



Directorate General for
Enterprise and Industry

European Commission

The New Legislative Framework - Market Surveillance

EMARS WORKSHOP

Paris, 11 July 2008

Rita L'Abbate

Unit C1: Regulatory approach for the free circulation of goods

Points to cover

- **The New Legislative Framework (NLF)**
- **Market surveillance framework**
- **Implementation phase ...**

Points to cover

- **The New Legislative Framework (NLF)**
- **Market surveillance framework**
- **Implementation phase ...**

Complementary legislative tools

REGULATION

- **Market surveillance**
 - internal
 - imported product
- **Financing elements**

CE marking

**Applicable from
1 Jan 2010**

DECISION

- **Definitions**
- **Obligations of economic operators**
- **Conformity of the product**
- **Safeguard mechanisms (& market surveillance)**
- **CE marking**

Basis for future legislation

Points to cover

- **The New Legislative Framework (NLF)**
- **Market surveillance framework**
- **Implementation phase ...**

Market Surveillance – Overall framework

- **Strengthening of Market surveillance**
 - **Scope**
 - **Organisation / Surveillance measures**
 - **Restrictive measures – rapid information**
 - **Communication and Co-ordination**
 - **Control of products entering the Community
(ex Regulation 339/93)**

Market Surveillance - Scope (1)

PART I (controls on the EU market)

- **General – applies to “industrial products” covered by Community harmonisation legislation**

Market Surveillance – Scope (2)

➤ EXCLUSIONS :

1. **via the product definition (Article 15): food - feed, living plants, animals, human tissues, ...**
2. ***Lex specialis* :**
 - **GPSD (General Product Safety Directive) in Article 15**
 - **Pharmaceuticals, aviation, drug precursors, medical devices and motor vehicles given as examples in recitals**

Market surveillance –Requirements (1)

➤ Organisation

- Organise and carry out market surveillance activities**
- Inform on the responsible national authorities**
- Establish adequate procedure to manage non-compliances**
- Have the necessary powers and resources**
- Establish programmes (general or sectoral)**
-**

Market Surveillance - Requirements (2)

- **Surveillance measures**
 - **Perform appropriate checks on an adequate scale**
 - **Enter the premises of economic operators, and destroy unsafe products, if necessary**
 - **co-operation with economic operators (require documentation, reduce the risks, etc.)**
 - **Alert the users, where appropriate**
 - **Observe independence, confidentiality, professional secrecy**

Market Surveillance - Requirements (3)

- **Restrictive measures – rapid information**
 - **Rapid intervention in case of serious risks also if the effects are not immediate**
 - **Inform the economic operators of remedies taken**
 - **Inform rapidly via the existing RAPEX system**
 - **Develop a general IT tool for the exchange of information**

Market Surveillance - Requirements (4)

- **Communication and Co-ordination**
 - **Ensure efficient co-operation at EU and national levels**
 - **Provide assistance and information to other Member States**
 - **Share, as far as possible, expertise and best practices, improve the overall system, develop and organise trainings and exchange of officials, etc.**

Market Surveillance – Scope imported products

PART II :

- **Control of products entering the
Community
by customs authorities (ex Regulation
339/93)**
- **Scope: General – applies to “all products”
covered by Community legislation**
- **Exclusions: Lex specialis**

Market Surveillance – imported products

- **Requirements**
- **Perform checks on adequate scale**
 - **Suspend the release for free circulation if there are grounds to believe that the product presents a serious risk**
 - **Restore the release if no action**
 - **Prohibit the placing on the market by stamping on the official document : dangerous product or non- conforming product**

Market Surveillance – CE marking

CE marking

- The only conformity mark
- Rules and conditions for affixing the marking
- ... Community trade mark

Points to cover

- **The New Legislative Framework (NLF)**
- **Market surveillance framework**
- **Implementation phase ...**

Implementation phase(1)

REGULATION

- **Work plan to ensure consistent application**

- **Wider consultation**
 - **with MS and Stakeholders**
 - **Internal to the Commission**

Implementation phase (2)

REGULATION

- **Agreement on scope (Art. 15 – sectoral legislation and GPSD)**
- **Extension of RAPEX**
- **General IT tool, possible use of ICSMS**
- **Co-ordination infrastructure**
- **Customs co-operation (e.g. RIF review)**

Implementation phase (3)

REGULATION

- Identify best practices
- Coordination of ADCO groups
- Elaborate the relevant guidelines
- Budget, etc....

Implementation phase(4)

REGULATION – CE Marking

- **In-depth study on the feasibility of a consumer safety mark**
 - **IPM Questionnaire – 3 sections**
 - **Evaluation of the background**
 - **Commission information – September**

http://ec.europa.eu/yourvoice/consultations/index_en.htm

Implementation phase(5)

REGULATION – CE Marking

- Finalise registration of **CE** marking as a collective mark
- Feed into National legislation concerning sanction of misuse and abuse

Implementation phase(6)

DECISION:

- **By issue / by sector**
- **Practical issues**
 - **NANDO**
 - **Validity of existing notifications – “clean-up”**
 - **Information mechanisms – safeguard mechanism application**

Implementation phase ...(7)

***In other words create a new
complete environment to
strengthen
market surveillance and
reinforce safety***

Timeframe / Process

- **Council adoption : 23 June 2008**
- **Publication in OJEU ~ Autumn**
- **Entry into force 20 days after publication**
- **Date of application of Regulation is 1 Jan 2010**
- **Decision ‘*sui generis*’ = can be used immediately**

- Thank you for your attention!

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

Questions:

Entr-reg-approach-for-free-circ@ec.europa.eu