PBT/vPvB and Endocrine Disruptors – Latest Developments

October 13, 2021

Ales Bartl

Ales has a broad experience in EU product regulatory law, including REACH, CLP, POPs, biocidal legislation, food law, medical devices, electronic products and product and food safety. He advises on regulatory compliance of a broad range of products marketed in the EU and represents clients before EU and national competent authorities on compliance and enforcement issues. Ales also advises on product recalls and withdrawals.

Ales primarily focuses on EU regulation of chemicals and food, including representing clients in various procedures before the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA).

bartl@khlaw.com • +32 (0) 2 645 5085

Context

- Chemicals strategy for sustainability (CSS)
- Published: 14 October 2020
  - Communication from the European Commission

    https://ec.europa.eu/environment/strategy/chemicals-strategy_en
- Goals:
  - Toxic free environment by 2030
  - Global standard
- PBT/vPvB and Endocrine Disruptors one of the priorities of CSS

I. PBT/vPvB

Current status

- Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB) substances
- Obligation for REACH registrants to carry out PBT/vPvB assessment under Annex XIII REACH
- Annex XIII REACH: provides numerical criteria for identification, based on the weight of evidence assessment of screening and assessment data
- If identified as PBT/vPvB: minimize exposure and emissions based on exposure estimation
- PBT/vPvB a group of SVHCs
- But not a hazard classification yet

New classification PBT/vPvB

- Ad Hoc Meeting of CARACAL of 30 September 2021 agreed on criteria for CLP classification of PBT/vPvB (not an official proposal yet)
- The Commission intends to use the existing numerical criteria of Annex XIII to REACH as the starting point to establish the draft proposal. Annex XIII would be deleted from REACH
- Only two categories: PBT and vPvB
- Proposal to introduce Category 2: ‘Suspected PBT/vPvB’ based on screening data not supported by CARACAL

Relevancy of screening data?

- Based on Commission's survey:
  - About 25% of the Annex X substances (>1000 tons) would likely meet the PB(T) screening criteria. More specifically, 33 % met the P screening criteria, 47% the B screening criteria and 6 % the T
    - This would mean that 25 % of all registered substances (roughly more than 5000 substances) would be identified as suspected PBT/vPvB
    - In category 1, it is estimated that there could be about 400 of all registered substances (23751 substances) which may be identified as PBT/vPvB

Other considerations for PBT/vPvB

- Threshold for classification of mixtures: 0.1%
- It is proposed to include endocrine disruption to the toxicity part of the PBT rules (not currently included)
- Open questions:
  - If Annex XIII is deleted from REACH, then how will SVHC listing be determined for PBT/vPvBs?
  - Will existing relemmission vance of screening criteria for identification of PBT/vPvB set out in the CoGuidance documents continue to apply? (Trigger for higher tear studies? Use of QSAR in screening? Relevance of screening data in the weigh-of-evidence?)

PMT/vPvM substances

- Persistent, Mobile and Toxic (PMT) and very Persistent and very Mobile Substances (vPvM)
- Currently a group of SVHCs (‘similar concern’ as PBT/vPvB)
- Highly soluble in water and have a low adsorption potential, so are not impeded in their travels by solids such as sediments
- They are thought to be able to travel long distances
- A low adsorption potential also means that standard water treatment processes don't work. "If they enter drinking water, current cleaning technologies can only remove them at high societal costs, if at all,"
- A continuous presence in water is believed to result in continuous bioavailability

Classification PMT/vPvM

- Ad Hoc meeting of CARACAL PBT/vPvB/PMT/vPvM criteria 30 September 2021 (Ad-hoc CA/03/2021)
- Proposal: mobility could be based exclusively on the logarithm of the water to organic carbon partition coefficient (logKoc) (water to soil). German UBA: logKoc of 3-4 = M, logKoc < 3 = vM; (i.e., not taking into account environmental parameters)
- Industry: tiered approach that includes consideration of ‘leachability’ via modelling and experimental data
- Commission: the approach based on leaching is more specific for risk assessment
- However, it also says that "a clear majority" at ECHA’s PBT expert group prefer lowering the LogKoc values by 1

