PPE 2017

Workshop following up on

the 13th European Seminar on

Personal Protective Equipment

One year after: Are you ready for the PPE Regulation now?

Conformity assessment including questions of notification

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ESF

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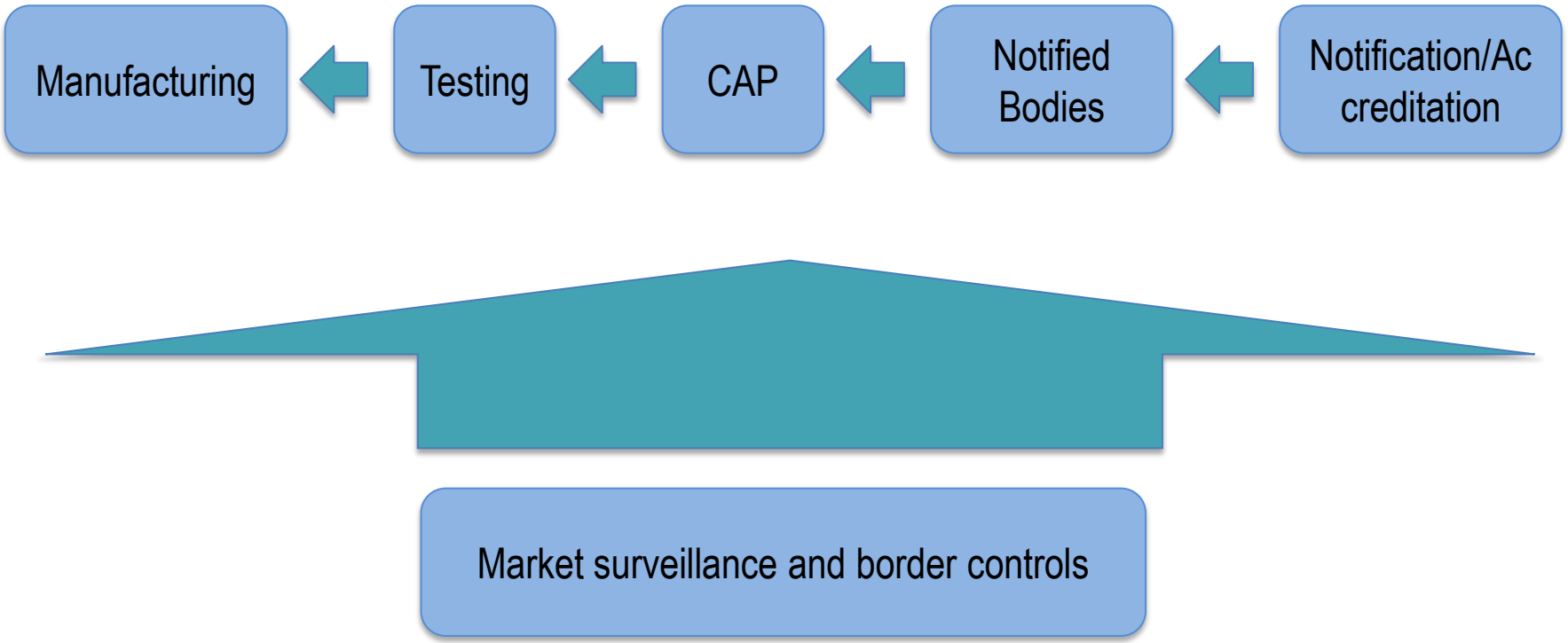
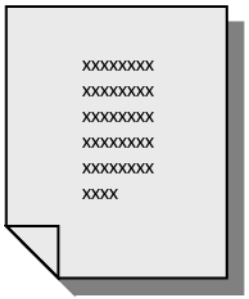
"EU quality chain" – level of safety



Which requirements have to fulfil a PPE to be in conformity with the Directive 89/686/CEE/Regulation (EU) 2016/425?

- **Be safe** → **Comply with the basic/essential health and safety requirements establish in Annex II**

- **Has the evidences** → **Follow the corresponding certification/conformity assessment procedures**



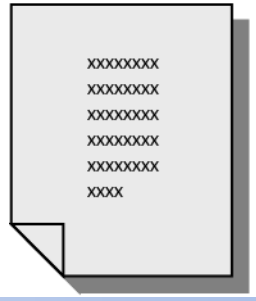
How is claimed conformity with the Directive 89/686/CEE/Regulation (EU) 2016/425?

