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Eurometaux Position Paper on the simplification of REACH

The REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) is a cornerstone of European chemicals policy, aiming to ensure a high level of protection for human health and the environment. Despite its many successes, the current REACH framework has proven to be cumbersome and time-consuming for authorities and industry alike. The slow pace of risk management (RM) hinders the timely identification and mitigation of risks, spreads resources thin, resulting in a chemicals policy that sometimes contrasts sharply with the sustainability priorities of the EU and impacts the predictability and certainty needed for business investment in the EU. Additionally, the use of data in risk management processes remains uneven, while information requirements have grown throughout the years. Likewise, the communication along the supply chain can be improved. These elements hamper robust risk assessments and effective regulatory decisions.

As the Draghi report noted, the current regulatory framework can create barriers and uncertainties for manufacturing investment, as well as negative costs stemming from regulatory overlaps. At REACH level, these challenges all **require a significant rethink and redesign** of the risk management process and tools, from the identification (starting from the chemicals universe mapping) up to the selection of the relevant Risk Management Option (RMO). The European Commission's efforts to tackle the shortcomings of REACH through its simplification are therefore a step in the right direction, which will require a careful balancing act between the different perspectives and ideas about what "simplification" means.

Simplification should not come at the expense of the application of the precautionary principle and result in over-regulation of substances. For instance, simplification should come in the form of identifying those substances that pose actual risk and focusing attention on mitigation those risks rather than grouping "similar" substances together and thus applying regulation to a broad and over-inclusive set of substances. Although we support simplification, we do not believe substance specificities should be sacrificed for simplification; rather, simplification should be achieved through targeted attention where exposures create risks (risk control).

Eurometaux supports a REACH revision **that identifies and effectively addresses current weaknesses and inefficiencies, to achieve more action-oriented, timely and predictable legislation that focuses on uncontrolled risks**. Due to the complexities of REACH, and the careful balancing act needed between efficiency, support for competitiveness and upholding high levels of protection, it may be realistic to target an increase in **efficiency and transparency** in how we work with chemicals. This position paper will outline key recommendations in this direction to ensure that REACH remains fit for purpose in the 21st century for a competitive and safe European metals industry.

Key recommendations

1. Chemicals management, including REACH, **should focus on uncontrolled risks and avoid scattered, overlapping regulatory actions to increase the predictability of risk management.** Set up a clear, agreed EU regulatory plan to address uses of substances that need to be risk managed (i.e. uncontrolled emissions/exposures). An upfront analysis of the best regulatory path to control the risks (RMOA type analysis) will allow the best use of scattered resources and the existing toolkit of EU legislations (see also short paper on RMOA and spaghetti slide). For metals, this analysis also allows to bring in the criticality, climate action, circularity, and substitution dimensions in addition to the chemicals management aspects

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2. **Ensure communication along the value chain and have the right information on substances' hazards, uses, exposure, functionality & alternatives for adequate RMO* selection.** This requires collecting the data needed to feed the RMOA early in the process by giving a signal to the value chain when a substance is considered for regulatory action. Set up proper, user-friendly systems with targeted questions (like the calls for evidence)to collect data early in the process.

3. **Make the risk management process fit for purpose, covering the whole life cycle.** This would require redesigning the Autorisation system for very specific cases and adjusting the prioritisation criteria for Annex XIV to consider aspects like exposure (better proxy than volumes for metals). Additionally, restrictions should be targeted and implementable, based on unacceptable risk and covering the whole lifecycle. Finally, we should avoid incoherences between regulatory objectives (climate, circularity, chemicals and criticality) when deciding on control measures and automatic consequences in downstream legislation. It should be clarified when concerns have been addressed (in PACT) to prevent impacts on downstream legislation.

4. **Better consider metal specificities in REACH**, e.g. on grouping and complex metal-containing materials like alloys and UVCBs. Avoid the integration of a default MAF in REACH for naturally occurring substances. Follow materials and their emissions from cradle to cradle, covering their whole life cycle, working on consistency and coherence with end of life, waste and recycling.

