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Sir Edward Mountain
Convener of the Net Zero, Energy and Transport
Committee
Scottish Parliament
Edinburgh
EH99 1SP

03 March 2023

Dear Edward,

THE REACH (AMENDMENT) REGULATIONS 2023 EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

I am writing in relation to the protocol on obtaining the approval of the Scottish Parliament to proposals by the Scottish Ministers to consent to the making of UK secondary legislation affecting devolved areas arising from EU Exit.

That protocol, as agreed between the Scottish Government and then Parliament, accompanied the letter from the then Cabinet Secretary for Government Business and Constitutional Relations, Michael Russell MSP, to the Conveners of the Finance & Constitution and Delegated Powers and Law Reform Committees on 4 November 2020 and replaced the previous protocol that was put in place in 2018.

I attach a Type 1 notification which sets out the details of the SI which the UK Government propose to make and the reasons why I am content that Scottish devolved matters are to be included in this SI. We have received a copy of the final draft of this SI and I am content that the final SI is in keeping with the terms of this notification.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee. Grateful if the Committee could note the notification accompanying this letter.

I look forward to hearing from you by 31st March.

Yours sincerely,

MÀIRI MCALLAN

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NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s)

The REACH (Amendment) Regulations 2023

Is the notification Type 1 or Type 2

Type 1

Brief overview of the SI (including reserved provision)

The REACH (Amendment) Regulations 2023 (“the 2023 regulations”) amend the retained EU law version of Regulation (EC) 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2022/21/EC (“the UK REACH regulation”) to extend the registration deadlines for chemical substances under the transitional provisions.

To enable the UK REACH regulation to function properly as UK law, deficiency fixes were made previously to it. Five sets of regulations were made for that purpose:

1. The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758);
2. The REACH etc. (Amendment etc.) (EU Exit) (No. 2) Regulations 2019 (S.I. 2019/858);
3. The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 (S.I. 2019/1144);
4. The REACH etc. (Amendment etc.) (EU Exit) (No. 4) Regulations 2020 (S.I. 2020/1577).
5. The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/).

Previous notifications were made to the Scottish Parliament Environment Climate Change and Land Reform Committee on 27 November 2018, 2 April 2019, 18 June 2019 and 28 September 2020 and 26 February 2021, respectively. The Scottish Parliament agreed with Scottish Ministers’ intention to consent to the listed regulations.

This is the first time that powers in the Environment Act 2021 (section 140 and paragraph 1 of schedule 21) are being used to amend the UK REACH regulation. The UK Government intends to lay the 2023 regulations at Westminster under the affirmative procedure on 20 April 2023.

Chemicals policy, including in relation to REACH, engages a complex mixture of reserved and devolved competence. Environmental protection, waste management and public health are devolved while product safety, animal testing as well as health and safety at work are reserved.

Details of the provisions that Scottish Ministers are being asked to consent to.

Regulation (EC) 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is the main legislation controlling the manufacture, marketing and use of chemicals in Europe. The UK REACH regulation replicates this regime for Great Britain. UK REACH applies to substances placed on the market in quantities of one tonne or more per year by any individual GB-based manufacturer or supplier.

This instrument specifically makes two amendments to the UK REACH regulation.

First, it will amend the dates (currently set out in article 127P(4B) of the UK REACH regulation) by which manufacturers or suppliers (including importers) must register their substances based on the amount they manufacture or supply annually (tonnage bands), and in some cases on the substances' intrinsic hazard. To this end the existing deadlines for all three tonnage bands/hazard categories will be extended by three years:

(a) the deadline will be 27 October 2026 for those substances either: on the UK REACH Annex 14 candidate list¹ on or before 31st December 2023; or are classified as carcinogenic, mutagenic or toxic for reproduction and manufactured in Great Britain or imported in quantities ≥ 1 tonne per year; or are substances that are classified as aquatic chronic or aquatic acute in category 1 for the environment and are manufactured in Great Britain or imported in quantities ≥ 100 tonnes per year; or substances manufactured in Great Britain or imported in quantities ≥ 1000 tonnes per year.