- **CE marking**

Cat. I & II: CE

Cat. III: CE YYYY

- **EC/EU declaration of conformity**



Compliance with the EHSR

Directive 89/686/CEE	Regulation (EU) 2016/425
Article 3 The PPE referred to in Article 1 must satisfy the basic health and safety requirements laid down in Annex II.	**Article 5 - Essential health and safety requirements** PPE shall meet the essential health and safety requirements set out in Annex II which apply to it.

Applicable when designing and manufacturing PPE to be made available on the market in order to **ensure protection of health and safety of users** and establish rule on its free movement in the Union

Responsibility of manufactures but…….check by Notified Bodies and National Authorities

Basic HSR vs Essential HSR

- **Rewording for more clarity**
- **Some changes:**

1.4 User information

2.13 PPE capable of signalling the user´s presence visually
"PPE in the form of clothing intended for…" vs "PPE intended for"

3.1.3 Mechanical vibration
"Under not circumstances….exceed the limit values" vs deleted

3.5 Protection against the harmful effects of noise
"labelling indicating….value of comfort index.." vs deleted

3.8 Protection against electrical shock
Differentiate Insulating equipment and Conductive equipment

3.9 Radiation Protection
"Manufacturer´s notes must indicate the transmission curves" vs "protection factors"

but……..Preliminary Remarks

Directive 89/686/CEE	Regulation (EU) 2016/425
Annex II – BASIC HEALTH AND SAFETY REQUIREMENTS	**Annex II – ESSENTIAL HEALTH AND SAFETY REQUIREMENTS** **PRELIMINARY REMARKS** 1. The essential health and safety requirements laid down in this Regulation are **compulsory**. 2. Obligations related to essential health and safety requirements **apply only where the corresponding risk exists for the PPE in question**. 3. The essential health and safety requirements are **to be interpreted and applied in such a way as to take into account the state of the art and current practice** at the time of design and manufacture, as well as **technical and economic considerations which are consistent with a high degree of health and safety protection**. 4. The **manufacturer shall carry out a risk assessment** in order to identify the risks which apply to his PPE. He shall then design and manufacture it taking into account that assessment. 5. **When designing and manufacturing the PPE, and when drafting the instructions**, the manufacturer shall envisage not only the **intended use of the PPE**, but also the **reasonably foreseeable uses**. Where applicable, the health and safety of persons other than the user shall be ensured.

Preliminary Remarks - How to be taken into account by manufacturers, Notified Bodies and Market surveillance authorities?

