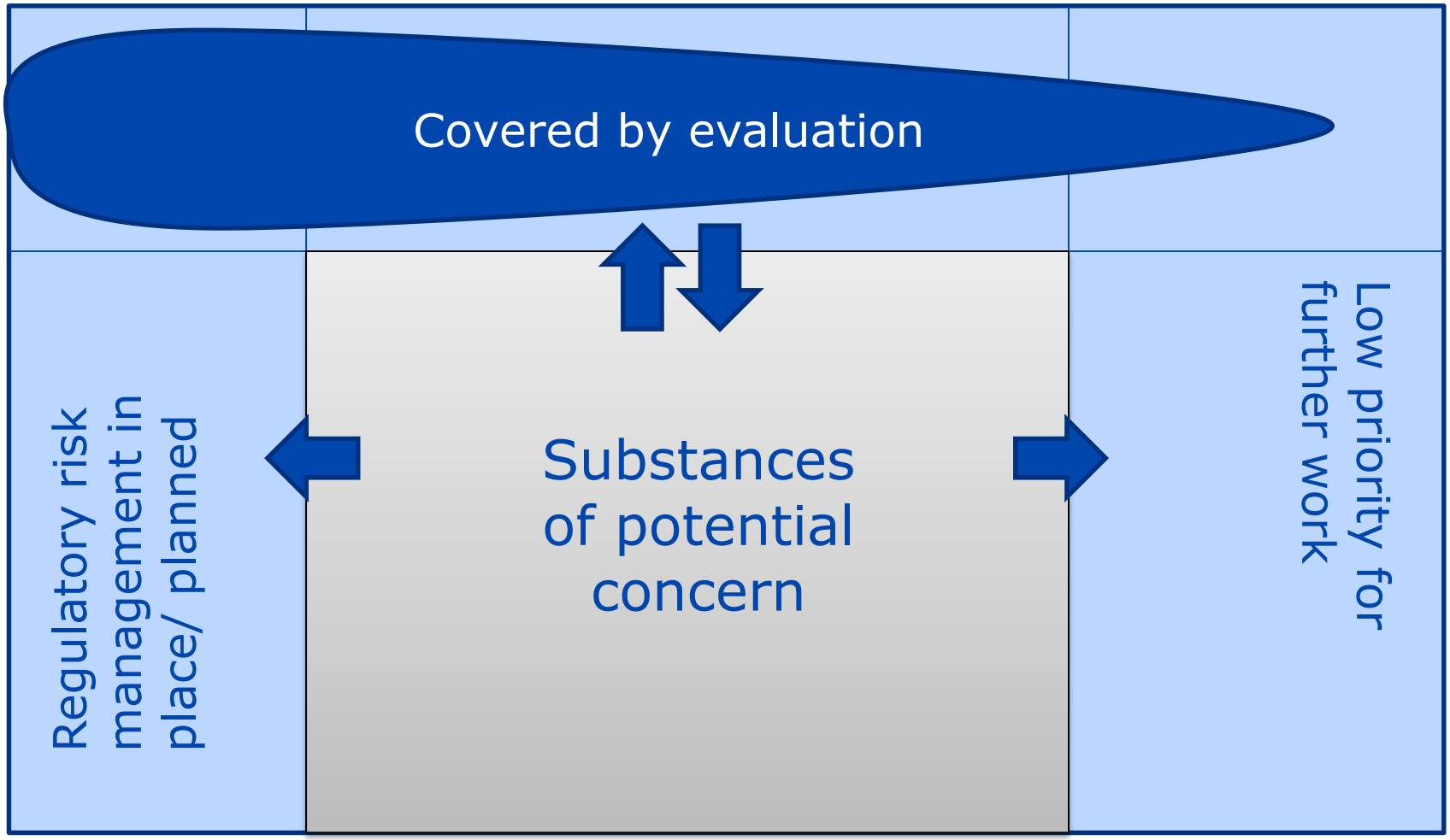



https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

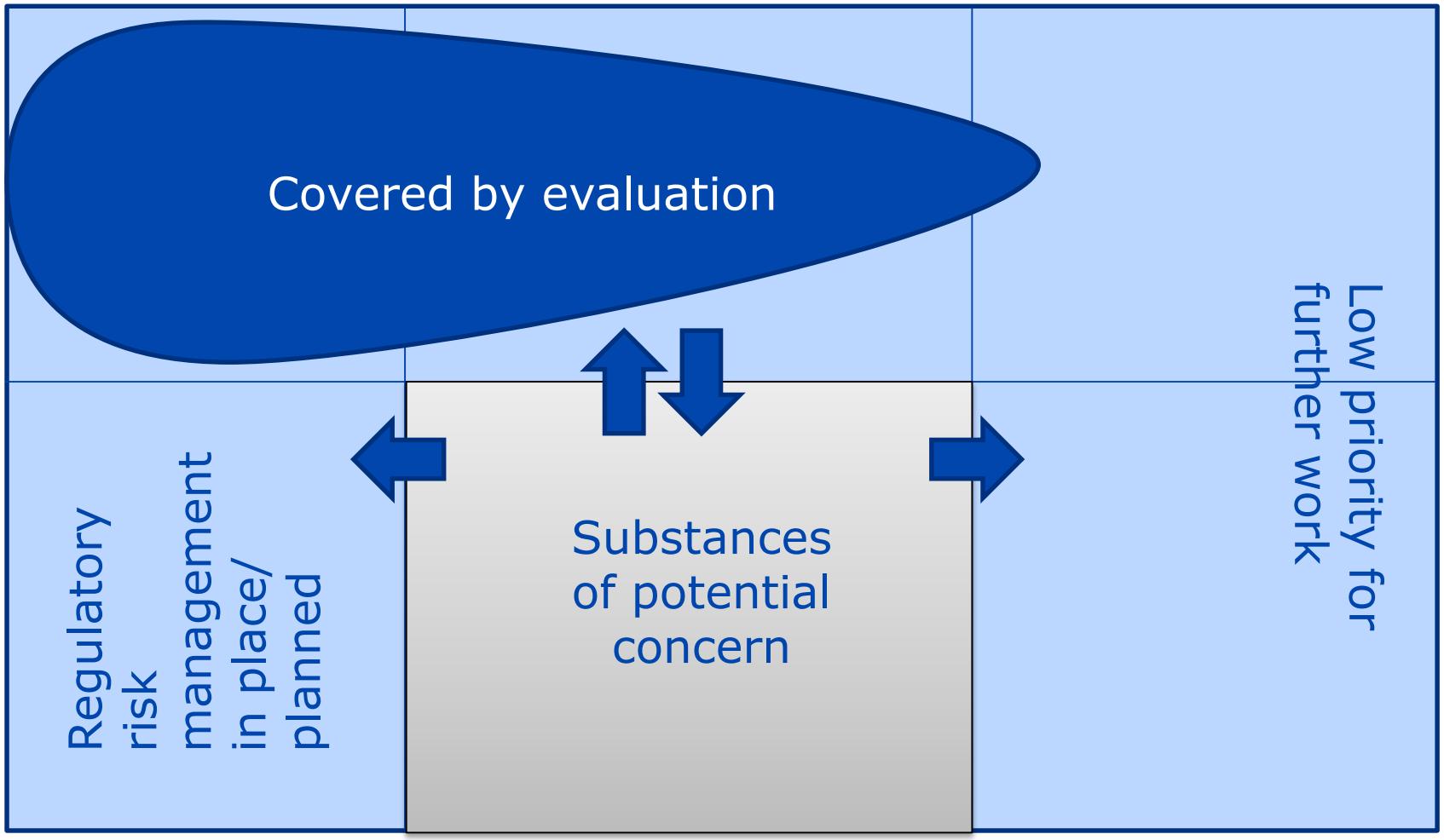
# Situation now



# Situation: short term



# Situation: mid term



# Common screening approach

To identify substances that matter

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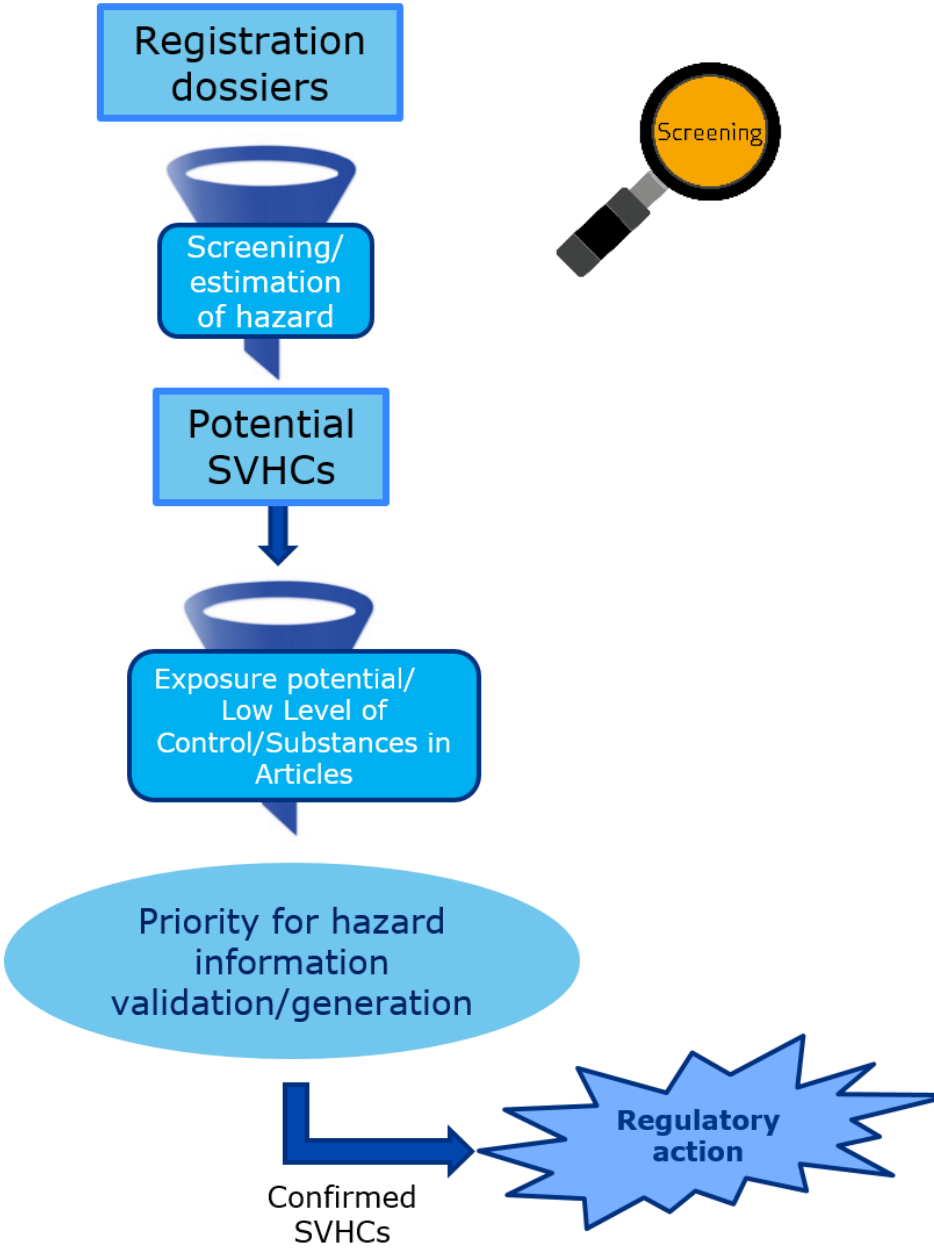
# Common screening approach

- 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*



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# Hazard identification

- IT screening to search for either **indications of hazard** or **data gaps** in hazard endpoints
- Focus on eight super endpoints for human health and environment linked to clarification of CMR and PBT concern:
  - ✓ genotoxicity
  - ✓ repeated-dose toxicity
  - ✓ pre-natal developmental toxicity
  - ✓ reproduction toxicity
  - ✓ carcinogenicity
  - ✓ long-term aquatic toxicity
  - ✓ biodegradation and
  - ✓ bioaccumulation

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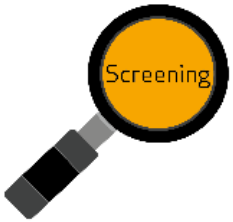
# Estimating exposure: info sources




## Registrations

- Overall tonnage used
- Indication of widespread professional uses, consumer uses, article service life
- Indication of high containment

## External sources

- CDR (US EPA) and SPIN database

## Monitoring data?

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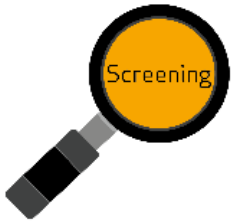


