PPE Conformity Assessment in the EU

Conformity Assessment on Non-Respiratory Personal Protective Equipment (PPE) Public Meeting

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Overview

- Principles of conformity assessment
- Hazard-based product categories
- Conformity assessment requirements
- Market surveillance system
- Roles and shared responsibilities

Conformity assessment principles

- Established by EU law (PPE Directive)
- Consistent with ISO CASCO standards
- Manufacturers are required to fulfill Basic Health and Safety Requirements before placing products on the market (voluntary consensus standards; not mandatory)
- Hazard-based conformity assessment procedures
- Post-market surveillance of PPE designed to protect against serious hazards; risk-based corrective actions
- Shared responsibilities – economic operators, private sector 3rd party bodies, government authorities, NGOs
- Transparency, collaboration, coordination

Hazard-based conformity assessment

PPE is placed in categories based on type of hazard the product is designed to protect the user from

- Category I hazards (gradual or unexceptional hazards)
  - e.g., cleaning materials of weak action and easily reversible effects
- Category II hazards (medium hazards)
- Category III hazards (serious & irreversible harm)
  - e.g., low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less

CA procedures: Category 1 hazards

Requires:

- a Supplier's Declaration of Conformity (SDoC)
- technical documentation (documents the methods used by the manufacturer to ensure that the PPE complies with the basic requirements relating to it), and
- CE mark, affixed to all products

Performed by manufacturer; 3rd party testing not required

CA procedures: Category 2 hazards

Requires:

- SDoC; technical documentation, with additional detail; and the CE mark.
- EC type-examination: a check by a 3rd party on the design and documentation of an item of PPE to ensure it satisfies the basic requirements
- EC Certificate of Conformity: issued by a 3rd party when product model passes the EC type-examination

The production process is not independently assessed, but regular product samples are submitted for testing.

CA procedures: Category 3 hazards

Requires:

- SDoC; technical documentation with additional detail; CE mark; EC type-examination; EC Certificate of Conformity
- Quality Assurance procedures: periodic checks by a 3rd party to ensure the production versions of the PPE continue to comply with the initial sample previously approved either
  - random sample testing, or
  - Quality Monitoring System: 3rd party checks if manufacturing quality systems are capable of enabling consistent production of the certified product

Risk-based market surveillance actions

- Carried out by authorized, private sector 3rd party bodies, which are accredited and periodically evaluated
- Proactive and reactive market surveillance, focused on Category 3 PPE
- National Market Surveillance Plans required, updated annually, evaluated every 4 years, posted online
- Risk-based corrective actions
- Online tools helps authorities identify the level of risk to the worker, share information about findings

Role of EU Parliament & European Commission

- Set policy
  - establish the “Basic Health and Safety Requirements” manufacturers are required to fulfill
  - define hazard-based conformity assessment requirements
  - assign PPE to hazard categories
  - define market surveillance requirements
- Provide technical assistance
- Maintain online tools to exchange information, share best practices, ensure transparency
- Encourage cooperation, coordination
- Contribute to voluntary consensus standard setting

Role of EU Member States

- Designate, coordinate and monitor 3rd party bodies
- Designate National Accreditation Body
- Develop, submit & post National Market Surveillance Plan
- Ensure at border crossing that technical documentation has been provided for imported products, including the manufacturer's and importer's contact information*
- Coordinate with and inform the Commission about market surveillance activities and about measures taken against products posing a serious risk
- Enforce market surveillance corrective actions and sanctions

