

# UK REACH: Article 1 Consistency Statement

Consultation on Extending the UK REACH Transitional Registration Submission Deadlines 2025

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# Foreword

This statement is made in accordance with Paragraph 1 of Schedule 21 to the Environment Act 2021<sup>1</sup>, which requires the Secretary of State, when exercising the power in Paragraph 1(1) of Schedule 21 of the Act to amend the UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation, to make a formal statement explaining why he considers the proposed changes are consistent with Article 1 of the UK REACH Regulation (aim and scope).

The UK REACH Regulation is one of the main pieces of legislation for the regulation of chemicals in Great Britain (GB), which replaced EU REACH in GB following the UK's withdrawal from the European Union. It sets out a framework to ensure a high level of protection for human health and the environment, while also supporting the functioning of the market and encouraging innovation and competitiveness within the chemicals sector.

This Consistency Statement relates to proposed legislative amendments to extend registration submission deadlines for transitional registrants under UK REACH. The statement explains that while extending the deadlines will delay the full submission of registration data, this is not expected to compromise the overall ability of the UK REACH framework to deliver its objectives through the various provisions in Article 1. To support this conclusion, the statement evaluates the potential impact of the proposed extensions on each relevant element of Article 1. It also acknowledges the associated risks and outlines the measure in place to mitigate them.

This Consistency Statement accompanies the consultation for proposed legislative amendments of the UK REACH transitional registration submission deadlines, and confirms that, in the opinion of the Secretary of State, the proposed amendments are consistent with the objectives set out in Article 1 of the UK REACH Regulation, namely:

- Ensuring a high level of protection of human health and the environment,
- The promotion of alternative methods for assessment of hazards of substances,
- Free circulation of substances while enhancing competitiveness and innovation,
- The principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment,
- The provisions within it are underpinned by the precautionary principle.

The statement underscores the UK Government's ongoing commitment to ensuring that the chemical industry remains a vital and competitive part of the nation's economy, contributing to innovation, sustainability, and economic resilience.

## Introduction

- The UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation<sup>1</sup> is one of the main pieces of legislation for the regulation of chemicals in Great Britain (GB), which replaced EU REACH<sup>2</sup> in GB from 31 December 2020 (European Union (EU) exit). UK REACH establishes a regulatory framework for the manufacture, import, placing on the market, and use of chemical substances in GB. EU REACH continues to apply in Northern Ireland<sup>3</sup>.
- 2. UK REACH requires substances that are manufactured in, or imported into, GB to be registered with the Agency for UK REACH (the Health and Safety Executive (HSE)). Registrations include information on the hazards, uses and exposure of the substance. Registration information is used by HSE for regulatory purposes and by the registrants to identify appropriate risk management measures for themselves and other users down the supply chain.

# The Environment Act and Article 1 of UK REACH

3. Paragraph 1(1) of Schedule 21 to the Environment Act 2021 gives the Secretary of State the power to amend the UK REACH Regulation. The Secretary of State can only exercise this power if he considers that the amendments are consistent with Article 1 of the UK REACH Regulation, which sets out its aim and scope. The Secretary of State must publish an explanation of why he considers this condition is met. This must be published no later than the time when the Secretary of State begins the consultation on the exercise of the power. This statement has been produced to meet this requirement, in relation to proposed legislative amendments to extend registration deadlines for transitional registrants under UK REACH.

# **Policy Context**

- 4. The UK REACH Regulation came into effect on 31 December 2020 as part of the category of UK law created under sections 2 to 4 of the European Union (Withdrawal) Act 2018. It included transitional provisions to help industry with the move from the EU REACH to UK REACH. Registrations made under the EU regime were transferred into the domestic regime, with a requirement for registrants to provide HSE with an initial notification.
- 5. UK REACH places a new registration duty on importers of chemicals from the EU (previously classed as downstream users under EU REACH). To help with the move into the domestic regime, transitional provisions are also in place for these duty holders, again requiring an initial notification to HSE. There were some differences in the information required under these two notifications.

