Experts in Safety

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expert guide /

A summary of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment

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Arco is the UK and Ireland's leading supplier of personal protective equipment, workwear and workplace safety products offering a world-class range of over 170,000 products.

As Experts in Safety we are widely recognised as a provider of specialist advice through our branch network and this is further supported by our training and consultancy division. We reach our customers through an extensive product catalogue, interactive website, local sales offices and a 48 strong store network. We pride ourselves on providing customers with great availability, quality, and price.

Founded in 1884 Arco has a heritage spanning four generations. With traditional family values at the heart of the business we pride ourselves on our core values; respect, hard work, enterprise and excellence in reputation. We fully subscribe to the ETI's Nine Principles Base code and have fully incorporated the internationally recognised code of labour practice into our own ethical policy. Our quality assurance surveillance of our manufacturers also includes checking the quality of the safety, health and welfare of our manufacturers' employees. In 2007 Arco was the first distributor in our industry to become a member of the Ethical Trading Initiative (ETI) and in 2010 we became a member of Sedex, the Supplier Ethical Data Exchange. We continually support local communities and charities donating in excess of 1% of pre tax profits annually.

As we are members of the BSIF Registered Safety Suppliers Scheme you can be confident that we will supply safety equipment which is genuine and compliant with the relevant standards and regulations. The BSIF monitor and regulate members of the scheme by conducting regular standards audits.

Bsif Registered Safety Supplier

Enabling responsible supply chains Sedex

Ethical Trading Initiative

Awarded for Quality Reliability Distinction UK Superbrands 2016

best company "one to watch" 2016

Foreword from the joint MDs

Arco warmly welcomes the introduction of the new PPE Regulation and the focus it brings on raising standards of Personal Protective Equipment (PPE).

The UK has one of the best combined health and safety records in the world, of which we are very proud and the new PPE Regulation stands to enhance this provided it is implemented effectively. Changes such as moving hearing protection from Category 2 to Category 3, an increased focus on supply chain accountability and the introduction of a five year renewal for CE Certification are major opportunities to raise standards of protection, drive product innovation and eliminate inferior products from the market.

The challenge will be making sure that these opportunities become a reality. This is especially true in light of evidence that substandard products are entering the UK market, something which has been highlighted by both the British Safety industry Federation (BSIF) and our own research.

Of serious concern is evidence that procedural weaknesses within the EC type approval and CE marking process is resulting in the sale of substandard products accompanied by legitimate CE Certificates. These weaknesses can allow a less reputable manufacturer or importer to gain CE Certification for products they wish to market, and then subsequently make changes to the product. Consequently, the altered products may not meet the required safety performance despite being presented with CE Certification.

As the BSIF recently wrote to its members to say: "This situation poses an obvious risk to end users, and is a timely reminder that only relying on CE certification for certain product types is no guarantee of ongoing quality assurance."

The new emphasis on supply chain accountability, as well as the requirement for a five year renewal for CE Certification, will go some way towards addressing this but as the period for these changes to be implemented could take until 2018, action is needed now. Even once the new Regulation becomes effective, with the UK's competent authorities for market surveillance of PPE under increasing pressure due to reduced budgets, the Regulation needs pro-active support from the industry to ensure its full impact is felt.

This is an area where Arco is leading the way. Arco takes the issue of PPE quality very seriously and has representation on the BSIF's Federation Council. We are the only distributor in the UK to have invested in developing our own independently accredited Product Assurance Laboratory for the testing of PPE. With our full PPE product offering, we comply with the obligations laid down by the EU Parliament.

The success of the new PPE Regulation depends upon everyone working together. Purchasers need to remain vigilant to safeguard workers; don't be afraid to ask suppliers about their quality assurance processes. Meanwhile Manufacturers, Importers and Distributors need to have the necessary measures in place to ensure that the products they supply are capable of doing the job they are intended for and they need to be ready to communicate this with customers.

With safety at the forefront of everything we do, Arco will continue to lead the way and raise the standards of compliance across the UK.

Thomas Martin **Neil Jowsey**

Executive Summary

April 2016 saw the introduction of a new PPE Regulation which updates and strengthens the rules governing the placement of Personal Protective Equipment (PPE) on the market in the European Union (EU).

PPE refers to any equipment designed to be worn or held by an individual for protection against one or more health and safety hazards.