* In process for PPE

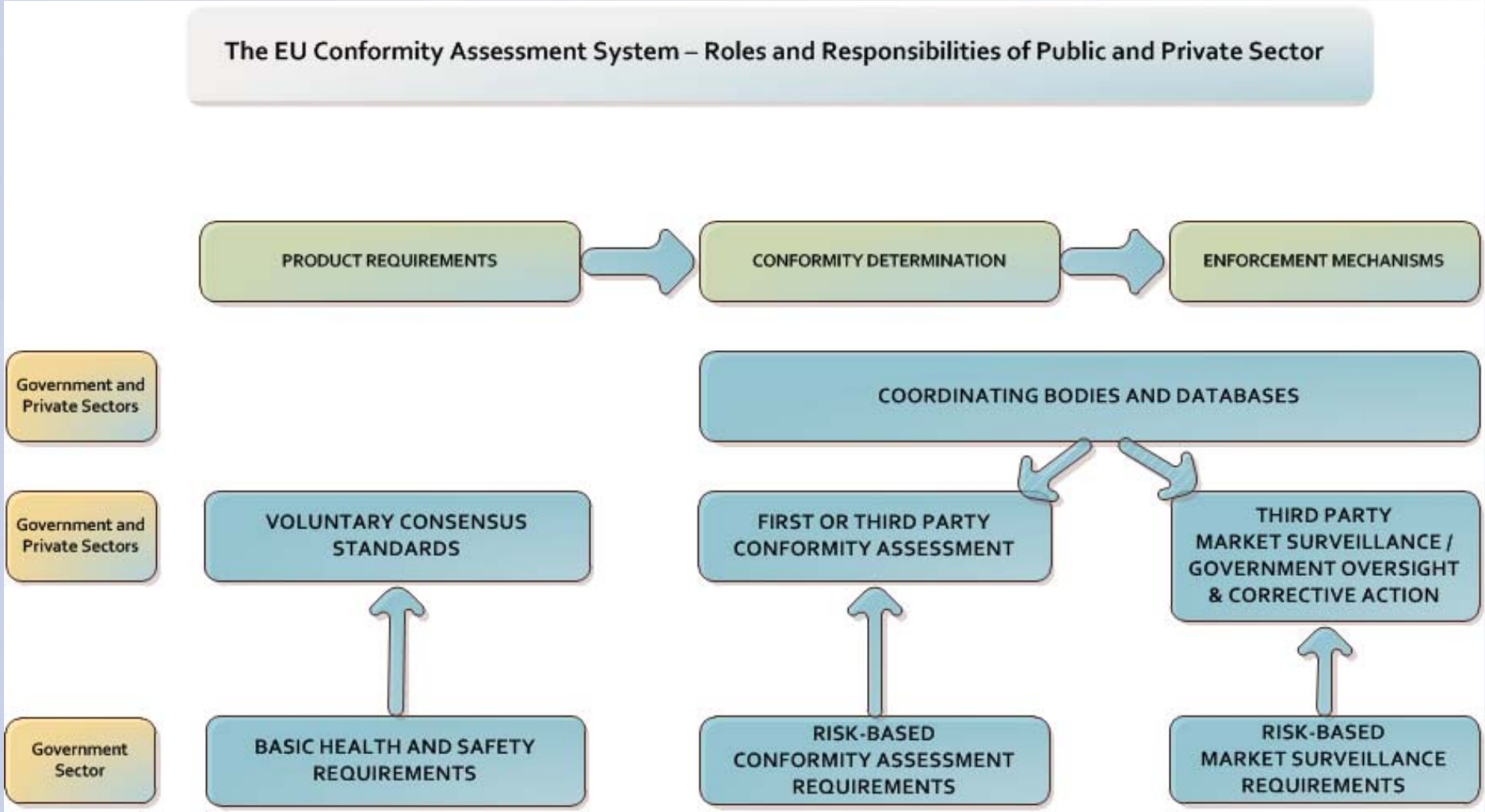
Role of economic operators

- Assume ultimate responsibility and liability for product safety
- Fulfill Basic Health and Safety Requirements (BHSRs)
- Select method to demonstrate product fulfills BHSRs (e.g., through European standards)
- Carry out all required conformity assessment procedures (enlisting 3rd party services for Category 2 & 3 PPE)
- Document compliance with BHSRs through the Suppliers Declaration of Conformity (SDoC), technical documentation and affixing the CE Mark

Role of private sector 3rd party bodies

- Provide pre-market and post-market CA services to manufacturers for Category 2 & 3 PPE
- Issue Certificate of Conformity for Category 2 & 3 PPE
- Conduct both proactive and reactive market surveillance activities, following approved Market Surveillance Plan
- Participate in various conformity assessment coordination committees
- Participate in various market surveillance coordination committees

Summary of roles & responsibilities



More Information

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