



STATUTORY INSTRUMENTS.

S.I. No. 325 of 2022



EUROPEAN UNION (PERSONAL PROTECTIVE EQUIPMENT)
(AMENDMENT) REGULATIONS 2022

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I, LEO VARADKAR, Minister for Enterprise, Trade and Employment, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) (as amended by section 2 of the European Communities Act 2007 (No. 18 of 2007)) and for the purpose of giving full effect to Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019¹ and of giving further effect to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016², hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Personal Protective Equipment) (Amendment) Regulations 2022.

(2) In these Regulations “Principal Regulations” means the European Union (Personal Protective Equipment) Regulations 2018 (S.I. No. 136 of 2018).

(3) These Regulations and the Principal Regulations may be cited together as the European Union (Personal Protective Equipment) Regulations 2018 and 2022.

(4) A word or expression which is used in these Regulations and which is also used in the Market Surveillance Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Market Surveillance Regulation.

(5) References to Articles 15 to 29 of Regulation (EC) No. 765/2008 of 9 July 2008³ in the Principal Regulations shall be construed as references to the Market Surveillance Regulation and shall be read in accordance with the correlation table in Annex III to the Market Surveillance Regulation, the text of which is set out in Regulation 2(23) of these Regulations.

(6) Any reference to the entirety of Regulation (EC) No. 765/2008 in the Principal Regulations shall, to the extent that it refers or otherwise relates to Articles 15 to 29 of Regulation (EC) No. 765/2008, be construed as a reference to the Market Surveillance Regulation and shall be read in accordance with the correlation table in Annex III to the Market Surveillance Regulation, the text of which is set out in Regulation 2(23) of these Regulations.

¹ OJ No. L 169, 25.6.2019, p. 1

² OJ No. L 81, 31.3.2016, p. 51

³ OJ No. L 218, 13.8.2008, p. 30

2. (1) The “Arrangement of Regulations” of the Principal Regulations is amended-

- (a) by inserting after “9. Obligations of distributors.” the following:

“9A. Obligations of fulfilment service providers.”,
- (b) by inserting after “11. Identification of economic operators.” the following-

“11A. Distance sales.

11B. Obligation of cooperation.”,
- (c) by inserting after “27. Procedure for dealing with PPE presenting a risk at national level.” the following-

“27A. Corrective actions that may be required of economic operators.”,
- (d) by inserting after “29. Compliant PPE which presents a risk.” the following-

“29A. Formal non-compliance.”,
- (e) by deleting “33. Direction to end non-compliance.”,
- (f) by inserting after “35. Appeal against contravention notice.” the following:

“35A. Order of High Court to direct compliance with a contravention notice.”, and
- (g) by inserting after “SCHEDULE 10 TEXT OF ANNEX X TO THE PPE REGULATION” the following-

“SCHEDULE 11

TEXT OF ANNEX XIII TO REGULATION (EU) 2019/1020

Correlation Table”.

(2) The Principal Regulations are amended by inserting into Regulation 2(1) the following-

““corrective action” means any action taken by an economic operator to bring any non-compliance to an end where required by a market surveillance authority or on the economic operator's own initiative;

“end user”, in relation to PPE, means any natural or legal person residing or established in a Member State, to whom PPE has been made available either as a consumer outside of any trade, business, craft or profession or as

a professional end user in the course of its industrial or professional activities;

“fulfilment service provider” means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the PPE involved, excluding postal services as defined in Article 2(1) of Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997⁴, parcel delivery services as defined in Article 2(2) of Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018⁵, and any other postal services or freight transport services;

“information society service provider” means a provider of a service as defined in Article 1(1)(b) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015⁶;

“Market Surveillance Regulation” means Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019;

“non-compliance” means any failure to comply with any requirement under the PPE Regulation, the Market Surveillance Regulation or these Regulations;

“online interface” means any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end users access to the economic operator's PPE;

“PPE presenting a risk” means PPE having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests, protected by the PPE Regulation and the Market Surveillance Regulation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the PPE concerned, including the duration of use and, where applicable, its putting into service, use and maintenance requirements;

“PPE presenting a serious risk” means PPE presenting a risk, for which, based on a risk assessment and taking into account the normal and foreseeable use of the PPE, the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate;

“risk” means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;”.

