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
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
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) No 765/2008: market surveillance for products covered by EU legislation
  - Product-specific rules in EU sector legislation – e.g. medical devices, energy efficiency, etc.
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
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 surveillance
  - Develop market surveillance programmes, with periodic updates
  - Establish complaint procedures and monitoring of accidents related to products

- **Information obligations**
• 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
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
• 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
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
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
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
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
Useful links

- Market surveillance for products, DG GROW website:

- Regulation (EC) N°765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products:

- EU general risk assessment methodology implementing Article 20 of Regulation (EC) N°765/2008

- Goods package: Commission proposal for a Regulation on Compliance and Enforcement, Dec. 2017