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Eurometaux response to the public consultation on the Inception Impact Assessment (IIA) on the Revision of REACH

1. INTRODUCTION

Metals are inorganic chemicals used across a range of European industrial ecosystems, including mobility, construction, electronics, digital, health, and renewable energy. Their demand is projected to increase significantly in line with society's transition away from fossil fuels towards climate-neutrality, with recycling as a key route to improving Europe's resilience.[1] The industry maintains that Europe's priorities on REACH should be to implement robust and efficient measures for controlling harmful exposure from metals across their lifecycle, while promoting closing materials circles and ensuring safe recycling of metals and inorganics. In turn industry has made significant investments to make REACH a success as a cornerstone of the EU's chemicals management and the most comprehensive chemicals legislation in the world.

The Chemicals Strategy for Sustainability (CSS) explicitly states that "the EU must strengthen its open strategic autonomy with resilient value chains and diversify sustainable sourcing for those chemicals that have essential uses for our health and for achieving a climate-neutral and circular economy." On 5 May 2021, the Commission published its updated industrial strategy[2], confirming the need to reduce our dependencies from third countries for these substances, especially the so-called Critical Raw Materials (CRMs). A few days later, the International Energy Agency (IEA) published a special report on "The Role of Critical Minerals in Clean Energy Transitions"[3], warning industry and policymakers that if the adequacy of access to metals is left unaddressed, our progress towards climate neutrality is at severe risk. Metals and inorganics play a critical role in all those policies.

The European Green Deal has set the ambitious and necessary target for Europe to be the first carbon-neutral continent by 2050. It explicitly calls for all EU actions and policies to contribute to this objective. This was further supported by the European Council in its Conclusions of 12 December 2019. The European metals industry, believes that the Chemicals Strategy for Sustainability and in particular REACH, should contribute to the same objective.

In this document, we share our views on the Commission's plans, and more specifically on the possible impacts of the suggested options (e.g., MAF, Essential Uses Concept).
These views are based on our reflections for the future of the REACH Regulation and how it can better embrace sustainability aspects such as circularity, climate and environmental footprints and effectively contribute to the objectives of the Green Deal.

To conclude, Eurometaux is ready to engage with the European Commission and other stakeholders to secure REACH and its revision process deliver their full potential.

[1] World Bank, Mineral Production to Soar as Demand for Clean Energy Increases, May 2020
[2] COM(2021) 350 final, Updating the 2020 New Industrial Strategy, May 2021,
[3] IEA, The Role of Critical Minerals in Clean Energy Transitions, May 2021

Eurometaux - European Association of Metals
Avenue de Tervueren 168, Box 13 | B-1150 Brussels | Tel: +32 (2) 775 63 11 | www.eurometaux.eu | eurometaux@eurometaux.be | @Eurometaux

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2. REGISTRATION REQUIREMENTS

- **Information requirements for low tonnage substances**

Eurometaux concurs that the need to complete existing data gaps is important to ensure a profound knowledge of substances used, as well as to define the need for risk identification and risk management. The CSS foresees amending REACH information requirements to enable identification of all CMR substances manufactured or imported in the EU, "irrespective of the volume". The IIA rightly points out that this will increase the administrative burden and related compliance costs. This is a significant concern for many of our members, including for European SMEs.

We believe that the additional REACH information requirements for low tonnage substances should remain proportionate to the needs of society and the risk potential of low volume substances present**.** Moreover, small volume substances play an important role in research and development. So unnecessary pressure on them will undoubtedly have an impact on European innovation and R&D capacities.

Eurometaux therefore suggests focussing on "what matters" in respect to the potential for risk, hence, to include exposure and use considerations as prioritisation criteria (e.g., use descriptors highlighting exposure could be a concern). In addition, a tiered approach is recommended to allow industry to generate this new information in an efficient manner.

If these elements are not considered, this extension may lead to significant negative socio-economic impacts, increased administrative burden, hampered innovation, more (animal) testing – all without necessarily fulfilling the initial objectives of REACH, the CSS, and the Zero Pollution Ambition.

Eurometaux recommends the following on information requirements for low tonnages:

- Additional REACH information requirements for low tonnage substances should remain proportionate and risk-based to avoid unnecessary costs, testing, and barriers to innovation.
- We would like the following issues to be covered by the impact assessment underpinning the REACH Revision: socio-economic assessments with attention for the administrative burden, measuring improvements to health and safety, considering exposure, potential impact on innovation (especially for SMEs), and assessing the impact on animal welfare (and how to alleviate this impact with in vitro alternatives).

