

## TRACING THE PATH THE ALUMINIUM JOURNEY TOWARDS ENVIRONMENTAL STEWARDSHIP

### LEAD ENVIRONMENTAL CLASSIFICATION

Brussels, 29 April 2024

Guidance note

## Contextual Overview

The European Chemicals Agency (ECHA) Risk Assessment Committee (RAC) produced an opinion on 16 September 2021 concerning a reassessment at the request of the Commission to review the harmonised classification of lead (EC 231-100-4/CAS 7439-92-1).

Although longer than the simplified process outlined below, the European Commission received the proposal from ECHA to update the CLP Regulation by means of the instrument known as “Adaptation to Technical Progress” (ATP). Once it had been reviewed by the Commission services (DG Environment and DG Grow) the 21st ATP to CLP was shared with the European Parliament and the Council, and afterwards published in the Official Journal of the European Union on 5 January 2024.

Member States will have to apply the environmental classification of lead at the same time as the previously existing classification for health hazards as from 1 September 2025.

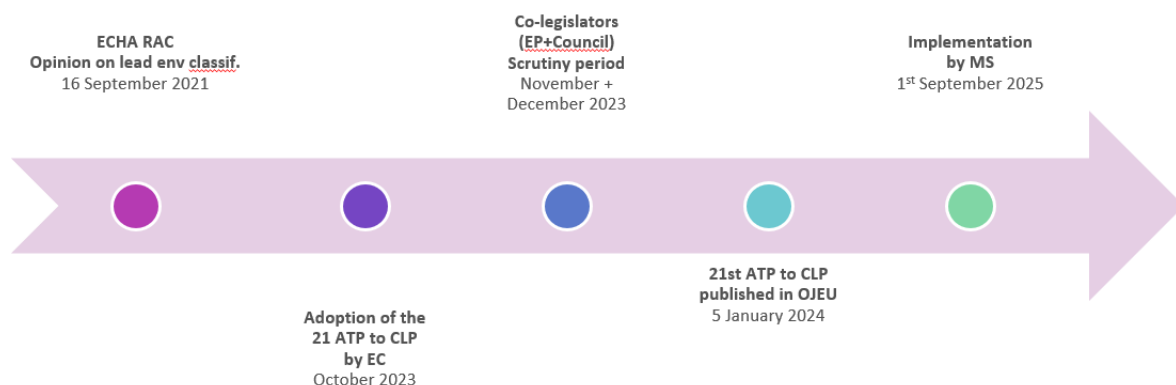


Figure 1: Lead Environmental Classification timeline. European Aluminium.

## Practical Implications of the Lead Environmental Classification

The environmental classification of lead, as specified in the latest adaptation to the CLP Regulation, Adaptation to Technical Progress 21 (i.e. ATP from now onwards), will take effect from 1 September 2025. The details of this classification have been officially published in the Official Journal of the European Union (OJEU) OJ L, 2024/197, dated 05.01.2024.

Suppliers have the option to voluntarily apply the new or updated harmonised classifications and adapt the labelling and packaging accordingly before this date.

The compromise proposal put forward by the Commission featured a consensus consisting in opting for a split entry for the two forms of lead metal, namely, massive and powder.

- When is lead metal considered massive form?
- When the particle diameter is  $\geq$  (superior or equal to) 1mm.
- When is lead metal considered powder form?
- When the particle diameter is (minor than) 1mm.

Additionally, it's crucial to emphasise that waste, as administratively defined, falls outside the purview of the CLP Regulation. This distinction ensures clarity regarding the materials and substances subject to the regulation's guidelines, explicitly excluding waste from its scope as per Article 1 Purpose and scope, indent 3. This clarification serves to prevent any misunderstandings about what is and isn't covered under the CLP Regulation, ensuring all stakeholders are accurately informed of their responsibilities and the CLP regulation's boundaries.

### In practice this means the following:

In the CLP Regulation, Article 2, definitions, features (27) 'alloy' means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means; alloys are considered to be mixtures for the purposes of this Regulation (i.e.) CLP.