<sup>&</sup>lt;sup>1</sup> Regulation (EC) No 1907/2006

<sup>&</sup>lt;sup>2</sup> EUR 2006/1907

<sup>&</sup>lt;sup>3</sup> Under the Windsor Framework

- 6. In relation to substances which had previously been registered with EU REACH and which now need to be registered with UK REACH, in 2019<sup>4</sup>, a single deadline of October 2021 was initially set for completing the transitional registration process. This was later replaced in 2020 by a phased approach, with new deadlines<sup>5</sup> in October 2023, October 2025, and October 2027, depending on tonnage bands and the hazard profile of substances.
- 7. In response to stakeholder concerns regarding the costs associated with acquiring the data required for these registrations under UK REACH, the transitional registration submission deadlines were extended<sup>6</sup> in 2023 to give the Government time to develop an alternative transitional registration model (ATRm), to legislate for this new registration model and provide industry with a two-year transition period. The aim of the ATRm is to reduce the costs for businesses transitioning from EU REACH to UK REACH while ensuring a high level of protection for human health and the environment.
- 8. The current Government, in cooperation with the Devolved Governments in Scotland and Wales, is considering the next steps. Given that the detailed design of the ATRm is still under review, we cannot confirm at this stage exactly what information industry will be required to provide by the submission deadlines. However, it is our expectation that the final information requirements will not exceed those outlined in the 2024 ATRm consultation.
- 9. Given these ongoing considerations, it will no longer be possible to deliver the legislative changes to implement ATRm before the current first submission deadline in October 2026 together with a suitable transition period. It is therefore necessary to consult on revised transitional submission deadlines, which provide sufficient time for the Government to complete the ATRm and for industry to prepare to comply. The proposed new deadlines under consultation are:
  - Option 1: October 2029, October 2030, October 2031
  - Option 2: April 2029, April 2031, April 2033
  - Option 3: April 2029, April 2030, April 2031
- 10. Option 1 is the Government's preferred option as it allows time to finalise the design and implementation of the ATRm and provide industry approximately 2 years from the planned completion date for the ATRm to prepare for registration. Moving from a two, to a one-year gap between deadlines would still allow time for information to be gathered and submitted by industry, while managing down the overall period before the regulators are in receipt of complete registration date as legally required.

<sup>&</sup>lt;sup>4</sup> Article 127E(2) of UK REACH

<sup>&</sup>lt;sup>5</sup> The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020

<sup>&</sup>lt;sup>6</sup> The REACH (Amendment) Regulation 2023 Article 127P

- 11. The current deadlines for extra compliance checks under Article 41 REACH also need to be amended to reflect the proposed industry registration deadlines to enable HSE make the relevant checks after the transitional data has been submitted. This would not be possible if HSE continued to apply to the current deadlines, as no data would have been submitted to check for compliance. Amending Article 41 of the UK REACH Regulation does not prevent industry submitting dossiers before the deadlines or HSE from carrying out compliance checks on those dossiers. It does not on its own have a significant impact on the protection of human health and the environment.
- 12. Article 1 of UK REACH relates to its aim and scope of UK REACH. The aims set out in Article 1 are:
  - ensuring a high level of protection of human health and the environment.
  - the promotion of alternative methods for assessment of hazards of substances.
  - free circulation of substances while enhancing competitiveness and innovation.
  - the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment (producer responsibility).
  - the provisions within it are underpinned by the precautionary principle.

# **Consistency with Article 1**

#### Human health and the environment

- 13. Scientific and other data submitted through the registration process plays an important role in delivering the regulatory objectives of UK REACH. It provides the basis for compliance checks ensuring that those who are manufacturing, importing and using substances are fulfilling their registration obligations under the UK REACH legislation to submit suitable and complete data. It can also help inform HSE's ability to prioritise substances for further regulatory scrutiny. Both of these aspects contribute to ensuring a high standard of protection for human health and the environment.
- 14. The transitional registration deadlines under UK REACH were previously extended in 2023 to provide additional time for Government to develop a new registration model and then for industry to prepare for compliance. The Government is now consulting on further extending these deadlines, recognising the need to align them with the ongoing development and delivery of the ATRm.
- 15. An additional extension would prolong the period during which the HSE lacks complete information on the highest tonnage and most hazardous substances. Specifically, this data would not be available for an additional six years beyond the original phased deadline of October 2023. Under Option 1, the data gap would be extended by three years for the first deadline, reducing to two and then one year for the later tonnage bands; under Option 2, the extension would be 2½ years across all tonnage bands. Under Option 3, the extension would be 2½ years for the first deadline, reducing to 1½ years and then six months for the later deadlines.

