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The PPE Regulation and Key Changes to European Glove Testing Standards

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Who is SATRA?

- Notified Body for PPE Regulation based in UK and Ireland
- Extensive physical and chemical testing laboratories for testing of gloves, footwear and consumer products
- Office and laboratory in Dongguan, China
- Exhibition booth W57

Contents

PPE Regulation:

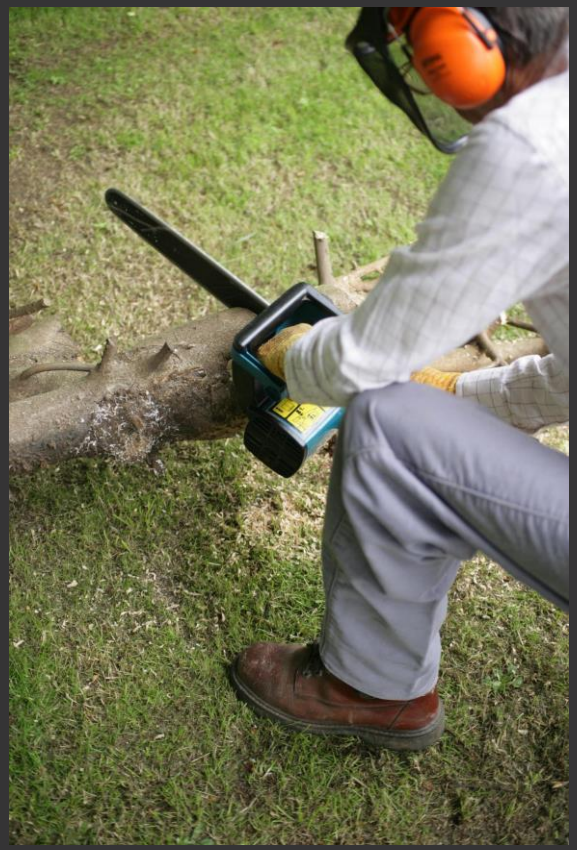
- Changes from the PPE Directive
- Timescales
- What do I need to do?

Changes to key European standards:

- EN ISO 21420 (replacement for EN 420:2003 + A01:2009)
- EN ISO 374-2
- EN ISO 374-4

PPE Regulation (EU) 2016/425

- European Regulation, not a Directive
- Incorporates technological advances not incorporated in 89/686/EEC
- Objective of Regulation to better protect the health and safety of the PPE user and to ensure a level playing field within the internal market



Changes from the Directive

- Scope
- Risk categorisation
- Conformity assessment procedures (modules A, B, C, C2 & D)
- Documentary requirements (DoC, risk assessments)
- Product must be ‘state of the art’
- 5 year validity of certificates

Scope and Product Categories

- Scope has been enlarged, with private use against heat (domestic oven gloves) no longer excluded
- Product categories I, II and III defined by risk alone
- Some products changed categories. Protecting against risks from:
  - Drowning
  - Harmful biological agents
  - Cuts by hand held chainsaws
  - High pressure jets
  - Bullet wounds or knife stabs
  - Harmful noise

Category I

Minimal risks

- Superficial mechanical injury;
- Contact with cleaning materials of weak action or prolonged contact with water;
- Contact with hot surfaces not exceeding 50 °C;
- Damage to the eyes due to exposure to sunlight (other than during observation of the sun);
- Atmospheric conditions that are not of an extreme nature.

Category III

Serious risks

Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to:

- Substances and mixtures which are hazardous to health;
- Harmful biological agents;
- Ionising radiation;
- Electric shock and live working;
- Bullet wounds or knife stabs;

This list only includes those risks that could be relevant to gloves – there are many more risks that will be category III

Category II

Intermediate risks

- Category II includes risks other than those listed in Categories I and III;

- Includes risks that are neither simple nor complex categories.

Conformity Assessment Procedures

PPE Category	PPE Directive 89/686/EEC	PPE Regulation (EU) 2016/425
Category I (Simple)	Manufacturer's self-declaration	Module A – Internal Production Control
Category II (Neither simple nor complex)	Article 10 – EC Type Examination	Module B – EU Type Examination *plus* Module C – Internal Production Control
Category III (Complex)	Article 10 – EC Type Examination *plus either*	Module B – EU Type Examination *plus either*
	Article 11A – On-going surveillance through testing *or*	Module C2 – Product Verification *or*
	Article 11B – On-going surveillance through FPC auditing	Module D – Production Quality Assurance

Type Examination Certificates

- Regulation - EU Type Examination certificate (Directive – EC Type Examination certificates)
- Validity limited to maximum of 5 years (many EC certificates have no expiry date and are to superseded versions of standards)
- Under the Regulation all certificates require renewal to the latest version of product standards , e.g EN ISO 374-1:2016

What Happens when my EU Certificate Expires?

