

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 II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of manufacturers

1 When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.

2 Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the ^{F1}... declaration of conformity referred to in Article 15 and affix the [^{F2}UK] marking referred to in Article 16.

3 Manufacturers shall keep the technical documentation and the ^{F3}... declaration of conformity for 10 years after the PPE has been placed on the market.

4 Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in the design or characteristics of the PPE and changes in the [^{F4}designated] standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

5 Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or in a document accompanying the PPE.

6 Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and [^{F5}the market surveillance authority].

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

7 Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II [^{F6}and that they are clear, legible and in easily understandable English].

8 The manufacturer shall either provide the ^{F7}... declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of Annex II the internet address at which the ^{F7}... declaration of conformity can be accessed.

9 Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the [^{F8}enforcement authority] to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

10 Manufacturers shall, further to a reasoned request from [^{F9}the enforcement authority], provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

Textual Amendments

- F1** Word in Art. 8(2) 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(8)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in Art. 8(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(8)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Word in Art. 8(3) 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(8)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in Art. 8(4) 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(8)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 8(6) 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(8)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 8(7) 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(8)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Word in Art. 8(8) 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(8)(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 8(9) 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(8)(g)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Words in Art. 8(10) 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(8)(h)**; 2020 c. 1, Sch. 5 para. 1(1)

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Modifications etc. (not altering text)

- C1** Art. 8(2) restricted (E.) (31.12.2020) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (England) Regulations 2020 (S.I. 2020/1484), regs. 1(1), **2, 3**
- C2** Art. 8(2) restricted (W.) (31.12.2020) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020 (S.I. 2020/1489), regs. 1(1), **2, 3**
- C3** Art. 8(2) restricted (S.) (1.2.2021) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Scotland) Regulations 2021 (S.S.I. 2021/50), regs. 1, **2, 3** (with reg. 4(4))

Article 9

Authorised representatives

1 A manufacturer may, by a written mandate, appoint [^{F10}a person established in the United Kingdom as their]^{F11}... authorised representative.

The obligations laid down in Article 8(1) and the obligation to draw up the technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.

2 An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- a keep the ^{F12}... declaration of conformity and the technical documentation at the disposal of the ^{F12}... market surveillance [^{F13}authority] for 10 years after the PPE has been placed on the market;
- b further to a reasoned request from [^{F14}the enforcement authority], provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;
- c cooperate with the [^{F15}enforcement authority], at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

Textual Amendments

- F10** Words in Art. 9(1) inserted (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(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Word in Art. 9(1) 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(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Words in Art. 9(2)(a) 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(9)(b)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Word in Art. 9(2)(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(9)(b)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Words in Art. 9(2)(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(9)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** Words in Art. 9(2)(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(9)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

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Article 10

Obligations of importers

1 Importers shall place only compliant PPE on the market.

2 Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 19 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the ^[F16]UK marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not place it on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the importer shall inform the manufacturer and the market surveillance ^[F17]authority to that effect.

3 Importers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted ^{F18}.... The contact details shall be in a language easily understood by end-users and market surveillance ^[F19]authority.]

^[F20]The obligation set out in this paragraph 3 to indicate information on the PPE does not apply where—

a either—

i it is not possible to indicate that information on the PPE, or

ii the importer has imported the PPE from an EEA state or Switzerland and places it on the market within the period of ^[F21]seven years beginning with IP completion day, and

b before placing the PPE on the market, the importer sets out the information referred to in this paragraph 3 on the packaging of the PPE or in a document accompanying the PPE.]

4 Importers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II ^[F22]and that they are clear, legible and in easily understandable English].

5 Importers shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.

6 When deemed appropriate with regard to the risks presented by PPE, importers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

7 Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the ^[F23]enforcement authority to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

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8 Importers shall, for 10 years after the PPE has been placed on the market, keep a copy of the ^{F24}... declaration of conformity at the disposal of the market surveillance [^{F25}authority] and ensure that the technical documentation can be made available to [^{F26}that authority], upon request.

