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Stakeholder Dialogue – Belgium
29 January 2021

The Chemical Strategy for Sustainability and the implementation of the PMT/vPvM criteria

#ChemicalsStrategy
#EUGreenDeal

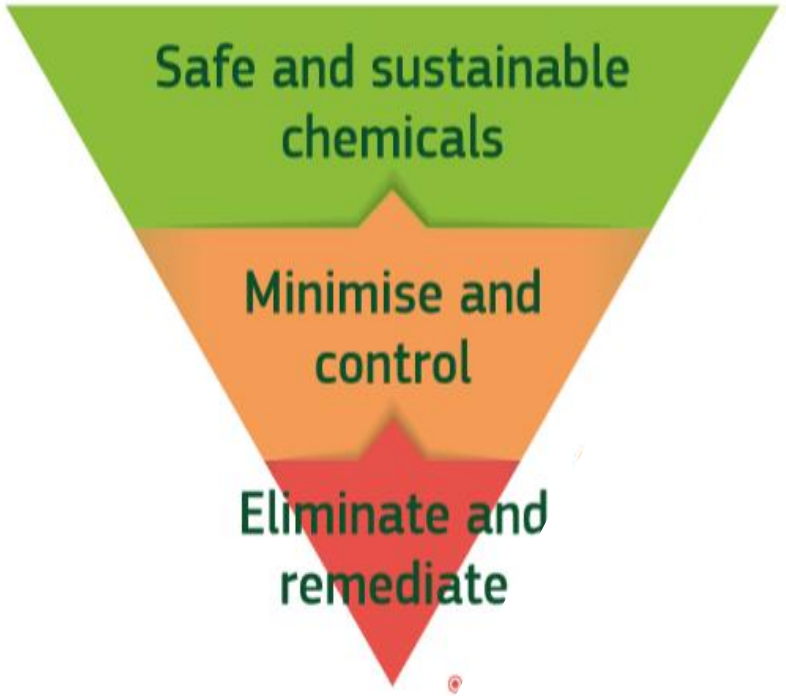
European Commission

Building on an advanced framework and extensive policy evaluations and input

REACH Review March 2018
Fitness check of the most relevant chemicals legislation (excluding REACH) July 2019
Many other specific evaluations
Conference in June 2019

Council Conclusions 2019
EP Resolution 2020

2030 vision – towards a toxic-free environment



- Chemicals are produced/used in a way that **maximises their benefits to society** while **avoiding harm to planet & people**
- **Production and use of *safe and sustainable chemicals*** becomes the EU market norm and a global standard

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2030 vision –safe and sustainable alternatives, and increase industry's global competitiveness

- Support the innovation for a green transition of the chemical Industry and its value chain
- **Safe and sustainable –by –design** approach to chemicals
- **Strengthening EU's open strategic autonomy**
- **Non toxic material cycles**
- **Innovating industrial production**

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TOXIC-FREE ENVIRONMENT: 5 building blocks

Innovation, competitiveness, recovery

Strengthen legislation for better protection

Simplification & coherence

Knowledge and science

Global

=> Most relevant actions for REACH & CLP

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Strengthening legislation (**REACH**/ **CLP**)

- Ensure that the **most harmful chemicals are not contained** in particular in consumer products such as **food contact materials, toys, childcare articles, cosmetics, detergents, furniture** and **textile => Generic Approach to Risk (e.g., 68(2) to REACH) =>** need to focus more resources on hazard identification
  - In addition to CMRs, address as a priority **endocrine disruptors** and substances that are **persistent, bioaccumulative and toxic or very persistent and very bioaccumulative**
  - and define the modalities and timing for extending this approach (second phase) to chemicals affecting **immune, neurological** and **respiratory** systems and chemicals **toxic to specific organs**.
- Roadmap to prioritise CMRs, ED, PBT, vPvB, immunotoxicants, neurotoxicants, STOTs and respiratory sensitisers for (group) restrictions under REACH
- Increase **protection of children** (68(2) restrictions in REACH for childcare articles and other products for children (other than toys), **professional users** (extend the protection that REACH provides for consumers via 68(2))

Strengthening legislation (REACH/ CLP)

- Ban PFAS i.a. via a restriction under REACH - unless essential for society
- Define criteria for essential uses
- Update information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH
- Introduce (a) mixture assessment factor(s) in Annex I of REACH
- Amend REACH Article 57 to add EDs, **PMT and vPvM** to the list of SVHCs
- Amend CLP to introduce new hazard classes on endocrine disruptors, PBTs/vPvBs , PMTs/vPvMs, and apply them across all legislation;
- Assessment of the added value to use toxicity data obtained on terrestrial organisms in the classification criteria for the environment;
- Assessment of the need for specific criteria for immunotoxicity and neurotoxicity, currently covered under 'Specific target organ toxicity' and 'reproductive toxicity', and their amendment if necessary;

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Simplifying and consolidating

- 'One substance, one assessment':
  - Improve transparency via a tool to give overview of all planned and ongoing initiatives
  - Redistribute the work amongst agencies and reduce overlaps
  - Establishment of a EU repository of human and environmental health-based limit values (DNEL, EQS, PNEC, …)
  - Establishment of an open platform on chemical safety data and tools for accessing relevant academic data
- Possibility for Commission(via ECHA) to initiate harmonised classification
- Reform the authorisation and restriction process (ensure a better level playing field)
- Streamline substance evaluation
- **Strengthen compliance, enforcement and market surveillance,** by i.e.
  - **Audits** on enforcement systems
  - **Full Compliance** of registration dossiers, revocation of registration number
  - **More and better (targeted) controls** e.g. online sales and imported articles

