

Market surveillance in the EU

Implications for the mechanical engineering industry

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EU Internal Market Legislation

- Provides free circulation of products within the entire EU
- Requires that products fulfil “essential requirements”, namely that they are safe = do not present a risk to health and safety

Examples

- Machinery Directive (2006/42/EC)
- Lifts Directive (95/16/EC)
- Pressure equipment Directive (97/23/EC)

Mechanisms to ensure that products are compliant with EU law (1)

Ex-ante:

- Responsibility of economic operators (manufacturer, importer, retailer)
- Documentation
- Conformity Assessment procedures
- Involvement of testing houses/notified bodies

→ CE marked products

Mechanisms to ensure that products are compliant with EU law (2)

Ex-post:

- Market surveillance
- Safeguard clause proceedings
(mechanism of cooperation between Member States and Commission)

Market Surveillance

Why?

- Safe/compliant products
- Fair competition

Market surveillance

History

- An issue since more than 20 years
- Member States regards MS as pure national responsibility
 - Subsidiarity
 - No room for EU action?

Market surveillance

Almost all EU harmonisation legislation set out clear obligations and procedures (safety requirements, documentation, testing and certification requirements, for a product **BEFORE** marketing but remained silent for post marketing controls

Market surveillance

One exception: the General Products Safety Directive of 2001 for consumer products:

- Attempted to open the door to Community market surveillance
- Has been a success in changing mindsets and on exchange of information
- Remains weak on effective product controls by national authorities

Market surveillance

In 2000 EU Heads of State recognised that incoherent and uncoordinated market surveillance created problems for EU Industry.

They set the development of a EU market surveillance programme as one of the priorities of the Lisbon Agenda.

The New Legal Framework (NLF)

- Regulation 765/2008 (applicable since 01.01.2010)
Major principles and rules for Member States
- Decision 768/2008,
More precise and detailed procedural elements (→ to be inserted in specific EU product legislation)

The Regulation Market Surveillance

- First: It contains rights and obligations for Member States but also for economic operators as it is directly applicable.

If national authorities do not react, economic can go to the courts

- Second: It creates clear obligations on national authorities to act in relation to non conforming or dangerous products. They must require corrective action, withdraw or even have a product destroyed.

- Third: it brings together the obligations for products made in the EU and products entering the EU: controls of products from third countries are subject to market surveillance and should be carried out with same effectiveness.

Scope

- All products covered by Community harmonisation legislation:
 - ‘Product’ means: substance, preparation or good produced through a manufacturing process
 - ... unless specific provisions already exist (*Lex specialis* principle)
 - Excluded: food, feed, living plants and animals, products of human origin

The role of EU Member States

- Entrust MS with necessary powers, resources, knowledge to carry out their tasks
- Establish appropriate coordination between MS
- Publish information on competent authorities
- Set-up procedures to follow-up of complaints, monitor accidents
- Establish market surveillance programmes

Cooperation between authorities

- Enhanced cooperation amongst market surveillance authorities of Member States
 - Information exchange, common databases
 - Mutual assistance
 - Participation in administrative cooperation
 - Possibility to develop cooperation with third countries

Controls at the borders of the EU

- Reinforced controls of imported goods
 - Customs must carry out checks of product characteristics
 - Suspension of release for free circulation if product
 - present a serious risk
 - is not properly marked or documentation is missing
 - Information of market surveillance authorities
 - Prohibition measures
 - Release for free circulation not authorised

Tools for information exchange

- RAPEX in case of serious risk
 - Rapid Alert System existing since 2004 for consumer goods based on GPSD (Directive 2001/98/EC, Art 12)
- Regulation 765/2008 extends RAPEX to:
 - Professional goods
 - Risks others than health and safety (e.g. environment)

- Interim solution:

General information support system for market surveillance activities in liaison with RAPEX



New complementary tool (Art 23 Regulation) until new RAPEX platform

Information on measures taken against non-compliant products which do **not present a serious risk or on cases of « formal » non-compliance**

Example of EU Market Surveillance System

- Non-compliant product found
- Take action
 - Withdrawal, recall, prohibition of marketing or other restrictive measure
- Inform Commission and other Member States
 - Serious cases: RAPEX (interim solution)
 - Other cases: Art 23 (interim solution)
- Safeguard clause procedure?

Market Surveillance

Next steps (1)

- Implementation of new system by Member States
 - National MS programmes
 - Development of common criteria (for serious risk, risk assessment,adequate/appropriate checks)
 - (penal) sanctions
 - Co-ordination to bring customs and market surveillance authorities closer together

Market Surveillance

Next steps (2)

- Market surveillance in specific sectors
→ investment goods (!)
- Raise awareness, improve mechanisms
- COM conference in autumn 2011

Thank you for your attention!

Further information?

- http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/index_en.htm