9 Importers shall, further to a reasoned request from [^{F27}the enforcement authority], provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

Textual Amendments

- F16** Word in Art. 10(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(10)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Word in Art. 10(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(10)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F18** Words in Art. 10(3) 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(10)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F19** Word in Art. 10(3) 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(10)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F20** Words in Art. 10(3) inserted (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(10)(b)(iii)** (as amended by S.I. 2019/1246, regs. 1(3), **5**; S.I. 2020/1460, reg. 1(4), Sch. 3 para. 2(1)(n); and S.I. 2020/852, regs. 2(2), 4(2), Sch. 1 para. 1(u)(iv)); 2020 c. 1, Sch. 5 para. 1(1)
- F21** Words in Art. 10(3)(a)(ii) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 4, **Sch. 3 para. (q)**
- F22** Words in Art. 10(4) 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(10)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in Art. 10(7) 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(10)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F24** Word in Art. 10(8) 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(10)(e)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F25** Word in Art. 10(8) 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(10)(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in Art. 10(8) 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(10)(e)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in Art. 10(9) 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(10)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

Modifications etc. (not altering text)

- C4** Art. 10(2) restricted (E.) (31.12.2020) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (England) Regulations 2020 (S.I. 2020/1484), regs. 1(1), **2, 3**

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| C5 | Art. 10(2) restricted (W.) (31.12.2020) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020 (S.I. 2020/1489), regs. 1(1), 2, 3 |
| C6 | Art. 10(2) restricted (S.) (1.2.2021) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Scotland) Regulations 2021 (S.S.I. 2021/50), regs. 1, 2, 3 (with reg. 4(4)) |

Article 11

Obligations of distributors

1 When making PPE available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2 Before making PPE available on the market, distributors shall verify that it bears the [F28UK] marking, is accompanied by the required documents and by the instructions and information set out in point 1.4 of Annex II [F29and that they are clear, legible and in easily understandable English] and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.

Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance [F30authority].

3 Distributors shall ensure that, while PPE is under their responsibility, its storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.

4 Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring it into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where the PPE presents a risk, distributors shall immediately inform the [F31enforcement authority] to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

5 Distributors shall, further to a reasoned request from [F32the enforcement authority], provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have made available on the market.

Textual Amendments

- F28** Word in Art. 11(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(11)(a)(i)(aa); 2020 c. 1, Sch. 5 para. 1(1)
- F29** Words in Art. 11(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(11)(a)(i)(bb); 2020 c. 1, Sch. 5 para. 1(1)
- F30** Word in Art. 11(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(11)(a)(ii); 2020 c. 1, Sch. 5 para. 1(1)

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- F31** Words in Art. 11(4) 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(11)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F32** Words in Art. 11(5) 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(11)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Modifications etc. (not altering text)

- C7** Art. 11(2) restricted (E.) (31.12.2020) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (England) Regulations 2020 (S.I. 2020/1484), regs. 1(1), **2, 3**
- C8** Art. 11(2) restricted (W.) (31.12.2020) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020 (S.I. 2020/1489), regs. 1(1), **2, 3**
- C9** Art. 11(2) restricted (S.) (1.2.2021) by The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Scotland) Regulations 2021 (S.S.I. 2021/50), regs. 1, **2, 3** (with reg. 4(4))

Article 12

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that compliance with this Regulation may be affected.

Article 13

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance [^{F33}authority]:

- (a) any economic operator who has supplied them with PPE;
- (b) any economic operator to whom they have supplied PPE.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the PPE and for 10 years after they have supplied the PPE.

Textual Amendments

- F33** Word in Art. 13 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(12)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:

There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 3(2) words substituted by [S.I. 2019/696 Sch. 35 para. 3\(4\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 24(4))
- Art. 3(3) words substituted by [S.I. 2019/696 Sch. 35 para. 3\(4\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 24(4))
- Art. 3(5) substituted by [S.I. 2019/696 Sch. 35 para. 3\(4\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(b) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- Art. 3(5) words substituted in earlier amending provision S.I. 2019/696, Sch. 35 para. 3(4)(b) by [S.I. 2020/852 reg. 4\(2\) Sch. 1 para. 1\(u\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(u)(ii) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))
- Art. 24(2A) inserted by [S.I. 2024/504 reg. 17\(b\)](#)