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PPE update

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At present, the legislation for placing PPE (personal protection equipment) on the EU market is Directive 89/686/EEC, which became an active part of European law in 1995 and was designed to eliminate barriers to trade and improve health and safety. Since then, manufacturers of PPE have been required to follow certain defined approval procedures before affixing the now familiar CE mark to the product. It is soon to be replaced by a new Regulation (EU) 2016/425.

PPE is defined as 'any device or appliance designed to be worn or held by an individual for protection against one or more safety or health hazards'. This captures a wide variety of products which the Directive divides into one of three categories based on associated hazards (*Figure 1*). Procedures for demonstrating compliance and the involvement of a Notified Body (*Figure 2*), differ for each category as shown in *Table 1*. Most

types of PPE footwear fall into the middle category, which is often referred to as 'Category II' or 'Intermediate design', although the directive does not give it a name. For this category, initial examples of products and associated documentation must be tested and assessed by a Notified Body (NB).

EC TYPE-EXAMINATION

An EC type-examination is a check by the NB on the design and documentation of a 'model' or initial example of a PPE item to ensure that it satisfies the basic health and safety requirements of the directive. The process typically involves carrying out a series of tests and examinations that

FIGURE 1: PPE CATEGORIES

Category I ('simple design') – products offering protection against low-risk hazards such as dish washing or gardening gloves.

Category II ('intermediate design') – products offering protection against serious or severe risks such as safety footwear providing toe protection.

Category III ('complex design') – products offering protection against high-risk hazards that could give serious injury or even prove fatal such as footwear protecting against high voltages, chemicals, fire or molten metal.

FIGURE 2: NOTIFIED BODIES

Notified Bodies are predominantly Europe-based organisations which have been appointed by member state governments and notified to the European Commission on the basis of their ability to carry out the tasks defined in, and meet the obligations of, the particular directive or regulation.

are usually specified in a harmonised European standard such as described below. If successful, a certificate is issued to prove conformity. For category II products, this is effectively the end of the NB's involvement and the certificate holder becomes responsible for ensuring compliance of subsequent production.

In addition to initial type-examination, category III PPE is subject to ongoing checks by an NB to ensure that production versions are the same as the initial EC type-certified model. The NB that carries out the ongoing assessment need not, however, be the same as the one that conducted the original type examination. A manufacturer or authorised representative can choose one of two alternative methods for the NB to use when checking the conformity of ongoing production. The first is Article 11A (product monitoring), where the NB takes random samples of manufactured PPE and tests them using the same methods as in the original EC type-examination to ensure continuing compliance. The second method Article 11B (quality system monitoring), requires an audit of the production control system at the manufacturing site. Both assessments are carried out on a regular basis while that item of PPE remains in production.

NEW REGULATION

On March 31st 2016, the European Commission published new PPE legislation (EU) 2016/425 which will replace the current directive in 2018. The EC considers experience gained from working with the current directive has shown the basic principles to work well, so the new



Toe protection is a vital test under ISO standards. CREDIT: SATRA

regulation builds on this success, although some specific areas are changing. One major legislative alteration is that the PPE Directive is being replaced by a regulation that will apply directly in all member states without requiring transposition into national legislation. A number of changes will also be implemented such as the scope and certification requirements. Scope will be extended to cover items intended to provide protection to private users from heat as, for example, in the case of domestic

oven gloves. Commercial users are already covered.

The regulation clearly defines the obligations and responsibilities of the economic operators involved in the sector, including manufacturers, authorised representatives, importers and distributors of PPE. In general, anyone involved in the supply and distribution chain should study the regulation very carefully to ensure they are meeting all required obligations. The new regulation also introduces definitions and adapted conformity assessment procedures for made-to-measure and individually adapted PPE. This will be of particular interest to manufacturers of products such as orthopaedic safety footwear.

Furthermore, a number of types of protection have moved from category II to category III. These include protection against harmful noise, drowning, cutting by hand-held chainsaws, bullet wounds or knife stabs, harmful bacteria and equipment protecting against high-pressure jets. Several of these areas of protection relate to certain types of specialist footwear and, for these, manufacturers will be subject to the strictest conformity procedures. These are EU type-examination in accordance with Module B of the regulation, plus monitoring of ongoing production conformity in accordance with either Modules C2 or D, the equivalents under the current directive being Articles 10, 11A and 11B (Table 1).

