REACH revision: Eurometaux examples why the current REACH Regulation requires improvements & concrete proposals

August 2025

Introduction

Eurometaux has provided over these past months several comments/proposals aimed at improving the current REACH Regulation to further increase its efficiency and meet its objectives. These proposals require practical changes of different REACH processes (information requirements, evaluation and risk management measures). To facilitate the understanding of why such changes are needed and how they could be included in the REACH 2.0. proposal, this document suggests concrete amendments of the REACH legal text, supported by examples from the metals industry.

This document focuses on **3 key priorities**: REACH information requirements, REACH evaluation and risk management.

1. Information requirements

1.1. Information requirements for low-tonnage substances

So far, the low-volume substances (between 1-10t) must comply with REACH Annex VII, outlining a limited set of testing requirements. A draft proposal for additional testing requirements has been discussed in a dedicated CARACAL sub-group early 2025 but there is currently no clarity on the final proposal. Based on the most recent proposal discussed on **23 April 2025**, the impact on the industry would be significant whilst - depending on the conditions- providing limited added value for human health and environment.

Assuming the possibility to use a read-across approach, this increase of information requirements is estimated to cost up to 5 million euros for the precious metals industry, which has 100 registered substances, of which 35% fall in the 1-10 tonnage band. It is worth noting that a lot of the substances below 10t are often substances produced and used as intermediates in a well-controlled industrial environment. This is why our proposal is for a set of strict criteria that allow low-volume substances, for which both human health and environmental risks are well controlled, to be exempt from the additional testing requirements.

PROPOSAL:

Article [XXX] – Targeted exemption for substances currently registered under Annex VII

1. Substances manufactured or imported in quantities of 1 to 10 tonnes per year, which:
    a. Fulfil the standard information requirements set out in Annex VII of Regulation (EC) No 1907/2006 (REACH) and,

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

b. Are used exclusively in industrial settings; and
c. Are produced, handled, and disposed of in well-controlled environments with documented and effective risk management measures in place.

shall be exempted from additional testing obligations beyond Annex VII, including but not limited to:

a. Further toxicological or ecotoxicological studies
b. Chemical Safety Assessments beyond the scope of Annex VII.

2. This exemption shall not apply where:
   a. The use pattern changes to include consumer or professional uses.
   b. The operational conditions and risk management measures are not sufficient anymore to demonstrate acceptable risk.

3. Registrants claiming exemption for industrial uses shall:
   a. Submit a declaration of exclusive industrial use;
   b. Include a demonstration of effective risk management measures and operational conditions in the technical dossier associated to Annex VII;
   c. Maintain records of risk management measures and operational conditions supporting the exemption.

Justification

This amendment would reduce unnecessary regulatory burdens for substances with low exposure potential and minimal risk, while maintaining a high level of protection for human health and the environment. It supports innovation and competitiveness, particularly for SMEs, without compromising safety.

1.2. Endocrine Disruptors (ED) requirements for all tonnages

Currently, there are no specific testing requirements related to the ED endpoint despite the obligations to perform an ED assessment for each substance under the CLP Regulation. The last discussions on ED testing requirements occurred on **23 April 2025** and additional comments have been sent by NGOs, industry and Member States in May 2025.

Based on a first assessment, the first tier of testing requirements alone would cost industry around 200.000 euros per substance or group of substances if read-across can be justified. In case the *in vitro* testing is positive or unclear, the additional testing required would increase the cost further. The next tier will involve animal testing directly, undermining the animal testing reduction goals of the European Commission. Moreover, this unnecessary testing could lead to an issue of laboratory capacity, already limited. These existing limited resources should be used efficiently to identify relevant hazards/substances for relevant risk management.

The current proposal still requires discussions and refinements to ensure that the appropriate strategy and test methods are considered. For most of the industrial chemicals, already classified as reproductive toxicity Category 1A or 1B, additional ED requirements for human health would not change risk management measures to be put in place.

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

As illustrated in the table below[1], these substances are already subject to stringent risk management measures. (e.g., OEL, restriction or authorisation).

Legislation	Hazard classification	
	Repr. 1B	ED
CLP Regulation	✓	✓
REACH – Registration (TITLE II – Annex II)	✓	✓
REACH – Authorisation (TITLE VII - Annex XIV)	✓	✓
REACH – Restriction (TITLE VIII – Annex XVII)	✓	✓
Pregnant Workers Directive	✓	
Young Workers Protection Directive	✓	
Water Framework Directive	✓	✓
Ground Water Directive	✓	✓
Waste Framework Directive	✓	
General Product Safety Directive	✓	✓
Industrial Emissions Directive	✓	
Toy Safety Directive	✓	✓
Cosmetics Regulation	✓	✓
Construction Products Regulation	✓	✓
Machinery Directive	✓	
Regulation on Medical Devices	✓	✓
Regulation on In Vitro Devices	✓	✓
PPP Regulation	✓	✓
Detergents Regulation	✓	
Textile Regulation	✓	
Eco-Design Directive/ESPR	✓	✓
Mining Waste Directive	✓	
End of life vehicle (ELV) Directive	✓	
Biocidal Products Regulation (BPR)	✓	✓
Marine Environmental Policy Framework Directive	✓	✓
Water Environmental Quality Standards Directive	✓	✓
Food Contact Materials (FCM) Regulation	✓	✓
Chemical Agents Directive (CAD)	✓	✓
Prior Informed Consent (PIC) Regulation	✓	✓

[1] Table drafted using the Eurometaux Classification mapping tool: **Classification Mapping Tool - REACH Metals Gateway**.

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

PROPOSALS:

1. *Ensure proper finalisation of the ongoing technical discussions related to ED testing strategy. The information requirements and ED testing strategy should be made adaptable. Furthermore, under the one substance one assessment (OSOA) approach, the promotion of data exchange should be promoted. It should be ensured that this strategy can be reviewed after 3-5 years to refine/adapt it based on experience.*

2. *New Article – Exemption from Additional ED Testing for Severely Classified Substances:*

1. Substances that already meet the classification criteria for Category 1A or 1B Carcinogenicity, Mutagenicity, or Reproductive toxicity (CMR), or are otherwise classified under Category 1A or 1B for systemic target organ toxicity (STOT), shall be exempted from further testing requirements related to endocrine disrupting properties, provided that:

(a) The substance is self-classified as ED, or

(a) The substance is not intended for consumer use, and
(b) The exposure is adequately controlled under current use conditions, and
(c) The CMR classification is based on robust, reliable data and risk management measures are documented in the registration dossier.

2. This exemption does not apply to ED assessments, only to ED testing.

3. This exemption aims to prevent redundant testing and prioritise regulatory attention on substances where endocrine-disrupting potential has not yet been assessed.

4. The Agency may request further information if it deems there are indications that ED-related effects, despite a negative classification assessment, and that these effects are not sufficiently covered by the existing classification and risk management. This does not apply to substances with an ED self-classification.

Justification

This amendment aims to reduce unnecessary regulatory burdens for substances with minimal risk, while maintaining a high level of protection for human health and the environment. It supports innovation and competitiveness, particularly for SMEs, without compromising safety.

2. Make REACH Evaluation more proportionate

The substance evaluation ('SEv') process under REACH is an important regulatory tool to address concerns and to clarify whether and to what extent a substance poses a risk to human health or the environment.

However, recent experience with the implementation of REACH shows that when used disproportionately, the substance evaluation requires significant time and resources from ECHA, the Member States and industry, without bringing tangible benefits.