- **More attention for alternatives to animal testing and smart information requirements**

REACH standard information requirements have caused an enormous need for animal testing. While we support the principle of effects knowledge-building, we are concerned about the way the rigid implementation of REACH has caused too much unnecessary animal testing. The focus on higher tier confirmatory testing to demonstrate the negative (i.e. ,absence of effects) or testing on multiple species (like for the PNDT) should therefore be reviewed for its efficiency before potentially requesting further vertebrate testing. More balanced

Eurometaux - European Association of Metals
Avenue de Tervueren 168, Box 13 | B-1150 Brussels | Tel: +32 (2) 775 63 11 | www.eurometaux.eu | eurometaux@eurometaux.be | @Eurometaux

views on read-across and more attention to and recognition of alternative testing strategies may prevent unnecessary animal vertebrate testing.

Furthermore, the demand for vertebrate testing exclusively related to the volume produced without due consideration of exposure or exposure potential may result in testing materials with lack of exposure or bioavailability potential.

The overall aim is the demonstration of "safe use" whereby in general REACH focusses too extensively on the effects side of the equation and probably not enough on the exposure side. A more balanced attention to exposure evidence could help define the need for and the relevance of refinement of hazard properties through further vertebrate testing. Such smart testing and information gathering system should be the overall aim of REACH 2.0.

Eurometaux recommends the following on smart information gathering:

- The need for higher tier confirmatory testing and double species testing should be reconsidered based on a systematic review of existing experience.
- Higher tier vertebrate testing -when all lower tiers are negative- should be halted until the efficiency and relevancy of such additional testing are confirmed.
- A smart testing approach should be developed whereby exposure plays a much more distinctive role in defining the need for further vertebrate testing.
- More attention for balanced read-across (positive and negative) and alternative non-animal testing approaches such as bioavailability-based assessment techniques, is required to align REACH 2.0 better to today's societal concerns and needs.

- **Information requirements on environmental footprint**

The European metals industry takes note that the CSS would like to introduce the need for REACH information requirements on "the overall environmental footprint of chemicals, including emissions of greenhouse gases." We question whether REACH is the right and most efficient place to gather this information (as e.g., REACH is largely focused on individual registrants while assessing the environmental footprint would require a collective view).

We are a frontrunner in the transition to a climate-neutral society. Our industry has made several important changes to reduce its environmental footprint and there is consensus[1] over the fact that most of our substances will form the major parts of decarbonisation pathways for other energy-intensive sectors and industry overall.

Introducing information requirements on the environmental footprint in REACH would require great attention to prevent overlaps with existing legislation (e.g., Battery Regulation) and to ensure they reflect on this footprint as accurately as possible, meaning *the impact of a service provided by a substance from cradle to cradle*. This should therefore cover relevant footprint aspects of manufacturing, the full use phase of the substance, while accounting for the gains made during recycling; all this expressed for the longevity of the service provided.

[1] See abovementioned World Bank and IEA reports, both recognising the crucial role of metals for the energy transition and to reach climate neutrality.

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Another key element of the CSS is reaching a clean circular economy. It should be noted that Europe has the capacity and the technology to become a global leader in recycling of complex products, such as electrical and electronic equipment. Hence, we recommend that the REACH text recognises the benefits of recycling and recycled materials in an objective way including their positive contributions to other goals of the Green Deal (e.g., climate).

Eurometaux questions whether REACH is the most efficient place to gather information on the environmental footprint. If such information requirements are included:

- We believe that using the full lifecycle of a substance - from cradle to cradle – is needed to evaluate the environmental footprint of substances in order to avoid information requirement on single indicators or parts of the lifecycle of a given substance.
- The methodology needs to consider the longevity of use, the effectiveness in functionality during use, the potential for recycled substances to preferably have performance equivalent to primary ones.
- The methodology should also consider the objectives of the Green Deal (climate transition, circularity and chemicals management).
- The climate mitigation potential of a given substance (e.g., metals used in solar photovoltaic cells, for energy storage, or for conductivity) should also be taken into account in the methodology.
- Finally, we call on the Commission to ensure consistency between these information requirements, existing legislations and the ongoing work on Safe and Sustainable by Design (SSbD) concept.

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3. COMBINED TOXICITY

The IIA confirmed the upcoming introduction of one or more Mixture Assessment Factors (MAFs) to address longstanding concerns over risks from unintentional exposure to several substances (also known as combination/cocktail effects).

As we write this paper, preliminary impact assessment work on MAFs has already begun, by both regulators and industry. In this regard, we welcome the recognition for metals specificities in the Terms of Reference of the dedicated preliminary impact study on this issue and we hope that its conclusions will feed into the impact assessment underpinning the REACH revision.

Besides recognition for the specific aspects of metals and inorganics, like their natural occurrence, we fear that the proposed MAF approach would affect the demonstration of safe use of chemicals, mainly because of the accumulation of precautionary and default conditions. We therefore call upon the Commission to design or allow industry to demonstrate a pragmatic assessment scheme that balances the need for precaution at a relevant level.

Eurometaux recommends the following regarding the introduction of a MAF under REACH:

- The default MAF should (only) be used to set aside substances for which no further demonstration of the exposure risks of unintentional mixtures is required. Hence, allowing refinement schemes for other substances and providing realistic time frames to demonstrate those.
- Refinement approaches should remain science-based, balanced and pragmatic to remain suitable and relevant to the overall aim, i.e., prevent combination effects. We question how the MAF can and will be integrated into the assessment framework that already exists in the REACH guidance.
- Such approaches should not be designed with only one type of chemical in mind. Those should also be suitable for inorganics.
- Neither should the MAF approach duplicate existing functional approaches such as OSH (workers' legislation) or good water status under the Water Framework Directive.
- While exposure to metals is well-documented and can often be monitored, effects interactions between metals and organic substances still require further research. We encourage the Commission to provide the necessary information to enable the most appropriate evidence-based approach for metals.
- The impact on industry of the introduction of the MAF concept will to a great extent depend on the permitted degree of flexibility and pragmatism in demonstrating that effects of combined exposure can be prevented. Hence the metals industry therefore makes a strong call for a system that recognises such a balance.

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4. EVALUATION

The CoRAP, as well as the critical conclusions by the Board of Appeal, have allowed a focussed and priority-based selection of chemicals and concerns for Substance Evaluation. On the other hand -and contrary to dossier evaluations- the identification of further information needs and how to fulfil them lies firstly in of the responsibility of the evaluating Member State. This resulted in practice in a wide variety of requests, some of them aiming for resolving research and development interests of a Member State (e.g., on nano materials). This problem could in principle be prevented if ECHA was responsible for defining the non-standard data information needs, based upon a concern of a Member State.

The IIA also foresees the revocation of registration numbers. While industry is convinced that this can be relevant and useful especially in cases of deliberate and serious non-compliance (e.g., fraud, free-riding, …), it believes that such a final measure should be proportionate and based on clearly defined conditions after a due assessment process. Revocation of registration numbers would however be disproportionate where registrants sought to adapt information requirements and where ECHA disagreed with the justification of the adaptation.

The lack of a clear trigger to challenge free riders on cost-sharing for updates is a major hurdle that slows or prevents regular updates of registration files. We believe this is a critical concern that can be prevented by re-introducing the token system, and regret that here the IIA does not foresee further action.

A last but important concern relates to the burdensome and formalistic approach and language used in the decision-making process on evaluations. Consequently, registrants often do not recognise the options for further strengthening the read-across or waiving, hence start unnecessary vertebrate testing. A clear action for a more informative, cooperative and even voluntary compliance update approach[1] as a precursor to a dossier evaluation or substance evaluation could therefore be considered under the IIA to improve compliance in a far more efficient and faster way than the current procedures.
Moreover, industry has concerns about the strict deadlines applied for the implementation of the decision.

To improve the effectiveness and efficiency of evaluations, Eurometaux recommends:

- That ECHA should take responsibility for defining the additional information needs under the Substance Evaluation programme to ensure more consistency in information requests and to prevent demands for R&D reflective of national interests.
- To consider under the IIA, less formalistic, more cooperative and informative processes to promote alternatives to vertebrate testing where relevant, as a precursor to a Dossier Evaluation and Substance Evaluation.
- Revocation of registration numbers can address some of our difficulties in cost-sharing and updates, although these should be proportional and include clear conditions, legal rights and a due process, allowing differentiation between different cases of non-compliance (e.g., fraud).

[1] As in the Metals and Inorganics Sectoral Approach. MISA has resulted in an enhancement of the speed of updates and improved mutual understanding of the challenges and relevant solutions.

