

**EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION
WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE
WINDSOR FRAMEWORK**

Regulation (EU) 2024/2747 of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulations (EC) No 2679/98. (Text with EEA relevance).

and

Regulation (EU) 2024/2748 of the European Parliament and of the Council of 9 October 2024 amending Regulations (EU) No 305/2011, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/988 and (EU) 2023/1230 as regards emergency procedures for the conformity assessment, *presumption of conformity*, adoption of common specifications and market surveillance due to an internal market emergency. (Text with EEA relevance)

and

Directive (EU) 2024/2749 of the European Parliament and of the Council of 9 October 2024 amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regards emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency (Text with EEA relevance)

Submitted by the Department for Business and Trade, on 13 November 2024

SUBJECT MATTER

1. On 26 September 2024, the EU adopted a Regulation for the provision of a new framework aimed at ensuring the security and resilience of the EU's Single Market and its supply chains during emergency and crisis situations. The framework, known as the Internal Market Emergency and Resilience Act (IMERA), will enter into force on 28 November 2024. The Regulation will apply from 29 May 2026.
2. The IMERA applies to most goods and services, but with limited exception does not apply to medicinal products, medicinal devices, other medical countermeasures, semiconductors, energy products, electricity, financial services and defence-related products. It sets out measures which aim to protect the functioning of the EU's Single Market during an emergency situation and, in doing so, secure the supply of critically important and "crisis-relevant" goods and services.

3. Under the IMERA, the internal market “vigilance mode” and the internal market “emergency mode” can be activated by implementing acts. These modes can be activated for up to an initial six months, extendable by a further six-month period. There is no limit to the number of extensions.
4. In parallel, on 26 September 2024 the EU adopted two separate legal acts which supplement the IMERA. Regulation (EU) 2024/2748 and Directive (EU) 2024/2749 between them amend 16 existing product sector legislative acts, by introducing emergency procedures pertaining to conformity assessment measures and market surveillance cooperation. Please see Annex A for the full list of the amended product sector legislation.
5. These emergency procedures will apply only to those goods designated (in an implementing act) as “crisis relevant goods” and may only be activated following the activation of the internal market emergency mode, where there is a wide-ranging crisis that severely disrupts the free movement of goods, or the functioning of supply chains that are of vital societal or economic activities, in the EU Single Market. Corrective and restrictive actions, specific procedures as well as specific labelling and traceability requirements for specified goods may be made via implementing acts.

SCRUTINY HISTORY

6. The Department for Business and Trade, in its previous form as Department for Business, Energy and Industrial Strategy, published an explanatory memorandum in October 2022 on the European Commission’s proposal to establish a Single Market emergency instrument.

MINISTERIAL RESPONSIBILITY

7. The Secretary of State for the Department for Business and Trade is responsible for the UK’s overarching conformity assessment policy as well as the coordination of the UK’s market surveillance and enforcement policy.
8. The Secretary of State for the Department for Business and Trade is responsible for product safety legislation.
9. The Secretary of State for the Department for Transport is responsible for cableway installations and transportable pressure equipment.
10. The Secretary of State for the Ministry of Housing Communities and Local Government has responsibility for construction product policy.
11. The Secretary of State for the Department of Health and Social Care has responsibility for healthcare product policy.

12. The Secretary of State for the Department of Work and Pensions has responsibility for explosive products as the sponsoring department for the Health and Safety Executive.

13. The Secretary of State for the Department for Environment Food and Rural Affairs has responsibility for batteries, timber, tests on chemicals, certain hazardous substances and pollutants, fertilisers, detergents, mercury, and waste policy.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

14. This is a substantively reserved policy matter which the UK Government will continue to discuss with devolved counterparts as needed.

LEGAL AND PROCEDURAL ISSUES

15. i. EU Legal Basis

Article 114 of the Treaty on the Functioning of the European Union, which allows the European Parliament and the Council to adopt measures to establish and ensure the well-functioning of the EU Single Market.

ii. Voting Procedure

Qualified Majority Voting.

iii. Timetable for adoption and implementation

Regulation (EU) 2024/2747, Regulation EU 2024/2748 and Directive (EU) 2024/2749 will all enter into force 20 days after their publication in the Official Journal of the European Union.

Regulation (EU) 2024/2747 will apply from 18 months after its entry into force and Regulation (EU) 2024/2748 will apply from the same date as Regulation (EU) 2024/2749.

Insofar as Directive (EU) 2024/2749 is concerned, the amendments it makes to Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU would need to be implemented by way of secondary legislation.

POLICY IMPLICATIONS

Domestic Policy Context

16. During times of emergency, the UK Government will continue to make decisions that are of benefit and interest to the UK. Emergency provisions pertaining to product regulation are currently being considered in Parliament.
17. National emergencies, such as COVID 19, have highlighted the importance of ensuring the UK's product safety framework allows for flexibility in times of national emergency. The UK is now pursuing an Emergency Derogation power under Clause 4 of the Product Regulation and Metrology Bill. This will enable the UK to have an emergency derogation process to help ensure the supply of critical products in emergency situations.

