2 February 2022

Draft background document for lead

Document developed in the context of ECHA's eleventh recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during the consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of lead in the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 2 May 2022) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

Name: lead
EC Number: 231-100-4
CAS Number: 7439-92-1

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[2]. Results of the prioritisation of all substances included in the Candidate List by July 2021 and not yet recommended or included in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/17232/prior_results_cl_subst_february_2022_en.pdf.

2.1. Intrinsic properties

Lead was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1A, H360FD ("May damage fertility. May damage the unborn child") and effects on or via lactation, H362 ("May cause harm to breast-fed children") and was therefore included in the Candidate List for authorisation on 27 June 2018, following ECHA's decision ED/61/2018.

2.2. Volume used in the scope of authorisation

The amount of lead manufactured and/or imported into the EU is according to registration data (ECHA, 2021) above 1,000,000 t/y. Part of this tonnage is exported outside the EU. Some uses appear not to be in the scope of authorisation such as the use as intermediate (e.g. in the manufacture of lead oxide for stabiliser manufacturing) and, to the extent the conditions for the generic exemption for the use in Scientific Research and Development are met, the uses as laboratory agent and in chemical analysis.

Based on use and tonnage information provided by the Lead REACH Consortium during the SVHC identification process (Annex XV SVHC report, 2018) it is estimated that more than 90% of the total amount of lead metal manufactured and/or imported into the EU is used for uses falling in the scope of authorisation.

Therefore, in conclusion, the volume in the scope of authorisation is estimated to be >>10,000 t/y.

More detailed information on the main uses and the relative share of the total tonnage is provided in section 1 of Annex I.

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] Document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf

2.3. Wide-dispersiveness of uses

Registered uses of lead in the scope of authorisation include uses at industrial sites (such as in the production of lead batteries, lead articles or alloys, in the production and use of solder, in galvanisation, as heat transfer fluid or in formulation and use of lubricant) and uses by professional workers (e.g. use of lead solder) (ECHA, 2021).

The consumer use of solder reported in a high number of registration dossiers has been advised against by the lead registrant and falls under a generic restriction on CMR substances used as substances or in mixtures sold to the general public above the concentration limit (REACH Annex XVII, entry 30). Therefore, consumer uses of the substance should not take place and are not considered for the priority assessment.

Furthermore, according to registrations and substance in article notifications (ECHA, 2021), the substance is used in a wide variety of articles, e.g. for automotive, construction, electronic or sanitary applications (such as batteries, cast, rolled or extruded articles, screws, nuts, bolts, valves, bearings, faucets or cable sheathing). For some articles releases of the substance cannot be excluded (e.g. lead sheets in the building sector). The volume used in those articles is >10 t/y.

More detailed information on uses is provided in section 2 of Annex I.

2.4. Further considerations for priority setting

None.

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
Lead is classified as toxic for reproduction 1A meeting the criteria of Article 57 (c). Score: 1	The amount of lead used in the scope of authorisation is above 10,000 t/y. Score: 15	Lead is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles in volumes >10 t/y. Refined score: 12	28

Conclusion

On the basis of the prioritisation criteria, lead receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise lead for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the Annex XIV entries approach[3] and the criteria described in the implementation document[4]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

A summary of the information currently available is provided in section 3 of Annex I.

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 11th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for lead.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

[3] General approach can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_2020_en.pdf/
[4] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of lead on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Lead and lead compounds are covered by an extensive body of existing EU legislation. An analysis of the possibility to grant specific exemptions under Article 58(2) for a number of uses of lead compounds (including e.g. uses in batteries) has been performed in the context of previous recommendations. ECHA's detailed assessment of the requests taking into account the relevant EU legislation is provided in the section 'C.2.1. Response to requests for exemptions under Art. 58(2)' of the response document to the comments submitted during the public consultation on lead monoxide, Orange lead, tetralead trioxide sulphate and pentalead tetraoxide sulphate[5]. In these assessments ECHA has not been in the position to consider the impact of potential new legislation or amendments to the current legislation, including the proposed new Battery Regulation replacing the current Batteries Directive.