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5. RISK MANAGEMENT

- **General considerations: selecting the best risk management measure(s)**

The CSS states that it will reform the authorisation and restriction processes based on key findings from the practicalities of their implementation. These findings have shown that there (a) is scope to improve the way we decide on the most appropriate risk management measure(s) to adopt and (b) lack of an efficient approval system to grant authorisations. It is therefore necessary to address these issues in addition to reforming the authorisation and restriction processes.

Efficient and effective risk management of chemicals that require further risk control, depends on making the right choice(s) of the most relevant and optimal risk management option. Such an option can and will depend on the use as well as on where the potential for exposure occurs (workplace, releases from articles, environment, …). Moreover, and most importantly such steps can also define what uses could potentially be exempted from further risk management based on their societal value (e.g., required for a vaccination strategy, Green and Digital Transition) as well as prevention of a regrettable risk management measure or substitution resulting in ineffective risk control.

This all emphasises the role of a proper and well conducted Risk Management Option analysis (RMOA) prior to regulatory risk management action. RMOAs have been shown to be very efficient, cost-effective, and less time consuming overall (especially if one considers the time and resources lost when the wrong risk management measure has initially been chosen).

The implementation of the Green Deal further requires attention to other pillars such as impact on climate or circularity, complementary to the demonstration of the safe use of chemicals during manufacturing, importing and use. Such considerations should be included in a more holistic integrated manner when defining the optimal risk management option.

Eurometaux recommends the systematic, transparent, and consistent use of RMOAs:

Before risk management measures are decided upon, Regulators shall be tasked to develop a holistic RMOA that should cover:

- The substances concerned and their properties causing the concern. An assessment as to whether the hazardous properties do trigger a real risk and, if so, where and to what extent the risk would arise.
- Main information on existing uses (consumer and professional) and exposure to the chemicals.
- Mapping of the uses within the relevant industrial ecosystems and critical value chains, as well as initial socio-economic data
- Considering chemicals management as well as socio-economic impacts (including climate and circularity evidence)

On that basis the RMOA could suggest specific use and exposure risk management measures that make optimal use of the available regulatory risk management options under REACH and beyond. This assessment should be driven purely by efficiency, effectiveness and less burdensome implementation of the risk management measures.

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If the RMOA would consider substitution as being appropriate, then an estimate of the technical and economic feasibility of alternatives and potential substitutes should be considered, based on their comparative risks, impact on climate and circularity and costs.

- **Restriction-specific considerations**

The IIA points out that the current restriction process is slow to sufficiently protect consumers and professional users against risks from the most hazardous substances. The need for a faster decision-making was therefore highlighted in the most recent REACH Review.

The CSS further proposes expanding the existing **generic approach to risk management**, currently used only for CMRs in consumer products, to cover EDs, PBTs, and vPvBs. It further mentions that it will assess the modalities and timing necessary to extend the same approach to immunotoxicants, neurotoxicants, respiratory sensitisers and STOTs.
In parallel the CSS foresees to apply the same existing rules for consumer products to products used by professionals.

We would advise caution regarding a few crucial elements:

Article 68 of the REACH Regulation specifically mentions that Annex XVII shall be amended "when there is an unacceptable risk to human health or the environment (…) which needs to be addressed on a Community-wide basis". On the other hand, the text of the CSS only speaks about the presence of the 'most harmful chemicals' in certain products, which is a completely hazard-based approach that goes against the REACH Regulation *ratio legis* for restrictions. Hence, we object to amend this specific sentence in Article 68(1).

In addition, the mere presence of a hazardous metal or inorganic substance does in, and by itself, not imply a risk. We outline three arguments supporting this:

- First, many metal containing materials (e.g., alloys such as stainless-steel products, ceramic wear and others) are characterised by a matrix effect that affects the release of metal ions and hence their bioavailability and toxicity. These products are safe throughout their lifecycle although they often contain 'most harmful chemicals'. Applying a generic risk management approach to one of these used substances would have no benefits in terms of protecting consumers or the environment, whilst having massive socio-economic impacts for numerous value chains.

- Secondly, beyond the matrix effect described above, often substances – and even more so when it comes to hazardous metals – are not directly accessible to consumers or professional users (e.g., the metals that are on a printed circuit board or in a sealed battery, the many metals contained in your smartphone).

- Finally, when a hazard applies by one route e.g., inhalation, but there is no potential of exposure possible via that route during consumer/professional uses, this absence of risk would need to be taken into consideration.

