Draft recommendation of priority substances for inclusion in Annex 14 of UK REACH 2025

Background document for tetraethyllead

- EC: 201-075-4
- CAS: 78-00-2

October 2025

Contents

1 Introduction

The Health and Safety Executive (HSE), as the Agency for UK REACH (with support from the Environment Agency on environmental matters), is required to recommend priority substances from the UK REACH Candidate List to be included in the Authorisation List (Annex 14) of UK REACH.

The criteria used by HSE are set out in the document entitled “Approach to recommendation of priority substances for inclusion in Annex 14 (list of substances subject to authorisation) of UK REACH”[1].

The following document contains information to support the inclusion of tetraethyl lead (TEL) in HSE’s draft recommendation (2025) of priority substances for inclusion in the Authorisation List of UK REACH.

Further information on the approach to this recommendation is provided in the document entitled “Technical rationale for the development of the recommendation”[2].

[1] “Approach to recommendation of priority substances for inclusion in Annex 14 (list of substances subject to authorisation) of UK REACH”, available from here; https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx.

[2] “Technical rationale for the development of the recommendation”, available from here: https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx

2 Background information for prioritisation

2.1 Substance Identity

Identity of the substance in the UK REACH Candidate List:

Name: Tetraethyllead

EC Number: 201-075-4

CAS Number: 78-00-2

2.2 Intrinsic properties

Tetraethyllead (TEL) is identified as a Substance of Very High Concern (SVHC) according to Article 57(c) of UK REACH owing to its classification in the GB Mandatory Classification and Labelling (MCL) list as toxic for reproduction, category 1A, Repr 1A; H360Df ("May damage the unborn child. Suspected of damaging fertility."). The substance is covered by the entry for lead alkyls with index number 082-002-00-1 and has a specific concentration limit for Repr.1A; H360Df of C ≥ 0.1% w/w (based on the mass of lead: equivalent to 0.156% w/w based on TEL).

Tetraethyllead was included in the UK REACH Candidate List on 1st January 2021 in accordance with Article 59(1A).

2.3 Volume used in the scope of authorisation

There is one GB-based entity that has registered TEL under UK REACH. From the available information (including comments submitted to the European Chemicals Agency (ECHA) in response to the consultation on their draft 9th recommendation (ECHA, 2019a) of priority substances for inclusion in Annex 14 of EU REACH), they are understood to be the sole global manufacturer of this substance.

TEL is manufactured at a single facility in GB where it is also blended into a fuel additive formulation. The additive formulation is exported in its entirety to fuel blenders outside of GB (including to facilities in the EU) that use it to formulate aviation fuel "Avgas 100LL", where the LL stands for "low lead", for use in piston-engine aircraft. TEL is typically present in this fuel mixture at < 0.1% w/w (i.e., below the specific concentration limit for classification as Repr.1A; H360Df).

Avgas 100LL is re-imported for use in GB, but HSE does not have information on the overall quantity of TEL reimported in the fuel. It is noted however, that this reimport information is not relevant in the context of this prioritisation as the provisions for authorisation in UK REACH would not apply to the reimported fuel due to the TEL concentration being below 0.1% w/w. There are 3 Downstream User Import Notifications (DUINs)[3] for TEL. However, this information does not indicate that TEL is reimported in a form that is within scope of authorisation. Furthermore, there is significant uncertainty[4] in the DUIN database and whilst one of the enterprises that has submitted a DUIN appears to import Avgas 100LL (containing TEL at < 0.1% w/w), there is no evidence to indicate any import of TEL from the other companies.

2.4 Wide-dispersiveness of uses

The manufacture and blending of TEL into the fuel additive formulation occurs at only one industrial facility in GB, before the formulation is exported in its entirety. Blending of TEL concentrates into fuel formulations requires highly specialised equipment and needs to be performed to precise standards (hence Avgas formulation is restricted to a few sites worldwide).

The reimported Avgas 100LL is only used to fuel certain types of small aircraft with spark ignition piston engines. Consumer use is not expected.

Given the low concentration of TEL in Avgas 100LL, the only use potentially in scope of authorisation in GB is the blending of TEL into this fuel additive formulation at a single industrial facility.

[3] GB-based companies who imported substances from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a Downstream User Import Notification (DUIN) submitted to HSE.

[4] DUINs could be submitted for substances imported from the EU-27 into GB at any point within the two years prior to EU exit. They represent an approximate snapshot of substances on the GB market in the period before EU exit. As DUIN submission was a simple process and free of charge, companies may have under or over-reported substances (potentially erring on the side of caution to be compliant). Consequently, the DUIN data needs to be treated with caution. Many former DUs will not (currently) have full information on the identity of the substances they import from the EU. This is because most substances are placed on the market as mixtures and the full composition of those mixtures is not always given on a Safety Data Sheet (SDS) or a SDS may not be required. In addition, substances could be imported by multiple importers in lower volumes (i.e. below 1 tonne/year/importer); in these cases, the substances did not need to be included in a DUIN submission as there would be no registration duty under UK REACH for each importer.

