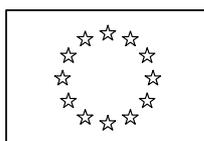


**THE ACQUIS OF THE EUROPEAN UNION UNDER THE
MANAGEMENT OF DG ENTERPRISE AND INDUSTRY**

LIST OF MEASURES
(The “Pink Book”)



**European
Commission**

31 December 2009

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Introduction

This document provides a structural list of the EU *acquis* under the management of the Directorate General for Enterprise & Industry, setting out the references for existing Community legislation and other measures. It includes both 'hard' law, by which is meant that which creates legal obligations, and 'soft' law, meaning those measures which, while not in themselves creating legal obligations, have a bearing on the application of hard law.

This list also shows the relationship between different instruments. For example, when a measure has been modified, adapted to technical progress, or has had implementing measures added, the original measure and the modifying, adapting or implementing measures are included in a box along with it. In the many areas which are regulated by means of a basic measure and implementing measures, the relationships between the different groups of instruments are shown. In this way, the often complicated and sometimes opaque relationships between different measures should become clearer.

The list has been organised under chapter headings, which broadly reflect industrial sectors and the internal organisation of the DG for Enterprise and Industry. As of 2001, this list also includes the measures relating to processed agricultural products which are managed by the DG for Enterprise and Industry. In the context of enlargement negotiations, the list corresponds to three negotiating chapters of the EU *acquis*: Chapter 1 - Free movement of goods (DG Enterprise and Industry part), Chapter 7 – Agriculture (DG Enterprise and Industry part) and Chapter 20 – Enterprise and industrial policy.

This edition is a follow-up and a review of the 12th edition of 31 December 2008. It includes all new measures adopted between that date and 31 December 2009.

Please note that, from 2010, the Pharmaceuticals, Cosmetics and Medical Devices sectors will be under the management of the DG for Health and Consumer Safety (DG SANCO). Therefore, the legislative acts adopted in 2010 for these sectors will not appear in the next edition of this publication.

This document has been elaborated by Unit C/1 of the DG for Enterprise and Industry.

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1. MOTOR VEHICLES

Outline:

1. 1. Structure

1. 2. Enumeration of the legislation

1.2.1. Motor vehicles and their trailers

1.2.2. Two or three-wheel motor vehicles

1.2.3. Wheeled agricultural or forestry tractors

1.3. Other measures relating to motor vehicles

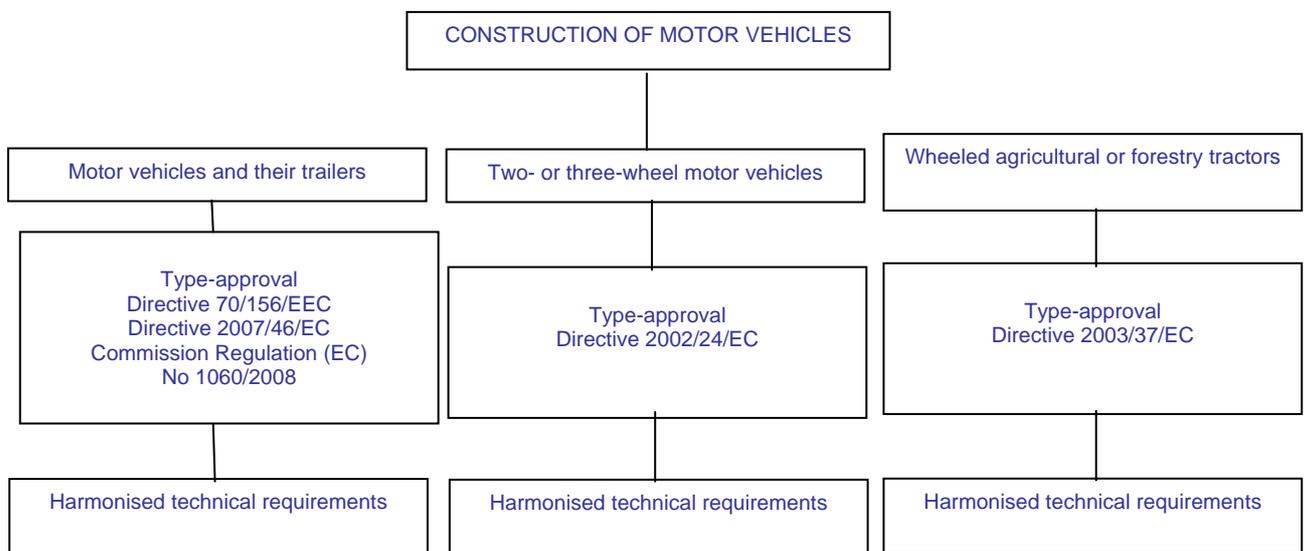
1.1. STRUCTURE

Community legislation in the field of motor vehicles can be divided into two groups: that which applies to the construction of motor vehicles; and that which applies to the use of motor vehicles.

Legislation on the construction of motor vehicles can further be divided into three groups:

1. *Motor vehicles and their trailers*
2. *Two or three-wheel motor vehicles*
3. *Wheeled agricultural or forestry tractors*

The Enterprise DG is responsible for all the legislation on the construction of motor vehicles.*)



*) The Transport and Energy DG is responsible for the legislation on the use of motor vehicles. That legislation is not included in this list.

1.2. ENUMERATION OF THE LEGISLATION

1.2.1. MOTOR VEHICLES AND THEIR TRAILERS

1.2.1.1. Type approval

Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive)

Amended by:

Regulation (EC) No **78/2009**

Regulation (EC) No **79/2009**

Regulation (EC) No **595/2009**

Regulation (EC) No **661/2009**

Commission Regulation (EC) No 1060/2008 of 7 October 2008 replacing Annexes I, III, IV, VI, VII, XI and XV to Directive 2007/46/EC of the European Parliament and of the Council establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive)

Commission Regulation (EC) No 385/2009 of 7 May 2009 replacing Annex IX to Directive 2007/46/EC of the European Parliament and of the Council establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive)

1.2.1.2. Permissible sound level and the exhaust system of motor vehicles

Council Directive 70/157/EEC on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles, amended by:

Council Directive **77/212/EEC**

Council Directive **84/424/EEC**

Council Directive **87/354/EEC**

Council Directive **92/97/EEC**

Adaptations to technical progress:

Commission Directive **73/350/EEC**

Commission Directive **81/334/EEC**

Commission Directive **84/372/EEC**

Commission Directive **89/491/EEC**

Commission Directive **96/20/EC**

Commission Directive **1999/101/EC**

Commission Directive **2007/34/EC**

1.2.1.3 Measures to be taken against air pollution by emissions from motor vehicles

Council Directive 70/220/EEC on the approximation of the laws of the Member States on measures to be taken against air pollution by emissions from motor vehicles, amended by:

Council Directive **83/351/EEC**

Council Directive **88/76/EEC**

Council Directive **88/436/EEC**

Council Directive **89/458/EEC**

Council Directive **91/441/EEC**

Council Directive **93/59/EEC**

European Parliament and Council Directive **94/12/EC**

European Parliament and Council Directive **96/69/EC**

European Parliament and Council Directive **98/69/EC**

European Parliament and Council Directive **2001/1/EC**

European Parliament and Council Directive **2001/100/EC**

Adaptations to technical progress:

Council Directive **74/290/EEC**

Commission Directive **77/102/EEC**

Commission Directive **78/665/EEC**

Commission Directive **89/491/EEC**

Commission Directive **96/44/EC**

Commission Directive **98/77/EC**

Commission Directive **1999/102/EC**

Commission Directive **2002/80/EC**

Commission Directive **2003/76/EC**

Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information

amended by:

Regulation (EC) No **595/2009**

Commission Regulation (EC) No 692/2008 of 18 July 2008 implementing and amending Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information

1.2.1.4 Fuel tanks and rear under run protection of motor vehicles and their trailers

Council Directive 70/221/EEC on the approximation of the laws of the Member States relating to liquid fuel tanks and rear under run protection of motor vehicles and their trailers

Adaptations to technical progress:

Commission Directive **79/490/EEC** (amended by Commission Directive **81/333/EEC**)

Commission Directive **97/19/EC**

European Parliament and Council Directive **2000/8/EC**

Commission Directive **2006/20/EC**

Directive 70/221/EEC will be repealed with effect from 1 November 2014

1.2.1.5 Space for mounting and the fixing of rear registration plates on motor vehicles and their trailers

Council Directive 70/222/EEC on the approximation of the laws of the Member States relating to the space for mounting and the fixing of rear registration plates on motor vehicles and their trailers

Directive 70/222/EEC will be repealed with effect from 1 November 2014

1.2.1.6 Steering equipment for motor vehicles and their trailers

Council Directive 70/311/EEC on the approximation of the laws of the Member States relating to the steering equipment for motor vehicles and their trailers

Adaptation to technical progress:

Commission Directive **92/62/EEC**

Commission Directive **1999/7/EC**

Directive 70/311/EEC will be repealed with effect from 1 November 2014

1.2.1.7 Doors of motor vehicles and their trailers

Council Directive 70/387/EEC on the approximation of the laws of the Member States relating to the doors of motor vehicles and their trailers

Adaptations to technical progress:

Commission Directive **98/90/EC**

Commission Directive **2001/31/EC**

Directive 70/387/EEC will be repealed with effect from 1 November 2014

1.2.1.8 Audible warning devices for motor vehicles

Council Directive 70/388/EEC on the approximation of the laws of the Member States relating to audible warning devices for motor vehicles, amended by:

Council Directive **87/354/EEC**

Directive 70/388/EEC will be repealed with effect from 1 November 2014

1.2.1.9 Rear-view mirrors of motor vehicles

Council Directive 71/127/EEC on the approximation of the laws of the Member States relating to the rear-view mirrors of motor vehicles, amended by:

Council Directive **87/354/EEC**

Adaptations to technical progress:

Commission Directive **79/795/EEC**
Commission Directive **85/205/EEC**
Commission Directive **86/562/EEC**
Commission Directive **88/321/EEC**

European Parliament and Council Directive 2003/97/EC on the approximation of the laws of the Member States relating to the type-approval of devices for indirect vision and of vehicles equipped with these devices, amending Directive 70/156/EEC and repealing Directive 71/127/EEC
(Directive 71/127/EEC will be repealed on 24 January 2010)

Adaptations to technical progress:
Commission Directive **2005/27/EC**

Directive 2003/97/EEC will be repealed with effect from 1 November 2014

1.2.1.10 Braking devices of certain categories of motor vehicles and their trailers

Council Directive 71/320/EEC on the approximation of the laws of the Member States relating to the braking devices of certain categories of motor vehicles and their trailers

Adaptations to technical progress:
Commission Directive **74/132/EEC**
Commission Directive **75/524/EEC**
Commission Directive **79/489/EEC**
Commission Directive **85/647/EEC**
Commission Directive **88/194/EEC**
Commission Directive **91/422/EEC**
Commission Directive **98/12/EC**
Commission Directive **2002/78/EC**

Directive 71/320/EEC will be repealed with effect from 1 November 2014

1.2.1.11 Radio interference (electromagnetic compatibility) of vehicles

Council Directive 72/245/EEC on the approximation of the laws of the Member States relating to the radio interference (electromagnetic compatibility) of vehicles

Adaptations to technical progress:
Commission Directive **89/491/EEC**
Commission Directive **95/54/EC**
Commission Directive **2004/104/EC**
Commission Directive **2005/49/EC**
Commission Directive **2005/83/EC**
Commission Directive **2006/28/EC**
Commission Directive **2009/19/EC**

Directive 72/245/EEC will be repealed with effect from 1 November 2014

1.2.1.12 Measures to be taken against the emission of pollutants from diesel engines for use in vehicles

Council Directive 72/306/EEC on the approximation of the laws of the Member States relating the measures to be taken against the emission of pollutants from diesel engines for use in vehicles

Adaptations to technical progress:

Commission Directive **89/491/EEC**

Commission Directive **97/20/EC**

Commission Directive **2005/21/EC**

Directive 72/306/EEC will be repealed with effect from 2 January 2013

1.2.1.13 Interior fittings of motor vehicles

Council Directive 74/60/EEC on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles

Adaptation to technical progress:

Commission Directive **78/632/EEC**

European Parliament and Council Directive **2000/4/EC**

Directive 74/60/EEC will be repealed with effect from 1 November 2014

1.2.1.14 Devices to prevent the unauthorised use of motor vehicles

Council Directive 74/61/EEC on the approximation of the laws of the Member States relating to devices to prevent the unauthorised use of motor vehicles

Adaptation to technical progress:

Commission Directive **95/56/EC**

Directive 74/61/EEC will be repealed with effect from 1 November 2014

1.2.1.15 Interior fittings of motor vehicles

Council Directive 74/297/EEC on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles

Adaptation to technical progress:

Commission Directive **91/662/EEC**

Directive 74/297/EEC will be repealed with effect from 1 November 2014

1.2.1.16 Seats, their anchorages and head restraints in motor vehicles

Council Directive 74/408/EEC on the approximation of the laws of the Member States with regard to seats, their anchorages and head restraints in motor vehicles, amended by:

Council Directive **81/577/EEC**

European Parliament and Council Directive **2005/39/EC**

Adaptation to technical progress:

Commission Directive **96/37/EC**

Directive 74/408/EEC will be repealed with effect from 1 November 2014

1.2.1.17 External projections of motor vehicles

Council Directive 74/483/EEC on the approximation of the laws of the Member States relating to the external projections of motor vehicles, amended by:

Council Directive **87/354/EEC**

Adaptation to technical progress:

Commission Directive **79/488/EEC**

Commission Directive **2007/15/EC**

Directive 74/483/EEC will be repealed with effect from 1 November 2014

1.2.1.18 Reverse and speedometer equipment of motor vehicles

Council Directive 75/443/EEC on the approximation of the laws of the Member States relating to the reverse and speedometer equipment of motor vehicles

Adaptation to technical progress:

Commission Directive **97/39/EC**

Directive 75/443/EEC will be repealed with effect from 1 November 2014

1.2.1.19 Statutory plates and inscriptions for motor vehicles and their trailers, and their location and method of attachment

Council Directive 76/114/EEC on the approximation of the laws of the Member States relating to statutory plates and inscriptions for motor vehicles and their trailers, and their location and method of attachment, amended by:

Council Directive **87/354/EEC**

Adaptation to technical progress:

Commission Directive **78/507/EEC**

Directive 76/114/EEC will be repealed with effect from 1 November 2014

1.2.1.20 Anchorages for motor vehicle safety belts

Council Directive 76/115/EEC on the approximation of the laws of the Member States relating to anchorages for motor vehicle safety belts, amended by:

Council Directive **81/575/EEC**

European Parliament and Council Directive **2005/41/EC**

Adaptations to technical progress:

Commission Directive **82/318/EEC**

Commission Directive **90/629/EEC**

Commission Directive **96/38/EC**

Directive 76/115/EEC will be repealed with effect from 1 November 2014

1.2.1.21 Installation of lighting and light-signalling devices on motor vehicles and their trailers

Council Directive 76/756/EEC on the approximation of the law of the Member States relating to the installation of lighting and light-signalling devices on motor vehicles and their trailers, amended by:

Council Directive **83/276/EEC**

Adaptations to technical progress:

Commission Directive **80/233/EEC**

Commission Directive **82/244/EEC**

Commission Directive **84/8/EEC**

Commission Directive **89/278/EEC**

Commission Directive **91/663/EEC**

Commission Directive **97/28/EC**

Commission Directive **2007/35/EC**

Commission Directive **2008/89/EC**

Directive 76/756/EEC will be repealed with effect from 1 November 2014

1.2.1.22 Retro-reflectors for motor vehicles and their trailers

Council Directive 76/757/EEC on the approximation of the laws of the Member States relating to retro-reflectors for motor vehicles and their trailers, amended by:

Council Directive **87/354/EEC**

Adaptation to technical progress:

Commission Directive **97/29/EC**

Directive 76/757/EEC will be repealed with effect from 1 November 2014

1.2.1.23 End-outline marker lamps, front position (side) lamps, rear position (side) lamps, stop lamps, daytime running lamps and side marker lamps for motor vehicles and their trailers

Council Directive 76/758/EEC on the approximation of the laws of the Member States on end-outline marker lamps, front position (side) lamps, rear position (side) lamps, stop lamps, daytime running lamps and side marker lamps for motor vehicles and their trailers, amended by:

Council Directive **87/354/EEC**

Adaptations to technical progress:

Commission Directive **89/516/EEC**

Commission Directive **97/30/EC**

Directive 76/758/EEC will be repealed with effect from 1 November 2014

1.2.1.24 Direction indicator lamps for motor vehicles and their trailers

Council Directive 76/759/EEC on the approximation of the laws of the Member States relating to direction indicator lamps for motor vehicles and their trailers, amended by:

Council Directive **87/354/EEC**

Adaptation to technical progress:

Commission Directive **89/277/EEC**

Commission Directive **1999/15/EC**

Directive 76/759/EEC will be repealed with effect from 1 November 2014

1.2.1.25 Rear registration plate lamps for motor vehicles and their trailers

Council Directive 76/760/EEC on the approximation of the laws of the Member States relating to the rear registration plate lamps for motor vehicles and their trailers, amended by:
Council Directive **87/354/EEC**
Adaptation to technical progress:
Commission Directive **97/31/EC**

Directive 76/760/EEC will be repealed with effect from 1 November 2014

1.2.1.26 Motor vehicle headlamps which function as main-beam and/or dipped-beam headlamps and to light sources (filament lamps and others) for use in approved lamp units of motor vehicles and of their trailers

Council Directive 76/761/EEC on the approximation of the laws of the Member States relating to motor vehicle headlamps which function as main-beam and/or dipped-beam headlamps and to light sources (filament lamps and others) for use in approved lamp units of motor vehicles and of their trailers, amended by:
Council Directive **87/354/EEC**

Adaptation to technical progress:
Commission Directive **89/517/EEC**
Commission Directive **1999/17/EC**

Directive 76/761/EEC will be repealed with effect from 1 November 2014

1.2.1.27 Front fog lamps for motor vehicles

Council Directive 76/762/EEC on the approximation of the laws of the Member States relating to front fog lamps for motor, amended by:
Council Directive **87/354/EEC**
Adaptation to technical progress:
Commission Directive **1999/18/EC**

Directive 76/762/EEC will be repealed with effect from 1 November 2014

1.2.1.28 Motor vehicle towing devices

Council Directive 77/389/EEC on the approximation of the laws of the Member States relating to motor vehicle towing devices
Adaptation to technical progress:
Commission Directive **96/64/EC**

Directive 77/389/EEC will be repealed with effect from 1 November 2014

1.2.1.29 Rear fog lamps for motor vehicles and their trailers

Council Directive 77/538/EEC on the approximation of the laws of the Member States relating to rear fog lamps for motor vehicles and their trailers, amended by:

Council Directive **87/354/EEC**

Adaptation to technical progress:

Commission Directive **89/518/EEC**

Commission Directive **1999/14/EC**

Directive 77/538/EEC will be repealed with effect from 1 November 2014

1.2.1.30 Reversing lamps for motor vehicles and their trailers

Council Directive 77/539/EEC on the approximation of the laws of the Member States relating to reversing lamps for motor vehicles and their trailers, amended by:

Council Directive **87/354/EEC**

Adaptation to technical progress:

Commission Directive **97/32/EC**

Directive 77/539/EEC will be repealed with effect from 1 November 2014

1.2.1.31 Parking lamps for motor vehicles

Council Directive 77/540/EEC on the approximation of the laws of the Member States relating to parking lamps for motor vehicles, amended by:

Council Directive **87/354/EEC**

Adaptation to technical progress:

Commission Directive **1999/16/EC**

Directive 77/540/EEC will be repealed with effect from 1 November 2014

1.2.1.32 Safety belts and restraint systems of motor vehicles

Council Directive 77/541/EEC on the approximation of the laws of the Member States relating to safety belts and restraint systems of motor vehicles, amended by:

Council Directive **81/576/EEC**

Council Directive **87/354/EEC**

European Parliament and Council Directive **2005/40/EC**

Adaptations to technical progress:

Commission Directive **82/319/EEC**

Commission Directive **90/628/EEC**

Commission Directive **96/36/EC**

Commission Directive **2000/3/EC**

Directive 77/541/EEC will be repealed with effect from 1 November 2014

1.2.1.33 Field of vision of motor vehicle drivers

Council Directive 77/649/EEC on the approximation of the laws of the Member States relating to the field of vision of motor vehicle drivers

Adaptations to technical progress:

Commission Directive **81/643/EEC**

Commission Directive **88/366/EEC**

Commission Directive **90/630/EEC**

Directive 77/649/EEC will be repealed with effect from 1 November 2014

1.2.1.34 Interior fittings of motor vehicles

Council Directive 78/316/EEC on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles

Adaptation to technical progress:

Commission Directive **93/91/EEC** (amended by Commission Directive **94/53/EC**)

Directive 78/316/EEC will be repealed with effect from 1 November 2014

1.2.1.35 Defrosting and demisting systems of glazed surfaces of motor vehicles

Council Directive 78/317/EEC on the approximation of the laws of the Member States relating to the defrosting and demisting systems of glazed surfaces of motor vehicles

Directive 78/317/EEC will be repealed with effect from 1 November 2014

1.2.1.36 Wiper and washer systems of motor vehicles

Council Directive 78/318/EEC on the approximation of the laws of the Member States relating to the wiper and washer systems of motor vehicles

Adaptation to technical progress:

Commission Directive **94/68/EC**

Directive 78/318/EEC will be repealed with effect from 1 November 2014

1.2.1.37 Heating systems for motor vehicles and their trailers

European Parliament and Council Directive 2001/56/EC on the approximation of the laws of the Member States relating to heating systems for motor vehicles and their trailers **Adaptation to technical progress:**