The PPE Regulation, which replaces the old Personal Protective Equipment (PPE) Directive (89/686/EEC), comes into force in April 2016 twenty days after it was published in the Official Journal of the European Union (OJ). It will become fully into force 24 months later.

Whereas the PPE Directive sets out a goal for EU countries to achieve, its reclassification as a Regulation makes it a binding legislative act which must be applied in its entirety across the EU. Unlike the PPE Directive, the new Regulation does not have to be transposed into each Member State's national law. The PPE Regulations 2002, through which the PPE Directive was implemented in the UK are therefore now obsolete.

As well as reclassifying some products and introducing a five year limit on CE certificates, one of the most significant changes of the new PPE Regulation is that it clearly identifies the obligations of all economic operators in the supply chain. It also clearly defines that an importer or distributor who markets a product in Europe under their own name, brand or trademark becomes liable for the full manufacturer's obligations. These are significant areas of clarification for the whole supply chain so it is essential for all those involved to understand their obligations and for PPE customers to know what they can expect from their suppliers.

In this guide we set out these changes in more detail and discuss how they will impact us and you.

The History of PPE Regulation in Europe

Objectives of the PPE Directive

The PPE Directive was one of the first New Approach Directives when it was drawn up in 1989. In order to facilitate a single European market for goods over 20 years ago the European Union (EU) began what is described as the New Approach.

The principal aim of the 'New Approach' was to remove barriers to trade by requiring all products to meet common minimum health and safety requirements, which were supported by agreed standards at the product level. This framework was intended to be applied equally and consistently throughout the EU and the other trade partners of the European Economic Area (EEA).

It is generally accepted that the PPE Directive was a success; it led to the harmonisation of standards for PPE, removed barriers to trade and helped to develop a large European PPE market.

Why change the PPE regulations?

The Directive had its limitations.

- There were concerns that product's coverage and conformity assessments were inadequate and inconsistent.
- there were questions over the effectiveness of market surveillance.
- technologies and processes for developing and bringing PPE to the market had changed.

Following consultation with major stakeholders it was decided to make some key changes and to transform the rules from a Directive into a Regulation.

The new PPE Regulation came into force twenty days after it was published in the Official Journal of the European Union, (OJ). It will become fully effective 24 months later and will then be mandatory for all EU member states. EC type-examination certificates that have already been issued remain valid until 2024, provided those EC type-examination certificates do not become invalid for any other reason, such as expiry dates, classification changes or product changes requiring reassessment.

Transitional Timescales

PPE directive transition period and entry into force

<table>
<tr><th>Date of Publication</th><th>Entry into Force</th><th>Date of Application</th><th>Application + 1 Year</th><th>Application + 6 Years</th><th>Transition Complete</th></tr>
<tr><td>Q1 2016</td><td>21 April 2016</td><td>21 April 2018</td><td>21 April 2019</td><td>21 April 2023</td><td>21 April 2023</td></tr>
<tr><td colspan="4">PPE certified 89/686 can still be placed on the market</td><td rowspan="2">Exiting certificates still valid if no expiry date</td><td rowspan="2">All old certificates become invalid</td></tr>
<tr><td colspan="3">New Cat III item to be recertified</td></tr>
<tr><td colspan="6">New articles requiring certification follow new regulation procedure process</td></tr>
</table>

- Provisions on Notified Bodies shall apply already six months after the entry into force of the PPE Regulation
- To allow notified Bodies to fulfil its recertification tasks, the manufacturer shall submit his application for certification at the earliest 12 month's and at the latest 6 month's prior to the expiry date of the certification

PPE Categories explained

Each Category of PPE must comply with clearly defined conformity assessment modules prior to being placed on the market. The categories include:

Category 1 - Simple PPE

PPE in this category is designed to protect people from minimal risks.

These include:

- Superficial mechanical injury
- Contact with cleaning materials of weak action or prolonged contact with water
- Contact with hot surfaces not exceeding 50°C
- Damage to the eyes due to exposure to sunlight (other than during observation of the sun)
- Atmospheric conditions that are not of an extreme nature.

Manufacturers of simple design PPE are allowed to assess the level of protection via internal production control and declare conformity by means of a Declaration of Conformity, without verification by a notified body.

