MEED for risk assessment and regulatory compliance, addressing the Zero Pollution Ambition and Biodiversity Goals

Background

The Green Deal is at the heart of EU Commission's strategy to implement and meet a series of Sustainable Development Goals and targets, including biodiversity as mentioned in the 2030 Agenda on Sustainable Development. Europe's climate and digital transition foreseen by the Green Deal will be founded on a shift away from fossil fuel-based energy systems towards technologies utilising higher volumes of metals and inorganics. The EU has also promised to strive for autonomy and promote its key value chains, relevant for both the manufacturing and use levels of metals/inorganics.

It is well understood by all stakeholders that metals will play a pivotal role to achieve the objectives outlined above. However, there are also concerns that the increased use of "(eco)toxic" metals as well as their circularity -linked to recycling- would ***increase metal releases and possible impacts on the environment***, potentially encouraging authorities, and markets to substitute metals by other materials. Demonstrating that the manufacturing and use of metals are safe will be crucial in the coming years to preserve access to the markets, to finance and maintain our license to operate, whilst ensuring that sufficient metals will be available to deliver on the Green Deal objectives.

More specifically, the "Zero Pollution Ambition" building-block of the Green Deal creates long-term regulatory challenges for chemicals management due to the **'hazard focus'** of some of its proposals (e.g., banning of SVHC, minimisation and restrictions of substances of concern and most harmful chemicals). To defend an alternative management model, based on the **control of risks**, we will need to demonstrate control of exposure and emissions, supported by high quality EU representative data, as well as absence of risk.

Working on exposure and risk assessment also fits in with DG ENV's statement that the ***Zero Pollution Ambition*** "*is not an absolute utopian zero but a requirement that exposures should be reduced to levels that are no longer expected to be harmful to health and the environment*" (Florika Fink-Hooijer, DG ENV).

As a pillar of the Zero Pollution Ambition, the Chemicals Strategy for Sustainability (CSS) will be implemented through revisions of key chemicals legislations like REACH and CLP bringing in new challenges like the Mixture Assessment Factor (MAF), additional effects information requirements and endpoints (including for lower tonnage substances) and revised risk management tools. All these CSS elements will challenge the **demonstration of risk control and safe use** for metals and require, besides compliant effects datasets, *good quality exposure data covering the EU and the identification of the emission sources, today and in future.*

In terms of dynamics, regulators and society expect that the overall impacts of a sector are to be addressed **collectively**, with the value chain moving away from a substance-by-substance approach as seen in REACH.

Finally, ***the cooperative programme between ECHA and the metals' sector (MISA)*** that formally ends in December 2021, identified some open action points in the REACH environmental exposure assessments of metals and inorganics to ensure they are better aligned with today's REACH requirements.

In summary, to be a credible sector to meet the Green Deal while metal volumes and uses will increase, we need to show a good understanding of today's exposures, risks, and their control. This should be complemented with a good knowledge and management of expected future emissions and/or trends ("today and tomorrow"). This requires the development of approaches and the collection of exposure data, to help demonstrate no harm to health, environment and biodiversity. This will be communicated in the relevant regulatory discussions. To ensure credibility, relevance and consistency of the gathered data, it is proposed to work collectively, to make the best use of our stretched resources.

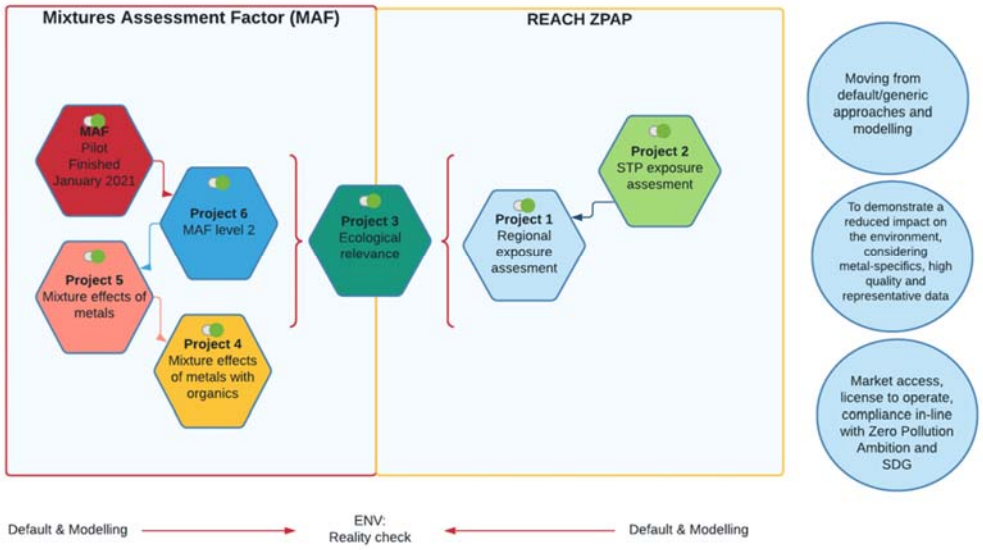
Programme

Eurometaux, in close cooperation with the consortia/commodities/associations/companies (further called 'partners'), designed a comprehensive "environmental exposure gathering programme" covering *today's and expected needs for tomorrow to comply with the Zero Pollution Ambition and biodiversity objectives*.