- 16. These longer data gaps may constrain HSE's capacity to carry out some regulatory functions, potentially reducing the impact of compliance checks and delaying the identification of substances requiring further evaluation potentially resulting in reduced regulatory oversight during the intervening period. However, in practice, HSE currently relies on the European Chemicals Agency (ECHA) data as a proxy and will continue to do so during the longer data gaps. While this approach does not typically lead to delays, it does necessitate making assumptions in the absence of GB-specific data.
- 17. Nonetheless, we consider it likely that any impacts will be limited under all three options but particularly under the Government's preferred approach (Option 1). Any associated risks are expected to be manageable and fall within an acceptable level of regulatory tolerance, allowing UK REACH to maintain high standards of protection of human health and the environment while also balancing the practical impacts on industry. This assessment is based on the following considerations:

• Continued availability of EU REACH information

- The information and knowledge on chemicals registered under EU REACH that is available to both HSE and GB registrants. As well as the information publicly available on the EU REACH database, those previously involved in EU REACH registrations will be familiar with information relating to hazards, uses and exposure. As hazard information relates to the intrinsic properties of a substance, there should not be divergence between EU and GB conclusions. It is expected that the value of some of the use and exposure information may diminish over time if industry practices diverge, but that it will still be useful over the period of the extended submission deadlines.
- Access to EU REACH-compliant Safety Data Sheets
   GB importers importing substances from the EU will continue to receive EU REACH compliant Safety Data Sheets from their EU suppliers which will enable them to
   identify and apply appropriate risk management measures.

#### • HSE's access to alternative data sources and expertise

HSE can continue to seek risk management data from other sources, if necessary, as they did when acting as a Competent Authority under EU REACH. This could include calls for evidence and using data from EU REACH and other relevant sources that can provide GB-specific hazard and exposure information (such as academic journals). They can also draw on their own considerable experience and expertise from their previous work under EU REACH, and external expertise as provided for under UK REACH, e.g. under Article 77.

• Complementary risk management regimes remain in force

Other requirements that will continue to apply to manufacturers and users of chemicals such as the Control of Substances Hazardous to Health Regulations 2002 and the CLP Regulation<sup>7</sup>.

- Industry's ongoing risk management responsibilities
   Industry will continue to have a duty to understand and manage risk based on their
   knowledge of the hazards and associated risks and compliance with other
   regulatory regimes.
- HSE's ongoing regulatory capacity and action
   HSE will still have the capability and capacity to carry out its regulatory obligations
   and make decisions. Industry continues to carry out the registration of novel
   substances and HSE carry out compliance checks on them and also assess
   notifications for exemption for product and process orientated research and
   development (PPORDs), carry out compliance checks of novel substances, and
   consider all testing proposals. They have used Regulatory Management Option
   Analyses (RMOAs) to identify and assess the potential risks posed by substance
   groups such as PFAS. HSE continue to process industry driven applications for
   authorisations.

#### The purpose of promoting alternatives to animal testing

18. The generation of information by alternative means will not be compromised by extending the deadlines. Where vertebrate animal testing proposals are submitted to HSE as part of registrations, the last resort principle will continue to apply<sup>8</sup>. More broadly, The Government is committed to supporting the uptake and development of alternative methods to the use of animals in science. Defra, along with partners from sectors with interests in animal science and on a cross-Government level are currently engaging with DSIT to develop the publishing of a strategy to support the development, validation and uptake of alternative methods. It is possible that this work will mean that there will have been further reductions in the potential likelihood of animal studies being needed when the revised deadlines fall due.

