

PROPOSED REPLACEMENT EU ACT

INITIAL ASSESSMENT OF IMPACT

Date: 11/09/2025

DSC REF: DSC/15a/2025

Proposed Replacement

Proposal for a [REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Chemicals Agency and amending Regulations \(EC\) No 1907/2006, \(EU\) No 528/2012, \(EU\) No 649/2012 and \(EU\) 2019/1021.](#)

This regulation will amend the following Regulations,

- [Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 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 2000/21/EC.](#) Listed in Annex 2 of the Windsor Framework, Heading 23 on chemicals and related.
- [Regulation \(EC\) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.](#) Listed in Annex 2 of the Windsor Framework, Heading 24 on pesticides, biocides.
- [Regulation \(EU\) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals \(recast\).](#) Listed in Annex 2 of the Windsor Framework, Heading 23 on chemicals and related.
- [Regulation \(EU\) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants \(recast\).](#) This legislation is a recast of Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC which is listed in Annex 2 of the Windsor Framework, Heading 23 on chemicals and related.

Summary of the Act

This regulation is linked to the EU's "One Substance, One Assessment" package which aims to streamline assessments of chemicals across EU legislation,

strengthen the knowledge base on chemicals and ensure early detection and action on emerging chemical risks. As part of this, significant tasks will be reallocated and consolidated between four EU agencies, including the European Chemicals Agency (ECHA), to ensure coherent and transparent safety assessments of chemicals.

The Regulation makes the following specific changes:

- Strengthening the capacity of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC).
- Reallocating the Scientific Committee on Consumer Safety (SCCS) from the European Commission to ECHA and clarifying its remit. With this reallocation, SCCS will be a standalone committee of the Agency, similar to RAC, SEAC and the Biocidal Products Committee (BPC).
- Contribution of SEAC to the work of the BPC on the assessment of active substances.
- Enhancing cooperation across EU agencies and across different EU chemicals regulations.
- Formalising ad hoc agreements to form part of ECHA's mandate (such as European Observatory for Nanomaterials, EU Chemicals Legislation Finder, Occupational Exposure Limits).
- Participation of ECHA in research in the framework of EU research programmes.
- Obliging Member States to nominate at least two members for RAC and two members for SEAC to respond to increased workload and representation at Management Board.
- Increasing the sustainability of ECHA's financial model by removing segregation of budgets across different pieces of legislation.
- Providing a legal framework to manage the tasks across different pieces of legislation and ensure consistency, efficiency, and transparency of chemical assessments across legislation implemented by ECHA.
- Enhancing ECHA's cooperation with other EU agencies, to avoid divergent scientific opinions and to foster assessments in line with the 'One Substance, One Assessment' approach.

Department(s) Responsible

Responsibility for this Regulation is shared in Northern Ireland between the Department of Agriculture, Environment and Rural Affairs (DAERA) and the Department for Economy (DfE) as follows:

- **DAERA** and **DfE** share competence for Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

- **DfE** has competence for Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR).
- While **DfE** leads on Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (Prior Informed Consent - PIC) for Northern Ireland this remains a reserved matter.
- **DAERA** has competence for Regulation (EU) 2019/1021 on persistent organic pollutants (POPs).

Responsibility in GB for the primary chemicals regimes is split between the Secretary of State for Environment, Food and Rural Affairs (REACH & POPs) and the Health and Safety Executive (Classification, Labelling and Packaging (CLP), BPR & PIC).

Initial Assessment of Impact

The proposed regulation aims to update and strengthen the EU's system for regulating chemicals, giving ECHA a more central and clearly defined role in managing chemical risks and promoting a sustainable chemicals industry.

As this Regulation concerns the re-organisation of internal EU institutional and regulatory management structures, there are no anticipated direct effects or implications for Northern Ireland. It is therefore our assessment that the application of the proposed replacement act would not have a significant impact to everyday life of communities in Northern Ireland in a way that is liable to persist.

As above, as this Regulation concerns the re-organisation of internal EU institutional and regulatory management structures, there are no anticipated direct effects or implications for Northern Ireland. However, if the Regulation did not apply here, it is unclear if this would have any impact for Northern Ireland's interaction with the affected EU institutions. As such, our assessment is that it is unclear if not applying the proposed replacement act would have a significant impact to everyday life of communities in Northern Ireland.

The legal basis of the proposal is Article 114 of the Treaty of the Functioning of the EU. In order for this Regulation to effectively govern ECHA, consequential amendments are necessary to delete the corresponding provisions concerning the establishment, governance and management of ECHA which were previously included in Regulation (EC) No 1907/2006 and Regulation (EU) No 528/2012.

Creating a more coherent legislative foundation for ECHA and its activities should reinforce the EU's 'One Substance, One Assessment' package and in turn provide a clearer regulatory structure for NI companies complying with EU legislation as well as GB companies trading into the EU market.

UK Government Explanatory Memorandum

ECHA ("the Agency") was originally set up under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) but over time its responsibilities have grown to encompass additional areas of chemical regulation such as Classification, Labelling and Packaging (CLP), Biocidal Products Regulation (BPR), Persistent Organic Pollutants (POPs) and Prior Informed Consent (PIC). The "One Substance, One Assessment" package will also see ECHA take on new tasks. To accommodate this and ensure ECHA can effectively carry out its responsibilities across a range of chemical regimes, this proposal will establish a dedicated regulation for ECHA which will provide an autonomous legal framework and enhance its governance.

The Regulation also outlines amendments to improve the consistency of safety assessments, efficiency of underlying technical and scientific work, and consistency of transparency rules.

Analysis by the European Commission on its Impact Assessment

An impact assessment was not required for this proposal since assessments were carried out by the Commission in the context of the revisions of some of the other EU legislation which assign tasks to the Agency, among others the revision of the CLP Regulation and the proposed Toys Regulation.

Departmental Engagement

Officials in relevant departments, namely the Department of Agriculture Environment and Rural Affairs, the Department for Economy, and the Health and Safety Executive Northern Ireland were consulted during the preparation of the Department for Environment, Food & Rural Affairs (Defra) explanatory memorandum (EM) for the proposal.