ECHA had concluded based on its review that it is not clear if there is sufficient basis to propose Art 58(2) exemptions for any uses of lead compounds and had therefore not suggested exemptions for uses of any lead compound. ECHA concluded in addition that if the Commission were to consider Art 58(2) exemptions possible, uses of lead compounds exempted and subject

[5] The document is available here: https://echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375

to regular review under RoHS and ELV legislation may have a stronger case for Art 58(2) exemption than other uses.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[6], there is no need to propose an additional specific exemption.

3.3.2 Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of lead for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for lead[7].

[6] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/17232/generic_exempt_auth_2020_en.pdf
[7] As of 1 August 2021

4. References

Annex XV SVHC report (2018): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Lead (lead powder and lead massive). Submitted by Sweden, February 2018.

https://echa.europa.eu/documents/10162/85bb0106-73dd-c39b-4389-c221d066b36e

ComRef (2015): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 01/09/2014 – 01/12/2014 on ECHA's proposal to include lead monoxide in its 6th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/d0b2bc8b-3eba-4bca-87b8-f6b5a0979082

ECHA (2021): Lead. ECHA's dissemination website on registered substances. Accessed on 1 August 2021.

https://echa.europa.eu/search-for-chemicals

RCOM (2012a): "*Responses to comments*" document. Document compiled by ECHA from the commenting period 03/09/2012-18/10/2012 on the proposal to identify lead monoxide as a Substance of Very High Concern.

Link

RCOM (2012b): "*Responses to comments*" document. Document compiled by ECHA from the commenting period 03/09/2012-18/10/2012 on the proposal to identify lead tetroxide as a Substance of Very High Concern.

Link

RCOM (2018): "*Responses to comments*" document. Document compiled by Sweden from the commenting period 08/03/2018-23/04/2018 on the proposal to identify lead as a Substance of Very High Concern.

https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e1822e2dc5

Annex I: Further information on uses

1. Main (sector of) uses and relative share of the total tonnage

The amount of lead metal manufactured and/or imported into the EU is according to registration data above 1,000,000 t/y. According to information provided by the lead REACH Consortium (Annex XV SVHC report, 2018), the volume of lead used in the EU was 1,517,000 t in 2015. Of this volume, 84 % was used in batteries (53 % for automotive use and 31 % for industrial batteries). Other major uses are in rolled and extruded products, shot and ammunition, production of lead compounds and cable sheathing (see table below).

Table: EU uses of lead in 2015 (Annex XV SVHC report, 2018)

Area of application	Volume tonnes
Batteries	1,274 000 (84%)
Rolled and extruded products	91 000 (6%)
Shot and ammunition	61 000 (4%)
Lead compounds	61 000 (4%)
Cable sheathing	15 000 (1%)
Miscellaneous (including alloys and solders)	15 000 (1%)

For the purpose of prioritisation, it has been assumed that the uses reported under the terminology 'Lead compounds' in the table may correspond to use of lead as intermediate and the corresponding tonnage may therefore not fall in the scope of authorisation.

Some uses of lead metal in shot and ammunition may not exist anymore in the future, considering the recently adopted restriction on the use of lead shots over wetlands (REACH ANNEX XVII, entry 63 update[8]) and the proposed restriction on lead in projectiles (for firearms and airguns), and in fishing sinkers and lures for outdoor activities (see Registry of restriction intentions until outcome - ECHA (europa.eu)). The fraction of the currently reported volume falling in the scope of those proposed/adopted restrictions is not known precisely. Based on the information available, it appears that the priority of lead remains high even if considering no remaining uses of lead in shot and ammunition.

