EXPLANATORY MEMORANDUM TO

THE PERSONAL PROTECTIVE EQUIPMENT (TEMPORARY ARRANGEMENTS) (CORONAVIRUS) (ENGLAND) REGULATIONS 2020

2020 No. 1484

1. Introduction

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

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This instrument continues temporary regulatory arrangements to facilitate the production and supply of Personal Protective Equipment (PPE) during the Covid-19 pandemic. These arrangements modify the effect of 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 ("the PPE Regulation") (as it has been amended and retained in UK law) and the effect of sanctions under the Personal Protective Equipment (Enforcement) Regulations 2018, S.I. 2018/390 ("the 2018 Regulations").

2.2 The temporary arrangements were adopted by the UK government in March 2020 following Commission Recommendation 2020/403. The Recommendation will not carry over in to domestic law in GB at the end of the Transition Period, so new provision is being made to continue with the easements so long as they are needed. This instrument therefore makes specific provision for arrangements continuing after the end of the Transition Period, modifying the effect of the PPE Regulation (as it has been amended and retained in UK law) and the effect of sanctions under the Personal Protective Equipment (Enforcement) Regulations 2018, S.I. 2018/390 ("the 2018 Regulations").

2.3 These arrangements ease the regulatory requirements for conformity assessment for certain categories of PPE while maintaining process to ensure essential safety, for a limited time in order to increase the supply of essential Covid-19-related PPE on the UK market and for healthcare or specified health and care sector frontline workers. The easements are time limited, in that they require a Health and Safety Executive (HSE) assessment by specified dates.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is made under section 45C of the Public Health (Control of Disease) Act 1984 ("the 1984 Act").

3.2 Departmental lawyers have considered whether there are alternative powers to continue the effect of the Commission Recommendation in UK law for a limited period and have concluded that there is not an alternative suitable power.

3.3 Accordingly this instrument is made under section 45C for the purpose of increasing the availability of PPE and reducing the public health risks posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2)

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.4 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The 1984 Act and regulations made under it provide a legislative framework for health protections in England and Wales.

6.2 Section 45C of the 1984 Act provides a power for the appropriate Minister to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in England and Wales.

6.3 This instrument is made under section 45C for the purpose of increasing the availability of PPE and reducing the public health risks posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2).

6.4 Regulation 1 sets out the commencement date of this instrument and the definitions of terms used in this instrument.

6.5 Regulation 2 provides that PPE that usually requires conformity assessment by a conformity assessment body (which includes a conformity mark) can instead be placed on the market without having completed the conformity assessment process. However in order to be eligible for this, the PPE must be PPE that is needed for protection in the context of Covid-19, the conformity assessment procedure must have been initiated and the HSE must have certified that the PPE is compliant with the relevant parts of the essential health and safety requirements set out in the PPE Regulation. The HSE will only undertake this assessment and certification process until 31 March 2021. After 31 March 2021 the arrangements will fall away and the conformity assessment requirements which applied before March 2020 will apply to unassessed PPE again.

6.6 Regulation 3 provides that PPE that usually requires conformity assessment by a conformity assessment body can instead be provided to healthcare workers or specified frontline health and care sector workers without having completed the conformity assessment process. However in order to be eligible for this, the PPE must be PPE that is needed for protection in the context of Covid-19, it must have been purchased by or on behalf of the NHS and only for provision for the use by

healthcare or specified frontline health and care sector workers, and the HSE must have certified that the PPE is compliant with the relevant parts of the essential health and safety requirements set out in the PPE Regulation. The HSE will only undertake this assessment and certification process until 30 June 2021. After 30 June 2021 the arrangements will fall away and the conformity assessment requirements which applied before March 2020 will apply to unassessed PPE again.

6.7 Regulation 4 provides that where a supplier such as a manufacturer, importer or distributor has relied on one of the arrangements to supply PPE without completing the conformity assessment process, they will not be guilty of an offence, and the enforcing authority (the HSE) is not compelled to take action in respect of the non-compliance for the supplier's failure to complete the conformity assessment procedure or to affix the conformity marking.

6.8 Regulation 4 also provides that where any PPE has been assessed under the regulatory arrangement which was in place under the Commission Recommendation 2020/403 up to 31 December 2020, nothing in this instrument affects the validity of any HSE assessment, or conditions set by HSE in respect of the assessment, in respect of that PPE.