2.5 Further considerations for priority setting

There is increasing global pressure to eliminate the use of lead in aviation fuel, by identifying alternatives that can be used without compromising safety or affecting the existing fleet of aircraft reliant on leaded fuel. This includes the Eliminate Aviation Gasoline Lead Emissions (EAGLE) initiative, which is a partnership between the US Federal Aviation Administration (FAA), fuel producers and other relevant parties. This initiative builds on previous work and has been accelerated by a report from the US Environmental Protection Agency (EPA 2023) that found that lead emissions from aircraft engines that operate on leaded fuel cause or contribute to air pollution that may reasonably be anticipated to endanger public health and welfare. The EAGLE initiative aims to safely eliminate the use of leaded aviation fuel by the end of 2030. The GB-based manufacturer of TEL engaged with this initiative.

HSE understands that alternatives are emerging from this work (and previous initiatives such as the Piston Aviation Fuel Initiative - PAFI), although further consideration by the relevant international authorities will be required to ensure the safety and efficacy of those alternatives and that appropriate infrastructure is in place to support their use. Whilst these efforts are underway, it is understood that no viable alternatives are yet widely available and approved for general aviation use across the entire fleet of piston engine aircraft.

3 Other factors and considerations

In addition to the above, HSE notes the 'Defra rationale for prioritising substances in the UK REACH work programme; 2025-2026'[5], which states:

"The Appropriate Authorities will consider the criteria set out in the UK REACH Regulations, alongside a range of relevant factors including those identified in the '*New approach to ensure regulators and regulation support growth*'[6] UK Government Action Plan. In taking forward this strategic approach, the Appropriate Authorities will consider drawing from the regulatory decisions that the EU has made in this area (where appropriate)."

Recognising this, information is provided below to support the Appropriate Authorities consideration of regulatory consistency with decisions made by the EU.

3.1 EU prioritisation activity

TEL was included in the EU Candidate List for authorisation on 19th December 2012, following ECHA's decision ED/169/2012 (ECHA, 2012).

TEL was prioritised by ECHA and included in its 9th recommendation (ECHA, 2019a). The following points were noted in ECHA's Annex 14 background document (ECHA, 2019b) at that time:

- The amount of TEL imported into the EU according to registration data was in the range of 1,000 - < 10,000 tonnes per year.
- Registered uses of TEL in scope of authorisation were considered to include uses at industrial sites (formulation of fuel additives and formulation of fuels with additives). The use of the final fuel was considered to be out of scope of authorisation as the TEL content was noted to be below 0.1%.

TEL was added to Annex 14 of EU REACH on the 8th April 2022 (Commission Regulation (EU) 2022/586).

[5] Defra rationale for prioritising substances in the UK REACH work programme; 2025-2026, available at: https://www.gov.uk/government/publications/uk-reach-rationale-for-priorities-2025-to-2026/rationale-for-prioritising-substances-in-the-uk-reach-work-programme-2025-to-2026

[6] '*New approach to ensure regulators and regulation support growth, available at* 'https://www.gov.uk/government/publications/a-new-approach-to-ensure-regulators-and-regulation-support-growth

It is noted that, at the time of this recommendation, the substance is now registered in the EU with a lower reported aggregated tonnage of 100 to 1,000 tonnes per year[7].

3.2 EU authorisations

Three applications for authorisation (ECHA 2024a, 2024b and 2024c) have been submitted to ECHA covering the use of TEL in the formulation/blending of aviation fuel at EU facilities.

ECHAs Committee for Risk Assessment (RAC) and Committee for Socioeconomic Analysis (SEAC) have adopted opinions on all three applications. At the time of drafting, the EU Commission has not yet provided regulatory decisions on these opinions. Broadly the conclusions of the ECHA (RAC and SEAC) opinions are:

- Occupational conditions (OCs) and risk management measures (RMMs) described by applicants are appropriate and effective in limiting the risk.
- RAC proposed monitoring arrangements on the basis that these will provide further information of the effectiveness of the OC and RMMs.
- Conditions were also applied to further minimise exposure to TEL.
- There are no technically and/or economically feasible alternatives which provide the applicant with the same function and level of performance.
- For all applications, a review period until April 2032 was recommended. For one application, SEAC noted the limitations in research and development towards testing with regard to engagement with the programmes set up to facilitate approval and substitution. However, the publicly available mandate from the EAGLE programme towards the elimination of leaded Avgas and replacement with a lead-free alternative by 2030 was used as a benchmark for an anticipated phase out date for all applications.
- SEAC concluded that even after 2030, time will be required for the EU certification process to be completed. They further noted that it is reasonable to expect that a further 2 years would be needed to obtain this EU approval.
- Two of the 3 applicants applied for longer review periods (10 years and 12 years) in their applications.

