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

DIRECTIVE (EU) 2025/2456 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 26 NOVEMBER 2025 AMENDING DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS THE REATTRIBUTION OF SCIENTIFIC AND TECHNICAL TASKS TO THE EUROPEAN CHEMICALS AGENCY

REGULATION (EU) 2025/2457 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 26 NOVEMBER 2025 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 REATTRIBUTION OF SCIENTIFIC AND TECHNICAL TASKS AND IMPROVING COOPERATION AMONG UNION AGENCIES IN THE AREA OF CHEMICALS

Submitted by the Department for Environment, Food and Rural Affairs on 06 January 2026

SUMMARY MATTER

1. The two legislative acts form a core part of the European Union's "One Substance, One Assessment" package, part of the Chemicals Strategy for Sustainability. The overarching goal of the package is to streamline the EU's chemical risk assessment framework by reducing duplication, ensuring consistency and transparency, and by fully utilising the use of scientific expertise and resources across EU legislation.

2. Both the Directive and Regulation aim to re-attribute scientific and technical tasks and enhance cooperation among EU agencies dealing with chemicals. The proposals outline procedural changes for evaluating exemption requests and reviewing substance restrictions giving the European Chemicals Agency (ECHA) and its scientific committee a formal role in these processes.

<u>Directive (EU) 2025/2456</u>

3. The Directive amends Directive 2011/65/EU (The Restriction of Hazardous Substances Directive also referred to as RoHS), which regulates the use of 10 hazardous substances in electrical and electronic equipment. The amendment reassigns the scientific and technical tasks, currently handled by the European Commission, to the European Chemicals Agency (ECHA). This aligns the RoHS restriction process with equivalent processes under EU legislation concerning Registration, Evaluation, Authorisation, Evaluation, Authorisation and Restriction of Chemicals (also known as REACH).

4. This Act outlines the procedural changes for evaluating exemption requests and reviewing substance restrictions, giving ECHA and its scientific committees a formal role in these processes. There is a twenty-month transitional period before ECHA takes on the new responsibilities.

Regulation (EU) 2025/2457

5. The Regulation amends four distinct pieces of EU legislation to reallocate tasks and improve inter-agency cooperation. These are:

    a. Regulation (EC) No 178/2002 (general food law and the European Food Safety Authority) - this introduces a legal obligation for the European Food Safety Authority (EFSA) to cooperate with ECHA, including on data exchange, harmonisation of assessment methodologies, and resolving divergent scientific opinions in the area of chemicals.
    b. Regulation (EC) No 401/2009 (European Environment Agency) – introduces obligations for the European Environment Agency (EEA) to cooperate with ECHA and EFSA on chemicals assessments, data and methodologies.
    c. Regulation (EU) 2017/745 (medical devices) – this reattributes tasks regarding the assessment of chemical substances in medical devices to ECHA, including substances (other than phthalates) that are classified as carcinogenic, mutagenic, or toxic to reproduction (CMR) Category 1A or 1B; and substances which have endocrine-disrupting properties.
    d. Regulation (EU) 2019/1021 (persistent organic pollutants) – this reattributes tasks for ECHA and the Commission concerning persistent organic pollutants in waste.

SCRUTINY HISTORY

6. There has been no previous scrutiny of these legislative acts, though the changes are linked to the European Commission's Communications on Chemicals Strategy for Sustainability, and "One Substance, One Assessment".

7. The Department for Environment, Food and Rural Affairs submitted an explanatory memorandum COM (25) 386 **regarding 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** on 21 August 2025, which is linked to the "One Substance, One Assessment" package and reflects ECHA's role in supporting scientific tasks across various areas of EU legislation.

MINISTERIAL RESPONSIBILITY

8. Responsibility for chemicals policy in England is split. The Secretary of State for Environment, Food and Rural Affairs is responsible for RoHS and Persistent Organic Pollutants, as well as environmental legislation. The Secretary of State for Health and Social Care is responsible for the regulation of medical devices. The Food Standards Agency is responsible for food safety regulation.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

9. Chemicals policy engages a mix of reserved and devolved competence in Great Britain (GB), and the proposed EU delegated act will apply fully in Northern Ireland (NI) under the terms of the Windsor Framework. Environmental protection and public health are devolved to Scotland, Wales and Northern Ireland. Scottish, Welsh and Northern Ireland Ministers therefore have an interest in elements of chemicals regulation that affect these.

10. The devolved governments have been consulted in the preparation of this Explanatory Memorandum and raised no concerns.

LEGAL AND PROCEDURAL ISSUES

11.

i. **EU Legal Base**

Article 114 of the Treaty on the Functioning of the European Union, which allows the European Parliament and the Council to adopt measures to establish and ensure the proper functioning of the EU Single Market.

ii. **Voting Procedure**

The Parliament adopted its position (the final text) for both acts by a **simple majority of votes cast** in the plenary session of 21 October 2025, by ordinary legislative procedure.

iii. **Timetable for adoption and implementation**

Both the Directive and Regulation shall enter into force on the twentieth day following its publication in the Official Journal of the European Union. The Directive shall apply from 13 August 2027, whereas the Regulation is directly applicable from 1 January 2026.

POLICY AND LEGAL IMPLICATIONS

12. These changes support the EU's 'one substance, one assessment' initiative, which seeks to streamline chemical safety evaluations, improve transparency around

chemical approvals, and ensure consistency across EU legislation, particularly aligning with the EU Restriction, Evaluation and Authorisation of Chemicals (REACH) Regulation. The changes should improve timescales for consideration of RoHS exemption applications.

13. The acts include a 12 month transition period (20 months for RoHS) and modest resource increases for ECHA. The initiative is expected to enhance scientific quality, reduce duplication, and make better use of existing data. Stakeholder consultations showed general support, despite some concerns being raised about ECHA's capacity and the need for additional expertise in electronics and waste management.

14. The reattribution of scientific and technical tasks and improving cooperation among EU agencies in the area of chemicals are purely administrative changes. It is not expected to have an impact on the supply of goods to Northern Ireland, including medical devices.

CONSULTATION

15. There has been no public consultation by Defra on the impact of this Commission proposal as it relates to internal procedural changes within ECHA that do not apply to GB as a result of the UK's withdrawal from the EU but will apply automatically in Northern Ireland to facilitate its dual market access under the Windsor Framework.

FINANCIAL IMPLICATIONS

16. The proposal outlines a modest increase in EU-level resources (an additional 4.3 FTE and €33,000 annually from 2026 onward) to support ECHA's new responsibilities. These costs are at EU level and not directly assigned to any individual Member state, or Northern Ireland.

17. There is potential for some Northern Ireland-based stakeholders to experience indirect costs or benefits depending on how the new procedures affect compliance, transparency and efficiency with the EU's new system.

18. Overall, we expect the changes introduced by the legislative acts to make ECHA's work more effective and coherent. As the acts are primarily tasked with reorganising internal EU institutional and regulatory management structures, we do not anticipate there to be any negative effects or implications for Northern Ireland.

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