



# EPMF Position Paper

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26 May 2021

## **Inception Impact Assessment – Revision of the EU legislation on Registration, Evaluation, Authorisation and Restriction of Chemicals**

The European Precious Metals Federation (EPMF) supports the ambition of the European Green Deal and the objectives of the Chemicals Strategy for Sustainability. To achieve them, a targeted revision of the REACH Regulation was launched, focusing on the main problems identified during the last evaluation of REACH in 2018.

The EPMF shares concerns related to some of the identified issues, including the quality of the dossiers, the need to fill in existing data gaps or the need to have more efficient Risk Management Measures like Authorisation and Restriction for a better integration of the different EU policies.

We carefully reviewed the Inception Impact Assessment and fully support the comments submitted by Eurometaux. In addition, the EPMF would like to provide more specific comments:

- **Filling in data gaps on many substances:** to increase data requirements on critical endpoints (carcinogenicity, neurotoxicity, immunotoxicity and endocrine disruptors) for all the substances, including intermediates and lower tonnages.

The EPMF supports the need to fill in existing data gaps to ensure a good knowledge of substances produced by the precious metals industry and adequate risk management. The identified endpoints are critical to ensure the protection of human health and environment. However, the EPMF members are deeply concerned by the increase of current REACH requirements especially concerning the low tonnage substances. Currently, we have in our portfolios more than 50% of our substances (39 in total) in the low tonnage band (1-10t). These substances are used at industrial level and for niche applications. If the data requirements for these substances will increase the impact on the precious metals industry will be enorm. Therefore, the EPMF suggests to focus on what matters and to establish prioritisation criteria (e.g.: based on exposure, type of uses etc.) to increase the data requirements of some substances. A tiered approach is recommended to allow industry to get organized to generate this new information. More efforts are also needed for the alternatives to animal testing in order to keep the exercise proportionate. In the assessment of the options and the best way forward it is essential to consider the risk to see the cease of production of some of these very special substances. If requirements are disproportionally high regarding the marketing value, some producers would indeed consider stopping the production in the EU. This would increase EU dependency on the 3<sup>rd</sup> countries for special substances used in niche applications. This is against the principle of economic independency of the EU from the 3<sup>rd</sup> countries.

- **Combined effects:** to introduce one or more MAFs in Annex 1.  
Along with the concerns raised by Eurometaux, the EPMF wants to emphasize the need to have an approach suitable to the precious metals. The current proposal is not considering metals specificities. This will have an impact on precious metals business and the benefits for the environmental protection are not yet very clear. An important step to circumvent this is to favour a refined (modelled or monitoring based) combined exposure to a default MAF approach.



- **Evaluation of registration dossiers and substances is too complex and insufficient:** several options are under consideration to ensure compliance and availability of necessary data to conclude on potential concerns, including the options to revoke registration number and to allow authorities to commission tests to obtain hazard information.

The EPMF agrees with the conclusion that the Evaluation of registration dossiers and substances is too complex and very often too slow. As a matter of fact, the current system rather focuses on administrative requirements blocking the update of critical dossiers (like the UVCBs) without providing any advantage of protection of human health and environment. A pragmatic approach is needed and once again the work should focus on what matters, especially in a dossier compliance or in a Substance Evaluation. It is important that these tools help to achieve the CSS/REACH objectives and do not become a tick box exercise nor a full research program in the case of Substance Evaluation. Balance and common sense are needed here. The proposal allowing authorities to assign studies is very surprising since REACH introduces the burden of proof on industry. Allowing authorities to start long and extensive test programs with little relevance to regulatory compliance (and financed by industry) is a step back. Lastly, regarding the dossiers evaluation, it is worth to consider the revocation of registration number, especially under the light of data sharing dispute or free riding of some companies vis-à-vis the joint submission or for serious incompliance of the dossiers. However, this mechanism should be used diligently and focus again on serious breaches and not on small administrative issues. In the context of the review of the testing proposal submitted by industry a particular attention to the timing is required to ensure that data gaps are filled in in due time and no delay is caused in the identification of potential concerns related to the substance.

- **Authorisation procedure is too heavy and inflexible:** heavy burden for all stakeholders which places EU-based companies at a competitive disadvantage compared to non-EU competitors, without any advantage of the risk control of SVHC.
- **Current Restriction process is too slow to protect professional users and consumers:** to extend the generic approach to other endpoints than CMR and professional users, operationalizing the concept of essential use in restrictions.

The EPMF recommends reviewing the Authorisation and Restriction procedures in a holistic manner in the context of a Risk Management procedure, which could also be extended to other legislation (like OHS). This fits with the proposal to integrate the Authorisation and Restriction processes. This could be a significant improvement in the Risk Management of chemicals if risk based. We agree that the main aim of Authorisation (risk management and substitution) could be achieved by other means. The merge of two procedures could bring some efficiency and efficacy to the system, which is currently not fulfilling its objectives as current Authorisation is not efficient enough when tackling the issue of import of articles made from SVHC. However, if the Authorisation would be maintained, it is important to change the perspective and move from a substance to a use approach. The latter is also more motivated from some aspect of the Restriction process. Coming to this process and the current proposal to increase the scope of the horizontal approach, it is important not to confuse efficiency with haste. A restriction should remain risk driven and not hazard driven and must take into account different parameters like exposure and also ensure consistency with other EU policy. Chemicals management, Circular Economy and Climate neutrality must be reviewed in a holistic way avoiding any contradiction with each other and their objectives. Another concern raised by the current proposal is the “Essential Use concept”. This concept is currently unclear and could be extremely harmful for industry and future R&D if applied within the definition set in the Montreal Protocol. Therefore, before operationalizing this concept in the Restriction procedure, first of all it is critical to understand its final objective. Secondly, to assess if this concept is the most suitable to achieve



it and lastly, to define it properly if still considered as a must in the overall Risk Management process. The EPMF supports therefore the need for the specific work commissioned by the European Commission on this concept and is willing to contribute to the reflection.

## ABOUT THE EPMF

*Since 2007, the European Precious Metals Federation has supported European companies working with gold, silver, rhenium, and the six metals referred to as the Platinum Group including platinum, palladium, osmium, rhodium, ruthenium, and iridium.*

*Our 35 Member Companies and 3 national associations include world leaders in extraction, refining, and recycling of precious metals. They also include a highly diverse range of companies involved in consumer and industrial applications that touch the lives of European citizens from jewelry to financial investments to the mobile phones in their pockets to the catalytic converters in their vehicles to the solar panels and rapid chargers at their homes.*

*As the European body for advocacy, the EPMF facilitates the interface between policy makers, regulatory authorities, and the precious metals industry on a wide range of issues.*