(b) the deadline will be 27 October 2028 for substances added to the REACH Annex 14 candidate list between 1 January 2024 and 27 October 2026 or substances manufactured in Great Britain or imported in quantities ≥ 100 tonnes per year.

(c) the deadline will be 27 October 2030 for substances manufactured in Great Britain or imported in quantities ≥ 1 tonne per year.

Second, and as a consequence of extending those registration deadlines, it will amend the dates by which the Health and Safety Executive ("HSE"; the UK Agency for REACH) must have completed compliance checking under article 41(5) of the UK REACH regulation of at least 20% of the registrations in relation to the three different registration tonnage bands/hazard categories (specified in Article 127P(4B)). These dates will then relate to the registration deadlines for the three categories of substances listed above, and the proposals are to extend the compliance check deadlines to:

(a) 27 October 2027 (one year after the registration deadline)

¹ The Candidate List lists substances that have been identified under UK REACH as Substances of Very High Concern based on their intrinsic hazardous properties. Substances from the candidate list are periodically prioritised by the HSE for inclusion in annex 14 of UK REACH, which means they cannot be used unless authorisation to do so is sought and approved.

(b) 27 October 2030 (two years after the registration deadline)

(c) 27 October 2035 (five years after the registration deadline)

Summary of the proposals

UK REACH requires substances that are manufactured in, or imported into, Great Britain to be registered with the HSE. Registration includes provision of information on the hazards, uses and (environmental and human) 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 in the supply chain.

Following EU exit, GB-based companies with existing registrations under EU REACH were able to transfer these to UK REACH, and GB-based suppliers and users of chemicals (that were registered in EU REACH but for which they were not the registration holder) were given time to prepare for UK REACH registration. The aim of these transitional provisions inserted into UK REACH was to reduce the disruption to industry as UK REACH entered into force. Companies seeking to use these transitional arrangements had to submit basic initial registration data within 120 days after IP completion day. Subsequently, companies were then to be required to provide full registration information within prescribed deadlines set in article 127P(4B) of the UK REACH regulation: these were 300 days after IP completion day plus (1) two years (27 October 2023); (b) four years (27 October 2025); or, six years (27 October 2027). The deadline applicable was determined by the quantity of the substance on the market and its hazard profile. Chemicals falling under these transitional arrangements will represent the majority of chemicals registered in UK REACH.

Registration is a key component of UK REACH, demonstrating that companies understand the hazards of the chemicals they supply and how they can be used safely. Registration data are used by the HSE to conduct further regulatory work such as identifying Substances of Very High Concern and proposing restrictions where there is evidence that risks are not adequately controlled. Without UK REACH registration, a company cannot legally manufacture or supply their chemicals on the GB market. Although the UK REACH registration process mirrors that of EU REACH, there will be differences between the EU and UK databases of registrations by virtue of differences between the EU and GB markets for chemicals. The delay to completion of the UK REACH registration database may have knock-on consequences for regulation; for example, in some cases GB-specific information may not be available for “Government-led” risk management processes. This could result in delays to additional controls to protect human health and the environment, causing divergence from EU REACH where these additional controls are already in place.

The transitional provisions in the UK REACH regulation apply to those that were registrants, downstream users or distributors under EU REACH before UK REACH came into force. The UK REACH regime does not apply to Northern Ireland which remains subject to EU REACH as required by the Protocol on Northern Ireland.

Stakeholders had raised significant concerns around current transitional registration arrangements in the UK REACH regulation, mainly in relation to the cost of acquiring the data to complete their registrations. This prompted an ongoing UKG-led programme of work to investigate alternative registration models to lower the burden on industry whilst maintaining protections for the environment and human health. In order to allow this programme of work to be completed, consent is being sought to amend the UK REACH regulation in order to extend the registration deadlines by three years:

- (a) from 27 October 2023 to 27 October 2026 for the most hazardous substances (which will cover substances included on the UK REACH candidate list before 31 December 2023 (instead of before IP completion day), substances classified as carcinogenic, mutagenic or toxic for reproduction and manufactured or imported in quantities of 1 tonne a year or more, and substances that are very toxic to aquatic life and manufactured or imported in quantities of 100 tonnes or more a year) and substances manufactured or imported in quantities of 1,000 tonnes or more a year;
- (b) from 27 October 2025 to 27 October 2028 for substances added to the UK REACH candidate list between 1 January 2024 and 27 October 2026 (instead of before 27 October 2023), and substances manufactured or imported in quantities of 100 tonnes or more a year; and
- (c) from 27 October 2027 to 27 October 2030 for substances manufactured or imported in quantities of 1 tonne or more a year.

Under article 41(5) of the UK REACH Regulation, the HSE must check a proportion of registrations for quality through a process called a compliance check, completing this by set dates after the registration deadlines. These dates need to be amended to ensure that they apply after the new registration deadlines have passed, otherwise no data may have been submitted for the HSE to carry out compliance checks on. These dates will be amended to account for the changes in registration deadlines described above, as follows:

- (a) In relation to the first registration deadline amended through this instrument to 27 October 2026, the compliance check deadline will be extended from 31 December 2023 to 27 October 2027;
- (b) In relation to the second registration deadline amended through this instrument to 27 October 2028, the compliance check deadline will be extended from 31 December 2027 to 27 October 2030;
- (c) In relation to the third registration deadline amended through this instrument to 27 October 2030, the compliance check deadline will be extended from 31 December 2027 to 27 October 2035.

Under article 41(5) at present these compliance check deadlines are set only in relation to the tonnage bands of substances. The amendments being made will set

three compliance check deadlines aligned to the three new registration deadlines. Relative to the new registration deadlines, these compliance checking dates will be increased in effect from two months to one year for substances subject to the first registration deadline, from two months to two years for substances subject to the second registration deadline and from two months to five years for substances subject to the third registration deadline. These differences reflect a balance between the resources required to complete the checks and a realistic timeframe for the work. The exclusion from the obligation to carry out compliance checks on “grandfathered” registrations (those transferred from EU REACH to UK REACH) over 100 tonnes (Article 127B(9)) will continue to apply.

Does the SI relate to a common framework or other scheme?

Yes. The UK REACH regulation forms part of the relevant regulations set out within the scope of the Chemicals and Pesticides Common Framework.

Summary of stakeholder engagement/consultation

The UK Government held a “Consultation on extending the UK REACH submission deadlines” from 05 July 2022 to 01 September 2022. Stakeholder engagement sessions were also held during the summer of 2022 where the proposal was raised and responses to the consultation prompted. Officials also informally raised with Scottish stakeholders the consultation, setting out the general approach being proposed. However, these measures are aimed solely at ensuring the functioning of the UK REACH regulation across GB and, therefore, we have not undertaken any formal consultation about these specific amendments.

Stakeholder interest can be summarised as: industry generally welcoming the delay of three years for the three deadlines, citing the likelihood of a better quality of registration dossier as an additional benefit, and; NGOs frustrated that a key aspect of the REACH regime (registration information) is being delayed and their concern that the continued absence of a UK REACH registration database will hinder the UK REACH Agency’s (the HSE) ability to carry out risk management work under UK REACH.

This is a particularly complex area of legislation and regulation. It took the EU, through transitional “phase in” arrangements in EU REACH, over a decade to collate relevant registration data. Within Great Britain we would expect industry and regulators to welcome government departments and Devolved Administrations working together on making amendments of this nature to ensure that the quality of data collected is the best available.

A note of other impact assessments, (if available)

No additional impact assessment has been prepared. The proposals do not constitute a policy change and are aimed at ensuring effective operation of the UK REACH regulation.

Summary of reasons for Scottish Ministers' proposing to consent to UK Ministers legislation

Scottish Ministers consider that consenting to the 2023 regulations is the most effective and transparent way to make these amendments, as the UK REACH regulation operates across GB. Officials have worked with Defra to ensure the drafting delivers for our interests and respects devolved competence in Scotland, and so Scottish Ministers propose to consent to these amendments to the regulation. Scottish Ministers understand the proposed changes to be the most practical approach to ensuring this key aspect of UK REACH functions for UK business and regulators.

