

UPDATE ON THE IMPLEMENTATION OF THE NEW LEGISLATIVE FRAMEWORK

UNECE WP 6 on Regulatory Cooperation and Standardisation Policies

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Outline

- Brief recall of the NLF legal provisions
- State of play of implementation and next steps

Focus on:

- ⇒ Market Surveillance
- ⇒ Alignment of sectoral legislation

The New Legislative Framework

- **Regulation (EC) 765/2008** of European Parliament & Council of 9 July 2008 – for accreditation & market surveillance
(OJ L218/30 of 13/08/2008)
- **Decision (EC) 768/2008** of European Parliament & Council of 9 July 2008 on common framework for the marketing of products (OJ L218/82 of 13/08/2008)

The New Legislative Framework

REGULATION

- **Accreditation**
- **Market surveillance**
 - internal
 - imported products
- **CE general principles**
- **Financing elements**

Applicable from 1 Jan 2010

Lex Specialis

sectorals/GPSD

DECISION

- **Definitions / obligations**
- **Notification (criteria / process / accreditation)**
- **Conformity assessment procedures**
- **Safeguard mechanisms (& market surveillance)**
- **CE marking**

Basis for future legislation

The Regulation & the Decision

REGULATION

- Covers elements not already included in sectoral legislation
- Complementary to sectoral legislation
- Applicable in all Member States on 1 January 2010
- Creates direct rights and obligations for Member States and individuals

DECISION

- Covers elements already included in legislation
- *Sui Generis* Decision - applies to European legislator (Council, EP and COMM)
- No immediate effects for Member States or individuals
- Better Regulation tool: model Articles - “toolbox”

Accreditation

- **Public authority activity** completely separated from commercial conformity assessment activities
- **1 national accreditation body (NAB) per Member State** (=> main changes necessary in Germany and Italy)
- **Prevention of competition for NABs within the EU internal market**
- **Set of requirements for NABs** (including not-for-profit)
- **EA (European co-operation for accreditation) as European accreditation infrastructure** (Guidelines for Cooperation signed 1 July 2009, Framework Partnership Agreement signed 30 June 2010)
- **Cross border accreditation**
- **Peer evaluation (EA role)**

Market Surveillance

Lex generalis Regulation 765/2008 vs. *Lex specialis* General Product Safety Directive (GPSD) 2001/95/EC

- The Regulation applies to **products covered by EU harmonising legislation**, except sectors where a specific market surveillance system already exist such as foodstuff, feedstuff, agricultural products, pharmaceuticals, medical devices, motor vehicles, etc.
- In addition, for **consumer products covered by EU harmonising legislation** more specific measures provided for in the GPSD can be taken

EU Market surveillance – product coverage

GPSD

Non-harmonised areas

Harmonised areas

Non-consumer products

**NLF Reg 765/2008 +
Sectoral legislation**

Market surveillance

Obligations of Member States

- **Establish adequate procedures to: follow up complaints, monitor accidents, order corrective action and verify its implementation.**
- **Entrust market surveillance authorities with necessary powers, resources and knowledge + adequate technical means (even to destroy)**
- **Perform appropriate checks on an adequate scale, based on risk assessment**
- **Take appropriate measures (also on following up on other Member States' actions): corrective action, withdrawal, recall, destruction (principle of proportionality: distinguish serious risk cases requiring rapid intervention from other cases; procedural safeguards for economic operators)**
- **Exchange information with COM and other Member States on serious risk cases via the Community Rapid Information System (=> extension of RAPEX to non-consumer products)**

Market surveillance

Obligations of Member States (2)

- **Organise cooperation between authorities within their territory**
- **Develop national market surveillance programmes**, share them with COM and other Member States and publish them on the web
- **Periodically review the functioning of their surveillance activities**
- **Provide for penalties** (effective, proportionate, dissuasive) for economic operators in case of infringements
- **Empower customs authorities with authority and resources to effectively control products imported from third countries** at the border, before they are released for free circulation (same principle of appropriate checks on an adequate scale – suspension of free circulation if serious risk, CE marking not affixed or required accompanying docs not in order)

NLF Implementation - Market Surveillance

Complex process

- Many parties involved:
 - Commission (DGs ENTR, SANCO, TAXUD)
 - Member States (both sectoral and coordination levels – customs authorities)