In order to ensure that PPE is examined on the basis of being state-of-the-art, a key change is the introduction of time-limited EU type-examination certificates. These will be valid for a maximum of five years, after

TABLE 1 – COMPARISON BETWEEN DIRECTIVE 89/686/EEC AND REGULATION (EU) 2016/425

PPE category	PPE Directive 89/686/EEC	PPE Regulation (EU) 2016/425
I	Self-declaration (manufacturer's responsibility).	Module A – internal production (manufacturer's responsibility)
II	Article 10 – EC type-examination (Notified Body's responsibility).	Module B – EU type examination (NB's responsibility)
III	Article 10 – EC type-examination plus either Article 11A – ongoing surveillance through testing or Article 11B – ongoing surveillance through factory auditing (all Notified Body's responsibility).	Module B – EU type examination plus either Module C2 – production verification or Module D – production quality assurance.

**To ensure easy access to the declaration of conformity, manufacturers will need to ensure that when PPE is supplied to an end user, it is accompanied by either a full hard copy of the declaration or the internet/website address where the declaration can be accessed.*

FIGURE 3: PLACING AND MAKING AVAILABLE ON THE MARKET

In broad terms, placing on the market is when an individual product is made available in the EU for the first time. Hence, it is transferred from the stage of manufacture (if within the EU) or imported to the EU with the intention of distribution. The only economic operators that can place product on the market are therefore manufacturers or importers.

Making available on the market is when an individual product, already placed on the market, is supplied on the EU market for distribution, consumption or use and so would be typically further down the supply chain. When made available on the market, products must have been in compliance with relevant EU legislation applicable at the time of 'placing on the market'.

**The published official definitions of these two terms include much greater detail, so these descriptions should not be taken as being authoritative.*

which they will need to undergo a revalidation procedure in order to be extended. To ensure sufficient time for any required renewal, the regulation specifies the application must be submitted to the NB at least six months prior to the certificate's expiry date. A simplified renewal procedure is applied when there has been no change to the product, harmonised standard or associated guidance. The regulation also specifies in more detail than the directive, the information that must be contained in the certificate.

The new regulation came into force on 21st April 2016 but will not be applied until 21st April 2018 after which there will be a one-year transition period until 21st April 2019. During this time, it will be possible to place on the market PPE complying with either the Directive or the Regulation. After the transition period, it will still be possible to make *available* on the market PPE according to the directive, but it will no longer be possible to *place* such PPE on the market (Figure 3). NBs can issue EU type-examination certificates against the new regulation before 21st April 2018 but they cannot be used for product placed on the market until after this date.

STANDARDS FOR PPE FOOTWEAR

Neither the PPE Directive nor the Regulation describes in detail how particular types of product should be tested. Hence, to support the legislation, the European Standards agency Comité Européen de Normalisation (CEN) created a number of Technical Committees (TC) in order to develop a

series of harmonised European standards to be used in the testing and certification of PPE. CEN/TC161 is responsible for standards covering products providing foot and leg protection. The European Commission reviews these standards and, if suitable, they become officially harmonised throughout Europe. This means that they have a 'presumption of conformity' to the parts of the PPE legislation detailed in Annex ZA of the particular standard. The publication of harmonised standards is also routinely mentioned in the Official Journal of the EU.

EN ISO 20345: 2011, EN ISO 20346: 2014 to EN ISO 20347: 2012 standards cover safety, protective and occupational footwear which terms are used within these standards to define the level of toe protection provided to the wearer, ISO denoting International Standards Organization, which means they are applicable in many countries throughout the world. These three can be considered as the core documents featuring requirements for most components within footwear, including assessment of durability such as tear or tensile strength, plus flexing and abrasion resistance on the outsole, lining, upper materials, footbeds and insoles. There are also comfort-related assessments that cover the water vapour permeability and absorption properties of the upper materials and ergonomic procedures for the whole footwear. In addition, there is a range of tests for various safety properties that address the protective performance of the footwear.

Some of these tests form part of the basic requirements of the standard,

such as toe protection and slip resistance, while others are considered additional requirements that are only tested if those properties are to be claimed. These additional tests include nail perforation resistance of the outsole, electrical properties such as for antistatic or conductive footwear, heat and cold insulation, resistance to water penetration, ankle and metatarsal impact protection and cut resistance of the upper. To denote whether footwear is provided with a particular safety feature, there is a series of marking codes. In addition to these core standards for general purpose safety footwear, there are also a number of other standards designed for specific end uses.

EN ISO 17249: 2013 safety footwear with resistance to chainsaw cutting.

Accidents involving powered chainsaws can have serious consequences. As detailed above, this type of protection will be moving to category III (currently referred to as complex design) in the new regulation. This means that, in addition to the EU type-examination of the initial products, manufacturers will also be subject to ongoing conformity assessments.

