

PROPOSED REPLACEMENT EU ACT INITIAL ASSESSMENT OF IMPACT

DSC REF: DSC/25a/2025

Proposed Replacement EU Act

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005 [\[link\]](#)

This Regulation will replace Regulation (EC) No 273/2004 [\[link\]](#) of the European Parliament and of the Council of 11 February 2004 on drug precursors: **Protocol Annex 2, Heading 23 on Chemicals and related**. The regulation will also replace Council Regulation (EC) No 111/2005 [\[link\]](#) of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors: **not listed in Protocol Annex 2**.

Summary of the Act

The general objective of this regulation is to modernise EU rules on drug precursor control, addressing the rise of “designer chemicals” and improving trade oversight while reducing the administrative burden for legitimate operators. Drug precursor chemicals (DPCs) are chemicals which may be used for the illicit manufacture of narcotic drugs or psychotropic substances. However, they can also have legitimate use. International duties to control DPCs are designated by the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (the 1988 Convention), to which the UK (and EU Member States) are a signatory.

The Convention establishes controls on DPCs to prevent the illicit manufacturing of drugs while also allowing for legitimate trade, delivered through a requirement for licensing and, additionally in some cases, for “pre-export notifications” (“PENs”) to the receiving country and export checks. The DPC control system is therefore one of international cooperation between exporting and importing jurisdictions to check that the receiving jurisdiction accepts the DPCs being imported, before export is permitted.

Regulation (EC) No 273/2004 of the European Parliament and of the Council lays down measures for monitoring trade in DPCs within the EU, while Council Regulation (EC) No 111/2005 governs trade in DPCs between the EU and third countries. The two Regulations jointly implement the measures envisaged by Article 12 of the 1988 Convention.

The proposed replacement EU Regulation consolidates and replaces Regulations (EC) No 273/2004 and (EC) No 111/2005 with a single, streamlined legal framework covering both internal and external trade.

The Regulation seeks to:

- Prevent diversion of chemicals into illicit drug production.
- Respond to evolving drug markets and novel precursors.
- Maintain compliance with the UN 1988 Convention.
- Facilitate legitimate trade and reduce administrative burden.

NB – The Home Office (HO) is the UK Competent Authority for DPC control. Advice and licensing of DPCs in Northern Ireland is led by the Home Office.

Department(s) Responsible

- **Department of Health (DoH)** – Minister Mike Nesbitt
- **The Home Office (HO)** - Secretary of State for the Home Department, The Rt Hon Shabana Mahmood MP

Initial Assessment of Impact

Q: Does it appear likely that the application of the proposed 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: Not known. DoH's current understanding is that there will not be a significant impact specific to the everyday life of communities in a way that is liable to persist in relation to the proposed amendment to Regulations (EC) No 273/2004 and (EC) No 111/2005. No practical impacts are anticipated for DoH.

Q: Does it appear likely that not applying the proposed 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: Not known. DoH's current understanding is that **non-application** of this proposed EU act will not significantly impact everyday life of communities in a way that is liable to persist. No practical impacts are anticipated for DoH.

UK Government Explanatory Memorandum

Not yet available. UK Government (UKG) colleagues at the Home Office are working to produce an explanatory memorandum (EM), as soon as practicable.

Analysis by the European Commission on its Impact Assessment

The European Commission (EC) conducted an extensive impact analysis process for various proposed policy options, producing a comprehensive impact analysis report attached as **Annex 1**. The impacts were assessed for each proposed policy option with stakeholder views and preferences integrated into the decision-making approach to the selection of the preferred policy option.

The EC evaluation of Regulations (EC) No 273/2004 and (EC) No 111/2005 (the EU drug precursor regulations) identified some deficiencies in them. Specifically, drug precursors continue to be available for the illicit production of drugs, increasingly in respect of designer precursors - substances that can be used as precursors and do not have a known legal use other than research and innovation. A further deficiency identified was that economic operators and public authorities engaged in the legal trade in the substances have to contend with unnecessary burdens and inefficiencies in performing their activities.

The EC clarifies their preferred option is to conduct a comprehensive review of the rules and merge the two drug precursor regulations. A new regime to ban a range of designer precursors would be introduced, with exemptions for small quantities if authorities are given advance notice. Larger quantities would require a licence. The obligations of economic operators would be adapted to reflect the risk of various transactions, avoid creating loopholes in the control regime and avoid imposing an unnecessary burden. Procedures would be fully digitalised which should lead to reduced administrative costs for operators and public authorities. This preferred option was chosen as it was deemed to address the risks of designer precursors and diversion without hampering legal trade, innovation and research.

The EC assessment of impact by stakeholder group for their preferred option suggested that both industry and Member States were supportive. The impact assessment considers that the preferred policy option would lead to a substantial decline in the trafficking of designer precursors and other non-scheduled precursors and a more robust supply chain control system. It would also entail quicker and more efficient processes that would be more harmonised and less prone to error. Lower compliance costs for economic operators to fulfil specific obligations were anticipated. The EC anticipated public authorities would benefit from more efficient processes reducing administrative costs by 25-50% and would reduce them altogether for export/import and annual reporting.

The impact assessment concluded EU countries may face some adaptation costs to adjust to new procedures, especially IT procedures; but will benefit from the removal of reporting requirements and from streamlined administrative procedures. The scheduling of designer precursors is expected to lead to some enforcement costs. Overall, it is anticipated that the proposal will result in reduced costs due to the simplification and automation of processes.

Departmental Engagement

DoH Officials have been liaising with colleagues from the Home Office (HO). DoH will continue this engagement and review the future UKG EM, when available, to understand any possible implications for NI.