

EXPLANATORY MEMORANDUM TO
THE PERSONAL PROTECTIVE EQUIPMENT (ENFORCEMENT) REGULATIONS
2018

2018 No. 390

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department for Business, Energy and Industrial Society (BEIS) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 The purpose of this statutory instrument (“SI”) is to provide for the enforcement of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment (OJ No L81, 31.3.2016, p51) (“the EU PPE Regulation”), which repeals Directive 89/686/EEC.
- 2.2 The EU PPE Regulation applies to personal protective equipment (“PPE”) which is new to the Union market when it is placed on the market on or after 21st April 2018; which means either new PPE made by a manufacturer in the Union or PPE whether new or second hand imported from a third country.
- 2.3 This SI will enable enforcement authorities in the United Kingdom (such as Trading Standards Authorities, the Health and Safety Executive, and the Office for Nuclear Regulation) to take action against “economic operators” (i.e. manufacturers, importers and distributors) if they do not comply with the obligations in EU PPE Regulation. The EU PPE Regulation is aimed at ensuring that PPE entering the Union market fulfils a high level of protection of health and safety for users.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Other matters of interest to the House of Commons

- 3.2 As this instrument is subject to the negative resolution procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

- 4.1 This SI is made to provide an enforcement and penalty regime in the United Kingdom (“UK”) for contraventions by economic operators of the obligations contained in the EU PPE Regulation, as required by Article 45 of that Regulation. The EU PPE Regulation repeals and replaces Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (OJ No L399, 30.12.1989, p18) and which is implemented in the UK by the Personal Protective Equipment Regulations 2002 as amended (S.I. 2002/1144) (“the 2002 PPE Regulations”).

- 4.2 In accordance with Article 47 of the EU PPE Regulation, this instrument will revoke and replace the 2002 PPE Regulations subject to transitional and savings provisions with respect to PPE placed on the Union market before 21st April 2019, and with respect to the validity of EU type-examination certificates and quality assurance approval decisions issued under the 2002 PPE Regulations before 21st April 2019. There is a transitional period of a year spanning from 21st April 2018 until 20th April 2019 where both the 2002 PPE Regulations and the new regime (i.e. the EU PPE Regulations and this instrument) will operate.

5. Extent and Territorial Application

- 5.1 The extent of this instrument is the United Kingdom.
- 5.2 The territorial application of this instrument is the United Kingdom.

6. European Convention on Human Rights

- 6.1 The Minister for Small Business, Consumers and Corporate Responsibility, Andrew Griffiths MP, has made the following statement regarding Human Rights:

“In my view the provisions of the Personal Protective Equipment (Enforcement) Regulations 2018 are compatible with the Convention rights.”

7. Policy background

What is being done and why

- 7.1 The aim of the EU PPE Regulation is to
- lay down requirements for the design and manufacture of personal protective equipment (PPE)
 - ensure the health and safety of users, domestic animals and property
 - allow the equipment to be sold and used throughout the European Union (EU).
- 7.2 The EU PPE Regulation replaces earlier legislation (Council Directive 89/686/EEC).
- 7.3 Personal protective equipment will therefore only be permitted to be sold and used in the EU if it complies with the EU PPE Regulation, when properly maintained and used for its intended purpose, and when it does not endanger the health or safety of people, pets or property.
- 7.4 The scope of the EU PPE Regulation applies to equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety. This includes interchangeable components of the personal protective equipment which are essential to its protective function. Additionally included are connection systems for personal protective equipment (not held or worn) that are designed to connect equipment to an external device or anchor point, that are not designed to be permanently fixed and that do not require fastening works before use.
- 7.5 The EU PPE Regulation creates a number of obligations on economic operators (manufacturers, importers and distributors). For example
- Manufacturers (in accordance with Article 8 of the EU PPE Regulation) must keep relevant technical documentation and the EU declaration of conformity for 10 years after the placing on the market of the equipment and inform national authorities of any equipment that might pose a risk.

- Importers (in accordance with Article 10) must ensure that equipment that they place on the market comply with this regulation, including that conformity assessment procedures have been carried out and that the CE marking and documentation drawn up by manufacturers are available for inspection by the authorities. Their name and contact details should be indicated on the equipment, or where the size or nature of the equipment does not permit, on the packaging or documentation accompanying the equipment.
 - Distributors (in accordance of Article 11) must ensure they act with due care to ensure that their handling of equipment does not affect its compliance; verify that any equipment they make available on the market bears the CE marking and is accompanied by a declaration of conformity.
- 7.6 This instrument creates offences for contravening the requirements and obligations set out in Articles 8, 10 and 11. Additionally, offences are created in respect of
- Article 13 (relating to the identification of economic operators)
 - Article 16 (general principles of CE marking)
 - Article 17 (rules and conditions for affixing the CE marking)
 - Article 38 (failure to cooperate with, provide information to and comply with a requirement made by a market surveillance authority)
 - Article 40 (failure by an economic operator to act where a compliant appliance of fitting presents a risk)
 - Article 41 (failure by an economic operator to act when an EU Member State has identified a formal non-compliance of a requirement).
- 7.7 The instrument therefore provides an enforcement regime for the EU PPE Regulation in regards to breaches of the obligations/requirements set down in that Regulation by economic operators (e.g. manufacturers, importers and distributors).
- 7.8 The policy intention is to maintain an effective regulatory regime in the UK for personal protective equipment and continue to ensure there are effective, proportionate and dissuasive sanctions to deal with any economic operators who do not comply with their requirements and obligations contained in the EU PPE Regulation.
- 7.9 The instrument seeks to align with the EU's New Legislative Framework (NLF) principles (as has been done with other product safety legislation).
- 7.10 The NLF consists of Decision 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products (OJ No 218, 13.8.2008, p82) and Regulation (EC) No 765/2008 on requirements for accreditation and market surveillance relating to the marketing of products. It is a framework of general principles and rules, which aims to make legislation for goods in the Union market clearer, more consistent and more effective.
- 7.11 The NLF is designed to make it easier for economic operators from anywhere in the EU to comply with legislation by setting a consistent assessment and enforcement regime across a number of product areas. This instrument maintains consistency by mirroring the NLF approach to enforcement. The NLF makes explicit the specific contraventions on each of the economic operators which have been set out as obligations in these regulations.

- 7.12 This instrument replicates provisions in other recent product safety legislation for regulators to seek court orders for a fine and or imprisonment for non-compliance. BEIS is currently reviewing the penalty regimes for product safety legislation in general to assess whether a broader set of sanctions would give regulators more options to ensure proportionate use of criminal sanctions for serious or persistent offenders. BEIS will revisit this legislation, as part of the wider product safety framework, in the light of the conclusions of that review.
- 7.13 A Transposition Note is attached to this Memorandum.
- 7.14 On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation.

8. Consultation outcome

- 8.1 This instrument provides an enforcement and penalty regime for non-compliance of the EU PPE Regulation. It was not considered necessary to undertake a formal public consultation on the specific enforcement and penalty provisions in these Regulations because they mirror existing NLF enforcement provisions, which were consulted on in 2012, and were already familiar to the industry. Please see - (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/31800/12-550-proposals-align-directives-with-new-legislative-framework-consultation.pdf). There has instead been informal consultation with the enforcement authorities and industry to explain the regime being introduced. Informal discussions have taken place with the Health and Safety Executive and BEIS has disseminated information via its Business Reference Panel to industry associations and through the knowledge hub to trading standards representatives. Responses have been generally favourable.

9. Guidance

- 9.1 BEIS will produce guidance on the instrument before the provisions enter into force. This will be made available on <https://www.gov.uk/government/collections/new-legislative-framework>

10. Impact

- 10.1 There is no impact, or no significant impact, on business, charities or voluntary bodies.
- 10.2 There is no impact, or no significant impact, on the public sector.
- 10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

- 11.1 The legislation applies to activities that are undertaken by small businesses. The Government considers that the legislation is not expected to impose a disproportionate cost to small businesses.

12. Monitoring & review

- 12.1 The instrument provides for periodic review of their regulatory provision and sets out report requirements. The first review report must be published before the 5 year

anniversary of the coming into force of the Regulations, with subsequent review reports being published at intervals not exceeding 5 years.

13. Contact

- 13.1 Mr Peter Edwards at the Department for Business, Energy and Industrial Strategy (Peter.edwards@beis.gov.uk; telephone 020 7215 1862) can answer any queries regarding the instrument.