- PPE will be reassessed to determine if the original assessment is still ’state of the art’
- If product standards have not been revised since original assessment, re-issuing certificate will be paperwork exercise only
- If product standards have been revised, additional testing will be required
- Innocuousness requirements will also need to be ‘state of the art’

EU Declaration of Conformity

- An EU Declaration of Conformity (DoC) must accompany each item of PPE, or the user instructions include a web address where the DoC can be accessed
- Content of DoC is defined in Annex IX of the regulation and contains basic information including:
  - PPE (product, type, batch or serial number)
  - Name and address of the manufacturer
  - Where applicable, the notified body who performed the EU type-examination (Module B) and issued the EU type-examination certificate
  - Where applicable, a statement that the PPE is subject to the conformity assessment procedure Module C2 or Module D and who is the surveillance notified body

Risk Assessment

An assessment of the risks which the PPE is intended to protect against

Generally disposable gloves will require a simple risk assessment – template document available from SATRA

Timescales

- PPE Regulation was implemented on 21st April 2018
- 12 month Transition Period started on this date. From 21st April 2018 products can be certified to the Directive or to the Regulation.
- Transition Period Ends 21st April 2019. After this date only products compliant to the Regulation can be placed on the market.
- After 21st April 2019, PPE certified to the Directive cannot be placed on the market, only made available on the market
- After 21st April 2023 only products certified to the Regulation can be placed on the market or made available on the market

‘Placed on the Market’

- Defined as when an **individual** product is made available on the Union market for the first time.
- Hence, product is transferred from the stage of manufacture with the intention of distribution.
- Therefore, the only economic operators that can ‘place product on the market’ are manufacturers or importers.
- ‘Individual’ product is expected to be specific to particular shipments (i.e. after 21st April 2019, no products certified to the Directive will be able to enter the EU)

‘Made Available on the Market’

- Defined as when an **individual** product is supplied on the EU market for distribution, consumption or use, so would be typically further down the supply chain.
- When made available on the market', products must have been in compliance with the relevant EU legislation applicable at the time of placing on the market.

Please note, the published official definitions of ‘placed on’ and ‘made available’ include much greater detail, so these descriptions should not be taken as authoritative text

SATRA Europe

- SATRA will continue to be a Notified Body for PPE after the UK leaves the EU ‘Brexit’

- SATRA Europe has been established as a Notified Body in Ireland (number 2777)

Preparing for the Regulation

- Identify your current PPE Directive certificates
- Assign the priorities for recertification
- Assess the associated technical files against the criteria laid out in Annex III of the new regulation.

- Determine the preferred option for making available your EU Declaration of Conformity information and if this is to be via the internet start background construction on the necessary website.

- Decide whether the route of Module C2 or Module D is appropriate for ongoing conformity

- Work with SATRA to identify what needs to be done

Summary

- PPE Regulation is here!
- Transition period ends on 21st April 2019
- PPE certified to Directive will not be able to be placed on the market after 21st April 2019
- Additional requirements for Declaration of Conformity, risk assessment
- Different conformity assessment procedures (Modules A, B, C, C2 and D)
- Maximum 5 year EU-type examination certificate validity
- SATRA Europe has been established as a Notified Body for post ‘Brexit’

Key Forthcoming Changes to European Glove Testing Standards

Revision to EN 420:2003 +A1:2009

New standard will be **EN ISO 21420**

- Required to include new glove marking as a result of revisions to specific standards such as EN 388 and EN ISO 374-1
- Will incorporate revised pictograms
- Important to ensure products are ‘state-of-the-art’ under the Regulation

EN ISO 21420 – Key Changes

- Resistance to water penetration removed
- Innocuousness expanded to include nickel release from metallic materials and dimethylformamide (DMFa) in gloves containing PU
- Extractable proteins removed from innocuousness clause – but Notified Bodies may still require testing if claims are made
- Increase in size range from size 4 to 13, however a different sizing systems can be used

EN ISO 374-2 and EN ISO 374-4

- EN ISO 374-2 Determination of resistance to Penetration
- EN ISO 374-4 Determination of resistance to Degradation by Chemicals
- Both standards will be revised as ISO methods with no significant technical changes

- Expected to be published late 2018 or early 2019

Thank you for listening

Any questions?

(Also you can visit us at booth W57)

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