⁴ OJ No. L 15, 21.1.98, p. 14

⁵ OJ No. L 112, 2.5.2018, p. 19

⁶ OJ No. L 241, 17.9.2015, p. 1

(3) The Principal Regulations are amended by the substitution in Regulation 2(1) of-

- (a) the following definition for the definition of “authorised representative”-

““authorised representative” means any natural or legal person established within a Member State who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the PPE Regulation, the Market Surveillance Regulation or under the requirements of these Regulations;”,

- (b) the following definition for the definition of “economic operator”-

““economic operator” means a manufacturer, an authorised representative, an importer, a distributor, a fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of PPE, making it available on the market or putting it into service in accordance with the PPE Regulation and the Market Surveillance Regulation;”, and

- (c) the following definition for the definition of “market surveillance”-

““market surveillance” means the activities carried out and measures taken by market surveillance authorities to ensure that PPE complies with the requirements set out in the PPE Regulation and these Regulations and to ensure protection of the public interest covered by that legislation;”.

(4) The Principal Regulations are amended by inserting after Regulation 5(2) the following-

“(3)(a) A person shall not place PPE on the market unless there is an economic operator of the type referred to in Article 4(2) of the Market Surveillance Regulation established in a Member State and who is responsible for the tasks as set out in Article 4(3) of the Market Surveillance Regulation.

(b) The economic operator referred to in subparagraph (a) shall indicate its name, registered trade name or registered trademark, and contact details, including the postal address on the PPE or on its packaging, the parcel or an accompanying document.”.

(5) The Principal Regulations are amended by inserting after Regulation 7(3) the following-

“(4) In addition to the above, where an authorised representative has been designated by the manufacturer for the purposes of Article 4 of the Market Surveillance Regulation as referred to in Regulation 5(3)(a) herein, that authorised representative shall—

- (a) perform the tasks listed in Article 4(3) of the Market Surveillance Regulation;
- (b) provide a copy of the mandate to the market surveillance authorities on request, in an official language of the State; and
- (c) have the appropriate means to be able to fulfil the tasks as referred to in subparagraph (a).”.

(6) The Principal Regulations are amended by the insertion after Regulation 9 of the following-

“Obligations of fulfilment service providers

9A. A fulfilment service provider established in a Member State, where there is no other economic operator established in a Member State with respect to the PPE it handles, shall—

- (a) when making PPE available on the market, act in accordance with the requirements of the PPE Regulation and these Regulations,
- (b) before making PPE available on the market, verify that the EU declaration of conformity and technical documentation have been drawn up,
- (c) for 10 years after the PPE has been placed on the market by the fulfilment service provider—
 - (i) keep a copy of the declaration of conformity at the disposal of the relevant market surveillance authority, and
 - (ii) ensure that the technical documentation can be made available to those authorities upon request,
- (d) further to a reasoned request from a market surveillance authority, provide that authority with all information and documentation necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority,
- (e) when having reason to believe that PPE in question presents a risk, inform the relevant market surveillance

authority as designated by Regulation 3 of the Principal Regulations,

- (f) cooperate with the relevant market surveillance authority, at its request, making sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in the PPE Regulation, and
- (g) where the corrective action referred to in subparagraph (f) is not possible, mitigate the risks presented by that PPE, in either of the following circumstances:
 - (i) when required to do so by the relevant market surveillance authority, or
 - (ii) on its own initiative, where the fulfilment service provider considers or has reason to believe that the PPE in question presents a risk.”.

(7) The Principal Regulations are amended by inserting after Regulation 11 the following-

“Distance sales

- 11A. (a) PPE offered for sale online or through other means of distance sales shall be deemed to be made available on the market if the offer is targeted at end users in a Member State.
- (b) An offer for sale shall be considered to be targeted at end users in a Member State if the relevant economic operator directs, by any means, its activities to a Member State.

Obligation of cooperation

- 11B. (a) Economic operators shall cooperate with market surveillance authorities in accordance with Article 7(1) of the Market Surveillance Regulation.
- (b) Information society service providers shall cooperate with market surveillance authorities in accordance with Article 7(2) of the Market Surveillance Regulation.”.