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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

ZnO Substance Evaluation: where the absence of an identified risk, disproportionate proposed requirements, lack of socio-economic considerations and concerns over animal welfare threaten a key industrial sector for Europe. (See Annex 1 for full example)

Key learnings

Industry fully supports the Commission's recommendations that are in line with the desired simplification and modernisation of REACH. ZnO SEv is a clear example however, where the over-regulation, the legal uncertainty as well as excessive demands for testing, result in a high level of disproportionality which serves no EU policy or regulatory objectives.

The lessons learnt from the REACH implementation should trigger an immediate shift in the way the evaluation dossiers are treated. This is of paramount importance, especially in the case of ZnO, whose critical applications are enabling innovation in strategic downstream user industries in Europe. The ZnO case is a perfect opportunity for the Commission, ECHA as well as the EU Member States to reflect on the challenges that we all face and adjust to information requests that are proportionate and reflect the realities that the EU is facing now whilst also ensuring protection of human health and the environment.

PROPOSAL:

Proposed amendments to the REACH Regulation (EC) No 1907/2006 targeting evaluation provisions. Each amendment is presented in a side-by-side format, with the current text shown on the left and the proposed amended text on the right in bold.

Section TITLE VI EVALUATION (p. 121 onwards)

Chapter 2: Substance evaluation

Article 44 – Substance Evaluation

Current Text	Proposed Amendment
Article 44(1–2) Criteria for substance evaluation	Article 44(1–2) + Add new point: **3) Substance Evaluation decisions shall: (a) be based on evidence of a plausible risk to human health or the environment; (b) apply the principles of proportionality to ensure measures are no more burdensome than necessary; (c) include a brief socio-economic assessment; (d) if requiring vertebrate testing, explicitly document compliance with Article 25(1); (e) ensure that information requests are limited to clarifying specific concerns and are not used as a general research**

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

	programme, including for nanoforms, unless conditions demonstrating a plausible risk are explicitly met.

Other sections:

TITLE III DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

Article 25 – Testing on vertebrate animals

Current Text	Proposed Amendment
Article 25(1) "*In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.*"	Article 25(1) "*In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.*" + Add new points: **(1a) Before requiring any test on vertebrate animals, the Agency or the competent authority shall:** **(a) document the existence of a plausible risk to human health or the environment;** **(b) demonstrate that all relevant and validated alternative methods have been considered and found insufficient;** **(c) apply the principles of replacement, reduction and refinement;** **(d) consider socio-economic implications of the requirement, including cost, feasibility, and availability of lower-tier data.**

Annex XI – General rules for adaptation of the standard testing regime set out in Annexes VII to X (p371 onwards)

Current Text	Proposed Amendment

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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

Annex XI currently covers rules for adaptations from standard testing requirements (weight-of-evidence, QSAR, grouping, etc.).	Add new point: **1.6 Risk and proportionality considerations.** **Testing proposals and information requests shall take into account the level of risk identified, the proportionality of the measure in regards with the tangible regulatory benefit, and the availability of socio-economic information relevant to the decision.**

Recitals

Current Text	Proposed Amendment
Recital 37 *"If tests are performed, they should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[1], and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of*	**Recital 37 (in addition to the *existing* wording on animal testing)** **"Where vertebrate animal testing is proposed, all relevant alternative methods must be considered, and the principles of replacement, reduction, and refinement shall be applied. In accordance with Article 25, testing on vertebrate animals should be undertaken only as a last resort."** **Recital 37a (risk-based evaluation)** **"Additional information requests under REACH should only be made where there is a documented and plausible risk to human health or the environment. Requests must be proportionate to the risk and justified by specific concerns regarding the substance."**

[1] OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of the European Parliament and of the Council (OJ L 230, 16.9.2003, p. 32).

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

their application for tests on chemical substances[1]."	**Recital 37b (proportionality, socio-economic factors)** **"Evaluation decisions should be based on proportionality, considering the expected regulatory benefit, technical feasibility, socio-economic implications, and potential impact on innovation."** **Recital 37c (prohibition on using SEv as a research programme)** **"Substance evaluation is a targeted process aimed at addressing specific concerns about a substance. It shall not be used as a general research programme, including to gather information on nanoforms, unless justified by documented risks to human health or the environment."**

3. Improve the Risk Management system

This paragraph will give examples to help better understand the needed changes and some proposals to improve the current system.

During the past 20 years, the metals industry has been through different risk management processes with different levels of efficiency and drawbacks. Please find here below some examples (fully detailed in Annex 1):

EU Nickel regulatory actions – most significant events

Key learnings

Regulation of several economically important nickel inorganic compounds started after the implementation of REACH and CLP in 2010, driven by CMR properties identified under CLP. Because of their hazard, these substances are only used in industrial settings. The use of the Risk Management Options Analysis (RMOA) in the first instance by the French authorities have prevented unnecessary efforts from regulators, industry and Member States, by identifying the most suitable risk management measures (RMMs) for the scope of the risk to be managed (i.e., workplace) by 2014. This process was very efficient and done in good collaboration between the different stakeholders. However, some improvements are needed in the follow-up actions, since

[1] OJ L 50, 20.2.2004, p. 44.

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

the EU Occupational Exposure Limit (OEL) discussions started in 2017. When a Risk Management Option (RMO) is identified, it must be implemented without undue delay.

EU Cobalt regulatory actions – most significant events

Key learnings

The use of RMOA in the first instance would have prevented 10 – 15 years of effort from regulators, industry and Member States, by implementing the RMM most suitable for the scope of the risk to be managed (i.e., in the workplace).

Regulation of several economically important cobalt substances started after the implementation of REACH and CLP in 2009, driven by CMR hazard classifications. Multiple regulatory risk management measures (e.g., Authorisation, Restriction) were proposed and ultimately dismissed. Measures taken under REACH to regulate substance uses ultimately failed either because the scope of the measure did not match the uses, and the measure was not proportionate nor efficient. Eventually in 2022, risk management was started under workplace legislation, covering relevant cobalt compounds that met the criteria under the CMRD. Eventually in 2022 a regulatory action was started under workplace legislation, covering all relevant compounds.

EU Lithium regulatory actions – most significant events

Key learnings

In 2021, ECHA's Risk Assessment Committee proposed to classify three lithium salts as toxic for reproduction Category 1A. The discussion on the resulting Adaptation to Technical Progress (ATP) entries is ongoing. This case illustrates that regulatory uncertainty hampers investment, with an impact on EU's competitiveness but also that a clear regulatory roadmap may identify efficient regulatory measures where needed.

The possible classification of lithium salts, despite scientific doubts and disagreement of international partners, has created significant regulatory uncertainty. This ambiguity makes it difficult for industry to plan and invest in EU-based lithium mining, refining, and recycling operations, a key target of the Critical Raw Materials Act. This might lead to the postponement or relocation of major projects outside of Europe.

As regulatory hurdles increase, the EU risks losing vital investments in the battery materials sector to other regions, undermining its ambitions for a robust, self-sufficient battery value chain. Instead of attracting industrial activity and supporting the green transition, these uncertainties push key players to invest elsewhere, which threatens job creation, technological leadership, and strategic autonomy.

