For use only if the UK has left the EU without a deal

EU Regulation 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

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1. Introduction

EU Regulation 2016/425 sets out the essential health and safety requirements which must be met before personal protective equipment (“PPE”) products can be placed on the UK market. The purpose of the legislation is to ensure safe products are placed on the market by requiring manufacturers to show how their products meet the ‘essential health and safety requirements’. The Personal Protective Equipment (Enforcement) Regulations 2018 provide a regime for the enforcement of the EU PPE Regulation.

This guidance is designed to help you understand EU Regulation 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018, now the UK has left the EU, (collectively the “Amended PPE Regulations”, and individually the “EU PPE Regulation” and the “2018 Regulations” respectively), as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

2. Legislative Background

EU Regulation 2016/425 was directly applicable from 21 April 2018. The enforcement and sanctions regime was implemented into UK law by the Personal Protective Equipment (Enforcement) Regulations 2018 (SI 2018 No. 390). The EU Withdrawal Act 2018 preserves these regulations and enables them to be amended so as to continue to function effectively now that the UK has left the EU. Accordingly, the 2019 Amendment Regulations fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the UK market.

3. Scope

The Amended PPE Regulations apply to PPE which is:

- equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person’s health or safety;
- interchangeable components for equipment referred to in point (a) which are essential for its protective function;
- connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use.

The Amended PPE Regulations do not apply to PPE:

- specifically designed for use by the armed forces or in the maintenance of law and order;
- designed to be used for self-defence, except for PPE intended for sporting activities;
- designed for private use to protect against:
  - atmospheric conditions that are not of an extreme nature,
  - damp and water during dishwashing;
- for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable to the UK;
• for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motorcycles and mopeds.

4. Requirements

The essential health and safety requirements (listed in Annex II) apply to PPE within the scope of the EU PPE Regulation as amended as appropriate. Under article 19, all PPE within scope must undergo a conformity assessment procedure in accordance with its risk categorisation (specified in Annex I) to demonstrate compliance with the essential requirements.

5. Obligations of manufacturers

A manufacturer is a person who manufactures PPE, or has PPE designed or manufactured, and markets that PPE under their name or trade mark.

The obligations of manufacturers of PPE include:

1. Before placing PPE on the market, a manufacturer must ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements. These are set out in Annex II to the Regulation. They must also have had a relevant conformity assessment procedure carried out and technical documentation drawn up.

2. Once this has been done a manufacturer must draw up a declaration of conformity; ensure that the declaration accompanies the product; and affix the UKCA marking to the PPE.

3. Manufacturers must keep the declaration of conformity and the technical documentation for 10 years after the PPE has been placed on the market.

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

5. 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.

6. The manufacturer must ensure that all PPE placed on the market bears a type and serial or batch number, or other element allowing its identification. The manufacturer should also include its name, registered trade name or registered trade mark and postal address. Where the size or nature of the PPE does not allow this then it may be provided on the packaging or accompanying documentation.

7. The manufacturer must ensure that PPE is accompanied by instructions and safety information as set out in point 1.4 of Annex II to the Regulation, which is clear, legible and in easily understandable English.
6. Obligations of authorised representatives

Manufacturers are able to appoint authorised representatives to perform certain tasks on their behalf under a written mandate.

Mandated authorised representatives established in the EEA or Switzerland prior to the UK leaving the EU continue to be recognised as authorised representatives by the UK to act in the UK for the purposes of the legislation. However, any authorised representatives appointed and mandated after the UK has left the EU to act in the UK must be established in the UK to be recognised under UK law.

Businesses with an existing authorised representative based in an EU Member State, the EEA or Switzerland can therefore continue to use the same authorised representative.

No UK-based authorised representatives are recognised under EU law. This means they cannot carry out tasks on the manufacturer’s behalf for PPE being placed on the EU market. Therefore, a manufacturer exporting PPE to the EU, who wishes to appoint an authorised representative to carry out tasks for them in respect of that PPE, must appoint an authorised representative based in the EU.

The mandate shall at least allow the authorised representative to perform the following tasks:

- keeping the declaration of conformity and the technical documentation at the disposal of the market surveillance authority in the UK for 10 years after the PPE has been placed on the market.
- further to a reasoned request from the enforcement authority in the UK, providing that authority with all the information and documentation necessary to demonstrate the conformity of the PPE.
- cooperating with the enforcement authority in the UK, at its request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative’s mandate.