(8) The Principal Regulations are amended by inserting after Regulation 27 the following-

“Corrective actions that may be required of economic operators

27A. (1) Further to Regulation 27(3)(a), the market surveillance authority may require the economic operator to take corrective action, which may include, *inter alia*,

- (a) bringing the PPE into compliance, including by rectifying formal non-compliance as set out in Regulation 29A or by ensuring that the PPE no longer presents a risk,
- (b) preventing the PPE from being made available on the market,
- (c) withdrawing or recalling the PPE immediately and alerting the public to the risk presented,
- (d) destroying the PPE or otherwise rendering it inoperable,
- (e) affixing to the PPE suitable, clearly worded, easily comprehensible warnings in an official language of the State of the risks that it might present,
- (f) setting prior conditions for making the PPE concerned available on the market, and
- (g) alerting end users at risk immediately and in an appropriate form, including by publication of special warnings in the language which can be easily understood by the market surveillance authority.

(2) The corrective actions referred to in subparagraphs (1)(e), (f) and (g) may only be required in cases where the PPE is liable to present a risk only in certain conditions or only to certain end users.”.

(9) The Principal Regulations are amended by inserting after Regulation 29 the following-

“Formal non-compliance

29A. (1) Without prejudice to Regulation 27, the market surveillance authority shall require the relevant economic operator to put an end to the non-compliance concerned where it finds that-

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No. 765/2008 or of Article 17 of the PPE Regulation or of Regulation 17 of these Regulations,
- (b) the CE marking has not been affixed,
- (c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 17 of the PPE Regulation or Regulation 17 of

these Regulations or, where required by that Article or Regulation to be affixed, has not been affixed,

- (d) the EU declaration of conformity has not been drawn up,
- (e) the EU declaration of conformity has not been drawn up correctly,
- (f) the technical documentation is either not available or not complete,
- (g) the information referred to in Article 8(6) or 10(3) of the PPE Regulation or Regulation 6(i) or 8(2)(c) of these Regulations is absent, false or incomplete, or
- (h) any other administrative requirement provided for in Article 8 or 10 of the PPE Regulation or Regulation 6 or 8 of these Regulations is not fulfilled.

(2) Where the non-compliance referred to in paragraph (1) persists an Authorised Officer may serve a direction on the relevant economic operator to put an end to the non-compliance within a specified period of time.”.

(10) The Principal Regulations are amended by inserting “the Market Surveillance Regulation,” before “the PPE Regulation” in Regulation 30.

(11) The Principal Regulations are amended in Regulation 32 by-

- (a) inserting in paragraph (1) “the Market Surveillance Regulation,” before “the PPE Regulation”,
- (b) substituting for subparagraph (1)(a)(i) the following:
 - “(i) any premises, land or means of transport that the economic operator in question uses for purposes related to the economic operator’s trade, business, craft or profession, in order to identify non-compliance and to obtain evidence, or”,
- (c) substituting for subparagraph (1)(q) the following:
 - “(q) cause any PPE found at any place to be subjected, at the place it is found or any other location, to any testing, examination or analysis (but not so as to damage or destroy it unless this is necessary for the purposes of the PPE Regulation or these Regulations) and where an Authorised Officer proposes to exercise the power conferred by this subparagraph and if so requested by the person in charge, cause anything that is to be done by virtue of this subparagraph to be done

in the presence of the person in charge save that the person in charge is responsible for his or her own costs in attending at the exercise of any power under this subparagraph and cannot unreasonably delay the Authorised Officer in the exercise of those powers;”, and

