THE NEW REGULATION FOR PERSONAL PROTECTIVE EQUIPMENT (EU) 2016/425

Paul Verhelst, Business Development Manager SIP Protection

From 21st April 2018, the PPE Directive 89/686/CEE has been replaced by the new PPE Regulation (EU) 2016/425.

We are regularly contacted by customers and end-users to understand what this means for us, for our products and most importantly, for them.

This document resumes the modifications and the impact of them on the transition from Directive to Regulation.

MOST IMPORTANT CHANGES FROM 21ST APRIL 2019

- Change of categorisation for certain categories of products; « Protective Clothing for Users of Hand-held Chainsaws » changes from category II to category III (see overview below)
- Declaration of conformity EU to be supplied with for each product (or internet link)
- Validity/expiration of new EU certificats limited to 5 years.
- Manufacturer's Address on the label

CLASSIFICATION OF CATEGORIES

PPE CATEGORY	DESCRIPTION	ACTIVITY	EXAMPLE
Category I	PPE « of simple design » (protection against superficial mechanical injury or athmospheric conditions that are not exceptional)	Manufacturers self- declaration – Module A	• Sleeves • Waterproof jacket
Category II	« intermediate » PPE – neither simple nor complex design (includes risks other than those listed in categories II and III)	EU Type Examination – Module B	• Schock absorbing helmet • EN 388 – mechanical resistance of gloves
Category III	« complex » PPE (PPE protecting against mortal danger or dangers that may seriously and irreversibly harm the health of the user)	**Module C2 (old 11A)** - Quality Assurance Procedures on the product– EC-Type Examination **Module D (old 11B)** - Quality Assurance Procedures on the Production, with surveillance ***We have chosen Module D procedure***	• Chainsaw Protective Trousers • Chainsaw Protective Jacket • Chainsaw Protective Gloves and Boots • EN 381

CALENDAR

The new PPE Regulation (EU) 2016/425 has entered into forcet on 21st April 2018.

Manufacturers can continue to supply ('placing on the market') according to the old PPE Directive 89/686/CEE until 20th April 2019.

ADVANTAGES OF THE NEW PPE REGULATION (EU) 2016/425

The new legislation stimulates the increase of the safety level of available PPE, in order to guarantee that all PPE commercialized on the European market are in conformity with the PPE Regulation (EU) 2016/425, and by consequence et consequently, to the relevant standards in force.

For category III products, it will also help to assure that the products always respect the requirements of the standard, and have not been tested only once at the initial submission for CE approval.

And products introduced on the market will be approved to the latest versions of the standards.

At SIP Protection, we welcome these modifications introduced in the new PPE Regulation (EU) 2016/425 that will improve even more improve safety for the users.

HOW DOES THIS AFFECT THE OBLIGATIONS AND RESPONSABILITIES OF ALL CONCERNED PARTIES ?

THE MANUFACTURER

As from 21st April 2019, end of the transition time, all obligations must be put in place. At the same time, manufacturers are no longer allowed to place PPE on the market that are improper.

Obligations of certification :

1. Align conformity :
   Category II PPE becoming category III must be regularized
   - Certification files with the Notified Bodies
   - Marking of the garments

   Action SIP Protection : An important part of our products has already been regularized, and we will be completely in compliance latest April 2019.

Documentary and administrative obligations :

1. Access to EU Declaration of Conformity :
   For all PPE, the EU Declaration of Conformity will have to be accessible.
   Action SIP Protection : We will create an internet portal, where everyone will has access to all DoC's. The address will be mentioned on the User Manual and on the label in each garment.
2. Set-up traceability of the PPE :
   The manufacturer must guarantee traceability of every product.
   Action SIP Protection : We already have for our garments, even in category II, a system for traceability, with a style number and a production number.
3. Follow-up of quality :
   The Regulation imposes the manufacturer to have a follow-up system for the quality of the productions.
   Action SIP Protection : We already have a follow-up system in place for the quality of our productions.
   Our follow-up system allows us already now to trace back
   - The date of production
   - The production plant
   - The production line
   - The production batch number of raw materials used (fabrics, blocking material, ..) is linked to our delivery systems and our quality control systems.