The case illustrates the importance of a clear, politically validated regulatory roadmap. By conducting a thorough risk management option analysis (RMOA) upfront, policymakers and stakeholders can identify effective regulatory tools, balance policy objectives, and provide certainty for long-term investment decisions. Such an approach would help distinguish between uses that require strict control and those that can be safely managed through existing legislation, reducing unnecessary barriers and supporting both worker safety and industrial competitiveness.

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

EU Lead regulatory actions – most significant events

Key learnings

Significant effort was expended by ECHA, its Member States Committee (MSC), the Commission, and industry prior to the ECHA recommendation to include lead metal in the REACH Authorisation List. Commission and industry's work continued long after the recommendation while the former considered whether to add lead to REACH Annex XIV.

Lead was prioritised because of its high use volume in the EU, its classification as a Category 1A reprotoxic substance, and its range of applications. An upfront assessment of what specific risk(s) were to be targeted would have been more efficient and effective than proposing a REACH Authorisation listing based on the current priority scoring system, a hazard-based approach which uses tonnage as a surrogate for exposure.

More than 30 pieces of lead-specific legislation were – and are – already in place in the EU, a legislative framework enacted to control risks from exposure to lead. Upfront consideration of the benefit of strengthening that existing framework to deliver improved risk management should have been carried out in consultation with industry, prior to the ECHA recommendation process.

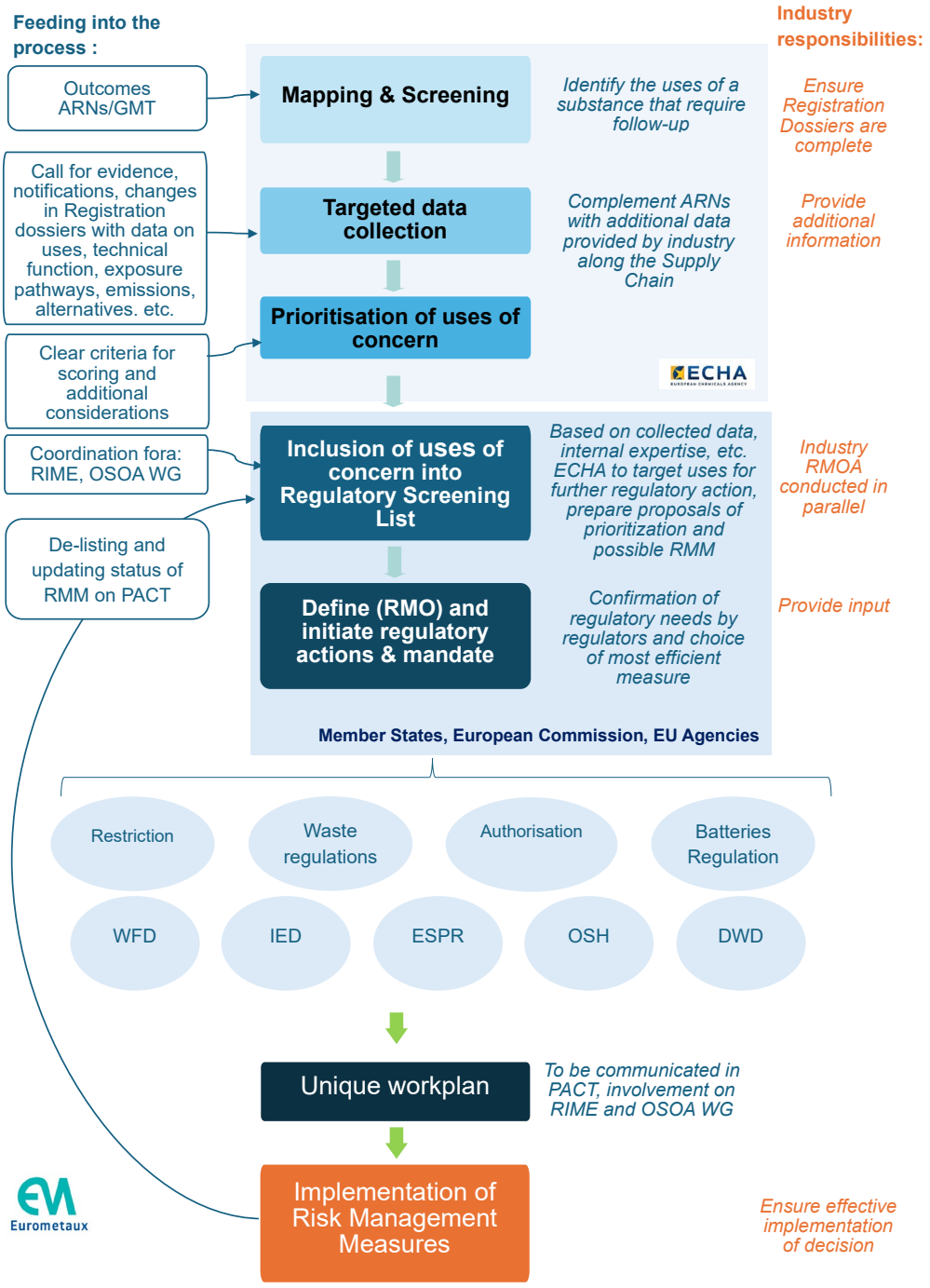
Most of the lead used in the EU is used in specialised battery production; almost all other uses also take place in highly regulated industrial settings. As such, it is unlikely that Authorisation listing would have substantially or proportionately improved protection of human health or the environment. Industry carried out an RMOA-type exercise as part of its preparations for the consultation period. The exercise concluded that exposure and emissions could be reduced more effectively via e.g., a review of the existing workplace exposure limits and targeted restrictions than via REACH Authorisation listing. An upfront RMOA, carried out before the ECHA recommendation processes were started, would have concluded that Authorisation listing would not be the most effective or proportionate measure.

The number of potential Applications for Authorisation, if lead metal were added to REACH Annex XIV, was of concern to both industry and authorities. Industry considered Authorisation listing a disproportionate measure that could lead to a significant backlog in the processing of Authorisation applications and other activities under the remit of the ECHA committees, Commission and its REACH Committee.

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

PROPOSALS

OSOA



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

This can be translated into the following amendments to the REACH Regulation:

1. *Add Title VII – Identification of the best Risk Management Option*

N.B.: Current title VII (Authorisation) and title VIII (Restriction) can be kept with some amendments to reflect the inclusion of the new Title VII.

Article XX1 – Mapping and Screening of substances uses

1. ECHA shall, in cooperation with Member States, perform systematic mapping and screening of substances registered under this Regulation to identify specific uses requiring further regulatory follow-up.
2. Mapping can be based on:
    a. Outcomes from Assessment of Regulatory Needs (ARNs) and Grouping of Substances (GMTs);
    b. Information submitted in REACH registration dossiers. Registrants shall ensure that all relevant registration dossiers are kept complete and up to date for this purpose.

Article XX2 – Targeted data collection

1. Where mapping identifies data gaps for specific uses, ECHA may require targeted data collection, including additional information regarding uses, technical function, exposure pathways, emissions, and available alternatives
2. Registrants and downstream users shall provide requested information within 6 months after the formal request received from ECHA.
3. ECHA can launch a Call for Evidence in parallel (6 months deadline)

Article XX3 – Prioritisation of Uses of Concern

1. ECHA, with the support of MSC, and applying clear and transparent scoring criteria, shall prioritise identified uses of concern for further regulatory consideration within 12 months after closure of the data collection.
2. Scoring criteria must consider exposure potential during the entire lifecycle in addition to the hazard and volume of the substance used in the identified use of concern and availability of suitable alternatives.
3. For uses of metals and inorganics, prioritisation shall take into account natural occurrence, essentiality, co-occurrence, recyclability, and value chain interdependencies.
4. Priority lists shall be published in the Public Activities Coordination Tool (PACT) as soon as ECHA prioritisation is finalised and no later than 1 month after.

