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REACH and Beyond – Global Chemicals Management and Status of Polymers

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EU REACH

Registration of Polymers under the former Dangerous Substances Directive

- Polymers were not added to the European Inventory of Existing Chemical Substances (EINECS).
- If the polymer contained a non-EINECS listed monomer at 2% or more w/w, it needed to be notified to the European List of Notified Chemical Substances (ELINCS).

2003 REACH Proposal for Registration of Polymers

- Manufacturer or importer of a polymer in quantities of 1 tonne or more per year was to register the polymer if the polymer:
  - met the criteria for classification as dangerous under the Dangerous Substances Directive 67/548/EEC (DSD) and the polymer has
    - ✓ a number-average molecular weight less than 10000 Dalton, or
    - ✓ a content of greater than or equal to 2% of low molecular weight (i.e. less than 1000 Dalton) species.
- Polymers which result from a chemical reaction occurring upon end-use of other polymers were to be exempted from registration
- Polymers which are used as isolated intermediates on site or transported were also exempt.

Estimates of Number of Polymer Registrations (RPA 2003)

Table 6.3: Estimates of Polymer Registrations from RPA (2003)			
Quantity	**Total Polymers Potentially Undergoing Registration**		**Percentage of Total**
	Lower Bound	**Upper Bound**	
>1,000 t/y	1,750	10,000	5%
>100 t/y	5,250	30,000	15%
>10 t/y	14,000	80,000	40%
>1 t/y	14,000	80,000	40%
Total	***35,000***	***200,000***	***100%***

REACH as Adopted in 2006

- 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 polymer, 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)

- 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. (Japan 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 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.

2017 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."

KOREA

K-REACH Expansion

- Comes into force on January 1, 2019
- Companies to register all new substances to be placed on the market in excess of 100 kg/yr unless otherwise exempt.
- Companies to pre-register all existing substances placed on the market in excess of 1 tonne/yr unless otherwise exempt.
- Registration of pre-registered existing substances within certain periods:

    1) Existing Chemical Substances in CMR category 1/and 2 and in > 1,000 ton/y: Dec. 31, 2021
    2) Existing Chemical Substances in 100 - < 1,000 ton/y: Dec. 31, 2024
    3) Existing Chemical Substances in 10 - <100 ton/y: Dec. 31, 2027
    4) Existing Chemical Substances in 1 - <10 ton/y: Dec 31. 2030

- Registration for certain Existing Chemical Substances ≥ 10 ton/yr in aggregate tonnage if MOE considers that registration is necessary even though annual volume is less than 1 ton/yr per company.

Pre-registration of Existing Chemicals

- From Jan. 1 to June 30, 2019.
  1. Chemical name
  2. Annual volume of manufacture or import
  3. Use
  4. Other details such as company name as prescribed in the Ministerial Decree

Registration of Existing Polymers

- Existing polymers are exempt from registration if the polymer meets the following criteria:
  - ① Polymers with number average molecular weight (Mn) > 10,000: Mw < 1,000: < 5%; Mw < 500: < 2%
  - ②Polymers with number average molecular weight (Mn) > 1,000 ~ <10,000: Mw < 1,000: < 25%; Mw < 500: < 10%
  - However, following polymers are not exempt even though the polymer falls within above ① or ② in case of:
    - Cationic polymers (however, excluding cases where used only in its solid state, or not dissolved or dispersed in water)
    - Polymers with number average molecular weight <10,000 in which any new chemical substance, hazardous chemical substance (as designated by MOE), or substance requiring special management (as designated by MOE) are used as monomer or reactant, and the residual content exceeds 0.1wt% in unreacted form.
  - Exempt polymers require confirmation of exemption
  - Many non-exempt polymers will benefit from reduced test data requirements if not classified for health hazards or environmental hazards; test data requirements is reduced to the level of 1-10t/y irrespective of volume bands.

Next Steps

DISCUSSION

THANK YOU

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