An authorised representative must comply with all the duties, imposed on the manufacturer under the EU PPE Regulation, that they are appointed for and mandated by the manufacturer to perform. A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf and an authorised representative is under a duty to perform those tasks, and any failure to do so may make the authorised representatives liable to penalties.

7. Obligations of importers

An importer is a person or business based in the UK who places PPE on the UK market from a country outside the UK. This means that UK businesses who used to act as a ‘distributor’ legally become an ‘importer’ if they place PPE from an EEA country or Switzerland on the UK market.

Importers have additional legal obligations which go beyond those of distributors, such as checking that manufacturers have carried out the right conformity assessment procedures and included their name, registered trade name or mark and a postal address on the equipment or, where this is not possible, on its packaging or in accompanying documentation.
To assist with the transition, the UK is applying a transitional period of 18 months to allow UK economic operators who import goods from the EEA or Switzerland (who post exit are importers) to provide their details on the accompanying documentation as an alternative to placing them on the equipment itself.

The EU does not have any such transitional provision. In the absence of this, PPE being exported from the UK to the EU must be labelled with the EU-based importer’s address.

The obligations of importers include the following:

1. Before placing PPE on the market, an importer must ensure that the appropriate conformity assessment procedures referred to in article 19 have been carried out by the manufacturer. This means that the PPE must comply with the essential health and safety requirements set out in Annex II of the EU PPE Regulation. They must ensure that the manufacturer has drawn up technical documentation; the PPE bears the UK marking and is accompanied by the declaration of conformity and required documents and identification marks.

2. When deemed appropriate, regarding risk presented by an item of PPE, the importer must carry out sample testing, investigate and, if necessary, keep a register of complaints, of non-conforming PPE and recalls of such PPE, and keep distributors informed of any such monitoring.

3. Importers must indicate on the PPE their name, registered trade name or registered trade mark and postal address. This obligation does not apply where the importer has set out such information on the packaging of the PPE and 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 18 months from the date the UK leaves the EU.

4. The importer must ensure that PPE is accompanied by instructions and safety information as set out in point 1.4 of Annex II to the EU PPE Regulation ensure that they are clear, legible and in easily understandable English.

5. The importer must keep a copy of the declaration of conformity and technical documentation for a period of 10 years after the PPE has been placed on the market at the disposal of the market surveillance authority and ensure that the technical documentation can be made available to that authority, upon request.

6. The importer must ensure that PPE under their responsibility are safely stored and transported in such a way that does not jeopardise conformity with the essential health and safety requirements.

7. Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with the EU PPE Regulation must 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 enforcement authority in the UK to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
8. Importers must, further to a reasoned request from the enforcement authority in the UK, 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.

8. **Obligations of distributors**

UK businesses which were distributors of PPE within the EU single market should now consider whether they are importers from the EU single market and therefore what additional requirements they may face – see section 7 above. The same applies to distributors of goods from the EEA and Switzerland.

A distributor is any person, other than the manufacturer or importer, who makes PPE available on the market.

The obligations of distributors include the following:

1. Before making PPE available on the market, a distributor must act with due care to ensure that it is in conformity with the EU PPE Regulation, which includes ensuring that the PPE must be in conformity with the essential health and safety requirements.

2. Before making PPE available on the market, a distributor must ensure that it bears the UK marking (or for a time limited period the CE marking); is accompanied by instructions and information as set out in point 1.4 of Annex II to the Regulation and ensure that they are clear, legible and in easily understandable English; and that the manufacturer and importer have complied with the marking requirements as to required labelling.

3. The distributor must ensure that PPE under their responsibility are safely stored and transported in such a way that does not jeopardise its conformity with the essential health and safety requirements.

4. Distributors who consider or have reason to believe that PPE which they have placed on the market is not in conformity with the EU PPE Regulation must 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 enforcement authority in the UK to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

5. Distributors must, further to a reasoned request from the enforcement authority in the UK, 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.
9. Transitional arrangements

‘Deeming’ provision

PPE which has undergone full conformity assessment with the equivalent EU requirements and bears the CE marking are deemed compliant with the UK legislation and can be placed on the UK market as if it had been UK conformity marked.

The UK continues to recognise the competency of EU recognised conformity assessment bodies (notified bodies) to assess PPE for the UK market. PPE assessed by an EU recognised notified body prior to the UK leaving the EU will not need reassessment before being placed on the UK market. Furthermore, for a time-limited period, PPE assessed by an EU recognised notified body can be placed on the UK market. (For the status of UK notified bodies please see section 10 below).

This ‘deeming provision’ will be available for a time-limited period. This will be the subject of amending legislation in the future at a time yet to be decided. The Government will consult with industry and provide notice before ending this time-limited period.

10. UK Conformance Mark

Assessment through third-party organisations:

The UKCA conformity mark will replace the CE marking for PPE placed on the UK market which has been assessed by a UK approved body. In all other cases, manufacturers will be able to continue using the CE marking for PPE being placed on the UK market instead of the new UKCA marking for a time-limited period. The Government will engage with industry before making any decision on when this period will end.

Rules around physically affixing the new UKCA conformity marking mirror those which currently apply for the application of the CE marking.

Self-assessment:

CE marking based on self-declaration of conformity by the manufacturer is still possible, including when exporting to the EU.

Manufacturers selling PPE on the UK market can alternatively affix the new UKCA conformity marking before placing PPE on the UK market. It will also be possible to affix both the UKCA marking and the CE marking to the same product on the basis of self-declaration. When exporting to the EU, the CE marking remains mandatory.

Placing CE marked goods on the UK market:

PPE that meets EU regulatory requirements, including PPE with a CE marking, which has been assessed by an EU recognised conformity assessment body or which has been self-declared can still be placed on the UK market for a time-limited period. ‘EU-recognised’ does not include UK approved bodies. Manufacturers which have had their products assessed by EU recognised bodies are obliged to use the CE marking and cannot use the UKCA marking.

Testing Certificates:

Where conformity assessment is a 2-stage process, it is possible for PPE to have an EU-type-examination certification (1st stage) followed by a UK declaration by the manufacturer or third party of the production process under the responsibility of a UK Approved Body (2nd stage). Such equipment and protective systems should have the UK conformity mark followed by the UK Approved Body Number.
Further guidance on UKCA marking can be found here:

From 21 April 2019, only PPE compliant with EU Regulation 2016/425 as applied in the EU may be exported to the EU Single Market.

11. Approved Bodies

The UK has established a new framework for UK based bodies to assess PPE against UK rules. The existing UK notified bodies have been granted new UK ‘approved body’ status and listed on a new UK database. There is no need for existing notified bodies to seek re-accreditation in order to benefit from UK approved body status. These approved bodies have been given a 4-digit approved body number.

Approved bodies can assess PPE for the UK market against UK essential health and safety requirements (which are substantially the same as EU essential requirements).

Approved bodies are conformity assessment bodies which were notified bodies before the UK left the EU or have been approved by the Secretary of State to carry out the procedures for conformity assessment and certification for the UK market as set out in the EU PPE Regulation.

UK Approved bodies must be established in the UK and be independent of the manufacturer. Approved bodies must examine the technical documentation and supporting evidence in respect of a product to assess the adequacy of the technical design.

Where an approved body finds that essential safety requirements have not been met by a manufacturer, they must not issue a certificate of conformity and they must require the manufacturer to take corrective measures.

A list of UK approved bodies can be found [link to be added].

12. Enforcement

As set out in the Enforcement Regulations (Personal Protective Equipment (Enforcement) Regulations 2018 (SI 2018 No. 390)), for PPE intended for workplace use, or for use otherwise than at work in non-domestic premises made available to persons at a place where they may use the PPE provided for their own use there, the Health and Safety Executive (HSE) is responsible for the enforcement of the Regulations in Great Britain. In Northern Ireland enforcement is the responsibility of the Health and Safety Executive for Northern Ireland (HSENI).

In Great Britain trading standards authorities, and in Northern Ireland district councils, are responsible for enforcing the Amended PPE Regulations in relation to PPE retained for private use or consumption (other than in circumstances subject to the remit of HSE/HSENI).

Where the PPE are intended to be used exclusively or primarily on relevant nuclear sites as defined in Regulation 3(4) of the 2018 Regulations, the Office for Nuclear Regulation is responsible for enforcing the Amended PPE Regulations (http://www.onr.org.uk/).

The Enforcement Regulations provides the power to enforcement authorities to take action against economic operators for PPE that are not in conformity with the EU PPE Regulation. There are requirements on manufacturers, distributors and importers to co-operate with the enforcement authority as appropriate on request.
The 2018 Regulations also provide powers to the Secretary of State to enforce the EU PPE Regulation and RAMS (Regulation (EC) 765/2008) as retained in UK legislation, which sets out requirements for market surveillance of products. UK market surveillance authorities will take all appropriate measures to withdraw from the market or to prohibit and restrict the supply of products which may endanger the health and safety of persons, property or the environment.

Regulators’ Code

Market surveillance authorities (Local Authority Trading Standards) must continue to have regard to the Regulators’ Code when developing the policies and operational procedures that guide their regulatory activities in this area. They should carry out their activities in a way that supports those they regulate to comply and grow, including choosing proportionate approaches that reflect risk.

In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required, or decisions taken, and the reasons for these. Unless immediate action is needed to prevent a serious breach, regulators should provide an opportunity for dialogue in relation to the advice, requirements or decisions, with a view to ensuring that they are acting in a way that is proportionate and consistent. The Secretary of State takes account of the provisions of both the Regulators’ Code and the Growth Duty in exercising his regulatory functions.

A link to the Regulators’ Code can be found here:

Penalties

A person committing an offence under the 2018 Regulations may be liable to a penalty. Penalties can include a fine or a prison sentence of up to three months for the most serious offences. It is matter for the enforcement authority to decide whether prosecution is appropriate in each case taking into account the circumstances of the case and the enforcement authority’s own policies, operational procedures and practices in line with the Regulators’ Code. Should a prosecution take place, it is at the discretion of the court to decide the penalties imposed on the offender.

13. Where to find EU guidance about The EU Regulation on Personal Protective Equipment 2016/425

EU Regulation 2016/425 was directly applicable in UK law before the UK left the EU but is EU legislation. It has been retained in UK law and adapted for UK purposes in the form of the EU PPE Regulation (as defined above). As a result, while the general principles may be the same, there may be differences between EU Regulation 2016/425 as applied in the EU and the EU PPE Regulation as applied in the UK.

You can find further and more detailed guidance on Regulation (EU) 2016/425 here:
https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en
The European Commission’s ‘Blue Guide’ aims to give a better understanding of EU product safety rules and to their application across different sectors and throughout the EU single market. You can view that here:

http://ec.europa.eu/DocsRoom/documents/18027/

14. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a ‘Notified Body’ prior to the UK leaving the EU.

- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly. This includes persons who are based in the EU or Switzerland, if they were appointed before the UK left the EU.

- **Declaration of conformity** – A document prepared by the manufacturer which must detail, among other things, the following:
  - The specific product to which the declaration is referring;
  - The name and address of the manufacturer and, where applicable, their authorised representative.

  This must be kept by the manufacturer for a period of ten years from the date on which the product was placed on the market. This declaration must be made available to the enforcing authority upon request.

- **Distributor** – Any person in the UK supply chain, other than the manufacturer or the importer, who makes a PPE available on the UK market.

- **Enforcement Authority** – In Great Britain, for products in use in the workplace, this is the Health and Safety Executive. For PPE for consumer use this is local Trading Standards authorities. In Northern Ireland, for PPE in use in the workplace, this is the Health and Safety Executive Northern Ireland. For PPE for consumer use this is district councils. For nuclear sites in Great Britain, the Office for Nuclear Regulation is the enforcing authority.

- **Importer** – A person established in the UK who places PPE from a country outside of the UK on the market. A person who before the UK left the EU distributed PPE within the EU (including the UK) or from Switzerland will now be an importer if they are bringing PPE into the UK from another country (including EU Member States, the EEA and Switzerland).

- **Manufacturer** – A person who manufactures PPE or has PPE designed or manufactured and markets that PPE under their name or trademark.

**UK Conformity Marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the UK market, in place of the CE marking which is the conformity marking used in the European Union.
This will only apply if the UK leaves the EU without a deal.