Commission Directive **2004/78/EC**

Commission Directive **2006/119/EC**

Directive 2001/56/EC will be repealed with effect from 1 November 2014

1.2.1.38 Wheel guards of motor vehicles

Council Directive 78/549/EEC on the approximation of the laws of the Member States relating to the wheel guards of motor vehicles

Adaptation to technical progress:

Commission Directive **94/78/EC**

Directive 78/549/EEC will be repealed with effect from 1 November 2014

1.2.1.39 Head restraints of seats of motor vehicles

Council Directive 78/932/EEC on the approximation of the laws of the Member States relating to head restraints of motor vehicles, amended by:
Council Directive **87/354/EEC**

Directive 78/932/EEC will be repealed with effect from 1 November 2014

1.2.1.40 Fuel consumption of motor vehicles

Council Directive 80/1268/EEC on the approximation of the laws of the Member States relating to the fuel consumption of motor vehicles, amended by:

European Parliament and Council Directive **2004/3/EC**

Adaptations to technical progress:

Commission Directive **89/491/EEC**

Commission Directive **93/116/EEC**

Commission Directive **1999/100/EC**

Directive 80/1268/EEC will be repealed with effect from 2 January 2013

1.2.1.41 Engine power of motor vehicles

Council Directive 80/1269/EEC on the approximation of the laws of the Member States relating to the engine power of motor vehicles

Adaptations to technical progress:

Commission Directive **88/195/EEC**

Commission Directive **89/491/EEC**

Commission Directive **97/21/EC**

Commission Directive **1999/99/EC**

Directive 80/1269/EEC will be repealed with effect from 31 December 2013

1.2.1.42 Emissions from heavy duty vehicles

Directive 2005/55/EC of the European Parliament and the Council on the approximation of the laws of the Member States related to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous and particulate pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles, implemented by:

Commission Directive **2005/78/EC**, amended by:

Regulation (EC) No **715/2007**

Commission Directive **2008/74/EC**

Adaptation to technical progress:

Commission Directive **2006/51/EC**

Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC

Directives 2005/55/EC and 2005/78/EC will be repealed with effect from 31 December 2013

1.2.1.43 Lateral protection (side guards) of certain motor vehicles and their trailers

Council Directive 89/297/EEC on the approximation of the laws of the Member States relating to the lateral protection (side guards) of certain motor vehicles and their trailers

Directive 89/297/EEC will be repealed with effect from 1 November 2014

1.2.1.44 Spray-suppression systems of certain categories of motor vehicles and their trailers

Council Directive 91/226/EEC on the approximation of the laws of the Member States relating to the spray suppression systems of certain categories of motor vehicles and their trailers

Directive 91/226/EEC will be repealed with effect from 1 November 2014

1.2.1.45 Masses and dimensions of motor vehicles of category M₁

Council Directive 92/21/EEC on the masses and dimensions of motor vehicles of category M₁

Adaptation to technical progress:

Commission Directive **95/48/EC**

Directive 92/21/EEC will be repealed with effect from 1 November 2014

1.2.1.46 Safety glazing and glazing materials on motor vehicles and their trailers

Council Directive 92/22/EEC on safety glazing and glazing materials on motor vehicles and their trailers

Adaptation to technical progress:

Commission Directive **2001/92/EC**

Directive 92/22/EEC will be repealed with effect from 1 November 2014

1.2.1.47 Tyres for motor vehicles and their trailers and their fitting

Council Directive 92/23/EEC relating to tyres for motor vehicles and their trailers and to their fitting, amended by:

European Parliament and Council Directive **2001/43/EC**

Adaptations to technical progress:

Commission Directive **2005/11/EC**

Directive 92/23/EC will be repealed with effect from 1 November 2017

1.2.1.48 Speed limitation devices or similar speed limitation on-board systems of certain categories of motor vehicles

Council Directive 92/24/EEC relating to speed limitation devices or similar speed limitation on-board systems of certain categories of motor vehicles, amended by:

European Parliament and Council Directive **2004/11/EC**

Directive 92/24/EEC will be repealed with effect from 1 November 2014

1.2.1.49 External projections forward of the cab's rear panel of motor vehicles of category N

Council Directive 92/114/EEC relating to the external projections forward of the cab's rear panel of motor vehicles of category N

Directive 92/114/EEC will be repealed with effect from 1 November 2014

1.2.1.50 Mechanical coupling devices of motor vehicles and their trailers and their attachment to those vehicles

European Parliament and Council Directive 94/20/EC relating to the mechanical coupling devices of motor vehicles and their trailers and their attachment to those vehicles

Directive 94/20/EC will be repealed with effect from 1 November 2014

1.2.1.51 Burning behaviour of materials used in interior construction of certain categories of motor vehicles

European Parliament and Council Directive 95/28/EC relating to the burning behaviour of materials used in interior construction of certain categories of motor vehicles

Directive 95/28/EC will be repealed with effect from 1 November 2014

1.2.1.52 Protection of occupants of motor vehicles in the event of a side impact

European Parliament and Council Directive 96/27/EC on the protection of occupants of motor vehicles in the event of a side impact and amending Directive 70/156/EEC

Directive 96/27/EC will be repealed with effect from 1 November 2014

1.2.1.53 Protection of occupants of motor vehicles in the event of a frontal impact

European Parliament and Council Directive 96/79/EC on the protection of occupants of motor vehicles in the event of a frontal impact and amending Directive 70/156/EEC

Adaptation to technical progress:

Commission Directive 1999/98/EC

Directive 96/79/EC will be repealed with effect from 1 November 2014

1.2.1.54 Masses and dimensions of certain categories of motor vehicles and their trailers

European Parliament and Council Directive 97/27/EC relating to the masses and dimensions of certain categories of motor vehicles and their trailers and amending Directive 70/156/EEC, amended by:

European Parliament and Council Directive 2001/85/EC

Adaptation to technical progress:

Commission Directive 2003/19/EC

Directive 97/27/EC will be repealed with effect from 1 November 2014

1.2.1.55 Motor vehicles and their trailers intended for the transport of dangerous goods by road

European Parliament and Council Directive 98/91/EC relating to motor vehicles and their trailers intended for the transport of dangerous goods by road and amending Council Directive 70/156/EEC

Directive 98/91/EC will be repealed with effect from 1 November 2014

1.2.1.56 Front underrun protection

European Parliament and Council Directive 2000/40/EC on the approximation of the laws of the Member States relating to the front underrun protection of motor vehicles and amending Council Directive 70/156/EEC

Directive 2000/40/EC will be repealed with effect from 1 November 2014

1.2.1.57 Buses and coaches

European Parliament and Council Directive 2001/85/EC relating to special provisions for vehicles used for the carriage of passengers comprising more than eight seats in addition to the driver's seat, and amending Directives 70/156/EEC and 97/27/EC

Directive 2001/85/EC will be repealed with effect from 1 November 2014

1.2.1.58 Pedestrian protection

Regulation (EC) No 78/2009 of the European Parliament and of the Council of 14 January 2009 on the type-approval of motor vehicles with regard to the protection of pedestrians and other vulnerable road users, amending Directive 2007/46/EC and repealing Directives 2003/102/EC and 2005/66/EC, implemented by:

Commission Regulation (EC) No 631/2009

1.2.1.59 Reusability, recyclability and recoverability

Directive 2005/64/EC of the European Parliament and Council on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC

Adaptation to technical progress:

Commission Directive 2009/1/EC

1.2.1.61 Mobile air-conditioning systems

Directive 2006/40/EC of the European Parliament and Council of 17 May 2006 relating to the use of mobile air-conditioning systems on motor vehicles and amending Council Directive 70/156/EEC, implemented by:

Commission Regulation (EC) N° 706/2007

1.2.1.62 Hydrogen-powered vehicles

Regulation (EC) No 79/2009 of the European Parliament and of the Council of 14 January 2009 on type-approval of hydrogen-powered motor vehicles, and amending Directive 2007/46/EC

1.2.1.63 General safety of vehicles

Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor

1.2.2. TWO- OR THREE-WHEEL MOTOR VEHICLES

1.2.2.1. Type approval

**European Parliament and Council Directive 2002/24/EC relating to the type-approval of two- or three-wheel motor vehicles, amended by:
European Parliament and Council Regulation (EC) N° 1137/2008**
Adaptation to technical progress:
Commission Directive **2003/77/EC**
Commission Directive **2005/30/EC** (corrected and amended by Commission Directive 2006/120/EC)

1.2.2.2. Braking of two- or three-wheel motor vehicles

Council Directive 93/14/EEC on the braking of two- or three-wheel motor vehicles
Adaptation to technical progress:
Commission Directive **2006/27/EC**

1.2.2.3. Identification of controls, tell-tales and indicators for two- or three-wheel motor vehicles

Directive 2009/80/EC of the European Parliament and of the Council of 13 July 2009 on the identification of controls, tell-tales and indicators for two or three-wheel motor vehicles (Codified version)
Council Directive 93/29/EEC is repealed

1.2.2.4. Audible warning devices for two- or three-wheel motor vehicles

Council Directive 93/30/EEC on audible warning devices for two- or three-wheel motor vehicles

1.2.2.5. Stands for two- or three-wheel motor vehicles

Directive 2009/78/EC of the European Parliament and of the Council of 13 July 2009 on stands for two-wheel motor vehicles
Council Directive 93/31/EEC is repealed

1.2.2.6. Passenger hand-holds on two- or three-wheel motor vehicles

Directive 2009/79/EC of the European Parliament and of the Council of 13 July 2009 on passenger hand-holds on two-wheel motor vehicles (Codified version)
Council Directive 93/32/EEC is repealed

1.2.2.7. Protective devices intended to prevent the unauthorised use of two- or three-wheel motor vehicles

Council Directive 93/33/EEC on protective devices intended to prevent the unauthorised use of two- or three-wheel motor vehicles

Adaptation to technical progress:

Commission Directive 1999/23/EC

1.2.2.8. Statutory markings for two- or three-wheel motor vehicles

Directive 2009/139/EC of the European Parliament and of the Council of 25 November 2009, on statutory markings for two- or three-wheel motor vehicles
OJ L 322 of 09.12.2009

Council Directive 93/34/EEC to be repealed

1.2.2.9. Installation of lighting and light-signalling devices on two- or three-wheel motor vehicles

Directive 2009/67/EC of the European Parliament and of the Council of 13 July 2009 on the installation of lighting and light-signaling devices on two or three-wheel motor vehicles

Council Directive 93/92/EEC is repealed

1.2.2.10. Masses and dimensions of two- or three-wheel motor vehicles

Council Directive 93/93/EEC on the masses and dimensions of two- or three-wheel motor vehicles

Adaptation to technical progress:

Commission Directive 2004/86/EC

1.2.2.11. Space for mounting the rear registration plate of two- or three-wheel motor vehicles

Directive 2009/62/EC of the European Parliament and of the Council of 13 July 2009 relating to the space for mounting the rear registration plate of two or three-wheel motor vehicles (Codified version)

Council Directive 93/94/EEC is repealed

1.2.2.12. Maximum design speed, maximum torque and maximum net engine power of two- or three-wheel motor vehicles

European Parliament and Council Directive 95/1/EC on the maximum design speed, maximum torque and maximum net engine power of two- or three-wheel motor vehicles

Adaptation to technical progress:

Commission Directive 2002/41/EC

Commission Directive 2006/27/EC

1.2.2.13. Certain components and characteristics of two- or three-wheel motor vehicles

European Parliament and Council Directive 97/24/EC on certain components and characteristics of two- or three-wheel motor vehicles, amended by: European Parliament and Council Directive 2002/51/EC

Adaptation to technical progress:

Commission Directive 2003/77/EC

Commission Directive 2005/30/EC (corrected and amended by Commission Directive 2006/120/EC)

Commission Directive 2006/27/EC

Commission Directive 2006/72/EC

Commission Directive 2009/108/EC

1.2.2.14. Speedometers for two- or three-wheel motor vehicles

European Parliament and Council Directive 2000/7/EC on speedometers for two- or three-wheel motor vehicles and amending Council Directive 92/61/EEC on the type-approval of two- or three-wheel motor vehicles

1.2.3. WHEELED AGRICULTURAL OR FORESTRY TRACTORS

1.2.3.1. Type approval

European Parliament and Council Directive 2003/37/EC on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units and repealing Directive 74/150/EEC (Directive 74/150/EEC has been repealed on 1 July 2005), amended by:

Commission Directive 2005/13/EC

European Parliament and Council Regulation (EC) N° 1137/2008

Adaptations to technical progress:

Commission Directive 2005/67/EC

1.2.3.2. Certain parts and characteristics of wheeled agricultural or forestry tractors

Directive 2009/63/EC of the European Parliament and of the Council of 13 July 2009 on certain parts and characteristics of wheeled agricultural or forestry tractors (codified version)

Council Directive 74/151/EEC is repealed

1.2.3.3. Maximum design speed and load platforms

Directive 2009/60/EC of the European Parliament and of the Council of 13 July 2009 on the maximum design speed of and load platforms for wheeled agricultural or forestry tractors (Codified version)

Council Directive 74/152/EEC is repealed

1.2.3.4. Rear-view mirrors

Directive 2009/59/EC of the European Parliament and of the Council of 13 July 2009 on rear-view mirrors for wheeled agricultural or forestry tractors (Codified version)

Council Directive 74/346/EEC is repealed

1.2.3.5 Field of vision and windscreen wipers

Directive 2008/2/EC of the European Parliament and of the Council on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (Codified version)

repeals Council Directive 74/347/EEC as amended

1.2.3.6 Steering equipment

Directive 2009/66/EC of the European Parliament and of the Council of 13 July 2009 on the steering equipment of wheeled agricultural or forestry tractors (Codified version)

Council Directive 75/321/EEC is repealed

1.2.3.7 Suppression of radio interference produced by agricultural or forestry tractors (electromagnetic compatibility)

Directive 2009/64/EC of the European Parliament and of the Council of 13 July 2009 on the suppression of radio interference produced by agricultural or forestry tractors (electromagnetic compatibility)

Council Directive 75/322/EEC is repealed

1.2.3.8 Braking devices

Council Directive 76/432/EEC on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors, amended by:

Council Directive **82/890/EEC**

Commission Directive **96/63/EC**

European Parliament and Council Directive **97/54/EC**

1.2.3.9 Passenger seats

Council Directive 76/763/EEC on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors, amended by:

Council Directive **82/890/EEC**

European Parliament and Council Directive **97/54/EC**

Adaptation to technical progress:

Commission Directive **1999/86/EC**

1.2.3.10 Driver perceived noise level

Directive 2009/76/EC of the European Parliament and of the Council of 13 July 2009 relating to the driver-perceived noise level of wheeled agricultural or forestry tractors (Codified version)

Council Directive 77/311/EEC is repealed

1.2.3.11 Roll-over protection structures

Directive 2009/57/EC of the European Parliament and of the Council of 13 July 2009 relating to the roll-over protection structures of wheeled agricultural or forestry tractors

Council Directive 77/536/EEC is repealed

1.2.3.12 Measures to be taken against the emission of pollutants from diesel engines

Council Directive 77/537/EEC on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors, amended by:

Council Directive 82/890/EEC

European Parliament and Council Directive 97/54/EC

1.2.3.13 Driver's seat

Council Directive 78/764/EEC on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors, amended by:

Council Directive 82/890/EEC

Council Directive 87/354/EEC

European Parliament and Council Directive 97/54/EC

Adaptations to technical progress:

Commission Directive 83/190/EEC

Commission Directive 88/465/EEC

Commission Directive 1999/57/EC

1.2.3.14 Installation of lighting and light-signalling devices

Directive 2009/61/EC of the European Parliament and of the Council of 13 July 2009 relating to the installation of lighting and light-signalling devices on wheeled agricultural and forestry tractors (Codified version)

Council Directive 78/933/EEC is repealed

1.2.3.15 Component type-approval of light and light-signalling devices

Directive 2009/68/EC of the European Parliament and of the Council of 13 July 2009 on the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors (Codified version)

Council Directive 79/532/EEC is repealed

1.2.3.16 Coupling device and the reverse

Directive 2009/58/EC of the European Parliament and of the Council of 13 July 2009 on the coupling device and the reverse of wheeled agricultural or forestry tractors (Codified version)

Council Directive 79/533/EEC is repealed

1.2.3.17 Roll-over protection structures (static testing)

Directive 2009/75/EC of the European Parliament and of the Council of 13 July 2009 on roll-over protection structures of wheeled agricultural or forestry tractors (static testing)

Council Directive 79/622/EEC is repealed

1.2.3.18 Operating space, access to the driving position and the doors and windows

Council Directive 80/720/EEC on the approximation of the laws of the Member States relating to the operating space, access to the driving position and the doors and windows of wheeled agricultural or forestry tractors, amended by:

Council Directive **82/890/EEC**

European Parliament and Council Directive **97/54/EC**

Adaptation to technical progress:

Commission Directive **88/414/EEC**

1.2.3.19 Power take-offs and their protection

Council Directive 86/297/EEC on the approximation of the laws of the Member States relating to power take-offs of wheeled agricultural or forestry tractors and their protection, amended by:

European Parliament and Council Directive **97/54/EC**

1.2.3.20 Rear-mounted roll-over protection structures of narrow track wheeled agricultural and forestry tractors

Council Directive 86/298/EEC on rear-mounted roll-over protection structures of narrow track wheeled agricultural and forestry tractors, amended by:

Council Directive **89/682/EEC**

Adaptation to technical progress:

Commission Directive **2000/19/EC**

Commission Directive **2005/67/EC**

1.2.3.21 Installation, location operation and identification of the controls

Council Directive 86/415/EEC on the installation, location operation and identification of the controls of wheeled agricultural or forestry tractors, as amended by:

European Parliament and Council Directive **97/54/EC**

1.2.3.22 Roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors

Council Directive 87/402/EEC on roll-over protection structures mounted in front of the driver's seat on narrow track wheeled agricultural and forestry tractors, amended by:
Council Directive **89/681/EEC**
Adaptation to technical progress:
Commission Directive **2000/22/EC**
Commission Directive **2005/67/EC**

1.2.3.23 Certain components and characteristics

Council Directive 89/173/EEC on certain components and characteristics of wheeled agricultural or forestry tractors, amended by:
European Parliament and Council Directive **97/54/EC**
Adaptation to technical progress:
Commission Directive **2000/1/EC**
Commission Directive **2006/26/EC**

1.2.3.24 Emission of gaseous and particulate pollutants by engines intended to power agricultural or forestry tractors

European Parliament and Council Directive 2000/25/EC on action to be taken against the emission of gaseous and particulate pollutants by engines intended to power agricultural or forestry tractors and amending Council Directive 74/150/EEC, amended by:
Commission Directive **2005/13/EC**

1.3. OTHER MEASURES RELATING TO MOTOR VEHICLES

- Council Decision 97/836/EC with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement'), OJ L 346, 17.12.1997
- Council Decision 2000/125/EC of 31 January 2000 concerning the conclusion of the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ('Parallel Agreement'), OJ L 35, 10.02.2000
- Council Decision of 28 February 2000 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe concerning uniform provisions for the approval of tank vehicles of categories N and O with regard to roll-over stability (*not yet published*)
- Council Decision of 28 February 2000 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe concerning the approval of specific components of motor vehicles using compressed natural gas (CNG) in their propulsion systems and of vehicles with regard to the installation of specific components of an approved type for the use of compressed natural gas (CNG) in their propulsion systems (*not yet published*)
- Council Decision 2000/710/EC of 7 November 2000 on the accession by the European Community to United Nations Economic Commission for Europe Regulation No 67 on the approval of special equipment for motor vehicles fuelled by liquefied petroleum gas, OJ L 290, 17.11.2000, p. 29
- Council Decision of 7 November 2000 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe concerning the approval of motor vehicle headlamps emitting an asymmetrical passing beam or a driving beam or both and equipped with filament lamps (*not yet published*)
- Council Decision 2001/395/EC of 14 May 2001 on the accession of the European Community to the United Nations Economic Commission for Europe Regulation No 13-H on the component approval of passenger cars in respect of their braking, OJ L 139, 23.05. 2001, p.14
- Council Decision 2001/505/EC of 26 June 2001 on the accession of the European Community to United Nations Economic Commission for Europe Regulation No 105 on the approval of vehicles intended for the carriage of

dangerous goods with regard to their specific constructional features, OJ L 183, 6.7.2001, p. 33

- Council Decision 2001/506/EC of 26 June 2001 on the accession of the European Community to United Nations Economic Commission for Europe Regulation No 104 on the approval of retro-reflecting markings for heavy and long vehicles and their trailers, OJ L 183, 6.7. 2001, p. 34
- Council Decision 2001/507/EC of 26 June 2001 on the accession of the European Community to Regulation 109 of the United Nations Economic Commission for Europe concerning the approval for the production of retreaded pneumatic tyres for commercial vehicles and their trailers, OJ L 183, 6.7.2001, p. 35
- Council Decision 2001/508/EC of 26 June 2001 on the accession of the European Community to the United Nations Economic Commission for Europe Regulation No 106 concerning the approval of pneumatic tyres for agricultural vehicles and their trailers, OJ L 183, 6.7.2001, p. 36
- Council Decision 2001/509/EC of 26 June 2001 on the accession of the European Community to Regulation 108 of the United Nations Economic Commission for Europe concerning the approval for the production of retreaded pneumatic tyres for motor vehicles and their trailers, OJ L 183, 6.7.2001, p. 37
- Council Decision of 21 May 2002 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe concerning the approval of an airbag module for a replacement airbag system, a replacement steering wheel equipped with an airbag module of an approved type and a replacement airbag system other than that installed in a steering wheel (*not yet published*)
- Council Decision of 6 March 2003 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe concerning the approval of uniform provisions concerning the approval of I. Specific LPG retrofit systems to be installed in motor vehicles for the use of LPG in their propulsion system II. Specific CNG retrofit systems to be installed in motor vehicles for the use of CNG in their propulsion system (*not yet published*)
- Council Decision of 26 April 2004 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe on uniform prescriptions concerning the approval of cornering lamps for power-driven vehicles (*not yet published*)
- Council Decision of 26 April 2004 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe on uniform prescriptions applicable to the approval of internal combustion engines to be installed in agricultural and forestry tractors and in non-road mobile machinery, with regard to their net power, net torque and specific fuel consumption (*not yet published*)