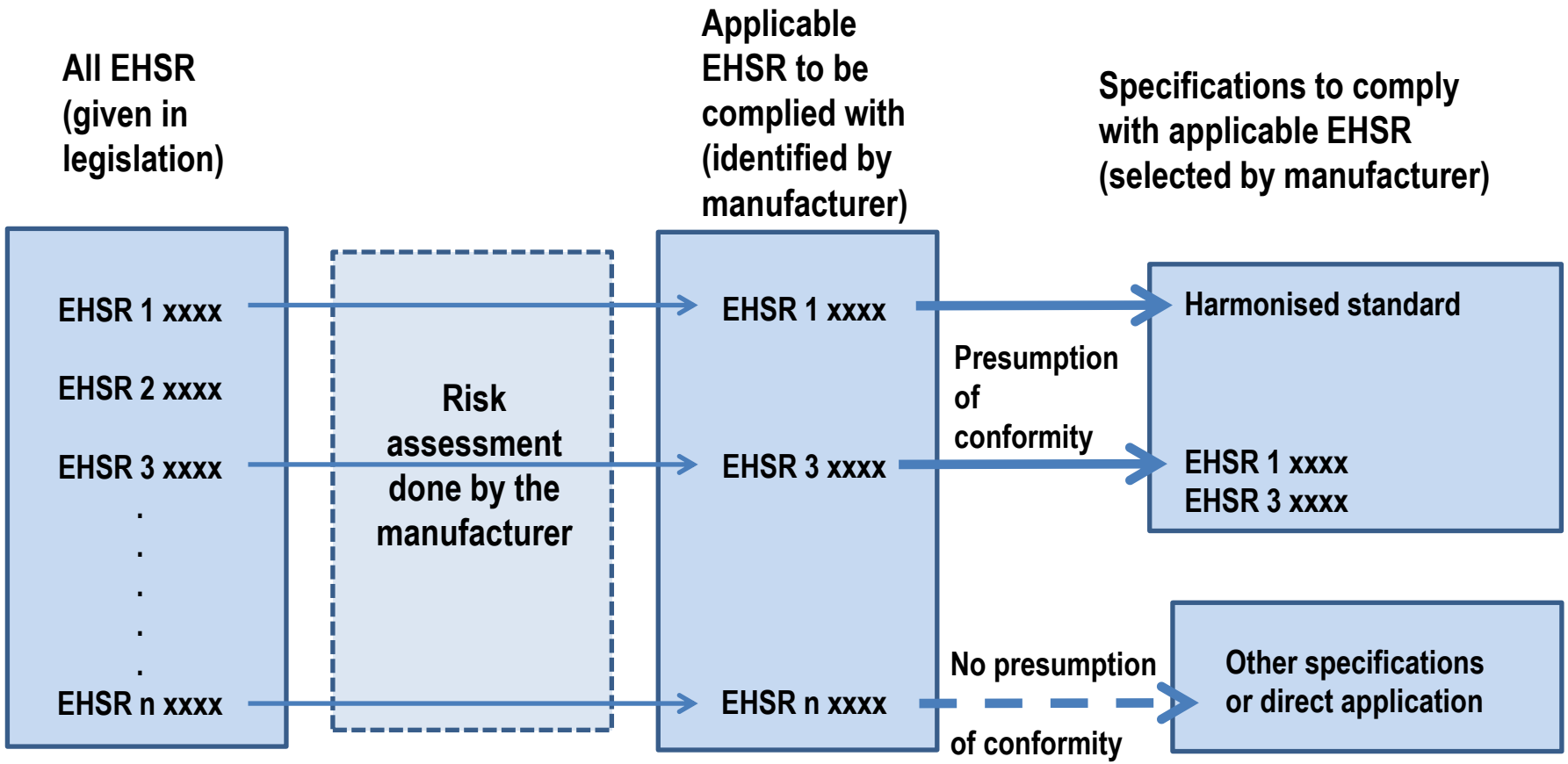
- The EHSR are **to be interpreted and applied in such a way as to take into account the state of the art and current practice** at the time of design and manufacture, as well as **technical and economic considerations which are consistent with a high degree of health and safety protection**.

- The **manufacturer shall carry out a risk assessment** in order to identify the risks which apply to his PPE. Design and manufacture it taking into account that assessment.

  Risks the PPE would protect against
  Risks produced by the PPE when in use

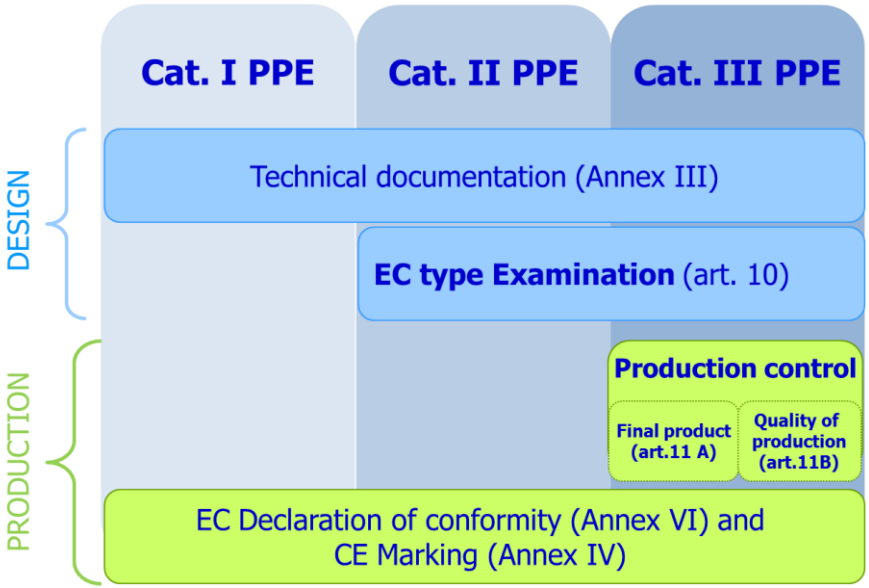
- **When designing and manufacturing the PPE, and when drafting the instructions**, the manufacturer shall envisage not only the **intended use of the PPE**, but also the **reasonably foreseeable uses**.

The role of harmonised standards when complying with applicable essential requirements identified by a manufacturer

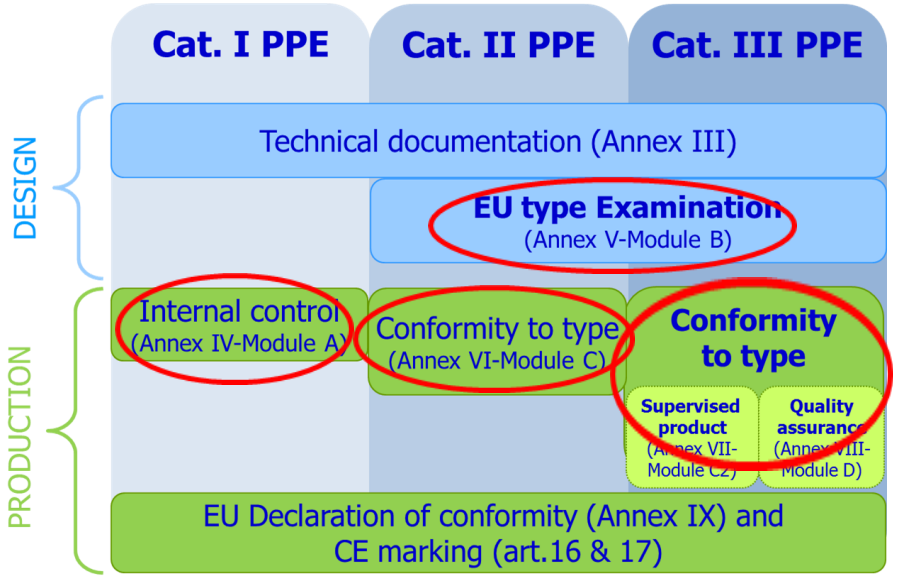


Conformity assessment

Directive 89/686/CEE – Certification procedures (article 8)



Regulation (EU) 2016/425 - Conformity Assessment Procedures (article 19)



5 years validity of the EU type examination certificate

Conformity assessment procedures when a 3rd party is needed:

Notified Bodies

Directive 89/686/CEE	Regulation (EU) 425
Article 9 1. Each Member State shall inform the Commission and the other Member States of the approved bodies responsible for the execution of the certification procedures referred to in Article 8. For information purposes, the Commission shall publish in the Official Journal of the European Communities and keep up to date a list giving the names of these bodies and the distinguishing numbers it has assigned to them. 2. Member States shall apply the criteria laid down in Annex V in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relevant harmonized standards shall be presumed to fulfil those criteria. 3. A Member State shall withdraw its approval from such a body if it establishes that the latter no longer satisfies the criteria referred to in Annex V. It shall inform the Commission and the other Member States of its action forthwith.	**NOTIFICATION OF CONFORMITY ASSESSMENT BODIES** **Article 20 - Notification** **Article 21 - Notifying authorities** **Article 22 - Requirements relating to notifying authorities** **Article 23 - Information obligation on notifying authorities** **Article 24 - Requirements relating to notified bodies** **Article 25 - Presumption of conformity of notified bodies** **Article 26 - Subsidiaries of and subcontracting by notified bodies** **Article 27 - Application for notification** **Article 28 - Notification procedure** **Article 29 - Identification numbers and lists of notified bodies** **Article 30 - Changes to notification** **Article 31 - Challenge of competence of notified bodies** **Article 32 - Operational obligations of notified bodies** **Article 33 - Appeal against decisions of notified bodies** **Article 34 - Information obligation on notified bodies** **Article 35 - Exchange of experience** **Article 36 - Coordination of notified bodies**