5. **Make sure REACH is enforceable for a level playing field** by weighting the enforceability of the proposed REACH and non-REACH measures throughout all stages of decision-making.

1. REACH should focus on uncontrolled risks, by ensuring, upfront, transparent identification, selection, and prioritisation of risk by use

The REACH processes related to risk management identification and implementation are cumbersome, slow and complex, as highlighted by the conclusions of the REACH 2017 Evaluation. Among the causes of the inefficiency of some steps of the risk management processes are the 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, as well as the granting process itself (e.g. chromium (VI)).

We should be targeting an **increase in efficiency and transparency** in the risk management of chemicals. More efficiency could be achieved by focusing resources on what matters, i.e., uses with concerning exposure to humans and the environment, and with the biggest harm potential (endpoints of concern e.g., CMR or PBT). This requires **setting up a clear, agreed EU regulatory plan to address uses of substances that need to be risk managed (i.e. uncontrolled emissions/exposures).** An upfront analysis of the best regulatory path to control the risks (RMOA type analysis) will allow the best use of scattered resources and the existing toolkit of EU legislations (see also short paper on RMOA and spaghetti slide, in annex). For metals, this analysis also allows to bring in the criticality, climate action, circularity, and substitution dimensions in addition to the chemicals management aspects

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Such a system should work based on a **combination of uses and substances**, rather than just substances, since it would promote the selective prioritisation of the most relevant risks and most relevant use-specific risk management measures. The system could comprise the following sequential steps (see Annex I for a visual representation):

1. **Mapping and screening.** The first step would require ECHA to, based on the Integrated Regulatory Strategy (IRS)[1] and Assessments of Regulatory Needs (ARNs)[2], screen the substance database, identify what data is missing, and identify the uses of a substance that require follow-up. Industry would be responsible for ensuring that Registration Dossiers are complete and up to date for ARNs to have the right data, but this requires the active contribution of DUs.

2. **Targeted data collection.** The Registration dossiers and the outcomes of the ARNs are a good starting point but need to be complemented with relevant and needed additional data on uses, technical function, exposure pathways, emissions, alternatives and possibly key aspects for the EU Green Deal objectives (e.g., criticality, climate, and circularity considerations) provided by industry along the value chain, collected by ECHA and announced in an extended Public Activities Coordination Tool (PACT)[3] via calls for evidence. Additional data could at this point be collected through calls for evidence, notifications, updates of Registration dossiers, etc. This would allow the supply chain to prepare and submit relevant information for risk management.

3. **Prioritisation of "uses of concern".** Clear criteria should be set to establish a scoring system that would help to select uses of substances for required regulatory action. This could be done by adapting the ECHA priority scoring system used for Annex XIV/authorisation and including, on top of risk, additional criteria such as exposure/emissions potential, criticality and strategic nature, and circularity.

4. **Inclusion of the prioritised uses of concern into a Regulatory Screening List.** Based on the result of the prioritisation, collected data, internal expertise, etc. ECHA could select specific uses for further regulatory action(s) and prepare proposals of prioritization and possible Risk Management Measures. Coordination in fora such as RIME+[4] or the OSOA Expert Group[5] would be required for all the competent authorities and regulators to be involved in the process. Moreover, industry could conduct its own RMOa[6] in parallel to inform the process.

5. **Define the right Risk Management Option (RMO) and initiate regulatory actions and mandate.** The European Commission would confirm the regulatory needs upon the proposal of the OSOA Expert Group and choose the most efficient Risk Management Measure to tackle the risk posed by the targeted use. This decision should consider the full chemicals toolbox available at EU level, which includes a diverse array of REACH and also non-REACH measures, such as the Industrial Emissions Directive (IED), Occupational Safety and Health (OSH), Waste regulations, Ecodesign for Sustainable products (ESPR), etc, to avoid double-regulation. This will

[1] Integrated Regulatory Strategy, **https://echa.europa.eu/-/integrated-regulatory-strategy-annual-report**

[2] Assessment of Regulatory Needs, **https://echa.europa.eu/understanding-assessment-regulatory-needs**