- Council Decision of 29 April 2004 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe on uniform technical prescriptions relating to the protection of motor vehicles against unauthorised use (*not yet published*)
- Council Decision of 29 April 2004 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe on uniform prescriptions concerning the type approval of tyres with respect to tyre rolling noise (*not yet published*)
- Council Decision of 29 April 2004 on the position of the European Community on the draft Regulation of the United Nations Economic Commission for Europe on uniform technical prescriptions concerning the burning behaviour of materials used in the interior construction of certain categories of motor vehicles (*not yet published*)
- Council Decision 2005/614/CE of 18 July 2005 on the accession of the European Community to United Nations Economic Commission for Europe Regulation No 94 on provisions concerning the approval of vehicles with regard to the protection of the occupants in the event of a frontal collision and Regulation No 95 on provisions concerning the approval of vehicles with regard to the protection of the occupants in the event of a lateral collision; OJ L 217, 22.8.2005, p. 1
- Council Decision 2006/443/EC of 13 March 2006 amending Decisions 2001/507/EC and 2001/509/EC with a view to making United Nations Economic Commission for Europe (UN/ECE) Regulation Nos 109 and 108 on retreaded tyres compulsory; OJ L 181, 4.7.2006, p. 1
- Council Decision 2006/444/EC of 13 March 2006 on the accession of the Community to United Nations Economic Commission for Europe Regulation No 55 on provisions concerning the approval of mechanical coupling components of combinations of vehicles; OJ L 181, 4.7.2006, p.53
- Council Decision 2006/363/EC of 15 May 2006 on the position of the European Community in relation to the draft Regulation of the United Nations Economic Commission for Europe on wheels for passenger cars and their trailers; OJ L 135, 23.5.2006, p.11
- Council Decision 2006/364/EC of 15 May 2006 on the position of the European Community in relation to the draft Regulation of the United Nations Economic Commission for Europe concerning the approval of adaptive front-lighting systems (AFS) for motor vehicles; OJ L 135, 23.5.2006, p.11
- Council Decision 2007/159/EC of 22 February 2007 on the position of the Community in relation to the draft Regulation of the United Nations Economic Commission for Europe concerning the approval of motor vehicles with regard to the forward field of vision of the motor vehicle driver, OJ L 69, 9.3.2007, p. 37-38
- Council Decision 2007/160/EC of 22 February 2007 on the position of the Community in relation to the draft Regulation of the United Nations Economic

Commission for Europe concerning the approval of partitioning systems to protect passengers against displaced luggage, supplied as non original vehicle equipment, OJ L 69, 9.3.2007, p. 39

- Council Decision 2009/433/EC of 5 May 2009 on the accession of the European Community to United Nations Economic Commission for Europe Regulation No 61 on uniform provisions for the approval of commercial vehicles with regard to their external projections forward of the cab's rear panel, OJ L 144, 9.6. 2009, p. 24
- Communication from the Commission to the Council and the European Parliament - A community strategy to reduce CO2 emissions from passenger cars and improve fuel economy
COM/95/0689 final
- Communication from the Commission to the Council and the European Parliament - Implementing the Community strategy to reduce CO2 emissions from cars: an environmental agreement with the European automobile industry
COM/98/0495 final
- 1999/125/EC: Commission Recommendation on the reduction of CO2 emissions from passenger cars, OJ L 040, 13.02.1999
- Decision No 1753/2000/EC of the European Parliament and of the Council of 22 June 2000 establishing a scheme to monitor the average specific emissions of CO2 from new passenger cars, OJ L 202, 10.8.2000, p. 1
- 2000/303/EC Commission Recommendation of 13 April 2000 on the reduction of CO2 emissions from passenger cars (KAMA), OJ L 100, 20.4.2000, p. 55
- 2000/304/EC Commission Recommendation of 13 April 2000 on the reduction of CO2 emissions from passenger cars (JAMA), OJ L 100, 20.4.2000, p. 57
- Communication from the Commission to the Council and the European Parliament - Implementing the Community Strategy to Reduce CO2 Emissions from Cars First annual report on the effectiveness of the strategy
COM/2000/0615 final
- Communication from the Commission to the Council and the European Parliament - Implementing the Community Strategy to Reduce CO2 Emissions from Cars - Second annual report on the effectiveness of the strategy (Reporting year 2000)
COM/2001/0643 final
- Communication from the Commission to the Council and the European Parliament - Implementing the Community Strategy to Reduce CO2 Emissions from Cars: Third annual report on the effectiveness of the strategy (Reporting year 2001)
COM/2002/0693 final
- Communication from the Commission to the Council and the European Parliament - Implementing the Community Strategy to Reduce CO2 Emissions

from Cars: - Fourth annual report on the effectiveness of the strategy (Reporting year 2002)

COM/2004/0078 final

- Communication from the Commission to the Council and the European Parliament. Implementing the Community Strategy to Reduce CO2 Emissions from Cars: Fifth annual communication on the effectiveness of the strategy
COM/2005/269 final
- Communication from the Commission to the Council and the European Parliament Implementing the Community Strategy to Reduce CO2 Emissions from Cars: Sixth annual Communication on the effectiveness of the strategy
COM/2006/0463 final
- Communication from the Commission to the Council and the European Parliament – Results of the review of the Community Strategy to reduce CO2 emissions from passenger cars and light-commercial vehicles
COM/2007/0019 final
- Communication from the Commission to the Council and the European Parliament - Monitoring the CO2 emissions from cars in the EU: data for the years 2005, 2006 and 2007
COM/2009/0009 final
- Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO 2 emissions from light-duty vehicles, OJ L 140, 5.6.2009, p. 1
- Communication from the Commission to the Council and the European Parliament - Pedestrian protection: Commitment by the European automobile industry
COM/2001/0389 final
- Commission Staff Working Paper - Fiscal Incentives for Motor Vehicles in Advance of Euro5
SEC(2005) 43, 12.1.2005
- Communication on the application and future development of Community legislation concerning vehicle emissions from light-duty vehicles and access to repair and maintenance information (Euro 5 and 6), OJ C 182, 19.7.2008, p. 17
- Commission Staff Working Document Guidance on Financial Incentives for vehicles
SEC(2009) 1589 final
- Communication from the Commission to the Council and the European Parliament - A Competitive Automotive Regulatory Framework for the 21st Century – Commission's position on the CARS 21 High Level Group Final Report
COM/2007/0022 final

- Communication from the Commission - "Responding to the crisis in the European automotive industry"
COM/2009/0104 final

ACTS AMENDING DIRECTIVES/REGULATIONS IN VIEW OF ACCESSION OF NEW MEMBER STATES TO THE EUROPEAN UNION

1972 Act of Accession

amending:

Council Directive 70/156/EEC
Council Directive 70/157/EEC
Council Directive 70/220/EEC
Council Directive 70/221/EEC
Council Directive 70/222/EEC
Council Directive 70/311/EEC
Council Directive 70/387/EEC
Council Directive 70/388/EEC
Council Directive 71/127/EEC
Council Directive 71/320/EEC

1979 Act of Accession

amending:

Council Directive 70/156/EEC
Council Directive 70/388/EEC
Council Directive 74/150/EEC
Council Directive 71/127/EEC
Council Directive 76/114/EEC
Council Directive 76/757/EEC
Council Directive 76/758/EEC
Council Directive 76/759/EEC
Council Directive 76/760/EEC
Council Directive 76/761/EEC
Council Directive 76/762/EEC
Council Directive 77/536/EEC
Council Directive 77/541/EEC
Council Directive 77/538/EEC
Council Directive 77/539/EEC
Council Directive 77/540/EEC
Council Directive 78/764/EEC
Council Directive 78/932/EEC

1985 Act of Accession

amending:

Council Directive 70/156/EEC
Council Directive 70/157/EEC
Council Directive 70/388/EEC

Council Directive 71/127/EEC
Council Directive 74/150/EEC
Council Directive 74/483/EEC
Council Directive 76/114/EEC
Council Directive 76/757/EEC
Council Directive 76/758/EEC
Council Directive 76/759/EEC
Council Directive 76/760/EEC
Council Directive 76/761/EEC
Council Directive 76/762/EEC
Council Directive 77/536/EEC
Council Directive 77/538/EEC
Council Directive 77/539/EEC
Council Directive 77/540/EEC
Council Directive 77/541/EEC
Council Directive 78/764/EEC
Council Directive 78/932/EEC
Council Directive 79/622/EEC

1994 Act of Accession

amending:

Council Directive 70/156/EEC
Council Directive 70/157/EEC
Council Directive 70/388/EEC
Council Directive 71/127/EEC
Council Directive 74/150/EEC
Council Directive 74/483/EEC
Council Directive 76/114/EEC
Council Directive 76/757/EEC
Council Directive 76/758/EEC
Council Directive 76/759/EEC
Council Directive 76/760/EEC
Council Directive 76/761/EEC
Council Directive 76/762/EEC
Council Directive 77/536/EEC
Council Directive 77/538/EEC
Council Directive 77/539/EEC
Council Directive 77/540/EEC
Council Directive 77/541/EEC
Council Directive 78/764/EEC
Council Directive 78/932/EEC
Council Directive 79/622/EEC

Council Directive 86/298/EEC
Council Directive 87/402/EEC
Council Directive 88/77/EEC
Council Directive 89/173/EEC
Council Directive 91/226/EEC
Council Directive 92/22/EEC
Council Directive 92/23/EEC

2003 Act of Accession

amending:

Council Directive 70/156/EEC
Council Directive 70/157/EEC
Council Directive 70/220/EEC
Council Directive 70/221/EEC
Council Directive 70/388/EEC
Council Directive 71/127/EEC
Council Directive 71/320/EEC
Council Directive 72/245/EEC
Council Directive 74/61/EEC
Council Directive 74/150/EEC
Council Directive 74/408/EEC
Council Directive 74/483/EEC
Council Directive 75/322/EEC
Council Directive 76/114/EEC
Council Directive 76/757/EEC
Council Directive 76/758/EEC
Council Directive 76/759/EEC
Council Directive 76/760/EEC
Council Directive 76/761/EEC
Council Directive 76/762/EEC
Council Directive 77/536/EEC
Council Directive 77/538/EEC
Council Directive 77/539/EEC
Council Directive 77/540/EEC
Council Directive 77/541/EEC
Council Directive 78/318/EEC
Council Directive 78/764/EEC
Council Directive 78/932/EEC
Council Directive 79/622/EEC
Council Directive 86/298/EEC
Council Directive 87/402/EEC
Council Directive 88/77/EEC
Council Directive 89/173/EEC
Council Directive 91/226/EEC
European Parliament and Council Directive 94/20/EC
European Parliament and Council Directive 95/28/EC
European Parliament and Council Directive 2000/25/EC
European Parliament and Council Directive 2000/40/EC
European Parliament and Council Directive 2001/56/EC
European Parliament and Council Directive 2002/24/EC

Council Decision of 1 January 1973

amending:

Council Directive 70/156/EEC
Council Directive 70/388/EEC
Council Directive 71/127/EEC

Council Decision 95/1/EC of 1 January 1995

Council Directive 2004/66/EC

amending:

European Parliament and Council Directive 2003/37/EC

2006 Act of Accession

Council Directive 2006/96/EC of 20 November 2006 adapting certain Directives in the field of free movement of goods, by reason of the accession of Bulgaria and Romania (OJ L 363, 20.12.2006)

Commission Directive 2006/81/EC of 23 October 2006

2. CHEMICALS

Outline:

2.1. Structure

2.2. Enumeration of the legislation

2.2.1 REACH

2.2.2. Restrictions on the marketing and use of certain dangerous substances and preparations

2.2.3. Classification, packaging and labelling

2.2.4. Detergents

2.2.5. Fertilisers

2.2.6. Drug precursors

2.2.7. Explosives for civil uses

2.2.8. Pyrotechnics

2.2.9. Good laboratory practice

2.2.9.1. Application of principles of Good Laboratory Practice and verification of their application for tests on chemical substances

2.2.9.2. Inspection and verification of Good Laboratory Practice

2.3. Other measures relating to chemicals

2.1. STRUCTURE

Community legislation in the field of chemicals emanates from different DG's. The following groups fall under the management of the Enterprise DG:

REACH

Restrictions

Classification, packaging and labelling

Detergents

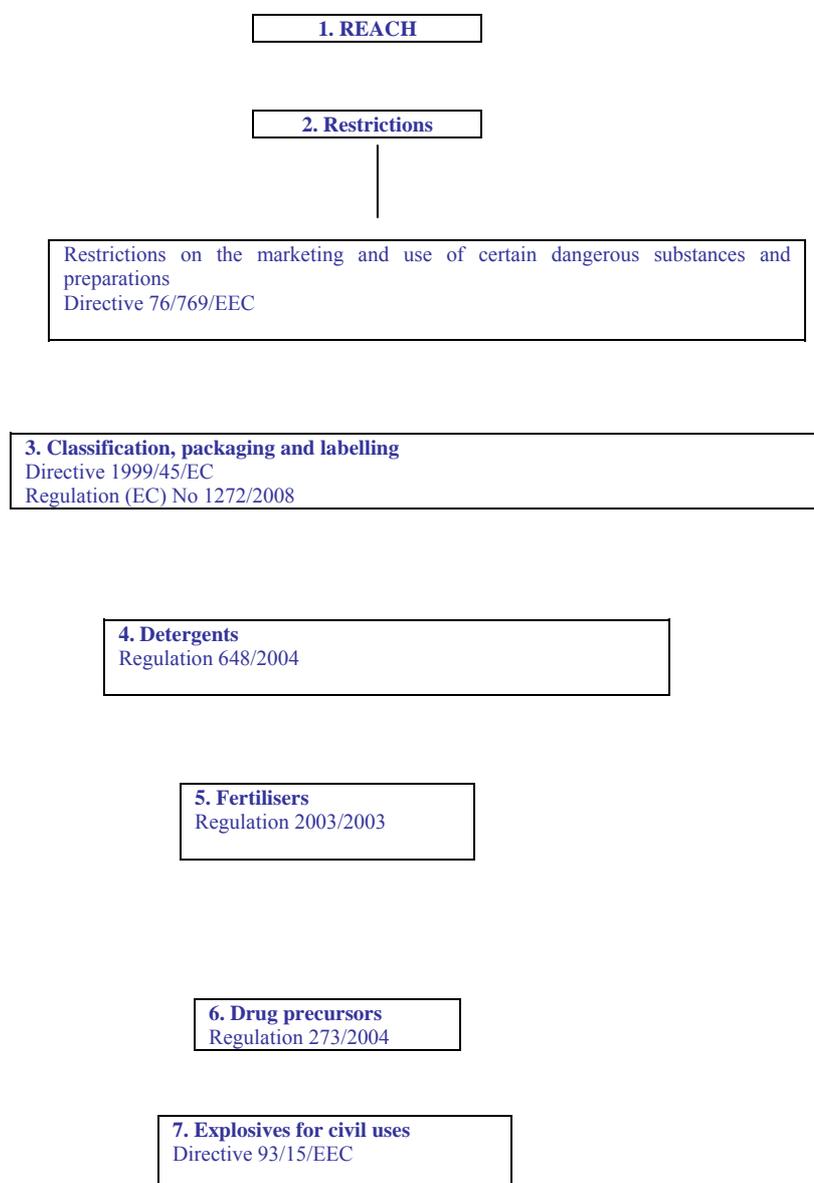
Fertilisers

Drug precursors

Explosives for civil uses

Pyrotechnic articles

Good laboratory practice



8. Pyrotechnics
Directive 2007/23/EC

9. Good Laboratory Practice

Application of principles of Good
Laboratory Practice and verification
for tests on chemicals
Directive 2004/10/EC

Inspection and verification of Good Laboratory Practice
Directive 2004/9/EC

2.2. ENUMERATION OF THE LEGISLATION

2.2.1. REACH

REGULATION (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Amended by:

COUNCIL REGULATION (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), by reason of the accession of Bulgaria and Romania

COMMISSION REGULATION (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V

COMMISSION REGULATION (EC) No 134/2009 of 16 February 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XI

COMMISSION REGULATION (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII

Affected by:

Decision of the EEA Joint Committee No 25/2008 of 14 March 2008 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

Communication from the Commission pursuant to Article 67(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (2009/C 130/03)

Corrected by:

Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 141, 31.5.2008, p. 22

Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 36, 5.2.2009, p. 84

Implementing measure:

COMMISSION REGULATION (EC) No 1238/2007 of 23 October 2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency

COMMISSION REGULATION (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency

COMMISSION REGULATION (EC) No 761/2009 of 23 July 2009 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

2.2.2. LIMITATIONS

2.2.2.1. Restrictions on the marketing and use of certain dangerous substances and preparations

Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, amended by:

Council Directive **79/663/EEC**

Council Directive **82/806/EEC**

Council Directive **82/828/EEC**

Council Directive **83/264/EEC**

Council Directive **83/478/EEC**

Council Directive **85/467/EEC**

Council Directive **85/610/EEC**

Council Directive **89/677/EEC**

Council Directive **89/678/EEC**

Council Directive **91/157/EEC** (*under the management of the Environment DG*)
(adapted to technical progress by Commission Directive **93/86/EEC**)

Council Directive **91/173/EEC** (derogations in Commission Decision **94/783/EC** and Commission Decision **96/211/EC**)

Council Directive **91/338/EEC**
Council Directive **91/339/EEC**
European Parliament and Council Directive **94/27/EC**
European Parliament and Council Directive **94/48/EC**
European Parliament and Council Directive **94/60/EC**
European Parliament and Council Directive **97/16/EC**
European Parliament and Council Directive **97/56/EC**
European Parliament and Council Directive **1999/43/EC**
European Parliament and Council Directive **2001/41/EC**
European Parliament and Council Directive **2002/45/EC**
European Parliament and Council Directive **2002/61/EC**
European Parliament and Council Directive **2003/11/EC** (*Corrigendum OJ L 170, 09.07.2003*)
European Parliament and Council Directive **2003/34/EC**
European Parliament and Council Directive **2003/36/EC**
European Parliament and Council Directive **2003/53/EC**
European Parliament and Council Directive **2005/59/EC** (toluene and trichlorobenzene)
European Parliament and Council Directive **2005/69/EC** (PAH in extender oils and tyres)
European Parliament and Council Directive **2005/84/EC** (phthalates in toys)
European Parliament and Council Directive **2005/90/EC** – substances classified as carcinogens, mutagens or toxic to reproduction (CMR) (29th amendment)

Directive **2006/122/EC** of the European Parliament and of the Council of 12 December 2006 amending for the 30th time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (**perfluorooctane sulfonates**)

Directive **2007/51/EC** of the European Parliament and of the Council of 25 September 2007 amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain **measuring devices containing mercury**

Decision **1348/2008/EC** of the European Parliament and of the Council of 16 December 2008 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate

Decision **455/2009/EC** of the European Parliament and of the Council of 6 May 2009 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of dichloromethane

Adaptations to technical progress:

Commission Directive **91/659/EEC**
Commission Directive **96/55/EC**
Commission Directive **97/10/EC**
Commission Directive **97/64/EC**
Commission Directive **98/101/EC**
Commission Directive **1999/51/EC**
Commission Directive **1999/77/EC**
Commission Directive **2001/90/EC** (derogation in Commission Decision **2002/844/EC**)
Commission Directive **2001/91/EC**
Commission Directive **2002/62/EC**
Commission Directive **2003/2/EC**
Commission Directive **2003/3/EC**

Commission Directive **2004/21/EC**

Commission Directive **2004/96/EC** as regards restrictions on the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex I to technical progress (Text with EEA relevance)

Commission Directive **2004/98/EC** as regards restrictions on the marketing and use of pentabromodiphenyl ether in aircraft emergency evacuation systems for the purpose of adapting its Annex I to technical progress (Text with EEA relevance)

Commission Directive **2006/139/EC** of 20 December 2006 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of **arsenic compounds** for the purpose of adapting its Annex I to technical progress

Commission Decision **2009/424/EC** amending, for the purpose of adapting to technical progress, Annex I to Council Directive 76/769/EEC as regards restrictions on the marketing and use of lamp oils and grill lighter fluids

Commission Decision **2009/425/EC** amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of organostannic compounds for the purpose of adapting its Annex I to technical progress

Council Directive 76/769/EEC was repealed and replaced by REACH on 1 June 2009

2.2.3. CLASSIFICATION, PACKAGING AND LABELLING

2.2.3.1. Classification, packaging and labelling of dangerous preparations

European Parliament and Council Directive 1999/45/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (*This Directive repeals Directive 78/631/EEC, as amended by Directives 79/831/EEC, 81/187/EEC and 92/32/EEC and as adapted by Directive 84/291/EEC, Directive 88/379/EEC, as amended by Directive 92/32/EEC and as adapted by Directives 89/178/EEC, 90/492/EEC, 93/18/EEC and 96/65/EC, Directive 90/35/EEC and Directive 91/442/EEC*)

Commission Directive 2006/8/EC amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparation

Adaptation to technical progress:

Commission Directive **2001/60/EC**

2.2.3.2 Classification, labelling and packaging of substances and mixtures

REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Amended by:

COMMISSION REGULATION (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixture

2.2.4. DETERGENTS

European Parliament and Council Regulation (EC) No 648/2004 on detergents repealing Council Directive 73/404/EEC on the approximation of the laws of the Member States relating to detergents

Commission Regulation (EC) No 907/2006 of 20 June 2006 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes III and VII thereto (OJ L 168, 21.6.2006)

Commission Regulation (EC) No 551/2009 of 25 June 2009 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes V and VI thereto (surfactant derogation)

2.2.5. FERTILISERS

European Parliament and Council Regulation (EC) No 2003/2003 relating to fertilisers

1) **Commission Regulation (EC) No 2076/2004** of 3 December 2004 adapting for the first time Annex I of Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers (EDDHSA and triple superphosphate)(Text with EEA relevance)

2) **Commission Regulation (EC) No 162/2007** of 19 February 2007 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I and IV thereto to technical progress

3) Commission Regulation (EC) No 1107/2008 of 7 November 2008 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purpose of adapting Annexes I and IV thereto to technical progress.

