CSS and its impact on industry – part 1

GROUPING OF CHEMICALS AND GENERIC RISK ASSESSMENT – potential practical implications

[redacted] Ökopol – Institute for Environmental Strategies (Hamburg)
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Agenda

- Grouping of Chemicals
  - Current situation and planned changes
  - Challenges for industry

- Generic Risk assessment
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  - Challenges for industry

Grouping of Chemicals

Current Situation

- Grouping only in exemptional cases:
  - Restriction more common based on hazard:
    - e.g. certain CMR in consumer mixtures
    - Substances/mixtures classifies for hazard categories in certain products (Annex XVII Entry number 3, ornamental articles, games etc,)
  - Restriction more common based on structural relation (and resulting hazard)
    - e.g. Cadmium, Arsenic, Mercury compounds
  - SVHC identification usually for specific substances (structurally related often simultaneously but in separated processes)
  - Some exemptions:
    - OPE/NPE ⇒ focus on a common degradation product

Potential upcoming changes

- More use of grouping based on
  - Structural relation of substances
    - e.g. PFAS (characterised by Fluorine Carbon bound)
  - Assumed risks effects
    - E.g. Phthalates, exposure towards population can be shown, at least some members of group with adverse effects
  - Functional relation of substances
    - e.g. flame retardants in certain products, many with adverse effects (not always the same)

⇒ prevention of regrettable substitution

⇒ increased speed of overall substance evaluation and risk management process (Aim: non toxic environment)

Grouping of Chemicals – Challenges for the industry

- Adaptation of R&D strategies:
  - Substances of one group will most likely be regulated together
  - ⇒ **No** "similar" **substance available** form the usual substance catalogue
  - ⇒ more **fundamental product design changes** needed
  - ⇒ Potentially **high number** of substances reflecting an even **higher number of mixtures (products)** may need to be **substituted simultaneously** (depending on product development and qualification timelines, usual *REACH periods* for substitution **may not fit**)
  - **More resources needed** in R&D to react on loss of substances (even category 3 very ambitious timeline for adapting products when additional product approval legislation needs to be covered as well)
  - Potential **short coming of experts**, research staff to support such activities

- Adaptation of Regulatory Affairs strategies:
  - **Interaction** on technical issues **in regulatory processes necessary** (given that product adaptations may not be possible within timelines)
  - ⇒ **stronger involvement of company units** traditionally not involved in regulatory affairs
    - ⇒ e.g. **sales** (socio-economic effects), R&D (substitution potential), **production** (detailed information on condition of use, risk management, potentially introduction of processes to reduce exposure/emission)

Generic Risk assessment

Current Situation

- Article 68 (2) defines a risk (assumption) per default if
  - substances are CMR cat. 1A or 1B
  - and are contained in consumer products

- REACH Articles 69 -73 do not apply
  - ⇒ no need to demonstrate exposure – large degree hazard based
  - ⇒ no need to demonstrate availability of alternatives
  - ⇒ no need to justify measure via socio-economic arguments
  - ⇒ No formalised public consultations (consultations may be initiated under COM´s better regulation initiative)

Potential upcoming changes

- **Extending the generic risk approach** to restrictions on **new hazard categories** endocrine disruptors, PBT/vPvB substances, immunotoxics, neurotoxics, respiratory sensitisers and substances affecting specific organs;
- **Extending the generic risk approach** to products marketed for **professional use**;
- Operationalising the concept of **essential use** in restrictions, including the criteria **for granting exemptions**.

Generic Risk assessment - Challenges for the industry

- May increase speed until regulation

  - sector may be seen as **professional use rather than industrial**
  - But: **generic risk assumption** might **not** be **appropriate** for sector with **high benefits for public health** (continuation of specific risk assessment according to "old" restriction approach – Article 68 (1) more appropriate

⇒ **follow discussion** on new elements under **CSS**

⇒ Prepare **sector position** with strong argumentation on

⇒ Technical obstacles that prevent a generic risk approach (e.g. duration for product changes)

⇒ Potentially increased acceptance of somewhat higher risk which is not reflected by generic risk assumption (low tonnage, benefit for public health)

⇒ Note: also focus on environmental aspects during risk assessement (wastewater emissions, waste etc.)

⇒ If **essentiality** becomes relevant discuss why **substance´s function*** is **essential** in their function **not** your **business**

⇒ ***maybe also based on **grouping** (e.g. detergents etc.)

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