Personal Protective Equipment: Current and future legislation

Personal Protective Equipment

Worn/held by an individual for protection against hazards

professional / private use







PPE that is excluded

- *PPE for military or law enforcement*
- *PPE for self-defence*
- *Some PPE for private use*
- *PPE for seagoing ships or aircraft covered by international conventions*
- *Helmets for 2 or 3 wheeled vehicles*

It is a "New Approach" Directive

provides Basic Health and Safety Requirements

- **Which PPE must satisfy**

Refers to harmonised European standards

- **Which set special requirements for certain types of PPE**
- **Application is voluntary**

Requires conformity assessment by a Notified Body for most types of PPE

Why a revision?

- The current legislative framework (Directive 89/686/EEC in force since 1st July 1992) has been substantially successful
- However, a broad consensus exists among Member States and other stakeholders on the need for some improvements
- With time (text is older than 20 years) and experience: certain adjustments are needed
- Alignment with New Legislative Framework Decision 768/2008 (NLF)

Regulation as the legal instrument chosen

- **Proposal to change the Directive into a Regulation:**

  - Simplification: no need of 28 (more in the future) national transposition acts; a single text throughout the EU for all the economic operators

  - Legal certainty: keep total harmonisation, avoid the risk of "gold plating" in the area of internal market legislation

  - No conflict with the subsidiarity principle (Art. 114 TFUE)

  - No change in the regulatory approach: full preservation of the characteristics of the New Approach

Legislative Proposal: structure in Chapters and Annexes

Keeping the structure of a typical internal market harmonisation legislation, with 7 Chapters (42 Articles) and 11 Annexes:

- Chapter I - General provisions
- Chapter II - Obligations of economic operators
- Chapter III - Conformity of the PPE
- Chapter IV - Conformity assessment
- Chapter V - Notification of conformity assessment bodies
- Chapter VI - Delegated and implementing acts
- Chapter VII - Final and transitional provisions
- Annex I - Risk Categories for PPE
- Annex II - Essential health and safety requirements
- Annex III - Technical documentation for PPE
- Annex IV to VIII - Modules A, B, C, F and D
- Annex IX and X - EU declaration of conformity
- Annex XI - Correlation table

Proposed Changes

Changes to

- **the scope**
- **the conformity assessment procedures**
- **documentary requirements**
- **basic health and safety requirements**

+ alignment with the NLF Decision 768/2008

Legislative proposal: main changes

- **Alignment with NLF Decision 768/2008/EC** on a common framework for the marketing of products, including:
  - the definitions set out in chapter R1 of Decision 768/2008/EC
  - the obligations of economic operators (manufacturers, importers, distributors) set out in chapter R2 of Decision 768/2008/EC
  - the obligations for the notification of conformity assessment bodies set out in chapter R4 of Decision 768/2008/EC
  - the modules for conformity assessment set out in Annex II of Decision 768/2008/EC

Legislative proposal: main changes

- **Articles 8 to 13 - Obligations of economic operators**:
  - Mainly taken from NLF Decision 768/2008/EC for Manufacturers, Authorised Representatives, Importers and Distributors
  - The manufacturer of PPE must draw up a technical documentation
  - PPE must be accompanied by a copy of the EU Declaration of Conformity (DoC) or a simplified DoC, according to Annex IX or X respectively
  - Art. 8(4): Manufacturers shall ensure that procedures are in place for series production to remain in conformity with the PPE Regulation. Changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account

Legislative proposal: main changes

- **Article 17 - Risk Categories of PPE**:
  - PPE Categories in the legal text: PPE shall be classified into the risk categories set out in Annex I

- **Annex I - Risk Categories of PPE**:
  - Simplification: only risk-based definitions and exclusive lists of risks. PPE intended to protect users against:
    - Minimal risks: Category I
    - Other risks than Categories I and III and made-to-measure PPE: Category II
    - Very serious risks: Category III. Some risks added, more types of PPE are subject to the most stringent conformity assessment procedure: drowning, cuts by hand held chain-saws, high-pressure cutting, bullet wounds or knife stabs, harmful noise

Legislative proposal: main changes

adapt the conformity assessment procedure to the modules of NLF Decision 768/2008/EC

Cat I -> Module A

Cat II -> Module B

Cat III -> Module B + F1 or D

Aim:

Not to change the existing procedures

Legislative proposal: main changes

- **Articles 19 to 35 - Notification of conformity assessment bodies**:

  - Requirements for national authorities responsible for conformity assessment bodies (Notified Bodies), in line with the NLF Decision 768/2008/EC

  - Article 30: Challenge to the competence of notified bodies

    (3) Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary

Legislative proposal: main changes

- **Articles 39 to 42 - Final and transitional provisions**:

  - The current PPE Directive 89/686/EEC will be repealed and replaced by the PPE Regulation
  - Specific transitional provisions for products manufactured and certificates issued under the PPE Directive 89/686/EEC
  - Transitional period: the PPE Regulation will become applicable two years after its entry into force
  - But: provisions on Notified Bodies shall apply already six months after the entry into force of the PPE Regulation

Thank you for your attention!

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