4) Commission Regulation (EC) No 1020/2009 of 28 October 2009 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I, III, IV and V thereto to technical progress

2.2.6. DRUG PRECURSORS

European Parliament and Council Regulation (EC) No 273/2004 on drug precursors repealing Council Directive 92/109/EEC on the manufacture and placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances

Implementing measures:

Commission Regulation (EC) No 1277/2005 of 27 July 2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Commission Regulation (EC) No 297/2009 of 8 April 2009 amending Regulation (EC) No 1277/2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

2.2.7. EXPLOSIVES FOR CIVIL USES

Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses

Implementing measures:

1) Commission Directive 2004/57/EC on the identification of pyrotechnic articles and certain ammunition for the purposes of Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses

2) Commission Decision 2004/388/EC on an Intra-Community transfer of explosives document

3) Commission Directive 2008/43/EC of 4.04.2008 setting up, pursuant to Council Directive 93/15/EEC, a system for the identification and traceability of explosives for civil uses

2.2.8 PYROTECHNICS

Directive 2007/23/EC of the European Parliament and of the Council of 23/5/2007 on the placing on the market of pyrotechnic articles (OJ L 154, 14.6.2007, p. 1–21)

2.2.9. GOOD LABORATORY PRACTICE

2.2.9.1 Application of principles of Good Laboratory Practice and verification for tests on chemical substances

European Parliament and Council Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version)

2.2.9.2. Inspection and verification of Good Laboratory Practice

European Parliament and Council Directive 2004/9/EC on the inspection and verification of good laboratory practice (GLP) (codified version)

2.3. OTHER MEASURES RELATING TO CHEMICALS

- Commission Communication in the framework of the implementation of Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses (*OJ C 192, 14.08.2003*)
- Commission Communication in the framework of the implementation of Directive 2002/61/EC of the European Parliament and of the Council of 19 July 2002 amending for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (azocolourants) (*OJ C 214, 09.09.2003*)
- Guide to the compilation of a technical file on applications to designate fertilisers EC fertiliser pursuant to Regulation 2003/2003
- Commission Communication in the framework of the implementation of Parliament and Council Directive 94/27/EC of 30 June 1994 amending for the twelfth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (Text with EEA relevance) (*OJ C 205, 20/07/1999 p. 5*)
- Commission Recommendation C/2005/5677 of 23 December 2005 : "Tiered approach guidance document : Methodology for the tiered approach to testing in the context of Annex IV of Regulation (EC) No 648/2004"

3. PHARMACEUTICALS

Outline:

3.1. Structure

3.2. Enumeration of the legislation

3.2.1. Medicinal products for human use

3.2.1.1. Marketing authorisation

3.2.1.1.1. Granting and mutual recognition of national market authorisations

3.2.1.1.2. Community approval system

3.2.1.2. Testing

3.2.1.3. Manufacturing

3.2.1.4. Distribution

3.2.1.5. Classification

3.2.1.6. Labelling

3.2.1.7. Advertising

3.2.1.8. Prices and reimbursement

3.2.1.9. Intellectual property

3.2.1.10. Colouring matters

3.2.1.11. Orphan medicinal products

3.2.1.12. Medicinal products for paediatric use

3.2.1.13. Advanced Therapies

3.2.2. Veterinary medicinal products

3.2.2.1. Marketing authorisation

3.2.2.1.1. Granting and mutual recognition of national market authorisations

3.2.2.1.2. Community approval system

3.2.2.2. Testing

3.2.2.2.1. Standards and protocols in testing of proprietary medicinal products

3.2.2.2.2. Good clinical practice in clinical trials on medicinal products

3.2.2.3. Manufacturing

3.2.2.4. Maximum residue limits for veterinary medical products in foodstuffs of animal origin

3.2.2.5. Intellectual property

3.2.2.6. Colouring matters

3.2.2.7. Classification

3.2.2.8. Treatment of equidae

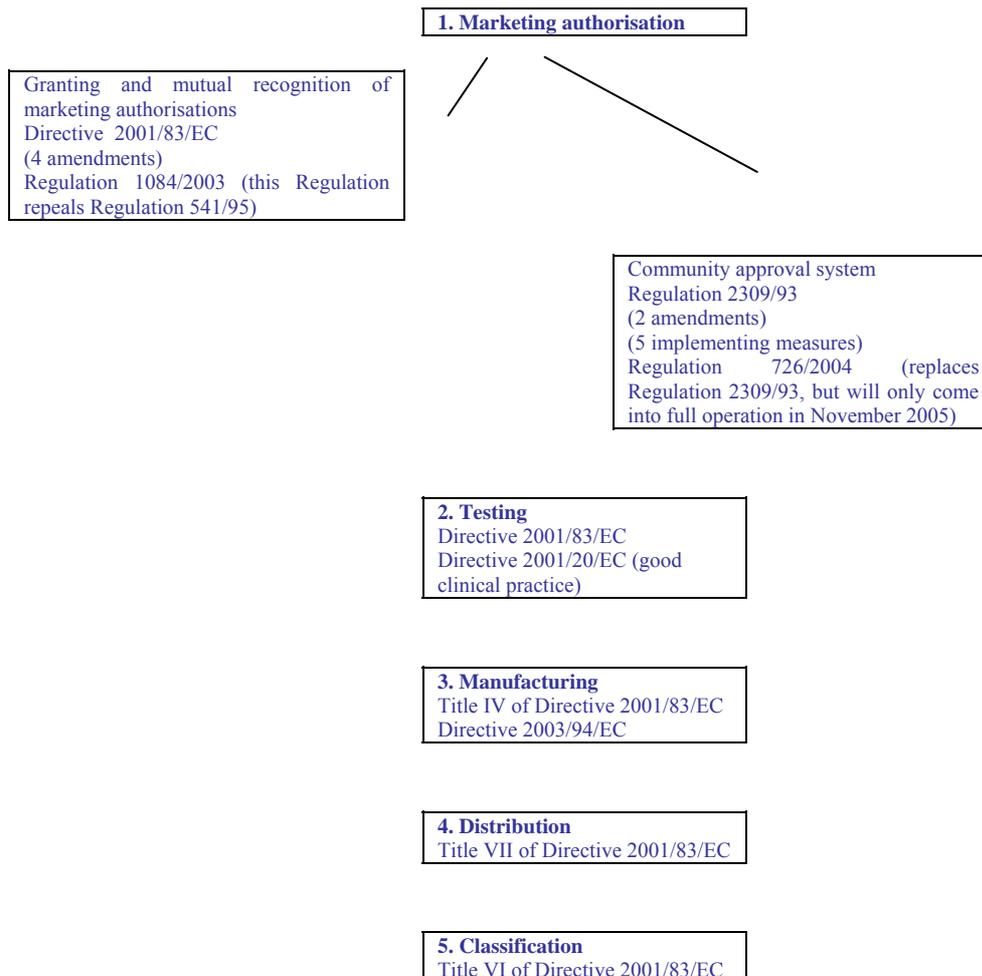
3.3. Other measures relating to pharmaceuticals

3.1. STRUCTURE

Community legislation in the field of pharmaceuticals can be divided into two groups: medicinal products for human use and veterinary medicinal products.

The legislation on medicinal products for human use can further be divided into eleven groups:

- 1. Marketing authorisation**
- 2. Testing**
- 3. Manufacturing**
- 4. Distribution**
- 5. Classification**
- 6. Labelling**
- 7. Advertising**
- 8. Prices and reimbursement**
- 9. Intellectual property**
- 10. Colouring matters**
- 11. Orphan medicinal products**
- 12. Medicinal products for paediatric use**
- 13. Advanced Therapies**



6. Labelling
Title V of Directive 2001/83/EC

7. Advertising
Title VIII of Directive
2001/83/EC

8. Prices and reimbursement
Directive 89/105/EEC

9. Intellectual property
Regulation 1768/92
(under the management of DG
Internal Market)

10. Colouring matters
Directive 78/25/EEC
(1 amendment)

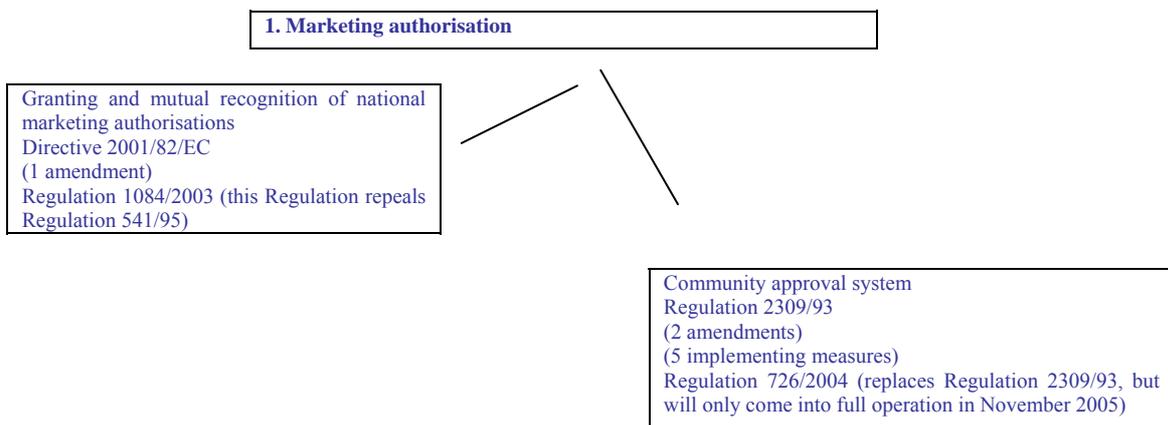
11. Orphan medicinal products
Regulation (EC) 141/2000
(1 implementing measure)

**12. medicinal products for
paediatric use**
Regulation (EC) 1901/2006
(1 amendment)

13. Advanced Therapies
Regulation (EC) n° 1394/2007

The veterinary medicinal products can further be divided into six groups:

- 1. Marketing authorisation**
- 2. Testing**
- 3. Manufacturing**
- 4. Maximum residue limits for veterinary medical products in foodstuffs of animal origin**
- 5. Intellectual Property**
- 6. Colouring matters**
- 7. Classification**
- 8. Treatment of equidae**



2. Testing
Directive 2001/82/EC

3. Manufacturing
Title IV of Directive 2001/82/EC
Directive 91/412/EEC

4. Maximum residue limits for veterinary medical products in foodstuffs of animal origin
Regulation 2377/90
(103 amendments)

5. Intellectual property
Regulation 1768/92 (under the management of DG Internal Market)

6. Colouring matters
Directive 78/25/EEC
(1 amendment)

7. Classification
Directive 2001/82/EC – article 67
(1 implementing measure)

8. Treatment of equidae
Commission Regulation (EC) n° 1950/2006

The Enterprise DG is responsible for most of this legislation.

3.2. ENUMERATION OF THE LEGISLATION

3.2.1. MEDICINAL PRODUCTS FOR HUMAN USE

3.2.1.1. Marketing authorisation

3.2.1.1.1. *Granting and mutual recognition of national market authorisations*

1) European Parliament and Council Directive 2001/83/EC on the Community code, repealing Directive 65/65/EEC (as amended by Directives 66/454/EEC, 75/319/EEC, 83/570/EEC, 87/21/EEC, 89/341/EEC, 92/27/EEC, 93/39/EEC and 2000/38/EC and as implemented by 89/342/EEC, 89/343/EEC, 89/381/EEC and 92/73/EEC), relating to medicinal products for human use, amended by:
European Parliament and Council Directive **2002/98/EC** (under the management of the Health and Consumer Protection DG)
European Parliament and Council Directive **2003/63/EC**
European Parliament and Council Directive **2004/24/EC**
European Parliament and Council Directive **2004/27/EC**
European Parliament and Council Regulation (EC) No **1901/2006**
European Parliament and Council Directive **2008/29/EC**
European Parliament and Council Regulation (EC) n° **1394/2007**
Amended by:
Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 as regards variations to the terms of marketing authorisations for medicinal products. (Official Journal L 168, 30/6/2009, p. 33 - 34)

3.2.1.1.2. *Community approval system*

Council Regulation (EEC) n° 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, amended by:
Commission Regulation (EC) n° **649/98**
Council Regulation (EC) n° **1647/2003**
Repealed and replaced by European Parliament and Council Regulation (EC) n° 726/2004 amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council and by European Parliament and Council Regulation (EC) n° 1394/2007
Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 amending Regulation 726/2004 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny - Part Two (Official Journal L 87, 231/3/2009, p. 109 - 154, especially p. 116 – 118

Implementing measures:
1) Council Regulation (EC) n° 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products amended by:
Council Regulation (EC) n° **2743/98**
Commission Regulation (EC) n° **494/2003**
Council Regulation (EC) n° **1905/2005**

- Commission Regulation (EC) n° 2049/2005
Commission Regulation (EC) n° 312/2008
- 2) **Commission Regulation (EC) n° 540/95** laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorised in accordance with the provisions of Council Regulation (EEC) n° 2309/93
 - 3) **Commission Regulation (EC) n° 1662/95** laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorisations for products for human or veterinary use
 - 4) **Commission Regulation (EC) n° 2141/96** concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) n° 2309/93
 - 5) **Commission Regulation (EC) n° 1085/2003** concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) n° 2309/93
 - 6) **Commission Regulation (EC) n° 507/2006** on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004
 - 7) **Commission Regulation (EC) No 658/2007** of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council
 - 8) **Commission Regulation (EC) No 249/2009** of 23 March 2009 amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate (Official Journal L 79, 25/3/2009 p. 34 - 36)

3.2.1.2. Testing

3.2.1.2.1. Standards and protocols in testing of proprietary medicinal products

European Parliament and Council Directive 2001/83/EC on the Community code, repealing Directive 75/318/EEC (as amended by 83/570/EEC, 87/19/EEC, 89/341/EEC, 91/507/EEC, 93/39/EEC, 1999/82/EC and 1999/83/EC), relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products

3.2.1.2.2. Good clinical practice in clinical trials on medicinal products

European Parliament and Council Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, as amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance) (OJ L 091 09.04.2005 p. 13)

3.2.1.3. Manufacturing

- 1) **European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use (Title IV relating to good manufacturing practice for medicinal products for human use)**
- 2) **Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use**

3.2.1.4. Distribution

European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use (Title VII relating to the wholesale distribution of medicinal products for human use, repealing Directive 92/25/EEC)

3.2.1.5. Classification

European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use (Title VI concerning the classification for the supply of medicinal products for human use, repealing Directive 92/26/EEC)

3.2.1.6. Labelling

European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use (Title V relating to the labelling of medicinal products for human use and on package leaflets, repealing Directive 92/27/EEC)

3.2.1.7. Advertising

European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use (Title VIII relating to the advertising of medicinal products for human use, repealing Directive 92/28/EEC)

3.2.1.8. Prices and reimbursement

Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems

3.2.1.9. Intellectual property

Council Regulation (EEC) n° 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (*under the management of DG Internal Market*) as amended by **Regulation (EC) No 1901/2006 of the European Parliament and of the Council
Regulation (EC) No 816/2006 compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems**

3.2.1.10. Colouring matters

Council Directive 78/25/EEC on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products, amended by:
Council Directive **81/464/EEC**

3.2.1.11. Orphan medicinal products

1) European Parliament and Council Regulation (EC) n° 141/2000 on orphan medicinal products
Implementing measure:
Commission Regulation (EC) No 847/2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'

3.2.1.12. Medicinal products for paediatric use

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use

2008/C 243/09 - Guideline on the format and content of applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies (*Official Journal C 243/1, 2008*)

3.2.1.13. Advanced Therapies

European Parliament and Council Regulation (EC) n° 1394/2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (shall apply from 30 December 2008)

3.2.2. VETERINARY MEDICINAL PRODUCTS

3.2.2.1. Marketing authorisation

3.2.2.1.1. Granting and mutual recognition of national market authorisations

- 1) European Parliament and Council Directive 2001/82/EC on the Community code, repealing Directive 81/851/EEC (as amended by Directives 90/676/EEC, 93/40/EEC and 2000/37/EC), relating to veterinary medicinal products, amended by:**
European Parliament and Council Directive **2004/28/EC**
Commission Directive 2009/9/EC of 10 February of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (Official Journal L 44, 14/2/2009 p. 10 - 61)
- 2) Commission Regulation (EC) No 1084/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State**

3.2.2.1.2. Community approval system

- Council Regulation (EEC) n° 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, amended by:**
Commission Regulation (EC) n° **649/98**
Council Regulation (EC) n° **1647/2003**
Repealed and replaced by European Parliament and Council Regulation (EC) n° 726/2004 (enters into full operation on 20 November 2005)
Implementing measures:
- 1) Council Regulation (EC) n° 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products, amended by:**
Council Regulation (EC) n° **2743/98**
Commission Regulation (EC) n° **494/2003**
Council Regulation (EC) n° **1905/2005**
Commission Regulation (EC) n° **2049/2005**
- 2) Commission Regulation (EC) n° 540/95 laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorised in accordance with the provisions of Council Regulation (EEC) n° 2309/93**
- 3) Commission Regulation (EC) n° 1662/95 laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorisations for products for human or veterinary use**
- 4) Commission Regulation (EC) n° 2141/96 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) n° 2309/93**
- 5) Commission Regulation (EC) n° 1085/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) n° 2309/93**

6) Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council

3.2.2.2. Testing

European Parliament and Council Directive 2001/82/EC on the Community code, repealing Directive 81/852/EEC (as amended by Directives 87/20/EEC, 92/18/EEC, 93/40/EEC and 1999/104/EC), relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

3.2.2.3. Manufacturing

Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products

European Parliament and Council Directive 2001/82/EC on the Community code relating to veterinary medicinal products (Title IV laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products)

3.2.2.4. Maximum residue limits for veterinary medicinal products in foodstuffs of animal origin

Council Regulation (EEC) n° 2377/90 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin, amended by:

Commission Regulation (EEC) n° 762/92

Commission Regulation (EC) n° 2701/94

Commission Regulation (EC) n° 2703/94

Commission Regulation (EC) n° 3059/94

Commission Regulation (EC) n° 1102/95

Commission Regulation (EC) n° 1441/95

Commission Regulation (EC) n° 1442/95

Commission Regulation (EC) n° 1798/95

Commission Regulation (EC) n° 2796/95

Commission Regulation (EC) n° 2804/95

Commission Regulation (EC) n° 281/96

Commission Regulation (EC) n° 282/96

Commission Regulation (EC) n° 1140/96

Commission Regulation (EC) n° 1147/96

Commission Regulation (EC) n° 1311/96

Commission Regulation (EC) n° 1312/96

Commission Regulation (EC) n° 1433/96

Commission Regulation (EC) n° 1742/96

Commission Regulation (EC) n° 1798/96

Commission Regulation (EC) n° 2010/96

Commission Regulation (EC) n° 2017/96

Commission Regulation (EC) n° 2034/96

Commission Regulation (EC) n° 17/97

Commission Regulation (EC) n° 211/97

Commission Regulation (EC) n° 270/97

Council Regulation (EC) n° 434/97

Commission Regulation (EC) n° 716/97

Commission Regulation (EC) n° **748/97**
Commission Regulation (EC) n° **749/97**
Commission Regulation (EC) n° **1836/97**
Commission Regulation (EC) n° **1837/97**
Commission Regulation (EC) n° **1838/97**
Commission Regulation (EC) n° **1850/97**
Commission Regulation (EC) n° **121/98**
Commission Regulation (EC) n° **426/98**
Commission Regulation (EC) n° **613/98**
Commission Regulation (EC) n° **1000/98**
Commission Regulation (EC) n° **1076/98**
Commission Regulation (EC) n° **1191/98**
Commission Regulation (EC) n° **1568/98**
Commission Regulation (EC) n° **1569/98**
Commission Regulation (EC) n° **1570/98**
Commission Regulation (EC) n° **1916/98**
Commission Regulation (EC) n° **1917/98**
Commission Regulation (EC) n° **1958/98**
Commission Regulation (EC) n° **2560/98**
Commission Regulation (EC) n° **2686/98**
Commission Regulation (EC) n° **2692/98**
Commission Regulation (EC) n° **2728/98**
Commission Regulation (EC) n° **508/99**
Commission Regulation (EC) n° **804/99**
Commission Regulation (EC) n° **953/99**
Commission Regulation (EC) n° **954/99**
Commission Regulation (EC) n° **997/99**
Commission Regulation (EC) n° **998/99**
Commission Regulation (EC) n° **1308/99**
Commission Regulation (EC) n° **1931/99**
Commission Regulation (EC) n° **1942/99**
Commission Regulation (EC) n° **1943/99**
Commission Regulation (EC) n° **2385/99**
Commission Regulation (EC) n° **2393/99**
Commission Regulation (EC) n° **2593/99**
Commission Regulation (EC) n° **2728/99**
Commission Regulation (EC) n° **2757/99**
Commission Regulation (EC) n° **2758/99**
Commission Regulation (EC) n° **1286/2000**
Commission Regulation (EC) n° **1295/2000**
Commission Regulation (EC) n° **1960/2000**
Commission Regulation (EC) n° **2338/2000**
Commission Regulation (EC) n° **2391/2000**
Commission Regulation (EC) n° **2535/2000**
Commission Regulation (EC) n° **2908/2000**
Commission Regulation (EC) n° **749/2001**
Commission Regulation (EC) n° **750/2001**
Commission Regulation (EC) n° **807/2001**
Commission Regulation (EC) n° **1274/2001**
Commission Regulation (EC) n° **1322/2001**
Commission Regulation (EC) n° **1478/2001**
Commission Regulation (EC) n° **1553/2001**
Commission Regulation (EC) n° **1680/2001**
Commission Regulation (EC) n° **1815/2001**
Commission Regulation (EC) n° **1879/2001**
Commission Regulation (EC) n° **2162/2001**
Commission Regulation (EC) n° **2584/2001**

