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

August 2021

Contents

1. Purpose/Aim: 2
2. Background and legislation: **2**
2.1. Criteria: 2
2.2 Timeline 3
2.3 Context: 3
3. HSE's Approach to prioritisation: **4**
3.1 STAGE 1: Initial Ranking 4
3.2 STAGE 2: Further refinement on the basis of regulatory effectiveness of Annex 14 recommendation 5
3.3 STAGE 3: Final adjustment 7
4. Prioritisation for the first recommendation – December 2021: **8**
5. Future stakeholder engagement: **8**
6. Declarations: **8**

1. Purpose/Aim:

This document aims to set out the approach of the Health and Safety Executive (HSE, as the Agency for UK REACH) to recommending priority substances from the UK candidate list to the Appropriate Authorities (defined in UK REACH as the (Defra) Secretary of State and the Scottish and Welsh Ministers). Following HSE's recommendation, the Appropriate Authorities will make a decision on whether to include those priority substances in the list of substances subject to authorisation (Annex 14 of UK REACH).

2. Background and legislation:

Following the UK's withdrawal from the EU, UK REACH (retained Regulation (EC) No 1907/2006) came into force at the end of the transition period on 31 December 2020. UK REACH regulates the access of chemicals to the Great Britain (GB) market (comprising of the territories of England, Scotland and Wales). Under Article 58(3) of UK REACH, there is a requirement for HSE to recommend priority substances for inclusion in Annex 14 from the UK candidate list of substances of very high concern (SVHCs). When exercising this function, HSE will use advice from the Environment Agency on any relevant environmental issues in accordance with Article 2B of UK REACH.

2.1. Criteria:

In relation to the criteria for recommending priority substances, Article 58(3) states:

Priority shall normally be given to substances with:
(a) PBT or vPvB properties[1]; or
(b) wide dispersive use; or
(c) high volumes.

An additional consideration under Article 58(3) is that the number of substances included in Annex 14 ***"shall also take account of the Agency's capacity to handle applications in the time provided for".***

Article 58(3) does not provide an exhaustive list of factors that can be considered when making a recommendation and therefore, HSE will also consider the following relevant factors[2]:

[1] Persistent Bioaccumulative and Toxic (PBT) or very Persistent very Bioaccumulative (vPvB)
[2] These factors are also considered by ECHA when making recommendations under the EU REACH Regulation.

- the regulatory effectiveness of a substance being added to Annex 14 (being an examination of the validity of that regulatory measure to ensure it meets the intended purpose and does not have unintended consequences); and

the coherence of adding a substance to Annex 14 taking into account other risk management regulatory activities (to avoid possible conflict with other activities under UK REACH and regrettable substitution)

HSE has set out these criteria in more detail under "HSE's Approach to prioritisation" below.

2.2 Timeline

Before HSE's final recommendation is sent to the Appropriate Authorities, its draft recommendation will be made publicly available on the HSE website. Interested parties are invited to submit comments within three months of publication in accordance with Article 58(4) of UK REACH. Comments on existing and future use of the substances in Great Britain (GB) and any particular uses that should be exempted from the GB authorisation requirement are particularly welcomed.

On the basis of comments received, HSE will update its draft recommendation to produce its final recommendation, which will be sent to the Appropriate Authorities by 31 December 2021. The Appropriate Authorities will then decide whether to make regulations under Article 58(1)[3] of UK REACH to add the recommended substances to Annex 14.

2.3 Context:

Article 59(1A) of UK REACH states:

The Agency must include in its candidate list every substance that is included in ECHA's candidate list under Article 59(1) of EU REACH immediately before the end of the implementation period.

Therefore, the UK candidate list of SVHCs from which substances can be prioritised for Annex 14 recommendation may include:

- Substances where the UK (when we were an EU Member State) disagreed that the hazard profile was of sufficient concern to warrant identification of the substance as an SVHC.
- Substances that were not added to the EU candidate list for the purposes of progression to authorisation but for other hazard identification related reasons or to gather more information on SVHCs in articles.

[3] Under Article 58(9), this function of making regulations is subject to the consent requirement set out in Article 4A.

- Substances for which an assessment of the appropriateness of authorisation as a regulatory measure may not have been performed for the reasons set out in the point above.

Importantly, no substances in the UK candidate list will have had a specific assessment of the appropriateness of identification as an SVHC, and subsequent inclusion in Annex 14 as an appropriate measure for GB operating as a standalone country.

Additionally, the UK database (Comply with UK REACH-IT) currently has limited information on the volumes of these substances supplied to the GB market and on GB-specific uses of these substances.

ECHA will continue to produce recommendations in accordance with Article 58(3) of the EU REACH Regulation. ECHA will look at the whole of its candidate list[4] together with information it holds from its database and other information gathering activities. HSE will consider whether substances that ECHA recommends for inclusion in Annex 14 of the EU REACH Regulation in the future, might be appropriate for inclusion in Annex 14 of UK REACH.