Article XX4 – Inclusion into the Regulatory Screening List

1. Uses prioritised under Article XX3 shall be included in the Regulatory Screening List for consideration of regulatory Risk Management Options (RMOs)
2. Based on previous assessment and collected data, ECHA, with the support of RiME (Risk Management Experts) will prepare on a yearly basis a proposal to update the Unique Workplan including 10 uses and possible Risk Management Options, using the same model as the CoRAP.

Article XX5 – Definition of Risk Management Options

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

1. For each use included in the Regulatory Screening List, ECHA with the support of RiME, shall propose the relevant RMOs, indicating:
    a. The regulatory instrument(s) to be used -including but not restricted to Authorisation- under Title XXX, Restriction under Title XXX, waste legislation, occupational health measures, IED etc.
    b. The rationale for selection, based on efficiency, effectiveness, consistency with other regulations as outlined in the ECHA RMOA guidance.
2. The European Commission, in consultation with Member States, shall confirm the RMO and mandate the appropriate follow-up action.
3. ECHA shall maintain a Unique Workplan consolidating all confirmed RMOs and mandates
4. The Unique Workplan shall be updated on a yearly and published in PACT and communicated to relevant fora.

Article XX6 – Implementation of Risk Management Measures

4. Risk Management Measures (RMMs) mandated under Article XX5 shall be implemented in accordance with applicable Union legislation, including but not limited to:

4.1. (Former) REACH Titles VII and VIII;

4.2. Water Framework Directive (WFD), Industrial Emissions Directive (IED), Ecodesign for Sustainable Products Regulation (ESPR), Occupational Safety and Health (OSH) legislation, Drinking Water Directive (DWD), and Batteries Regulation

5. Registrants and other duty holders shall ensure effective implementation of the adopted measures within the prescribed deadlines.

Title VIII: Authorisation

Current Text	Proposed amendment
Article 56 – General provisions	**Remove all references to Articles 57-59** Add scope and objectives: 1. The purpose of the authorisation process under Title VIII shall be limited to specific cases not addressed by restrictions under Title IX, with the objective of facilitating substitution where, by example, the use prioritised under Article XX3 of a substance is in the process of being substituted but requires additional time for completion. 2. Authorisation shall not be used where other regulatory risk management measures under Union legislation are sufficient to address the identified risks. 3. The length and complexity of the authorisation decision-making processes shall be reduced

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

	through streamlined dossier assessment and decision steps. Keep the exemptions of Articles 56.4, 56. 5 and 56.6
Article 57 – Substances to be included in Annex XIV	**Delete**
Article 58 – Inclusion of substances in Annex XIV	**Delete**
Article 59 – Identification of substances referred to in Article 57	**Delete**
Article 60 – Granting of authorisations	11. Add Art. 60.11: The Commission shall establish a fast-track procedure for emergency cases where delay would cause significant economic, environmental, or safety impacts.

Title IX: Restriction

Current Text	Proposed amendment
Article 69 – Preparation of a proposal	**1.** Restrictions shall be targeted to uses presenting an unacceptable risk to human health or the environment in the European Union, based on best available scientific evidence including hazard, exposure, and risk data. **2.** Generic/grouped restrictions shall be avoided unless all uses present a demonstrated unacceptable risk. **3.** Restrictions shall be designed to cover the full lifecycle of the substance and ensure coherence with other European Union objectives on circularity, climate change mitigation, chemicals management, and critical raw materials availability. Risk management measures shall avoid regrettable outcomes where chemicals controls undermine Union climate or circularity targets. **4.** Generic Approach to Risk Management (GRA) should only be used to tackle uses of concern in a fast manner focusing on consumer uses only. Grouping decisions shall be supported by

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

	scientifically validated evidence, including but not limited to release tests and lifecycle emission estimates.

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

Annex 1: Fully detailed examples

***ZnO Substance Evaluation (SEv)**: where the absence of an identified risk, disproportionate proposed requirements, lack of socio-economic considerations and concerns over animal welfare threaten a key industrial sector for Europe.*

The current issues related to the evaluation process under REACH have been already identified in the context of the REACH evaluation. They are also reflecting the challenges and concerns related to the ZnO SEv case. It has been acknowledged that the costs associated with the dossier and substance evaluation are disproportionate, that "the formal evaluation processes cannot be the main data-gap filling solution" and that an effort needs to be made to speed up the processes by improving choices about whether to initiate dossier evaluation or substance evaluation; whether to run substance evaluation and compliance checks in parallel etc ".

Background on the ZnO SEv case:

The registrants of zinc oxide ('ZnO') have spent over €4million on tests required by a SEv decision regarding nanoforms of ZnO, adopted in 2019 (evaluating Member State: Germany). That SEv decision was largely focussed on challenging a hypothesis in the registration dossier that the properties of all zinc compounds can be predicted (in a precautionary/protective way) based on the properties of the zinc-ion. The results of the requested studies confirmed this so-called ion-only hypothesis.

However, a follow-up SEv draft decision ('DD') was notified to the ZnO registrants in February 2024. The DD requests **additional testing** (endpoints reprotoxicity/cardiotoxicity), for the most part to further examine the ion-only hypothesis with particular focus on nanoforms. This is both **unnecessary and disproportionate**. The tests requested would cost at least a further €18 million and involve the sacrifice of ca. 10,000 animals in total. The market for ZnO nanoforms in Europe is less than 1,000 tons (<0.3% of ZnO market). Complying with the DD will therefore simply destroy the market for innovative ZnO nanoforms.

The threat of such a level of costs, as implied by the DD, has already resulted in a significant number of registrants ceasing to manufacture or import ZnO nanoforms.

As a 'domino effect ', in line with the "one substance one registration" (OSOR) principle, non-compliance with the DD on ZnO nanoforms will also lead to the dossiers of registrants of all ZnO forms being considered non-compliant. This results in an existential threat that ZnO will no longer be manufactured in, or imported into, the EU at all. This would have massive negative consequences for EU industry, critical uses and the health of the EU population, as well as a loss of jobs and the generation of wealth in the EU. The ZnO SEv case clearly illustrates the knock-on problems that can arise when decisions require tests on a specific form (or forms) that is (are) part of a wider OSOR registration. OSOR makes sense conceptually but more complex scenarios such as those arising with ZnO were not contemplated/addressed.

Key considerations on the ZnO SEv case, demonstrating the current issues related to the evaluation process under REACH:

1. Principles of Proportionality

The Principles of Proportionality are not met by the Draft Decision (DD). Some important considerations:

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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

- No evidence of a potential concern for reproductive toxicity or cardiotoxicity
- The specific nanoforms to be tested according to the DD would not provide meaningful information on toxicity.
- ECHA fails to demonstrate and establish that the ion-only hypothesis is flawed. The onus of that was on ECHA, it is therefore not appropriate to ask for additional information
- If at all needed, alternative approaches do exist yet have not been adequately considered

2. Animal Welfare inadequately considered

- DD does not explain whether, and if so how, alternatives to animal testing have been considered and rejected
- DD is failing on the requirement to use the option where the minimum number of animals are sacrificed
- The proposed testing would sacrifice as many as 10,000 animals unnecessarily

The DD is the polar opposite to the position paper released by the German Federal Institute for Occupational Safety and Health (BAuA) (March 2025)[1]– that even specifically mentions ZnO. BAuA – as the evaluating Member State for ZnO SEv emphasises the need for new approach methodologies (NAMs) to reduce animal testing and enhance evaluation efficiency, yet the ZnO DD content is completely inconsistent with BAuA's public-facing pronouncements.

