

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)

CHAPTER VI

[^{F1}MARKET SURVEILLANCE AND CONTROL OF PPE ENTERING THE UNITED KINGDOM MARKET]

Article 41

Formal non-compliance

1 Without prejudice to Article 38, where [^{F1}the enforcement authority] makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- a the [^{F2}UK] marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Regulation;
- b the [^{F3}UK] marking has not been affixed;
- c the identification number of the [^{F4}approved] body involved in the production control phase has been affixed in violation of Article 17 or has not been affixed;
- d the ^{F5}... declaration of conformity has not been drawn up or has not been drawn up correctly;
- e the technical documentation is either not available or not complete;
- f the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;
- g any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.

2 Where the non-compliance referred to in paragraph 1 persists, the [^{F6}enforcement authority] shall take all appropriate measures to restrict or prohibit the PPE being made available on the market or ensure that it is recalled or withdrawn from the market.

Textual Amendments

- F1** Words in Art. 41(1) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(39)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in Art. 41(1)(a) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(39)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Word in Art. 41(1)(b) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(39)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in Art. 41(1)(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(39)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: This version of this Regulation was derived from EUR-Lex on IP completion day (31 December 2020 11:00 p.m.). It has not been amended by the UK since then. Find out more about legislation originating from the EU as published on legislation.gov.uk. (See end of Document for details)

- F5** Word in Art. 41(1)(d) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(39)(a)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 41(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(39)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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