WORKSHOP
« TRACEABILITY: A TOOL FOR MANAGING RISKS »

UNECE WP 6 on Regulatory Cooperation and Standardisation Policies

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Traceability in the context of EU technical harmonisation legislation for industrial products

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Why traceability matters from a regulator's perspective

- **Management of risks throughout the production process and supply / distribution chain** (=> up to factory gate, from factory to end user / consumer; control over production process is essential for conformity assessment: product safety assessment and preparation of the technical file)

- **Enable effective enforcement through market surveillance and product withdrawals / recalls** (=> trace non-compliant products back up the chain, identify roles and responsibilities throughout the chain and who is responsible for what, enable appropriate corrective measures including withdrawals and recalls)

General features of traceability in the EU system

- **EU legislation is prescriptive as to the ends but not as to the means to achieve those ends**

- **Technology-neutral**

Manufacturers should choose the traceability system which they deem most appropriate in relation to their products and their manufacturing and distribution system

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 on 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
- Define respective role in the supply chain
- Obligations in relation to product
- Obligations to inform
- Obligations to label
- Obligations to cooperate with market surveillance authorities

DEFINITIONS

- Manufacturer
- Authorised representative
- Importer
- Distributor

Traceability of the product – Basic requirement

Article R3(5) of Decision 768/2008/EC:

*« **Manufacturers** shall ensure that their products bear a **type, batch or serial number or other element allowing their identification**, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product »*

Obligations of Economic Operators

Responsible for the compliance of the product in relation to their role in the supply / distribution chain

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Obligations of Economic Operators

Manufacturer

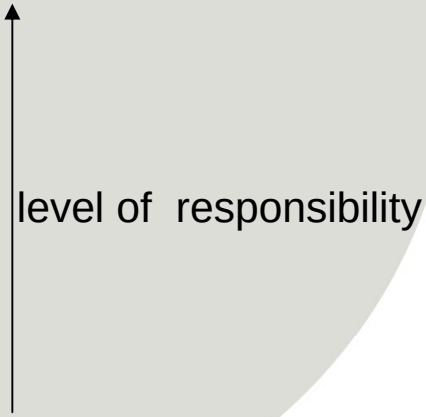
Designs and manufacturers in accordance with the requirements

Importer

Places only compliant products on the European market

Distributor

Acts with due care in relation to the applicable requirements



Authorised representative

Performs specific tasks other than conformity assessment on behalf of the manufacturer

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 manufacture only products in compliance with EU legislation
- Observe all applicable EU Directives / Regulations
- Label products with required information (name, address, type/batch/serial 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
  - Duty to identify downstream economic operators on request from market surveillance authorities

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 are on the 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
  - Duty to identify upstream / downstream economic operators on request from market surveillance authorities

Obligations of the Distributor

- Act with the due care that is expected of a professional in relation to the applicable requirements
- MUST verify that :
  - Product bears conformity mark and is accompanied by required documents, instructions and safety information
  - The manufacturer or importer's name and address are on the product

Obligations of the Distributor

- 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 :
  - Cooperate on corrective action – withdraw / recall
  - Duty to identify upstream / downstream economic operators on request from market surveillance authorities

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

The RAPEX process

- **RAPEX = Rapid Alert System for non-food dangerous goods** (set up under the General Product Safety Directive 2001/95/EC, now extended to both consumer and professional products by Regulation 765/2008/EC)

- Products presenting a serious safety risk => Competent national authorities notify the other authorities and the Commission via RAPEX

- Other countries determine if same product is on their market and whether they should take action

The RAPEX process

- Information on product identification and traceability is vital to the process

- Number of untraceable products decreasing but still accounting for about 10% of all serious risk notifications in 2010

Latest developments

- **Informal Expert Group on Product Traceability set up by DG Health and Consumers in September 2011**

  => independent experts to look at state-of-the-art and voluntary/best practices in the field of traceability; how economic operators are copying with their obligations; final report with recommendations to stakeholders expected by September 2013.

Case-study: traceability in the new Toy Safety Directive 2009/48/EC (OJEU L 170, 30.6.2009, p. 1)

- **Basic traceability obligation** for manufacturers (same as in NLF):

  Article 4(4): «*Manufacturers shall ensure that their toys bear a* ***type, batch, serial or model number or other element allowing their identification****, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy*»

Case-study: traceability in the new Toy Safety Directive 2009/48/EC (OJEU L 170, 30.6.2009, p. 1)

- Obligation for manufacturers to carry out a **safety assessment**:

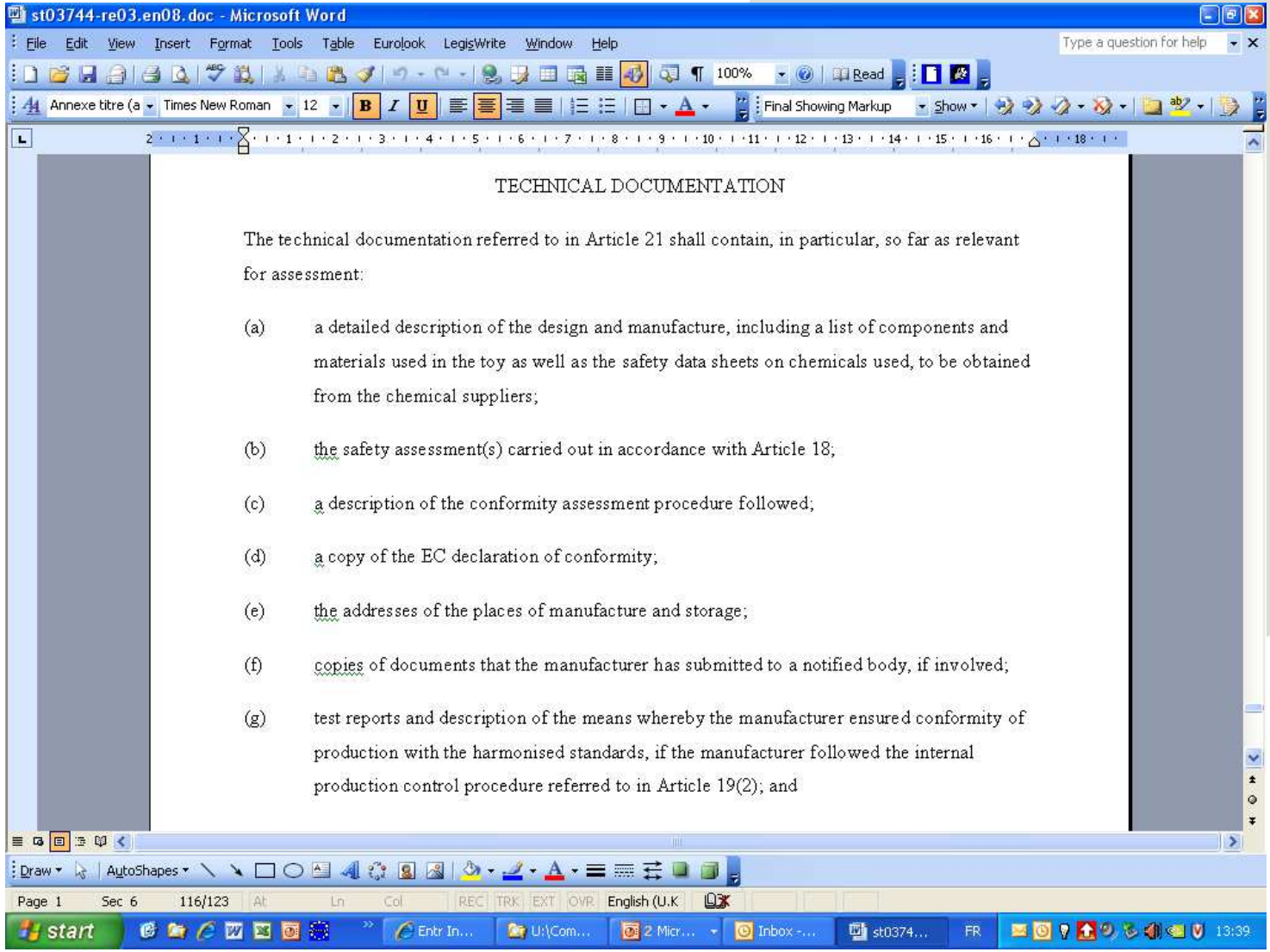
  Article 18: « *Manufacturers shall, before placing a toy on the market, carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards* »

Case-study: traceability in the new Toy Safety Directive 2009/48/EC (OJEU L 170, 30.6.2009, p. 1)

- Obligation for manufacturers to compile **technical documentation** in support of their safety assessment:

  Article 21(1): « The technical documentation referred to in Article 4(2) shall contain **all relevant data or details of the means used by the manufacturer to ensure that toys comply with the requirements** … It shall, in particular, contain the documents listed in Annex IV»

DIRECTIVE 2009/48/EC



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Case-study: traceability in the new Toy Safety Directive 2009/48/EC (OJEU L 170, 30.6.2009, p. 1)

Obligation for manufacturers to include in the technical documentation:

- **a list of components and materials**:
  - ⇒Bill of Materials
  - ⇒Good materials management system (=> traceability)
- **Safety data sheets on chemicals** used, to be obtained from the chemical suppliers

Traceability - Conclusions

- **Traceability enhances:**

  => compliance by the manufacturer through **effective management of the production process and supply / distribution chain** (=> control over the integrity of the manufacturing process through good materials and component management)

  => it is vital for an effective **market surveillance**, as it enables to **trace products up the chain and identify the economic operators** who can take the appropriate corrective measures

WEB ADDRESSES

More information can be found at:

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

RAPEX:
http://ec.europa.eu/consumers/safety/rapex/index_en.htm

Toy Safety:
http://ec.europa.eu/enterprise/sectors/toys/index_en.htm

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FOR YOUR ATTENTION