STRENGTHENING COMPLIANCE WITH EU PRODUCT RULES

The EU Regulation on market surveillance and compliance of products
Reg. 2019/1020
MARKET SURVEILLANCE IN THE EU

• Single market for goods
  • Free movement of goods: harmonisation legislation, national rules (mutual recognition)
  • Member States are responsible for the enforcement of EU product legislation
  • Common framework to ensure adequate market surveillance

• Market surveillance for non-food products
  • Regulation (EU) 2019/1020: market surveillance for products covered by EU harmonisation legislation
  • General Product Safety Regulation (EU) 2023/988: extends the application of Regulation 2019/1020 to non-harmonised products (GPSR will replace the GPSD, entry into application Dec. 2024)
  • Harmonised product requirements and obligations of economic operators are defined in sector-specific directives and regulations.
COMMON FRAMEWORK FOR MARKET SURVEILLANCE

Product legislation at EU level

Common market surveillance framework

• How to organise and investigate
• What procedures to follow when problems are found
• How to cooperate between MSAS & with customs
• Obligations of economic operators vis-à-vis enforcement authorities

Chapter III of Regulation (EC) N°765/2008
Replaced by Regulation (EU) 2019/1020

Member States responsible for enforcement

Market surveillance authorities (MSAs)
**SCOPE OF THE REGULATION**

- **Market surveillance provisions**
  - **EU harmonisation legislation on non-food products**: initially 70 pieces of legislation listed in Annex I, scope evolving as product legislation is being adopted/repealed
  - **Lex specialis**: provisions do not apply where already specifically regulated in the product-specific legislation itself

- **Controls at the external borders**
  - All EU product legislation, unless specific provisions in that legislation

- **Specific scope for Article 4** (economic operator in the EU)
  - Currently applies to 19 product sectors, including toys, electrical and electronic products and others
CORE OBJECTIVES

- **Improve compliance upfront**: information to economic operators
- **Strengthen market surveillance effectiveness and cooperation**
- **Modernise the framework**: online sales & new actors in the supply chain
- **More effective controls at the EU borders**: cooperation customs - MSAs
1) **IMPROVE COMPLIANCE UPFRONT**

- **Product regulation:** free of charge information to businesses
  - On-line through *Your Europe* portal
  - Through national Product Contact Points

- **Joint activities between MSAs & business or consumer organisations**
  - Raising awareness, providing guidance
  - Identifying non-compliance: results may be used for investigations

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**https://trade.ec.europa.eu/access-to-markets/en/content/**

2) **Strengthen Effectiveness...**

- **Organisation of market surveillance**
  - Designate one or more market surveillance authorities
  - Provide them with the necessary resources
  - Provide the necessary powers (minimal list in the Regulation)

- **Investigations**
  - Perform appropriate checks, on an adequate scale, on the characteristics of products
  - By means of documentary checks and, where appropriate, physical and laboratory checks
  - Prioritise resources and actions to ensure effective market surveillance
  - Risk-based approach taking into account factors linked to products and economic operators
... AND COOPERATION

• At national level
  • Creation of a Single Liaison Office
  • National market surveillance strategies: at least every 4 years; considering all sectors; setting priorities

• Between Member States
  • Cross-border mutual assistance: information and enforcement measures
  • Voluntary peer reviews

• EU-wide
  • EU Product Compliance Network
  • EU Testing Facilities (EUTFs): enhance laboratory capacity and ensure reliability & consistency of testing
  • Coordinated inspections (Joint Actions)
  • Better data sharing in EU market surveillance database (ICSMS)
**Permanent structure** for coordination & cooperation between MS authorities and the Commission

**The EU Product Compliance Network**

- **European Commission**
- **capacity building**
- **cooperation with customs**
- **indicators/benchmarks**
- **data/information exchange**
- **joint inspections**
- **best practice exchange**

**European Product Compliance Network**

- **ABCO chairs**
- **Secretariat in the Commission**
- **27 single liaison offices + optional national experts**

**Work Programme**

**National market surveillance strategies**

**Regulation on Market Surveillance and Compliance**

- **Entry into force: 1 January 2021**
3) ADDRESS ONLINE SALES

- Notion of “placing on the market” in relation to online sales
- Responsibilities & obligations of MSAs and economic operators
- Economic operator established in the EU for specific product sectors
- New powers & tools for market surveillance authorities
4) **Better Controls at the EU Borders**

- **Risk analysis and information sharing MSA - Customs**
  - MSA information to customs on higher risk product categories and economic operators
  - Development of a dynamic interface ICSMS – national customs systems relying on the EU Single Window environment for customs (operational by end 2025)

- **Data and analysis of customs compliance controls**
  - Annual statistical data by customs + Commission report and analysis

- **Cooperative framework for controls**
  - Risk-based controls by customs authorities
  - Suspension of release for free circulation by customs if they notice an issue *(e.g. documentation, markings and labellings, CE marking or other)* and notification to MSAs
  - MSA reaction within maximum 4 working days from suspension of release for free circulation
KEY ACHIEVEMENTS TO DATE

• EU Product Compliance Network
  • Financing (15M€/year), 20 meetings since 2021, market surv. strategies, indicators…

• EU Testing Facilities
  • Annual designation process (max. 2 sectors)
  • 2023: toys, radio equipment; 2024: ecodesign and energy labelling; next call under preparation.

• Market surveillance intelligence
  • ICSMS development, proactive webcrawler, use of AI…

• Joint Actions
  o Rotation system between product sectors
  o +/- 10 sectors/year
Joint Actions 2024

9 Sectors

17 Product Specific Activities

**Medical devices**
- PSA 1 – Dental implants
- PSA 2 – Hyaluronic acid injectables and dermal fillers
- PSA 3 – Bioprosthetic valve implants

**Toys**
- PSA 4 - Toys (Indoor climbing toys, Indoor swings, Outdoor swings, Activity towers)

**Explosives for civil use**
- PSA 7 - Detonators, Boosters and Cartridge Explosives

**Eco-design and energy labelling**
- PSA 8 – Fridges
- PSA 9 – Solid fuel boilers
- PSA 10 – Air cooling
- PSA 11 – Refrigerating appliances with direct sales function
- PSA 12 – Electric motors

**Automotive**
- PSA 14 – Child Safety Equipment (CSE)

**Measuring instruments**
- PSA 15 - Non-Automatic Weighing Instruments (NAWI) sold online

**Transportable pressure equipment**
- PSA 5 - Small receptacles (cylinders) containing gas (gas cartridges) mainly sold online
- PSA 6 - Receptacles (refillable cylinders) for domestic use

**Marine equipment**
- PSA 13 - Lifeboats

**Electrical appliances and equipment under LVD**
- PSA 16 - Installation cables
- PSA 17 - LED replacement tubes