- **Article 26** Subsidiaries and subcontracting by notified bodies
- **Article 31** Challenge of the competence of notified bodies
- **Article 33** Appeal against decisions of notified bodies
- **Article 36** Coordination of notified bodies

PPE 2017

Notification procedure

- **Application** (from 21.10.16)
- **Description of conformity assessment activities**
- **Kind of PPE**

} **Accreditation certificate** or documentary evidence of compliance with article 24

Accreditation of notified bodies in Europe

PRODUCTOS:

EN ISO 17025

- Máscaras (excepto máscaras tipo 3)
- Medias máscaras y cuartos de máscaras
- Medias máscaras filtrantes
- Filtros
- Mascarillas sin válvulas de inhalación y con filtros desmontables
- Casco de seguridad (incluido aislante baja tensión, sin ventilación)
- Arnés anticaídas
- Cinturón de sujeción
- Cinturón de retención
- Componente de amarre de sujeción
- Arnés de asiento
- Absorbedor de energía
- Dispositivo anticaídas deslizante sobre línea de anclaje flexible
- Dispositivo anticaídas retráctil
- Equipo de amarre
- Conector
- Guantes de protección contra los productos químicos y los microorganismos

DOCUMENTOS NORMATIVOS:

Para Máscaras (excepto máscaras tipo 3):
UNE-EN 136:1998
UNE-EN 136:1998/AC:2004
UNE-EN 148-1:1999

Para Medias máscaras y cuartos de máscaras:
UNE-EN 140:1999
UNE-EN 140:1999/AC:2000
UNE-EN 148-1:1999

Para Medias máscaras filtrantes:

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EN ISO 17065

Accreditation for the purpose of Notified Body Activity taking into account EA2/17

Directive / Regulation	Conformity Assessment procedure/ Module/article	Category of products or individual products	Essential requirements: Product specification / Properties/Standards
Personal Protective Equipment - 89/686/EEC Implemented in UK Law by: The Personal Protective Equipment Regulations 2002 (SI 2002/1144)	EC Type Examination Article 10, EC Quality Control System for the Final Product Article 11A System for Ensuring EC Quality of Production by Means of Monitoring Article 11B	Equipment providing eye protection Equipment providing foot and leg protection Equipment providing general body protection (clothing) Equipment providing hand and arm protection Equipment providing head protection Equipment providing hearing protection Equipment providing respiratory protection Protective equipment against drowning and buoyancy aids Protective equipment against falls from a height Protective equipment against risks arising from sports activity Specialised areas of competence: High visibility clothing	Basic Health and Safety requirements Annex II of the Directive and Schedule II of the Regulations

Accreditation/Notification of CNMP-INSHT

1. Accreditation by ENAC

2. Application to notifying authorities

3. Resolution of Notification

4. Communication to the Commission and publication on NANDO

EUROPEAN COMMISSION
Directorate General for Internal Market, Industry, Entrepreneurship and SMEs

Resources Based, Manufacturing and Consumer Goods Industries
Advanced Engineering and Manufacturing Systems

