



EU legislation on Personal Protective Equipment (PPE)

**European Commission
Directorate-General for Internal Market, Industry,
Entrepreneurship and SMEs (Growth)**

Unit C3 – Advanced Engineering and Manufacturing Systems

Personal Protective Equipment (PPE)

- Council **Directive** of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (**89/686/EEC**), as amended (OJ L 399, 30.12.1989, p. 18): applicable from 1 July 1992 until 20 April 2019
- **Regulation (EU) 2016/425** of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51): applicable from 21 April 2018 (with exceptions)

Personal Protective Equipment

As defined in Directive 89/686/EEC and Regulation (EU) 2016/425:

- Worn or held by an individual / a person for protection against health and safety hazards / risks
- For professional or private use



PPE excluded from the scope

- PPE for use by the armed forces or in the maintenance of law and order
- PPE for self-defence
- Some PPE for private use
- PPE for seagoing vessels or aircraft covered by international conventions
- Helmets for 2 or 3 wheeled vehicles

The "New Approach" and the "New Legislative Framework"

Provide Basic / Essential Health and Safety Requirements (BHSRs / EHSRs)

- **which PPE must satisfy to be placed on the market**

Refer to harmonised European standards (hENs)

- **which provide technical solutions to comply with the legal requirements for certain types of PPE**
- **application is voluntary**

Require conformity assessment by a third party ("notified body") for most types of PPE (categories II and III)

- **to support the issue of the EC / EU declaration of conformity**



From Directive 89/686/EEC to Regulation (EU) 2016/425

- The current Directive 89/686/EEC has been substantially successful; however, a broad consensus existed among Member States and other stakeholders on the need for some improvements:
 - a directly applicable **Regulation** instead of a Directive requiring national transposition acts
 - alignment to the "**New Legislative Framework**" (NLF) Decision No 768/2008/EC and other EU legal instruments
 - certain **changes / adjustments** needed in contents (scope, requirements, risks, etc.) according to more than 20 years' experience, and the technological evolution / "state of the art"



Regulation (EU) 2016/425: structure

Keeping the structure of a typical EU internal market total harmonisation legislation, with **8 Chapters (48 Articles)**...

- Chapter I - General provisions (Articles 1-7)
- Chapter II - Obligations of economic operators (Articles 8-13)
- Chapter III - Conformity of the PPE (Articles 14-17)
- Chapter IV - Conformity assessment (Articles 18-19)
- Chapter V - Notification of conformity assessment bodies (Articles 20-36)
- Chapter VI - Union market surveillance, control of PPE entering the Union market and Union safeguard procedure (Articles 37-41)
- Chapter VII - Delegated and implementing acts (Articles 42-44)
- Chapter VIII - Transitional and final provisions (Articles 45-48)



Regulation (EU) 2016/425: structure

... and **10 Annexes**:

- Annex I - Risk categories of PPE
 - Category I: minimal risks
 - Category II: other risks than Categories I and III
 - Category III: risks that may cause very serious consequences
- Annex II - Essential health and safety requirements
 - General requirements applicable to all PPE
 - Additional requirements common to several types of PPE
 - Additional requirements specific to particular risks
- Annex III - Technical documentation for PPE
- Annex IV to VIII - Conformity assessment procedures
 - Modules A, B, C, C2, D
- Annex IX - EU declaration of conformity
- Annex X - Correlation table

Information sources and references: vertical

- **Commission's sectorial website on Personal Protective Equipment (PPE):**
<http://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment/>, including:
 - legal texts
 - guidance documents
 - lists of harmonised European standards (hENs)
 - lists of conformity assessment bodies ("notified bodies")
 - contact points
- **CIRCABC** <https://circabc.europa.eu> Interest Groups: PPE Committee, PPE Working Group, PPE Administrative Cooperation Group, Personal Protective Equipment Notified Bodies group



Information sources and references: horizontal

- **CE marking:** <http://ec.europa.eu/growth/single-market/ce-marking/>
- **New Legislative Framework (NLF):**
<http://ec.europa.eu/growth/single-market/goods/new-legislative-framework>
- **The 'Blue Guide' on the implementation of EU product rules:**
<http://ec.europa.eu/DocsRoom/documents/18027>



Thank you for your attention!

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