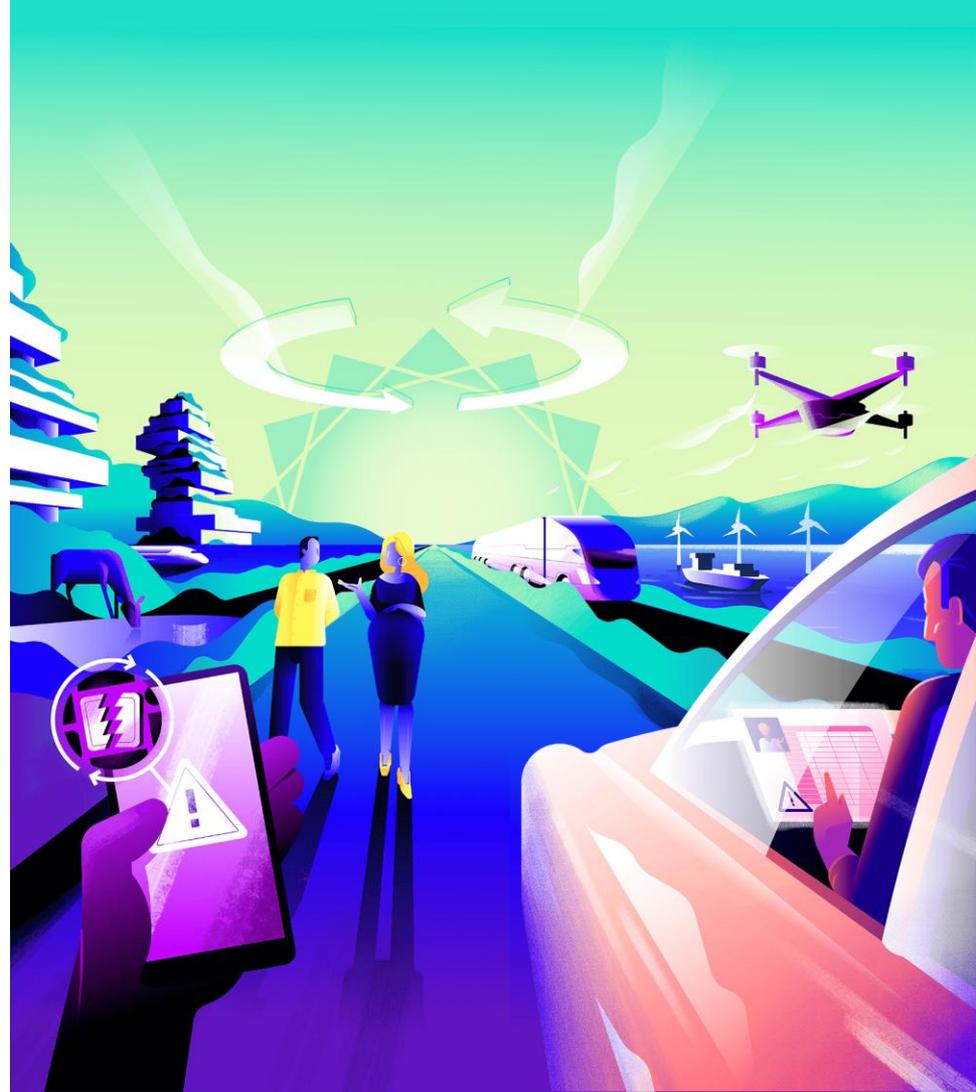


REACH review

First view of the technological
industry 6/6/2025

.AGORIA



Objectives of REACH review (CIP)

Revision of REACH

- Simplification for companies and authorities
- Modernisation after 20 years
- Strengthen enforcement

Meanwhile Caracal discussion on certain proposed amendments

Revision of REACH annexes

- Update of information requirements
- Modernisation of REACH annexes (CLP updates, UNGHS, etc.)



