EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION/DOCUMENTS WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK

COM (2025) 386 FINAL + ANNEXES 1 to 2

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

Submitted by the Department for Environment, Food and Rural Affairs on
21 August 2025

SUBJECT MATTER

1. 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.

2. 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. It also amends four regulations:

    - Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
    - Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products
    - Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (Prior Informed Consent - PIC)
    - Regulation (EU) 2019/1021 on persistent organic pollutants

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

4. As set out in the European Commission's proposal 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.
    - Obligating 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 (EFSA, EU-OSHA, EMA and EEA) to avoid divergent scientific opinions and to foster assessments in line with the 'One Substance, One Assessment' approach.

SCRUTINY HISTORY

5. The Parliamentary scrutiny history relevant to this Explanatory Memorandum is contained in Annex A.

MINISTERIAL RESPONSIBILITY

6. 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 (CLP, BPR & PIC).

INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)

7. In Northern Ireland (NI), EU REACH and other EU chemicals legislation continue to apply in NI. The Department of Agriculture, Environment and Rural Affairs (DAERA) and Department for Economy (DfE) are the policy leads on chemicals. The enforcing authorities for REACH provisions are the NI Environment Agency (NIEA), Health and Safety Executive for Northern Ireland (HSENI), and local authorities/district councils. HSENI are the Competent Authority for REACH.

8. Devolved Governments have reviewed this Explanatory Memorandum and did not have any comments.

LEGAL AND PROCEDURAL ISSUES

9.

i. Legal Base

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.

The amendments are as follows:

- Regulation (EC) No 1907/2006 on the REACH - corresponding provisions deleted.
- Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products - deleting requirement for segregation of budgets and enabling the Committee for Socio-economic Analysis to contribute to the Biocidal Products Committee.
- Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (Prior Informed Consent - PIC) - deleting requirement for segregation of budgets.
- Regulation (EU) 2019/1021 on persistent organic pollutants - deleting requirement for segregation of budgets.

ii. Voting Procedure

The voting procedure for the new Regulation was by ordinary legislative procedure whereby both the Council of EU and European Parliament jointly agree legislation.

iii. Timetable for adoption, entry into force and full application

The Regulation shall enter into force on the twentieth day following its publication in the Official Journal of the European Union. It shall apply from one year from the date of entry into force. Article 29(5) and (6), Article 49(3) and Articles 50 and 51 shall apply from 1 January 2028. This should be deferred to the date of application of the post-2027 Multiannual Financial Framework to allow alignment with the next Multiannual Financial Framework.

POLICY AND LEGAL IMPLICATIONS

10. ECHA was created and set up under EU REACH, but as the agency has taken on more responsibilities under later EU legislation, e.g. CLP, biocides and POPs, this arrangement is increasingly struggling under the strain. In addition, there are some tasks that the European Commission has asked ECHA to take on that are not adequately backed up by legislation.

11. The proposal for a standalone regulation for ECHA should resolve these issues and make ECHA's work more effective and coherent.

12. The proposed measures are not anticipated to create costs for UK businesses or have any significant economic impact. 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.

13. As this Regulation seeks to lead to the re-organisation of internal EU institutional and regulatory management structures, we do not anticipate there to be any negative effects or implications for NI.

14. ECHA should be able to operate more efficiently as a result of these changes and Northern Ireland should benefit from this.

CONSULTATION

15. Stakeholder consultations undertaken by the EU as part of the second REACH review (which covered review of ECHA) showed general support from businesses, trade bodies, Non-Governmental Organisations and other stakeholders such as Member States and EU agencies.

FINANCIAL IMPLICATIONS

16. Costs associated with this proposal would be incurred at the EU level and not directly assigned to individual Member States or NI. ECHA's activities are partially funded through fees and charges on industry, where there should be benefits from a more efficient Agency.

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ANNEX A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A:

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

COM(2023) 781 FINAL: PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS THE RE-ATTRIBUTION OF SCIENTIFIC AND TECHNICAL TASKS TO THE EUROPEAN CHEMICALS AGENCY

COM(2023) 783 FINAL : PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATIONS (EC) NO 178/2002, (EC) NO 401/2009, (EU) 2017/745 AND (EU) 2019/1021 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS THE RE-ATTRIBUTION OF SCIENTIFIC AND TECHNICAL TASKS AND IMPROVING COOPERATION AMONG UNION AGENCIES IN THE AREA OF CHEMICALS

Proposal COM(23)781 (alongside COM(23)783) was not deposited for scrutiny by the Parliamentary EU Select Committees following a decision by the Committee clerks that an EM was not required as the two proposals were “entirely about increasing the efficiency of EU internal processes and should be no impact on NI under the Windsor Framework."