

The problem

Concerns have been raised that the current system for regulating chemicals is too complex, slow and consumes too many resources.

Chemicals are governed by more than 40 different pieces of EU legislation (COM(2019) 264 final)¹, recently a few more were added². Each of them have their own processes deciding what and how to regulate. The vast majority of the final rules are set via implementing legislation (mix of implementing acts, delegated acts and RPS measures).

As a result the regulatory system is a maze of rules. One a chemical enters you don't know if, when and how it will come out. See annex for more details.

Responsibilities are divided across multiple directorates and agencies, with different degrees of competencies:



Under some legislations, like REACH, also Member States can initiate EU-wide regulatory action adding further complexity.

The solution

To make the current system simpler, more effective and more predictable, one doesn't need to overhaul existing legislation. It is all about better identification of the 'problem substances', and choosing the best tool to control exposure or risks to humans and the environment.

This requires an upfront analysis from available data on chemicals resulting in (1) the identification of priority substances and (2) a regulatory plan for identified priority chemicals for which action can be taken under REACH or other legal instruments.

Scarce EU and Member State resources would be best served by entering such joined-up program. It will serve protection of health and environment more efficiently, lines up with a new spirit of law-making, brings clarity to industry on where to invest and prioritise resources to substitute problematic substances and uses.

¹Commission staff working document: Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries; COM(2019) 264 final

² Ecodesign for Sustainable Products Regulation, Packaging and Packaging Waste legislation, Sustainable Batteries Regulation.

The machinery for delivering the necessary risk management measures for a targeted group of substances already exists. Building upon the data generated via REACH registration, ECHA has identified ± 700 substances³ that would benefit from more action.

The levels of 'readiness' for action and benefits of action, varies across these substances. Industry⁴ can work with authorities to provide more granular data⁵ helping them to identify uses for which action is most pressing.

Once done, authorities can identify the type of regulatory action drawing upon today's available regulatory toolbox. Upfront agreed principles guide the selection of effective regulatory tools considering a.o. EU policy goals set, feasibility of risk control, enforceability, essentiality of uses, readiness of alternative solutions.

See annex for a schematic overview of how such process could work.

REACH allows such an approach, but it is applied in a scattered way. There is no systematic, overarching approach for setting priorities. Different processes⁶ are feeding in mixed with national priorities. The current restriction roadmap is more a collection of potential actions, not a clear roadmap. Upfront analysis of regulatory options is voluntary and if done there is a bias towards REACH regulatory actions as for these are typically the processes one knows best.

Discussions on usefulness and effectiveness of action typically happens when regulatory action is initiated leading to suboptimal outcomes, inefficient use of resources and delayed decision making⁷.

Enshrining the outlined systematic process into the operation of REACH would help to address this.

The system could help as a consolidation of Commission's, Agencies' and Member States' resources, reducing overlaps and duplication.

³ ECHA workshop on Integrated regulatory Strategy 6 March 2024 (<https://echa.europa.eu/-/irs-06/03/2024>). For another 700 substances additional data is being generated on hazard properties. Depending on the generated data, the number might go up to approximately 1400 substances.

⁴ Manufacturers, importers, distributors, downstream users.

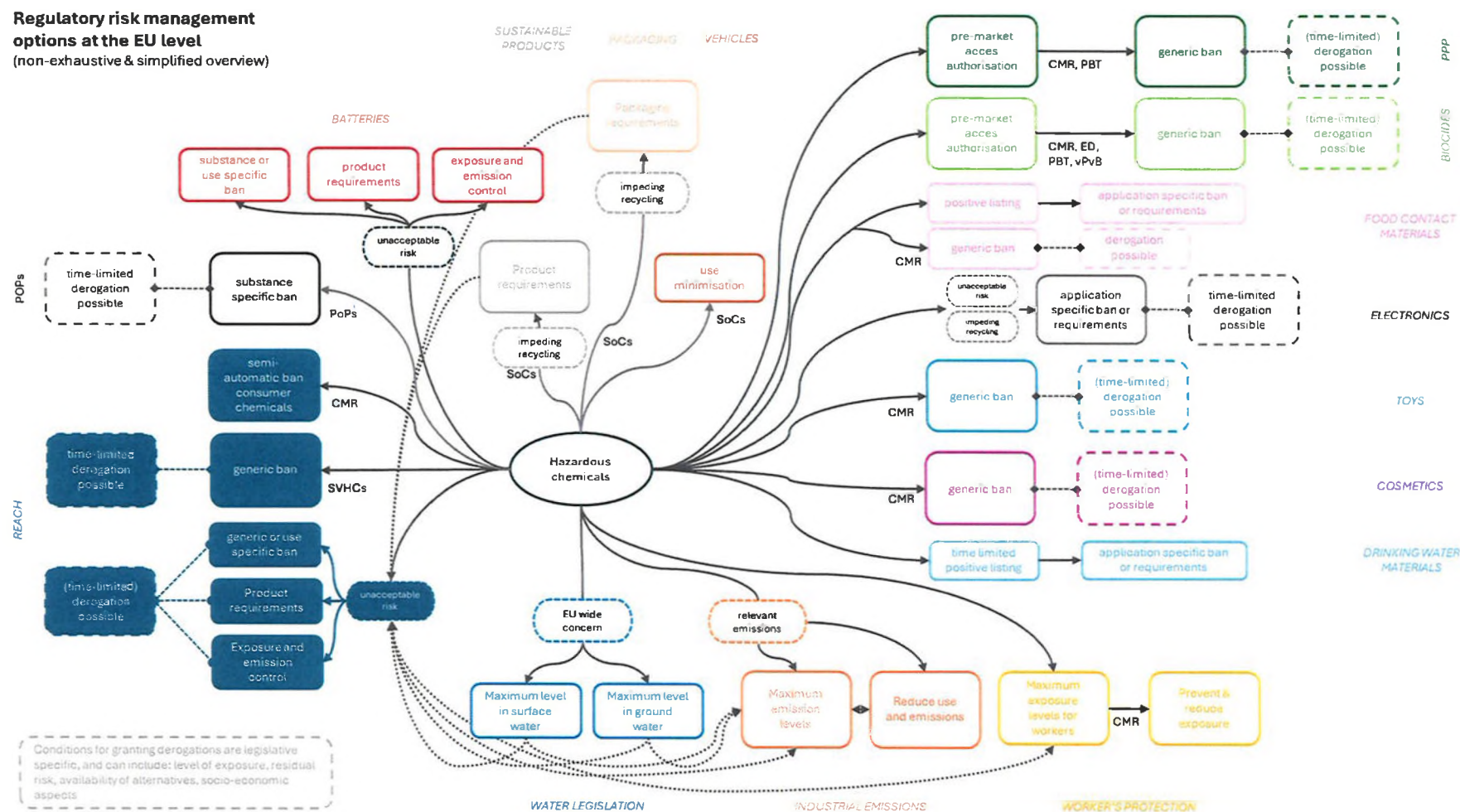
⁵ Information on uses, exposure data, emission data, information on potential alternatives, waste management practices, data on the real-life occurrence of listed chemicals in the environment and their burden on health and the environment, etc.