Clarity on PFAS

- Clarify policy intentions on PFAS

REACH review must deliver real simplification without compromising the protection of human health and the environment

Our key recommendations

- Focus on uncontrolled risks and avoid scattered overlapping regulatory actions to increase the predictability of risk management (RMOA)
- Ensure communication along the value chain and have the right information on substances hazards, uses, exposures, functionality and alternatives for adequate RMO selection
- Make the risk management process fit for purpose, covering the whole life cycle
- Better consider metal specificities in REACH
- Make sure REACH is enforceable for a level playing field

Uncontrolled risks vs hazard approach

- The REACH processes related to risk management identification and implementation are cumbersome, slow and complex due to:
 - Ad-hoc MS prioritisation process for the SVHC identification,
 - The “steps” being used for other purposes than originally intended (e.g., Candidate Listing to gather exposure information),
 - The automated prioritisation system for Annex XIV candidates applied by ECHA that does not consider exposure potential, nor the scope and relevancy of authorisations,
 - The granting process itself (e.g. chromium (VI)).
- Targeting an increase in efficiency and transparency in the risk management of chemicals by focusing resources on what matters:
 - Uses with concerning exposure to humans and the environment, and with the biggest harm potential (endpoints of concern e.g., CMR or PBT).
- Setting up a clear, agreed EU regulatory plan to address uses of substances that need to be risk managed (i.e. uncontrolled emissions/exposures).

Uncontrolled risks: proposal RMOA based approach

- Mapping & screening of the substances database
 - Based on the integrated regulatory strategy & assessment of regulatory needs
 - Identification of what data is missing -> follow up by industry involving also downstream users
- Targeted data collection
 - Additional data needs are uses, technical function, exposure pathways, emissions, alternatives and possible key aspects for the EU green deal objectives (criticality, climate & circularity)
 - Provided by industry (value chain) through calls for evidence, notifications and updates of registration files and collected by ECHA
- Prioritisation of 'uses of concern'
 - Adapting current scoring system including on top of risk also other parameters such as exposure/emission potential, criticality, climate, strategic nature & circularity
- Inclusion of prioritized uses of concern into a regulatory screening list:
 - Based on result ECHA could select specific uses for further regulatory actions (RMM)
 - Coordination with other regulatory fora is needed (BIME/OSQA)

Uncontrolled risks: proposal RMOA based approach

- Define the right risk management option and initiate regulatory actions & mandate
 - Decision by the EC based upon the OSOA recommendation and including the full chemicals toolbox available both REACH and non-REACH risk management options (IED/OSH/Waste regulation/ESPR/etc) to avoid double regulation
 - Allowing participation of industry in assessment of RMO
- Drawing up of an unique workplan based on the RMM:
 - Inclusion of specific conditions regarding regulatory actions, timeline and resources needed
 - Communication in an extended PACT
 - Involving RIME / OSOA & stakeholders
 - One workplan (REACH & non-REACH) = avoiding overlap
- Implementation & clarification when concern has been addressed:
 - Inclusion in PACT for follow-up

Ensure communication along value chain

- Involvement of all stakeholders to properly scope the risk management measure option upfront, provide information and avoid regrettable substitution
 - move away from a purely hazard-based approach and transition towards a more nuanced and effective risk- and lifecycle-based approach to manage potential risks,
 - leading to less focus on uses with low exposure potential and more efficient allocation of resources while supporting EU industry
- Direct communication along the value chain rather than new information requirements downstream Users to provide relevant, targeted data if registration dossier information is not sufficient or relevant for the proposed prioritisation system such as:
 - Information on covering tonnage/use along the supply chain, up to the articles' functionalities and final uses, as much as possible, exposure/emission data and potentially information on alternatives (e.g., feasibility).
 - Monitoring data at the workplace could be useful to be collected from Downstream Users where generic exposure tools are not available
 - Better alignment between REACH and OSH will be useful

