



# EU PPE Regulation 2016/425

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# New PPE Regulation

- Regulation (EU)2016/425 published 31/3/2016
- Replacing Directive 89/686/EEC
- Applicable from 21/4/2018
- 1 year transition period for economic operators
- Alignment with New Legislative Framework
  - Definitions
  - Responsibilities economic operators
  - Stricter rules for Notified Bodies, Authorities, ...

# New PPE Regulation

- Changes in scope :
  - Including ‘oven gloves’ for private use
- Change description of categories : risk based
- Change of category for some products
  - Harmful noise
  - Bullets wounds or knife stabs
  - Cuts by hand-held chainsaws
  - High-pressure jets
  - Drowning

# New PPE Regulation

- New : validity of EU type examination certificates is limited to max 5 years
- New : Declaration of Conformity with each PPE (at least website link)
- New : obligations for importers and distributors (including online sales), e.g.
  - Name and address of importer
  - User instructions available and in correct language
  - ...

# New PPE Regulation

- Very little change :
  - Essential health and safety requirements (annex II) : only a few changes
  - Most PPE do not change technically
  - Most harmonised standards (published in OJ EU) do not have to change

# New PPE Regulation

- PPE use Directive not changed !
  - Obligations employers
  - Care and maintenance

# Selling PPE

- ‘making available on the market’ means any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge
- ‘placing on the market’ means the first making available of PPE on the Union market

# Economic operators

- ‘manufacturer’ means any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark



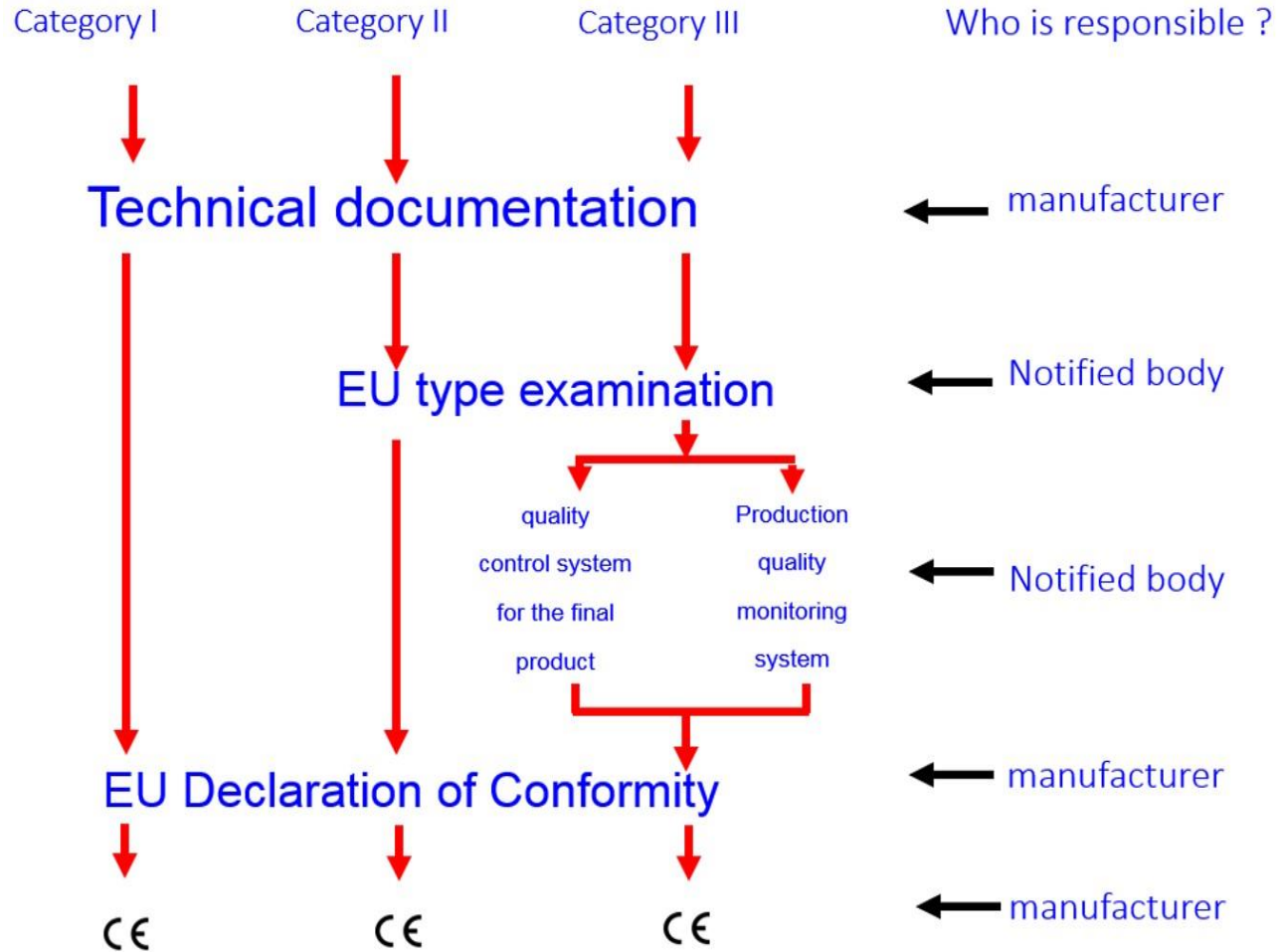
# Economic operators

- ‘importer’ means any natural or legal person established within the Union who places PPE from a third country on the Union market

# Economic operators

- ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market

# Conformity assessment



# Obligations economic operators - marking

|                                   | Manufacturer | Importer | Distributor |
|-----------------------------------|--------------|----------|-------------|
| CE mark                           | Do it        | Check it | Check it    |
| For cat III :<br>NB               | Do it        | Check it | Check it    |
| Name (...) +<br>postal<br>address | Do it        | Do it    | Check it    |
| Pictograms<br>+ info              | Do it        | Check it | Check it    |



# Obligations economic operators - documents

|                | Manufacturer | Importer   | Distributor |
|----------------|--------------|------------|-------------|
| Technical file | Do it        |            |             |
| Instructions   | Do it        | Check it + | Check it +  |
| DoC            | Do it        | Check it + | Check it    |

# Obligations economic operators - other

- +1 / -1 rule between economic operators
- Product identification
- Cooperation with market surveillance
- Keep documents (10 years)

# Economic operators

- What is my role ?
  - Distributor ?
  - Importer ?
  - Manufacturer ?
- Agreements/contracts between economic operators !
- User/employer is not economic operator

# Implementation

- Many questions raised
- FAQ published by EU Commission mid March 2017 – update foreseen September
- NBs working on revision/update RfUs
- ESF working on guidance (see ESF website)
  - Flowchart ‘certification for manufacturers’
  - Flowchart ‘who am I ?’
  - Q&A



# Implementation - NB

- Coordination of NBs strengthened
- Status of decisions coordination (e.g. RfUs)
- Challenge of competence of NB possible
- Active in standardisation

# Implementation – Market Surveillance

- Clearer rules
- E.g. formal non compliance
- Different way of operating ?
- Internet sales ?
- How will they deal with transition ?

# Consequences for market

- PPE placed on the market before 21/4/2019
- PPE placed on the market from 21/4/2019 onwards
- No technical change needed (for vast majority of products) !
- PPE to Directive are not unsafe on 21/4/2019 !

# Usefull links

- ESF : [www.eu-esf.org](http://www.eu-esf.org)
- EU Commission PPE :  
<http://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment/>
- NANDO (list of NBs) :  
<http://ec.europa.eu/growth/tools-databases/nando/index.cfm>
- CEN PPE sector :  
<http://www.cencenelec.eu/standards/Sectors/healthSafety/PersonalProtectiveEquipment/Pages/default.aspx>





Thank you for your attention

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