[7] ECHA CHEM; ECHA's public chemicals database (https://chem.echa.europa.eu/).

3.3 Consideration of regulatory decisions in the EU

HSE notes that at the time of this recommendation, no decision had been made by the EU Commission on the opinions of ECHA. However, the opinions indicate that a key factor in deciding the review period where authorisation is granted should be that alternatives to TEL will be available in 2030, and that some additional time (~2 years) will be required after the alternatives become available to gain EU certification. Upon which, SEAC argue that a transition is possible and should be undertaken as soon as EU approval occurs. Any delay in this development/approval timeline will require review reports to be submitted by the 3 applicants.

The opinions from RAC and SEAC, prepared after public consultation, indicate that currently there are no available alternatives to TEL use in aviation fuel.

3.4 Overall conclusion

HSE notes that whilst TEL is manufactured in GB and used to formulate a fuel additive, all the material manufactured is subsequently exported. Therefore, the use profile for TEL in GB is slightly different to that in the EU where the fuel additive is then used at multiple sites to formulate aviation fuel. HSE does not know of any GB-based fuel blending facilities for Avgas 100LL and would not expect to receive applications for authorisation for that use. Likewise, the re-imported fuel mixture is expected to be outside the scope of authorisation, with concentrations of TEL below 0.1 % w/w of the formulation.

Consequently, if TEL was added to Annex 14 of UK REACH, a single application to cover the blending of TEL into a fuel additive for subsequent export may be expected.

HSE also notes that viable and approved/certified alternatives are not widely available for general aviation use across the entire fleet of piston engine aircraft and that global initiatives (i.e., the EAGLE programme) are driving the elimination of leaded aviation fuel. The conclusions of ECHA's opinions on the applications for authorisation of TEL in the EU also conclude there are no technically and/or economically feasible alternatives which provide the applicant with the same function and level of performance as TEL.

As noted above, the basis for the review period recommended in the ECHA opinions is that alternatives are anticipated to be available in 2030 (the target from the EAGLE programme) and transition should be possible and should be undertaken as soon as EU approval of those alternatives (by the appropriate bodies) occurs. If there is a delay in this timeline, the applicants are required to submit a review report. This action could therefore encourage commitment to transition and phase-out of TEL as soon as alternatives are available and approved for use i.e., to avoid submission of review reports, and the future uncertainty around review periods and acceptance of further extensions to authorisation applications.

HSE concludes that adding TEL to Annex 14 of UK REACH at this time would have limited effectiveness in driving the phase-out of leaded aviation fuel. However, it would provide consistency in decision making and could lead to clarity for those users who trade with the EU. This alignment of regulatory requirements for chemicals reduces the administrative workload of companies in the chemicals sector or those using chemicals and therefore has positive socio-economic benefits.

4 Background information for the proposed Annex 14 entry

4.1 Latest application and sunset dates

HSE proposes the following transitional arrangements as referred to in Article 58(1)(c):

Latest application date (LAD):	Date of inclusion in Annex 14 plus 18, 21 or 24 months
Sunset date:	18 months after LAD

HSE will set the LAD when finalising the recommendation and will use all available relevant information, including that received in the consultation. It has been estimated that a period of 18 months is required to prepare good quality applications for authorisation. When setting the LADs, HSE also considers its capacity to process authorisation applications. If a high workload is anticipated, a later LAD may be allocated.

4.2 Review period for certain uses

Review periods will be considered during the decision on whether to grant authorisation for specific applications submitted by manufacturers, importers or downstream users. All authorisation decisions will include specific review periods based on information provided in the application.

4.3 Uses or categories of uses exempted from authorisation requirement

4.3.1 Exemption under Article 58(2)

HSE proposes not to recommend exemptions for uses of tetraethyllead based on Article 58(1)(e) in combination with Article 58(2) of UK REACH.

According to Article 58(2) of UK REACH it is possible to exempt from the authorisation requirement uses or categories of uses ‘provided that, on the basis of the existing specific 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’.

In deciding whether to recommend an exemption, HSE considers if:

- There is existing legislation addressing the specific use (or categories of use) that is proposed to be exempted;
- The existing 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 14; generally, the legislation in question should specifically refer to the substance to be included in Annex 14 either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;
- The existing 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) has to allow more stringent requirements than the specific minimum requirements set out in the legislation in question to be imposed. 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).

Requests for exemption from authorisation under Art. 58(2) for a particular use will be assessed by HSE on a case-by-case basis.