The standard includes a cut test using an electrically powered chainsaw running at a controlled speed that is dropped onto the test sample. As the chain drops, the power is cut so that a fixed quantity of energy remains in the system stored in a flywheel. The product fails the standard if the chain cuts through the footwear before the chain has come to rest. There are three levels of protection, based on the linear speed of the chain at the point of contact with the test specimen as follows: Class 1 (20m/s), Class 2 (24m/s) and Class 3 (28m/s). The standard also includes specific design requirements, such as a definition of protective coverage area for those parts of the footwear offering chainsaw cut resistance plus it references EN ISO 20345 for all other non-chainsaw-related properties.

EN 13832: 2006 footwear protecting against chemicals.

In terms of splashes and spills from liquid chemicals, the lower limbs and feet of a worker can be at particular risk, so

specialist footwear is often needed to protect against exposure to chemicals. This standard is being revised at present but the current 2006 version of EN 13832 is split into three parts.

Part 1 covers terminology and provides details of specialised test procedures such as permeation and degradation. Permeation is a process by which a chemical moves through a material at the molecular level and degradation is a measure of how much a material deteriorates after exposure to a chemical. Part 2 specifies requirements for footwear that only has limited resistance to chemicals and the intention is to include a splash test in this standard during the revision process. Part 3 specifies requirements for footwear more highly resistant to chemicals and only covers all-rubber and all-polymeric footwear, specifically excluding leather footwear and low shoe and ankle boot designs. Unlike part 2, it requires the chemical permeation resistance of the footwear materials to be tested, as well as their chemical degradation resistance.

EN 13634: 2015 protective footwear for motorcycle riders. Riding a motorcycle can be hazardous, with a potential for injury due to falling off or being in a collision with another vehicle or obstacle. EN 13634 makes reference to EN ISO 20345 for certain core test properties but in addition also includes specific motorcycle-orientated requirements for ergonomics and protective performance of materials. A number of these specialised tests are cross-referenced to the European standards for motorcyclists' clothing and gloves. A revision to EN 13634 is currently being finalised.

EN ISO 20349: 2017 footwear protecting against molten metal splashes. Accidents involving molten metal can cause significant injuries. When molten metal comes into contact with the outer surface of protective footwear, heat can be transmitted to the wearer's foot either by conduction through the footwear materials or by molten droplets penetrating into the footwear. The former of these two risks will be greatly increased if the molten metal adheres to, or is trapped by, the outer surface of the footwear.

Hence, for foundry footwear to work



Resistance to nail penetration is a further key test for safety footwear.

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effectively, it should quickly shed the molten metal and also have a good level of thermal insulation. The EN ISO 20349 standard is divided into two parts with one covering foundry footwear and, the other, footwear to be worn during welding and allied processes. Both parts require footwear to comply with EN ISO 20345, but also include a number of additional tests and requirements to assess protection against molten metal.

EN 15090: 2012 footwear for firefighters. Firefighters are involved in a variety of activities in addition to fighting fires such as dealing with chemical spills. It is a particularly hazardous occupation and footwear for such rigorous applications may need to offer protection against the hazards associated with impact and crushing of toes, together with protection against various thermal hazards. EN 15090 references EN ISO 20345 for most physical requirements. In terms of thermal testing, firefighters' boots are subject to flame and radiant heat tests on the upper and flame and contact heat tests on the outsole.

EN 50321: 1999 electrically insulating footwear. If an electric current is able to pass through a person's body, there is a risk of injury. These boots are generally worn when working on live equipment and test methods in EN 50321 include measuring leakage

currents through the full thickness of the boot's construction when voltages such as 10,000V are applied between the inner and outer surfaces while the boot is partially immersed in a tank of water. A revision to EN 50321 is currently being finalised.

As is the case with several of the above, all standards are subject to regular reviews. At this time, the Technical Committee can decide to revise, amend, withdraw or just reconfirm a standard. The TCs also consider new work items in areas where no current standards already exist. For example, a new standard is currently being developed for overshoes, overboots and accessories. If all goes to plan, this will eventually be published as EN ISO 2135 and will probably be in several parts.

Footwear that is designed to provide a specific type of protection and is placed on the European market currently falls within the scope of the European PPE Directive and requires CE marking as such. On 21st April 2018, the current directive will be repealed and after 21st April 2019 all product placed on the market will need to conform to regulation (EU) 2016/425. To help with the certification process to both the current directive and the forthcoming regulation, there are a number of European standards that describe in detail how various types of footwear should be tested and what performance requirements should be met. 