Absence of risk is not considered- the 3-part necessity test established by the ECHA Board of Appeal ('BoA'), and confirmed by the EU Court, requires that a potential risk needs to be demonstrated, and that this potential risk needs to be clarified by requesting additional information on the hazard and/or exposure concerned. A risk requires exposure to a harmful substance. In this case, there is no inhalation exposure to the nanoforms of ZnO. Workplace uses are all fully automated and strict risk management measures are applied, meaning that there is no worker exposure via the inhalation route. Furthermore, the uses of the substance mean there is no possibility for consumers to inhale ZnO nanoforms. Therefore, the risk by inhalation is negligible. Tests by the inhalation route should therefore not be required to address what is in reality a purely theoretical risk.

A SEv decision cannot be used for research - BoA case law has confirmed that information requests pursuant to a SEv decision cannot be used as, in effect, a research programme. Whilst information on the effects of nanoforms [generally] on reproductive toxicity is limited, a SEv decision is not the appropriate instrument to collect information on nanoforms generally. Certain conditions must be met before information can be requested pursuant to a SEv decision. These conditions have absolutely not been met in this case.

Perspective of German Authorities and the European Commission:

The German Federal Institute for Occupational Safety and Health (BAuA) **shed light on** the inefficiencies and lack of clarity in nanoform evaluations in its March 2025 report. The German report acknowledges widespread scientific and legal uncertainty in defining when nanoforms are 'sufficiently similar' to justify grouping. This directly mirrors the ZnO registrants' concerns that the selected test forms, that are chosen based on parameters like dustiness or coatings, do not meaningfully contribute to understanding ZnO's overall

[1] BAuA, 25 March 2025– "Assessment of the enforceability of the rules for nanomaterials in REACH – review five years after entry into force"; prepared for 54th Meeting of Competent Authorities for REACH and CLP

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toxicology. BAuA's assessment also stresses the need to streamline decision-making between dossier and substance evaluations, avoid redundant parallel processes, and improve procedural efficiency, all of which directly impact how ZnO and other nanoforms are currently handled under REACH. In addition, the German paper recognises the growing momentum for new approach methodologies (NAMs) to reduce animal testing and enhance evaluation efficiency.

The European Commission has concluded in the REACH evaluation report[1] that "further modifications to the existing procedures could be considered to improve the level of efficiency and effectiveness".

Conclusion:

Industry fully support Commission's recommendations that are in line with the desired simplification and modernisation of REACH. ZnO SEv is a clear example however, where the over-regulation, the legal uncertainty as well as excessive demands for testing, result in a high level of disproportionality which serves no EU policy or regulatory objectives.

The lessons learnt from the REACH implementation should trigger an immediate shift in the way the evaluation dossiers are treated. This is of paramount importance, especially in the case of ZnO, whose critical applications are enabling innovation in strategic downstream user industries in Europe. The ZnO case is a perfect opportunity for the Commission, ECHA as well as the EU Member States to reflect on these existing challenges and adjust to information requests that are proportionate and reflect the realities that the EU is currently facing, whilst also ensuring protection of human health and the environment.

EU Nickel (Ni) regulatory actions

Summary of risk management measures

Measure	Scope	Date(s)	Status	Comments
CLP CLH	138 Ni substances, Ni metal	2009-10 (ATP01)	Adopted	Comprises Ni metal and Ni compounds, with some of them not placed on the EU market
REACH Authorisation	Assessment of $NiSO_4$ and NiO, representing 8 Ni compounds	2011-2014	Concluded	The implementation of Occupational Exposure Limits (OELs) for Ni compounds was seen as most adequate risk management option
REACH Restriction	Ni compounds	February 2012	Adopted	138 Ni compounds including 115 Ni compounds not placed on the EU market, no consumer use

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2018:58:FIN

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	Ni metal	October 2013	Adopted	Ni metal listed as Entry 27 in Annex XVII of REACH Regulation
CLP CLH	Ni Metal	2009-10 (ATP01)	Adopted	As part of same ATP as Ni compounds
OSH EU-OEL	Ni metal and Ni compounds	2018 (RAC opinion) 2022-2025 + transitional period for industry	Adopted	OELs for Ni metal under Chemicals Agents Directive (CAD); for Ni compounds under Carcinogens, Mutagens, Repro Directive (CMRD)

Background

Nickel metal and its compounds are substances with strategic and critical importance for the future of the EU, as noted in the EU Critical Raw Materials Act[1]. Nickel metal and nickel compounds are used in alloys such as stainless steel, EV batteries, catalysts, surface finishing and foundries. According to recent market data[2], stainless steel is the predominant use with 70% market coverage, followed by the use of nickel in batteries with 16%. In alloys as well as in plating, nickel is exclusively used and occurring in its metallic form.

Nickel compounds have harmonised CMR hazardous classifications under the EU CLP regulation. Nickel compounds are only used in industrial and professional working environments. And if risks were to occur, they are exclusively limited either in the production process of the substances, at the workplace where nickel compounds are processed or at the end of life when nickel and nickel compounds containing articles such as e.g., catalyst or EV batteries are recycled.

Nickel compounds harmonised classification

In total 138 nickel compounds were included in the 1st ATP (Adaptation to Technical Progress) to the EU CLP Regulation, which was published on 29 September 2009, and entered into force on 1 December 2010. There are different hazard classifications applying for nickel compounds. For those nickel compounds registered under the EU REACH regulation, an overview is provided in a table published by the Nickel Consortia.[3]

Various hazard classifications apply. All nickel compounds are classified as Carc. Cat.1. They therefore qualify as "substance of very high concern". The nickel compounds covered in the 1st ATP to EU CLP are:

- Nickel oxides (monoxide, oxide, bunsenite, dioxide, trioxide)
- Nickel sulfides (nickel (II) sulfide, sulfide, millerite, disulfide, subsulfide, hazelwoodite)
- Nickel hydroxides (hydroxide, dihydroxide)
- Nickel sulfate

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L_202401252

[2] SMR End use report. 2025. SMR Consulting, Austria.

[3] https://www.nickelconsortia.eu/assets/files/consortia/Classification/210603-Classification%20summary%20table-%20FINAL-REVISED.pdf

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- Nickel carbonates (basic carbonate, carbonic acid, and others)

There are >120 inorganic and organic nickel compounds which are however not placed on the EU market

REACH Authorisation

Since 2009, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) assessed nickel compounds in the context of the EU RECH regulation. In 2011, ANSES officially proposed 8 nickel compounds for Substances of Very High Concern (SVHC) identification. A risk management option analysis (RMOA) was conducted based on two compounds that were seen to be representative as covering main uses of nickel salts (nickel sulphate and nickel oxide). Different aspects were considered such as e.g., Authorisation, Restrictions, or measures at the workplace to protect workers.

