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Plans to Significantly Increase Data Requirements at the 1-10 Tonne/Year Level for REACH Registration

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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).

Marie Escornebouleu

- Marie Escornebouleu counsels clients on regulatory and compliance matters related to food and drug law, with an emphasis on food and drug packaging, cosmetics, chemical control, and environmental issues.

- She assists companies in obtaining regulatory clearances for food-contact materials at the European Union (EU) and Member State level and advises clients with respect to mutual recognition. She also advises companies on sustainability initiatives; REACH matters; the Classification, Labelling, and Packaging (CLP) Regulation; and Biocidal Products Regulation (BPR).

Announced Revision of REACH Information Requirements

- CARACAL CA/09/2022: announces framework for discussion of the review of REACH information requirements in the context of the IA
  - IA will be the basis for the REACH revision
  - Revision proposal expected Q1 2023
- Current state
  - Annexes VI to X of REACH define minimum data requirements based on tonnage
  - Information shall be generated “whenever possible by means other than vertebrate animal tests, through the use of alternative methods”
  - Testing on vertebrate animals for the purposes only as a last resort
- What is foreseen
  - Now COM foresees merging of Annexes VII and VIII, new adaptations, and additional data requirements for all tonnage bands

I. Current Requirements for 1 to 10 tons and 10-100 tons Bands (Annexes VII and VIII)

Current Requirements for 1 to 10 tons Band (Annex VII)

- Technical dossier shall include, as a minimum (Column 1):
  - Physicochemical properties; AND
  - Toxicological information including: skin corrosion/irritation; serious eye damage/irritation; **skin sensitization (vertebrate)**; mutagenicity; **acute toxicity (oral)(vertebrate)**; AND
  - Ecotoxicological information: **aquatic toxicity (vertebrate)** and degradation
- No chemical safety assessment required

Current Requirements for 10 to 100 tons Band (Annex VIII)

- In addition to req under Annex XVII, Annex VIII includes the following:
  - Physicochemical properties assessment for nanoforms; AND
  - Toxicological information, including additional hazards compared to 1-10 tons band:
    - Skin corrosion/irritation **(vertebrate);** Acute toxicity (inhalation/dermal) **(vertebrate);** Repeated dose toxicity **(vertebrate);** Reproductive toxicity **(vertebrate);** Toxicokinetics; AND
  - Ecotoxicological information:
    - Short-term toxicity testing on fish, activated sludge respiration inhibition testing, degradation, fate and behavior in the environment
- Chemical safety assessment required

Adaptations Common to all Bands (Annex XI)

- Beyond column 2, adaptations may be sought under Annex XI when:
  - Testing does not appear scientifically necessary, because:
    - Existing data
    - Weight of evidence information
    - Qualitative or Quantitative structure-activity relationship ((Q)SAR);
    - Suitable in vitro methods
    - Grouping of substances and read-across approach
  - Testing is technically not possible as a consequence of the properties of the substance

II. Revised information requirements under consideration

Background for the Amendment to Information Requirements (1)

- Foreseen substantially increased information requirements under REACH
  - Need for increased testing for certain hazards at ALL tonnage bands:
    - Carcinogenicity, neurotoxicity, immunotoxicity, and endocrine disruption
  - Expansion of testing due to polymer registration requirements
- In parallel, increased support for inclusion of New Approach Methodologies (NAMs)
  - 3Rs approach to animal testing (Replacement, Reduction, and Refinement)
  - NAMS include: various methods in silico approaches, in chemico and in vitro assays; new testing tools; as well as some "conventional" methods that aim to improve understanding of toxic effects

Background for the Amendment to Information Requirements (2)

- Current situation:
  - NAMS currently not considered as adaptations to the standard testing methods
  - NGO and industry pressuring for prioritization under REACH
- Remaining issues: not yet established that NAMs can provide comparable level of information

Currently Foreseen Amendments to the Information Requirements (1)

- Five options currently foreseen, all having in common:
  - Chemical safety assessment (CSA) conducted at all tonnage levels
    - Previously not included for Annex VII
    - Also, CSR
  - Merging of Annex VII and VIII
    - Justified by increased requirements at Annex VII level
    - However, COM reserved itself possibility to keep the two annexes apart
  - Intention to further encourage NAM-based adaptations by revising Annex XI

Currently Foreseen Amendments to the Information Requirements (2)

- The options differ on the following:
  - Reliance on NAMs for critical hazards testing
    - As a complement to existing requirement, or
    - As a first screening tool
  - Extent of the revision of standard information requirements
    - More use of NAMs = less possibility to rely on REACH registration information for C&L (as these are largely based on animal testing)

Currently Foreseen Amendments to the Information Requirements (3)

Comparison with baseline (existing requirements)	Option				
	1A	1B	1C	1D	1E
CSA carried out at all tonnage levels	?	?	?	?	?
Annexes VII and VIII merged so that annex VIII SIRs apply at 1 t.p.a	?	?	?	?	?
Remove need for testing proposals for non-vertebrate studies	?	?	?	?	?
Revisions to Annex XI	?	?	?	?	?
Additional NAM-based testing for ADME and critical hazards.		?	?	?	?
Revisions to merged Annexes VII and VIII			?	?	?
Revisions to Annex IX as well as merged Annexes VII and VIII				?	?

Source: CA/09/2022 (Commission)

Example of NAMs Inclusion Under Option 1b as a Complementary Source of Information

- Option 1 B: presented as “most extreme”
  - Option best supporting C&L but most burdensome
  - NAMs are used as a complement to existing sources (and not as adaptations)
  - Therefore, most expensive option but providing maximal information
- Content:
  - Using NAMs for:
    - ADME and critical hazards incl: ED, immunotixicity, respiratory sensitization, neurotoxicity, bioaccumulation in aquatic species
    - Support read-across and grouping arguments as well as in vitro to in vivo extrapolation (IVIVE), in the context of Annex XI adaptations
    - Supplement information from traditional repeat dose toxicity studies, thereby supporting weight of evidence arguments and the formulation of hazard statements in CLP
    - Also support ECHA’s efforts in grouping chemicals for regulatory risk management

Long-term View (1)

- COM also presented its long-term goals:
  - Will to achieve higher safety by having basic knowledge about a higher number of substances
  - While minimizing animal testing with the “eventual aim of complete replacement”
- COM foresees a change of paradigm:
  - End of the tonnage bands
  - Substances divided into three groups based on generic considerations;
    - Low concern (initially, Annex VII + Annex VIII)
    - Medium concern (initially, Annex VII + Annex VIII, Annex IX)
    - High concern (initially, Annex VII + Annex VIII, Annex IX, Annex X)

Long-term View (2)

- Scope of the low concern group “could go” to lower tonnage levels than 1 ton
- No more testing at each level:
  - If concern profile indicates no need for further testing in high tier, testing stops
  - In case of positive results within a tier “certain general restrictions in marketing or a higher safety factor, can be applied, but this is **not triggering further testing”**

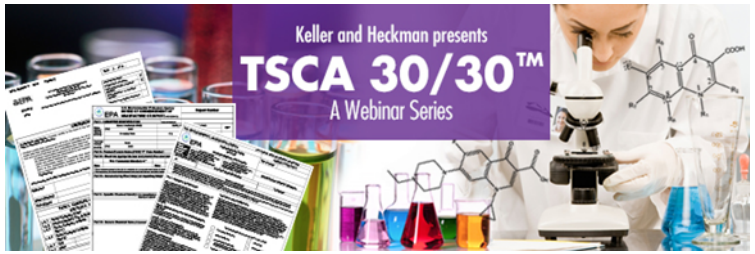
Overall Intake

- Extended testing requirements for low tonnage substances
- Additional information requirements for all tonnage bands for polymers registration
- Additional information requirements related specifically to ED, neurotoxicity, and immunotoxicity
- Role of NAMs will be the key: additional adaptation methods, or additional data requirements?

Other Recent News Regarding REACH Registration

- ECHA announced on July 27 that companies may now downgrade the tonnage band in their registration **after** ECHA's draft decision
  - Companies will need to provide evidence showing the volume of their substance that was imported or manufactured **over the preceding calendar year**
- Once dossier evaluation is adopted, all information requirements must be fulfilled regardless of any following tonnage band changes

Please join us at 1:00 PM Eastern U.S.
Wednesday, August 17, 2022
www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, September 14, 2022
www.khlaw.com/TSCA-3030

Please join us at 1:35 PM Eastern U.S.
Wednesday, October 12, 2022
www.khlaw.com/REACH-3030

Thank You

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