

CHEMICALS - NOTIFICATION TO THE SCOTTISH PARLIAMENT

The REACH etc. (Amendment etc.) (Amendment) (EU Exit) Regulations 2019

1. Name of instrument:

The REACH etc. (Amendment etc.) (Amendment) (EU Exit) Regulations 2019 (the new amending regulations) make adjustments to the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (the original amending regulations).

The Scottish Parliament agreed with Scottish Ministers' intention to consent to the original amending regulations on 19 December 2018 and the SI was subsequently laid at Westminster on 5 February. This notification should be read together with the previous notification on the original amending regulations which was issued to the Scottish Parliament Environment Climate Change and Land Reform Committee on 27 November 2018.

2. Explanation of law that the proposals amend and summary of the proposals

Controls on the use of chemicals in the EU are set out in Council Regulation (EC) 1907/2006, which provides for the registration, evaluation, authorisation and restriction of chemicals (the EU REACH Regulation). The EU REACH Regulation will be retained EU law after EU Exit.

In its consideration of the notification on the original amending regulations SI, the Environment, Climate Change and Land Reform Committee gathered evidence which suggested the SI posed significant challenges for industry to ensure the continued supply and use of chemicals in compliance with the current standards. Similar concerns were raised during the consideration of the REACH SI at Westminster and the timescales for the submission of data packages have already been amended. The committee was notified of this change on 7 February 2019. Industry have identified two issues with the proposals in the original amending regulations, which may create risk for existing chemical supply chains involving importation of chemicals to the UK.

Both issues concern Only Representatives (OR) under the REACH regime. An OR in the EU REACH Regulation is natural or legal person established within the EU, who is appointed by a natural or legal person established outside of the EU, to fulfil obligations under EU REACH of the non-EU based entity. The OR appointment is subject to mutual agreement of both parties. The proposed amendments simplify how substances imported into the UK transition into the new UK system.

These issues are explained below in hypothetical scenarios, the countries used are purely for illustrative purposes.

Issue 1

Issue: A UK company imports a chemical directly from the US but the chemical was covered by an EU REACH registration belonging to a German OR. Before exit, the UK company could rely on the registration held by the German OR, which registered the chemical for the whole of the EU, and did not require their own REACH registration.

After exit, the UK company will become the first point of entry for the chemical into the UK.

Industry have identified that the transitional provisions, as previously drafted, apply to importers importing directly from the EU but do not apply to chemicals imported from outside the EEA, which were registered in EU REACH by an EU based OR. Instead of using the transitional arrangements under UK REACH of supplying the initial data package within 180 days following by full registration within 2 years, the UK company would have had to apply for registration in UK REACH immediately, causing a risk of immediate disruption to supply chains. Regardless of whether the transitional or full process is used, there would have been substantial administrative and financial costs involved.

The proposed change under the new amending regulations is to allow the UK company to use the transitional arrangements within UK REACH for imports of any chemical *as long as it is registered under EU REACH at the point of exit*, regardless of where it comes from. Our assessment is that this maintains high standards of protection for human health and the environment as the substance already has a registration under EU REACH and will transition into the UK system in an appropriate timescale.

Issue 2

Issue: Only downstream users and distributors can make use of the transitional arrangements under UK REACH of supplying the initial data package within 180 days following by full registration within 2 years. However, UK-based ORs cannot, so a French manufacturer would not have been able to ask a UK-based OR to make use of the transitional arrangements within UK REACH.

The requirement to provide an initial notification to the HSE during the first 180 days would fall to the UK importer of the chemical. The UK importer would have been a downstream user under EU REACH and would have relied on EU REACH registrations higher up the chemical supply chain. The requirement to provide the initial notification may be a challenge for some companies, who were formerly downstream users, particularly SMEs. Even if the UK company has the capability and capacity to do so, the French company may only be willing to share information with their appointed OR on the grounds of commercial sensitivity.

The proposed change in the new amending regulations is to allow the UK-based OR to submit notifications to HSE on behalf of the French company, which other UK companies could reference in order to maintain supply chains. Our assessment is that this approach maintains high standards of protection for human health and the environment as the substance will still have to be notified by the OR and downstream users will still have to identify themselves as such.

3. Why are these changes necessary?

Not addressing the first issue could create an interruption in supply while the UK company applied for a new registration in UK REACH, despite the fact that the

chemical was formerly covered by a valid EU REACH registration held by the EU based OR.

Not addressing the second issue could significantly disrupt supply chains. The proposals allow UK-based entities to perform the OR role on behalf of EU based companies which would allow other UK users to continue using the substance.