Impact of the IMERA on Northern Ireland

18. To facilitate dual access to both the UK Internal Market and EU Single Market, Northern Ireland continues to apply certain EU rules relating to product safety. The following subset of legislative changes brought about by IMERA and accompanying legislation amend or replace legislation covered by Annex 2 of the Windsor Framework. Accordingly, these changes will apply in Northern Ireland, subject to the democratic scrutiny mechanisms set out in Article 13 of the Windsor Framework and Schedule 6B of the Northern Ireland Act 1998.
 - a. The amendments Article 47(2) of Regulation 2024/2747 makes to Regulation (EC) No 2679/98.
 - b. Regulation (EU) 2024/2748 and Directive (EU) 2024/2749 make certain changes to product sector legislation (see list of affected legislation at Annex A).
19. The impact of the amendments will be dependent on the substance of implementing acts. However, we expect that any measures introduced would be targeted and with the aim of easing the flow of goods. We do not expect these measures would introduce any significant additional regulatory burdens for business. Further detail is set out below.

Amendment to Council Regulation (EC) 2679/98

20. IMERA itself comes outside the scope of Article 13(3) of the Windsor Framework, and therefore will not apply in Northern Ireland under that process. The one exception is that Article 47(2) of IMERA amends Council Regulation (EC) No 2679/98 on the functioning of the internal market in relation to the free movement of goods among Member States.
21. Articles 3-5 of Regulation (EC) No 2679/98 provide for mechanisms for bilateral discussion and notifications of obstacles for the functioning of the EU Single

Market. IMERA amends the Regulation to disapply these rules where the internal market emergency mode has been activated.

Legislation amending product sector regulations

22. Aside from the exception above, IMERA itself does not apply under Article 13(3) of the Windsor Framework so has no further application in Northern Ireland. However, the accompanying legislation does amend certain product legislation covered by Annex 2 of the Windsor Framework. Any implications are likely to be confined to the conformity assessment and market surveillance of relevant products.
23. Specifically, IMERA provides a mechanism to allow for crisis-relevant goods to be fast tracked through conformity assessment processes and for market surveillance to be prioritised, so shortages can be addressed quickly. Regulation (EU) 2024/2748 and Directive (EU) 2024/2749 list product safety legislation, some of which is covered by Annex 2 of the Windsor Framework, where this fast-track mechanism can be used.
24. In practice, this means that - in the event of an emergency - implementing acts could set out that:
 - a. Market surveillance authorities and conformity assessment bodies should make efforts to prioritise crisis-relevant goods. The legislation specifies that this should not result in additional disproportionate costs for manufacturers who have lodged requests. Goods must still adhere to all applicable essential safety requirements before being authorised to be placed on the market. Where derogations are authorised the relevant marking (e.g. CE marking) should not be affixed to products.
 - b. Manufacturers will be able to rely on alternative methods for presumption of conformity of safety for placing crisis-relevant goods on the market. This could mean relying on national, international or other appropriate standards or common specifications, rather than harmonised standards.
25. Should these measures be adopted for products falling under any of the applicable 16 product sector regulations, we do not expect this would create significant additional regulatory burdens for businesses and traders as the intention is to ease the flow of goods.

26. The European Commission ran a public consultation from 13 April 2022 until 11 May 2022. 25 responses were received, none of which were from the United Kingdom¹.

FINANCIAL IMPLICATIONS

27. We do not expect the measures described above to cause significant additional regulatory costs, as they relate only to the administration of market surveillance and conformity assessment activities, which are in any case already undertaken for the products in question.

MINISTERIAL NAME AND SIGNATURE

A handwritten signature in black ink, reading "Douglas Alexander". The signature is written in a cursive style with a large initial 'D' and 'A'.

The Rt Hon Douglas Alexander MP

Minister of State for Trade Policy

¹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13181-Single-market-new-EU-instrument-to-guarantee-functioning-of-single-market-during-emergencies/public-consultation_en

ANNEX A: LIST OF PRODUCT SECTOR REGULATIONS SUBJECT TO SPECIFIC EMERGENCY PROCEDURES CONCERNING CONFORMITY ASSESSMENT AND MARKET SURVEILLANCE

Amending Regulation:

1. Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC Text with EEA relevance
2. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (Text with EEA relevance)
3. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (Text with EEA relevance)
4. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (Text with EEA relevance)
5. Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance)
6. Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (Text with EEA relevance)

Amending Directive:

7. Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors
8. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (Text with EEA relevance)

9. Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (Text with EEA relevance)
10. Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (recast) Text with EEA relevance
11. Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) Text with EEA relevance
12. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (recast) Text with EEA relevance
13. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast) Text with EEA relevance
14. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast) Text with EEA relevance
15. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC Text with EEA relevance
16. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast) Text with EEA relevance