#### Free circulation of substances while enhancing competitiveness and innovation

19. A key aim of UK REACH is to support the continued circulation of chemical substances within GB. The transitional provisions were introduced to protect existing supply chains and maintain access to essential substances, particularly for downstream users reliant on imports. These substances, many of which are not manufactured in GB, play a critical role in sectors such as water purification, pharmaceuticals, industrial operations, and the production of cleaning agents. Their uninterrupted availability contributes significantly to safeguarding human health and the environment.

<sup>&</sup>lt;sup>7</sup> Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (EUR 2008/1272)

20. Extending the current registration deadlines will help to preserve access to these vital substances, avoiding the health, environmental, economic, and operational risks that could arise from supply disruptions. It will also provide businesses with greater certainty and flexibility to respond to the ongoing development of the ATRm, reducing the likelihood of market exit and supporting continued supply. This analysis applies to all 3 options.

#### <u>The principle that manufacturers, importers and downstream users are responsible for</u> <u>the chemicals they manufacture, place on the market and use</u>

21. Responsibility for ensuring substances do not adversely affect human health or the environment will continue to lie with manufacturers, importers and downstream users of these substances. The extension of the current deadlines will not remove the obligation on businesses to ensure safety of the substances they manufacture, place on the market or import by passing recommended risk management measures and other safety information down the supply chain<sup>9</sup>. Companies whose registrations were transferred into the domestic regime must also continue to adhere to their obligations to update their registrations with relevant new information and submit it to the HSE<sup>10</sup>.

#### UK REACH is underpinned by the precautionary principle

22. The precautionary principle remains a fundamental component of the UK REACH framework. It is reflected in key regulatory mechanisms such as producer responsibility, substance evaluation, and restrictions. It has also been re-emphasised in the Environment Principles Policy Statement<sup>11</sup>. The consideration of risk reduction measures when the risk is uncertain, but a significant hazard has been identified, will continue to apply under UK REACH during the extended period of data submission, maintaining a high level of protection of human health and the environment.

### Conclusion

- 23. Article 1 of the UK REACH Regulation establishes the overarching objectives outlined above in paragraph 12. The proposal to extend the transitional registration deadlines under UK REACH has been developed with these objectives in mind. While an extension will delay the full submission of registration data, we assess that it will not compromise the overall ability of the UK REACH framework to deliver its protective aims.
- 24. Although registration data plays a foundational role in supporting the effective functioning of UK REACH, the regulatory system is not solely dependent on it. During the extended period, HSE will continue to undertake key regulatory activities such as evaluation, authorisation, and restriction by making use of alternative data sources, including information from ECHA, international databases, and scientific literature.
- 25. The extension of the deadlines is practically necessary during the ongoing development of the ATRm. It will provide businesses with greater certainty and flexibility to respond to

<sup>&</sup>lt;sup>9</sup> Article 33 of UK REACH

<sup>&</sup>lt;sup>10</sup> Article 22 of UK REACH

<sup>&</sup>lt;sup>11</sup> Policy Paper

that process, reducing the likelihood of market exit and supporting continued supply, and contributing to the aim of free circulation, innovation and competitiveness.

- 26. HSE also applies risk-based and other prioritisation approaches, including identifying substances for the candidate list, the use of hazard flags and undertaking RMOA. These measures help maintain regulatory oversight even in the absence of complete UK-held registration data, ensuring that higher-risk substances can still be identified and addressed.
- 27. The UK REACH framework is underpinned by the precautionary principle, which encourages regulatory action where there is evidence of a significant hazard, even in the absence of complete data to fully define the risk. This ensures that the absence of GB-specific data does not prevent risk-reduction measures from being applied where needed or there is uncertainty about the level of risk. During the extension period, this principle will continue to guide regulatory decisions and uphold the protective aims of Article 1.
- 28. In summary, while extending the deadlines may delay access to some data, the UK REACH framework retains a wide range of tools and safeguards to uphold high standards of protection. Alternative data sources, various prioritisation approaches, the precautionary principle, and continued regulatory action all combine to ensure that Article 1 objectives remain fully supported throughout the extension period under any of the options proposed.