PERSPEKTIVEN FÜR UMWELT & GESELLSCHAFT umweltbundesamt

Endocrine Disruptors within the context of REACH

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4 Major Processes in REACH

New instrument

Registration	Evaluation	Authorisation Annex XIV	Restriction Annex XVII
≥ 1 t/year, Data submission to ECHA, ≥ 10 t/y: Chemical safety assessment	Control Clarification of potential risks	Managing risks of substances of very high concern (SVHC) Stoffe	EU-wide management of substances with unacceptable risks for human health and/or environment

EDs in REACH

- In Titel VII – dealing with authorisation
- In Article 138 (7) dealing with hazard description and the adequate route for an application for authorisation
- No definition of EDs is provided in REACH, nevertheless the **WHO / IPCS definition** is used in the REACH context:
  - Adversity
  - Endocrine Mode of Action (MoA)
  - Plausible link between adversity and endocrine MoA
- Official ED-Status by Member State Committee (MSC)/Commission, when a substance is identified as a substance of very high concern (SVHC) because of ist ED properties

ED & Authorisation

- Goal is to control risks of SVHCs/ substitution
- Criteria according to Art. 57: CMRs (1A, 1B), PBTs, vPvBs and substances of equivalent level of concern like EDs
- 2-step system:
  - Candidate list: http://www.echa.europa.eu/web/guest/candidate-list-table; mainly information duties
  - Annex XIV = List of substances subject to authorisation: User needs to apply for an authorisation

ED in SVHC Roadmap to 2020

- gives an EU-wide commitment for having all relevant currently known substances of very high concern (SVHCs) included in the Candidate List by 2020
- A plan has been developed on how to implement the SVHC Roadmap until 2020. The SVHC Roadmap implementation plan focuses on organisation of
  - Screening to identify new substances of concern, and analysing the risk management options (RMOs) appropriate to the particular substance of concern
  - Outline of how progress monitoring and communication towards stakeholders and the general public is foreseen

EDs part of the SVHC Roadmap 2020

- The SVHC Roadmap to 2020 anticipates the use of screening methods and risk management option analysis (RMOA) to identify the relevant substances of concern using information from the ECHA registration database, other REACH and CLP databases and additional relevant data
- Certain groups of substances are covered:
  - Carcinogens, mutagens, reprotoxicants (Categories 1A/1B),
  - Sensitisers,
  - Persistent, bioaccumulative and toxic (PBTs) or very persistent, very bioaccumulative (vPvBs),
  - **Endocrine disruptors (EDs),** and
  - Petroleum/coal stream substances that are CMRs or PBTs

EDs on the candidate list

Substance	Property	MS
4-(1,1,3,3-tetramethylbutyl)phenol, 4-tert-octylphenol; 4-tert-octylphenol	ED (Environment)	DE
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated*	ED (Environment),	DE
4-Nonylphenol, branched and linear	ED (Environment)	DE
4-Nonylphenol, branched and linear, ethoxylated	ED (Environment),	DE
Bis (2-ethylhexyl)phthalat (DEHP)	ED (Environment)	DK

- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated under discussion for priorisation for Annex XIV
- For 4 phthalates (DEHP, Dipentyl phthalate, Benzylbutylphthalate & Diisopentyl phthalate) there is a majority vote that these substances are EDs for human health. Decision needs to be taken by the commission.

3 new SVHC proposed for ED + new intention for BPA

- **Dicyclohexyl phthalate** (DCHP): because of
  - Reproductive toxicity (1B) acc. to Art. 57c)
  - Equivalent level of concern having probable serious effects to human health (Art. 57f)
  - Equivalent level of concern having probable serious effects to the environment (Art. 57f)
- **4-methylbenzylidene camphor**: Art. 57f for Env.
- **3-benzylidene camphor:** Art. 57f for Env.

- **BPA**: France has intention for an SVHC dossier for BPA because of its reprotoxic & ED effects

Threshold discussion in REACH

- Acc. Article 138 (7): Commission has to assess until 1st of June 2013, whether EDs are substances for which a threshold is derivable
- Result (CARACAL document): Baseline is assumption that because of current uncertainties there is no threshold, unless the applicant can prove the threshold
- Uncertainties (i.a.):
  - ➢ Limited number of available tests
  - ➢ Limitations from test design – e.g. critical phases in development/life cycle or decisive parameters were not looked at
  - ➢ Potential effects at low doses
- ✓ As a result the socio-economic route is the baseline route for the applicant (as for carcinogens), while for adequate control route (which is normally used for reprotoxicants) is only possible, if the applicant can prove the threshold