Main conclusion was that the risks identified can be managed efficiently by implementing occupational exposure limits (OELs). An Authorisation was seen as disproportionate. The process to derive and implement OELs was started after the RMOA was concluded.

REACH Restriction

Following the addition of nickel compounds to the 1st ATP to the EU CLP Regulation, all 138 nickel compounds were added to Annex XVII of the EU REACH Regulation as published in February 2012 and entering into force on March 2013[1]. It must be noted that only 23 out of those 138 are registered under the EU REACH regulation. Also, nickel compounds are mainly used as intermediates and there is no identified consumer use. The impact of those restrictions is therefore negligible.

For nickel metal, restrictions exist related to its hazard property as a skin sensitiser. Nickel metal was added to Annex XVII of the EU REACH Regulation in October 2013 as Entry 27. It replaced the existing Directive 94/27/EU ("Nickel Directive")[2] defining maximum releases for nickel from articles that come into prolonged and direct skin contact.

Nickel metal harmonised classification

The harmonised classification for nickel metal under the EU's CLP Regulation was published in the EU Official Journal on 10th August 2009 as part of the 1st Adaptation to Technical Progress (ATP) and entered into force on 1st July 2009.

This update classified nickel metal as:

- Skin sensitisation Cat. 1
- STOT RE Cat. 1
- Carcinogenicity C Cat. 2
- Hazardous to aquatic environment (powder form only): Chronic 3

[1] OJ L37/1, 10.02.2012: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:037:0001:0049:en:PDF

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31994L0027

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EU wide OELs

Due to the varying hazard profiles of nickel metal and nickel compounds, the substances are covered under different EU regulatory frameworks. Nickel metal fall into the scope of the Chemicals Agents Directive (CAD) while nickel compounds are covered under the Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD).

The OELs for nickel metal and nickel compounds were discussed by the Scientific Committee on Occupational Exposure Limits (SCOEL) before being further assessed by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). The final discussion took place in the Working Party Chemicals of DG Employment with experts from governments, civil society and industry. The OELs were incorporated into the revision proposals for the above-mentioned directives.

This was implemented under the Carcinogens, Mutagens and Reprotoxic Substances Directive (2004/37/EC). The values proposed are 0.01mg Ni/m³ (respirable fraction) and 0.05mg Ni/m^3 (inhalable fraction) with a transition period to apply until 18th January 2025.

Conclusions

The regulation of several economically important nickel inorganic compounds started after the implementation of REACH and CLP in 2010, driven by CMR properties identified under CLP. Because of their hazard, these substances are only used in industrial settings. The use of RMOA in the first instance by the French authorities has prevented unnecessary efforts from regulators, industry and Member States, by identifying the risk management measures most suitable for the scope of the risk to be managed (i.e., workplace) by 2014.

This process was very efficient and done in good collaboration between the different stakeholders. However, some improvements are needed in the follow-up actions, since the EU OEL discussions only started in 2017-2018 due to resources issues. When a RMO is identified, it must be implemented without undue delay.

EU Cobalt regulatory actions

Summary of risk management measures

Measure	Scope	Date(s)	Status	Comments
CLP ATP01	Cobalt metal and 7 cobalt compounds	2009/2010	In force	Cobalt metal and 7 cobalt compounds had pre-existing classifications under the EU Dangerous Substances Directive (DSD) translated into EU CLP.

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REACH SVHC listing and inclusion on candidate list	5 cobalt compounds / 'The 5 cobalt salts'[1]	2010	In force	The 5 cobalt compounds with CMR classifications were given SVHC listing by ECHA and placed on the candidate list for Authorisation
REACH Authorisation	5 cobalt compounds / 'The 5 cobalt salts'	2010-2012	Terminated	Not effective as majority of uses are intermediate (out of scope). Only these 5 cobalt compounds were in included.
REACH Restriction	5 cobalt compounds / 'The 5 cobalt salts'	2018-2022	Terminated	Not proportionate. Only covered these 5 cobalt substances.
CLP CLH	Cobalt metal	2020-2021 (ATP14)	In force	Addition of CMR classifications to existing harmonised classification. Unintended consequences for mixtures (e.g., alloys)
CLP CLH	8 Co compounds	2025+	In progress	Legal testing proposal data may not be available before harmonised classification discussions are started.
OSH EU-wide BOELVs (CMRD)	Cobalt Metal and Co compounds meeting the criteria under CMRD	2022 -	In progress	Cobalt substances meeting the criteria under the CMRD; focus on workplace

Background

As an EU and NATO Critical and Strategic Raw Material, cobalt is vital to Europe's shared priorities: security, circular economy, energy transition, and strategic autonomy.

Cobalt metal and cobalt compounds have critical/essential functions in batteries (e.g., electric vehicles, portable batteries, etc.), alloys (e.g., for defence and aerospace), hard metals (e.g., tools, construction), catalysts (e.g., for the petrochemical industry), tyres, pigments, and many others. Cobalt in the form of vitamin B12 and inorganic cobalt are essential to life (i.e., humans, plants, animals). The cobalt industry has spent over €30 million EUR to generate data under REACH for hazard and risk assessment of cobalt and cobalt compounds.

[1] Cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt diacetate, cobalt carbonate

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Certain cobalt substances have been classified for hazards such as carcinogenicity and sensitisation. Six cobalt substances have legally harmonised CMR classifications under EU CLP, with the main exposure risk to humans existing in the workplace (industrial / professional).

Multiple risk management measures have been proposed in the EU over the last 15 – 20 years, however only one (i.e., EU-wide BOELVs) was identified to address the exposure risk and as a proportionate measure. This measure is still going through EU Parliament and Council approval.

Details on the regulatory actions and risk management options proposed for cobalt and certain cobalt compounds are summarised below.

Harmonised classification under EU CLP

There were several cobalt substances that had existing classifications translated and included in the 1st ATP to the EU CLP Regulation, which was published on 29 September 2009, and entered into force on 1 December 2010.

Substances of Very High Concern (SVHC) Listing

Of the cobalt substances with classifications translated under EU CLP, five cobalt compounds (listed below i.e., 'The 5 cobalt salts') were nominated for inclusion as 'substances of very high concern' due to their CMR classifications and subsequently placed on the candidate list for Authorisation in 2010:

- Cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate, cobalt diacetate

REACH Authorisation

The 5 cobalt salts were recommended for inclusion in the Authorisation List (Annex XIV – 3rd recommendation) in 2011. The majority (i.e. over 70%) of the uses of these substances are as intermediates, therefore falling outside of the scope of Authorisation. The substances have not been included in Annex XIV.

REACH Restriction

The same five cobalt compounds ('The 5 cobalt salts') were then proposed for Restriction under the EU REACH Regulation by the European Chemicals Agency (ECHA) in December 2018.

These substances were targeted due to their classification as Category 1B carcinogens. The proposal aimed to limit their manufacture, market placement, and use in industrial and professional applications unless strict exposure controls were met, including an extremely low reference exposure value (a value similar to an OELV) of 0.01 µg Co/m³. The Committee for Risk Assessment (RAC) adopted its opinion by February 2020, concluding that the restriction was justified from a health risk perspective. However, the Committee for Socio-Economic Analysis (SEAC) found that the proposed restriction was not the most appropriate EU-wide measure in terms of socio-economic proportionality. Ultimately, the European Commission terminated the restriction process on 8 April 2022, opting instead to pursue EU-wide binding occupational exposure limit values (BOELVs) under worker protection legislation.