3. HSE's Approach to prioritisation:

HSE's approach will be a three-step process. This process is based on how ECHA prioritise substances and takes into account the Article 58(3) criteria, in combination with other relevant factors as described below. This process is consistent with previous recommendations produced by ECHA while the UK was a member of the EU. HSE has drawn from ECHA's process on Annex 14 prioritisation as:

- The prioritisation criteria are the same in both EU and UK REACH;
- ECHA's prioritisation approach has been refined over a number of EU recommendations ensuring that this is a workable and consistent way of scoring the substances;
- Under Article 59(1A), the UK has retained the EU candidate list (as it was at the end of the transition period) and drawing from ECHA's approach ensures HSE will be considering the substances within this list in a uniform way when making our early recommendations.

3.1 STAGE 1: Initial Ranking

This stage takes into account the criteria identified in Article 58(3) and will follow the process set out in the ECHA guidance note "Prioritisation of substances of very high

[4] ECHA will consider new additions that have been on the list for at least 6 months and re-evaluate older substances if there has been a significant change in circumstances (such as new uses identified, tonnage changes, etc) – based on previous experience when the UK was a Member State and page 11 of ECHAs guidance note (cited below)

concern (SVHCs) for inclusion in the authorisation list (Annex XIV)" 2014 (amended 2020) [5]
HSE will use ECHA's scoring system, which is set out in detail in the following sections of ECHA's guidance note:

- 5.1 Inherent properties
- 5.2 Volume
- 5.3 Wide-dispersive use
- 5.4 Overview of scoring for each criterion
- 5.5. Total Score

As previously noted, it will take some time for the UK database to become fully populated with information on substances registered under UK REACH (in accordance with the transitional arrangements provided for in UK REACH).

In the absence of detailed information on volume and use of substances within GB, HSE will take ECHA data into account for its draft recommendations[6]. This is based on an assumption that the industrial profile for GB is not substantially different to the EU – however this assumption will be tested at the draft recommendation commenting phase of the process. Using ECHA information will:

- secure consistency between early recommendations in the first few years after the UK's withdrawal from the EA; and
- help HSE to prepare its first recommendation within the timescales required under UK REACH.

When the UK database is populated, HSE will primarily use this GB specific information to make its recommendations, HSE may also use calls for evidence or undertake regulatory management options analyses (RMOAs)[7] to gain further data prior to recommendation.

3.2 STAGE 2: Further refinement on the basis of regulatory effectiveness of Annex 14 recommendation

Some of the substances currently on the UK candidate list (having been included directly from ECHA's candidate list under EU REACH), may not be good candidates for authorisation in GB. In order to decide which substances are taken forward to create good, effective regulation, stage 2 will look at regulatory effectiveness[8].

---

[5] "prioritisation of substances of very high concern (SVHCs) for inclusion in the authorisation list (Annex XIV)" 2014 (amended 2020).https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930

[6] HSE will make clear where ECHA data has been used within the recommendation documents.

[7] A Regulatory Management Options Analysis (RMOA) is a process that is used to clarify whether regulatory action is necessary for a given substance and to identify the most appropriate measures to address a concern.

[8] Regulatory effectiveness is a collective term for examination of the validity of a particular regulatory measure to ensure it meets the intended purpose and does not have unintended consequences.

Regulatory effectiveness considerations may include some of the following criteria (this may not be relevant for all substances).

Criteria	**Rationale**
All identified uses are subject to specific legislation imposing minimum requirements relating to the protection of human health or the environment ensuring that risks are properly controlled.	To document the regulatory landscape for a substance in GB and demonstrate that adding the substance to Annex 14 provides additional protection to humans and/or the environment. This criterion could result in substances being de-prioritised if it seems unlikely that authorisation will lead to further improvements in protection for humans or the environment. For example, if a substance that has been identified as an SVHC because it is carcinogenic and the only groups likely to be exposed are workers, it may be concluded that the provisions within the Control of Substances Hazardous to Health Regulations (COSHH) 2002 are sufficient to manage the risks to workers.
All or most known uses can easily be replaced by a related substance with a similar (or even worse) hazard profile, which is not on the candidate list (e.g. one metal salt on the candidate list can be replaced by another salt of the same metal with the same hazard profile, but this salt is not on the candidate list).	To ensure regulatory coherence between similarly hazardous substances from within a chemical group thereby avoiding regrettable substitution. This criterion could result in a substance being de-prioritised while additional work is done to identify those related hazardous substances as SVHCs so that the group can be progressed to Annex 14 at the same time. As far as possible, HSE will try to avoid this situation arising because it will take account of possibilities to group substances during RMOA work.
Uses have been identified, but the resulting exposures/releases to the environment that arise from uses that are within scope of the authorisation regime are insignificant, or insignificant compared to exposures/releases resulting from natural sources and/or uses not in the scope of authorisation.	To provide evidence of the level of additional protection (or lack of additional protection) that will be obtained by adding the substance to Annex 14. For example, article 2(8)(b) excludes on-site isolated intermediates and transported isolated intermediates from the authorisation provisions. However, it can be the case that residues of an intermediate remain within the new substance that the intermediate is being used to manufacture. If exposure/releases arising from the use of a substance containing residues of the intermediate far exceed exposure/releases from uses that are in scope of authorisation, the substance may be de-prioritised in favour of an alternative risk management approach. It is also the case that certain hazardous