- (d) inserting after subparagraph (1)(s) the following-
- “(t) require an economic operator to provide relevant documents, technical specifications, data or information on compliance and technical aspects of the PPE, including access to embedded software in so far as such access is necessary for the purpose of assessing the PPE’s compliance with these Regulations and the PPE Regulation, in any form or format and irrespective of the medium of storage or the place where such documents, technical specifications, data or information are stored;
 - (u) take or obtain copies of documents, technical specifications, data or information referred to in subparagraph (t);
 - (v) require an economic operator to provide any information that in the opinion of the Authorised Officer is relevant for compliance;
 - (w) require an economic operator to provide relevant information on the supply chain, on the details of the distribution network, on quantities of PPE on the market and on other models of products that have the same technical characteristics as the PPE in question, where relevant for compliance with the applicable requirements of these Regulations or the PPE Regulation;
 - (x) require an economic operator to provide relevant information required for the purpose of ascertaining the ownership of websites, where the information in question is related to the subject matter of investigation;
 - (y) acquire product samples, including under a cover identity, to inspect those samples and to reverse engineer them in order to identify non-compliance and to obtain evidence;
 - (z) where no other effective means are available to eliminate a serious risk-

- (i) require the removal of content referring to the related PPE from an online interface or to require the explicit display of a warning to end users when they access an online interface; or
- (ii) where a request according to clause (i) has not been complied with, require information society service providers to restrict access to the online interface, including by requesting a relevant third party to implement such measures.”.

(12) The Principal Regulations are amended by the deletion of Regulation 33 and any reference elsewhere in the Principal Regulations to Regulation 33 shall be construed to be a reference to Regulation 29A.

(13) The Principal Regulations are amended in Regulation 34-

(a) by substituting for paragraph (1) the following-

“(1) An Authorised Officer who is of the opinion that-

- (a) an economic operator is contravening or has contravened any of the provisions of the PPE Regulation, the Market Surveillance Regulation or these Regulations,
- (b) an information society service provider has failed to comply with a request under Regulation 11B(b) or Regulation 32(1)(z), or
- (c) any PPE does not comply with the PPE Regulation, the Market Surveillance Regulation or these Regulations for the purposes of Article 28(2) of the Market Surveillance Regulation,

may serve a contravention notice on the economic operator or information society service provider.”,

(b) by substituting for subparagraph (2)(b) the following-

“(b) specify the exact grounds for the opinion,”,

(c) by substituting for subparagraph (2)(e) the following-

“(e) inform the person on whom the contravention notice is served that he or she may appeal the notice to the District Court within 14 days in accordance with Regulation 35,”,

(d) by deleting “and” after subparagraph (2)(f),

- (e) by deleting the full stop after subparagraph (2)(g) and inserting the following-

“, and

- (h) be communicated to the relevant economic operator or information society service provider without delay.”,

and

- (f) by inserting after paragraph (8) the following:

“(9) Subject to paragraph (10), the person on whom it is intended that a contravention notice will be served shall have the opportunity to make representations to a market surveillance authority within 10 working days of first being advised of the market surveillance authority’s intention to serve a contravention notice.

(10) Where an opportunity to make representations referred to in paragraph (9) is not possible because of the urgency of the measure directed in the contravention based on health or safety requirements or other grounds relating to the public interests covered by the PPE Regulation, the market surveillance authority shall give the person on whom the contravention notice is served the opportunity to be heard as soon as possible thereafter and the decision to issue the contravention notice shall be reviewed promptly.”.

- (14) The Principal Regulations are amended by inserting after Regulation 35 the following-

“Order of High Court to direct compliance with a contravention notice

35A. (1) Where a person fails to comply with a contravention notice, an Authorised Officer may apply ex parte to the High Court for an order directing immediate compliance with the notice.

(2) The High Court may, upon an application under this Regulation, if satisfied that the person on whom the contravention notice is served has failed to comply with the notice, grant an order referred to in paragraph (1).”.

- (15) The Principal Regulations are amended at Regulation 36-

- (a) by inserting at paragraph (1), “or information society service provider” after “economic operator”,

- (b) by substituting for subparagraph (3)(b) the following-

- “(b) specify the exact grounds for the opinion,”,
- (c) by inserting at subparagraph (3)(d), “or information society service provider” after “economic operator”,
- (d) by substituting for subparagraph (3)(e) the following-
 - “(e) inform the person on whom the prohibition notice is served that he or she may appeal the notice to the District Court within 7 days in accordance with Regulation 37,”,
- (e) by deleting “and” after subparagraph (3)(f),
- (f) by deleting the full stop after subparagraph (3)(g) and inserting the following-
 - “, and
 - (h) be communicated to the relevant economic operator without delay.”,
- (g) by inserting at subparagraph 4(a) “or information society service provider” after “economic operator”, and
- (h) by inserting after paragraph (9) the following-
 - “(10) A market surveillance authority shall give the recipient of a prohibition notice the opportunity to be heard as soon as possible after the service of the notice on that person and the decision to issue the notice shall be reviewed promptly thereafter.”.