   The quality control plan has been transmitted to a Notified Body, according the transmission of EU certificats from category II to category III, and this quality control plan will be audited every year. (Module D).
4. Respect for the calendrer of putting products on the market:
   Every product put on the market as from 21st April 2019 must comply to the requirements of the PPE Regulation (EU) 2016/425.
   Action SIP Protection : We commit ourselves to respect this calendar and the Regulation.

THE DISTRIBUTOR

The transition from category II to category III does not impose extra obligations for the distributor.

As long as the product is conform the legislation at the moment of purchase, there is no major reason to forbid the availability of the product.

This means that products that are conform the Directive 89/686/CEE at the moment of placing on the market can continue being sold.

The distributor has however the obligation to verify if the PPE has the CE marking (EU), if the PPE is accompanied with user instructions and information in a correct linguistic version, understandable for the users.

This means that it is important for the distributor to know where he is in the supply chain ;

- If he buys directly from the manufacturer, it is obvious that the PPE are put on the market at the moment that he purchases the goods.
  - » If the PPE were purchased before 21st April 2019, and if the comply with the 89/686/CEE, then they can be sold until 21st April 2023..
  - » If the PPE were purchases after the 21st April 2019, they must comply with the PPE Regulation (EU) 2016/425.
- If he buys via another distributor, he will have to ask his supplier for informations on the date of putting the PPE on the market.

THE IMPORTER

The obligations for the importers are very similar to the obligations of the manufacturers, but they must also add their company name and address on the PPE, and assure that the appropriate procedures for evaluation of the conformity have been realised by the manufacturer.

THE ECONOMIC OPERATORS (MANUFACTURER – IMPORTER - DISTRIBUTOR)

Obligation to have a traceability system and keep the information during 10 years from the date that they have supplied or been supplied the PPE

- From each operator that has supplied them a PPE
- From each operator whom they have supplied a PPE

THE EMPLOYER

For the employer, the transition from category II to category III, and from the Directive to the Regulation, does not impose extra obligations.

He has for obligation to assure the supply of PPE adapted to the risk, and the risk analysis, to his employees.

THE EMPLOYEE

For the employer, the transition from category II to category III, and from the Directive to the Regulation, does not impose extra obligations.

He must wear the PPE supplied by his employer, and take care of the state of the PPE, and inform himself via the user manual and the caring instructions, supplied with each PPE.

QUESTIONS ET ANSWERS

Q. How does all of the above affect my current SIP Protection products ?

R. The only tangible elements of the products concerned by the changes are the instructions and the markings on the products.
The product must mention brand, and address, in order to assure traceability.
The actual production process and the QA process of SIP Protection will not change. We already perform quality controls on the products that we manufacture, according to the category III requirements, regardless whether or not they were category II.

Q. What is the relation with the Standard EN 381 and class 3

R. The Standerd EN 381 « Protective Clothing for Users of Hand-held Chainsaws» does not change. Class 3 in this Standard corresponds to the speed of the chain of a chainsaw, but that is a different discussion.
The Standard EN 381, and the concerned products, change from category II to category III, with all consequences as written in the above article.
Attention : a new Standard EN ISO 11393 is actually being voted, and will most likely be published in Spring 2019. It will then replace the Standard EN 381. The EN 381 EU certificates will remain valid until their expiry date.

Q. What is the difference between a Directive and a Regulation ?

R. Directives establish certain results required to achieve, but each single member State can decide itself how to transpose into national laws.
Regulations are legally binding for each member State, and come into force on a well precise date in all membre States.

The earlier in the supply chain a non-conforming product is stopped, the easier and the more efficient. Working with a reliable and professional parnter for the supply of PPE is even more important in the future than it is already now.