Identification of OPnEO and NPnEO as SVHC; Workings of ED Expert Group

WS on Afa for ENV EDs

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Conor Clenaghan

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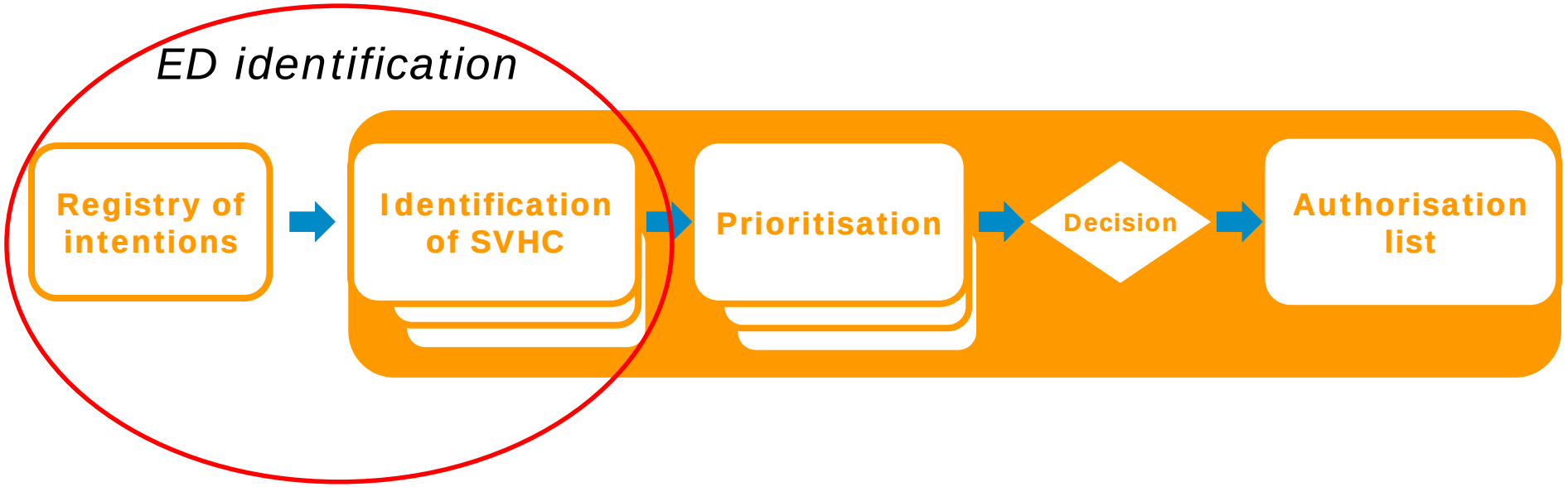
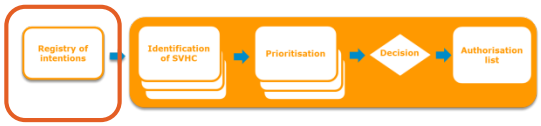
Regulatory process overview

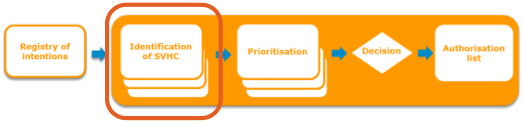
Authorisation regulatory process overview





Registry of current SVHC intentions

- As first step, MS or ECHA (on request of COM) usually inform all interested parties of their intention to identify substance as SVHC
- Intention is published in registry of intentions, on ECHA website
- No public consultation at this stage



Identification of SVHC

•MS / ECHA

•Proposal for SVHC identification

•Authority submits a proposal (Annex XV dossier) for the identification of the substance as a SVHC

•Public consultation

•Dossier published on ECHA website and submitted for public consultation for 45 days

•MSC

•Decision

•Decision taken by Member State Committee (MSC) or Commission

ECHA

•Candidate List

•Candidate List on the ECHA website is updated (if relevant)

- Timeline: about 5 months from the time the dossier is submitted

Regulatory process overview

Substance (groups) identified by MSC as SVHC due to ED properties for ENV and equivalent level of concern (proposed by DE):

- Dec 2011: 4-tert-OP
- Dec 2012: 4-tert-OPnEO and 4-NP
- June 2013: 4-NPnEO

SVHC Identification

SVHC Identification under Art 57(f)