[3] Public Activities Coordination Tool, **https://echa.europa.eu/pact**

[4] RiME+ (Risk Management and Evaluation) platform, **https://echa.europa.eu/rime**

[5] Expert Group on One Substance, One Assessment, **https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3792**

[6] Risk Management Options analysis (RMOa) is the application to chemicals management of a broadly used concept of identification, evaluation, prioritisation and addressing of risks. See Eurometaux guidance published in: **https://www.reach-metals.eu/rmoa/practical-guide-to-industry-risk-management-options/introduction**

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ensure that the most efficient and effective measure is implemented for (a) given use(s). The industry (supply chain) should be allowed to take part in the assessment of RMOs considering the information reported in the registration files and gathered from the notification process and downstream user information.

6. **Based on the Risk Management Measure chosen, a unique workplan should be drawn.** All concerns identified during the prioritisation, together with the most efficient Risk Management Measure identified, should be collectively and transparently reported in an agreed workplan. The document could include the specific conditions surrounding the regulatory action, timelines and resources to be dedicated to its implementation, with the involvement of RIME+ and OSOA EG as well as concerned stakeholders. This should be communicated in an extended PACT for transparency purposes. By consolidating the different regulatory activities (REACH and non-REACH) into a single workplan, the EU could avoid regulatory overlaps and coherence issues between different actions in chemicals legislations, agencies would gain a comprehensive overview of ongoing and planned initiatives across different sectors and facilitate their coordination.

7. **Implementation and clarify when the concern has been addressed**. There should be a procedure to make it clear when the concern has been addressed, once regulatory needs have been evaluated and allocated, or for which risks are demonstrated as being properly managed. The status for each of the uses of substances should be updated on PACT.

Having such a system in place would not only help the regulator identify the risks that should be tackled first, but would also help to prioritise those **tools that are the most effective, increase transparency, and predictability and allow better anticipation by industry on the potential risk reduction measure aimed for**. An adequate scoping of the restrictions would also likely result in a reduced need for derogations or exemptions, and properly scoped and targeted restrictions are the best way to make them more effective.

2. Ensure communication along the value chain and having the right information on uses, exposure, functionality and alternatives for adequate Risk Management Option selection

It would be impossible to focus on uncontrolled risks if authorities do not have access to the right information at the right moment. This is a shared responsibility across the value chain to ensure that updated dossiers have the appropriate information to launch targeted and effective risk management activities. Regulators should set up proper systems to collect the data needed early in the process so that RMOAs can be based on full data.

Within such a system, it should be noted that **early involvement of all stakeholders to properly scope the risk management measure option upfront, provide information and avoid regrettable substitution,** can avoid costly, time-consuming complications that have characterised the REACH process in the last years. This could be especially the case for Authorisation.

By prioritizing the collection and analysis of data early in the process (step 1), e.g., robust data on exposure, potential health effects, and the effectiveness of different control measures, decision-makers can **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 (chemical and downstream 'make' industry against import and manufacture drain outside EU). Finally, availability of information on the uses is key to avoid defaults on restrictions and assumptions on volumes. It is important to have the correct information from the value chain in order to launch targeted and effective risk management activities.

Along these lines, it is important to promote **better direct communication along the value chain rather than new information requirements**, as we need to avoid a 'detachment' between manufacturers or importers and Downstream Users (DUs). This means in practice obligations for Downstream Users to provide relevant, targeted data if registration dossier information is not sufficient or relevant for the proposed prioritisation system (for example, 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. OSH already requests this data; however, it does not always fit with REACH exposure scenario requirements. From this perspective, **better alignment between REACH and OSH will be useful**. All this information should be available before authorities assess the Risk Management Options (RMOA).

In practice, a **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. ECHA/MSs can evaluate when more information on uses/exposure is needed from manufacturers or importers and DUs. However, attention should be paid to possible double counting (for DUs operating in the same supply chain and in case of metal species transformation) and registrants may need to get access to the data that can be used to refine the CSRs. Therefore, resources to develop such a system should be foreseen.

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.

Finally, additional testing and information requirements for low-volume substances should be related to their potential for exposure to workers, consumers, or the environment.

3. Make the risk management process fit for purpose, covering the whole life cycle

The Authorisation process should be redesigned to avoid costly, time-consuming complications that have characterised the REACH process in the last years. The Chromium (VI) case is a good example, highlighting the problems with the current system. There is much merit in re-designing the Authorisation system for **very specific cases not covered by the Restriction system**, to overcome the present problem associated with "upstream authorisation applications" and avoid the system's congestion. The final aim of Authorisation is substitution, its use should therefore be limited for example, to cases where the use of a substance is in the process to be substituted but still requires additional time to be ready. The system should also allow a level of flexibility to allow simple changes and transfers of granted authorisations to accommodate business realities without undergoing the full decision process (e.g., activities involving concerned substance are transferred between sites, or for new activities/transformation of them). To limit legal uncertainty, the complexity and length of the decision-making processes should be shortened drastically, and a fast-track procedure for emergency cases established. Moreover, the prioritisation for Annex XIV presently based on criteria that are mainly "volume" and "hazard" driven, while both criteria are not predictive surrogates for actual risk management of metals. The prioritisation criteria should be adjusted to consider exposure potential.

There should be a procedure to make it clear when concerns have been addressed, once regulatory needs have been evaluated and allocated, or for which risks are demonstrated as being properly managed under SVHC identification, prioritisation lists, and Annex XIV. This could help alleviate the impact that chemicals management

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decisions (identification and listing of substances; risk management measures) have on other legislations and initiatives, creating obligations (e.g. CSRD) but also impacting access to finance and investments (taxonomy) once risks have been addressed. This will become increasingly challenging as preogressively more substances are considered "of concern" (SVHC, MHC, SoC) with overlapping definitions.

With regards to Restrictions, we should **ensure targeted and implementable Restrictions based on unacceptable EU risk, covering the whole life cycle.** Restrictions must be based on the best available scientific evidence, including data on hazard, exposure, and risk showing that there is an unacceptable risk to health or the environment. 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.

Additionally, risk management decisions should **ensure coherence between regulatory objectives (Circularity, Climate, Chemicals, Criticality)** when deciding on control measures and substitution. When risk management is required, the measure should ensure that the level of precaution embedded in chemicals management does not create a regrettable action, through a significant negative impact on circularity, availability of materials and climate objectives and vice-versa. Otherwise, we could face a phasing-out of materials that are critical for society to contribute and/or achieve the Green Deal objectives. For example, several base metals are used to produce and recycle other metals. Restrictions of these metals could hinder the EU's ability to achieve the recycling targets under the Critical Raw Materials Act (and the EU's strategic autonomy). Moreover, recycling metals typically uses between 5 and 30% (depending on the metal) of the energy that is needed to produce "new metal" from using only raw materials (with no recycling), with effects in the footprint of the materials we use. These considerations should be taken into account.

Finally, **automatic consequences in downstream legislation between legislations should be avoided**. These can create complex regulatory overlaps and even contradictions between different legal frameworks and potentially lead to unintended consequences that were not fully assessed. This can lead to confusion and uncertainty for businesses, hindering innovation and investment. For example, a chemicals management decision on a specific substance can create obligations under ESPR, ELV, Batteries, Taxonomy or CSRD, and impact access to finance and investments. This will become more challenging as increasingly more substances are considered "of concern" (SVHC, MHC, SoC) with overlapping definitions. For instance, following Appendix C of the Taxonomy Regulation, if substances enter the Candidate List, but are not de-listed when they are not going forward in the Authorization processes (or when the concern is addressed by other RMOs than Authorisation), reporting requirements would still remain. Moreover, some exemptions (e.g. restrictions in Products legislation) are not accepted for compliance with Do Not Significant Harm (DNSH).

4. Better consider the metals sector's specificities in REACH

Metal/inorganics-specific properties and their implications have a significant bearing on their identification, prioritisation and risk management within the REACH and CLP-based regulatory frameworks. **Therefore a "one size fits all" system (working for both organics and inorganics) is not fit for the efficient chemicals management of metals.**

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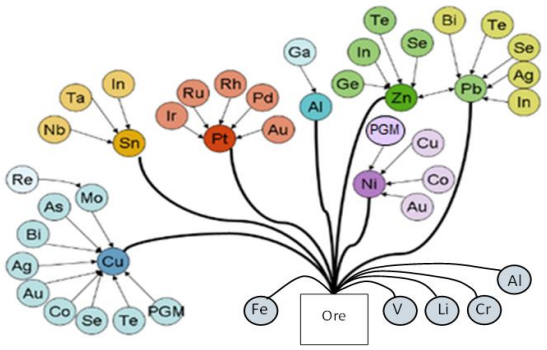

Primary metals and by-products

Illustrative of this are properties like **"co-occurrence"** (meaning that metals do not occur "alone" in nature and industrial processes) "**essentiality**" and "**recyclability**". In terms of risk management, it is crucial to bear in mind that the **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). The opposite exists as well: the substitution to a less hazardous metal can result in an increased production of the hazardous metal itself (e.g., bismuth can potentially substitute for lead in copper - or aluminium alloys but is extracted from lead ores where it is at concentrations < 1 %). For this reason, appropriate considerations as described in the OECD Guidance should be considered. In addition to known value chain impacts inherent to any risk management option (RMO), the interrelationship between metals and their respective lifecycles and value chains requires particular attention when selecting the most relevant RMO. Therefore, **circularity, critical materials availability, and climate considerations need to be assessed together with hazard to ensure that the alternative selected is safer and more or equally sustainable.**

Moreover, metals can often be grouped considering e.g. the presence of a common metal ion assumed to be driving their toxicity. But several **other factors need to be considered when performing grouping** and be part of the supporting justification (e.g., counter-ion, bioavailability, crystallinity, etc.). Tools and approaches have been developed to help authorities and industry to bring together the different sources of evidence[1].

Another key issue for metals is the Mixture Allocation Factor (MAF), which assesses the risk of cocktails of chemicals at the workplace and in the environment and will have a big impact on the metals REACH dossiers. Such a generic assessment factor does not consider a series of key metal specificities like their natural occurrence, their data-richness, essentiality and competitive uptake, etc. There will be limited possibility for refinement as we already use e.g., measured data and have risk management measures in place. We should therefore **avoid the integration of a default MAF in REACH for naturally occurring substances**. Instead of a default, we need an alternative, more refined scheme considering metal specificities and allowing the use monitoring evidence. The sector has engaged in a collective demonstration via a multi-year data gathering programme (MEED) to identify the issue and propose a science-based refinement of the MAF based on data and research. The refinement may include the use of an added risk approach, a focus on input from chemicals manufacturing and uses and an approach to reduce conservatism as a consequence of reduced uncertainty (MF and MOS approaches). It should also be noted that OSH legislation already includes a MAF (workplace assessment).

Finally, metal mixtures like alloys, pigments, ceramics, tiles, and complex metal substances may have very different hazard properties than those of their constituents due to e.g., the presence of a matrix in which metals are combined. 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 (e.g., nickel metal and stainless steel have very different sensitisation properties between nickel metal alone and when it is bound in a matrix like stainless steel). Therefore, with the prioritisation for Annex XIV presently based on criteria that are mainly "volume" and "hazard endpoint" driven, both criteria are not predictive surrogates for actual risk management needs for metals and inorganics. **Integrating materials flow assessment, following materials from cradle to cradle covering their whole lifecycle, combined**

[1] Metals release tests, transformation dissolution protocol.

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with the estimation of releases (emissions/exposures) and risk management by use (since metals often have many uses with different potential hazard and release patterns) would for example bring REACH closer to the realities of metals. This would improve consistency and coherence with end of life, waste and recycling.

5. Make sure REACH is enforceable

Enforcement ensures level playing field. In some cases, 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.

ABOUT EUROMETAUX

Eurometaux is the decisive voice of non-ferrous metals producers and recyclers in Europe. With an annual turnover of €120bn, our members represent an essential industry for European society that businesses in almost every sector depend on. Together, we are leading Europe towards a more circular future through the endlessly recyclable potential of metals.

