

Department for Environment Food & Rural Affairs

UK REACH: Article 1 Consistency Statement

Contents

| UK REACH: Article 1 Consistency Statement | 1 |
|---|---|
| Introduction | 3 |
| Consistency with Article 1 | 4 |
| Conclusion | 6 |

Introduction

The UK REACH Regulation¹ is one of the main pieces of legislation relating to the regulation of chemicals in Great Britain. It sets out requirements relating to the registration, evaluation, authorisation and restriction of chemicals. UK REACH regulates the use of chemicals in Great Britain as EU REACH continues to apply in Northern Ireland under the Northern Ireland Protocol.

The Environment Act and Article 1 of UK REACH

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 do so if 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 a statement to explain how this condition is met. This statement has been produced to meet that duty, by reference to those aspects of Article 1 that are relevant to the proposal.

Policy Context

The UK REACH Regulation came into effect on 31 December 2020, establishing the UK REACH regime (UK REACH). It included transitional provisions to help industry with the move from the EU to domestic regime. Registrations made under the EU regime were transferred into the domestic regime, with a requirement for registrants to provide the Health and Safety Executive (HSE - the Agency) with an initial notification. They then have to provide HSE with the rest of the technical dossier referred to in Article 10, and a chemical safety report where required, with submission deadlines in:

- October 2023 for substances included on the EU REACH candidate list before UK REACH came into effect on 31 December 2020; substances that are carcinogenic, mutagenic or toxic for reproduction and manufactured or imported in quantities of 1 tonne a year or more; substances that are very toxic to aquatic life and manufactured or imported in quantities of 100 tonnes or more a year; and all substances manufactured or imported in quantities of 1,000 tonnes or more a year.
- October 2025 for substances added to the UK REACH candidate list before the above submission deadline; and all substances manufactured or imported in quantities of 100 tonnes or more a year.
- October 2027 for all substances manufactured or imported in quantities of 1 tonne or more a year.

UK REACH places a new registration duty on importers of chemicals from the European Union (previously classed as downstream users under EU REACH). To help with the

¹ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (EUR 2006/1907).

move into the domestic regime, transitional provisions are also in place for these operators so that they follow the same submission deadlines for their registrations.

Concerns have been raised by industry about the costs of obtaining the data needed to comply with these transitional provisions. Defra is working with HSE and the Environment Agency to explore an alternative model for transitional registrations. The model aims to reduce the need for replicating EU REACH data packages by placing a greater emphasis on improving our understanding of the uses and exposures of chemicals in the GB context. This has the potential to provide clearer evidence on whether each dutyholder is managing chemicals safely and support more targeted, GB-focussed, regulatory actions, whilst also reducing burdens on businesses.

The government needs sufficient time to develop, and then legislate for, an alternative transitional registration model. Therefore, it is necessary to amend the legislation to extend the current submission deadlines.

The government is consulting on extending the first data submission deadline by 3 years to 2026, with two options for the spacing of the two subsequent submission deadlines, which would continue to be based on production tonnage and hazard profile.

- Option 1 would continue the 2-year gaps which are currently part of UK REACH, giving submission dates of October 2026, October 2028 and October 2030.
- Option 2 would reduce each of the gaps to 1 year, giving submission dates of October 2026, October 2027 and October 2028.

Both options preserve phasing over three deadlines to enable both registrants and HSE to spread the administrative tasks involved in a reasonable manner. Option 2 is the government's preference, subject to consultation, as it would lead to HSE having all of the transitional registration data two years earlier than under option 1.

It is also necessary to make related amendments to Article 41(5) of the UK REACH Regulation, which places deadlines on HSE of 31 December 2023 and 2027 to carry out compliance checks on no less than 20% of the registration dossiers received, according to tonnage. These deadlines should be amended to reflect the proposed data submission deadlines to ensure that this regulatory process is applied in the most effective manner. This would not be possible if the Agency continued to be subject to the current deadlines in Article 41, as they would fall before the relevant submission deadlines.

Consistency with Article 1

This assessment focuses on the UK REACH aims of ensuring a high level of protection of human health and the environment and the free circulation of chemical substances.

Human health and the environment

The scientific data yielded from the registration process contributes to ensuring high levels of human health and environmental protection through underpinning REACH regulatory processes such as compliance checks and the prioritisation of substances for evaluation. Extending the current transitional deadlines means gaps in information held by the Agency would remain on the highest tonnage and most hazardous substances for a further three years beyond the current deadline of October 2023. The gaps in information held on other substances would either also be extended by three years (option 1) or by two years and one year (option 2).

The absence of this data means that there could be impacts on the ability of HSE to carry out some regulatory processes - such as compliance checks and prioritisation of substances for evaluation. This could lead to reduced regulatory oversight and regulatory delays, because of the additional time needed to acquire the requisite data from other external sources.

However, we are confident that these impacts will not be significant, even under option 1, and that the UK REACH regime will still be able to ensure a high level of protection for human health and the environment because of:

- 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 involved in EU REACH registrations will be familiar with information relating to hazards, uses and exposure. It is expected that the value of some of this information may diminish over time, but that it will still be useful over the period of the extended submission deadlines.
- Importers 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 ability 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.
- Amending Article 41 of the UK REACH Regulation does not prevent HSE from carrying out compliance checks on dossiers that they receive before the submission deadlines and does not on its own have a significant impact on the protection of human health and the environment.

 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 Regulation².

HSE will still have the capability and capacity to carry out its regulatory obligations and make decisions. Industry will continue to understand and manage risk based on their knowledge of the hazards and associated risks and compliance with other regulatory regimes.

Under option 2 the second and third submission deadlines are pushed back by 2 years and one year, respectively, rather than three years. This means that the potential impacts on environmental and human health protections will be lower for option 2 than option 1.

Free circulation of substances

UK REACH aims to ensure the free circulation of substances. The transitional provisions were designed to protect existing supply chains and ensure the availability of vital chemicals on the GB market. This is particularly important for the uninterrupted import of chemicals by downstream users, as it allows the continued availability of substances not manufactured in GB. These chemicals are used for things like water purification, the production of medicines and cleaning materials, and facilitating the safe operation of industrial sites. Their availability therefore helps protect human health and the environment.

Extending the deadlines will help ensure that the free circulation of these vital substances can continue within GB, and avoid the health, environmental, financial and other impacts resulting from interruptions in supply. It will also enable dutyholders to reflect the development of an alternative transitional registration model in their business decisions, reducing the risk that they will simply exit the market and reduce the availability of these substances.

This analysis applies to both options. We do not consider that option 2 would lead to a reduction in the free circulation of substances compared to option 1.

Conclusion

For the reasons set out above, we consider that this proposal is consistent with Article 1 of the UK REACH Regulation. It means that HSE will not have access to transitional registration data for longer, and this could have an impact on the levels of protection of human health and the environment. However, we are confident that any impact will not be

² Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (EUR 2008/1272).

significant and UK REACH will continue to provide high levels of protection. Any impact will also be even lower in respect of the Government's preferred option. The proposal will also help ensure the continued availability of vital substances in GB.