NLF Implementation - Market Surveillance

National market surveillance programmes (NMSPs)

- EU methodology for the establishment of NMSP
 - Elements of a general NMSP
 - Elements of a sector specific NMSP
 - Template
 - Common indicators

NLF Implementation - Market Surveillance

National market surveillance programmes (NMSPs)

- Current situation
 - All MS have sent their NMSP
 - The majority of NMSPs are sectorals
 - Available on national WEB sites and on CIRCA
 - Examples:

UK: <http://www.bis.gov.uk/assets/biscore/business-sectors/docs/n/10-p92-new-legislative-framework-general-national-market-surveillance-2011>

Slovak Republic:

http://www.uvzsr.sk/en/docs/info/SK_NATIONAL_MARKET_SURVEILLANCE_PROGRAMME_2010.pdf

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National market surveillance programmes (NMSPs)

- What Next:
 - Translations, publication on Commission WEB site, general evaluation
 - Ensure NMSPs are comparable and comprehensive, aim for a coherent approach

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Market Surveillance Authorities (MSAs)

- Current situation
 - All MS have sent the list of their MSAs with the area of competence
 - Published on the Commission website:
http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/index_en.htm

NLF Implementation – Market Surveillance

Exchange of information tools: RAPEX

- **RAPEX** - Rapid Alert System for products presenting a serious risk
- **NLF Regulation** (Article 22 Reg 765/2008) extends RAPEX to:
 - Consumer and Professional goods
 - All risks including those others than health and safety
 - Restrictive Measures adopted by a Member State (mandatory) or by the economic operator concerned on a voluntary basis

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Exchange of information tools: RAPEX

‘new’ types of notifications (2010-2011)

- **Goods for Professional use** : Machineries for use in workplace, Equipment for use in potentially explosive atmospheres, Motor vehicles, Chemical products: fertilisers infringing Reg 2003/2003
- **Risks others than health and safety (e.g. environmental risk)**: Plastic products and plastic packages of various consumer products containing cadmium (REACH Regulation), Fireworks infringing Reg 850/2004 (persistent organic pollutants)

NLF Implementation – Market Surveillance

Exchange of information tools: RAPEX

Current main activities:

- Operation of RAPEX in relation to the Regulation needs
 - Adaptation of IT platform
- Common basis for the assessment of risks for products
 - Task Force is working to review the RAPEX risk assessment methodology

NLF Implementation – Market Surveillance

Exchange of information tools: RAPEX

MAIN ELEMENTS:

- **RAPEX Guidelines**
- RAPEX **Contact Points Network** at the EU level
- **RAPEX networks** at the MS level
- RAPEX Contact Points **Working Group**
- Online application “**REIS**” (to be soon replaced by the new “**GRAS**” application – General Rapid Alert System – Two layers: RAPEX contact points and MSAs)
- **Commission RAPEX Team**
- RAPEX **website** (www.ec.europa.eu/RAPEX)
- RAPEX paper and electronic **publications**
- **Seminars**



NLF Implementation - Market surveillance – Cooperation at EU level

- Commission to set up a **general information support system**
 - => EU-wide **market surveillance database** with
 - (i) information on general issues relating to market surveillance activities; and
 - (ii) information on products presenting a risk, identification of risks, test results, provisional measures, contacts with economic operators
 - => **State of play:** discussions ongoing with the board of **ICSMS** (internet-supported information and communication system for the pan-European market surveillance)

ICSMS currently used by Austria, Belgium, Cyprus, Estonia, Germany, Luxemburg, Malta, Slovenia, Sweden, Switzerland, The Netherlands and United Kingdom:

Market surveillance – cooperation at EU level

- **Cooperation** on market surveillance issues **between Member States and Commission**
- **Sharing of resources and common initiatives** (training programmes, exchange of officials, development of best practices, joint actions, common methodologies for product controls and risk assessment)

NLF Implementation – Market Surveillance

Control of imported products

- Obligation of border controls on an adequate scale before release for free circulation (Articles 27 to 29 of Regulation 765/2008)
 - customs must suspend release for free circulation
 - they must inform Market Surveillance Authorities (MSA)
 - MSA can prohibit marketing if products dangerous
- Apply to all products covered by EU legislation
- Cooperation between MSA and customs is a key factor: provide adequate training to customs
- **Guidelines** (general and sectoral) have been developed for customs officers for the effective control of products imported from third countries

NLF Implementation – Market Surveillance

International Dimension

- **INTERNATIONAL dimension**
 - **MED-RAS project** - started in 2009 – establishment in the Mediterranean region of a rapid alert system similar to RAPEX (in operation in 2012)
 - **RAPEX-China system** – started in 2006 – informs Chinese authorities on RAPEX notified products of Chinese origin – Reports on enforcement actions carried out
 - **EU-China dialogues** on consumer product safety, market surveillance and specific sectors: toys, electro-mechanical, etc.
 - **United States**—cooperation with CPSC on toys and other consumer products – strengthen exchange of information, joint outreach events in China, enhanced cooperation on product safety standards, aim for compatible regulatory frameworks, etc.
 - **UNECE, ICPSC, OECD, ...**

NLF Implementation - Market Surveillance

Important developments ahead

« Product Safety Package » as a strategic initiative in the Commission 2012 Work Programme:

- **Revision of the General Product Safety Directive** (=> alignment with NLF on obligations of economic operators, traceability, procedures re: harmonised standards, integration of food-imitating products directive into GPSD)
- **Multi-annual market surveillance action plan** (as one of the 12 actions identified in the 2011 Single Market Act)
- **Possible specific legislative proposal on market surveillance** in response to the European Parliament's call for a single framework for market surveillance (as opposed to current three-tier structure: Reg 765/2008, GPSD, sector-specific legislation)

Conclusions on Market Surveillance

1. Implementation takes time
2. Member States need to legislate, regulate, restructure & coordinate internally
3. Commission coordination is required
4. Need for a comprehensive and organised market surveillance programme
5. Strong interest of the European Parliament
6. RAPEX, New Approach, GPSD & NLF have “leap frogged” to progress for the Internal market. Coexistence of GPSD & NLF has led to a new situation: expression of need for an effective single coherent and integrated system

European CE Marking information campaign

Launched in April 2010 (ongoing)

* Objective

- = Provide target groups with a clear picture of what CE marking does/does not stand for.
- = Support Member States in their communication campaigns
- = Give means to stakeholders/economic operators to contribute to policing the CE marking

European CE Marking information campaign

* Target audience

All economic operators (manufacturers, importers, distributors, professional associations, specialized press, consumers)

* Tools

Workshops in each Member State, e-learning materials, leaflets and brochures

More at:

<http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/>

Alignment of existing legislation

Alignment of existing New Approach Directives to the requirements laid down in Decision 768/2008 :

= Definitions

= Obligations of economic operators (manufacturers (including traceability), importers, distributors)

= Safeguard procedures

= Notified bodies : designation, obligations

Alignment of existing legislation

- To have legal effect the Decisions' provisions need to be **integrated into existing legislation**
- **Two tracks** for alignment
- **(1) Full-scale revisions** of **sectoral** legislation will automatically include an alignment exercise (examples: Toy Safety, RoHS, PPE, R&TTE, Medical Devices directives)
- **(2) “Omnibus alignment”** for directives not going to be revised within the next 3-5 years
 - Modifications will be strictly limited to integrating the provisions of the Decisions. Sector-specific aspects (scope, essential requirements,..) will remain unaffected!

Alignment of existing legislation

Alignment package under preparation :

- = Low Voltage Directive 2006/95/EC
- = Simple Pressure Vessels Directive 2009/105/EC
- = Non-automatic weighing instruments Directive 2009/23/EC
- = Civil explosives Directive 93/15/EC
- = ATEX Directive 94/9/EC

The New Legislative Framework

Alignment package under preparation :

- = Lifts Directive 95/16/EC
- = Pressure Equipment Directive 97/23/EC
- = Measuring Instruments Directive 2004/22/EC
- = EMC Directive 2004/108/EC
- = Pyrotechnic Articles Directive 2007/23/EC

The New Legislative Framework

Alignment package - Timeline

Public consultation from May to October 2010

Impact Assessment finalised in the first half 2011

Commission proposal will be adopted by end 2011

Adoption by Council and European Parliament by end 2012?

Amended Directives applicable after implementation by EU Member States (12~18 months after adoption at EU level)

Web site addresses

New Legal Framework:

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

GPSD:

http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm

RAPEX:

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

