

## Draft recommendation of priority substances for inclusion in Annex 14 (list of substances subject to authorisation) of UK REACH 2025

Technical rationale for the development of the recommendation (2025)

October 2025

## Technical rationale for the development of the draft recommendation 2025

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).

Substances may be included on the UK REACH Candidate List when they:

- a) meet the criteria for classification as carcinogenic category 1A or 1B in accordance with the criteria in GB CLP
- b) meet the criteria for classification as germ cell mutagens 1A or 1B in accordance with the criteria in GB CLP
- c) meet the criteria for classification as reproductive toxicants category 1A or 1B in accordance with the criteria in GB CLP
- d) are considered Persistent, Bioaccumulative and Toxic (PBT) in accordance with the criteria in Annex 13 of UK REACH
- e) are considered very Persistent and very Bioaccumulative (vPvB) in accordance with the criteria in Annex 13 of UK REACH
- f) are substances such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis

Substances from the UK REACH Candidate List can be included in Annex 14 in accordance with Article 58 of UK REACH. Article 58(3) states that priority shall normally be given to substances with:

- (a) PBT or vPvB properties; or
- (b) wide dispersive use; or
- (c) high volumes.

However, these criteria are not exhaustive, and it is possible to take account of other factors when recommending substances from the UK REACH Candidate List.

The capacity of HSE to handle applications for authorisation can also be taken into consideration.

The general approach taken for the recommendation is set out in a separate document: "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.

As the transitional provisions for UK REACH have been extended to allow work to continue on the Alternative Transitional Registration model (ATRm)<sup>1</sup>, it will take time for specific information on the uses and volumes of substances on the market in Great Britain (GB) to become available in the UK database (Comply with UK REACH IT). In the absence of this detailed information for all substances, and as HSE's approach to prioritisation follows the same scoring system as the European Chemicals Agency (ECHA), we have used data on EU volumes and uses as a proxy to identify potential priorities. This is based on an assumption that the industrial profile for GB is not substantially different to the EU.

Where regulatory action has been taken in the EU, with addition of the substances to Annex 14 of EU REACH, HSE has looked at the information published by ECHA since our last recommendation (HSE 2023)<sup>2</sup>; including the available applications for authorisation. We have considered the relevance of these data for GB. Additional information that is available to HSE, including GB specific data where this has been obtained, is also taken into account.

Consequently, for this recommendation round, HSE has focused on the 5 substances from ECHA's 9<sup>th</sup> recommendation (<u>ECHA 2019</u>) that have been added to the EU authorisation list on the 8<sup>th</sup> April 2022 (<u>Commission Regulation (EU) 2022/586</u>). It is noted that no information has been made available since HSE's previous recommendation to suggest that other substances would be of higher priority.

HSE is including the substances below (Table 1) in the draft recommendation 2025. Information to support the draft recommendation is provided in the background documents provided for each substance, available at:

https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx.

<sup>&</sup>lt;sup>1</sup> The deadline for transitional registrations were extended to 27 October 2026, 27 October 2028 and 27 October 2030 depending on tonnage and toxicity. However, Defra have recently consulted on a further extension to allow for additional work on the ATRm.

<sup>&</sup>lt;sup>2</sup> Since HSE's recommendation in 2023, the sunset dates (May 2025) for the substances added to Annex 14 from ECHA's 9<sup>th</sup> recommendation have now passed.

Interested parties are invited to provide relevant GB specific information about these substances to help refine these assessments for the final recommendation.

Table 1: Substances included in the draft recommendation 2025

Substance	Intrinsic property
[EC number / CAS number]	
Tetraethyllead	Toxic for reproduction (Article 57c)
[201-075-4 / 78-00-2]	
2-ethylhexyl 10-ethyl-4,4- dioctyl-7-oxo-8-oxa-3,5- dithia-4-stannatetradecanoate (DOTE)	Toxic for reproduction (Article 57c)
[239-622-4 / 15571-58-1]	
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5- dithia-4-stannatetra decanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-11ethylhexyl)oxy]-2- oxoethyl]thio]-4-octyl-7- oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	Toxic for reproduction (Article 57c)
[915-270-3 / -]	

On the basis that regulatory action has been taken elsewhere (i.e., through addition to Annex 14 of EU REACH), but in the absence of any applications for authorisation or any additional information under EU REACH, HSE is seeking GB specific data on the following substances:

Reaction products of 1,3,4- thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥ 0.1% w/w 4-heptylphenol, branched and linear]
[There is no single EC or CAS No. Representative identifiers include EC No.; 939-460-0 and CAS No.: 1471311-26-8 and EC No.: 300-298-5 and CAS No: 93925-00-

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• 4,4'-bis(dimethylamino)- 4"-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]

[EC No.: 209-218-2 / CAS No.: 561-41-1]

The information currently available to HSE for these substances is provided in the supporting documents available at <a href="https://consultations.hse.gov.uk/">https://consultations.hse.gov.uk/</a>.

Information provided will be used to refine these assessments for consideration in future prioritisation work.

To provide comments on the above substances, please go to: https://consultations.hse.gov.uk/

HSE also invites interested parties to provide GB specific information about any of the other substances on the UK REACH Candidate List. This information can be submitted here; <a href="mailto:ukreach.clp@hse.gov.uk">ukreach.clp@hse.gov.uk</a>. This will be used to support consideration in future prioritisation work. HSE will continue to monitor international regulatory activity for any information (including on any nominations made under the UN Stockholm Convention), and consider further progress on EU REACH that could impact future Annex 14 recommendations.

## **Declarations**

Within this document we have provided links to the following documents:

<u>ECHA 2019</u>; Recommendation of the European Chemicals Agency of 1 October 2019 for the inclusion of substances in Annex XIV to REACH. Available at: <a href="https://echa.europa.eu/documents/10162/e4d061a6-9995-d688-f613-9efc7ecd504b">https://echa.europa.eu/documents/10162/e4d061a6-9995-d688-f613-9efc7ecd504b</a>

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: <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L..2022.112.01.0006.01.ENG&toc=OJ%3AL%3A202">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L..2022.112.01.0006.01.ENG&toc=OJ%3AL%3A202</a> 2%3A112%3ATOC

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## **Further information**

This publication is available on the HSE website at <a href="https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx">https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx</a>

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