(16) The Principal Regulations are amended at Regulation 39-

- (a) by substituting for subparagraph (3)(b) the following-
 - “(b) specify the exact grounds for the seizure and intended destruction or disposal of the PPE,”,
- (b) by substituting for subparagraph (3)(d) the following-
 - “(d) inform the person on whom the seizure notice is served that he or she may appeal the notice to the District Court within 21 days in accordance with this Regulation,”,

and
- (c) by inserting after paragraph (18) the following-
 - “(19) A market surveillance authority shall give the recipient of a seizure notice an opportunity to make representations as soon as possible after the service of the notice on that person

and the service of the notice shall be reviewed promptly thereafter.”.

(17) The Principal Regulations are amended at Regulation 41 by-

- (a) the inserting in paragraph (1) “the Market Surveillance Regulation,” before “the PPE Regulation”,
- (b) substituting for subparagraph (2)(a) the following-
 - “(a) state the exact grounds on which the requirement for information is based and shall inform the person on whom the information notice is served that he or she may appeal the notice to the District Court within 7 days in accordance with this Regulation,”,

and

- (c) inserting after paragraph (10) the following-

“(11) Subject to paragraph (12), a person against whom it is intended that an information notice shall be sought shall have the opportunity to make representations to a market surveillance authority within 10 working days of first being advised of the market surveillance authority’s intention to serve an information notice.

(12) Where an opportunity to make representations referred to in paragraph (11) is not possible because of the urgency of the serving of the information notice, as justified by health or safety requirements or other grounds relating to public interests, the market surveillance authority shall give the person on whom an information notice is served the opportunity to be heard as soon as possible after the service of the notice and the decision to serve an information notice shall be reviewed promptly thereafter.”.

(18) The Principal Regulations are amended in Regulation 42 by the insertion of “Member” between “another” and “State”.

(19) The Principal Regulations are amended in Regulation 44 as follows-

- (a) in subparagraph (1)(b) by substituting “Regulation 5(1), 5(2), 5(3), 6, 7, 8, 9, 9A, 11, 11B, 17(5), 27(2), 27(6) or 29(2)” for “Regulation 5(1), 5(2), 6, 7, 8, 9, 11, 17(5), 27(2), 27(6), 29(2)”,
- (b) in paragraph (2) by substituting “Regulation 29A(2), 34, 36 or 41” for “Regulation 34, 36 or 41”, and
- (c) by substituting for paragraph (8) the following-

“(8) A person who, in purported compliance with a requirement in an information notice furnishes information to a market surveillance authority that he or she knows or ought reasonably to know to be false or misleading in a material respect, commits an offence.”.

(20) The Principal Regulations are amended by the insertion after Regulation 45(2) of the following-

“(3) Where a person is convicted of an offence under these Regulations, the court by or before which he or she is convicted may, in addition to any other penalty or cost, order the forfeiture to the market surveillance authority of the PPE or any other relevant thing in respect of which the offence relates for destruction or disposal as the market surveillance authority sees fit.

(4) Where an order is made under paragraph (3), the court may, on application to it by or on behalf of the market surveillance authority, order the person convicted of the offence to pay for all or part of the destruction or disposal of such relevant thing, subject to such conditions, if any, as may be specified in the order.”.

(21) The Principal Regulations are amended by substituting the following for Regulation 47-

“47. Summary proceedings in relation to an offence under these Regulations may be brought and prosecuted by a market surveillance authority.”.

(22) The Principal Regulations are amended by the insertion after Regulation 48(1)(e) of the following-

“(f) If all of the methods set out at subparagraphs (a) to (e) are either not possible in the circumstances or have proved insufficient to effect service of the notice or document on the relevant person, by electronic means only.”.