Commission Regulation (EC) n° 77/2002
Commission Regulation (EC) n° 868/2002
Commission Regulation (EC) n° 869/2002
Commission Regulation (EC) n° 1181/2002
Commission Regulation (EC) n° 1530/2002
Commission Regulation (EC) n° 1752/2002
Commission Regulation (EC) n° 1937/2002
Commission Regulation (EC) n° 61/2003
Commission Regulation (EC) n° 544/2003
Commission Regulation (EC) n° 665/2003
Commission Regulation (EC) n° 739/2003
Commission Regulation (EC) n° 1029/2003
Commission Regulation (EC) n° 1490/2003
Commission Regulation (EC) n° 1873/2003
Commission Regulation (EC) n° 2011/2003
Commission Regulation (EC) n° 2145/2003
Commission Regulation (EC) n° 323/2004
Commission Regulation (EC) n° 546/2004
Commission Regulation (EC) n° 1101/2004
Commission Regulation (EC) n° 1646/2004
Corrigendum to Commission Regulation (EC) n° 1646/2004
Commission Regulation (EC) n° 1851/2004
Commission Regulation (EC) n° 1875/2004
Commission Regulation (EC) n° 2232/2004
Commission Regulation (EC) n° 75/2005
Commission Regulation (EC) n° 712/2005
Commission Regulation (EC) n° 869/2005
Commission Regulation (EC) n° 1148/2005
Commission Regulation (EC) n° 1299/2005
Commission Regulation (EC) n° 1356/2005
Commission Regulation (EC) n° 1518/2005
Commission Regulation (EC) n° 1911/2005
Commission Regulation (EC) n° 6/2006
Commission Regulation (EC) n° 205/2006
Commission Regulation (EC) n° 1055/2006
Commission Regulation (EC) n° 1231/2006
Commission Regulation (EC) n° 1451/2006
Commission Regulation (EC) n° 1729/2006
Commission Regulation (EC) n° 1805/2006
Commission Regulation (EC) n° 1831/2006
Commission Regulation (EC) n° 287/2007
Commission Regulation (EC) n° 703/2007
Commission Regulation (EC) n° 1064/2007
Commission Regulation (EC) n° 1323/2007
Commission Regulation (EC) n° 1353/2007
Commission Regulation (EC) n° 542/2008 of 16 June 2008 amending Annexes I and II to Council Regulation (EEC) No 2377/90

Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. (Official Journal L 152, 16/6/2009 p. 11 - 22)

Commission Regulation (EC) No 478/2009 of 8 June 2009 **amending Annexes I and III to Council Regulation (EEC) No 2377/90** laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as regards monepantel (Official Journal L 144, 9/6/2009 p.17-19)

Commission Regulation (EC) No 485/2009 of 9 June 2009 **amending Annex II to Council Regulation (EEC) No 2377/90** laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as regards tiludronic acid and iron fumarate (Official Journal L 145, 10/6/2009 p.31-33)

3.2.2.5. Intellectual property

Council Regulation (EEC) n° 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (*under the management of DG Internal Market*)

3.2.2.6. Colouring matters

Council Directive 78/25/EEC on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products, amended by:
Council Directive **81/464/EEC**

3.2.2.7. Classification

Article 67 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products as amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004

Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription was published in the Official Journal on 12 December 2006

3.2.2.8. Treatment of equidae

Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae

3.3. OTHER MEASURES RELATING TO PHARMACEUTICALS

- Council Decision 75/320/EEC setting up a pharmaceutical committee

(OJ L 147, 09.06.1975)

- Commission Communication on the implementation of the new marketing authorization procedures for medicinal products for human and veterinary use in accordance with Council Regulation (EC) n° 2309/93 of 22 July 1993 and Council Directives 93/39/EEC, 93/40/EEC and 93/41/EEC, adopted on 14 June 1993

(OJ C 82, 19.03.1994)

- Commission Communication on the Community authorisation procedures for medicinal products

(OJ C 229, 22.07.1998)

- Commission Communication No 141/2000 of the European Parliament and of the Council on orphan medicinal products

(OJ C 178, 29.07.2003)

- Council Regulation (EC) No 1905/2005 of 14 November 2005 amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency (Official Journal L 304, 23.11.2005, p. 1)

- Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p.4)

- 2006/C 133/05 - Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC (*Official Journal C 133, 8/6/2006 p. 5 - 7*)

- 2006/C 132/08 - Guideline on the definition of a potential serious risk to human or animal health or for the environment in the context of Article 33(1) and (2) of Directive 2001/82/EC (*Official Journal C 132, 7/6/2006 p. 32 – 35*)

4. COSMETICS

Outline:

4.1. Structure

4.2. Enumeration of the legislation

4.1. STRUCTURE

There is one basic Community directive in the field of cosmetics. It was adopted in 1976, has been amended 7 times by the European Parliament and the Council and already adapted to technical progress 48 times. It has 11 implementing directives, which relate to the methods of analysis necessary for checking the composition of cosmetic products and 4 other implementing directives dealing with some specific provisions regarding the labelling of ingredients and animal testing respectively. Furthermore, there is one decision related to the nomenclature of ingredients.

<p>Cosmetic products Directive 76/768/EEC (7 amendments) (53 adaptations to technical progress) (16 implementing measures)</p>

4.2. ENUMERATION OF THE LEGISLATION

Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, amended by:

Council Directive **79/661/EEC**

Council Directive **82/368/EEC**

Council Directive **83/574/EEC**

Council Directive **88/667/EEC**

Council Directive **89/679/EEC**

Council Directive **93/35/EEC**

European Parliament and Council Directive **2003/15/EC**

Adaptations to technical progress:

Commission Directive **82/147/EEC**

Commission Directive **83/191/EEC**

Commission Directive **83/341/EEC**

Commission Directive **83/496/EEC**

Commission Directive **84/415/EEC**

Commission Directive **85/391/EEC**

Commission Directive **86/179/EEC**

Commission Directive **86/199/EEC**

Commission Directive **87/137/EEC**

Commission Directive **88/233/EEC**

Commission Directive **89/174/EEC**

Commission Directive **90/121/EEC**

Commission Directive **91/184/EEC**

Commission Directive **92/8/EEC**

Commission Directive **92/86/EEC**

Commission Directive **93/47/EEC**

Commission Directive **94/32/EC**

Commission Directive **95/34/EC**

Commission Directive **96/41/EC**

Commission Directive **97/1/EC**

Commission Directive **97/45/EC**

Commission Directive **98/16/EC**

Commission Directive **98/62/EC**

Commission Directive **2000/6/EC**

Commission Directive **2000/11/EC**

Commission Directive **2002/34/EC**

Commission Directive **2003/1/EC**

Commission Directive **2003/16/EC**

Commission Directive **2003/80/EC**

Commission Directive **2003/83/EC**

Commission Directive **2004/87/EC**

Commission Directive **2004/88/EC**

Commission Directive **2004/93/EC**

Commission Directive **2005/9/EC**

Commission Directive **2005/42/EC**

Commission Directive **2005/52/EC**

Commission Directive **2005/80/EC**

Commission Directive **2006/65/EC**

Commission Directive **2006/78/EC**

Commission Directive **2007/1/EC**

Commission Directive **2007/17/EC**

Commission Directive **2007/22/EC**

Commission Directive **2007/53/EC**
Commission Directive **2007/54/EC**
Commission Directive **2007/67/EC**
Commission Directive **2008/14/EC**
Commission Directive **2008/42/EC**
Commission Directive **2008/88/EC**
Commission Directive **2009/6/EC**
Commission Directive **2009/36/EC**
Commission Directive **2009/129/EC**
Commission Directive **2009/130/EC**
Commission Directive **2009/134/EC**

Implementing measures:

1) First Commission Directive 80/1335/EEC on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products, amended by:

Commission Directive **87/143/EEC**

2) Second Commission Directive 82/434/EEC on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products, amended by:

Commission Directive **90/207/EEC**

3) Third Commission Directive 83/514/EEC on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

4) Fourth Commission Directive 85/490/EEC on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

5) Fifth Commission Directive 93/73/EEC on the methods of analysis necessary for checking the composition of cosmetic products

6) Commission Directive 95/17/EC laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products

7) Sixth Commission Directive 95/32/EC concerning the methods of analysis necessary for checking the composition of cosmetic products

8) Seventh Commission Directive 96/45/EC concerning the methods of analysis necessary for checking the composition of cosmetic products

9) Commission Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products

10) Commission Directive 97/18/EC postponing the date after which animal tests are prohibited for ingredients or combinations of ingredients of cosmetic products

11) Commission Directive 2000/41/EC postponing for a second time the date after which animal tests are prohibited for ingredients or combinations of ingredients of cosmetic products

12) Commission Directive 2004/94/EC of 15 September 2004 amending Council Directive 76/768/EEC as regards Annex IX

13) Commission Decision 2006/257/EC of 9.2.2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products

14) Commission Recommendation of 7.6.2006 establishing guidelines on the use of claims referring to the absence of tests on animals pursuant to Council Directive 76/768/EEC

15) Commission Recommendation of 22.9.2006 on the efficacy of sunscreen products and the claims made relating thereto (notified under document number C(2006) 4089)

16) Communication of the Commission 2007/C10/07 concerning the date of mandatory application of the updated inventory and common nomenclature of ingredients employed in cosmetic products (JO C10, 16.1.2007, p.5).

5. LEGAL METROLOGY AND PRE-PACKAGING

Outline:

5.1. Structure

5.2. Enumeration of the legislation

5.2.1. Legal metrology

5.2.1.1. Units of measurement

5.2.1.2. Common provisions

5.2.1.3. Non-automatic weighing instruments

5.2.1.4. Measuring instruments

5.2.1.5. Water meters

5.2.1.5.1. Cold-water meters

5.2.1.6. Alcohol meters, alcohol hydrometers and alcohol tables

5.2.1.6.1. Alcohol meters and alcohol hydrometers

5.2.1.6.2. Alcohol tables

5.2.1.7. Medium and above medium accuracy weights

5.2.1.7.1. 5 to 50 kilogramme medium accuracy rectangular bar weights and 1 gramme to 10 kilogramme medium accuracy cylindrical weights

5.2.1.7.2. 1 milligramme to 50 kilogramme of above medium accuracy weights

5.2.1.8. Tyre pressure gauges for motor vehicles

5.2.1.9. Standard mass of grain

5.2.1.10. Calibration of tanks of vessels (ships' tanks)

5.2.2. Pre-packaging

5.2.2.1. Volume of certain pre-packaged liquids

5.2.2.2. Bottles used as measuring instruments

5.2.2.3. Weight or volume of certain pre-packaged products

5.2.2.4. Ranges of nominal quantities and nominal capacities for certain pre-packaged products

5.3. Other measures relating to legal metrology and pre-packaging

5.1. STRUCTURE

Two sections can be distinguished: legal metrology and pre-packaging.
Community legislation in the field of legal metrology can be divided into fifteen groups:

Units of measurement
Common provisions
Non-automatic weighing instruments
Measuring instruments
Totalizing weighing machines and automatic checkweighing and weight grading machines
Water meters
Measuring systems for liquids other than water
Gas meters
Electricity meters
Material measures of length
Alcohol meters, alcohol hydrometers and alcohol tables
Medium and above medium accuracy weights
Taximeters
Tyre pressure gauges for motor vehicles
Standard mass of grain
Calibration of tanks of vessels (ships' tanks)

1. Units of measurement
Directive 80/181/EEC
(3 amendments)

2. Common provisions
Directive 71/316/EEC
(5 amendments)

3. Non –automatic weighing instruments
Directive 90/384/EEC
(1 amendment)

4. Measuring instruments
Directive 2004/22/EEC

5. Water meters

Cold-water meters
Directive 75/33/EEC



6. Alcohol meters, alcohol hydrometers and alcohol tables

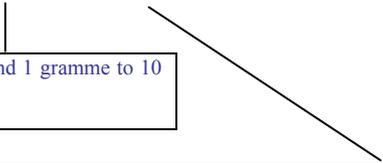
Alcohol meters and alcohol hydrometers
Directive 76/765/EEC
(1 adaptation to technical progress)



Alcohol tables
Directive 76/766/EEC

7. Medium and above medium accuracy weights

5 to 50 kilogramme medium accuracy rectangular bar weights and 1 gramme to 10 kilogramme medium accuracy cylindrical weights
Directive 71/317/EEC



Weights from 1 milligramme to 50 kilogramme of above medium accuracy
Directive 74/148/EEC

8. Tyre pressure gauges for motor vehicles
Directive 86/217/EEC

9. Standard mass of grain
Directive 71/347/EEC

10. Calibration of tanks of vessels (ships' tanks)
Directive 71/349/EEC

In the field of pre-packaging, 4 groups can be distinguished:

- 1. Volume of certain pre-packaged liquids**
- 2. Bottles used as measuring containers**
- 3. Weight or volume of certain pre-packaged products**
- 4. Ranges of nominal quantities and nominal capacities permitted for certain pre-packaged products.**

1. Volume of certain pre-packaged liquids Directive 75/106/EEC – repealed (4 amendments) (1 adaptation to technical progress) Directive 2007/45/EC

2. Bottles used as measuring containers Directive 75/107/EEC
--

3. Weight or volume of certain pre-packaged products Directive 76/211/EEC (1 adaptation to technical progress) (1 amendment) Directive 2007/45/EC
--

4. Ranges of nominal quantities and nominal capacities permitted for certain pre-packaged products Directive 80/232/EEC - repealed (2 amendments) Directive 2007/45/EC
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The Enterprise DG is responsible for all this legislation.

5.2. ENUMERATION OF THE LEGISLATION

5.2.1. LEGAL METROLOGY

5.2.1.1. Units of measurement

Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement, repealing Directive 71/354/EEC, amended by:
Council Directive 85/1/EEC
Council Directive 89/617/EEC
European Parliament and Council Directive 1999/103/EC

5.2.1.2. Common provisions

Council Directive 71/316/EEC on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control, amended by:
Council Directive 72/427/EEC
Council Directive 83/575/EEC
Council Directive 87/354/EEC
Council Directive 87/355/EEC
Council Directive 88/665/EEC

5.2.1.3. Non-automatic weighing instruments

Council Directive 90/384/EEC on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments, amended by:
Council Directive 93/68/EEC

5.2.1.4. Measuring instruments

European Parliament and Council Directive 2004/22/EC on measuring instruments
Directives repealed as from 30 October 2006:
Council Directive 75/410/EEC
Council Directive 78/1031/EEC
Council Directive 79/830/EEC
Council Directive 71/319/EEC
Council Directive 71/348/EEC
Council Directive 77/313/EEC
Council Directive 71/318/EEC
Council Directive 76/891/EEC
Council Directive 73/362/EEC
Council Directive 77/95/EEC

5.2.1.5. Water meters

5.2.1.5.1. *Cold-water meters*

Council Directive 75/33/EEC on the approximation of the laws of the Member States relating to cold-water meters (This Directive is partially repealed by Directive 2004/22/EC as of from 30 October 2006.)

5.2.1.6. Alcohol meters, alcohol hydrometers, and alcohol tables

5.2.1.6.1. Alcohol meters and alcohol hydrometers

Council Directive 76/765/EEC on the approximation of the laws of the Member States relating to alcohol meters and alcohol hydrometers
Adaptation to technical progress:
Commission Directive 82/624/EEC

5.2.1.6.2. Alcohol tables

Council Directive 76/766/EEC on the approximation of the laws of the Member States relating to alcohol tables

5.2.1.7. Medium and above medium accuracy weights

5.2.1.7.1. 5 to 50 kilogramme medium accuracy rectangular bar weights and 1 gramme to 10 kilogramme medium accuracy cylindrical weights

Council Directive 71/317/EEC on the approximation of the laws of the Member States relating to 5 to 50 kilogramme medium accuracy rectangular bar weights and 1 gramme to 10 kilogramme medium accuracy cylindrical weights

5.2.1.7.2. 1 milligramme to 50 kilogramme of above medium accuracy weights

Council Directive 74/148/EEC on the approximation of the laws of the Member States relating to relating to weights from 1 milligramme to 50 kilogramme of above medium accuracy

5.2.1.8. Tyre pressure gauges for motor vehicles

Council Directive 86/217/EEC on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles

5.2.1.9. Standard mass of grain

Council Directive 71/347/EEC on the approximation of the laws of the Member States relating to the measuring of the standard mass per storage volume of grain

5.2.1.10. Calibration of tanks of vessels (ships' tanks)

Council Directive 71/349/EEC on the approximation of the laws of the Member States relating to the calibration of the tanks of vessels

5.2.2. PRE-PACKAGING

5.2.2.1. Volume of certain pre-packaged liquids

Council Directive 75/106/EEC on the approximation of the laws of the Member States relating to the making-up by volume of certain pre-packaged liquids, amended by:

Council Directive **79/1005/EEC**

Council Directive **85/10/EEC**

Council Directive **88/316/EEC**

Council Directive **89/676/EEC**

Adaptation to technical progress:

Commission Directive **78/891/EEC**

Repealed by:

Directive 2007/45/EC of the European Parliament and of the Council of 5/9/2007 laying down rules on nominal quantities for pre-packed products

5.2.2.2. Bottles used as measuring containers

Council Directive 75/107/EEC on the approximation of the laws of the Member States relating to bottles used as measuring containers

5.2.2.3. Weight or volume of certain pre-packaged products

Council Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products

Adaptation to technical progress:

Commission Directive **78/891/EEC**

Amended by:

Directive 2007/45/EC of the European Parliament and of the Council of 5/9/2007 laying down rules on nominal quantities for pre-packed products

5.2.2.4. Ranges of nominal quantities and nominal capacities permitted for certain pre-packaged products

Council Directive 80/232/EEC on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain pre-packaged products, amended by:

Council Directive **86/96/EEC**

Council Directive **87/356/EEC**

Repealed by:

Directive 2007/45/EC of the European Parliament and of the Council of 5/9/2007 laying down rules on nominal quantities for pre-packed products

5.3. OTHER MEASURES RELATING TO LEGAL METROLOGY AND PRE-PACKAGING

- Commission Recommendation 76/223/EEC to the Member States concerning units of measurement referred to in patent conventions

(OJ L 43, 19.02.1976)

- Commission Regulation (EC) No 61/2004 of 13 January 2004 establishing unit values for the determination of the customs value of certain perishable goods

(OJ L 09, 15.01.2004)

- Commission Regulation (EC) No 150/2004 of 27 January 2004 establishing unit values for the determination of the customs value of certain perishable goods

(OJ L 24, 29.01.2004)

6. ELECTRICAL RISK AND ELECTRICAL EQUIPMENT

Outline:

6.1. Structure

6.2. Enumeration of the legislation

6.2.1. Low voltage

6.2.2. Electromagnetic compatibility

6.3. Other measures relating to electrical risk and electrical equipment

6.1. STRUCTURE

Community legislation in the field of electrical safety can be divided into two groups:

Low voltage

Electro-magnetic compatibility

The Enterprise DG is responsible for this legislation.

1. Low voltage Directive 2006/95/EC

2. Electromagnetic compatibility Directive 89/336/EEC (3 amendments) Directive 2004/108/EC
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6.2. ENUMERATION OF THE LEGISLATION

6.2.1. LOW VOLTAGE

Council Directive 2006/95/EC on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits.

2005/C284/01

Commission communication in the framework of the implementation of Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits

6.2.2. ELECTROMAGNETIC COMPATIBILITY

Council Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility, amended by:

Council Directive 91/263/EEC

Council Directive 92/31/EEC

Council Directive 93/68/EEC

Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

6.3. OTHER MEASURES RELATING TO ELECTRICAL RISK AND ELECTRICAL EQUIPMENT

Low voltage

- Commission Communication of 15 December 1981 concerning the operation of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits - the 'low-voltage Directive'

(OJ C 59, 09.03.1982)

- Commission Opinion of 30 March 2000 within the framework of Council Directive 73/23/EEC relating to electrical equipment designed for use within certain voltage limits

(OJ C 104, 12.04.2000)

- Commission Opinion within the framework of Council Directive 73/23/EEC relating to electrical equipment designed for use within certain voltage limits

(OJ C 29, 30.01.2001)

- Commission Opinion of 3 May 2002 within the framework of Council Directive 73/23/EEC relating to electrical equipment designed for use within certain voltage limits - Portable child-appealing luminaires

(OJ C 112, 09.05.2002)

- Commission Opinion within the framework of Council Directive 73/23/EEC relating to electrical equipment designed for use within certain voltage limits - Safety of toasters

(OJ C 300, 04.12.2002)

- Commission Communication in the framework of the implementation of Council Directive 73/23/EEC: Publication of titles and references of harmonized standards under the Directive

(OJ C 060, 14.03.2003)

(OJ C 202, 27.08.2003)

(OJ C 103, 29.04.2004)

- Commission opinion of 8 December 2003 within the framework of Council Directive 73/23/EEC relating to electrical equipment designed for use within certain voltage limits – Safety of cable reels

(OJ C 297, 09.12.2003)

Electromagnetic compatibility

- Commission Communication in the framework of the implementation of Council Directive 89/336/EEC: Publication of titles and references of harmonised standards under the Directive

(OJ C 074, 26.03.2003)

(OJ C 172, 22.07.2003)

(OJ C 271, 12.11.2003)

(OJ C 098, 23.04.2004)

7. CONSUMERS

Outline:

7.1. Structure

7.2. Enumeration of the legislation

7.3. Other measures relating to consumers

7.1. STRUCTURE

The Enterprise DG has one directive which relates primarily to consumer protection under its management. This directive relates to the safety of toys.