Intended laying date (if known) of instruments likely to arise

This instrument is subject to the affirmative procedure and will be laid at Westminster on 20 April 2023.

If the Scottish Parliament does not have 28 days to scrutinise Scottish Ministers' proposal to consent, why not?

The Scottish Parliament has 28 days to scrutinise this proposal.

Information about any time dependency associated with the proposal

The 2023 regulations extend the deadlines for registrations. The first deadline that is being extended falls on 27 October 2023. The 2023 regulations will therefore need to be made prior to 27 October 2023.

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

None.

Any significant financial implications?

None.

Lead Official:

Lead Solicitor:

SI NOTIFICATION: SUMMARY

Title of Instrument
The REACH (Amendment) Regulations 2023
Proposed laying date at Westminster
20 April 2023
Date by which Committee has been asked to respond
31 March 2023
Power(s) under which SI is to be made
Section 140 of, and paragraph 1 of Schedule 21 to, the Environment Act 2021.
Categorisation under SI Protocol
Type 1
Purpose
<p>This statutory instrument is to amend the retained EU law version of Regulation (EC) 1907/2006 (“the UK REACH regulation”), which was previously amended¹, to extend by three years the registration deadlines for chemical substances that fall within scope of transitional provisions in the UK REACH regulation .</p> <p>This instrument specifically makes two sets of amendments to the UK REACH regulation.</p> <p>First, it amends the dates by which manufacturers or suppliers (including importers) must register their substances based on the amount they manufacture or supply annually (tonnage bands), and in some cases on the substances’ intrinsic hazard. To this end the registration deadlines for all three tonnage bands (set out in Article 127P(4B) of the UK REACH Regulation) have been extended by three years:</p> <p>(a) the deadline will be 27 October 2026 for the most hazardous substances² in scope of UK REACH and substances manufactured in Great Britain or imported in quantities ≥1000 tonnes per year.</p>

¹ [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#); [The REACH etc. \(Amendment etc.\) \(EU Exit\) \(No. 2\) Regulations 2019](#); [The REACH etc. \(Amendment etc.\) \(EU Exit\) \(No. 3\) Regulations 2019](#); [The REACH etc. \(Amendment etc.\) \(EU Exit\) \(No. 4\) Regulations 2020](#); and [The REACH etc. \(Amendment\) Regulations 2021](#).

² substances either on the UK REACH Annex 14 candidate list* on or before 31st December 2023, classified as carcinogenic, mutagenic or toxic for reproduction and manufactured in Great Britain or imported in quantities ≥1 tonne per year, or that are classified as aquatic chronic or aquatic acute in category 1 for the environment and are manufactured in Great Britain or imported in quantities ≥100 tonnes per year.

* The Candidate List lists substances that have been identified under UK REACH as Substances of Very High Concern based on their intrinsic hazardous properties. Substances from the candidate list are periodically prioritised by the HSE for inclusion in annex XIV of UK REACH, which means they cannot be used unless authorisation to do so is sought and approved.

(b) the deadline will be 27 October 2028 for substances added to the REACH Annex 14 candidate list between 1 January 2024 and 27 October 2026 or substances manufactured in Great Britain or imported in quantities ≥ 100 tonnes per year.

(c) the deadline will be 27 October 2030 for substances manufactured in Great Britain or imported in quantities ≥ 1 tonne per year.

Second, and as a consequence of the changes to the registration deadlines, it amends the dates by which the Health and Safety Executive (HSE; the UK REACH Agency) must have completed compliance checking of at least 20% of the registrations in relation to the three different registration tonnage bands specified in Article 127P(4B). These dates correspond to the deadlines referred to above, and are:

- (a) 27 October 2027 (one year after the registration deadline)
- (b) 27 October 2030 (two years after the registration deadline)
- (c) 27 October 2035 (five years after the registration deadline)

Other information

SG Policy contact:

SGLD contact: