PUBLISHED AMENDING EU ACT
ASSESSMENT OF IMPACT

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Published Amending EU Act

Directive (EU) 2025/2456 of the European Parliament and of the Council of 26 November 2025 amending Directive 2011/65/EU as regards the reattribution of scientific and technical tasks to the European Chemicals Agency. OJ L 2025/ , 12.12.2025 – Directive (EU) 2025/2456.

This Directive applies from 13.08.2027 and amends Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Annex 2 – Heading 23 – Chemicals and related) - Directive 2011/65/EU.

Summary of the Act

This Directive 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 ("the Agency"), to ensure coherent and transparent safety assessments of chemicals.

The Directive follows the one substance, one assessment approach and provides for a limited amendment of Directive 2011/65/EU in order to allocate the existing scientific and technical tasks, in respect of the restriction of the use of certain hazardous chemicals, to the Agency. The objectives of the Directive are to ensure that:

- allocation of responsibilities for performing the assessments and the underlying technical and scientific work on chemicals is clear, exploits and maximises synergies and makes the best use of available expertise and resources;
- deliverables are of high scientific quality and the procedures are transparent and inclusive.

Summary of the main changes from the existing legislation:

- revised application procedure, with new and revised timelines, whereby an application for granting, renewing or revoking an exemption must be made to the Agency, rather than the Commission;
- requirement for the Agency to request the opinion of various EU committees in the case of an application for a new exemption, or where otherwise considered appropriate;
- requirement for the Commission to undertake a review of the list of restricted substances, based on restriction dossiers prepared by the Agency, listed in Annex 2 to Directive 2011/65/EU, at least every 4 years;
- initiation of a procedure for review and amendment of the list of restricted substances, listed in Annex 2 to Directive 2011/65/EU (the "restriction process").

Department(s) Responsible

The Department for Environment, Food and Rural Affairs is the lead department for Directive (EU) 2025/2456; as the restriction of the use of certain hazardous substances in electrical and electronic equipment is reserved to the UK Government.

Assessment of Impact

The application of Directive (EU) 2025/2456 is not likely to have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist. This Directive concerns increasing the efficiency of EU internal processes and should not impact on Northern Ireland.

Non-application of Directive (EU) 2025/2456 is not likely to have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist. Decisions on granting, renewing or revoking an exemption would merely continue to be undertaken by the Commission, under the current legislative framework.

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. It is relevant, however, that none of the costs or benefits will be incurred due to any additional barriers to trade.

The UK regulatory framework is based on assimilated law. In Northern Ireland the requirements and processes exactly match those in the EU. In Great Britain decisions on granting, renewing or revoking an exemption closely align with decisions taken by the EU. Although the adoption of Directive (EU) 2025/2456 will result in additional regulatory divergence, there are no operational impacts.

UK Government Explanatory Memorandum

Initially, the proposal for this Directive (COM(2023) 783 FINAL) 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 proposal was "entirely about increasing the efficiency of EU internal processes and should be no impact on NI under the Windsor Framework" (see page 6 of the linked explanatory memorandum below).

Explanatory Memorandum for EU legislation/documents within the scope of the UK/EU Withdrawal Agreement and the Windsor Framework

However, the UK Government recently drafted an explanatory memorandum and opined the reattribution of scientific and technical tasks is purely administrative and is not expected to have an impact on the supply of goods to Northern Ireland, including medical devices. Although the explanatory memorandum has not yet been published, a copy has been provided to the Committee.

There was no public consultation by Defra on this Directive as it relates to EU internal procedures. The UK Government concluded that, "… 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.".

Analysis by the European Commission on its Impact Assessment

Although the Commission states that reallocation of scientific and technical work to the Agency will improve the efficiency, consistency, quality and transparency of processes, it decided that a formal impact assessment was not required, given there is little discretion of the policy choice to achieve the stated objectives of the Directive.

EU Impact Assessment

It was recognised that the "one substance, one assessment" package will have a major impact on EU agencies' resource and capacity needs and an assessment was drafted as part of a Commission Staff Working Document (SWD (2023) 850) examining the impact on various EU agencies. With regard to the impact of the legislative proposals (including Directive (EU) 2025/2026), on the reattribution of tasks, it concluded that the "…proposal is expected to improve the efficiency, effectiveness, coherence and transparency of EU processes for chemical assessments for the benefit of all stakeholders. Citizens and the environment will benefit from better protection from dangerous chemicals as a result of more efficient and effective assessment processes.".

COMMISSION STAFF WORKING DOCUMENT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council amending… Directive 2011/65/EU… as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency

There was no evidence within either of the EU assessments of Northern Ireland stakeholders having any input.

Departmental Engagement

DAERA has not engaged with any stakeholders on this Directive. DAERA engages, as required, with colleagues in Defra on matters related to the grant, renewal or revocation of an exemption, in respect of the restriction of the use of certain hazardous substances in electrical and electronic equipment.