The programme is composed of two "data gathering packs" driven by the following regulatory concerns:

- the Mixture Assessment Factor (MAF) proposed under REACH by the CSS and,
- the Zero Pollution Action Plan /MISA/REACH pack

covering in total six projects all contributing in a stepwise and tiered way to the demonstration that metals environmental exposures are not expected to be harmful to health-and the environment.



The projects will run between 2022 and 2024 (for 3 years). The timeline has been defined to be able to feed *the deliverables in due time into regulatory debates* (e.g., REACH Revisions, MAF impact assessments and debates, Zero Pollution Action Plan activities, Water Framework Directive etc.)

The 6 projects and their aims can be summarised as following:

Project 1: regional exposure assessment

- Regional exposure sources for metals are often a large contributor in the overall emissions, hence the need to collect up-to-date regional exposure evidence in all relevant environmental compartments on a series of metals with attention for data quality and time and geographic representativity, as well as for the allocation of main contributing sources for immediate use to update the REACH registration files. In follow-up the project aims at emission characterisation and source allocation with a focus on water and air. This will allow to define a format for predictions on future regional exposure based on volume, use pattern and environmental condition changes, to promote the relevance of exposure control measures to reach the toxic-free environment status for metals in the longer run.

Project 2: STP exposure assessment

- Understanding the collective emissions from consumers and professional use by providing a better estimate of the fraction of metal emissions directed to water and sludge in Sewage Treatment Plants (STPs) and check for the contributions of these sources as estimated in the allocation assessment of the regional exposure project. A second

aim covers the concentrations of metals in STP sludge and the extent of STP sludge-containing metals used as agricultural fertilisers. National data will be collected, and the literature part of the project aims to run in 2022 with reporting by the end of 2022. A sampling exercise could be organised in follow-up if needed and be relevant in 2023. Focus will be on representativity of the data and covering a broad spectrum of metals.

Project 4: metal mixtures effects

- Provide scientific evidence to input in the discussions on the relevance of the magnitude of the MAF for naturally occurring substances, like metals and inorganics. Key questions that will be addressed: a) are the mixture effects of priority contributing inorganics (PCIs) (identified in project 6) relevant at regulatory relevant exposure levels? b) how conservative are the current PNEC values for the observed metal-mixture effects? c) can these effects be predicted based on standard mixture models? These questions will be addressed by reviewing the existing knowledge and performing a data-gap analysis, based on which an experimental design will be drafted. In the experimental phase, targeted experiments (potentially based in microcosm studies on the PCIs) will be carried out to evaluate the effects of the combination of priority contributing inorganics at regulatory relevant exposure levels, using single species and microcosm tests.

Project 5: metal – organics mixtures effects

- Evaluate if metals and organics can be considered separately and independently in mixture assessment approaches or not. Questions to be addressed: a) are mixture effects of inorganic priority contributing substances combined with organics relevant at regulatory relevant exposure levels? b) how conservative are the current PNEC values for the observed mixture effects? c) can these effects be predicted based on standard mixture models? These questions will be addressed by reviewing the existing knowledge on the mixture effects between inorganic and organic priority contributing substances (PCs) and performing a data gap analysis based on which an experimental design will be drafted to evaluate the combined effects of inorganics and organics at regulatory relevant exposure levels using microcosm tests. Unintentional mixtures will be further explored via a targeted real-world sampling campaign, looking into biodiversity effects.

Project 6: metal mixtures effects: identification or priority contributing inorganics and

- Identify the priority contributing inorganics (PCIs, e.g., 80 % RCR impact) based on their risk (combination of hazard and occurrence in the environment) and compare those with the metals identified in the priority list published by EEA. Risks will be evaluated based on monitoring data representative for natural background (minimal anthropogenic contribution) and for monitoring data on ambient regional concentrations (using the EEA Water database monitoring dataset and the GEMAS dataset). This project will also evaluate for different typical scenarios (data-rich, data-poor, …) how difficult it is to refine the RCR for metals.

Project 3: ecological relevance

- In order to check the impact on biota, we will use the evidence gathered in projects 4, 5, 6 to investigate the most impactful metals (PCIs) under EU realistic conditions (relevant species, environmental conditions) and define how the combined impact can be measured at local and regional scales in the receiving environment (e.g., emission dilution, or measured regional metals combined impact). We will develop a cost-efficient strategy and tools that help to define metals' good quality status in waters and how the lack of impact on biodiversity of metals on waters and sediments can be demonstrated through monitoring (at local and regional scale).

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