

# Methodology for the establishment of national market surveillance programmes under Regulation 765/2008

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**Unit C1: Regulatory approach for the free movement of goods**



**European Commission**  
Enterprise and Industry

## POINTS TO COVER

- Overview of the main market surveillance provisions
- Methodology for the establishment of national market surveillance programmes
- Implementing phase...

# New Legislative Framework

## 2 complementary instruments

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

# Regulation 765/2008/EC

- **Accreditation:** Community framework for the operation of accreditation
- **Market Surveillance**
  - Rules for the control of products circulating inside the EU
  - Rules for the control of imported products at the borders
- General principles of the **CE marking**

# Main objectives

- **Reinforce** national market surveillance
- Ensure a **more coherent** level of intervention and controls throughout Europe
- Ensure an **equal treatment** of non-compliant products throughout Europe = ensure **equal conditions** for economic operators
- **Protect** fair economic operators **against unfair competition** from “black sheep”
- Restore **confidence** in EU legislation and CE marking
- Make the **internal market** work **in practice** (and not only on paper)

# To this end, Regulation 765/2008..

- ..sets out **requirements** on
  - Organisation of market surveillance
  - Surveillance measures
  - Restrictive measures
- ..enhances **cooperation** amongst market surveillance authorities of MS
  - information exchange
  - mutual assistance
  - participation in administrative cooperation
- ..reinforces controls of **imported goods**

# Organisational requirements

- **Information requirements (Art. 17)**
  - **Inform Commission** of authorities and their competences
  - **Inform public** about authorities and contact possibilities
- **Organisational requirements (Art. 18)**
  - Provide necessary **infrastructures, resources, powers**
  - Establish **complaint procedures, monitoring of accidents**, follow up of scientific knowledge
  - Establish **market surveillance programmes** and communicate them to Commission – **first one for 1.1. 2010!!** Must be publicly available
  - **Regular reviews** to be sent to Commission and make them **publicly available**

# Methodology for the establishment of NMSPs

Article 18(5) obliges Member States :

- to establish, implement and periodically update
- to draw-up general market surveillance programme or
- to draw-up sector specific programmes
- to make them publicly available

by 1 January 2010



# NMSPs – General Objectives

A NMSP shall ensure that effective measures can be taken in relation to any product category covered by EU legislation

# NMSPs – General or Sectoral

What is meant by

- « General market surveillance programme »
- « Sector specific market surveillance programmes »

# NMSPs – General Elements

- Identify situations, sectors or products that could pose a risk
- Foresee preventive actions to avoid the placing on the market of unsafe or non-compliant products
- Clear restrictive measures, corrective actions and penalties
- Establish systematic strategies
- Ensure transparency

## NMSPs – General Activities

- Be annual or biennial
- Fix the objectives and actions to be carried out
- Be in line with the EU legislation
- Be adaptable and renewable
- Specify the general approach and procedures (samples, checks, priorities, risk assessment methodology, supply chain, proactive or reactive activities, sectoral or regional, ....)

## NMSPs – General specific elements

- Cover internal and at borders controls
- Have adequate resources
- Organise adequate cooperation at national (regional, local) and international levels
- Have efficient exchange of information and communication systems

# Elements of a general NMSP

- Objectives
- General national organisation (structure, distribution of responsibilities, ...)
- Monitoring intervention (reactive, proactive, precautionary principle)
- How to set up priorities
- General principles for evaluation of risks
- Etc.....

# Elements of a sectoral NMSP

- **Generalities** (national surveillance authority, contact person, etc.)
- **EU legislation applicable**
- **Product description**
- **Monitoring intervention** (internal or at borders controls, reactive/proactive, etc.)
- **Main monitoring motivation** (complaints, accidents, tests results, etc.)
- **Etc....**

WP SOGS-MSG N008 ADDENDUM

ANNEX – (TEMPLATE)

SECTORAL NATIONAL MARKET SURVEILLANCE PROGRAMME(s) (Sectoral NMSP)

Member State : .....

Surveillance Authority : .....

Person responsible for the Sectoral NMSP:.....

e-mail address: .....

Planning for : 2010

No of EU legislation applicable	Sector	Description of the product or category	Type of monitoring	Monitoring motivation	Monitoring activity	Priority	Starting period or date	Development	Outcomes or further initiatives	Project manager generalities
2006/42/EC	Machinery	Earth movers	Reactive Borders controls	complaints	Documents inspection	high	2 <sup>nd</sup> quarter	ADCO Machinery initiative	Improve cooperation	Contact person e-mail ...



# Implementation (1)

- Entry into force – **1 January 2010!!**
- Specific **subgroup of SOGS** created – “MS SOGS group” – liaison with sectors important
- Information exchange systems
  - **Rapid Information exchange**
    - adaptations to RAPEX needed?
  - **General Database**
    - What type of information should be in?
    - Possibility to use ICSMS? Adaptations needed?

# Implementation (2)

- **Market surveillance programmes**
  - Which information should be provided, common format?
- **Cooperation with customs**
- Obligation to perform “appropriate” checks on an **“adequate scale”** (Art. 19.1)
  - What is an adequate scale? appropriate checks? Sector – specific?
- Withdrawal/ notification of products presenting **“serious risk”**? (Art. 20 and 22)
  - What is a serious risk? Risk assessment guidelines?

# Web site addresses

- New Legal Framework:

[http://ec.europa.eu/enterprise/newapproach/index\\_en.htm](http://ec.europa.eu/enterprise/newapproach/index_en.htm)

- Contact: [Entr-reg-approach-for-free-circ@ec.europa.eu](mailto:Entr-reg-approach-for-free-circ@ec.europa.eu)



**Thank you for your attention!**