PUBLISHED AMENDING EU ACT
ASSESSMENT OF IMPACT

DSC REF: DSC/02/2026
Date: 05/01/26
Department: DAERA

Published Amending EU Act

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 as regards the reattribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals.
OJ L, 2025/2457, 12.12.2025

Amending

- **Regulation (EC) No 178/2002:** this establishes the general principles and requirements for food law in the EU, ensuring food safety and the establishment of the European Food Safety Authority (EFSA)
- Regulation (EC) No 401/2009: this establishes the European Environment Agency and the European Information and Observation Network
- Regulation (EU) 2017/745: known as the Medical Device Regulation (MDR), establishes a comprehensive framework for the regulation of medical devices in the European Union, ensuring high standards of safety and health
- Regulation (EU) 2019/1021: aims to protect human health and the environment by prohibiting and restricting the production and use of persistent organic pollutants (POPs)

Summary of the Act

Scientific and technical work on chemicals performed at a European Union level in this field needs to be consolidated in the relevant Union agencies, with obligations for them to work together in developing assessment methodologies and exchanging data and information introduced. This aims to simplify the current framework, improve the quality and coherence of safety assessments across Union legal acts and ensure that existing resources are used more efficiently.

This act forms 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.

Regulation (EC) No 401/2009 is not covered by the Windsor Framework and as such does not apply in Northern Ireland. DAERA does not have policy responsibility for Regulation (EC) No 178/2002 or Regulation (EC) No 2017/745.

DAERA does have policy responsibility for Regulation (EU) 2019/1021 and is the Competent Authority with responsibility for enforcing the EU POPs Regulation.

POPs are forever chemicals that do not break down in the environment and can travel long distances. This allows them to bioaccumulate in humans and large mammals causing health impacts. This regulation will reattribute tasks for the European Chemicals Agency (ECHA) and the Commission concerning persistent organic pollutants in waste.

Department(s) Responsible

DAERA is the lead Northern Ireland Department on Regulation (EU) 2019/1021.

Assessment of Impact

This amending Act, as it relates to Regulation (EU) 2019/1021, is unlikely to have a significant impact specific to the everyday life of communities in Northern Ireland in a way that is liable to persist.

The Act will result in high level EU reattribution of scientific and technical tasks among EU Agencies and so will not have a direct impact on the communities of Northern Ireland.

If the Act is not applied in NI the consolidation of chemicals workstreams within EU Agencies will still occur. This is unlikely to have a significant impact specific to the everyday life of communities in Northern Ireland in a way that is liable to persist. However non-application is likely to cause legal and business confusion over the operation of chemicals legislation in Northern Ireland.

There is likely to be a modest increase in EU-level resources needed to support ECHA’s new responsibilities. These costs are at EU level and not directly assigned to any individual Member state, or Northern Ireland.

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.

Overall, it is expected the changes introduced by the legislative act will make ECHA’s work more effective and coherent. As the act is 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.

UK Government Explanatory Memorandum

Defra has drafted an Explanatory Memorandum and it is due to be signed by Defra Ministers.

Analysis by the European Commission on its Impact Assessment

An impact assessment was not carried out for Regulation (EU) 2025/2457. The consolidation of the technical and scientific work on chemicals at the EU level is possible only in the EU Agencies and not at member state level.

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

Departmental Engagement

DAERA engages, as required, with colleagues in the Northern Ireland Environment Agency (NIEA) and Defra on matters related to POPs on a regular basis, including of proposed changes to EU legislation.

Due to the high-level nature of the Act, there are no resulting actions or consequences for DAERA.