A comprehensive knowledge base

- Revise requirements for registration in REACH to ensure:
  - the identification of substances with critical hazard properties, including effects on the nervous and immune systems,
  - Amend REACH information requirements to enable identification of all carcinogenic substances manufactured or imported in the EU, irrespective of the volume,
  - the registration of a sub-set of polymers,
  - information on the overall environmental footprint of chemicals, including on emissions of greenhouse gases
  - the obligation of chemical safety reports for substances between 1-10 tonnes
- Fund EU-wide human and environmental (bio)monitoring

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Setting the example globally

- Take a **leading role** to implement international instruments (Stockholm, Rotterdam and Minamata conventions)
- Amend legislation to **ban also the production of chemicals** that are banned to be used in the EU – so that they cannot be exported
- Proposal at the UN GHS level to introduce, adapt or clarify criteria/hazard classes in line with the CLP Regulation => **PMT/vPvM**; EDs, PBT/vPvB…next biennium?

Why do we need PMT/vPvM ?

- Combination of P and M increase the probability for substances to pass natural barriers like river banks and artificial barriers in water treatment facilities => contamination of groundwater that could become irreparable and very costly to produce drinking water.
- Aim: similarly to PBT/vPvB, prevent/minimize as much as possible the emission of such substances in the environment.
- CLP Regulation:
  - Tool to inform the presence of such substances in mixtures: User choice.
  - Tool to provide simple risk management measures: P-statement.
  - Classified substances as PMT/vPvM:
    - Could be prioritized for monitoring
    - Could be prioritized for legislative action (restriction, authorization)
    - Could be prioritized for substitution
- Question to the audience: Are PMT/vPvM the best hazard criteria to identify those substances polluting natural water resources?

PMT/vPvM criteria under CLP

- P and T criteria from Annex XIII
- M criteria:
  - UBA: Mobile: log Koc < 4 (pH range: 4-9); very Mobile: log Koc < 3 (pH range: 4-9).
  - US-EPA: Moderate mobility: log Koc: 1.5-2.4; Rapid mobility: log Koc: <1.5.
  - FAO: Mobile: log Koc 1-2; Highly Mobile: log Koc < 1 .
  - EFSA: Medium mobility: log Koc: 2.2-2.7; high mobility: log Koc < 2.2
  - OECD 106:Mobile: Kd ≤ 1 $cm^3\ g^{-1}$

⇒ Important variation but in the PMT/vPvM assessment, M should not taken in isolation but with P: A higher M criterion could be justified for P substances as they do not degrade and have longer time to travel.

PMT/vPvM criteria under CLP

- M criteria: Open questions
  - Do we want to limited to mobility in soil/sediment inducing groundwater pollution?
  - Should we also consider:
    - Air transport: POP atmospheric Long Range Transport?
    - Mobility via water => Already covered to some extend by the PBT/vPvB?

  - Impact Assessment:
    - avoid under/over classification of substances and mixtures.
    - efficiency of the action: Is identification and labelling for soil M the best tool to raise awareness about water polluting chemicals?
    - Cost of relabelling/additional assessment.

PMT/vPvM under CLP: issues for discussion

- Two hazard classes: vPvM/PMT
- Should we use the GCL for mixture classification?
- Need to assess the overlap with PBT/vPvB and existing environmental classification.
- Should we have a categorisation system?(confirmed /suspected PMT/vPvM)
  - UBA screening criteria for Mobility: log Dow or log Kow < 4.5
    - a) For ionisable substances, the lowest pH dependant octanol-water distribution coefficient (Dow) experimentally determined between pH 4-9 or estimated by (Q)SAR models.
    - b) For other substances, log Kow experimentally determined or estimated by (Q)SAR models.
    - c) Other information provided that its suitability and reliability can be reasonably demonstrated.
  - Low discriminatory power of M and P screening criteria: over classification?

PMT/vPvM under CLP

- **Labelling: several open issues**
  - Pictogram
    - Similar to Ozone depleting substance (ODP):

    - Similar to aquatic environment hazard class:

    - a new one on drinking water protection: **?**

  - H statement: on the basis of the one for ODP: H420: Harms public health and the environment by destroying ozone in the upper atmosphere (polluting water resource)?

  - P-statement:
    - P502: Refer to manufacturer or supplier for information on recovery or recycling.
    - P273: Avoid release to the environment.
    - P391: Collect spillage.
    - P501: Dispose of contents/ container to …
    - New one?

SVHC-identification of PMT/vPvM – Other consequences for REACH

- Substances identified as SVHC on the basis of PMT/vPvM properties will be subject to all provisions applicable for SVHCs, e.g.:

  - REACH authorisation (if prioritised);
  - article 33 to REACH (substances in articles);
  - ecolabel obligation like for other SVHC;
  - obligation for safety data sheet;

- Possible adaptation to REACH
  - Assessment to be performed in accordance with annex I to REACH.
  - Adsorption/desorption screening at Annex VII level.
  - Modify the adaptation rule of column 2 of Annex VIII: the study does not need to be conducted if it is expected that substance have a low potential for adsorption.

Indicative Timing

- Inception Impact Assessment (roadmap) for 4 weeks stakeholder consultation –April 2021
- Public stakeholder consultation for 12 weeks is planned in all EU languages –Q2 2021.
- Supporting actions –Q1 2021 to Q3
- Impact Assessment – Q42021
- Drafting proposal for revision of CLP : 2022

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