(23) The Principal Regulations are amended by the insertion after Schedule 10 of the following-

“SCHEDULE 11

TEXT OF ANNEX III TO REGULATION (EU) 2019/1020

CORRELATION TABLE

Regulation (EC) No. 765/2008	Regulation (EU) No. 2019/1020
Article 1(2)	Article 1(1)
Article 1(3)	Article 1(3)
Article 2, point 1	Article 3, point 1

Article 2, point 2	Article 3, point 2
Article 2, point 14	Article 3, point 22
Article 2, point 15	Article 3, point 23
Article 2, point 17	Article 3, point 3
Article 2, point 18	Article 3, point 4
Article 2, point 19	Article 3, point 25
Article 15(1) and (2)	Article 2(1)
Article 15(3)	Article 2(3)
Article 15(4)	—
Article 15(5)	Article 2(2)
Article 16(1)	Article 10(1)
Article 16(2)	Article 16(5)
Article 16(3)	—
Article 16(4)	—
Article 17(1)	Article 10(2)
Article 17(2)	Article 34(1), last sentence and Article 34(3), point (a)
Article 18(1)	Article 10(6)
Article 18(2), point (a)	Article 11(7), point (a)
Article 18(2), point (b)	—
Article 18(2), point (c)	Article 11(7), point (b)
Article 18(2), point (d)	—
Article 18(3)	Articles 10(5) and 14(1)
Article 18(4)	Article 14(2)
Article 18(5)	Article 13
Article 18(6)	Article 31(2), point (o)
Article 19(1), first subparagraph	Article 11(3)
Article 19(1), second subparagraph	Article 14(4), points (a), (b), (e) and (j)
Article 19(1), third subparagraph	Article 11(5)
Article 19(2)	Article 16(3), point (g)

Article 19(3)	Article 18(2)
Article 19(4)	Article 11(2)
Article 19(5)	Article 17
Article 20(1)	Article 19(1)
Article 20(2)	Article 19(2)
Article 21(1)	Article 18(1)
Article 21(2)	Article 18(2)
Article 21(3)	Article 18(3)
Article 21(4)	—
Article 22(1)	Article 20(1)
Article 22(2)	Article 20(2)
Article 22(3)	Article 20(3)
Article 22(4)	Article 20(4)
Article 23(1) and (3)	Article 34(1)
Article 23(2)	Article 34(4)
Article 24(1)	Article 22(1)
Article 24(2)	Article 22(2) to (5)
Article 24(3)	—
Article 24(4)	—
Article 25(1)	—
Article 25(2), point (a)	Article 31(2), point (f) and Article 33(1), points (i) and (k)
Article 25(2), point (b)	Article 31(2), points (g) and (m) and Article 33(1), points (i) and (k)
Article 25(3)	—
Article 26	—
Article 27(1), first sentence	Article 25(2)
Article 27(1), second sentence	Article 25(3)
Article 27(2)	Article 25(4)
Article 27(3), first subparagraph	Article 26(1)

Article 27(3), second subparagraph	Article 26(2)
Article 27(4)	—
Article 27(5)	—
Article 28(1)	Article 27, first paragraph, point (a)
Article 28(2)	Article 27, first paragraph, point (b)
Article 29(1)	Article 28(1)
Article 29(2)	Article 28(2)
Article 29(3)	Article 28(3)
Article 29(4)	Article 28(4)
Article 29(5)	Article 25(5)
Article 32(1), point (d)	—
Article 32(1), point (e)	Article 36(2), point (e)

”.



GIVEN under my Official Seal,
30 June, 2022.

LEO VARADKAR,
Minister for Enterprise, Trade and Employment..

EXPLANATORY NOTE

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations give full effect in Irish law to the provisions of Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 in relation to Personal Protective Equipment (PPE).

These Regulations amend European Union (Personal Protective Equipment) Regulations 2018 (S.I. No. 136 of 2018) that gave full effect to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016.

The purpose of these Regulations is to add the provisions relating to the market surveillance and compliance of PPE as required by Regulation (EU) 2019/1020. These Regulations provide the market surveillance authorities with the necessary enforcement powers and set out additional responsibilities for relevant economic operators with respect to market surveillance of PPE placed on the market within the EU.

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