4.3.2 Exemption of product and process-oriented research and development (PPORD)

HSE proposes not to recommend including in Annex 14 any exemption from authorisation for the use of tetraethyllead for PPORD.

At the EU level, no exemptions for PPORD have been recommended for any substance. If an operator wishes to use a substance included in Annex 14 for a PPORD activity, it is possible for the operator to obtain authorisation for that use of the substance in accordance with Articles 60 to 64 of UK REACH.

ECHA noted in its background document that no PPORD notifications had been submitted to it for tetraethyllead by the end of their consultation. As of October 2025, no PPORD notifications had been received by HSE.

5 References

Commission Regulation (EU) 2022/586 of 8 April 2022 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.112.01.0006.01.ENG&toc=OJ%3AL%3A2022%3A112%3ATOC

Defra (2025). Defra rationale for prioritising substances in the UK REACH work programme: 2025 to 2026 – July 2025. Available at: https://www.gov.uk/government/publications/uk-reach-rationale-for-priorities-2025-to-2026/rationale-for-prioritising-substances-in-the-uk-reach-work-programme-2025-to-2026

ECHA (2012). ECHA decision: ED/169/2012. Inclusion of substances of very high concern in the candidate list. December 2012. Available at: 0b417b76-b533-42a1-9bd2-519f1dc1990d

ECHA (2019a). Recommendation of the European Chemicals Agency of 1 October 2019 for the inclusion of substances in Annex XIV to REACH. Available at: https://echa.europa.eu/recommendations-for-inclusion-in-the-authorisation-list/-/dislist/details/0b0236e1828a5e98

ECHA (2019b). Background document for tetraethyllead. Document developed in the context of ECHA's ninth recommendation for the inclusion of substances in Annex XIV – October 2019. Available at: https://echa.europa.eu/documents/10162/f21d24f8-eca6-9696-e8db-f8c551ebd606

ECHA 2024a. Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), Opinion on an Application for Authorisation for use of tetraethyl lead in the formulation of aviation fuel. Submitting applicant Shell Nederland Raffinaderij B.V. RAC/SEAC: Opinion N°AFA-O-0000007351-80-01/D. Date: 28 August 2024. Available at https://echa.europa.eu/documents/10162/0f4b5afd-3ab2-58cd-0d61-a6100824c923

ECHA 2024b. Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), Opinion on an Application for Authorisation for use of tetraethyl lead in th e formulation of aviation fuel. Submitting applicant Trafigura Ventures V.B.V. ECHA/RAC/ SEAC: AFA-O-0000007395-68-01/F. Date: 29 August 2024. Available at https://echa.europa.eu/documents/10162/c59b0f28-6a14-24ef-5664-26d9658acd45

ECHA 2024c. Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), Opinion on an Application for Authorisation for use of tetraethyl lead in th e formulation of aviation fuel. Submitting applicant Warter Fuels Spółka Akcyjna ECHA/R

AC/SEAC: AFA-O-0000007396-66-01/ F. Date: 2 December 2024. Available at https://echa.europa.eu/documents/10162/dc1d3491-c824-591b-85f2-31138282fa67

ECHA; Adopted opinions and previous consultations on applications for authorisation; Tetraethyllead Available here: https://echa.europa.eu/applications-for-authorisation-previous-consultations?diss=false&search_criteria_ecnumber=201-075-4&search_criteria_casnumber=78-00-2&search_criteria_name=Tetraethyllead

Eliminate Aviation Gasoline Lead Emissions (EAGLE). Building an Unleaded Future by 2030. United States Department of Transportation, Federal Aviation Administration. Available at: https://www.faa.gov/unleaded

EPA (2023). Regulations for Lead Emissions form Aircraft. Final Finding that Lead Emissions from Aircraft Engines That Operate on Leaded Fuel Cause or Contribute to Air Pollution that May Reasonably Be Anticipated to Endanger Public Health and Welfare. United States Enivronmental Protection Agency. October 2023. Available at: https://www.epa.gov/regulations-emissions-vehicles-and-engines/regulations-lead-emissions-aircraft

Piston Aviation Fuel Initiative – PAFI. United States Department of Transportation, Federal Aviation Administration. Available at: https://www.faa.gov/about/initiatives/avgas/piston-engine-aviation-fuels-initiative-pafi-background-and-program-update

6 Declarations

Within this document we have provided links to documents and information found on ECHA's website: https://echa.europa.eu/

Any documents or information accessed via ECHA's website are subject to ECHA's Legal Notice (https://echa.europa.eu/legal-notice).

For the avoidance of doubt, no part of this document has been endorsed by ECHA.

Further information

This publication is available on the HSE website at;
https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx

Published by the Health and Safety Executive [10/25].