Cobalt metal harmonised classification

The harmonised classification for cobalt metal under the EU's CLP Regulation was published in the EU Official Journal on 18 February 2020 as part of the 14th Adaptation to Technical Progress (ATP). The classification

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entered into force on 9 March 2020 and became applicable from 1 October 2021. This updated the existing classifications for cobalt metal with the following classifications:

- Carcinogen Category 1B (H350) – via all exposure routes
- Reproductive Toxicant Category 1B (H360F)
- Mutagen Category 2 (H341)

Due to the legal wording of the CLP Regulation regarding 'conclusive evidence from other routes of exposure' the classification for carcinogenicity could not be limited to the inhalation route (the only route in which data exist). This was thought to be a precedent setting case under CLP and led to both the cobalt and nickel industries funding an oral carcinogenicity study programme due to the disproportionate impact of this classification on metal alloys. This programme was formally approved via a legal testing proposal under EU REACH.

Cobalt and inorganic cobalt compounds EU-wide binding OELs under the CMRD

These will be implemented under the Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD; 2004/37/EC).

Key milestones:

- November 2022: ECHA's Committee for Risk Assessment (RAC) adopted its scientific opinion recommending very low OELs:
    - 1 µg/m³ (inhalable fraction) and 0.5 µg/m³ (respirable fraction)
- September 2023: The Advisory Committee for Safety and Health at Work (ACSH) adopted the opinion proposed by its Working Party Chemicals (WPC) on cobalt and inorganic cobalt compounds. The ACSH proposed the following:
    - Interim BOELVs of 20 µg/m³ (inhalable fraction) and 4.2 µg/m³ (respirable fraction) for 6 years after the regulation comes into force. After 6 years in force, BOELVs of 10 µg/m³ (inhalable fraction) and 4 µg/m³ (respirable fraction) will apply for a further 7 years. After 13 years in force, a review is to be conducted as to if the respirable fraction BOELV should be revised.
- July 2025: The EU Commission released its OEL proposal for cobalt and inorganic cobalt compounds. The Commission proposed the following:
    - Interim BOELVs of 20 µg/m³ (inhalable fraction) and 4.2 µg/m³ (respirable fraction) for 6 years after the regulation comes into force. After this 6-year transition period, BOELVs of 10 µg/m³ (inhalable fraction) and 4 µg/m³ (respirable fraction) will apply.
- September 2025 and onwards: Discussion and agreement on the EU-wide BOELVs for cobalt and inorganic cobalt compounds in the EU Council and EU Parliament.

Industry supports the proposed 20 µg Co/m³ (inhalable) limit value and additionally supports the introduction of a 4.2 µg Co/m³ (respirable) limit value, as these protect workers, whilst ensuring that current and future jobs remain in Europe. Scientific data confirms safety at these levels. These levels enable Europe's cobalt industry

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to continue operating, investing, and growing – supporting job retention, attracting industrial investment, ensuring defence readiness, and strengthening Europe's competitiveness in global markets. In contrast, the 10 µg/m³ (inhalable) and 2.5 µg/m³ (respirable) limits – even with a six-year transition – would cause widespread site closures, job losses, and increased import reliance. There has been no socio-economic assessment of this transition, and the values are not economically viable for many key industries. This will ultimately undermine Europe's competitiveness, investment in growth, and its long-term strategic goals. The most likely outcome is jobs moving out of Europe, yet without additional benefit for workers' health.

EU Lithium regulatory actions

Summary of risk management measures

Measure	Scope	Date(s) of legislation	Status	Comments
CLP CLH	Lithium hydroxide, chloride, carbonate	Under discussion	Under discussion	
BOEL	Lithium hydroxide, chloride, carbonate	Under preparation	Under preparation	
RMOA performed by FR ANSES	Lithium hydroxide, chloride, carbonate and Li metal	-	Under finalisation	

Background

Lithium stands at the forefront of the European Union's ambitions for technological leadership, sustainability, and strategic autonomy. Recognised as a Critical and Strategic Raw Material under the EU Critical Raw Materials Act (CRMA), lithium plays a central role in supporting Europe's green transition, industrial competitiveness, and resilience across multiple sectors.

Lithium's critical status reflects its importance for Europe's battery value chain, encompassing mining, refining, and recycling. Lithium is the foundational component in rechargeable lithium-ion batteries, which power electric vehicles, portable electronics, grid storage solutions, and renewable energy systems. Reliable access to lithium is vital not only for the EU's climate targets and green deal objectives, but also for industrial growth and job creation in emerging battery manufacturing hubs. Beyond batteries, lithium is indispensable in a diverse array of industries, each contributing to the EU's technological and economic strength.

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- Pharmaceuticals: Lithium compounds are used therapeutically in the treatment of bipolar disorder and certain mental health conditions, forming a critical pillar of modern psychiatry.
- Semiconductors: Lithium's unique properties make it valuable in semiconductor fabrication, where it acts as a dopant and is used in specialty glasses and substrates for high-performance electronics.
- Ceramics and Glass: Lithium improves the thermal and mechanical properties of ceramics and glass, finding applications in household, industrial, and scientific products, including heat-resistant cookware and lab equipment.
- Greases and Lubricants: Lithium-based greases are widely used in automotive, industrial, and aerospace sectors for their stability and performance at extreme temperatures.
- Air Treatment and Desiccants: Lithium salts are employed in humidity control and air purification systems, supporting climate and environmental control in buildings and transport.

Harmonised classification under EU CLP

The possible classification of lithium carbonate, hydroxide and chloride as 1A toxic to reproduction is currently under discussion in CARACAL for possible inclusion in ATP.

In 2021, RAC published an opinion proposing the classification of the 3 Li salts as 1A reprotox. Following the adoption of the opinion, new evidence (Boyle et al., 2016) was presented by the industry, challenging the causality of the association between lithium exposure and reproductive effects.

RAC adopted a second opinion on 14 March 2024, confirming the proposed classification as 1A. Possible inclusion in the ATP is expected in 2026.

Industry stakeholders maintain their scientific disagreement with the classification, as remarked on several occasions during CARACAL meetings. These fundamental scientific weaknesses might lead other countries to reach a different conclusion on the intrinsic hazard of the substances, creating inconsistencies at global level. This is already happening, with several extra-EU jurisdictions either concluding that no classification is warranted at the moment due to lack of robust scientific justification or expressing doubts on the conclusion reached by RAC.

Binding EU-wide OEL

ECHA launched a call for evidence on lithium salts (i.e., lithium carbonate, lithium chloride, lithium hydroxide) related to the scientific evaluation of exposure limits at the workplace. Deadline for comments is the 29th of September 2025.

A final decision on the OEL can be expected after 2028.

ANSES RMOA

On 7 October 2024, the French Competent Authority for chemicals (ANSES) published a Risk Management Option Analysis (RMOA) on lithium and its salts. Industry provided its comments to ANSES on certain aspects of the RMOA in a cooperative manner, expressing doubts on certain aspects related to some endpoints and proposed RMOs. In principle, the development of such RMOA in cooperation with stakeholders is a welcomed step to clarify future regulatory actions.

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Conclusions

Regulatory uncertainty hampers investment: The possible classification of lithium salts as reprotoxic under CLP, despite scientific doubts and disagreement of international partners, has created significant regulatory uncertainty. This ambiguity makes it difficult for industry to plan and invest in EU-based lithium mining, refining, and recycling operations, a key target of the Critical Raw Materials Act. This might lead to the postponement or relocation of major projects outside Europe.

