

FOR CRISIS MANAGEMENT AND AMENDING REGULATION (EC) 816/2006 (COM
(2023) 224)

**Letter from the Chair to Viscount Camrose, Parliamentary Under Secretary of State,
Minister for AI and Intellectual Property, Department for Science, Innovation and
Technology**

Thank you for your Explanatory Memorandum, dated 22 May 2023, on the above proposed Regulation applying to Northern Ireland under the Windsor Framework. The House of Lords Sub-Committee on the Protocol on Ireland/Northern Ireland considered this document at its meeting on 11 July 2023.

We note your assessment that Part 2 of the described Regulation will apply to Northern Ireland by virtue of the provisions set out in the Windsor Framework. We further note your assessment that any impact of the Regulation on Northern Ireland will be minimal. In practical terms, can you characterise this potential impact?

We note that you are unable to provide any “information on timings at this stage” and that the Government “will continue to monitor the proposals as discussions develop in the European Parliament and the Council of the EU.” We ask that you write to the Committee once further details of the proposal have been ascertained and timelines have been established.

Finally, while we note that “the devolved governments [were] consulted in the preparation of this Explanatory Memorandum and had no comments.” Has the Government sought or received the views of stakeholders in Northern Ireland on this proposal? If so, what opinion did they express?

We would be grateful for a response to these questions by 26 July 2023. In the meantime, we retain an active interest in this document.

12 July 2023

**Letter to the Chair from Viscount Camrose, Parliamentary Under Secretary of State,
Minister for AI and Intellectual Property, Department for Science, Innovation and
Technology**

Thank you for your letter of 12 July 2023 regarding the above proposed EU Regulation, in which you ask about its potential impacts and views of stakeholders. Please accept my apologies for the delay in response.

As indicated in the Explanatory Memorandum, the Government’s initial assessment is that there is likely to be minimal impact on Northern Ireland.

Compulsory licences are issued in the absence of a voluntary agreement with the rightsholder. Consequently, patent rightsholders may argue that the availability of compulsory licences undermines incentives to invest in research and development. This is because under any compulsory licence, generic manufacturers may be able to manufacture or perform a patented product or process, without the consent of the patent rightsholder.

However, we expect the impact on R&D in Northern Ireland to be negligible because any effect on innovation, which we anticipate in any case would be limited, would be global and not focused on the EU or Northern Ireland specifically.

Conversely, the measure may increase the potential for generic medicine manufacture in Northern Ireland if compulsory licences are issued; however, in the short run, this may be unlikely as pharmaceutical manufacture in Northern Ireland is currently limited. In practical terms, it is worth noting, as set out in the Explanatory Memorandum, compulsory licensing is an exceptionally rarely used mechanism. The WTO website records only two historic notifications of requests in the context of export to countries with public health problems.

We have not received specific representations from stakeholders in Northern Ireland, though we have engaged with the pharmaceutical industry. The views received tally with the limited anticipated effect

on innovation explained above. As part of our monitoring of the proposals Official-Sensitive as they develop, we will be assessing the proportionality of the measure, and continuing our engagement with stakeholders.

The Government continues to monitor the proposals as discussions develop in the European Parliament and the Council of the EU, and I will write to the Committee once we have further details and timelines have been established. Should it be necessary, we would also be able to engage with the EU through the structures under the Withdrawal Agreement, including the Joint Consultative Working Group and its structured groups, to consider any relevant issues.

8 August 2023

Letter from the Chair to Viscount Camrose, Secretary of State for Science, Innovation & Technology, Minister for AI and Intellectual Property, Department for Science, Innovation and Technology

Thank you for your letter, dated 8 August 2023, providing an update on the above proposed Regulation applying to Northern Ireland under the Windsor Framework. The House of Lords Sub-Committee on the Protocol on Ireland/Northern Ireland considered these documents at its meeting on 13 September 2023.

We are grateful for the further detail provided on the practical potential impact of this proposal and on the views of stakeholders.

We welcome your commitment to write again once further details and timelines have been established and would be grateful for such an update in due course.

In the meantime we retain an active interest in these documents.

14 September 2023

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE APPROVAL AND MARKET SURVEILLANCE OF NON-ROAD MOBILE MACHINERY CIRCULATING ON PUBLIC ROADS AND AMENDING REGULATION (EU) 2019/1020 (EM 7992/23)

Letter from the Chair to the Rt Hon Jesse Norman MP, Minister of State (Decarbonisation and Technology), Department for Transport

Thank you for your Explanatory Memorandum, dated 28 June 2023, on the above proposed Regulation applying to Northern Ireland within the scope of the Windsor Framework. The House of Lords Sub-Committee on the Protocol on Ireland/Northern Ireland considered this document at its meeting on 19 July 2023.

We regret the poor quality of the provided EM. While we note your overview of the Regulation's individual articles, we would be grateful if you could set out in general terms what the proposed Regulation will do as a whole, how significant you view this Regulation to be in respect to its wider policy area, and when the Regulation will practically enter into force.

We note that the proposal is still in draft form and does not yet include technical requirements for affected non-road mobile machinery. Noting concern from industry stakeholders and officials in the Northern Ireland Executive, what are the possible scenarios in respect to regulatory divergence between Great Britain and Northern Ireland, and what steps will the Government take to address these? Noting the potential impact on the movement of machinery from Great Britain to Northern Ireland, what is the current scale of such movement under the proposed Regulation? What are the