SIN List of PMT/vPvM

- In November 2019 Swedish NGO ChemSec added 16 substances, including three per- and polyfluoroalkyl substances, to its Substitute It Now (SIN) list based on Germany's mobility criteria
- Chloroform; Carbon tetrachloride;1,1,1-Trichloroethane Tris(2-chloro-1-methylethyl) phosphate (TCPP); Pentasodium pentahydrogen -n-tetrakisphosphonate
- N-tetrakisphosphonic acid, sodium salt; Trifluoroacetic acid (TFA); PFBS; FC-3284; N-Butylbenzenesulphonamide; 2,2´-Azobis[2-methylbutyronitrile]; 2,2'-Dimethyl-2,2'-azodipropiononitrile; Melamine; 1,2,4-Triazole
- 1,4,5,6,7,7-Hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride;1,4-Dioxane

II. Endocrine Disruptors (ED)

Main initiatives regarding ED

- Endocrine disruptors are chemicals which can impact on the hormonal system of humans and animals
- Currently: a group of SVHCs under REACH + BPR/PPP criteria
- There are currently two ongoing initiatives:
  - Classification of ED under CLP
  - Specific information requirements for ED endpoints in REACH

Classification of ED

- 2 classes:
  - Category 1: Known (A) or presumed (B) endocrine disruptors (HH and ENV)
  - Category 2: Suspected endocrine disruptors (HH and ENV)

Proposed classification criteria: see Commission proposal discussed in the 4th Meeting of Competent Authorities Sub-Group on Endocrine Disruptors (CASG-ED) of 22 March 2021 (CASG-ED/2021/02) *[not an official Commission proposal]*

Additional REACH data requirements for ED

- Chemicals Strategy for Sustainability seeks to "*ensure that sufficient and appropriate information is made available to authorities to allow the identification of endocrine disruptors*
- To do this, the European Commission shall "*update information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH*"

Additional data requirements for ED

- Ongoing Commission project ‘Update of REACH Annexes for Inclusion of Data Requirements on Endocrine Disruption’: public consultation until October 15!
- Amend Annex I + Annexes VII-X REACH
- Potential need for registrants to update their dossier with new tests providing information on endocrine disrupting properties
- Impact Assessment of the relevant regulatory options: see report from the CASG-ED meeting in October 2020

Main elements of the proposed action

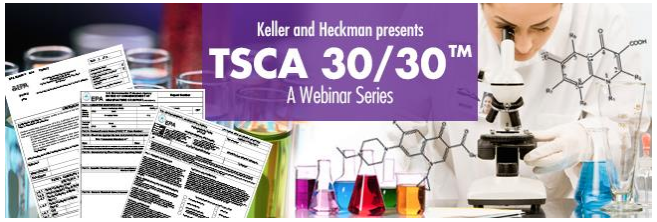
- Proposed 2008 cut-off point for existing data in Annex XI
- Only a positive result in Annex VII *in vitro* tests be the trigger to conduct or require appropriate *in vivo* mechanistic studies
- But: commission's concern about false positives of *in vitro* tests (but not false negatives (?))
- Document also includes proposed waivers, including the use EOGRTS TG 443 as waiver under Annex VIII REACH

III. Impact of PBT/ED classification

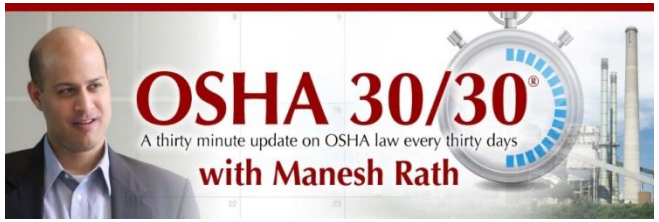
Impact of PBT/PMT/ED classification

- Generation of additional data under REACH for ED will lead to more substances being identified as ED
- If a substance is classified as ED/PBT/vPvB/PMT/vPvM:
  - Obligation to notify ECHA C&L inventory (publicly available!)
  - Potentially: automatic phase-out for professional and consumer uses based on the revision of the generic approach to risk management envisaged by the CSS (i.e., irrespective of the risk/exposure)
  - With the exemption for ‘essential uses’
  - How about Category 2 ED?

Please join us at 1:35 PM Eastern U.S.
Wednesday, November 10, 2021
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, November 10, 2021
www.khlaw.com/TSCA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, October 27, 2021
www.khlaw.com/OSHA3030

Thank You

NEXT REACH 30/30

November 10, 2021

Ales Bartl

Associate

Brussels, Belgium

+32 (0) 2 645-5085

bartl@khlaw.com