	substances occur in nature. A substance might therefore be-deprioritised if exposures to naturally occurring sources far exceed exposures from uses in scope of authorisations.
An alternative regulatory approach is more appropriate for GB as a standalone country.	At this time, no assessments have been performed for any SVHCs on the UK candidate list to decide what is the best regulatory approach for that substance in GB acting as a standalone country. To ensure that we only add substances to Annex 14 where this is the best regulatory approach for that substance or group of substances for GB, it will be necessary to consider if alternative options would manage the risks more effectively. In many cases, this will mean that a substance is de-prioritised and a RMOA is initiated. If the RMOA concludes that an alternative approach e.g. an occupational exposure limit or action under environmental legislation is a more efficient way to manage the risk, this alternative route will be pursued instead of Annex 14 listing.

3.3 STAGE 3: Final adjustment

As a final stage, the refined list from stage 2 of the process might be adjusted by adding SVHCs from the UK candidate list which may have a low score in stage 1 (e.g. due to tonnage/use) but could be alternatives to the substance recommended for Annex 14. Replacement of substances subject to authorisation by these alternatives could create an equal risk, leading to regrettable substitution. To justify a recommendation on this basis, HSE would need to undertake some information gathering as to the technical and economic feasibility of this substitution.

This is consistent with the approach taken by ECHA, as set out in section 6 of the ECHA guidance note:
"further considerations could relate to other substances already recommended or included in Annex XIV, in particular the potential interchangeability in (some of) their uses to avoid regrettable substitution".

In addition, HSE will ensure that risk-management activities that are being planned and taken-forward within UK REACH form a coherent regulatory strategy for that substance. For example, Article 58(5) places limitations on the scope of new restrictions that can be introduced for substances that are listed in Annex 14. To avoid a possible regulatory conflict, a substance might be de-prioritised whilst a restriction was being introduced,[9]. A substance might also be de-prioritised in cases where there is ongoing international work, such as a nomination under the Stockholm convention as a Persistent Organic

[9] Consideration would be required afterwards as to if Article 58(7) would apply if all uses have been prohibited under the particular restriction

Pollutant, to ensure that any action taken under UK REACH aligns with international efforts to manage global risks from chemicals.

This is also consistent with the steps ECHA takes to secure regulatory coherence. The ECHA guidance note states:
"Other on-going regulatory risk management activities can also be considered when deciding on which substances to include in a specific recommendation. This is to avoid undesired interference between different regulatory actions."

HSE is considering initiating RMOAs for several substances to help it gather GB specific information about the uses for those substances and the regulatory landscape that currently applies.

Additionally, HSE will take into account its own capacity to process applications for authorisation from substances newly included in Annex 14 and this may impact on the final number of substances recommended for inclusion in Annex 14.

4. Prioritisation for the first recommendation – December 2021:

HSE's first draft recommendation has now been published for consultation[10]. In order to make its first recommendation, HSE has considered substances recommended by ECHA in its 10th recommendation. HSE has also considered those substances recommended by ECHA in its 9th recommendation, which the EU Commission is proposing to include in Annex 14 of the EU REACH Regulation (and has notified to the World Trade Organisation accordingly)[11].

Also published alongside HSE's draft recommendation is a document setting out HSE's conclusions in relation to the other substances that were assessed but are not being recommended for inclusion in Annex 14 at this time.

5. Future stakeholder engagement:

The rationale behind HSE's first recommendation shows the scale of ongoing work with respect to RMOAs and calls for evidence that HSE will be undertaking. This work will enable HSE to consider further whether substances, which have not been included in the first recommendation, should be included in subsequent recommendations. HSE welcomes involvement and information from stakeholders in these activities, and we will look to publish opportunities for involvement on the HSE website.

6. Declarations:

[10] Health and Safety Executive - Citizen Space (hse.gov.uk)
[11] HSE has used these substances as a starting point for making its first recommendation, as they represent the latest recommendations taken forward by ECHA which take account of the potential lag within the UKs withdrawal from the EU.

Within this document we have provided links to the following ECHA documents found on ECHA's website:

- **Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)" 2014 (amended 2020):**

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

7. Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk/. You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

Published by the Health and Safety Executive 00/00