

CHEMICALS - NOTIFICATION TO THE SCOTTISH PARLIAMENT

The REACH (Amendment) (EU Exit) Regulations 2019

1. Name of instrument and summary of proposal:

The REACH (Amendment) (EU Exit) Regulations 2019 will amend existing EU and domestic legislation enabling the UK to continue to regulate substances placed on the market above 1 tonne per annum. The purpose of this regime is to provide a high level of protection for human health and the environment, to facilitate the greatest possible information sharing at all levels within the supply chain and to reduce animal testing. REACH stands for the Registration Evaluation Authorisation and restriction of Chemicals. This instrument aims to build a 'UK REACH system' which mirrors as closely as possible the current arrangements under EU REACH.

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

Controls on the use of chemicals 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 was introduced in 2007 and at the time was described as the most complex piece of legislation in the EUs history. This regulation established the European Chemicals Agency (ECHA) which occupies a central role in the regulation of chemicals across all 28 Member States.

The EU REACH Regulation creates a single market mechanism to promote the safe production, transport and use of chemicals to manage potential impacts on human health and the environment. There is a "no data, no market" rule, with industry responsible for providing the ECHA with data relating to the chemicals they use. Industry is also responsible for managing the risks from their use of chemicals. Decisions made under the EU REACH Regulation include the authorisation of chemicals for particular purposes and limiting or banning the placing on the market or use of specific substances. The REACH (Amendment) (EU Exit) Regulations 2019 are necessary to ensure the UK has an effective system of chemicals regulation after leaving the EU.

Under the new UK REACH regime, the functions of ECHA will be carried out by the Health and Safety Executive (HSE) (which already exercises some functions under the EU REACH Regulation), making use of their existing capacity and experience of carrying out this technical work. The HSE must take advice from the Environment Agency, who in turn must collaborate with and pass on any advice received from the Scottish Environment Protection Agency, when exercising functions involving the consideration of environmental issues. The HSE are also under an obligation to take into account relevant scientific knowledge and advice when forming opinions and recommendations. The devolved administrations may initiate the preparation of a dossier by the HSE for the inclusion of a substance on the lists of substances subject to authorisation or restrictions.

The EU REACH Regulation established a Board of Appeal within ECHA to hear appeals against Agency decisions. The decisions, which may be subject to appeal,

include specifying conditions on the manufacturer, importer or producer of a substance for the protection of workers and the environment and other issues. Since 2009, the Board of Appeal within ECHA has issued decisions in 148 appeals emanating from 28 Member States. The instrument does not continue with an appeal body within the UK Agency. Instead, it transfers the role of hearing appeals against the Agency's decisions to the First Tier Tribunal. The Tribunal has the power to dismiss an appeal, remit the decision back to the Agency for reconsideration, or to substitute its own decision.

Decisions currently taken by the European Commission will be transferred to institutions within the UK. Ministerial powers will transfer to the UK Secretary of State, who will need the consent of the Devolved Administrations to take decisions in areas of devolved competence. These powers include decisions on the restriction of chemicals, adding substances to the authorisation list and granting authorisations, as well as the powers to amend the Annexes of REACH. Devolved Administrations will be able to take urgent provisional action in relation to a substance of concern in their own nation. The urgent action must be followed up through the REACH restriction procedure to assess whether it is appropriate to apply a UK-wide control. Such UK measures will be taken by the Secretary of State acting with the consent of the Devolved Administrations. Within the new UK regime, the Health and Safety Executive will take on a role equivalent to that currently performed by the European Chemicals Agency in the EU regime.

The instrument amends the definition of dutyholders such as manufacturers, importers and downstream users. They are now defined as being established in the United Kingdom rather than established in the Community.

