Directorate General for
Enterprise and Industry

European Commission

The EU Market Surveillance Framework

European Commission
Directorate General for Enterprise and Industry
Unit C1: Regulatory approach for the free circulation of goods
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Content

1. Main elements of the New Legislative Framework

2. The new EU market surveillance framework

Main elements of the current Review

- Market surveillance
- Notified Bodies
- Role and significance of CE marking
- Common definitions & obligations/procedures

Strengthen system through review of the main features and addition of missing elements e.g. accreditation

Complementary legislative tools

REGULATION

- Accreditation
- Market surveillance
  - internal
  - imported products
- CE common elements
- Financing for inter-comparisons

Applicable from 1 Jan 2010

DECISION

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

Basis for future legislation

Why strengthen Market Surveillance?

- **Member State responsibility**
  - **Stop non-compliance / fraud / counterfeit**
  - **Check products internally/imported products**
  - **Take corrective measures – safeguard clause**

However, levels and rigour of Market Surveillance differ widely throughout the EU

=> Distortion of competition

=> Dangerous products on the market

Market surveillance - now

CURRENT SITUATION	
Obligations for Member States	Sectoral Directives & GPS-Directive
Post-market obligations for producers, distributors & economic operators	GPS-Directive
Sectoral AdCo Groups – Networks, Rapid intervention, Safeguards	Sectoral Directives & GPS-Directive

REGULATION - DEFINITION

Market surveillance means the activities carried out and measures taken by public authorities to ensure that products are in compliance with legal requirements set out in the relevant Community harmonisation legislation or do not endanger health, safety or other issues of public interest protection

Scope

- **Market Surveillance**
  - **Products = Substances, preparations & goods produced through a manufacturing process, except food, feed, human blood and tissues, living plants and animals**
- ***Lex Specialis***
  - **Pharmaceuticals, aviation, drug precursors, medical devices and motor vehicles - examples in recitals**
- **Border controls –**
  - **All products covered by Community harmonisation legislation**

Market Surveillance – Exemptions (1)

- **Exemptions via product definition**
  - **Food and feed, human blood and tissues, living plants and animals**
- **Exemptions via *lex specialis***
  - **Pharmaceuticals**
  - **Drug precursors**
  - **Civil aviation**
  - **Motor vehicles**
  - **Medical devices**
- **Authorities can take more specific measures according to GPSD (Consumer products)**

Market Surveillance – Exemptions (2)

Border controls

- Specific provisions relating to the organisation of border controls of specific products prevail

Market surveillance – Overall framework (1)

- Strengthening of Market surveillance
  - Scope
  - Organisation / Surveillance measures
  - Communication and Co-ordination
  - Restrictive measures
  - Control of products entering the Community
- CE Marking – General principles
  - Clarification on use and meaning
  - Clarification of role ‘v’ voluntary marks

Market surveillance - Main elements (1)

Common minimum requirements in all Member States

- ➢ **Organisational/operational requirements**
- **Infrastructures, resources and powers**
- **Oblige checks, take samples**
- **Checks at external borders**
- **Inform users of risks**
- **Ensure follow up of complaints and accidents**

Market surveillance - Main elements (2)

- Co-operation mechanism

- National level

- Community level

- Improvement of safeguard clause mechanism & information procedure (in Decision!)

Timeframe / Process

- Proposal was adopted by the Commission on 14 February 2007
- 3 Presidencies DE/PT/SI
- COREPER adoption 13 February 2008
- EP Plenary 21 February 2008
- Entry into force 1 January 2010

What next?

- In-depth analysis on the marking issues - preparation of a Communication
- Initiatives for Market Surveillance
- Implementation measures – EA
- Review of sectoral directives to bring into line with Decision

Review of sectoral directives

- **When?**

  Stable document: discussions start 2008

- **How?**
  - **By groups of directives**
  - **By modifying all at the same time**
  - **By issue**

To be decided with sectoral colleagues …..

Web site addresses

New Approach review:

http://ec.europa.eu/enterprise/newapproach/review_en.htm

New Internal Market Package for Goods:

http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm

Thank you for your attention