4. Scottish Government categorisation of significance of proposals

Category A. The overall intention of the approach taken by the UK Government in drafting the original amending regulations was to replicate the existing EU regime within the UK and to avoid introducing any substantive policy changes. There has been a clear and consistent desire to ensure that existing mechanisms are adapted in the simplest and most practical form in order to ensure as smooth as possible a continuation of the current chemicals regulatory regime. The amendments made by the new amending regulations are consistent with this approach, and are aimed at smoothing the transition rather than changing any of the objectives of the new regime.

5. Impact on Devolved Area

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 standards, animal testing as well as health and safety at work are reserved.

There are no significant impacts on devolved competence envisaged as a result of the new amending regulations.

6. Stakeholder engagement/consultation

Last year, Defra carried out stakeholder engagement in respect of the new UK REACH regime, as set out in the notification for the original amending regulations. The issues being addressed by the new amending regulations were identified as part of Defra's discussions with stakeholders on the new regime, particularly the Chemical Industries Association.

We have continued to engage with stakeholders to set out the general approach we are taking to correcting deficiencies in environmental legislation. However, these measures are aimed solely at translating the existing EU regime into a domestic UK context and we have not undertaken any focussed engagement on this basis.

7. Any other impact assessments

On the basis that the proposals transfer existing policy into a domestic context and do not constitute a policy change, no impact assessment has been prepared. These specific measures are aimed at easing the transition for business.

8. Summary of reasons for Scottish Ministers proposing to consent to UK Ministers legislating

This instrument addresses two issues identified in the UK REACH regime. The existing REACH provisions operate at EU level and the supporting domestic provisions were made at the UK level to reflect overlapping reserved and devolved responsibilities. In light of this, and the UK-wide nature of the proposed regime, it is most effective to make the changes to address deficiencies at UK level. Officials have worked with Defra to ensure the drafting delivers for our interests and respects devolved competence in Scotland.

9. Have Scottish Ministers had regard to the guiding principles on animal welfare and the environment?

Yes. The guiding principles on the environment as set out in Articles 13 and 191(2) in Titles II and XX respectively of the Treaty on the Functioning of the European Union are relevant to these proposals. The existing EU REACH regulation and the domestic legislation relating to it are already in line with these principles, and it is considered that these amendments are in adherence with these principles.

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

Scottish Ministers are consulting on the governance gaps that will be created once the UK leaves the EU, with a view to bringing proposals back to the Scottish Parliament on environmental governance arrangements once the future relationship is clear.

We remain engaged in framework discussions with all the administrations of the UK and the relevant regulators specifically looking at the regulation of chemicals and pesticides in the UK outside of the EU and its existing regimes.

The Scottish Government's position remains that future arrangements should be based on staying closely aligned with the EU chemicals regulatory regime and maintaining existing standards of protection for human health and the environment.

11. Intended UK laying date

Defra currently propose to make The REACH etc. (Amendment etc.) (Amendment) (EU Exit) Regulations 2019 under the negative procedure and to lay the SI for sifting on 2 April. However, it is possible that the sifting committee may recommend the SI is made under the affirmative procedure. In this event, and in order to ensure the SI is in place before a potential no deal EU Exit, Defra may lay the SI under the urgent made affirmative procedure as set out in Schedule 7, Part 1, paragraph 5 of the European Union (Withdrawal) Act 2018.

Unfortunately, we are unable to be more certain about the timing and procedure of this SI but an update will be provided to the Committee should there be a change in the planned laying date or procedure. Despite this uncertainty, it is anticipated that the content of the notification will remain unchanged.

12. Does the Scottish Parliament have 28 days to scrutinise?

The Regulations are considered to be critical to have in place for Exit Day to ensure the smooth operability of the UK REACH regime. The Scottish Government was only informed about the proposed amendments, and the necessity of them being in place for Exit Day, on 28 March.

To date we have been working with Defra on the basis that no negative EU Exit SIs would proceed to be made, until after they have been through the consent process agreed with the Scottish Parliament. However, in this instance due to the urgency of the Regulations and the limited time available before a potential no deal EU Exit, the Scottish Parliament will not have 28 days to scrutinise this proposal before the SI is made.

13. Information about any time dependency associated with the proposal?

These Regulations should be in force on Exit Day in the event of a no deal scenario to ensure that the chemical supply chain continues uninterrupted and that business have certainty about their obligations in the event of a no deal exit.

14. Any significant financial implication?

There are no significant financial implications for the Scottish Government associated with these proposals.

As set out in the notification on the original amending regulations, there is likely to be increased costs for stakeholders who have to re-register a substance in the UK REACH regime, having already met the associated costs in EU REACH.

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