REACH JANUARY 2019 UPDATE

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Today's Topics

- The second REACH review (REACH Refit evaluation)
- Progress in Meeting the Areas Identified for Action

The Second REACH Review

- The REACH Regulation includes the obligation for the EU Commission to conduct a review every 5 years on progress in achieving the REACH objectives.
- The results of the second REACH review were published in March 2018.
  - **Commission General Report** on the operation of REACH and review of certain elements Conclusions and Actions, COM/2018/0116 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN
  - **Commission Staff Working Document** accompanying the COM(2018) 116 Communication on Commission General Report on the operation of REACH and review of certain elements – Conclusions and Actions, https://ec.europa.eu/docsroom/documents/28202

Most Urgent Issues Identified

- The Review identified certain issues requiring most “urgent action”:
  - Non-compliance of registration dossiers;
  - Simplification of the authorization process;
  - Ensuring a level playing field with non-EU companies through effective restrictions and enforcement; and
  - Clarifying the interface between REACH and other EU legislation, in particular that on occupational safety and health (OSH) and on waste.

Non-Compliance of Registration Dossiers

- "**Incentives** are **lacking** for companies to update their registration dossiers and work is still needed to rectify **important data gaps** or **inappropriate adaptations** to testing."
- "Only 25% of dossier owners conduct a regular routine review of their REACH data."
- "ECHA concluded in 2016 that **stronger incentives may be needed** for companies to stimulate updates of registration dossiers, especially on the use, exposure and tonnage information."
- "The only incentive working in practice might be **enforcement actions** by the Member State Competent Authorities on **dossiers for which updates are overdue**."

Action to Improve Dossier Quality

- Workshop '**REACH Compliance – A workshop on data quality in registrations dossiers**' which took place at the German Federal Institute for Risk Assessment (BfR) in Berlin, on the 23/24 of August 2018.
- Project **assessed more than 3,800 registration dossiers** for substances that were produced or imported into the EU at tonnages of **at least 100 tons per year (tpa).**
- **"Current average rate of 'compliance'"was 31 %** for substances registered at 1000+ tpa and 44% for substances at tonnages between 100 and 1000 tpa.
- The **option to deviate** from standard testing requirements and to provide justifications for such deviations **was commonly used by registrants –** for the assessed endpoints on average of about 70% (range 50-93%).
- "However, **alternative data** (e.g. using read-across to other substances) or justifications for data waiving or adaptations **were often not sufficient**."
- https://www.bfr.bund.de/cm/349/reach-compliance-workshop-at-the-bfr.pdf

Enforcement Project on Chemical Safety Report (CSR) Quality

- Fifth REACH enforcement project (Ref-5) inspected the CSRs of 898 during 2017. The checks covered 1,435 substances.
- Many companies comply with the regulatory requirements, however, the following were noted:
  - "**poor-quality" information**, including lacking updates on harmonized classification of substances;
  - "**missing/incomplete**" exposure scenarios;
  - risk management measures that were "**not clearly specified**";
  - exposure models used "**outside their functional domain**"; and
  - "**questionable**" exposure estimates.

Safety Data Sheet Initiatives

- There has been a **continued increase** in the information passed through the supply chain, though it needs to be made **more efficient** (*e.g.* reduce costs of producing and supplying Safety Data Sheets), especially for Small Medium and Micro Enterprises (SMEs).
- Improvement is also needed in the ability of companies to develop **specific exposure scenarios**, in particular for **mixtures**, and in helping with implementing the obligation to **notify substances of very high concern (SVHCs) in articles**.

Additional Registration Requirements for Low Tonnage Substances

- Two changes to the registration requirements in the low tonnage band (1-10t) are being considered by the Commission to improve risk management of hazardous substances:
  - increasing standard information requirements and
  - requiring the Chemical Safety Report for the CMR 1A or 1B.

❖ Both need further study to assess the affordability for SMEs.

Access to Market for New Chemicals

- **Compared to previous** (i.e. pre-REACH) legislation, the broader exemption for research and development activities and the reduced information requirements for new substances below 10 tonnes per year have **stimulated the development of new substances**.
- There was an **increasing trend** for the overall number of Product and Process Orientated R&D (**PPORDs**). The PPORD exemption is popular with large companies and allows large-scale research and development without a heavy administrative burden, while ensuring safe use.
- Approximately **195 new substances** are brought to the market every year in quantities above 1 ton per company per year.
- **100 to 150 "new substances"** in average have been notified in the **Classification and Labelling Inventory** (C&L Inventory) each month during the period 2011-2016, representing about 20% of the total number of notifications.
- The **majority of PPORD notifications or inquiries** for new substances are **made by manufacturers** (71% and 54% respectively), which would support the idea that **manufacturing of new substances mainly takes place within the EU.**

Authorization and Imported Articles

- Authorization could be harming the competitiveness of EU companies because articles imported to the EU are exempt from the authorization obligations.
- Better **coordination** and **synchronization** of actions when enacting authorization and restriction is recommended.
- ECHA is requested to consider systematically preparing a restriction dossier before the sunset date of each substance that is subject to authorization and present in articles in accordance with Article 69(2).

Enforcement

- National enforcement activities should be reinforced, including controls on imported goods.

Fees and Future of ECHA

- Over the period 2007 – 2020, 70% of ECHA funding came from registration fees and the balance (30%) from subsidies.
- After 2020, the income from fees (in particular from registration) is expected to drop sharply.
- The sustainability of ECHA's financing, therefore, needs to be re-assessed.

REACH and Occupational Exposure

- Commission intends to reassign the responsibilities of DG Employment's Scientific Committee on Occupational Exposure Limits (SCOEL) to ECHA's risk assessment committee (RAC).
- Problem: Differences in RAC and SCOEL methodologies for deriving OELs and DNELS.
- Recommended Actions:
  - look into how to use REACH tools – such as exposure scenarios and safety data sheets – to enhance the effectiveness of OSH legislation;
  - improve coordination of national enforcement authorities of REACH and OSH; and
  - align methodologies to establish safe levels of exposure to chemicals in the workplace.

REACH and Polymers

- Polymers exempt from registration but,
- Art. 138(2) of REACH provides:

The Commission **may present** legislative proposals as soon as a **practicable and cost-efficient** way of selecting polymers for registration on the **basis of sound technical and valid scientific criteria** can be established, and after publishing a report on the following:

a) **the risks** posed by polymers **in comparison** with other substances;

b) the need, if any, to **register certain types of polymers**, taking account of **competitiveness and innovation** on the one hand and the **protection of human health and the environment** on the other.

Bio by Deloitte 2015 Report

Polymer of Low Concern (PLC) Proposal

- **Not applicable to polymers that are classified as hazardous in any of the following classes**:
  - Acute toxicity (Acute Tox. 1 to Acute Tox. 4);
  - Germ cell mutagenicity (Muta. 1A, Muta. 1B and Muta. 2);
  - Carcinogenicity (Carc. 1A, Carc. 1B and Carc. 2);
  - Reproductive toxicity (Repr. 1A, Repr. 1B, Repr. 2, Lact.);
  - Aspiration hazard (Asp. Tox. 1);
  - Respiratory/skin sensitization (Resp. Sens. 1 and Skin Sens. 1);
  - Specific target organ toxicity – single exposure (STOT SE1 to SE3)
  - Specific target organ toxicity – repeated exposure (STOT RE 1 and STOT RE 2);
  - Hazardous to the aquatic environment (Aquatic Acute 1, Aquatic Chronic 1 to 4);
  - Hazardous for the ozone layer (Ozone).
  - Furthermore, the polymer should not be identified as PBT or vPvB.
- **Similar classification for the monomers or other reactants disqualifies the polymer as a PLC**.

PLC Registration Options

- Registration Options
  - **Option 1** – Exemption from registration, with notification: the PLC is not registered, but the manufacturer must submit an application proving that the polymer is indeed a PLC. (Japanese and South Korean approach).
  - **Option 2** – Exemption from registration, without notification: the PLC is not registered nor does the manufacturer need to submit an application. However, he must keep all relevant documents proving the polymer is a PLC. (US approach).
  - **Option 3** – Registration with reduced requirements: the PLC is registered but with a lighter dossier than regular polymers. (Canadian, Australian, Chinese and Taiwanese approach).

March 27 2016 CARACAL Discussion

The document was not presented at the CARACAL. These are the key points of the discussion:

The EC introduced the report by asking whether it necessary to establish a subgroup for polymers.

Germany: Stated bluntly that it does not consider polymers to be a problem and the focus should be on monomers. It did not see it necessary to establish a subgroup.

UK: Concurred with Germany. It also expressed concern about the report assuming that all polymers should be brought within the scope of REACH and then identify whether there are certain categories that should be exempt. It indicated that this is the opposite position taken by Article. 138.

CEFIC: It said the report was interesting.

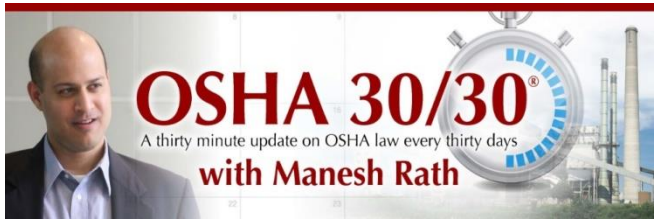
Commission: Other jurisdictions apply polymer restrictions apply only to new substances. We acknowledge that, our legislation is different and stated that it had a legal obligation to move forward.

Second REACH Review

- “The Commission will further investigate information necessary to … identify relevant polymers that could be subject to registration.”

2018 EU Commission Tender

- "Scientific and technical support for the development of criteria to identify and group polymers of concern for Registration /Evaluation under REACH and their impact assessment "
  - "**The contractor should develop scientific criteria**, which would be physical-chemical, structural or toxicological properties of polymers that can be used **to identify polymers with potential hazards to human health or the environment** within the large group of polymer substances."
- "Such polymers would be described as polymers of concern."
- "**Suggestions for grouping different polymers of concern** based on some shared properties should also be included."
- "Further, the contractor should **identify what characterisation and toxicological testing for such polymers of concern would make sense** under registration or evaluation."



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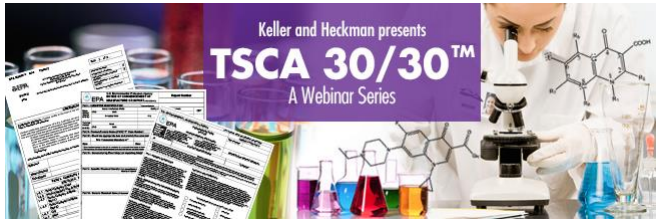

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