

The New Legislative Framework – Market surveillance – Traceability

Rita L'Abbate

Unit C1: Regulatory approach for free movement of goods

New Legislative Framework - Texts

OJ L218 - 13.08.08 :

- Regulation 765/2008 - requirements for accreditation and market surveillance relating to the marketing of products
- Decision 768/2008/EC - a common framework for the marketing of products

Complementary - market surveillance

REGULATION

- Market Surveillance
 - Internal
 - Imported products
- **CE** General principles

DECISION

- Definitions of economic operators
- Obligations of economic operators
- Safeguard mechanisms (& market surveillance)
- **CE** marking affixing rules

Overall traceability provisions

- Definitions of operators
- Role in the supply chain
- Obligations in relation to product
- Obligations to inform
- Obligations to label

DEFINITIONS

- Manufacturer
- Authorised representative
- Importer
- Distributor

Obligations of Economic Operators

- Responsible for the compliance of the product in relation to their role in the supply / distribution chain
- Distributors should be able to identify suppliers upstream and downstream

Obligations of economic operators

Only the manufacturer has detailed knowledge of design and production process

➔ Distinguish between manufacturer and operators in the chain: conformity assessment is the sole responsibility of the manufacturer

Obligations of the Manufacturer

- Design and manufacturer only products in compliance with EU legislation and then be safe
- Observe all applicable EU legislations
- Label products with required information (name, address, batch number, etc.)

Obligations of the Manufacturer

- If reason to believe that the product is not in conformity then
 - Cannot place the product on the market
 - Inform authorities of the risk
- If product already on the market :
 - Corrective action – withdraw / recall

Obligations of the Importer

- MUST ensure compliance of 3rd country products
- MUST ensure that :
 - Manufacturer has carried out conformity assessment
 - Manufacturer has drawn up the technical documentation
 - Product bears conformity mark
 - His name and address is on product

Obligations of the Importer

- If reason to believe that the product is not in conformity then
 - Cannot place the product on the market
 - Inform manufacturer & authorities
- If product already on market :
 - Corrective action – withdraw / recall

Customs controls – Obligations

- Checks on products entering the Community - on an adequate scale (check products, marking, documentation and conformity assessment)
- Co-operation between authorities
- Suspend release if:
 - Incorrectly marked
 - Presents serious risk
- Products can be retested or examined
- Destroy products presenting serious risk, if necessary

Traceability

- Economic operators must place information and/or marking on the products, on packaging or on documentation

Traceability in new TOYS Directive

Directive 2009/48/EC on the safety of toys

- TOYS traceability obligations for manufacturer, importer, distributor (Articles 4 to 9)
- Guidance document under discussion between national authorities and stakeholders

Traceability in EMC Directive

EMC Traceability obligations (Art. 9 2004/108/EC Directive)

- **for each apparatus** : type, batch, serial number, name and address of the manufacturer or his authorised representative or the person responsible for the placing on the market
- **Apparatus must be accompanied** : specific precautions for its appropriate use, restrictions and instructions for its use

Traceability

- Traceability is not an end in itself. It is what makes market surveillance effective whether for products manufactured inside the EU or imported
- The objective is to be able to find the products or the economic operators who can take the corrective measures

WEB ADDRESSES

More information can be found at:

[http://ec.europa.eu/enterprise/regulation/
internal_market_package/index_en.htm](http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm)



THANK YOU
FOR YOUR ATTENTION