ED Identification

Based on WHO/IPCS definition:

- Endocrine mode of action (MoA)
- Adverse effects
- Causal link between endocrine MoA & adverse effects

Equivalent Level of Concern

- To CMRs / PBTs / vPvBs

4-tert-OP and 4-NP

- Effects in fish species fit to estrogenic mode of action

- In fish species clear link between endocrine MoA and adverse effects from high quality studies

- Endocrine mediated adverse effects in fish at very low concentrations - **LOECs at low µg/L range** (4-tert-OP - fertility, fecundity; 4-NP – change in sex ratio)

- Indication of ED effects in invertebrates and amphibians at even lower concentrations – no definite conclusion owing to lack of knowledge on endocrine system / low quality data / lack of test systems

4-tert-OPnEO & 4-NPnEO

- Ethoxylates degrade to 4-tert-OP / 4-NP in waste water treatment plants or in receiving water bodies
- Remain a long-term source of 4-tert-OP / 4-NP in sediments
- Sediment and pelagic organisms may be exposed to 4-tert-OP / 4-NP resulting from the degradation of ethoxylates / remobilisation
- Available in vivo and in vitro data indicate that short chain ethoxylates are endocrine active in fish
- However no data available on adverse endpoints - not possible to conclude whether or not they are EDs

! Therefore SVHC identification based on degradation to 4-tert-OP and 4-NP

Important Considerations

- MSC produced an MSC Agreement document and MSC Support Document for each of these substances – SVHC identification based on unanimous decision
- MSC Support Documents for 4-tert-OP and 4-NP state that although there may be a safe level, it is difficult to estimate:
  - Wide variety of species potentially affected - which are most sensitive?
  - Effects on endpoints not considered in OECD test guidelines
  - Long-term / delayed effects
  - Potential ED effects on e.g. invertebrates at very low levels
  - Lack of knowledge and test systems for EDs e.g. in inverts
- NB The MSC does not try to determine safe levels during SVHC identification!

ED Expert Group

Background

- ED EG established on basis of agreement by competent authorities for REACH and Biocidal Products Regulation (BPR) on group's mandate (2013)

- ED EG to contribute to efficient assessment of substances with (potential) ED properties

- Important step forward in implementation of:
  - REACH Regulation, including achievement of the SVHC Roadmap to 2020 aims
  - BPR

ED EG set up

- Meetings coordinated, hosted and chaired by ECHA
- Participants from
  - Member State Competent Authorities (MSCA currently 17)
  - Accredited Stakeholder Organisations (currently 7) (IND, NGOs, Workers Organisation)
  - European Commission (DG GROW, DG ENV, DG SANTE, JRC)
  - Other authorities / organisations (EFSA, OECD, CH)
- More information on ECHA website: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/endocrine-disruptor-expert-groupexpert-group
- Contact: ed_eg@echa.europa.eu