Impact on EU Competitiveness: As regulatory hurdles increase, the EU risks losing vital investments in the battery materials sector to other regions, undermining its ambitions for a robust, self-sufficient battery value chain. Instead of attracting industrial activity and supporting the green transition, these uncertainties push key players to invest elsewhere, which threatens job creation, technological leadership, and strategic autonomy in the EU.

Need for Risk Management Option Analysis (RMOA): The lithium case illustrates the importance of a clear, politically validated regulatory roadmap. By conducting a thorough risk management option analysis upfront, policymakers and stakeholders can identify effective regulatory tools, balance policy objectives, and provide certainty for long-term investment decisions. Such an approach would help distinguish between uses that require strict control and those that can be safely managed through existing legislation, reducing unnecessary barriers and supporting both worker safety and industrial competitiveness.

EU Lead regulatory actions

Summary of risk management measures

Measure	Scope	Date(s) of legislation	Status	Comments
CLP CLH	Lead compounds with the exception of those specified elsewhere in this Annex	Carried over from Directive 67/548/EEC	In force	Metal not covered
CLP HH CLH	Lead metal	2016 [9th ATP]	In force 1st March 2018	Unintended consequences for mixtures (e.g., alloys)
CLP ENV CLH (ATP	Lead metal	2023 [21st ATP]	In force 1st Sept 2025	ECHA RAC supplementary opinion requested. Unintended consequences for mixtures (e.g., alloys), SEVESO status and transportation
REACH Authorisation	Lead metal and 12 compounds (plus	2016-2023	ECHA Recommendation	Commission did not progress to Annex XIV, a move

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	4 included in A.XIV)			supported by a number of Member States
REACH Restriction	Lead and lead compounds	2012-2023	In force	Entry 63
REACH Restriction	Lead sulphates	1989	In force	Entry 17
REACH Restriction	Lead carbonates	1989	In force	Entry 16
REACH Restriction	Lead and lead compounds in ammunition and fishing tackle	N/A	Awaiting Commission proposal	ECHA RAC supplementary opinion requested; would complement wetlands restriction introduced in 2021
REACH Restriction	Lead and lead compounds	1994	In force	Applies to supply to the general public
OSH EU-OEL	Metal and inorganic compounds	2024; 2026 for Member State implementation	In force, with transitional period for industry	All relevant substances included; focus on workplace

Background

Lead metal is used predominantly (85-90% of the annual EU tonnage) in production of batteries for automotive, industrial and energy storage applications. Four lead compounds – lead monoxide, orange lead, tetralead trioxide sulphate, and pentalead tetraoxide sulphate – are also used in the same battery production.

Lead metal is also used in a broad range of applications including radiation shielding, architectural lead sheet, in alloys for precision engineering, in solder, ammunition, architectural lead sheet, ballast, weights and counterweights, for fire assay, and as a nuclear reactor coolant. A more comprehensive list is available **here**.

Lead compounds are used mainly in industrial settings including for the manufacture of specialist rubber, as chemical intermediates for technical ceramics and glass, in specialist pigments, in explosives, in adsorbents, for fire assay, and other specialist applications.

Several lead-containing UVCBs (Unknown or Variable Composition, Complex Reaction Products and Biological Materials) exist as by-products from lead manufacturing and recycling and from the processing of lead-bearing materials such as zinc and copper ores, used lead batteries, and other scrap.

Lead substances are known to have hazardous properties, particularly reproductive toxicity and repeat-exposure specific target organ toxicity. Lead metal has harmonised hazard classification under EU CLP, and there is a generic entry for lead compounds not otherwise specified in CLP Annex VI – meaning that supply for consumer use is prohibited and the main exposure risk to humans is in the (industrial / professional) workplace.

Several different risk management measures have been implemented in EU over the past decades.

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Harmonised classification entries

The CLP Annex VI entry "Lead compounds with the exception of those specified elsewhere in this Annex" pre-dates CLP and was carried over from the Dangerous Substances Directive. It sets the following harmonised classification:

Repr. 1A (SCL Repr. 2; H361f: C ≥ 2,5 %), Acute Tox. 4 *, Acute Tox. 4 *, STOT RE 2 * (STOT RE 2; H373: C ≥ 0,5 %), Aquatic Acute 1, Aquatic Chronic 1.

Lead metal's CLH entry was first included for health, in 2016, and then updated in 2016 to introduce a toxic for reproduction classification. In 2023 a harmonised classification was introduced for aquatic toxicity. It establishes the following harmonised classification:

- Lead powder: Aquatic Acute 1 (M-factor 10), Aquatic Chronic 1 (M-factor 100), Lact., Repr. 1A (H360D: C ≥0.03%)
- Lead massive: Aquatic Chronic 1 (M-factor 10), Lact., Repr. 1A (H360D: C ≥0.03%)

REACH Authorisation

Under the EU REACH Regulation, lead metal and 16 lead compounds have been proposed for Authorisation due to their classification toxic to reproduction.

The four lead compounds used in battery production – lead monoxide, orange lead, tetralead trioxide sulphate, and pentalead tetraoxide sulphate – were added to the Candidate List for Authorisation in 2012 and recommended for inclusion in the Authorisation List (Annex XIV – 7th recommendation) in 2016. Lead metal was added to the candidate list in 2018 and recommended for inclusion in the Authorisation List (Annex XIV – 7th recommendation) in 2023.

The Commission decided not to propose these substances for inclusion in Annex XIV.

REACH Restriction

Lead and its compounds are restricted in jewellery, articles supplied to the general public, gunshot in or within 100 metres of wetlands, and articles produced from polymers or copolymers of vinyl chloride.

Another restriction proposal – lead in ammunition more generally and in fishing tackle – is currently awaiting a Commission proposal.

Lead and lead compounds are also prohibited for supply to the general public.

Binding EU-wide OEL

Lead substances have been subject to EU-wide binding limit values since 1980 under the Directive 80/1107/EEC. More recently, lead's occupational exposure limit values were regulated by the Chemical Agents Directive, 98/24/EC.

Lead and its compounds are reprotoxic substances; since 2022, reprotoxic substances fall within the scope of CMR Directive 2004/37/EC. Directive (EU) 2024/869 removed the limit values for lead from the Chemical Agents Directive and placed them – also making them more stringent – in the Carcinogens, Mutagens and Reprotoxic Substances Directive (2004/37/EC) in 2024.

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Key milestones:

- April to June 2019: ECHA's call for evidence on lead and its compounds and its properties related to scientific evaluation of health-based exposure limits at the workplace.
- October to December 2019: call for comments on ECHA scientific report
- November 2020: ECHA's Committee for Risk Assessment (RAC) adopted its scientific opinion recommending:
    - a very low limit value for lead in air of 4 µg Pb/m^3 (inhalable fraction)
    - a BLV of 150 µg Pb/L blood (30 µg Pb/L blood until 31 December 2028)
    - a BGV of 45 µg Pb/L blood
- 13 March 2024: The EU formally adopted new binding limit values for lead and its inorganic compounds under the sixth revision of the CMR Directive (Regulation 2024/869)
- Transitional measures are provided in the Regulation for workers whose blood lead level exceeds the relevant biological limit value due to exposure which has occurred before 9 April 2026; no transitional measure apply to the OEL
- Transposition deadline: Member States must implement the directive by 9 April 2026

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