By means of the 21st ATP to the CLP Regulation, aluminium (and other) alloys with lead will be classified as follows:

- Aquatic Chronic 1 – if lead present  $\geq$  2.5% w/w
- Aquatic Chronic 2 - if lead present  $\geq$  0.25% w/w
- Aquatic Chronic 3 - if lead present  $\geq$  0.025% w/w

Alloy (mixture)	Lead cut off value (%)
Aquatic Chronic 1	$\geq$ 2.5% w/w
Aquatic Chronic 2	$\geq$ 0.25% w/w
Aquatic Chronic 3	$\geq$ 0.025% w/w

## Conclusion

Mixtures like alloys that contain more than 0.25% of lead metal (weight by weight) will have to comply with additional risk management measures (RMM) or demonstrate on a case-by-case basis that the mixture has lower hazard properties by means of testing, for instance, using the test called transformation/dissolution protocol (T/ DP).

A transformation/dissolution protocol (T/ DP) for metals and sparingly soluble metal compounds is provided as a standard laboratory method for measuring the rate and extent of the release of metals into aqueous media from metal-bearing substances.<sup>1</sup>

Consequently, transformation/dissolution protocol testing could be used to refine CLP classification of an alloy based only concentration.

Hazard class		Cut-off value (%)	Requires label?	Safety Data Sheet (SDS)?	What compliance is needed?	
Hazardous to the aquatic environment	Chronic 1	2.5%	Yes (see below)	Yes	SEVESO III	<ul style="list-style-type: none"> <li>If there are less than 100 tonnes - nothing to do.</li> <li>If there are between 100 and 200 - lower tier establishment.</li> <li>if there are equal to or more than 200 tonnes - upper tier establishment.</li> </ul>
					ADR (UNECE, Transport of Dangerous Goods by Road)	Volume I (last update January 2023) Class 9 - Miscellaneous dangerous substances and articles M6-M8 Environmentally hazardous substances M7 Pollutant to the aquatic environment (UN number 3077)
	Chronic 2	0.25%	Yes (see below)	Yes	SEVESO III	<ul style="list-style-type: none"> <li>If there are less than 200 tonnes - nothing to do</li> <li>if there are between 200 and 500 tonnes - lower tier establishment</li> <li>if there are equal to or more than 500 tonnes - upper tier establishment</li> </ul>
						ADR (UNECE, Transport of Dangerous Goods by Road)
	Chronic 3	0.025%	No	Yes	n/a	n/a

<sup>1</sup> Skeaff, J. M., Hardy, D. J., & King, P. (2008). A new approach to the hazard classification of alloys based on transformation/dissolution. Integrated Environmental Assessment and Management, 4(1), 75–93. Retrieved from: [https://doi.org/10.1897/ieam\\_2007-050.1](https://doi.org/10.1897/ieam_2007-050.1)

Annotations to this table:

- The Seveso compliance is based on Directive 2012/18/EU<sup>2</sup>, Seveso III Directive, Annex I, Hazardous substances, Part I, Categories of dangerous substances. For counting the tonnes of alloys containing lead within a facility, the full weight of the alloy containing lead within the specified cut-off values has to be considered.
- Cut off values: Minimum concentrations for substances to be taken into account for classification in a mixture, even if they do not trigger classification of the mixture directly.
- With regards to the Summation method, this being the reason for which there is a multiplication by factor 10 between the chronic hazard categories, this information can be found in section 4.1.3.5.5. of Annex I to CLP: *“In case of the substance classification categories Chronic 1 to Chronic 3, the underlying toxicity criteria differ by a factor of 10 in moving from one category to another. Substances with a classification in a high toxicity band therefore contribute to the classification of a mixture in a lower band. The calculation of these classification categories therefore needs to consider the contribution of any substance classified as Chronic 1, 2 or 3”*.

## Regarding the consequences for non-compliance post-September 1, 2025, will there be penalties imposed?

Regarding penalties for non-compliance, it is mandatory for Member States (and their National/Regional responsible authorities) to establish and enforce penalties to ensure adherence to this Regulation. These penalties should be significant enough to enforce compliance, while also being fair and discouraging any violations. Additionally, Member States are required to communicate their penalty provisions to the Commission by June 20, 2010, and must also promptly report any changes to these provisions. This measure is essential for maintaining the Regulation's integrity and effectiveness.

This is contemplated in Article 47 of the CLP Regulation, entitled Penalties for non-compliance. Further information is available in Article 46, Enforcement and reporting.

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<sup>2</sup> European Parliament and Council of the European Union. (2012). Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (Text with EEA relevance). Official Journal of the European Union, L 197/1. Retrieved from <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0018>

## How to label

### Derogations from labelling requirements

According to Title III of the CLP Regulation, Hazard communications in the form of labelling, Article 23 lays down the derogations from labelling that are applicable, in this case, to substances and to mixtures (aluminium alloys are considered as mixtures for the purpose of the CLP Regulation).

Indent (d) of Article 23 specifies that *metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers* are exempt from labelling requirements.

Nevertheless, information about the hazards for human health and for the environment that arise from the presence of lead -or any other classified hazardous substance- need to be reflected in the accompanying Safety Data Sheet (SDS). For detailed information on Safety Data Sheets please refer to the REACH Regulation, Annex II on Requirements for compilation of Safety Data Sheets<sup>3</sup>.

### Rules for additional hazard statements to be included on the label of certain mixtures

Where a mixture contains any substance classified as hazardous, it shall be labelled in accordance with Part 2 of Annex II of the CLP Regulation. From the information above we have seen that alloys in massive form are exempted from labelling requirements. However, information about hazards from substances present in those mixtures has to be provided and this is done by means of safety data sheets that accompany the documentation of the shipment.

Additionally, the information under Annex III list of hazard statements is crucial for ensuring accurate and compliant labelling. These hazard statements must be applied following the guidelines set forth in Parts 2 through 5 of Annex I of the CLP Regulation. Suppliers are permitted to select appropriate hazard statements as mandated by Articles 21 and 27 when labelling products. Moreover, they can opt to use combined hazard statements provided in the Annex to convey risks effectively. It is essential that these selections adhere to the principles of precedence outlined in Article 27, which helps prioritise the hazard statements that are most applicable and critical, ensuring that the labelling is both clear and informative.

## What does it mean for a substance to be classified as chronic?

Chronic hazards refer to adverse effects that occur over an extended period due to repeated or prolonged exposure to a substance. These effects may not be immediately noticeable but can manifest over time.

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<sup>3</sup> European Parliament and Council of the European Union. (2006). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union. Retrieved from <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20231201>

<b>Chronic 1:</b>	<p>When a substance is classified as Chronic 1, it means it poses significant risks to human health over the long term. Specifically, it falls into one of the following categories:</p> <ul style="list-style-type: none"> <li>• <b>Carcinogenicity:</b> The substance is known or suspected to cause cancer.</li> <li>• <b>Mutagenicity (M):</b> The substance can induce genetic mutations, potentially leading to hereditary changes.</li> <li>• <b>Toxicity to Reproduction:</b> The substance adversely affects fertility, fetal development, or reproductive organs.</li> </ul>
<b>Chronic 2:</b>	<p><b>Definition:</b> A substance classified as Chronic 2 has moderate long-term health hazards.</p> <p><b>Criteria:</b> Chronic 2 classification applies when the substance meets specific criteria related to chronic toxicity. These criteria may include effects on organs, carcinogenicity, mutagenicity, or reproductive toxicity.</p> <p><b>Example:</b> A substance that causes moderate harm over prolonged exposure but is not as severe as Chronic 1 (e.g., a substance with moderate reproductive toxicity).</p>
<b>Chronic 3:</b>	<p><b>Definition:</b> A substance classified as Chronic 3 has low long-term health hazards.</p> <p><b>Criteria:</b> Chronic 3 classification applies when the substance meets specific criteria related to chronic toxicity, but the effects are less severe than those for Chronic 2.</p> <p><b>Example:</b> A substance that poses minimal risks over prolonged exposure (e.g., a substance with low carcinogenic potential).</p>

Figure 2: CLP Regulation, table 4.1.4 (excerpt). Label elements for hazardous to the aquatic environment.