The instrument provides for the automatic transfer of existing REACH registrations held by UK based companies, including UK-based "Only Representatives", into the REACH regime with no break in their validity. An Only Representative in the EU REACH Regulation is natural or legal person established within the EU, who is appointed by mutual agreement with a natural legal person established outside of the EU, to fulfil obligations under EU REACH of the non-EU based entity. The effect is that UK registrants and their access to the UK market is legally secure. The automatic transfer of UK registrations is extended to any registration held by UK companies in the two years up to exit. Companies will require to submit basic data to the HSE within 60 days to support the transfer, with the full data package, appropriate to the registrant's tonnage band, being submitted to the HSE within two years

UK companies who sourced substances from suppliers in the rest of the EU (known as downstream users) are not under an obligation to register the substance they use under the EU REACH Regulations. However, these UK companies will become importers into the UK market after exit and will be required to register the substance(s) they import. Transitional support is available to these companies through an interim notification system instead of requiring a full registration in the first instance. The interim notification must be converted into a full registration after two years. The EU REACH regime depends on a IT system known as REACH IT. A similar UK IT system is being built to facilitate the operation of the UK REACH regime, allowing UK companies to upload the data required of them.

The instrument also makes minor and technical changes to ensure the effective operation of the new UK REACH regime post-exit. The EU REACH Regulation cross-refers to a number of other pieces of EU legislation. The instrument amends cross references, which would be deficient post exit. Amounts specified in Euros are to be converted into pound sterling and references to the single market are amended so that the legislation operates by reference to the UK.

The instrument also amends domestic legislation, which implemented the EU REACH Regulations in the UK. The REACH (Appointment of Competent Authorities) Regulations 2007, which are UK-wide regulations that appoint the Competent Authorities for the purposes of the EU REACH regulation for England, Wales and Northern Ireland. The Competent Authority for Scotland is not designated in these domestic regulations as a decision was taken to do so administratively. The proposal is to revoke The REACH (Appointment of Competent Authorities) Regulations 2007. The effect of this, together with the removal of references to the Competent Authority within the new UK REACH regime, is to remove the role of Competent Authority in UK REACH. This is being done on the basis that is not appropriate in a UK-only REACH regime. Retaining the role of the Competent Authority, would create a situation whereby the HSE is asking for advice from itself. In Scotland, the Competent Authority for devolved matters is the Scottish Ministers and the Secretary of State for the Department for the Environment Food and Rural Affairs for reserved matters. HSE are also the UK Member State Competent Authority, a role which will become defunct when the UK is no longer an EU Member State. Those functions of the Competent Authority, which continue to be relevant under new UK REACH regime, have been transferred to the HSE, in their capacity as the UK Chemicals Agency, from the Secretary of State and the Devolved Administrations. Ministers in all of the administrations have always delegated their functions as a Competent Authority to the Health and Safety Executive (HSE) by Agency Agreement. Officials in all administrations have agreed that there should be no reduction in the capability of any devolved administration to act as a result of the Competent Authority role being removed in UK REACH. The instrument provides levers by which Devolved Administrations can request and access the same information or initiate processes by HSE, as the UK Chemicals Agency, as they could using their Competent Authority title under EU REACH. These levers are likely to be supplemented by a common framework for the regulation of Chemicals and Pesticides in the UK once the UK withdraws from the EU.

The REACH Enforcement Regulations 2008 are UK-wide regulations which created a UK enforcement regime as required by Article 126 of the EU REACH regulation. These regulations set out who is responsible for enforcing EU REACH, their powers of enforcement, and a list of offences along with the penalties for non-compliance. In Scotland, enforcement duties sit with either Local Authorities, the Scottish Environment Protection Agency (SEPA) or the Health and Safety Executive. The existing enforcing authorities throughout the UK will continue their roles after exit. The instrument establishes new enforcement duties with regard to the data requirements in the transitional provisions, which are enforceable by the HSE.

3. Why are these changes necessary?

The instruments in question are necessary to correct deficiencies arising from the UK's withdrawal from the EU and allow the continued and effective function of both domestic and retained EU law.

In the EU, the overall regulation of Chemicals is provided for by a range of legislative instruments. The REACH regulation is central to the overall chemicals regulatory regime, and establishes ECHA who provide scientific and technical advice on decisions, such as whether a substance should be subject to specific control measures. It is necessary to ensure that a body is identified within the UK, equipped with the necessary resources and expertise to provide such advice when the UK is no longer an EU Member State.

