# The new Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) and the transition from Directive 89/686/EEC

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# EU harmonisation legislation on products in the internal market for Personal Protective Equipment (PPE)

"*Total harmonisation*" legislation (Article 114 TFEU):

- 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as amended (OJ L 399, 30.12.1989, p. 18): applicable from 1 July 1992 until **20 April 2019** (formally repealed from **21 April 2018**)

- **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)

# EU legislation on use of Personal Protective Equipment (PPE) at the workplace

"*Minimum requirements*" legislation (Article 153 TFEU):

- Council **Directive 89/656/EEC** of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18)
  - currently under evaluation in view of a possible revision by the Directorate-General for Employment, Social Affairs and Inclusion of the European Commission (DG EMPL)

# Personal Protective Equipment (PPE)

As defined in Regulation (EU) 2016/425 (in substantial continuity with Directive 89/686/EEC):

- 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
- specific interchangeable components and connexion systems
- for professional or private use

with specific exclusions from the scope

# The “New Approach” and the “New Legislative Framework”

- provide for Essential Health and Safety Requirements (EHSRs)
  -> **which PPE must comply to be placed on the market** (made available on the market for the first time)
- refer to harmonised European standards (hENs)
  -> **of voluntary application**
  -> **which provide for technical solutions to comply with the legal requirements for certain types of PPE**
- require conformity assessment procedures by a third party (“notified body”) for most types of PPE (risk categories II and III)
  -> **to support the issue of the EU declaration of conformity and the affix of CE marking on PPE**

# 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, stakeholders and other interested parties 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** in contents (scope, risks, requirements, conformity assessment, etc.) according to more than 20 years' experience, and the technological evolution / "state of the art"

# Regulation (EU) 2016/425: main changes (I)

- **Alignment to Decision No 768/2008/EC** on a common framework for the marketing of products ("New Legislative Framework"), including:
  - the "Definitions" set out in Annex I, Chapter R1
  - the "Obligations of economic operators" (manufacturers, authorised representatives, importers and distributors) set out in Annex I, Chapter R2
  - the provisions on "Conformity of the product" set out in Annex I, Chapter R3
  - the provisions on "Notification of conformity assessment bodies" set out in Annex I, Chapter R4
  - the "Safeguard procedures" set out in Annex I, Chapter R5
  - the modules for "Conformity assessment procedures" set out in Annex II

# Regulation (EU) 2016/425: main changes (II)

- **Articles 8 to 13 - Obligations of economic operators**:
  - mainly taken from the NLF Decision No 768/2008/EC for manufacturers, authorised representatives, importers and distributors
  - the manufacturer of PPE must provide for adequate procedures for series production and draw up the technical documentation according to Annex III
  - PPE must be accompanied by a copy of the EU declaration of conformity (DoC) drafted according to Annex IX, or the internet address

# Regulation (EU) 2016/425: main changes (III)

- **Article 18 - Risk categories of PPE**:
  - classification of PPE in the legal text, according to the risk categories set out in Annex I
- **Annex I - Risk categories of PPE**:
  - simplification: only risk-based definitions and exclusive lists of risks, for PPE intended to protect users against
    - minimal risks: **category I**
    - other risks than categories I and III: **category II**
    - very serious risks: **category III**
  - some risks added, more types of PPE are subject to the most stringent conformity assessment procedures: drowning, cuts by hand-held chainsaws, high-pressure jets, bullet wounds or knife stabs, harmful noise

# Regulation (EU) 2016/425: main changes (IV)

- **Article 19 - Conformity assessment procedures:**
  - adaptation to the modules of the NLF Decision No 768/2008/EC:
    - cat. I -> module A (Internal production control, Annex IV)
    - cat. II -> module B (EU type-examination, Annex V) plus module C (conformity to type based on internal production control, Annex VI)
    - cat. III -> module B (EU type-examination, Annex V) plus either module C2 (conformity to type based on internal production control plus supervised product checks at random intervals, Annex VII) or module D (conformity to type based on quality assurance of the production process, Annex VIII)

# Regulation (EU) 2016/425: main changes (V)

- **Articles 20 to 36 - Notification of conformity assessment bodies**:
  - more detailed requirements for "notified bodies" and competent national authorities, according to the NLF Decision No 768/2008/EC
  - challenge to the competence of notified bodies
- **Articles 37 to 41 - Union market surveillance, control of PPE entering the Union market and Union safeguard procedure**:
  - simplified procedures to deal with PPE presenting a risk
- **Articles 42 to 44 - Delegated and implementing acts**:
  - specific empowerment to the Commission, assisted by the PPE Committee

# Regulation (EU) 2016/425: structure

Keeping the structure of a typical EU internal market total harmonisation legislation, with 57 Recitals, 8 Chapters (48 Articles) and 10 Annexes:

