

SL(5)694 – The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020

Background and Purpose

These Regulations implement temporary arrangements to facilitate the production and supply of PPE during the Covid-19 pandemic. These arrangements are similar to the proposals in the European Commission's Recommendation 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat, but the arrangements in these Regulations are specific to Wales and came into force on IP completion day. The easements are time limited, in that a Health and Safety Executive ("HSE") assessment of the PPE is required by specified dates.

Regulation 2 permits PPE to be placed on the market while it is undergoing conformity assessment procedures but before these have been completed and any conformity marking has been affixed. Regulation 3 permits PPE to be procured without undergoing conformity assessment procedures and conformity marking being affixed but this must only be made available to healthcare and frontline workers. In both cases, the PPE must have been assessed by the HSE and found to be compliant with the essential health and safety requirements in Annex II of Regulation 2016/425/EU of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (as amended and retained in UK law). Where the conditions are met, the obligations in Regulation 2016/425 will be treated as satisfied for the purposes of the Personal Protective Equipment (Enforcement) Regulations 2018 and in respect of PPE for healthcare workers and other frontline workers, the market surveillance authority will not require the non-compliance to be brought to an end. This is solely in cases where the conformity assessment procedure has not been completed and the conformity mark has not been affixed due to reliance on regulation 2 or 3 of these Regulations.

Procedure

Negative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.



Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following point is identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

This instrument is made under sections 45C, 45F(2) and 45P(2) of the Public Health (Control of Disease) Act 1984 ("the 1984 Act"). Section 45Q(2)(a) and (4)(b) of the 1984 Act provide that regulations made under section 45C may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, the Senedd (i.e. the affirmative procedure). However, section 45Q(3) of the 1984 Act provides that this does not apply if the instrument contains a declaration that the person making it is of the opinion that the instrument does not contain any provision made by virtue of section 45C(3)(c) of the 1984 Act which imposes or enables the imposition of a special restriction or requirement, or any other restriction or requirement which has or would have a significant effect on a person's rights.

The Welsh Ministers are of that opinion and a declaration has been included to that effect within the regulations. The instrument is therefore subject to the negative resolution procedure. The purpose of the instrument is to increase the availability of PPE and reduce public health risks, rather than impose special restrictions or requirements.

Implications arising from exiting the European Union

These Regulations are not being made under the European Union (Withdrawal) Act 2018 but relate to the withdrawal of the United Kingdom from the European Union.

These Regulations and Regulation 2016/425/EU of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (as amended), which the Regulations refer to, form part of retained EU law following IP completion day (i.e. the end of the implementation period, on 31 December 2020).

Welsh Government response

A Welsh Government response is not required.



Committee Consideration

The Committee considered the instrument at its meeting on 11 January 2021 and reports to the Senedd in line with the reporting point above and also to highlight issues as a result of the UK exiting the EU.