⁶ ECHA's integrated regulatory strategy, substance evaluation, identification of substances of high concern.

⁷ For example In December 2018 the Commission launched the process to limit the use of cobalt salts to address worker's exposure. ECHA committees delivered their opinions in September 2020. In April 2022 the decision was taken to withdraw the restriction to prevent a too big impact on availability of batteries and recycling of batteries. Instead the process was launched to set an EU-wide worker's exposure limit value. Until today this process is still ongoing.

Annex – overview of legislations governing hazardous substances

Regulatory risk management options at the EU level (non-exhaustive & simplified overview)

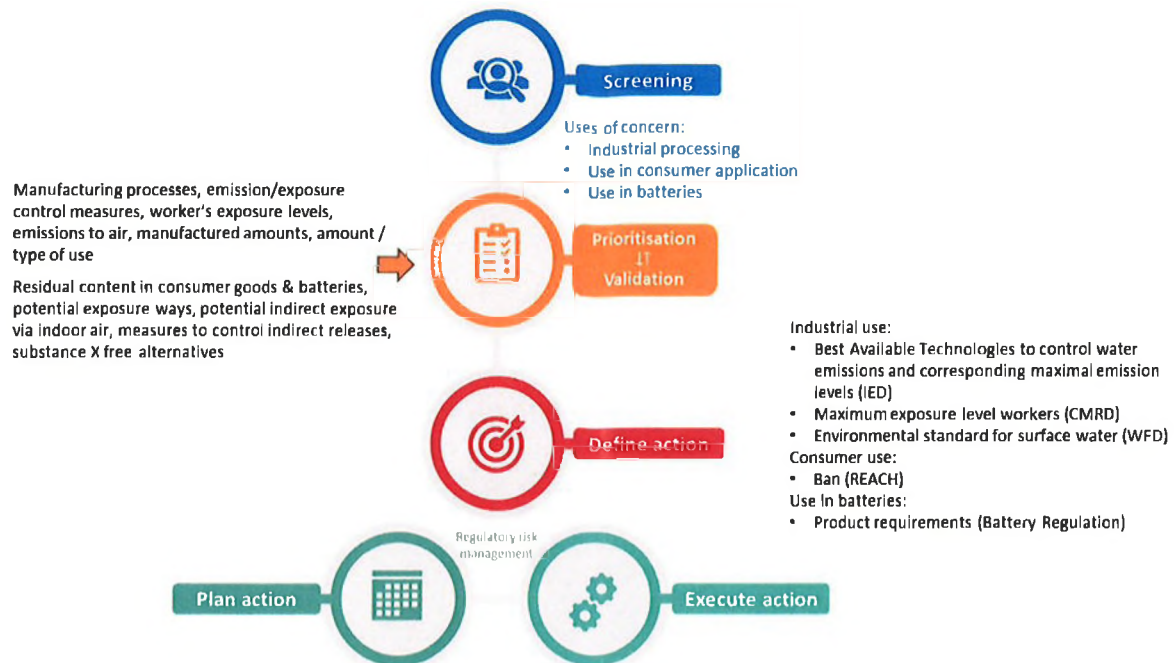


Annex 1 – schematic overview of the process



Annex 2: example

Reprotoxic substance used in a consumer application and in batteries.



Resulting regulatory roadmap:

