PUBLISHED REPLACEMENT EU ACT
ASSESSMENT OF IMPACT

DSC REF: DSC/02/2026
Date: 5 January 2026
Department: Department of Health (DoH)

Published Replacement 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. [link]

This regulation will amend Regulation (EU) 2017/745 as regards medical devices; Protocol Annex 2, Heading 21 on Medical Devices.

Summary of the Act

The European Union has developed a comprehensive regulatory framework for chemicals to ensure a high level of protection of human health and the environment from the harmful effects of chemicals and to support the efficient functioning of the internal market for chemicals while also promoting the competitiveness and innovation of EU industry. The framework consists of over 40 pieces of legislation addressing:

(i) the production and placing on the market of chemicals and products containing chemicals.
(ii) emissions of chemicals and safety of (iii) workers; (iv) consumer products; (v) food and feed stuff; (vi) and the environment.

This Regulation focuses on amending those pieces of legislation that are not currently being revised. It proposes targeted amendments to attribute tasks in Regulation (EU) 2019/1021 on persistent organic pollutants, and Regulation (EU) **2017/745 on medical devices**. The Regulation also amends Regulation (EC) No 401/2009 establishing the European Environmental Agency and Regulation (EC) No 178/2002 laying down the general principles and requirements of food law and establishing the European Food Safety Authority.

These amendments will ensure good cooperation among EU agencies on all aspects involving the consistency and efficiency of chemical assessments. These include the development of methodologies, data exchanges and reconciling divergence in scientific output.

Article 3 of the proposed regulation amends Annex I of **Regulation (EU) 2017/745** (the Medical Devices Regulation) to task the European Chemicals Agency (ECHA) with updating existing guidelines on conducting the risk-benefit assessment of the presence of phthalates in medical devices and scientific advice and guidance on specific substances which are carcinogenic, mutagenic or toxic to reproduction and substances which are classified as endocrine disruptors for human health.

DoH interest is limited to the amendments to **Regulation (EU) 2017/745.**

Department(s) Responsible

- **Department of Agriculture, Environment and Rural Affairs, Minister Muir (Lead)**
- **Department for Economy, Minister Archibald**
- **Department of Health, Minister Nesbitt (Interest)**

Assessment of Impact

Q: Does it appear likely that the application of the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

A: No.

Q: Does it appear likely that not applying the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

A: No.

UK Government Explanatory Memorandum

Not Available. DEFRA led at a UKG level; DoH officials have had no input, to date.

Analysis by the European Commission on its Impact Assessment

The European Commission considered impacts of this regulation for various key stakeholders but did not conduct a formal impact analysis. Considerations of impacts of the re-attribution of scientific and technical work related to chemicals to EU agencies, and regarding medical devices, specifically assessed the task created by the regulation as:

1) Preparation and review of the guidelines on how to perform the benefit-risk assessment of the presence of phthalates in medical devices;

2) Preparation and review of the guidelines on how to perform the benefit-risk assessment of the presence of CMR and endocrine disrupting substances in medical devices.

3) Ad hoc requests for opinion on safety of a chemical in medical devices (*not part of the proposal but possible based on general clause in ECHA founding regulation*).

The Commission's proposal with respect to medical device work would be requested of the ECHA and the overall assessment of impact to the ECHA was envisaged to be low/medium.

Departmental Engagement

DoH officials engage regularly with DHSC and MHRA colleagues in respect of medical devices, this remains ongoing.