REACH revision

Implementation of the Generic Risk Management Approach GRA

CARACAL-48 (28 March 2023)

GROW.F1

ENV.B2

Generic Risk Management Approach (GRA)

- Extension of existing **empowerment** to Commission in Article 68(2) (currently CMR cat 1A and 1B for consumer uses) to:
  - **New hazard classes**
    - Endocrine disruptors, cat. 1
    - STOT RE cat.1, including immunotoxic and neurotoxic substances
    - PBT/vPvB
    - Respiratory sensitisers
    - PMT/vPvM under discussion
  - **Professional uses**

Generic Risk Management Approach (GRA)

- Commission can, on the basis of the empowerment, **propose restrictions** without demonstrating an unacceptable risk on a case-by-case basis through an Annex XV dossier
- Based on **generic risk considerations** (i.e. not hazard based):
  - the concerned **hazards are particularly serious**
  - in the concerned situations, **possibilities to control risks are limited** or insufficiently effective

⇨ *Therefore a relevant **risk is assumed by default***

⇨ *Substances **should be substituted** in the concerned uses*

⇨ *Derogations only for **essential uses***

Generic Risk Management Approach (GRA)

- Restrictions are **proposed by the Commission**
- **ECHA** can, where necessary, be consulted but there is no obligation or formal process to do so
- Where risks are not addressed through GRA restrictions, risks can also be addressed through **specific restrictions under Article 68(1)** or, for SVHC on Annex XIV, through **measures under Title VII**

Generic Risk Management Approach (GRA)

- Implementation through a **work plan**, which is **jointly discussed and agreed in CARACAL**, in a similar process as for the restrictions roadmap
- Work plan shall give **predictability** for industry and allow early action to prepare substitution of the concerned substances in the concerned products
- **Priority** will be given to:
  - Substances on their own and in **mixtures**
  - **Articles for consumers *with* high potential for exposure** to humans or high emissions to the environment throughout the life cycle
  - **Professional uses with similar exposure patterns as for consumers** and limited possibilities to effectively control exposure or emissions

Generic Risk Management Approach (GRA)

- Currently, COM envisages that the **first work plan** will:
  - Focus on **substances with confirmed hazards** (harmonized classification or equivalent, e.g. identified as SVHC)
  - Focus on **most important hazard classes**, i.e. CMRs, endocrine disruptors, PBT, vPvB (potentially also PMT/vPvM);
  - Priority for **STOT RE1 and respiratory sensitisers** to be further discussed
  - Focus on substances on their own and in **mixtures and on consumer articles with high exposure or high environmental emissions throughout the life cycle** (same approach as taken for CMRs, where e.g. textiles were prioritized and a restriction for childcare articles is under preparations)
  - Priority for restrictions for **professional uses** to be further discussed
  - **No plans** to cover professional uses where **risks or emissions can be effectively controlled** or where substances are needed for essential uses

Generic Risk Management Approach (GRA)

- **Purpose of discussion** today:
  - Ensure **proper understanding** of Commission plans for implementing GRA
  - Get **initial feedback on the broad lines of implementing GRA** in the work plan, in particular on the following questions:
    - Does CARACAL agree on the **broad scope of the extension of the empowerment** to the Commission?
    - Does CARACAL agree on the **implementation through a jointly agreed work plan**?
    - Does CARACAL agree on the **priorities** envisaged by the Commission as regards **hazard classes and products/uses**
- **More specific consultation on the first work plan will follow**, once the Commission proposal has been published, in parallel to the legislative process

Thank you

European Commission