NOTE TO THE MEMBERS OF THE PPE WORKING GROUP

Provisions applicable to Notified bodies as of 21 October 2016

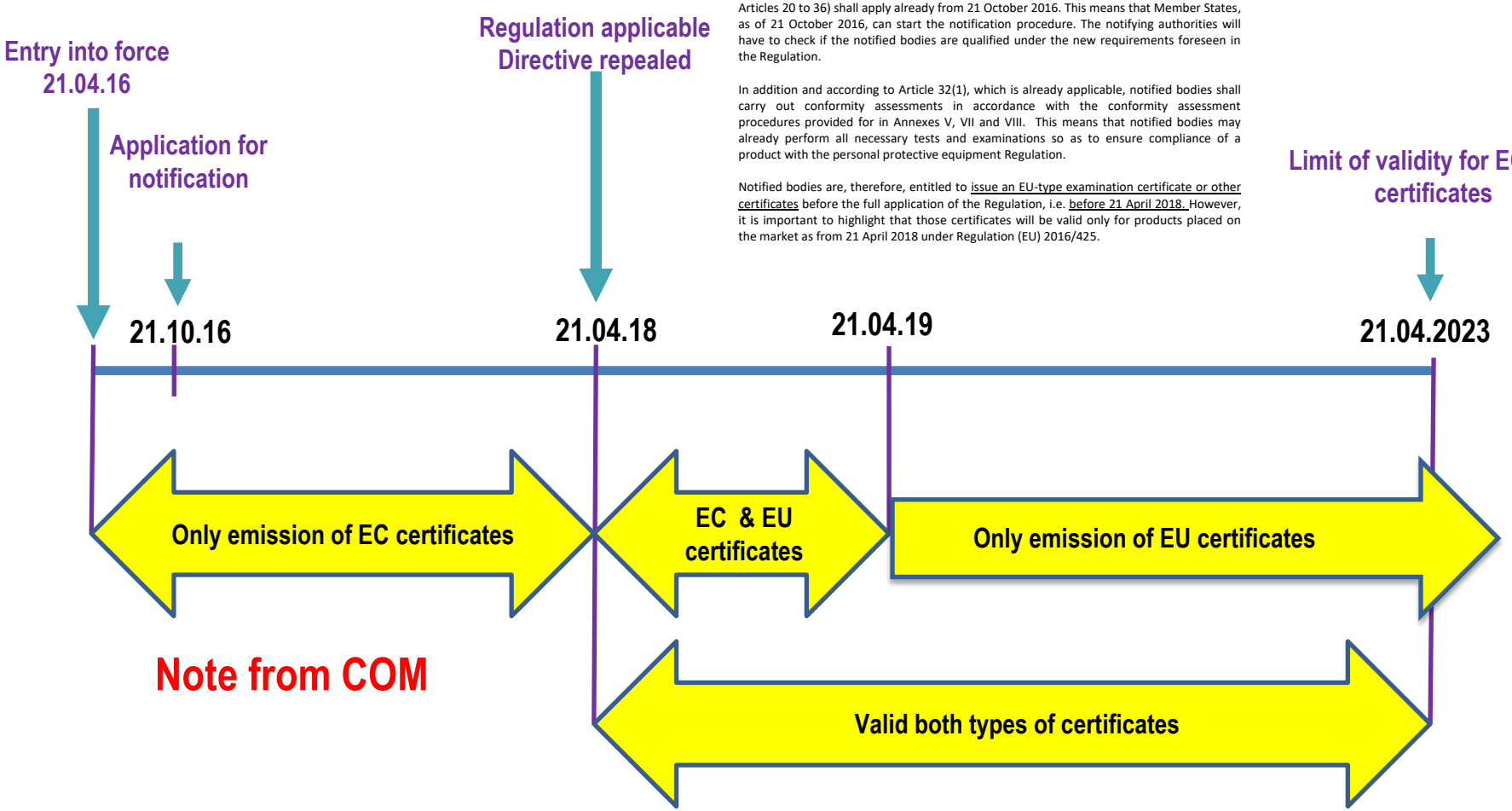
Regulation (EU) 2016/425, of the European Parliament and of the Council of 9 March 2016, on personal protective equipment entered into force on 21 April 2016 and will be fully applicable on 21 April 2018.

However, pursuant to Article 48(2)(a) of the Regulation, provisions on notified bodies (cfr Articles 20 to 36) shall apply already from 21 October 2016. This means that Member States, as of 21 October 2016, can start the notification procedure. The notifying authorities will have to check if the notified bodies are qualified under the new requirements foreseen in the Regulation.

In addition and according to Article 32(1), which is already applicable, notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII. This means that notified bodies may already perform all necessary tests and examinations so as to ensure compliance of a product with the personal protective equipment Regulation.

Notified bodies are, therefore, entitled to issue an EU-type examination certificate or other certificates before the full application of the Regulation, i.e. before 21 April 2018. However, it is important to highlight that those certificates will be valid only for products placed on the market as from 21 April 2018 under Regulation (EU) 2016/425.

When?



Thank you very much for your attention and now it is your turn!