# Assessing the potential of monitoring data in screening

| | |
|---|---|
| Current screening approach | • Monitoring data is not used as a selection criterion |
| Investigation started on using monitoring data | • Potential for assessing likelihood of exposure & hazard and the estimation of wide dispersive use |
| Data & sources | • Environmental and biomonitoring data<br>• Norman, IPChem, Regional Seas Conventions,.. |
| Substances in scope | • **Those not yet regulated (emerging)!** |

# Other approaches to identify substances that matter

- Working together with sectors, e.g. PetCo substances
- Screening by application, technical function, structural similarity
- Substances in articles

# PBT assessment

Role of monitoring data

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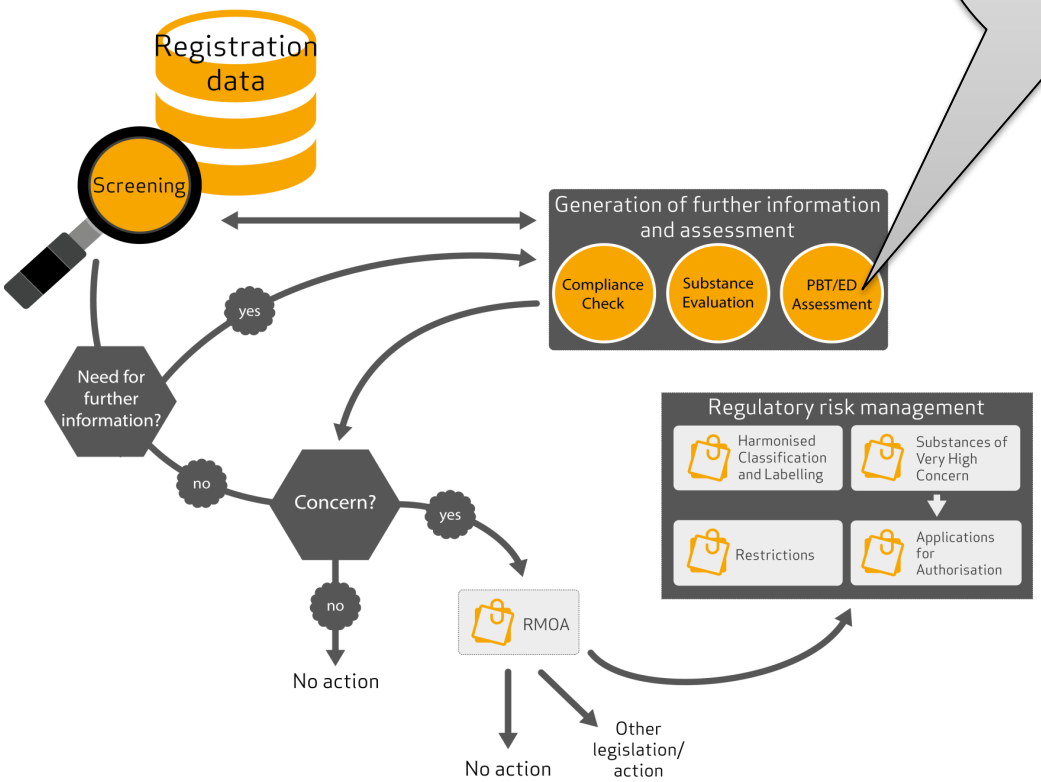


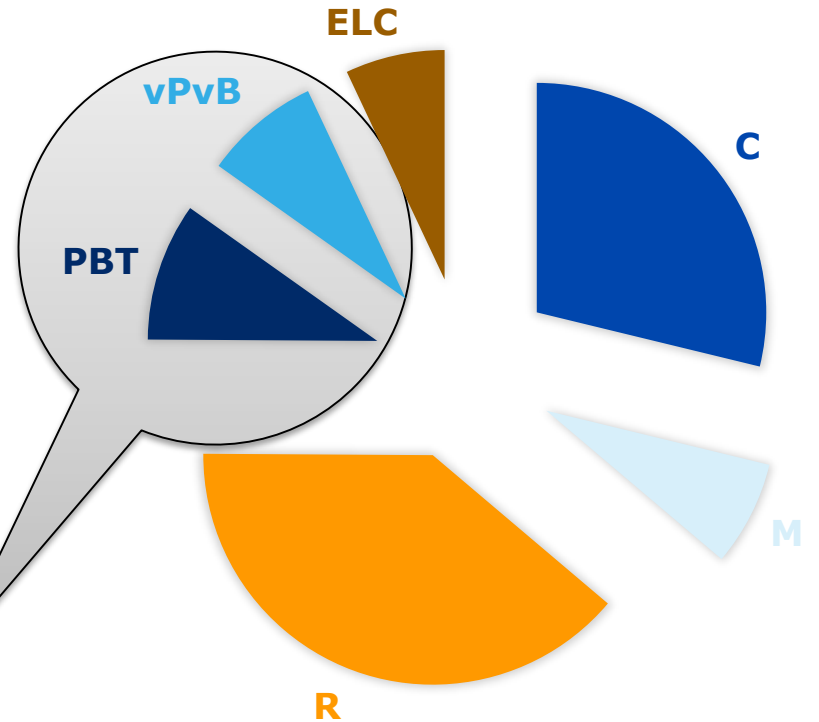


**Candidate list substances**

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# PACT – RMOA and hazard assessment activities

**PFHxSA, PFHxA, PFDA, siloxanes, bisphenols, Dechlorane plus,…**

| Name | EC/List No | CAS Number | Authority | Activity | Latest update | Scope | Outcome | |
|---|---|---|---|---|---|---|---|---|
| 2-(2'-Hydroxy -3' -tert-butyl-5'-methylphenyl)-5-chloro benzotriazole (UV-326) | 223-445-4 | 3896-11-5 | Germany | RMOA | 05/12/2014 | PBT; ENV | Under development | Details |
| 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol (UV-329) | 221-573-5 | 3147-75-9 | Germany | RMOA | 05/12/2014 | PBT; ENV | Under development | Details |
| 2-(2H-benzotriazol-2-yl)-4-methylphenol (UV-P) | 219-470-5 | 2440-22-4 | Germany | RMOA | 05/12/2014 | PBT; ENV | Under development | Details |
| 2,2’,6,6’-Tetra-tert-butyl-4,4’- methylenediphenol | 204-279-1 | 118-82-1 | Austria | Hazard assessment | 05/06/2015 | PBT; ED | Substance evaluation under development | Details |
| 6,6'-di-tert-butyl-4,4'-thiodi-m-cresol | 202-525-2 | 96-69-5 | Austria | Hazard assessment | 05/06/2015 | PBT; ED | Substance evaluation under development | Details |
| (ethoxymethoxy)cyclododecane | 261-332-1 | 58567-11-6 | Finland | Hazard assessment | 07/08/2015 | PBT | According to authority’s assessment NOT PBT/vPvB | Details |

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PBT/ED Assessment

# Monitoring data in PBT/vPvB assessment

- Always case-by-case
  - Additional information for assessing P, vP, B and vB properties using a WoE (weight of evidence) approach
- Suitable data
  1. Human body fluids/tissues (e.g. blood, milk, fat)
  2. Elevated levels in biota (in particular endangered species/vulnerable populations)
- ECETOC Special Report no 18: challenges for using monitoring data for PBT/vPvB assessment

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PBT/ED Assessment

# Approach development

## Assessing bioaccumulation in air-breathing organisms (NO & ECHA)

- Currently monitoring/screening data is the only source of information on bioaccumulation in air-breathing species
  - Lack of data!
- Important for finding persistent/potentially persistent substances which have 2 ≤ logKow ≤ ca. 4 and logKoa ≥ca.4
- Establishing monitoring trends in human blood for "emerging contaminants"

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PBT/ED Assessment

# Banks for abiotic samples

- Environmental specimen banks serve long-term screening and monitoring purposes
- Could be valuable sources of samples for REACH registrants

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# Concluding remarks

- Substances reaching the Arctic are under ECHA's radar
- Many "emerging substances" are part of ECHA's screening universe and can be selected for further risk management (substances that matter)
- PBT and vPvB substances are a priority; harmonised assessment approaches developed in the PBT Expert Group

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# Concluding remarks

- Information in registration dossiers on exposure and use is often missing; monitoring data could be a supporting screening criterion
- Particular need for monitoring data on non-regulated substances
- ECHA is interested in using available monitoring/screening data and to support identifying which substances to monitor in the future

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