

# Shaping the PPE Regulation

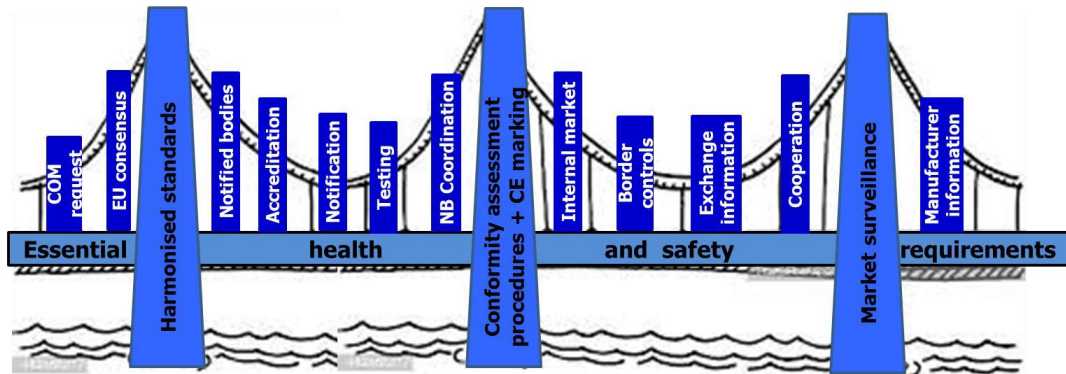
---

**Pilar Cáceres Armendáriz**





## Evaluation of conformity: the bridge to user's safety



Safe product

Risk assessment:

- intended use
- reasonable foreseeable uses

Safe use

P.Cáceres , CNMP-INSST





# Digital and Green Innovations



General Product Safety Regulation (GPSR)

Health Emergency Preparedness and Response (HERA)

REACH

Internal Market Emergency and Resilience Act (IMERA)

Eco-design for Sustainable Products Regulation (ESPR)

PFAS European Critical Raw Materials Act

Smart PPE

Regulation on Packaging and Packaging Waste

Artificial Intelligence Act

Data Act

Cyber Resilience Act (CRA)

Dual use products (civil and military use)

Market surveillance framework

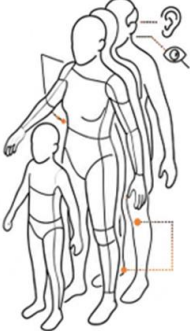
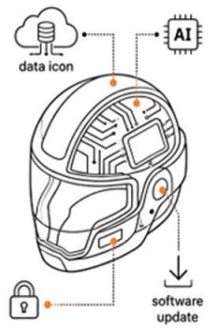
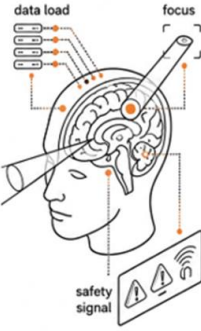
Safety gate



## Online Market

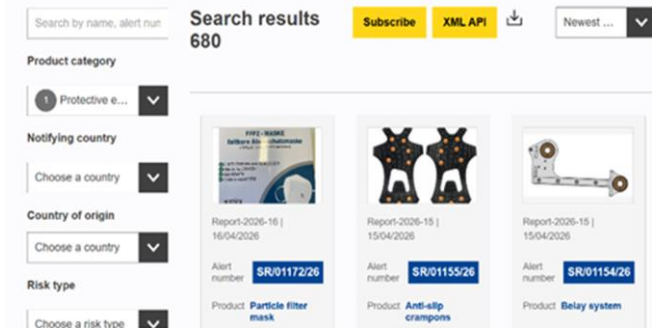


## Risk Assessment

<p><b>INCLUSIVITY</b></p> 	<p><b>NEW TECHNOLOGIES</b></p> 	<p><b>MENTAL HEALTH</b></p> 
<p><b>ASSESSMENT ACROSS ALL USERS:</b> children, elderly, persons with disabilities, neurodiversity, gender differences. Ensure PPE adapts to specific needs, avoids exclusion.</p>	<p><b>CONNECTED PPE IMPACT:</b> evaluating AI learning, software bugs, cybersecurity risks, adaptive features, and evolving connected functions.</p>	<p><b>COGNITIVE IMPACTS:</b> addressing cognitive overload, stress, overconfidence, behavioral changes, and safety of vulnerable users.</p>

## Safety Gate

<https://ec.europa.eu/safety-gate>






Search by name, alert num Search results 680 Subscribe XML API Newest ...

Product category: Protective e...

Notifying country: Choose a country

Country of origin: Choose a country

Risk type: Choose a risk type

 Report-2026-15   16/04/2026 Alert number <b>SR/01172/26</b> Product <b>Particle filter mask</b>	 Report-2026-15   15/04/2026 Alert number <b>SR/01155/26</b> Product <b>Anti-slip crampons</b>	 Report-2026-15   15/04/2026 Alert number <b>SR/01154/26</b> Product <b>Belay system</b>
--	--	--



# Comprehensive preparedness and crisis-response system within the single market

### CONTINGENCY MODE

Provides for certain preparedness measures: trainings, simulations and exchanges of best practices

TRAINING SIMULATION

EXCHANGE OF BEST PRACTICES

TRAININGS SIMULATIONS BEST PRACTICES

### VIGILANCE MODE

Trigger whenever there are elements that a crisis is likely to produce **imminent effects** on the functioning of the internal market in the very short time

NEWS

MARK INDICATORS

EARLY SIGNALS • MONITOR • ASSESS

### EMERGENCY MODE

Trigger when a crisis is **already negatively affecting** the functioning of the internal market

Delays

Shortages

Disruptions

## Are we getting ready?



# A hidden obligation?





- **Ecodesign for Sustainable Product Regulation**



- **Proposal for a Regulation as regards digitalization and common specifications**

**And so on.....**



# The multilayer system for PPE safety



Muchas gracias  
**Thank you**