For detailed information, please refer to the CLP Regulation, specifically Annex I, Part 4.1.21. Additionally, the criteria for mixtures are outlined in Annex VI, Section 1.1.22.

### Some further considerations ...

Lead was already classified for health hazards:

Lead has been previously granted a health classification under the CLP Regulation through the ATP number 9, which entered into force on 1 March 2018. The current briefing, however, focuses on the environmental classification of lead, which aims to provide additional information on its hazards to the environment. This environmental classification is featured in ATP number 21 to the CLP Regulation.

Differences Between CLP Regulation and REACH Regulation:

- **CLP Regulation:** Focuses on the classification, labelling, and packaging of substances and compounds, requiring that hazards (both to health and the environment) be communicated through proper labelling. The goal of the labelling is to ensure that information about a substance's hazards is transparent and accessible.

- REACH Regulation: Works alongside CLP by mandating the registration, evaluation, authorisation, and restriction of substances and compounds. While lead has been identified as a Substance of Very High Concern (SVHC) under REACH, it has not yet been listed in Annex XIV (the "Authorisation List"). Therefore, lead does not require authorisation for use under REACH at this time, and its future inclusion in Annex XIV remains uncertain. The timeline or decision to move lead to this annex is not currently known.

## Who is affected? Details on the scope of CLP Regulation

The latest developments on lead environmental classification fall within the scope of the Classification, Labelling, and Packaging (CLP) Regulation in the European Union. This regulation mandates uniform classification, labelling, and packaging requirements across all EU member states.

The CLP Regulation, as outlined in TITLE I: GENERAL ISSUES, Article 1, Purpose and scope, section (b), mandates compliance from several key audiences:

- Manufacturers, importers, and downstream users are obligated to classify substances and mixtures they place on the market.
- Suppliers are required to label and package substances and mixtures placed on the market appropriately.
- Manufacturers, producers of articles, and importers must classify substances not placed on the market but are subject to registration or notification under Regulation (EC) No 1907/2006 (REACH).

The geographical scope encompasses all EU member states and, by extension, countries in the European Economic Area (EEA).

The bodies in charge of ensuring compliance with these classifications are the Health and/or Environmental Authorities of each Member State, which are responsible for enforcement. These authorities play a crucial role in monitoring, regulating, and enforcing the premises set forth by the CLP Regulation, ensuring that stakeholders adhere to the updated classifications and labelling requirements.

To summarise the above, if there is Lead in aluminium alloys (mixtures) in the following outlined concentrations, the requirements of this table and of table X apply:

Pb	Requirement	Commentary
< 0.025	Nothing to do	Considered clean, no further action required
≥ 0.025	SDS	Safety Data Sheets (SDS) must be provided
≥ 0.25	Seveso	Falls under Seveso directive requirements

Figure 3: Summary table of lead cut-off values. European Aluminium.

This table offers a quick reference to the actions required based on different threshold values, ensuring clarity on the necessary steps or documents needed at each level.

## ANNEX I

Excerpt of the Official Journal of the European Union (OJEU). Table with limits for lead metal, divided by whether lead is present as a powder or if it's present as lead massive as published on 5 January 2024<sup>4</sup>.



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<sup>4</sup> European Commission. (2023). Commission Delegated Regulation (EU) 2024/197 of 19 October 2023 amending Regulation (EC) No 1272/2008 as regards the harmonised classification and labelling of certain substances. Official Journal of the European Union. Retrieved from [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L\\_202400197](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202400197)