7. Policy background

What is being done and why?

7.1 Under the EU framework which applies before the end of the Transition Period, PPE is a product which is subject to harmonised rules. Union harmonisation legislation is a body of law which governs the sale or supply of a harmonised good for commercial purposes on the European Union market. The harmonised technical requirements are set out in legislation and apply to all goods of this type.

7.2 The PPE Regulation sets out the harmonised rules that must be met before PPE products can be placed on the market. The purpose of the legislation is to ensure safe and effective products are placed on the market by requiring manufacturers to show how their products meet the 'essential health and safety requirements'.

7.3 In the UK, the 2018 Regulations provide a system for the enforcement of the PPE Regulation and designates the market surveillance authority. In Great Britain, this is a weights and measures authority or in circumstances where the PPE is to be made available to workers or members of the public for non-private use, this is the HSE.

7.4 In March 2020, the UK relied upon the European Commission's Recommendation 2020/403 (updated in July 2020) which contained a number of proposals to speed up the supply of PPE during the Covid-19 crisis, two of which relate to PPE that is not a medical device. These arrangements firstly enable the NHS and UK government bodies to procure non-conformity assessed PPE for healthcare or specified frontline health and care sector workers, as long as the PPE meets essential health and safety requirements, as approved by HSE. Secondly, they permit PPE which requires conformity assessment to be placed on the UK market before the full conformity assessment procedures have been completed and before a conformity mark has been affixed. The conformity assessment procedures should be completed as soon as possible afterwards. The HSE must also have certified that the PPE meets essential health and safety requirements.

7.5 The Department is bringing forward this instrument to provide additional clarity and ensure there is no confusion at the end of the Transition Period, and that legal certainty is provided to manufacturers, importers and distributors of PPE that the temporary arrangements relating to the conformity assessment process will continue in the short-term, in England. This is vital to speed up supply of essential Covid-19 related PPE.

7.6 The regulations set an end date for the HSE to make its assessments, thereby limiting the practical effect of these regulations to the anticipated needs associated with the pandemic.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is not being made under the European Union (Withdrawal) Act but relates to the withdrawal of the United Kingdom from the European Union.

8.2 Since March 2020, the UK has implemented the arrangements proposed in the European Commission Recommendation 2020/403. Following the end of the Transition Period, these will continue to apply in Northern Ireland only. This instrument provides further legal certainty on the corresponding arrangements which it is considered desirable should continue in England.

9. Consolidation

9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

10.1 The Government did not undertake a formal public consultation given this instrument's provisions are limited to extending the status quo, enabling the continuation of regulatory arrangements facilitating the supply of PPE whilst the Covid-19 pandemic continues.

10.2 Product safety is a reserved matter but as the enabling power in the 1984 Act is devolved, this instrument only extends and applies to England. Accordingly there has been informal engagement with the Welsh, Scottish and Northern Ireland governments, and the UK Government continues to support all the nations of the UK to secure adequate PPE supply to respond to the Covid-19 pandemic.

11. Guidance

11.1 The government has published guidance on GOV.UK on its regulatory arrangements to support PPE supply in response to the Covid-19 pandemic, and this guidance will be updated to include information about the specific provisions in this instrument applying in England. The guidance will be updated in due course before the end of 2020.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because the impacts are expected to be low level for business. The impact of this instrument is limited to

possible familiarisation costs to business to understand the implementation of the regulatory easements

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise the regulatory burdens on small businesses as no operational costs are anticipated.

13.3 The legal requirements on the industry do not differentiate between businesses in terms of their size, they are dependent on the type and nature of the product being produced and placed on the market. Therefore we are unable to take any mitigating actions to reduce burdens on small business.

14. Monitoring & review

14.1 The Department does not intend to monitor or review this instrument.

15. Contact

15.1 Natasha Chopra at the Department for Business, Energy and Industrial Strategy Telephone: 020 7215 1106 or email: natasha.chopra@beis.gov.uk can be contacted with any queries regarding the instrument.

15.2 Sarah Smith, Deputy Director and deputy Chief Executive of the Office for Product Safety and Standards, at the Department for Business, Energy and Industrial Strategy, can confirm that this Explanatory Memorandum meets the required standard.

15.3 Paul Scully, Parliamentary Under Secretary of State (Minister for Small Business, Consumers and Labour Markets), at the Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.