It is noted that uses in the scope of authorisation other than in batteries are taking place at very high volume, i.e. > 120,000 t/y, at least the uses in rolled and extruded products, cable sheathing and miscellaneous (see table above).

2. Further details on the type of applications, functions and market trend per use

The main use of lead metal is in batteries production. According to information provided in RCOM (2018), 99% of lead batteries are collected and recycled in Europe. Consequently, > 85 % of a new lead battery is made from recycled materials. Overall, lead batteries make up 90 % of the global market share for rechargeable batteries. There are indications, that the market trend has been consolidated in the last decades within the EU and the International Lead Association (ILA) estimates that there are fewer than 20 battery producers remaining on the EU market, while the import of lead batteries has increased in recent years (RCOM, 2018).

Lead is used in a number of alloys, including brass and steel, providing them specific properties, like workability, electrical conductivity or corrosion resistance. Such alloys are used in a wide variability of applications, including cables, pipes, vehicles and machinery (RCOM, 2018). Lead soldering takes place at many sites, in particular within the electronics sector.

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0057&from=EN

Lead metal is also widely used in cable sheathing (RCOM, 2018), in particular for chemically aggressive conditions and where higher mechanical and temperature resistance is required, e.g. in petrochemical industry, submarine cables or in saline ground. Still, the main application for lead sheathed cables is in the construction sector.

Additionally, a wide range of articles is directly produced from rolled and extruded lead metal, making this the use with the highest volume after the use in batteries (Annex XV SVHC report, 2018). The presence of lead in articles is confirmed by the high number of Substances in articles notifications received in the SCIP database (ECHA, 2021). Main types of articles notified include different parts of vehicles, electronic instruments or machines, furniture, lamps or metal articles (also in aluminium, steel or other metal articles).

Professional workers are also using lead metal (in mixtures or in articles) in a variety of applications (Annex XV SVHC report, 2018, ECHA, 2021), such as soldering, ammunition (non-military), installation and maintenance of lead sheathed cables, assembly of lead acid batteries, leaded steels or inert anodes.

3. Structure and complexity of supply chains

The following assumptions are made based on currently available information and will be used, together with any relevant information from consultation, to allocate the substance to a specific LAD slot in the final recommendation.

Lead is manufactured and/or imported by a high number of registrants. Based on information available in Annex XV SVHC report (2018) and RCOM (2018), the number of industrial sites where lead metal is used is well above 100.

The supply chain can be characterised[9] by the following actors: formulators, users at industrial sites, professional workers, articles producers, articles assemblers (multi-layer assembling chain), (relevant life cycle stages: F, IS, PW, SLs).

Lead seems to be used in the following product categories: Base metals and alloys;; fillers, putties, plasters, modelling clay; explosives; metal surface treatment products; heat transfer fluids; lubricants, greases, release products;; washing and cleaning products; welding and soldering products, flux products; oil and gas exploration or production products, electrolytes for batteries (relevant product categories: PC 7, PC 9b, PC 11, PC 14, PC 16, PC 24, PC 35, PC 38, PC41, PC42).

A number of sectors is relying on the substance in some of their uses including agriculture, forestry, fishery; manufacture of bulk, large scale chemicals (including petroleum products); manufacture of basic metals, including alloys; manufacture of fabricated metal products, except machinery and equipment; manufacture of computer, electronic and optical products, electrical equipment; general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment; manufacture of furniture; building and construction work; health services; electricity, steam, gas water supply and sewage treatment (relevant sector of use categories: SU1, SU 8, SU 14, SU 15, SU 16, SU 17, SU18, SU 19, SU 20, SU23).

Uses of leads in the scope of authorisation seem to be relevant for the production of a number of article types such as vehicles; machinery, mechanical appliances, electrical/electronic articles; electrical batteries and accumulators; metal articles (relevant article categories: AC 1, AC 2, AC 3, AC 7).

[9] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf

Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers, the Annex XV SVHC report (2018) and Substance in Articles notifications.