<p>Safety of toys Directive 88/378/EEC (1 amendment) (2 implementing measures)</p>

7.2. ENUMERATION OF THE LEGISLATION

**Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys, amended by:
Council Directive 93/68/EEC**

Implementing measures:

1) Commission Decision 96/450/EC concerning the withdrawal of the reference to harmonisation document HD 271 S 1 ‘Safety of household and similar electrical appliances - Particular requirements of electric toys supplied at safety extra low voltage not exceeding 24 V’

2) Commission Decision 2007/224/EC concerning the publication of the reference of the standard EN 71-1:2005 Safety of Toys — Part 1: mechanical and physical properties regarding the technical requirements on projectiles with suction cups as an impact area in accordance with Council Directive 88/378/EEC on the safety of toys (*notified under document number C(2007) 1460*)

7.3. OTHER MEASURES RELATING TO CONSUMERS

- Commission Communication pursuant to Article 9(2) of Council Directive 88/378/EEC regarding the list of bodies approved by the Member States responsible for carrying out the EC type-examination referred to in Articles 8(2) and 10 of that Directive (safety of toys)

(OJ C 87, 27.03.1993)

- Commission Communication in the framework of the implementation of the Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys (publication of titles and references of harmonised standards under the directive)

(OJ C 227, 22.09.2009)

8. OTHER PRODUCT GROUPS

Outline:

8.1. Structure

8.2. Enumeration of the legislation

8.2.1. Mechanical devices

8.2.1.1. Machinery

8.2.1.2. Lifting

8.2.1.3. Environmental Aspects

8.2.2. Personal protective equipment

8.2.3. Explosive atmospheres

8.2.4. Medical devices

8.2.4.1. Electro-medical equipment used in veterinary medicine

8.2.4.2. Active implantable medical devices

8.2.4.3. Medical devices

8.2.4.4. Reclassification of breast implants

8.2.4.5. In vitro diagnostic medical devices

8.2.5. Appliances burning gaseous fuels

8.2.6. Pressure vessels

8.2.6.1. Aerosol dispensers

8.2.6.2. Common provisions for pressure vessels and methods for inspecting them

8.2.6.3. Seamless, steel gas cylinders

8.2.6.4. Seamless, unalloyed aluminium and aluminium alloy gas cylinders

8.2.6.5. Welded unalloyed, steel gas cylinders

8.2.6.6. Simple pressure vessels

8.2.6.7. Pressure equipment

8.2.7. Rail and guided transport

8.2.8. Construction products

8.2.9. Recreational craft

8.2.10. Glass

8.2.11. Textiles

8.2.11.1. Textile names

8.2.11.2. Methods for quantitative analysis of binary textile fibre mixtures

8.2.11.3. Quantitative analysis of ternary fibre mixtures

8.2.12. Footwear

8.2.13. Wood

8.2.14. Firearms

8.2.15. Cultural Goods

8.2.16. Eco-Design

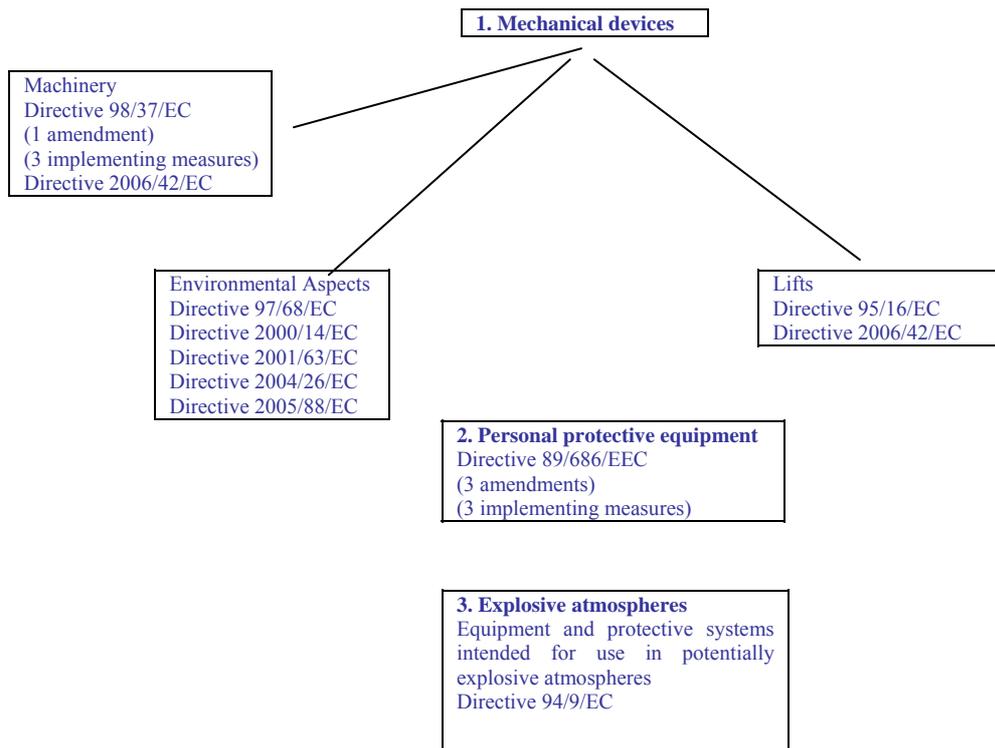
8.2.17. Pyrotechnics

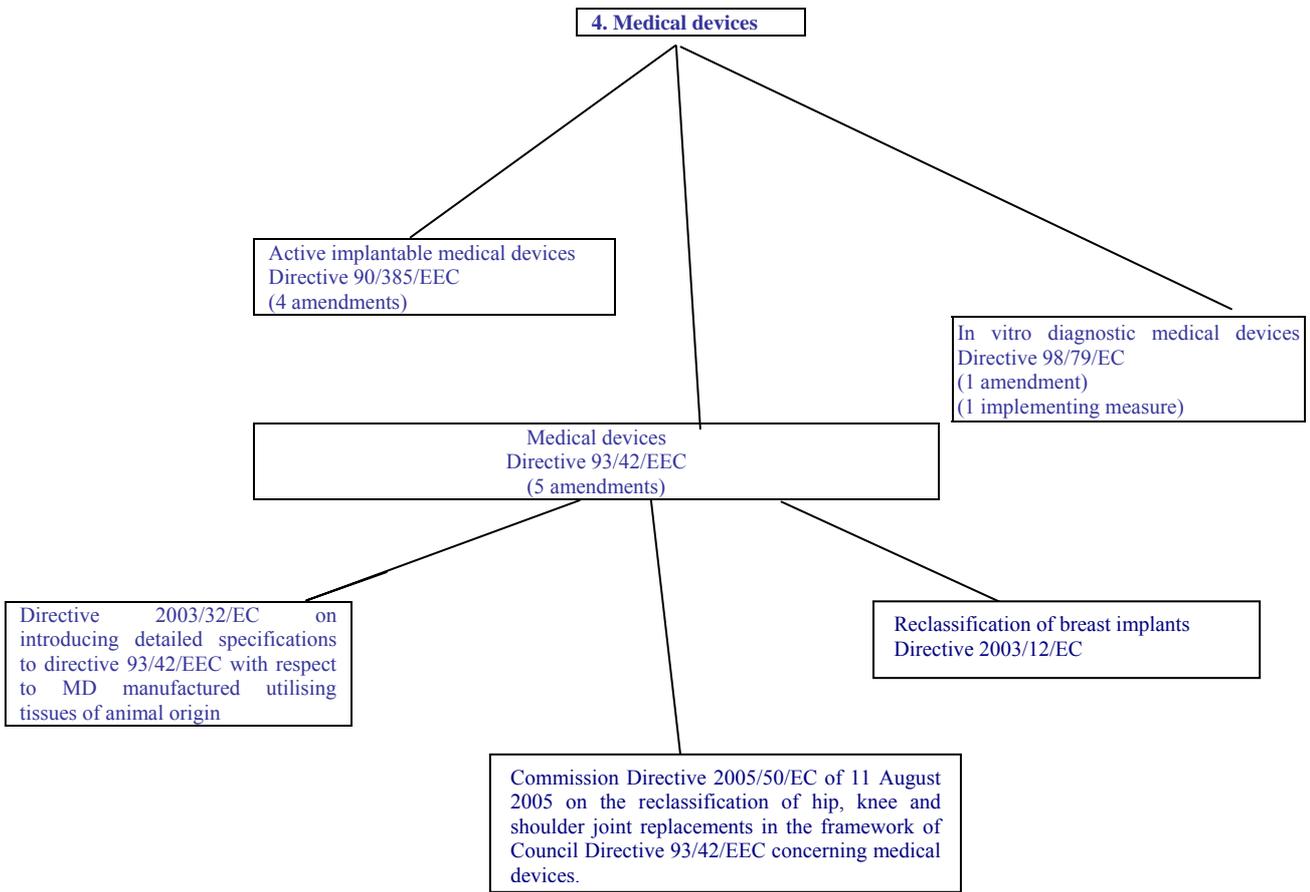
8.3. Other measures relating to other product groups

8.1. STRUCTURE

In this chapter, all product legislation for which the Enterprise DG is responsible but which does not fit within any of the other chapters, is brought together. It can be divided into the following groups:

1. *Mechanical devices*
2. *Personal protective equipment*
3. *Explosives atmospheres*
4. *Medical devices*
5. *Appliances burning gaseous fuels*
6. *Pressure vessels*
7. *Rail and guided transport*
8. *Construction products*
9. *Recreational craft*
10. *Glass*
11. *Textiles*
12. *Footwear*
13. *Wood*
14. *Firearms*
15. *Cultural Goods*
16. *Eco-Design*





5. Appliances burning gaseous fuels
 Council Directive 90/396/EEC
 Council Directive 93/68/EEC

6. Pressure vessels

(Old approach)

Aerosol dispensers
Directive 75/324/EEC
(1 adaptation to technical progress)

Common provisions for pressure vessels and
methods for inspecting them
Directive 76/767/EEC
(2 amendments)

Seamless, steel gas cylinders
Directive 84/525/EEC

Seamless, unalloyed aluminium and
aluminium alloy gas cylinders
Directive 84/526/EEC

Welded unalloyed steel gas cylinders
Directive 84/527/EEC

(New approach)

Simple pressure vessels
Directive 87/404/EEC
(2 amendments)

Pressure equipment
Directive 97/23/EC

7. Rail and guided transport
Cableways Directive
2000/9/EC

8. Construction products
Directive 89/106/EEC
(1 amendment)
(70 implementing measures)

9. Recreational craft
Directive 94/25/EC
(1 amendment)

10. Glass
Directive 69/493/EEC

11. Textiles

Textile names
Directive 96/74/EC
(4 adaptations to technical progress)
Directive 2008/121/EC

Quantitative analysis of ternary fibre mixtures
Directive 73/44/EEC

Methods for the quantitative analysis of binary textile fibre mixtures
Directive 96/73/EC
(2 adaptations to technical progress)

12. Footwear
Directive 94/11/EC

13. Wood
Directive 68/89/EEC - repealed

14. Firearms
Directive 91/477/EEC
Directive 2008/51/EC

15. Cultural Goods
Directive 93/7/EEC

16. Eco-Design
Directive 2005/32/EC
Directive 2009/125/EC

8.2. ENUMERATION OF THE LEGISLATION

8.2.1. MECHANICAL DEVICES

8.2.1.1. Machinery

European Parliament and Council Directive 98/37/EC on the approximation of the laws of the Member States relating to machinery, amended by European Parliament and Council Directive 98/79/EC

European Parliament and Council Directive 2006/42/EC of 17.5.2006 on the approximation of the laws of the Member States relating to machinery

Implementing measures:

1) Commission Decision 2000/361/EC on the publication of the references of standards EN 1459:1999 'Safety of industrial trucks – Self-propelled variable reach trucks' and EN 1726-1:1999 'Safety of industrial trucks – Self-propelled trucks up to and including 20 000 kg capacity and industrial tractors with a drawbar pull up to and including 20 000 N – Part 1: General requirements'

2) Commission Decision 2000/693/EC on withdrawing the references of standard EN 703 'Agricultural machinery – Silage cutters – Safety' from the list of references of standards in the framework of implementing Directive 98/37

3) Commission Decision 2003/224/EC on the publication of the reference of standard EN 1495:1997 "Lifting platforms - mast climbing work platforms" in accordance with Directive 98/37/EC of the European Parliament and of the Council

8.2.1.2. Lifting

European Parliament and Council Directive 95/16/EC on the approximation of the laws of the Member States relating to lifts

European Parliament and Council Directive 2006/42/EC of 17.5.2006 on the approximation of the laws of the Member States relating to machinery, and amending Directive 95/16/EC

8.2.1.3. Environmental Aspects

Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 059 27.02.1998 p. 1) amended by:

Commission Directive 2001/63/EC (OJ L 227, 23.8.2001, p.47)

European Parliament and Council Directive 2002/88/EC

Directive 2004/26/EC of the European Parliament and the Council (OJ L 225, 25.6.2004, p.3)

Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3/7/2000 p.1) amended by:

Directive 2005/88/EC of the European Parliament and the Council (OJ L 344, 27.12.2005, p.44)

8.2.2. PERSONAL PROTECTIVE EQUIPMENT

Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment, amended by:

Council Directive **93/68/EEC**

Council Directive **93/95/EEC**

European Parliament and Council Directive **96/58/EC**

Implementing measures:

1) **C/2000/225: Commission Decision of 4/2/2000 on the removal of the references to standard EN 959 “Mountaineering equipment - Rock anchors - Safety requirements and test methods” from the list of harmonised standards published in the *Official Journal C 183 of 13 June 1998* pursuant to Council Directive 89/686/EEC. Not published in the OJ, notified to Member States administrations.**

2) **C/2000/240: Commission Decision of 4/2/2000 on the publication in the *Official Journal of the European Communities* of a reference to standard EN 795 “Protection against falls from a height - Anchor devices – Requirements and testing”. Not published in the OJ, notified to Member States administrations;**

3) **C/2000/275: Commission Decision of 4/2/2000 on the publication in the *Official Journal of the European Communities* of a reference to standards EN 1496 “Rescue equipment - Rescue lifting devices”, EN 1497 “Rescue equipment - Rescue harnesses” and EN 1498 “Rescue equipment - Rescue loops”. Not published in the OJ, notified to Member States administrations;**

8.2.3. EXPLOSIVE ATMOSPHERES

European Parliament and Council Directive 94/9/EC on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres

Commission communication in the framework of the implementation of Directive 94/9/EC on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres

8.2.4. MEDICAL DEVICES

8.2.4.1. Active implantable medical devices

Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, amended by:

Council Directive **93/42/EEC**

Council Directive **93/68/EEC**

Regulation (EC) No **1882/2003** of the European Parliament and of the Council
European Parliament and Council Directive **2007/47/EC**

8.2.4.2. Medical devices

Council Directive 93/42/EEC concerning medical devices, amended by:

European Parliament and Council Directive **98/79/EC**

European Parliament and Council Directive **2000/70/EC**

European Parliament and Council Directive **2001/104/EC**
(both covering medical devices which incorporate stable derivatives of human blood or human plasma)
Regulation (EC) No **1882/2003** of the European Parliament and of the Council
European Parliament and Council Directive **2007/47/EC**

8.2.4.3. In vitro diagnostic medical devices

European Parliament and Council Directive **98/79/EC on in vitro-diagnostic medical devices**, amended by:
Regulation (EC) No **1882/2003** of the European Parliament and of the Council
Implementing measure:
Commission Decision **2002/364/EC on common technical specifications for in vitro-diagnostic medical devices**

8.2.4.4. Medical devices manufactured utilising tissues of animal origin

Commission Directive **2003/32/EC** introducing detailed specifications as regards the requirements laid down in Council Directive **93/42/EEC** with respect to medical devices manufactured utilising tissues of animal origin

8.2.4.5. Reclassification of breast implants

Commission Directive **2003/12/EC on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices**

8.2.4.6. Reclassification of hip, knee and shoulder joint replacements

Commission Directive **2005/50/EC** of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive **93/42/EEC** concerning medical devices

8.2.4.7. Electro-medical equipment used in human or veterinary medicine (repealed)

Directive **2008/13/EC** of the European Parliament and of the Council of 11 March 2008, repealing Council Directive **84/539/EEC** on the approximation of the laws of the Member States relating to electro-medical equipment used in human or veterinary medicine

8.2.5. APPLIANCES BURNING GASEOUS FUELS

Council Directive **90/396/EEC on the approximation of the laws of the Member States relating to appliances burning gaseous fuels**, amended by:
Council Directive **93/68/EEC**

8.2.6. PRESSURE VESSELS

8.2.6.1. Aerosol dispensers

Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers

Adaptations to technical progress:

Commission Directive 94/1/EC

8.2.6.2. Common provisions for pressure vessels and methods for inspecting them

Council Directive 76/767/EEC on the approximation of the laws of the Member States relating to common provisions for pressure vessels and methods for inspecting them, amended by:

Council Directive 87/354/EEC

Council Directive 88/665/EEC

8.2.6.3. Seamless, steel gas cylinders

Council Directive 84/525/EEC on the approximation of the laws of the Member States relating to seamless, steel gas cylinders

8.2.6.4. Seamless, unalloyed aluminium and aluminium alloy gas cylinders

Council Directive 84/526/EEC on the approximation of the laws of the Member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders

8.2.6.5. Welded unalloyed, steel gas cylinders

Council Directive 84/527/EEC on the approximation of the laws of the Member States relating to welded unalloyed steel gas cylinders

8.2.6.6. Simple pressure vessels

Council Directive 87/404/EEC on the harmonisation of the laws of the Member States relating to simple pressure vessels, amended by:

Council Directive 90/488/EEC

Council Directive 93/68/EEC

8.2.6.7. Pressure equipment

European Parliament and Council Directive 97/23/EC on the approximation of the laws of the Member States concerning pressure equipment

8.2.7. RAIL AND GUIDED TRANSPORT

European Parliament and Council Directive 2000/9/EC relating to cableway installations designed to carry persons

Commission Decision C(2008)7289 final, on the non-withdrawal of the reference of standard EN 12929-2:2004 "Safety requirements for cableway installations designed to carry persons - General requirements - Part 2: Additional requirements for reversible bi-cable aerial ropeways without carrier truck brakes" in the Official Journal of the European Union in accordance with Directive 2000/9/EC

8.2.8. CONSTRUCTION PRODUCTS

Council Directive 89/106/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products, amended by:
Council Directive 93/68/EEC

Implementing measures:

- 1) Commission Decision 94/23/EC on common procedural rules with regard to European technical approval
 - 1a) Commission Decision 94/611/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards Classes of reaction to fire performance of building products
 - 1b) Commission Decision 95/204/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards thermal insulating products / doors, windows, shutters, gates, and related building hardware / membranes / precast normal lightweight autoclaved concrete products
- 2) Commission Decision 95/467/EC implementing Article 20(2) of Council Directive 89/106/EEC on construction products as regards chimneys, flues and specific products, gypsum products, structural bearings, amended by:
Commission Decision 2001/596/EC
- 3) Commission Decision 96/577/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fixed fire-fighting systems
- 4) Commission Decision 96/578/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards sanitary appliances, amended by:
Commission Decision 2001/596/EC
- 5) Commission Decision 96/579/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards circulation fixtures, amended by:
Commission Decision 1999/453/EC
- 6) Commission Decision 96/580/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards curtain walling, amended by:
Commission Decision 2001/596/EC
- 7) Commission Decision 96/581/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards geotextiles

8) Commission Decision 96/582/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural sealant glazing systems and metal anchors for concrete

9) Commission Decision 96/603/EC establishing the list of products belonging to classes A ‘No contribution to fire’ provided for in Decision 94/611/EEC implementing Article 20 of Council Directive 89/106/EEC on construction products, amended by:

Commission Decision **2000/605/EC**

10) Commission Decision 97/161/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal anchors for use in concrete for fixing lightweight systems

11) Commission Decision 97/176/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural timber products and ancillaries, amended by:

Commission Decision **2001/596/EC**

12) Commission Decision 97/177/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal injection anchors for use in masonry

13) Commission Decision 97/462/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards wood-based panels, amended by:

Commission Decision **2001/596/EC**

14) Commission Decision 97/463/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards plastic anchors for use in concrete and masonry

15) Commission Decision 97/464/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards waste water engineering products

16) Commission Decision 97/555/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cements, building limes and other hydraulic binders

17) Commission Decision 97/556/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards external thermal insulation composite systems/kits with rendering (ETICS) , amended by:

Commission Decision **2001/596/EC**

18) Commission Decision 97/571/EC on the general format of European Technical Approval for construction products

19) Commission Decision 97/597/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council

- Directive 89/106/EEC as regards reinforcing and prestressing steel for concrete**
- 20) Commission Decision 97/638/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fasteners for structural timber**
- 21) Commission Decision 97/740/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards masonry and related products, amended by:**
Commission Decision 2001/596/EC
- 22) Commission Decision 97/808/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards floorings, amended by:**
Commission Decision 1999/453/EC
Commission Decision 2001/596/EC
- 23) Commission Decision 98/143/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards systems of mechanically fastened flexible roof waterproofing membranes**
- 24) Commission Decision 98/213/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal partition kits, amended by:**
Commission Decision 2001/596/EC
- 25) Commission Decision 98/214/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards structural metallic products and ancillaries, amended by:**
Commission Decision 2001/596/EC
- 26) Commission Decision 98/279/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards non load-bearing permanent shuttering kits/systems based on hollow blocks or panels of insulating materials and, sometimes, concrete, amended by:**
Commission Decision 2001/596/EC
- 27) Commission Decision 98/436/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards roof coverings, roof lights, roof windows and ancillary products, amended by:**
Commission Decision 2001/596/EC
- 28) Commission Decision 98/437/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal and external wall and ceiling finishes, amended by:**
Commission Decision 2001/596/EC
- 29) Commission Decision 98/456/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards post-tensioning kits for the prestressing of structures**

