

Implications of the Candidate Listing of Lead Metal: Frequently Asked Questions



1. What is latest development concerning REACH and lead metal?

Lead metal was included on the REACH [Candidate List](#) of Substances of Very High Concern (SVHC) for Authorisation on 27 June 2018. A formal [proposal](#) for Candidate Listing had been submitted by the Swedish Chemicals Agency (KemI) during Q1 2018; following a 45-day public consultation which closed on 23 April 2018, the ECHA Member State Committee (MSC) agreed unanimously at its meeting in June 2018 to include lead metal in the Candidate List in respect of its harmonised hazard classification as Toxic for Reproduction (Category 1A).

2. What are the impacts of the inclusion of lead metal in the Candidate List?

Companies may have [legal obligations](#) resulting from the inclusion of lead metal in the Candidate List. Candidate Listing means that EU and EEA suppliers of articles containing more than 0.1% by weight of lead – including lead-based batteries, architectural lead sheet, engineered lead products and those manufactured with lead-containing alloys – must provide information to the recipients which allows for safe use. Note that, in the case of complex objects (i.e. objects made up of more than one article joined or assembled together), the 0.1% threshold applies to each article.

As a minimum, the information provided by the article supplier must contain the name of the substance, if present above the 0.1% threshold. The information must be provided in writing and free of charge. This “Article 33” disclosure must be proactive for business-to-business supply; if the recipient of the article is a consumer, the information must be provided reactively within 45 days of a request.

If the lead metal present in those articles totals more than one tonne per producer or importer per year and if the substance is present in those articles above a concentration of 0.1% (w/w), there may also be a requirement to notify ECHA (REACH Article 7). This notification must be submitted by the importer/producer no later than 6 months after the substance was included in the Candidate List.

It should be noted that Article 7 notification is not required if lead metal has already been registered for use in that article type, or if the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. The extended safety data sheet received from your supplier should provide information to help you ascertain if your use has been included in the REACH Registration dossier. If in doubt, contact your supplier or the Lead REACH Consortium (reach@ila-lead.org).

Implications of the Candidate Listing of Lead Metal: Frequently Asked Questions



EU and EEA suppliers of substances on the Candidate List must provide their customers with a safety data sheet (SDS), including relevant exposure scenarios where relevant. Lead producers should already be doing so, but an update is recommended to notify their customers of the inclusion of lead metal in the Candidate List as a Substance of Very High Concern. The obligation to provide a SDS also applies to mixtures including solders and (pre-fabricated) alloys; however, if the mixture does not meet the criteria for classification as hazardous under CLP, the SDS needs only to be provided at the recipient's request. Note that no concentration threshold applies in that instance because lead is a substance for which there are Community workplace exposure limits (Article 31 (3)(c)).

3. Why did Candidate Listing happen?

Due to its harmonised EU classification as Toxic for Reproduction (Category 1A), lead metal was proposed for Candidate Listing by Keml on the basis that it meets the SVHC criterion in Article 57(c).

There is limited scope for challenging SVHCs proposals where they are based on harmonised classifications and labelling (CLH), as was the case for lead metal. However, the ECHA Member State Committee (MSC) has a degree of discretion in the agreement-seeking process for SVHCs. The SVHC Roadmap is designed to target only *relevant* SVHCs for inclusion in the Candidate List. Ideally, effectiveness in reducing the perceived risk, proportionality and socio-economic impacts of Candidate Listing should be taken into consideration before a substance is Candidate Listed. Conversely, some regulators may regard lead metal as meeting the relevancy criterion owing to the type of health effects and the volumes used in the EU.

In the case of lead metal, the ECHA MSC opted unanimously for Candidate Listing.

4. What are the next steps after Candidate Listing?

Since lead metal is now Candidate Listed, it may be included in future rounds of priority setting for inclusion in Annex XIV, the REACH Authorisation List. Each year, ECHA automatically assigns all substances on the Candidate List (and not already put forward for Authorisation) a prioritisation score by considering the total volume used in the EU for all relevant uses, combined with the hazard and the potential for exposure, particularly whether there are dispersive uses – for example where consumers may be exposed to the SVHC (including from the use and end-of-life of articles).

ECHA selects the highest-scoring SVHCs and makes a recommendation to the European Commission for their inclusion in REACH Annex XIV. Through 'comitology', a process involving representatives of each EU Member State on a REACH Committee, the Commission will then take a decision, on the

Implications of the Candidate Listing of Lead Metal: Frequently Asked Questions



inclusion in Annex XIV and whether to grant any exemptions for specific uses of the selected substances. A three-month period then provides the right of scrutiny to the European Parliament and the EU Council.

Due to the high tonnages of lead metal in use in the EU, lead metal will attract the highest volume-based score. Up to 16 additional points may be applied on the basis of wide dispersive uses in the professional and consumer markets, and on the hazard classification as Repro. 1A. Consequently, lead metal could quickly be recommended by ECHA for inclusion in Annex XIV.

5. What are approximate timings?

With lead metal included on the Candidate List in June 2018, it is expected to be included in ECHA's prioritisation exercise in 2019, with a formal recommendation likely to be submitted by ECHA to the European Commission the same year. If the REACH Committee of Member State representatives agrees to include lead metal in Annex XIV, the Authorisation List, the substance could be added as early as 2021; a transitional period would apply, potentially giving rise to a 'sunset date' (after which, REACH Authorisation would be required to use lead metal, unless exemption applied) in 2024. Companies applying for Authorisation to use lead metal in the EU/EEA would need to submit their application at least 18 months before the sunset date to prevent supply chain disruption.

Authorisation would only be granted if the risks to human health or the environment from the use of metallic lead on its own or in a mixture above the relevant concentration threshold is proven to be adequately controlled or, in the case where adequate control cannot be demonstrated, that the financial benefits of continued use outweigh the societal costs of the health and/or environmental impacts and that there are no suitable alternative substances or technologies for the use.

6. What is the Lead REACH Consortium doing to support its members and other users?

ILA as Secretariat to the Lead REACH Consortium is fully committed to coordinating and delivering a comprehensive advocacy and communications campaign on lead metal.

The Secretariat and two Consortium members met the Swedish Chemicals Agency in December 2017. Then, during early 2018, the Lead REACH Consortium started to coordinate initial advocacy via National Federations in key Member States. From late 2018, ILA and members of the Lead REACH Consortium will develop and deliver a more extensive advocacy and communications campaign at Member State and Commission level. A wider range of materials will be developed to support members and inform discussions with national associations, Member State representatives, MEPs,

Implications of the Candidate Listing of Lead Metal: Frequently Asked Questions



and other relevant stakeholders. Members should keep ILA informed of any contact they have with their Member State representatives and other key influencers and decision-making ministries.

The Consortium also developed a set of 'key messages' which was used to inform a [position statement](#) questioning the proportionality and the regulatory effectiveness of subjecting lead metal to REACH Authorisation, and emphasising the conclusions of the Consortium's own shadow assessment of potential risk management options. The advocacy materials developed around the Candidate Listing proposal also included a paper dedicated to lead as a '[key enabler of the circular economy](#)' for many [non-ferrous metals](#), and an [e-leaflet](#) discussing how lead-based batteries are vital to the day-to-day economic wellbeing of Europe, an application which represents more than 85% of the EU use of lead metal in terms of volume.

The Consortium responded to the public consultation on the Swedish proposal, emphasising that it agrees with the objective to reduce risks associated with lead exposure but questioning proportionality and regulatory effectiveness of Authorisation, highlighting the impact of REACH Authorisation on the circular economy, and the conclusions of its own assessment of potential risk management options. The Secretariat also represented the Consortium during the ECHA MSC meeting at which the Candidate Listing discussions took place. During the lead metal debate, Industry again questioned proportionality and effectiveness, highlighted concerns over regulatory overlaps, advocated proper consideration of most appropriate risk management option, and called again for the strengthening of existing legislation including an update to workplace limit values.

A Eurometaux cross-commodity platform, co-chaired by the Lead REACH Consortium's Secretariat, was also activated in early 2018, with the purpose of engaging in the Candidate Listing process stakeholders in industries where lead metal is used as a constituent of products other than lead-based batteries, in alloys, or is necessary in the recovery of other non-ferrous metals. Based on this existing Eurometaux platform, ILA is now working to establish an umbrella group to bring together some of the key partners for lead metal to build a campaign coalition which will include: Eurometaux, the Copper industry, recyclers, and other downstream users. Interested parties should contact the Lead REACH Consortium (reach@ila-lead.org) for more information.

7. Generally, what can Industry do to influence the process?

The aim of REACH Authorisation is to drive the substitution of SVHCs where alternatives exist. Companies should therefore build a case to justify where – in their opinion – substitution is not

Implications of the Candidate Listing of Lead Metal: Frequently Asked Questions



possible, assessing the availability of alternative substances and technologies for the end applications served by its products, to explain technical feasibility and limitations compared with use of lead.

If lead metal were to be prioritised for Authorisation, information on volumes, uses, supply chain complexity and the proportion of SMEs, availability of alternative substance and technologies, Industry's views on transition periods, and case studies and examples highlighting where REACH Authorisation would lead to regulatory overlap or inconsistency should be submitted in response in the consultation process: a 90-day public consultation is anticipated to start in September 2019. Industry groups are also encouraged to submit socio-economic consequences for their sector (direct and indirect) in a parallel call for information to be launched by the European Commission.

In considering the proportionality of Authorisation, ECHA's committees, Member States, and the Commission would consider risks and the benefits to society and the EU economy of the use of lead metal, compared with the cost to human health. Therefore, companies and Industry sectors should also gather additional information to demonstrate (ultimately, quantitatively) that the benefits to society and the economy of the continued use of lead metal, whether the use is of lead solely in an industrial setting, or if it is used to produce a lead-containing article placed on the EU market.

8. What impact will BREXIT have on the situation?

Until the terms of BREXIT are agreed and are made known to Industry, it is difficult to predict with certainty how the UK's departure from the EU will change the domestic regulatory obligations of legal entities situated in the UK. For example, it is possible that an agreement is reached with the EU which requires UK companies to continue to comply with EU legislation in exactly the same way, at least as a temporary measure, meaning that Candidate Listing and eventual Authorisation could still be relevant for UK entities. Another alternative is that the UK may adopt its own version of legislation such as REACH, choosing only the aspects the UK wishes to implement.

The situation is, however, already clear in the case of goods exported from non-EU countries to the EU: REACH and other EU legislation will apply from the point at which those goods enter the EU Customs area. For example, REACH Restrictions on the presence of chemicals of concern in articles would still apply.

REACH Authorisation does not apply to the supply of articles made outside the EU/EEA, but Article 33 disclosure of SVHCs present above 0.1% by weight would be necessary when they are supplied in

Implications of the Candidate Listing of Lead Metal: Frequently Asked Questions



the EU/EEA, and the obligation to make Article 7 notifications to ECHA would apply, where relevant. Note that, in the case of complex objects (i.e. objects made up of more than one article joined or assembled together), the 0.1% threshold applies to each article.

There are [webpages](#) on the ECHA website providing information, and advice to companies via Q&As, on how the UK's withdrawal from the EU may affect companies and other stakeholders. As future agreements between the EU and the UK have the potential to affect the validity of the information and answers given, ECHA will update the webpages as new information becomes available.