- 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)
- Annex I - Risk categories of PPE
- Annex II - Essential health and safety requirements
- Annex III - Technical documentation for PPE
- Annex IV, V, VI, VIII and VIII - Conformity assessment procedures (Modules A, B, C, C2, D)
- Annex IX - EU declaration of conformity (model structure)
- Annex X - Correlation table

# Sectoral parties for the EU legislation on PPE (I)

- **PPE Committee** for Regulation (EU) 2016/425, according to Article 44, created in March 2017: integrated by representatives of Member States, convened to deal with the procedures set out in Articles 31, 40 and others

- **PPE Committee Working Group**, created in March 2017, in continuity with the previous one for Directive 89/686/EEC: enlarged to interest parties at EU level. Two meetings per year; next one, on 19 November 2018

- **Administrative Co-operation ("AdCo") Group**: integrated by national market surveillance authorities. Two meetings per year; next one, initially scheduled for October 2018, postponed to 2019

# Sectoral parties for the EU legislation on PPE (II)

- **European Co-ordination of PPE Notified Bodies**: integrated by the "Horizontal Committee of Notified Bodies (HCNB) for PPE" and by the "Vertical Groups (VGs)". One or two meetings per year; last one, held on 29-30 May 2018

- **Technical Committees** of CEN (CEN/TC) and CENELEC (CLC/TC) for PPE standardisation: 8 CEN/TCs and 1 CLC/TC, and international activities with ISO and IEC

- **CEN-CENELEC PPE Sector Forum**: integrated by sectoral experts from different parties. Last meeting held on 10 October 2018

# The transition from the PPE Directive to the PPE Regulation

- **Articles 46, 47 and 48** of the "new" PPE Regulation (EU) 2016/425 establish specific repeal, transitional and application provisions with respect to the "old" PPE Directive:
  - Directive 89/686/EEC was repealed on **21 April 2018**, but products in conformity with the Directive can be still placed on the market until **20 April 2019**
  - Regulation (EU) 2016/425 is applicable from **21 April 2018** (Art. 48), with exceptions:
    - Articles 20 to 36 (on notified bodies) and Article 44 (on committee): from **21 October 2016**
    - Article 45(1) (on penalties): from **21 March 2018**
  - EC type-examination certificates and approval decisions issued under the Directive remain valid until **21 April 2023** unless they expire before that date

# State of play on the transition: PPE guidance

- **PPE Regulation Guidelines**:
  - 1st Edition April 2018, published in the Commission's sectoral website in May 2018
  - "editorial group" for pending issues and further improvements, to be re-set up in view of the next meetings of the PPE Working Group
- **Other guidance documents**:
  - "Guidance document on the PPE transition from Directive 89/686/EEC to Regulation (EU) 2016/425 (FAQ document)", published in March 2017
  - "Guidance document on the implementation of Article 47 on transitional provisions", published in December 2017
  - Other documents on validity of certificates and approval decisions, harmonised standards, placing on the market and stocks etc., still under discussion, to be approved likely in November 2018

# State of play on the transition: standardisation

- **Harmonised European standards**:
  - the last lists of references under Directive 89/686/EEC and the first lists of references under Regulation (EU) 2016/425, published in the Official Journal of the European Union on 27 March 2018 (OJ C 113)
  - new lists under Regulation (EU) 2016/425, published in the Official Journal on 15 June 2018 (OJ C 2019); next publication, under preparation (by the end of 2018)
- **Standardisation Request ("mandate")**:
  - first draft, submitted to the Committee on Standards at the meeting on 18 May 2018; still pending issues to clarify
  - revised draft presented at the meeting held on 15 October 2018, then to be submitted to a written procedure for approval by the end of the year

# State of play on the transition: notified bodies

- **Lists in NANDO**:
  - under Directive 89/686/EEC: valid until 20 April 2019
  - under Regulation (EU) 2016/425: published since October 2016, constantly updated
- **Activities of notified bodies during the "transitional period" (21 April 2018 – 20 April 2019)**:
  - Article 47(1) of Regulation (EU) 2016/425 should be interpreted as allowing for the possibility of bodies notified under Directive 89/686/EEC to continue to issue certificates and decisions regarding conformity of products with that Directive until 20 April 2019
- **Recommendations for Use (RfU) sheets:**
  - for Directive 89/686/EEC: updated in November 2017 and July 2018, valid until 20 April 2019
  - for Regulation (EU) 2016/425: first publication in January 2018, valid from 21 April 2018

# Information sources and references

- Commission's sectorial website on Personal Protective Equipment (PPE): http://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment/
- CE marking: http://ec.europa.eu/growth/single-market/ce-marking/
- "New Legislative Framework": 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
- CEN-CENELEC webpage on PPE standardisation: https://www.cencenelec.eu/standards/sectors/healthsafety/personalprotectiveequipment/
- CIRCABC https://circabc.europa.eu Interest Groups: "PPE Committee", "PPE Working Group", "PPE Administrative Cooperation Group", "Personal Protective Equipment Notified Bodies group"

# *Thank you for your attention!*

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