ED EG mandate and tasks

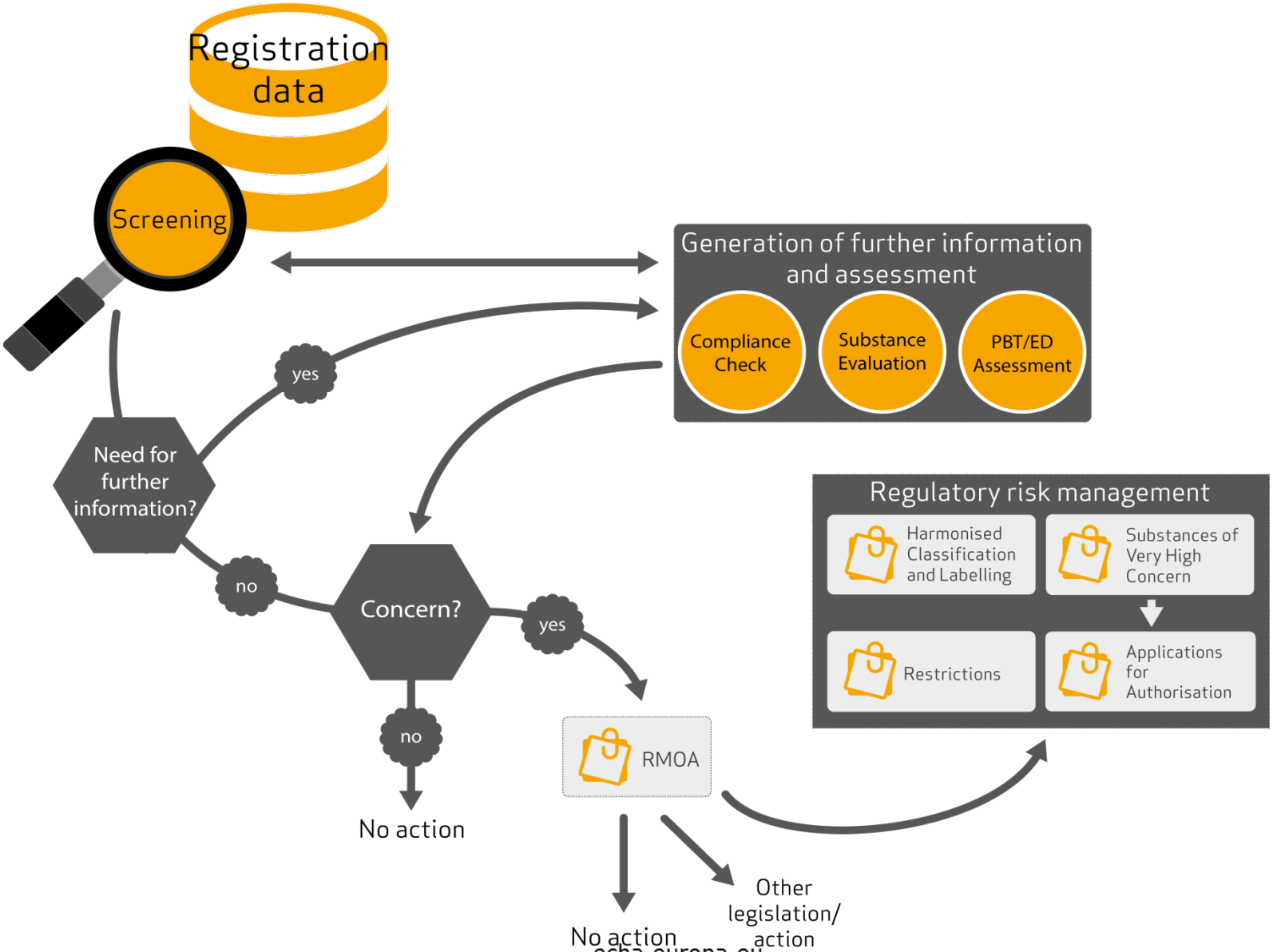
- ED EG provides informal and non-binding scientific advice on assessment of ED properties of chemicals
  - e.g. information and testing needs, data interpretation, screening development

- ED EG serves the evaluating agencies - MSCA requests advice and then decides how to take deliberations of EG into account

! Expert Group does not take formal decisions.

- Decisions remain responsibility of competent bodies designated under REACH and BPR

REACH / CLP machinery



ED EG work to date

- 8 meetings held since Feb 2014, approximately 50 substance cases discussed

EDEG discussions informed by e.g.:

- Widely accepted ED definition (WHO/IPCS, 2002) *"exogenous substances that alter function(s) of the endocrine system and consequently cause adverse health effects in an intact organism or its progeny, or (sub)populations"*
- Joint Research Centre ED Expert Advisory Group report and European Food Safety Authority (EFSA) opinion on identification of EDs
- OECD conceptual framework for testing and assessment of EDs and guidance documents

ED EG work to date

- Discussions mostly focussed on:
  - interpretation of available data
  - identification of further information requirements,
  - strategy to fill identified data gaps

- Implications of ED criteria to be established under Biocides and Plant Protection Product Regulations need to be considered

- **NB** ED Expert Group was set up after the SVHC identification of these phenols

CONCLUSION

- 4-tert-OP and 4-NP identified as endocrine disruptors, based on WHO/IPCS definition
- Strong evidence from high quality studies of endocrine mediated adverse effects in fish species with LOECs at low µg/L range
- Indication that effects in other taxa may be endocrine mediated also, at potentially even lower levels.
- Ethoxylates identified as SVHC as they degrade to 4-tert-OP and 4-NP in the environment

Thank you!

conor.clenaghan@echa.europa.eu

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