The legislation is important in order to protect human health and the environment, and to facilitate trade. The majority of chemicals legislation is directly applicable EU law. The domestic legislation, which implements the EU legislation, is UK-wide. After exit the directly applicable EU chemicals regulations will become retained EU law. The current approach to the regulation of chemicals has been a consistent and coherent EU-wide approach. The Scottish Government considers there is a continuing value in maintaining a consistent and coherent approach within the UK following EU Exit. Devolution is respected in the new UK REACH regime. The Devolved Administrations will be able to initiate processes leading to the authorisation or restriction of chemicals under the new UK REACH regime and will be able to take urgent safeguarding measures in their own territories. The Secretary of State will only be able to exercise functions in devolved areas with the consent of the Devolved Administrations.

4. Scottish Government categorisation of significance of proposals

Category B. We consider that the overall intention of the approach taken by the UK Government in drafting this instrument is to replicate the existing EU regime within the UK and to avoid introducing any substantive policy changes. Instead 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.

Nevertheless, this is one of the most substantial pieces of legislation needed to address the consequences of EU exit.

5. Impact on Devolved Area

Chemicals policy engages a complex mixture of reserved and devolved competence. Environmental protection, waste management and public health are devolved while product standards, consumer protection, animal testing and health and safety at work are reserved. Reserved and devolved interests are heavily intertwined in REACH.

Taking the current EU REACH regime as a starting point, there are no significant impacts on devolved competence envisaged as a result of this instrument given its intention in maintaining current arrangements as much as possible. Scottish Ministers are likely to be given greater influence over and sight of decisions taken by HSE on a UK-wide basis.

6. Stakeholder engagement/consultation

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

The UK Government are of the view that as this legislation does not produce any significant practical change, formal stakeholder or public consultation is not necessary. However, they have had a consistent programme of informal consultation with stakeholders through existing fora alongside engagements stemming from the decision to exit from the EU. Part of Defra's 'operational readiness' planning has been to build a UK REACH IT system to replace the current EU version used by organisations established in EU Member States, this has included demonstrations and invitations to participate in stress testing of the system as it develops.

A number of the stakeholders in this area are UK- or EU- wide, such as trade bodies, and they have been clear and consistent that they wish to see the regulatory systems of the EU-27 and the UK remain highly aligned post-Brexit.

7. Any other impact assessments

On the basis that this aims to translate existing policy into a domestic context, there is not a requirement to undertake any impact assessment.

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

The existing 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, and so Scottish Ministers propose to agree to a UK approach for these deficiencies.

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?

Later this year, Scottish Ministers will consult 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 medium and long term governance arrangements once the future relationship is clear.

We have been 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 regime. These framework discussions are progressing. The Scottish Government's position is that these 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

These instruments are subject to the affirmative procedure and will be laid in Westminster on 9 January. Defra have agreed that no EU Exit SIs will proceed to be made (for negative procedure SIs), or laid in draft (for affirmative SIs), until after they have been through the consent process agreed with the Scottish Parliament.

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

Yes

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

It is essential that the Regulations are in force on the day we exit the EU in the event of a no deal scenario to ensure that legislation is operable to allow continued high levels of protection for human health and the environment, continued facilitation of trade and continued supply of chemicals between the UK and the EU.

14. Any significant financial implication?

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

While the regulations provide for the greatest possible continuity of the current regulatory landscape, the new IT UK REACH IT system has estimated building cost

of £5.6 million which has been met by the UK Government, and will have ongoing running costs. There is also 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.

15. Additional Information to Note

Similar notifications have already been passed to the committee on the intention to consent to Statutory Instruments on Persistent Organic Pollutants (POPs) and Mercury with a further notification being prepared to deal with deficiencies in the Biocidal Products, Classification, Labelling & Packaging and the Prior Informed Consent regulations. All of these regulations exist as a package which form the current EU Chemicals regulatory regime.

Lead Official: Jason Sharp
Environmental Quality and Circular Economy Division
Tel: 0131 244 2040