Category 2 - Intermediate PPE

This category covers **risks other than those defined by neither Category I nor Category 3.**

Category 2 PPE is subject to an EU type examination by a notified body, following which the manufacturer will need to supply the customer with a Declaration of Conformity. The manufacturer must also have an internal production control system to ensure the product continues to conform.

Category 3 - Complex PPE

PPE that comes under Category 3 is designed to protect people from **risks that may cause very serious consequences such as death or irreversible damage to health.**

Category 3 relates to the following:

- Substances and mixtures which are hazardous to health
- Atmospheres with oxygen deficiency
- Ionising radiation
- High-temperature environments the effects of which are comparable to those of an air temperature of at least 100°C
- Low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less
- Falling from a height
- Electric shock and live working

The following risks have now been added to Category 3

- Harmful biological agents
- Drowning
- Cuts by hand-held chain-saws
- High-pressure jets
- Bullet wounds or knife stabs
- Harmful noise

Manufacturers of Category 3 PPE are subject to an EU type examination by a notified body and to one of the two quality assurance procedures as described in Article 19 of the PPE Directive. Upon completion, the manufacturer must compile a Declaration of Conformity.

Key Changes

The PPE Regulation replaces the PPE Directive

The PPE Directive has been replaced by a Regulation which is a binding legislative act that must be applied in its entirety across the EU. The PPE Directive had previously been implemented in the UK through the PPE Regulations 2002, but the new PPE Regulation does not have to be transposed into each Member State's national law meaning that the 2002 regulations have been repealed.

The Personal Protective Equipment (PPE) at Work Regulations 1992, which govern the employer on the suitability, provision, maintenance, instruction and use of PPE still stand.

The only change is that once they required employers to select appropriate PPE in line with the Personal Protective Equipment Regulations 2002, whereas now they require employers to select appropriate PPE in line with The PPE Regulation.

The PPE Regulation now affects the whole supply chain

The rules of the new PPE Regulation apply to the whole supply chain rather than just manufacturers. Now everyone involved in the manufacture, supply and distribution of PPE, referred to in the new regulation as 'Economic Operators', must ensure their PPE meets with the standard requirements.

Their responsibilities include getting product approval, making sure products conform to the regulation and keeping technical files and records. Importers are also obliged to sample test where appropriate their PPE unless they can provide a rationale why they do not need to.

The scope of the PPE Regulation has changed

For the purpose of the regulation PPE is defined as:

"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."

The scope of the new Regulation has been increased to include PPE designed and manufactured for private use protecting against heat (e.g. oven gloves). Distance selling is also now covered by the Regulation.

Areas where the Regulation does not apply to PPE.

These include:

- PPE which is specifically designed for use by the armed forces or in the maintenance of law and order
- PPE which is designed to be used for self-defence, with the exception of PPE intended for sporting activities
- PPE which is designed for private use to protect against atmospheric conditions that are not of an extreme nature and damp and water during dishwashing
- PPE for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States
- PPE 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 motor cycles and mopeds

In addition, PPE for use at trade fairs, exhibitions, demonstrations or similar events do not require certification, provided a visible sign indicates the PPE does not comply to the Regulation.

Some types of protection have moved from Category 2 to Category 3

Certain types of protection have moved from Category 2 (Intermediate) to Category 3 (Complex).

All types of hearing protection against harmful noise have been re-classified to Category 3 (Complex), which is designed to protect against very serious risk, where the hazard is not immediately obvious.

This move means these items are now subject to the strictest conformity assessment procedure which requires EU type-examination plus ongoing surveillance.

Type-examination certificates are to be valid for five years

EU type-examination certificates which apply to Categories 2 and 3 are to be time limited for a maximum of five years.

This brings the PPE Regulation in line with similar European requirements such as the Medical Devices Directive.

All PPE must be supplied with a Declaration of Conformity

There is now a requirement to supply a Declaration of Conformity with every item of PPE that is placed on the market. A Declaration of Conformity is a document which the manufacturer signs to say that the product meets all the requirements of the applicable legislation. It must be issued by the manufacturer, or by the person placing the product on the EU market if the manufacturer is not based in Europe.

Alternatively, a manufacturer can supply with the user instructions, a simplified Declaration of Conformity including a single sentence and a reference to the web address where the complete Declaration of Conformity can be found.