30) Commission Decision 98/457/EC concerning the test of the Single Burning Item (SBI) referred to in Council Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products

31) Commission Decision 98/598/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards aggregates

32) Commission Decision 98/599/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards liquid applied roof waterproofing kits, amended by:

Commission Decision **2001/596/EC**

33) Commission Decision 98/600/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards self-supporting translucent roof kits (except glass-based kits) , amended by:

Commission Decision **2001/596/EC**

34) Commission Decision 98/601/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards road construction products, amended by:

Commission Decision **2001/596/EC**

35) Commission Decision 1999/89/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards prefabricated stair kits, amended by:

Commission Decision **2001/596/EC**

36) Commission Decision 1999/90/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards membranes, amended by:

Commission Decision **2001/596/EC**

37) Commission Decision 1999/91/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards thermal insulating products, amended by:

Commission Decision **2001/596/EC**

38) Commission Decision 1999/92/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards light composite wood-based beams and columns

39) Commission Decision 1999/93/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards doors, windows, shutters, blinds, gates and related building hardware

40) Commission Decision 1999/94/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards precast normal/light-weight autoclaved aerated concrete products

40a) Commission Decision 1999/453/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards circulation fixtures and floorings

41) Commission Decision 1999/454/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fire stopping, fire sealing and fire protective products, amended by:

Commission Decision **2001/596/EC**

42) Commission Decision 1999/455/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards timber frame and log prefabricated building kits

43) Commission Decision 1999/469/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards products related to concrete, mortar and grout, amended by:

Commission Decision **2001/596/EC**

44) Commission Decision 1999/470/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards construction adhesives, amended by:

Commission Decision **2001/596/EC**

45) Commission Decision 1999/471/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards space heating appliances, amended by:

Commission Decision **2001/596/EC**

46) Commission Decision 1999/472/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards pipes, tanks and ancillaries not in contact with water intended for human consumption, amended by:

Commission Decision **2001/596/EC**

47) Commission Decision 2000/147/EC implementing Council Directive 89/106/EEC as regards the classification of the reaction to fire performance of construction products (*Corrigendum in 2001 to EN, FR, IT, PT and DK versions*)

48) Commission Decision 2000/245/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(4) of Council Directive 89/106/EEC as regards flat glass, profiled glass and glass block products, amended by:

Commission Decision **2001/596/EC**

49) Commission Decision 2000/273/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards seven products for European Technical Approvals without Guideline, amended by:

Commission Decision **2001/596/EC**

50) Commission Decision 2000/367/EC implementing Council Directive 89/106/EEC as regards the classification of the resistance to fire performance of construction products, construction works and parts thereof

51) Commission Decision 2000/447/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards prefabricated wood-based load-bearing

stressed skin panels and self-supporting composite lightweight panels, amended by:

Commission Decision 2001/596/EC

52) Commission Decision 2000/553/EC implementing Council Directive 89/106/EEC as regards the external fire performance of roof coverings

52a) Commission Decision 2000/605/EC amending Decision 96/603/EC establishing the list of products belonging to class A "No contribution to fire" provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products

53) Commission Decision 2000/606/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards six products for European Technical Approvals without Guideline

54) Commission Decision 2001/19/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards expansion joints for road bridges

55) Commission Decision 2001/308/EC of 31 January 2001 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards ventures

55a) Commission Decision 2001/596/EC amending 27 Decisions on the procedure for attesting the conformity of certain construction products pursuant to article 20 of Council Directive 89/106/EEC

56) Commission Decision 2001/671/EC implementing Council Directive 89/106/EEC as regards the classification of the external fire performance of roofs and roof coverings

57) Commission Decision 2002/359/EC on the procedure for attesting the conformity of construction products in contact with water intended for human consumption, pursuant to Article 20(2) of Council Directive 89/106/EEC

58) Commission Decision 2002/592 amending Decisions 95/467/EC, 96/577/EC, 96/578/EC and 98/598/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EC as regards gypsum products, fixed fire-fighting systems, sanitary appliances and aggregates respectively

59) Commission Decision 2003/43/EC establishing the classes of reaction-to-fire performance for certain construction products

60) Commission Decision 2003/312/EC on the publication of the reference of standards relating to thermal insulation products, geotextiles, fixed fire-fighting equipment and gypsum blocks in accordance with Council Directive 89/106/EEC

61) Commission Decision 2003/424/EC amending Decision 96/603/EC establishing the list of products belonging to Classes A "No contribution to fire" provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products

62) Commission Decision 2003/593/EC amending Decision 2003/43/EC establishing the classes of reaction-to-fire performance of certain construction products

63) Commission Decision 2003/629/EC amending Decision 2000/367/EC establishing a classification system for resistance-to-fire performance for construction products, as regards the inclusion of smoke and heat control products

64) Commission Decision 2003/632/EC amending Decision 2000/147/EC implementing Council Directive 89/106/EEC as regards the classification of the reaction-to-fire performance of construction products

65) Commission Decision 2003/639/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards pins for structural joints

66) Commission Decision 2003/640/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards kits for exterior wall claddings

67) Commission Decision 2003/655/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards watertight covering kits for wetroom floors and walls

68) Commission Decision 2003/656/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards seven products for European technical approvals without Guideline

69) Commission Decision 2003/722/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards liquid-applied bridge deck waterproofing kits

70) Commission Decision 2003/728/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal frame building kits, concrete frame building kits, prefabricated building units, cold storage room kits and rock-fall protection kits

71) Commission Decision 2004/663/EC of 20 September 2004 amending Commission Decision 97/464/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards waste water engineering products (notified under document number C(2004) 3488)(Text with EEA relevance)

72) Commission Decision 2005/403/EC of 25 May 2005 establishing the classes of external fire performance of roofs and roof coverings for certain construction products as provided for by Council Directive 89/106/EEC (notified under document number C(2005) 1501) (Text with EEA relevance)

73) Commission Decision 2005/484/EC of 4 July 2005 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards cold storage building kits and cold

storage building envelope kits (notified under document number C(2005) 1961) (Text with EEA relevance)

73) Commission Decision 2005/610/EC of 9 August 2005 establishing the classes of reaction-to-fire performance for certain construction products (notified under document number C(2005) 2925) (Text with EEA relevance)

74) Commission Decision 2005/823/EC of 22 November 2005 amending Decision 2001/671/EC implementing Council Directive 89/106/EEC as regards the classification of the external fire performance of roofs and roof coverings (notified under document number C(2005) 4437) (Text with EEA relevance)

75) Commission Decision 2006/190/EC amending Decision 1997/808/EC on the procedure for attesting the conformity of construction products pursuant to Article 20 (2) of Council Directive 89/106/EC as regards circulation fixtures and floorings

76) Commission Decision 2006/213/EC establishing the classes of reaction-to-fire performance for certain construction products as regards wood flooring and solid wood panelling and cladding

77) Commission Decision 2006/600/EC establishing the classes of reaction-to-fire performance for certain construction products as regards double skin metal faced sandwich panels for roofs

78) Commission Decision 2006/673/EC amending Decision 2000/43/EC establishing the classes of the reaction to fire for gypsum plasterboards

79) Commission Decision 2006/751/EC amending Decision 2000/147/EC implementing Council Directive 89/106/EC as regards the classification of the reaction to fire of electric cables

8.2.9. RECREATIONAL CRAFT

European Parliament and Council Directive 94/25/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, amended by:
European Parliament and Council Directive 2003/44/EC

8.2.10. GLASS

Council Directive 69/493/EEC on the approximation of the laws of the Member States relating to crystal glass

8.2.11. TEXTILES

8.2.11.1. Textile names

European Parliament and Council Directive 96/74/EC on textile names

Adaptation to technical progress:

Commission Directive 97/37/EC
Commission Directive 2004/34/EC
Commission Directive 2006/3/EC
Commission Directive 2007/3/EC

Consolidated and replaced by:

Directive 2008/121/EC on textile names

8.2.11.2. Methods for the quantitative analysis of binary textile fibre mixtures

European Parliament and Council Directive 96/73/EC on certain methods for the quantitative analysis of binary textile fibre mixtures

Adaptation to technical progress:

Commission Directive 2006/2/EC
Commission Directive 2007/4/EC

8.2.11.3. Quantitative analysis of ternary fibre mixtures

Council Directive 73/44/EEC on the approximation of the laws of the Member States relating to the quantitative analysis of ternary fibre mixtures

8.2.12. FOOTWEAR

European Parliament and Council Directive 94/11/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer

8.2.13. WOOD

Council Directive 68/89/EEC on the approximation of the laws of the Member States concerning the classification of wood in the rough, repealed by Decision n° 714/2007/EC of the European Parliament and of the Council of 20 June 2007

8.2.14. FIREARMS

Council Directive 91/477/EEC of 18 June 1991 on the control of the acquisition and possession of weapons (*OJ L 256 13.09.1991 p. 51*)

Directive 2008/51/EC of the European Parliament and of the Council of 21 May 2008 amending Council Directive 91/477/EEC on control of the acquisition and possession of weapons

8.2.15. CULTURAL GOODS

Council Directive 93/7/EEC of 15/3/1993 on the return of cultural objects unlawfully removed from the territory of a Member State, as amended (*OJ L 074, 27/3/1993 p.74*)

8.2.16. ECO-DESIGN

Directive 2005/32/EC of the European Parliament and of the Council of 6/7/2005 establishing a framework for the setting of eco-design requirements for energy-using products and amending Council Directive 92/42/EEC and Directives 96/57/EC and 2000/55/EC of the European Parliament and of the Council (*OJ L 191, 22/7/2005, p. 29*)

Repealed by:

Directive 2009/125/EC of the European Parliament and of the Council of 21/10/2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast) (*OJ L 285, 31/10/2009, p. 10*)

8.3. OTHER MEASURES RELATING TO OTHER PRODUCT GROUPS

Mechanical devices

- Commission Communication in the framework of the implementation of Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 in relation to machinery, as amended by Directive 98/79/EC: Publication of titles and references of European harmonised standards under the Directive
(OJ C 147, 24.06.2003)(OJ C 095, 20.04.2004)
- Commission Recommendation 95/216/EC concerning improvement of safety of existing lifts.
(OJ L 134, 20.06.1995)
- Commission Communication in the framework of the implementation of the European Parliament and Council Directive 95/16/EC in relation to lifts: Publication of titles and references of European harmonised standards under the Directive
(OJ C 090, 31.03.1999)
- Commission Communication in the framework of the implementation of Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 in relation to machinery amended by directive 98/79/EC
(OJ C 192, 14/08/2003)

Personal protective equipment

- Commission Communication in the framework of the implementation of Council Directive 89/686/EEC of 21 December 1989 in relation to personal protective equipment, as amended by Directives 93/68/EEC, 93/95/EEC and 96/58/EC: Publication of titles and references of European harmonised standards under the Directive
(OJ C 087, 10.04.2003) (Corrigendum OJ C 106, 03.05.2003)(OJ C 203, 28.08.2003)(OJ C 046, 21.02.2004)

Explosive atmospheres

- Commission Communication in the framework of the implementation of Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (text with EEA relevance): Publication of titles and references of harmonised standards under the Directive.
(OJ C 042, 21.02.2003)

(OJ C 118, 20.05.2003)
 (OJ C 192, 14.08.2003)
 (OJ C 020, 24.01.2004)
 (OJ C 204, 12.8.2004, p. 14-19)
 (OJ C 300, 30.11.2005, p. 29-34)
 (OJ C 57, 9.3.2006, p. 17-22)
 (OJ C 168, 20.7.2006, p. 6-12)
 (OJ C 306, 15.12.2006, p. 2-8)
 (OJEU C 300, 12.12.2007, p. 14-15 (only new CEN references))
 (OJEU C 90, 11.4.2008, p.24-32)
 (OJEU C 212, 20.8.2008, p. 22-28)
 (OJEU C 020, 27.01.2009, p. 16-23)

- Guidelines on the application of Directive 94/9/EC of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (first edition, May 2000)
- Guidelines on the application of Directive 94/9/EC of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (second edition, July 2005) – updated May 2007
- Guidelines on the application of Directive 94/9/EC - ATEX Guidelines (Second Edition - July 2005) - Updated August 2008
 (<http://ec.europa.eu/enterprise/atex/guide/index.htm>) + Borderline list - ATEX products (http://ec.europa.eu/enterprise/atex/guide/borderline_atex.pdf)
- Consideration Papers by the ATEX Standing Committee:
 - Transportable, pressurised cabins ("modules")
<http://ec.europa.eu/enterprise/atex/pressportmodules.htm>;
 - ExNBG Clarification Sheets: Status and use
<http://ec.europa.eu/enterprise/atex/exnbgclarifsheets.htm>
- Guidelines on the application of Directive 94/9/EC - Third edition June 2009
http://ec.europa.eu/enterprise/sectors/mechanical/documents/guidance/atex/application/index_en.htm
- **Consideration Papers** by the ATEX Standing Committee:
 - How should the Directive be applied to filter units and vented silo bins? (revised version)
http://ec.europa.eu/enterprise/sectors/mechanical/documents/guidance/atex/standing-committee/silo-bins/index_en.htm
 - Application of the directive 94/9/EC to Steam Turbines
<http://ec.europa.eu/enterprise/atex/steamturbines.htm>

Medical devices

- Commission Communication on the application of the transitional provisions of directive 93/42/EEC relating to medical devices.

(OJ C 242, 01.08.1998)

- Commission Communication on community and national measures in relation to breast implants
(COM(2001) 666 final, 15.11.2001)
- Commission Communication in the framework of the implementation of Council Directive 93/42/EEC of 14 June 1993 in relation to medical devices, Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices and Directive 90/385/EEC of 20 June 1990 in relation to "active implantable medical devices"
(OJ C 032, 11.02.2003)
- Commission Communication in the framework of the implementation of Council Directive 93/42/EEC of 14 June 1993 in relation to medical devices and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ C 182 of 31.7.2002)
(OJ C 273, 14.11.2003) (Corrigendum, OJ C 273, 14.11.2003)
- Commission Communication in the framework of the implementation of Council Directive 93/42/EEC in relation to "Medical Devices": Publication of titles and references of European harmonised standards under the Directive(*OJ C 075, 27.03.2003) (OJ C 247, 15.10.2003) (OJ C 268, 07.11.2003) (OJ C 165, 24.6.2004)*
- Commission Communication in the framework of the implementation of Council Directive 90/385/EEC of 20 June 1990 in relation to "active implantable medical devices"
(OJ C 042, 18.02.2004)
- Commission Communication in the framework of the implementation of Council Directive 90/385/EEC of 20 June 1990 in relation to "Active Implantable Medical Devices" and Council Directive 93/42/EEC of 14 June 1993 in relation to "Medical Devices"
(OJ C 270, 11/11/2003)
- Commission Communication in the framework of the implementation of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on "in vitro diagnostic medical devices"
(OJ C 280, 21.11.2003)
- Commission Communication in the framework of the implementation of Council Directive 90/385/EEC of 20 June 1990 in relation to "Active Implantable Medical Devices", Council Directive 93/42/EEC of 14 June 1993 in relation to "Medical Devices" and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

(OJ C 083, 02.04.2004)

- Commission staff working paper on National Measures adopted by Member States in relation to Breast Implants

(SEC (2003) 175 - 14.2.2003)

- Commission Communication in the framework of the implementation of Council Directive 90/385/EEC: Publication of titles and references of harmonised standards under the Directive

(OJ C 176, 08.07.2004)

Publication of the list of harmonized standards for medical devices

- Commission Communication in the framework of the implementation of Council Directive 90/385/EEC

(OJ C 176, 08.07.2004)

- Commission communication in the framework of the implementation of Council Directive 98/79/EC

(OJ C 8, 13.1.2006)

- Commission communication in the framework of the implementation of the Council Directive 93/42/EEC concerning medical devices

(OJ C 314, 22.12.2007)

- Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices

(OJ C 186, 23.07.2008)

- Commission communication in the framework of the implementation of the Council Directive 93/42/EEC concerning medical devices

(OJ C 186, 23.07.2008)

- Commission communication in the framework of the implementation of Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices

(OJ C 186, 23.07.2008)

Guidelines relating to Medical Devices Directives

See

http://ec.europa.eu/enterprise/medical_devices/meddev/meddev_index_en.htm

Gaseous Fuels

- Commission Communication in the framework of the implementation of Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels. Publication of titles and references of harmonised standards under the Directive

(OJ C 154, 02.07.2003)

(OJ C 196, 20.08.2003)

(OJ C 214, 09.09.2003)

(OJ C 313, 23.12.2003)

(OJ C 088, 08.04.2004)

Pressure vessels

- Commission Communication in the framework of the implementation of Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment: Publication of titles and references of European harmonised standards under the Directive

(OJ C 071, 25.03.2003)

- Commission Communication in the framework of the implementation of Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment: Publication of references of European Approval for Materials (EAMs)

(OJ C 233, 30.09.2003)

- Commission Communication to the Council and the European Parliament on the review of the application of the Simple Pressure Vessels Directive (87/404/EEC) in relation to the Pressure Equipment Directive (97/23/EC)
COM 2006 106 (10.3.2006)

- Commission Communication to the Council and the European Parliament on the evaluation of the use of User Inspectorates under the Pressure Equipment Directive (97/23/EC)
COM 2006 109 (10.3.2006)

Rail and Guided Transport

- Commission Communication in the framework of the implementation of the Council Directive 2000/9/EC: Publication of titles and references of harmonised standards under the Directive

(OJ C 097, 24.04.2003)

Construction products

- Commission Communication 1994/C62/04 with regard to the interpretative documents of Council Directive 89/106/EEC
(OJ C 62, 28.02.1994)
- Commission Communication 1994/C206/04 as part of the implementation of Council Directive 89/106/EEC on construction products as amended by Directive 93/68/EEC. Publication, for information purposes, of the names of the bodies authorised to issue European Technical Approvals
(OJ C 206, 26.07.1994)
- Commission Communication 1995/C211/03 as part of the implementation of Council Directive 89/106/EEC on construction products as amended by Directive 93/68/EEC. Publication, for information purposes, of the names of the bodies authorised to issue European Technical Approvals
(OJ C 211, 15.08.1995)
(OJ C 168, 03.06.1998)
(OJ C 212, 06.09.2002)
(OJ C 115, 30.04.2004)
(OJ C 183, 26.07.2005)
(OJ C 245, 05.10.2005)
- Commission Communication in the framework of the implementation of Council Directive 89/106/EEC: Publication of titles and references of harmonized standards under the directive
(OJ C 20, 23.01.2001)
(OJ C 180, 26.06.2001)
(OJ C 202, 18.07.2001)
(OJ C 358, 15.12.2001)
(OJ C 40, 14.02.2002)
(OJ C 154, 28.06.2002)
(OJ C 212, 06.09.2002)
(OJ C 320, 20.12.2002)
(OJ C 047, 27.02.2003)
(OJ C 075, 27.03.2003)
(OJ C 165, 16.07.2003)
(OJ C 271, 12.11.2003)
(OJ C 271, 12.11.2003)
(OJ C 067, 17.04.2003)
(OJ C 67, 17.03.2004)
(OJ C 263, 26.10.2004)
(OJ C 79, 01.04.2005)
(OJ C 139, 08.06.2005)
(OJ C 280, 12.11.2005)
- Commission Communication in the framework of the implementation of Council Directive 89/106/EEC: Publication of titles and references of earlier published harmonised technical specifications for which the coexistence period has been extended

(OJ C 120, 22.05.2003)
(OJ C 084, 03.04.2004)
(OJ C 097, 22.04.2004)
(OJ C 310, 13.12.2002)

- Corrigendum to Commission Decision 1998/437/EC on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards internal and external wall and ceiling finishes (*OJ L 278, 15.10.1998*)
- Corrigendum L85/43 to Commission Decision 2000/147/EC of 8 February 2000 implementing Council Directive 89/106/EEC as regard classification of the reaction to fire performance of construction products. Changes to EN, FR, IT, PT and DK versions. (*OJ L 85, 24.3.2001*)
- Commission Recommendation 2003/887/EC on the implementation and use of Eurocodes for construction works and structural construction products
- (*OJ L 332, 19.12.2003*)
- Commission Communication 2002/C282/01 related to the list of notified bodies designated by Member States and the EFTA countries (EEA members) under the construction products Directive 89/106/EEC
- Commission Communication 2006/C134/01 in the framework of the implementation of Council Directive 89/106/EEC: Publication of titles and references of harmonised standards under the Directive

Recreational craft

- Commission Communication in the framework of the implementation of Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 in relation to recreational craft: Publication of titles and references of European harmonised standards under the Directive

(OJ C 080, 03.04.2003)
(OJ C 118, 20.05.2003)
(OJ C 137, 12.06.2003)
(OJ C 163, 12.07.2003)
(OJ C 261, 30.10.2003)

Textiles

- Commission staff working paper – Commission report on the implementation of the action plan to increase the competitiveness of the European textile and clothing industry

(SEC (2000) 1531 – 19.09.2000)

- Enterprise Paper – “The textile and clothing industry in the EU – A survey”

(Enterprise Paper No. 2, June 2001)

- The future of the textiles and clothing sector in the enlarged Europe

(COM(2003)649 final)

- Textiles and clothing after 2005 – recommendations of the High Level Group for textiles and clothing

(COM(2004)668 final)

Footwear

- Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions – Evaluation Report on the Implementation of Directive 94/11/EC – Labelling the materials used in the main components of footwear

