



Directorate General for  
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European Commission

# The New Legislative Framework

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

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# Timeframe / Process

- **Commission adopted Proposal 14 Feb 2007**
- **Approved in EP Plenary 21 Feb 2008**
- **Formal Council adoption 23 June 2008**
- **Publication in OJEU 13 August 2008**
- **Entry into force 20 days after publication**
- **Date of application of Regulation is 1 Jan 2010**
- **Decision ‘*sui generis*’ = can be used immediately**

# Objectives

- **Overall New/Old approaches**
  - **Add missing chapters**
  - **Coherence for existing texts**
- **Both consumer & non consumer products**
- **Horizontal texts but no direct modifications to existing legislation**
  - **Role of European Standardisation**
    - **Regulation & Decision**

# Complementary legislative tools

## REGULATION

- Accreditation
- Market surveillance
  - internal
  - imported products
-  general principles

Applicable from 1 Jan 2010

*Lex Specialis*

sectorals/GPSD

## DECISION

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

**Basis for future legislation** <sup>4</sup>

# Scope of the package

- **Accreditation**
  - **Products & services**
- **Market Surveillance**
  - **Exclusions for : food - feed, human blood, cells, tissues and agricultural products via the product definition in Article 15**
- **Other sectors**
  - ***Lex specialis* - pharmaceuticals, aviation, drug precursors, medical devices and motor vehicles given as examples in recitals**

# Accreditation & Notified bodies

**Legal base for Accreditation**

**Role of accreditation**

**Reinforced criteria for NBs**

**Harmonised requirements for notification process**

**Clean up list of NBs?**

# Market Surveillance

- Change of mind-set on market surveillance
- **BEFORE**: Exception to free movement of goods
- **NOW**: Duty to enforce EU legislation properly  
and to withdraw non complying or dangerous  
products

# Market Surveillance

## MAJOR OBLIGATIONS

- **Appoint appropriate national authorities**
- **Ensure they are given appropriate authority,  
Powers and means to intervene**

**Obligation to intervene in case of non complying  
or dangerous products**

- **Obligations for Customs Authorities**
- **Obligation of coordination between national  
authorities and customs**

# Market Surveillance

## EU System:

### Cross frontier cooperation

- **Exchange of Information**
  - **RAPEX**
  - **General database**
- **Consultation Process at national level**
- **Coordination (ADCOS, Customs, Share resources, etc)**

# Conclusions

- **Accreditation**
- **Review of existing sectoral legislation**
- **Horizontal standardisation**
- **CE Marking or consumer mark?**
- **Market surveillance:**
  - **Effective protection**
  - **Equivalent level protection & burdens**
    - **Level playing field**
  - **Rebalance pre & post market controls**
  - **Integrated EU system: avoid EU decisions by taking coordinated positions earlier**

# Web site addresses

## **New Approach review:**

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

## **Questions:**

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