Where a product meets a combination of EU regulations, i.e. PPE, Food Contact etc. a single EU Declaration of Conformity can be used.

Technical documentation must be retained for 10 years after the PPE has been placed on the market.

During the transition period, certificates issued in 2018 will apply for six years.

Obligations Clearly Defined

Obligations of Economic Operators

An Economic Operator can be defined as 'the manufacturer, the representative, the importer and the distributor.

All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only PPE which is in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

What must manufacturers do?

- Provide the EU Declaration of Conformity with the PPE or provide with the user instructions an internet address at which the EU Declaration of Conformity can be downloaded.
- Ensure that procedures are in place for series production to remain in conformity with the PPE Regulation.
- Draw up all technical documentation referred to in Annex III.
- Carry out a product risk assessment and shall envisage not only the intended use but also the reasonably foreseeable uses (Annex III).
- Retain all technical documentation for 10 years after the PPE has been placed on the market.
- Carry out sample testing of PPE made available in the market, keep a register of complaints and keep distributors informed of such monitoring.
- Mark the product or packaging with their name or registered trade name or mark and a single point postal address.
- Inform the competent authorities when they become aware of PPE that presents a risk.
- Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity shall immediately take corrective measures necessary to bring it into conformity, to withdraw it or to recall as appropriate.
- Supply manufacturer instructions (IfU) with the smallest individual sales unit in a language easily understood by the end user and market surveillance authority.

What must importers do?

- Before placing PPE on the market importers shall ensure the conformity assessment procedure has been carried out by the manufacturer.
- Ensure the manufacturer has completed all technical documentation referred to in Annex III.
- Retain the Declaration of Conformity for 10 years after the PPE has been placed on the market and ensure the technical documentation is available to the authorities on request.
- Ensure instructions for use (IfU) to be supplied with the smallest individual sales unit in a language easily understood by the end user and market surveillance authority.
- Carry out sample testing where appropriate of PPE made available in the market, keep a register of complaints and keep distributors informed of such monitoring unless they have deemed it not appropriate.
- Mark the product or packaging with their registered trade name or mark and a single point postal address.
- Inform the competent authorities when they become aware of PPE that presents a risk.
- Importers who consider or have reason to believe that PPE which they have made available on the market is not in conformity shall make sure that the corrective measures necessary to bring it into conformity, to withdraw it or to recall it are taken.
- Be prepared to participate actively in market surveillance tasks.

What must distributors do?

- Act with due care when placing product on the market.
- Before placing PPE, Distributors shall verify that it bears the CE Marking, is accompanied by the required documents and the instructions for use and all required information.
- Before placing PPE on the market, distributors must ensure the conformity assessment procedure has been carried out by the manufacturer.
- Inform the competent authorities when they become aware of PPE that presents a risk.
- 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 are taken.
- Be prepared to participate actively in market surveillance tasks.

Cases in which obligations of manufacturers apply to importers or 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 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 the Regulation may be affected.

What we advise employers to do.

If you are responsible for the purchase of PPE you need to ensure that your PPE providers are able to meet with the new Regulation in the same way as you needed to ensure they met with the old Directive.

Identifying true product compliance is difficult for the user. The responsibility falls to the manufacturer, who may not have the resources in place to ensure regular testing. Anyone who has concerns over the safety of the equipment they are being supplied should follow these steps:

- Ask your suppliers for a declaration of conformity that shows original certification for the PPE you are purchasing.
- Ask your suppliers to define their process for sample testing to ensure safety products continue to meet the required standards.
- Ensure your suppliers are members of the BSiF Registered Safety Supplier Scheme.
- Ask your suppliers to define their process of quality assurance at the manufacturing facility to ensure the products are being manufactured as they were originally certified.
- Always buy from a trusted source.

Be aware that the following factors constitute formal non compliances:

- The CE marking has been affixed in procedural violation of the regulation
- The CE marking has not been affixed
- The identification number of the notified body involved in the production control phase has been affixed incorrectly or has not been affixed
- The EU declaration of conformity has not been drawn up or has not been drawn up correctly
- The technical documentation is either not available or not complete
- The technical information referred to in the manufacture/ importer obligations is absent, false or incomplete
- Any other administrative requirement provided for in the manufacture / importer obligations is not fulfilled

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