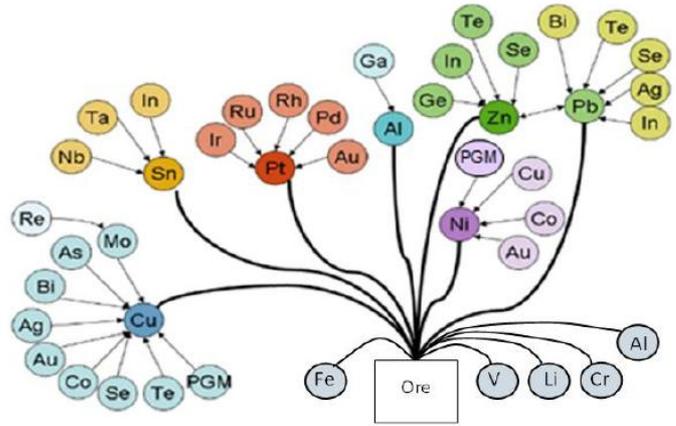
Ensure communication along value chain

- User-friendly notification system could help the actors in the supply chain to provide information to complement the information in the Registration dossiers:
 - The system could be set up so that downstream users could provide ECHA with more granular and updated targeted and scoped information associated to their specific case
- Additionally, a weak link in the value chain communication is between the end of the value chain (product/waste) and when it re-enters the loop as secondary raw material.
 - Information on exposure for this part of the chain is needed as well, and it will be key in the Circular Economy discussions.
 - We need a cradle-to-cradle concept in REACH dossiers to cover End of Life and recycling.
- Additional testing and information requirements for low-volume substances should be related to their potential for exposure to workers, consumers, or the environment.

Risk management process

- Ensure targeted and implementable restrictions based on unacceptable EU risk, covering the whole life cycle:
 - Rather than blanket bans, restrictions that target specific uses where the risk is highest should be prioritised.
 - This would ensure that the measures are effective in mitigating the identified risks and allow for the continued use of substances in applications where the risk is adequately controlled.
- Ensure coherence between regulatory objectives (Circularity, Climate, Chemicals, Criticality)
 - Otherwise potentially phasing-out of materials that are critical for society to contribute and/or achieve the Green Deal objectives.
- Automatic consequences in downstream legislation between legislations should be avoided

Better consider the metals specificities in REACH



Primary metals and by-products

- A “one size fits all” system (working for both organics and inorganics) is not fit for the efficient chemicals management of metals
 - Substitution of one metal may result in the non-availability of another critical metal, including for recycling (e.g., restricting lead affects the availability of silver because it is a carrier metal).
- Circularity, critical materials availability, and climate considerations need to be assessed together with hazard and potential risk to ensure that the alternative selected is safer and more or equally sustainable.

t

Better consider the metals specificities in REACH

- Grouping of metals considering e.g. the presence of a common metal ion assumed to be driving their toxicity is not the right tool
 - Several other factors need to be considered when performing grouping and be part of the supporting justification (e.g., counter-ion, bioavailability, crystallinity, etc.).
- The Mixture Allocation Factor (MAF) will have a big impact on the metals REACH dossiers and does not consider a series of key metal specificities (natural occurrence, their data-richness, essentiality and competitive uptake, etc.)
 - Limited possibility for refinement as we already use e.g., measured data and have risk management measures in place.
 - Therefore avoid the integration of a default MAF in REACH for naturally occurring substances.
|
- Instead of a default use of MAF use the metals sector developed MEED as alternative:
 - May include the use of an added risk approach

Better consider the metals specificities in REACH

- Metal mixtures (alloys, pigments, ceramics, tiles, and complex metal substances) may have very different hazard properties than those of their constituents
 - The concentrations of the metal ingredients in such complex materials are generally not good predictors of the actual contribution that those constituents make to the material's hazard and risks
- Integrating materials flow assessment, following materials from cradle to cradle:
 - Covering their whole lifecycle, combined with the estimation of releases (emissions/exposures) and risk management by use would for example bring REACH closer to the reality of metals
 - Metals often have many uses with different potential hazard and release patterns
 - This would improve consistency and coherence with end of life, waste and recycling.

Make sure REACH is enforceable

- Enforcement ensures level playing field.
- REACH would be more efficient if the already demanding rules were properly enforced.
- A key action would be weighting the enforceability of the proposed REACH and non-REACH measures throughout all stages of decision-making and giving a more prominent role to the Enforcement Forum.

Thank you

For your attention



Patrick Van den Bossche

Strategic advisor green transition

Patrick.vandenbossche@agoria.be

+32 2 706 80 12

.AGORIA