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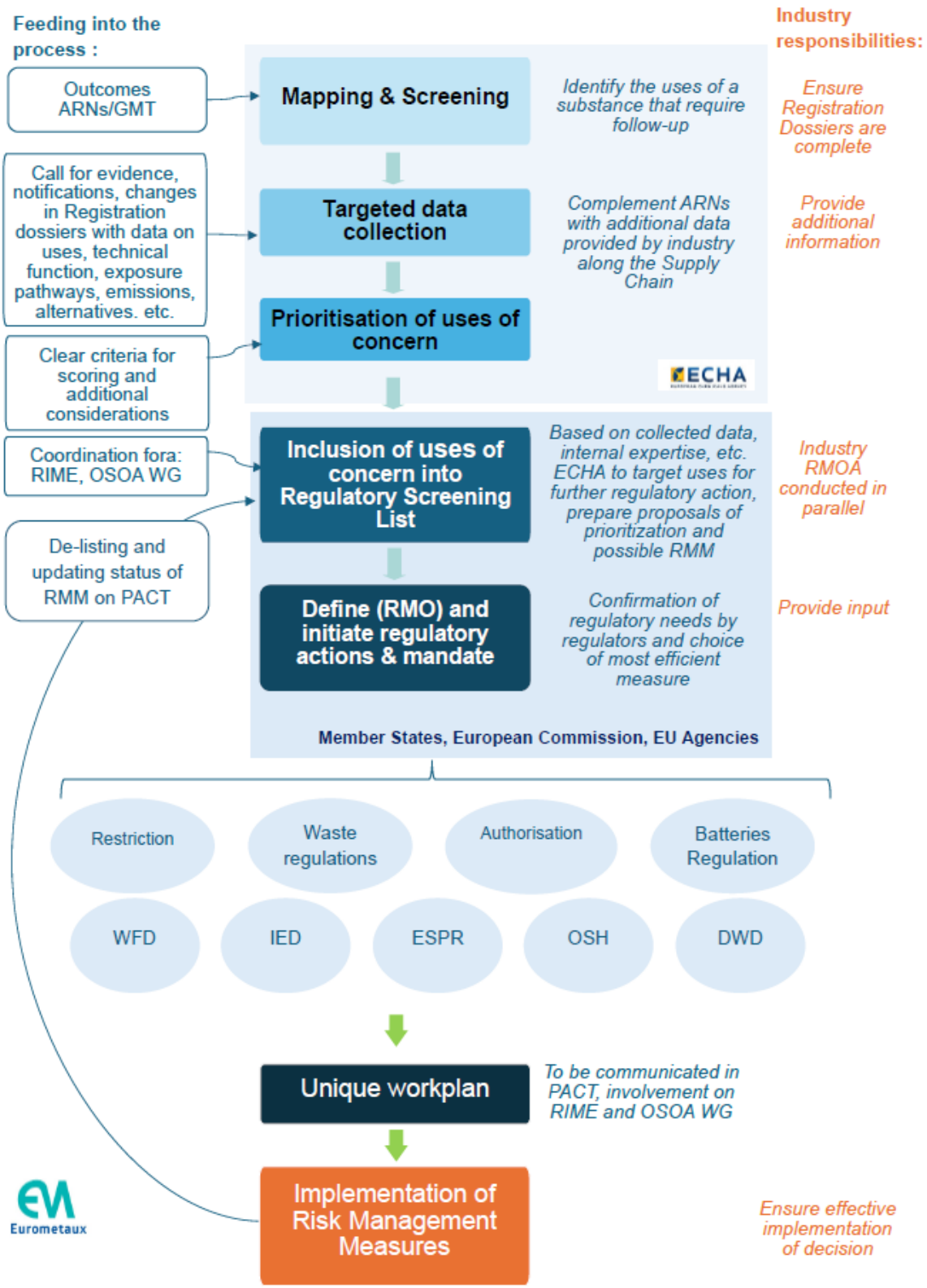
Annex I



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Zero Pollution Ambition: interrelations with other EU policies