



ENFORCEMENT OF LEGISLATION ON PRODUCTS: THE MARKET SURVEILLANCE FRAMEWORK IN THE EUROPEAN UNION

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INTRODUCTION

- What?
 - Check if products comply with all applicable requirements, and take remedial action if required
 - After placing on the market by economic operator (post-market controls)
- Why?
 - Protect consumers and users
 - Not restricted to consumer health and safety
 - Safeguard other public interests
 - Eliminate unfair competition





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WHY MARKET SURVEILLANCE MATTERS

A building block of modern and effective regulatory systems

- Crucial to enforcement of product legislation
- Complements the choice of conformity assessment procedures by putting emphasis on the entire life-cycle of products
- Objective is to achieve a balance between pre- and post-market controls according to the risk to be managed and the specific product market
- Development of adequate market surveillance capacity is key to enable regulators to choose more flexible conformity assessment procedures

→ **Facilitate trade and support the implementation of the TBT Agreement**





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MARKET SURVEILLANCE IN THE EU

- Specificity of EU Single Market
 - Free movement of goods
 - EU harmonisation legislation, national rules (mutual recognition)
- Market surveillance for non-food products
 - **Regulation (EC) N° 765/2008: market surveillance for products covered by EU legislation**
 - General Product Safety Directive 2001/95/EC: safety of consumer products, procedures for dangerous products
 - Product-specific rules in EU sector legislation – e.g. medical devices, energy efficiency, etc.





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MARKET SURVEILLANCE UNDER REGULATION 765/2008

- EU Member States are responsible for enforcement of EU product legislation
 - One single market, numerous market surveillance authorities (MSAs)
 - Cooperation between Member States' authorities is central to the system
- Set of common obligations to ensure effective market surveillance across the EU
 - General requirements for market surveillance
 - Surveillance obligations and market surveillance measures
 - Control of products entering the EU



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EU REQUIREMENTS FOR MARKET SURVEILLANCE

- General obligation for Member States to act against:
 - Products liable to compromise health and safety
or
 - Which otherwise do not conform to EU harmonisation legislation
- Obligations in terms of administrative organisation:
 - Provide the necessary infrastructures, resources and powers to perform market surv.
 - Develop market surveillance programmes, with periodic updates
 - Establish complaint procedures and monitoring of accidents related to products
- Information obligations



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SURVEILLANCE OBLIGATIONS & MEASURES

(1/2)

- Perform appropriate checks on products
 - Documentary, physical, laboratory checks
 - Ability to request documentation, enter premises, take samples
- Ensure that products presenting a serious risk are recalled or withdrawn (or destroyed if deemed necessary and proportionate)
 - Determination of serious risk based on appropriate risk assessment
 - General EU risk assessment methodology has been developed
- Principles of cooperation
 - Exchange of information, mutual assistance and cooperation with other Member States and Commission



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MARKET SURVEILLANCE MEASURES

(2/2)

- In case of non-compliance:

Voluntary measures by economic operators

vs. restrictive measures by market surveillance authorities (e.g. prohibitions, restrictions, recalls, withdrawals)

- Procedural rights:

- Restrictive measures must be proportionate and state the exact grounds on which they are based
- Economic operators must be informed of the measures taken and the remedies available
- Economic operators have the right to be heard, except if urgency



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CONTROL OF PRODUCTS ENTERING THE EU

- Control of products by authorities in charge of border control, usually customs
 - Checks at customs based on risk assessment
 - Suspension of 'release for free circulation' by customs authorities in case of suspicion that the product does not comply
 - Notification of suspension to MSAs, MSA assessment to customs (3 working days)
- Non-compliant products
 - Refusal to release: products are identified as '*dangerous product*' or '*product not in conformity*'
 - Responsible authorities may destroy or render product inoperable if deemed necessary and proportionate



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MARKET SURVEILLANCE TOOLS

- Tools for exchange of information and cooperation
 - RAPEX – Rapid alert system for products presenting a (serious) risk
 - ICSMS – Technical database for exchange of information on controls, tests and results
 - ADCOs - Administrative cooperation groups of national experts to coordinate enforcement and market surveillance in specific sectors
- ‘Safeguard clause’ procedures in specific sector legislation
 - Consultation of all Member States on restrictive measures taken by a national authority
 - Once adopted, measures apply across the EU



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EVALUATION OF THE EU FRAMEWORK 2016-2017

- Still too many non-compliant products on the EU market
- Main challenges
 - Fragmentation of organisation
 - Resource constraints for market surveillance authorities
 - Knowledge/information gaps for businesses
 - Low deterrence of the current enforcement tools
- A changing context
 - Import volumes on the rise
 - Booming on-line sales and international e-commerce



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TOWARDS MORE MODERN AND EFFECTIVE ENFORCEMENT

- Commission proposal for a Regulation on compliance of and enforcement with EU product legislation, COM(2017)795
 - Cooperation with economic operators: help businesses to comply
 - Stronger enforcement tools, particularly to address on-line sales
 - European Product Compliance Network
 - More effective controls at the external borders; international cooperation
- Legislative process is being finalized
 - Formal adoption by EP and Council expected in April 2019
 - Entry into force two years after publication in EU Official Journal: mid-2021



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CONCLUSION

- **Balanced product regulation:**
 - pre- and post-market controls are two sides of the same coin
 - Market surveillance complements pre-market requirements
 - Enables regulators to choose more flexible conformity assessment procedures, such as SDoC
- **Key elements of market surveillance**
 - Clear legal framework ensuring good governance:
 - evidence-based and risk-focused controls, proportionality, due process
 - Promote and support compliance + proactive and reactive investigations
 - Strategic planning, adequate resources and knowledge
 - Core powers and appropriate sanction mechanisms

**TRUST, BUT
VERIFY.**



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Useful links

- Market surveillance for products, DG GROW website:
https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance_en
- Regulation (EC) N°765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products:
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32008R0765&locale=en>
- EU general risk assessment methodology implementing Article 20 of Regulation (EC) N°765/2008
<https://ec.europa.eu/docsroom/documents/17107?locale=en>
- Goods package: Commission proposal for a Regulation on Compliance and Enforcement, Dec. 2017
http://europa.eu/rapid/press-release_IP-17-5301_en.htm