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Finally, the IIA mentions the potential for **the 'essential use' concept (EUC)** applied to the restriction process, "including the criteria for granting derogations". Recent debates in CARACAL expert group have shown the complexity of introducing such a concept and the need for further detailed work and discussion. In our view there are still many fundamental questions and issues relating to the EUC that need to be debated openly and clarified, including an assessment of the added value and benefits, the consequences (e.g., on innovation, EU competitiveness), and the concept's legal basis. It is also unclear who should be accountable for deciding what is essential or not, how the determinations of societal value and suitable alternatives would be made, and how the concept aligns with other EU policy objectives, and global considerations such as free trade. At this stage we neither welcome nor reject the EUC and invite the Commission to first further elaborate on why such a concept would be needed and what it is supposed to achieve before considering an EUC 'framework or criteria. In case the Commission progresses, we support the Council's position to develop an EUC 'framework' rather than strict criteria, and the Commission's intention to launch a study to assess and clarify the many complex and contentious issues.

Nevertheless, we believe that there are other more efficient ways to deal with the need for societal exemptions of risk management of consumer goods. Such derogations can be assessed and included during the RMOA phase when the scope of the restriction is defined. Leaving them out of the scope from the start seems a more practical approach than exempting them from the restriction in a later phase.

In addition, the CSS was promised to be built on the extensive recent policy evaluations and initiatives associated with the EU chemicals legislation, none of which mentioned the EUC as a proposed way forward to improve e.g., risk management processes. Therefore, the EUC needs to be properly addressed in the impact assessment underpinning the revision of REACH, in accordance with the Better Regulation principles.

Eurometaux recommends the following on restrictions:

- When adopting Article 68(1) of the REACH Regulation, the co-legislators' intention was to apply restrictions when there is an "unacceptable risk to human health or the environment (…) which needs to be addressed on a community-wide basis". We therefore reject the hazard-based approach proposed by the CSS and any amendment to Article 68 in this sense.
- The metals and inorganic specificities regarding matrix types of materials like alloys, ceramics, … must be taken into account in (generic) restrictions, as the mere presence of a (potentially most) hazardous substance in alloys does not necessarily pose a risk. Risk Management action based on hazard would therefore cause irreparable harm with no gain for society or the environment.
- We recommend keeping the balance between the use of targeted restrictions and the use of generic restrictions, to avoid regrettable consequences of "one-size-fits-all" approaches.
- The essential use concept is at this moment not mature enough to be implemented. We therefore propose that derogations for societal reasons are considered at the RMOA phase when scoping the restriction, as a more efficient way of working.
- As per our previous remarks on choosing the appropriate risk management measure (e.g., via RMOA like tools), restrictions shall take into account the objectives of the Green Deal, such as climate (mitigation potential and greenhouse gas emissions) and circularity.

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- **Authorisation-specific considerations**

The authorisation system has clearly shown its limits. As highlighted in the IIA, but also in the latest REACH Review, the process is "too heavy and inflexible", it is costly, and too resource intensive while neither transparent nor predictive in its outcome. Probably its biggest flaws are that it is not use specific, nor does it consider the risks of the alternatives in an appropriate manner. It has also placed EU-based companies at a competitive disadvantage to their non-EU competitors.

While it may have contributed to the successful substitution of certain SVHCs, that objective could probably have been achieved more efficiently by many other means (restrictions, incentives, etc.). The same applies to the claimed effectiveness of authorisations on exposure control and reduction.

Finally, the design of the authorisation system has proven to generate controversies, which instead of triggering innovation and substitution, rather leads to delays in regulatory decisions and creates uncertainties both for users of substances and alternative providers. Therefore, the system certainly needs to be overhauled – or even removed/merged with another risk management tool, as stated in the IIA.

Eurometaux recommends the following on authorisations:

- The system is not efficient and has shown its flaws. It therefore needs a complete overhaul or merger with other risk management tools like targeted restrictions.
- If the Commission decides to reform the authorisation process, we recommend:
    - that it can be applied in a targeted fashion to become use- and exposure control specific
    - streamlining it along the restriction system to make both more efficient, use- and exposure type-specific
    - embedding mechanisms of flexibility and fast track procedures to cope with reasonable lead-time with ever changing industrial and commercial environments.
- Substitution when evaluated as a valid option should always be based on proportionate consideration of technically and economically feasible alternatives for a specific use that takes into account chemicals management considerations as well as broader sustainability considerations (including impacts and benefits on climate and circularity).

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Avenue de Tervueren 168, Box 13 | B-1150 Brussels | Tel: +32 (2) 775 63 11 | www.eurometaux.eu | eurometaux@eurometaux.be | @Eurometaux