DEHP & European parlament

- Resolution in November 2015 regarding granting an authorisation for DEHP in recycled soft PVC
- Several critical points raised- inter alia that ED was not included in the assessment of the application for authorisation

Restriction of EDs: Nonylphenol & Nonylphenol ethoxylate

- **Nonylphenol & Nonylphenol ethoxylate:** Shall not be placed on the market or used as a substance or constituent of preparations in concentrations ≥ 0,1 % for the following purposes (e.g.):
  - industrial and institutional cleaning (with exceptions)
  - textiles and leather processing except (with exceptions)
  - metal working (with exceptions):
  - manufacturing of pulp and paper
  - co-formulants in pesticides and biocides

- Nonylphenol ethoxylates: Shall not be placed on the market after 3. 2. 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations ≥ 0,01 %

Restrictions with additional ED-concern

BPA: Restriction in thermal paper because of effects on female reproductive system, brain & behaviour, vulnerability of the developing mammary gland, metabolism & obesity

Decision in upcoming REACH Committee

Siloxane D4, D5 (Octamethylcycloterasiloxane, Decamethylcyclopentasiloxane): Restriction for personal care products that are washed off in normal use conditions (≥ 0.1%) because of PBT/vPvB properties: a potential ED concern for HH was identified by RAC but not further evaluated

ED & Substance evaluation (SEV)

- Registration dossiers + other information sources (e.g. US EPA ToxCast) are used to evaluate whether a risk can be identified or more data are needed to evaluate the potential risk
- On EU-wide list (CoRAP: Community Rolling Action Plan), there are several (currently 67) substances with identified ED concerns:– eg. Triclosan (DK), BPS (BE), Benzotriazole (DE), 2,2´,6,6´-tetra-tert-butyl-4,4´methylenediphendol (AT)
- For some substances an ED concern was/is identified during substance evaluation e.g for Octocrylene (FR)
- In many cases new tests are deemed necessary to clarify concern
- Outcome of a substance evaluation can be that risk management measures like an SVHC dossier are necessary

ED Screening under REACH

- Identification and investigation of substance (and dossier) specific information to make a preliminary assessment on whether that substance (or dossier) should be handled via a particular REACH or CLP process
- Manual screening: ECHA identifies concerns by using IT-tools for screening of REACH dossiers + external lists/information: A „short list“ is created
- Member states follow up by picking substances – a substantial portion have an ED concern
- ED concern is not splitted into human health or environment
- Possible to include a focus on worker exposure

ECHA ED-Expert Group – since 2014

- In 2014 an informal ED expert group was established as the assessment of ED is still difficult and Guidance is lacking
- The expert group will provide informal and non-binding scientific advice on questions related to the identification of endocrine disrupting properties of chemicals and, in particular, on:
  - Questions related to screening methods/activities to identify potential EDs (e.g. for the CoRAP and/or Candidate List)
  - Questions related to the development of integrated approaches to testing and assessment of ED properties

ECHA ED-Expert Group – since 2014

- Feedback and recommendations on complex (specific/generic) scientific issues related to information and (tiered) testing needs for potential EDs (e.g. under dossier or substance evaluation or under the evaluation by the evaluating competent authority of a biocides active substance application)
- Specific questions on the interpretation of test data as well as other relevant information in relation to the identification of ED properties (e.g. during the development of an SVHC dossier or a biocides active substance evaluation)

Participants of ED EG

- EU MS CA and EEA country representatives (currently from 15 MS + NOR)
- European Commission (DG ENV, GROW, SANTE)
- ECHA + EFSA
- Stakeholder organisations:
  - ChemTrust
  - Health and Environment Alliance (HEAL)
  - Humane Society International
  - European Environmental Bureau (EEB)
  - European Trade Union Confederation (ETUC)
  - European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)
  - The European Chemicals Industry Council (CEFIC)
  - Organisation for Economic Co-operation and Development (OECD)
- Swiss participants: Federal Office of Public Health + Ecotox Center Eawag

Work in ED-EG

- ED-relevant data (like in vitro data) often not included in the registration dossier – need to be gathered and assessed by MS
- Discussions often on specific substances – advice is rather case-specific

Some Outlooks

- The influence of the awaited criteria publication by the commission (laid down in biocidal and plant protection products regulation) needs to be awaited

- Other pathways than the estrogenic/anti-estrogenic or androgenic/ anti-androgenic pathway are gaining importance: Thyroid pathway (link i.a. to neurodevelopment), pathways dealing with metabolic disorders, immune system ….

Thank you for your attention!

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http://www.umweltbundesamt.at/umweltsituation/chemikalien/ed/

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