(COM (2000) 812 final, 07.12.2000)

- Commission staff working paper - Report on the promotion of competitiveness and employment in the European footwear industry

(SEC (2001) 366, 28.02.2001)

Lifts

- Commission Communication in the framework of the implementation of the European Parliament and Council Directive 95/16/EC of 29 June 1995 in relation to lifts

(OJ C 036, 10.02.2004)

Firearms

- Commission Report to the European Parliament and the Council on the implementation of Council Directive 91/477/EEC, on control of the acquisition and possession of weapons

9. HORIZONTAL AND PROCEDURAL MEASURES

Outline:

9.1. Structure

9.2. Enumeration of the legislation

9.2.1. Horizontal measures

9.2.1.1. New Legal Framework for marketing of products

9.2.1.2. Standardisation in the field of information technology and telecommunications

9.2.1.3. Modules for conformity assessment and rules on CE conformity marking

9.2.1.4. Interchange of data between administrations (IDA II)

9.2.1.5. Information and legal cooperation on information society services

9.2.1.6. External border checks

9.2.2. Notification procedure

9.2.3. Combating late payment

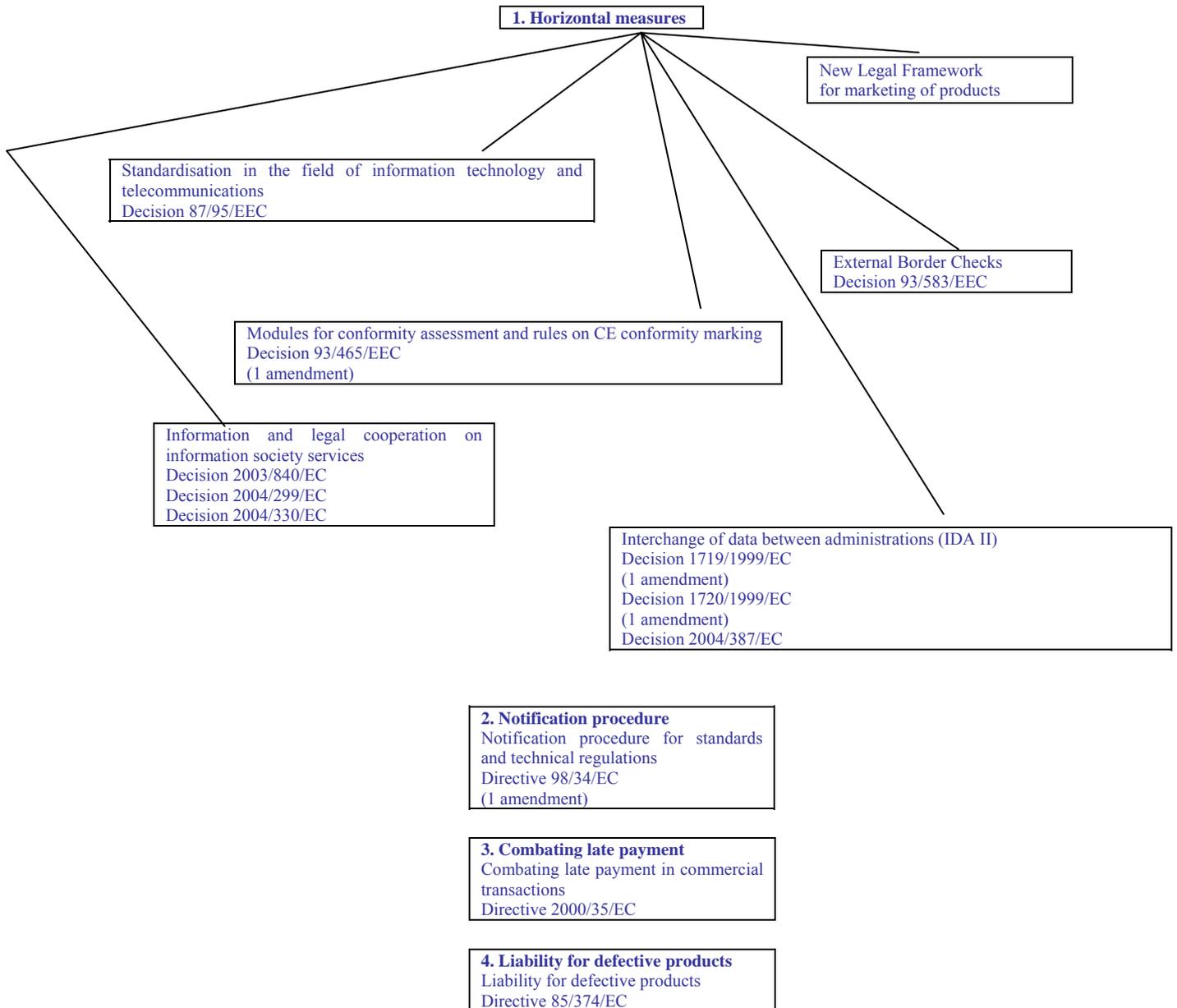
9.2.4. Liability for defective products

9.3. Other measures relating to horizontal and procedural measures

9.1. STRUCTURE

This chapter can be divided in 4 groups:

Horizontal measures
Notification procedure
Combating late payment
Liability for defective products



9.2. ENUMERATION OF THE LEGISLATION

9.2.1. HORIZONTAL MEASURES

9.2.1.1. New Legal Framework for marketing of products

Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products, and repealing Regulation (EEC) no 339/93

Decision 2008/768/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing decision 93/465/EEC

Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC Text with EEA relevance

9.2.1.2. Standardisation in the field of information technology and telecommunications

- 1) **Council Decision 87/95/EEC on standardisation in the field of information technology and telecommunications**
- 2) **Council Decision 2003/840/EC relating to the conclusion on behalf of the European Community of Council of Europe Convention No 180 on information and legal cooperation on information society services**

9.2.1.3. Modules for conformity assessment and rules on CE conformity marking

Council Decision 93/465/EEC concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives

9.2.1.4. Interchange of data between administrations (IDA II)

- 1) **European Parliament and Council Decision 1719/1999/EC on a series of guidelines, including the identification of projects of common interest, for trans-European networks for the electronic interchange of data between administrations (IDA II), amended by:**
European Parliament and Council Decision **2046/2002/EC**
- 2) **European Parliament and Council Decision 1720/1999/EC adopting a series of actions and measures in order to ensure interoperability of and access to trans-European networks for the electronic interchange of data between administrations (IDA II), amended by:**
European Parliament and Council Decision **2045/2002/EC**

3) European Parliament and Council Decision 2004/387/EC on the interoperable delivery of pan-European eGovernment services to public administrations, businesses and citizens (IDABC)

9.2.1.4. Information and legal cooperation on information society services

Council Decision 2003/840/EC relating to the conclusion on behalf of the European Community of Council of Europe Convention No 180 on information and legal cooperation on information society services

Council Decision 2004/299/EC on the conclusion of bilateral Agreements between the European Community and the Republic of Cyprus and the Government of the Republic of Hungary laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services

Council Decision 2004/330/EC on the conclusion of bilateral Agreements between the European Community and the Czech Republic, the Republic of Estonia, the Republic of Latvia, the Republic of Lithuania, the Republic of Malta, the Republic of Poland, the Slovak Republic, and the Republic of Slovenia, respectively, laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services

9.2.1.5. External Border Checks

Council Regulation (EEC) N° 339/93 of 8/2/1993 on checks for conformity with the rules on product safety in the case of products imported from third countries, as amended (*OJ L 040 17/2/1993 p.*)

Commission Decision 93/583/EEC of 28 July 1993 establishing the list of products provided for in Article 8 of Council Regulation (EEC) No 339/93 (*OJ L 279 12.11.1993 p. 39*)

9.2.2. NOTIFICATION PROCEDURE

**European Parliament and Council Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations, amended by:
European Parliament and Council Directive 98/48/EC**

9.2.3. COMBATING LATE PAYMENT

European Parliament and Council Directive 2000/35/EC on combating late payment in commercial transactions

9.2.4. LIABILITY FOR DEFECTIVE PRODUCTS

Council Directive 85/374/EEC of 25 July 1985, on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999.

Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee – third report on the application of Council Directive on the approximation of laws, regulation and administrative provisions of the Member States concerning liability for defective products (85/374/EEC of 25 July 1985, amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999). COM (2006) 496 final.

9.3. OTHER MEASURES RELATING TO HORIZONTAL AND PROCEDURAL MEASURES

- Completing the Internal Market. White Paper from the Commission to the European Council
(COM(85)310 final, 14.06.1986)
- Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards + Conclusions on Standardisation approved by the Council on 16 July 1984
(OJ C 136, 04.06.1985)
- Commission Communication to the Council. A Global Approach to Certification and Testing – Quality measures for industrial products
(COM(89)209 final, 24.07.1989 - OJ C 267, 19.10.1989)
- Council Resolution of 21 December 1989 on a global approach to conformity assessment
(OJ C 10, 16.01.1990)
- Council Resolution of 18 June 1992 on the role of European standardisation in the European economy
(OJ C 173, 09.07.1992)
- Commission Communication concerning the non-respect of certain provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations

(OJ C 245, 01.10.1986)

- Commission Communication concerning the publication in the Official Journal of the European Communities of the titles of draft technical regulations notified by the Member States pursuant to Council Directive 83/189/EEC, as amended by Council Directive 88/182/EEC

(OJ C 67, 17.03.1989)

- Council Resolution of 20 June 1994 on co-ordination with regard to information exchange between administrations

(OJ C 181, 02.07.1994)

- Commission Communication concerning the evaluation of the IDA programme and a second phase of the IDA programme

(COM(97)661 final, 12.12.1997 – OJ C 54, 21.02.1998)

- Communication on Efficiency and Accountability in European Standardisation under the New Approach

(COM(98)291 final, 13.05.1998)

- Council Resolution of 28 June 1999 on measures to address the year 2000 computer problems

(OJ C 200, 15.07.1999)

- Council Resolution of 28 October 1999 on the role of "Standardisation in Europe" *(OJ C 141, 19.05.2000)*

- Commission Report to the European Parliament and the Council – Evaluation of the operation of Directive 98/34/EC in the field of information society services

(COM(2003) 69 final, 13.02.2003)

- Commission Report to the Council, the European Parliament and the European Economic and Social Committee - The Operation of Directive 98/34/EC from 1998 to 2001

(COM(2003) 200 final, 23.05.2003)

- Commission staff working paper – European policy principles on international standardisation

(SEC(2001) 1296, 26.07.2001)

- Commission Report to the Council and the European Parliament – Actions taken following the Resolutions on European standardisation adopted by the Council and the European Parliament in 1999

(COM(2001) 527 final, 26.09.2001)

- Council Conclusions on Standardisation of 1 March 2002
(*OJ C 066, 15.03.2002*)
- The Enterprise Directorate General – Grants' Work Programme 2003
(*OJ C 033, 12.02.2003*) (*Corrigendum OJ C 157, 05.07.2003*)
- Council Resolution of 18 February 2003 on the implementation of the eEurope 2003 Action Plan
(*OJ C 048, 28.02.2003*)
- Report from the Commission to the European Parliament and the Council- IDA II Mid-Term Evaluation
(*COM (2003) 100 final, 07.03.2003*)
- General Guidelines for the Cooperation between CEN, Cenelec and ETSI and the European Commission and the European Free Trade Association - 28 March 2003
(*OJ C 091, 16.04.2003*)
- Commission Communication to the Council and the European Parliament - Enhancing the Implementation of the New Approach Directives
(*COM(2003) 240 final, 07.05.2003*)
- Statistics relating to technical regulations notified in 2002 under the Directive 98/34/EC procedure - Information supplied by the Commission in accordance with Article 11 of Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society
(*OJ C 131, 05.06.2003*)
- Council Conclusions of 13 May 2003 on "adapting e-business policies in a changing environment"
(*OJ C 149, 26.06.2003*)
- Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition
(*OJ C 265, 04.11.2003*)
- Council Resolution of 10 November 2003 on the Communication of the European Commission “Enhancing the Implementation of the New Approach Directives” (*OJ C 282, 25.11.2003*)

10. INDUSTRIAL POLICY

Outline:

10.1. Structure

10.2. Enumeration of the legislation

10.3. Other measures relating to industrial policy

10.3.1. General

10.3.2. Industrial cooperation

10.3.3. Quality promotion policy

10.3.4. Environment and industry

10.3.5. Chemical industry

10.3.6. Machinery construction industry

10.3.7. Aerospace industry

10.3.8. Aircraft industry

10.3.9. Defence-related industry

10.3.10. Construction industry

10.3.11. Textile industry

10.3.12. Steel industry

10.3.13. Maritime industry

10.3.14. Motor vehicles industry

10.3.15. Pharmaceutical industry

10.3.16. Information and communication technologies

10.3.17. Recycling industries

10.2.18. Forest-based and related industries

10.2.19. Innovation

10.1. STRUCTURE

In the field of industrial policy, the majority of the *acquis* consists of a list of ‘other measures’ which have a bearing on industrial policy in broad terms. They can be divided into nineteen groups:

1. *General*
2. *Industrial cooperation*
3. *Quality promotion policy*
4. *Environment and industry*
5. *Chemical industry*
6. *Machinery construction industry*
7. *Aerospace industry*
8. *Aircraft industry*
9. *Defence-related industries*
10. *Construction industry*
11. *Textile industry*
12. *Steel industry*
13. *Maritime*
14. *Motor vehicles industry*
15. *Pharmaceutical industry*
16. *Information and communication technologies*
17. *Recycling industries*
18. *Forest-based and related industries*
19. *Innovation*

10.2. ENUMERATION OF THE LEGISLATION

Commission Decision 83/247/EEC setting up a committee on Community policy regarding forestry and forestry-based industries, amended by Commission Decision 97/837/EC

Council Decision 96/413/EC on implementation of a Community Action Programme to strengthen the competitiveness of European Industry

European Parliament and Council Decision 2256/2003/EC adopting a multiannual programme (2003-2005) for the monitoring of the eEurope 2005 action plan, dissemination of good practises and the improvement of network and information security (MODINIS)

European Parliament and Council Decision 2318/2003/EC adopting a multiannual programme (2004 to 2006) for the effective integration of information and communication technologies (ICT) in education and training systems in Europe (eLearning Programme)

10.3. OTHER MEASURES RELATING TO INDUSTRIAL POLICY

10.3.1. General

- Industrial Policy in an Open and Competitive Environment: Guidelines for a Community Approach

(COM(90)556 final, 16.11.1990)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. An industrial competitiveness policy for the European Union.

(COM(94)319 final, 14.09.1994)

- Council Resolution of 21 November 1994 on the strengthening of the competitiveness of Community Industry

(OJ C 343, 06.12.1994)

- The Competitiveness of European Industry. Working document of Commission services, 23.12.1996

(SEC(96)2121)

- Commission Communication. Benchmarking the Competitiveness of European Industry

(COM(96)463 final, 19.10.1996)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Benchmarking – Implementation of an instrument available to economic actors and public authorities

(COM(97)153 final, 16.04.1997)

- Commission Communication on the contribution of business services to industrial performance – A Common Policy Framework

(COM(98)534 final, 21.09.1998)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – The competitiveness of European enterprises in the face of globalisation: how it can be encouraged

(COM(98)718 final, 20.01.1999)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Structural change and adjustment in European manufacturing
(COM(99)465 final, 05.10.1999)
- Commission Communication – Towards a strategic vision of life sciences and biotechnology: consultation document
(COM(2001) 454 final, 04.09.2001)
- Communication from the Commission – Corporate Social Responsibility: A business contribution to Sustainable Development
(COM(2002) 347 final, 02.07.2002)
- Communication from the Commission – Productivity: The Key to Competitiveness of European Economies and Enterprises
(COM(2002) 262 final, 21.05.2002)
- Communication from the Commission – Life sciences and biotechnology – A strategy for Europe
(COM(2002) 27 final, 23.01.2002)
- Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Industrial Policy in an Enlarged Europe
(COM(2002) 714, 30.09.2003)
- Commission staff working paper – Report on Community measures affecting tourism (2000)
(SEC(2002) 300 final, 15.03.2002)
- Commission Working Document – preparing for the Euro-Mediterranean Free Trade Area: Elements for Regional Industrial Co-operation 2002-2006
(SEC(2002) 130 final, 07.02.2002)
- Report from the Commission – Fifth report on the situation in world shipbuilding
(COM(2002) 205 final, 30.04.2002)
- Commission Staff Working Paper – Go Digital progress report 2001-2000
(SEC(2002) 566, 13.5.2002)

- Council Conclusions of 26 November 2002 on a more competitive environment for enterprises
(*OJ C 039, 18.02.2003*)
- Council Conclusions of 13 May 2003 on "industrial competitiveness in an enlarged Europe"
(*OJ C 149, 26.06.2003*)
- Communication from the Commission to the Council and the European Parliament - Productivity: The Key to Competitiveness of European Economies and Enterprises
(*COM(2002) 262 final, 21.5.2002*)
- Council Conclusions of 27 November 2003 on the contribution of industrial policy to European competitiveness
(*OJ C 317, 30.12.2003*)

10.3.2. Industrial cooperation

- Commission Communication to the Council and the European Parliament – Industrial cooperation with the Countries of Central/Eastern Europe
(*COM(95)71 final, 14.03.1995*)
- Council Resolution of 25 June 1996 on industrial cooperation with other regions and third countries, inter alia in the Mediterranean
(*OJ C 203, 13.07.1996*)

10.3.3. Quality promotion policy

- A European Quality Promotion Policy for Improving European Competitiveness
(*SEC(96)2000*)

10.3.4. Environment and industry

- Industrial Competitiveness and Protection of the Environment
(*SEC(92)1986*)

- Council Resolution of 3 December 1992 concerning the relationship between industrial competitiveness and environmental protection

(OJ C 331, 16.12.1992)

- Commission Communication: Promoting sustainable development in the EU non–energy extractive industry

(COM (2000) 265 final, 03.05.2000)

- Report from the Commission on the results reached for the period 1996-2000 by the implementation of Commission recommendation 98/480/EC of 22 July 1998, concerning good environmental practice for household laundry detergents.

(COM(2002) 287 final – 10.06.2002)

10.3.5. Chemical industry

- Commission Communication to the Council, the European Parliament and the Economic and Social Committee - An Industrial Competitiveness Policy for the European Chemical Industry: An example

(COM(96) 187 final, 30.04.1996)

10.3.6. Machinery construction industry

- Commission Communication on strengthening the competitiveness of the European machinery construction industry

(COM(94) 380 final, 25.10.1994)

- Council Resolution of 27 November 1995 on the strengthening of the competitiveness of the European mechanical engineering industry

(OJ C 341, 19.12.1995)

10.3.7. Aerospace industry

- Commission Communication to the Council of Ministers, the European Parliament, the Economic and Social Committee and the Committee of the Regions –The European Aerospace Industry: Meeting the Global Challenge

(COM(97) 466 final, 24.09.1997)

- Council Conclusions of 13 May 2003 on "the development of an overall European space policy"

(OJ C 149, 26.06.2003)

10.3.8. Aircraft industry

- Commission Communication to the Council - The European Aircraft Industry: First Assessment and Possible Community Actions

(COM(92) 164 final, 29.04.1992)

10.3.9. Defence related industries

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Implementing European Union Strategy on Defence-related Industries

(COM(97) 583 final, 04.12.1997)

- Council Conclusions of 13 May 2003 on "European defence-industrial and market issues: towards an EU defence equipment policy"

(OJ C 149, 26.06.2003)

10.3.10. Construction industry

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on: “The Competitiveness of the Construction Industry

(COM(97) 539 final, 04.11.1997)

10.3.11. Textile industry

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions - The impact of international developments on the Community’s textile and clothing sector

(COM(95) 447 final, 11.10.1995)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions - The competitiveness of subcontracting in the textile and clothing industry in the European Union

(COM(96) 210 final, 15.05.1996)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Plan of action to increase the competitiveness of the European textile and clothing industry

(COM(97) 454 final, 29.10.1997)

10.3.12. Steel industry

- Commission Communication to the Council, the European Parliament and the ECSC Consultative Committee – A Global approach to promote regional and social conversion and to facilitate industrial restructuring in the Central and Eastern European Countries: the case of steel

(COM(98) 220 final, 07.04.1998)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the ECSC Consultative Committee – The state of competitiveness of the steel industry in the EU

(COM(99) 453 final, 05.10.1999)

10.3.13. Maritime industry

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Towards a new shipbuilding industry

(COM(97) 470 final, 01.10.1997)

10.3.14. Motor vehicles industry

- Commission Communication to the Council and the European Parliament – A Community strategy to reduce CO₂ emissions from passenger cars and improve fuel economy

(COM(95) 689 final, 20.12.1995)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – European Automobile Industry

(COM(96) 327 final, 10.07.1996)

- Commission Communication to the European Parliament and the Council on a future strategy for the control of atmospheric emissions from road transport taking into account the results from the Auto-Oil Programme

(COM(96) 248 final, 18.06.1996)

- Commission Communication to the European Parliament – Implementing the Community Strategy to Reduce CO² Emissions from Cars: Third annual report on the effectiveness of the strategy (Reporting year 2001)

(COM(2002) 693 final, 09.12.2002)

10.3.15. Pharmaceutical industry

- Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted

(OJ C 115, 06.05.1982)

- Commission Communication on the compatibility with Article 30 of the EEC Treaty of measures taken by Member States relating to price controls and reimbursement of medicinal products

(OJ C 310, 04.12.1986)

- Commission Communication to the Council and the European Parliament on the outlines of an industrial policy for the pharmaceutical sector in the European Community

(COM(93) 718 final, 02.03.1994)

- Council Resolution of 23 April 1996 designed to implement the outlines of an industrial policy in the pharmaceutical sector in the European Union

(OJ C 136, 08.05.1996)

- Commission Communication on the Single Market in Pharmaceuticals

(COM(98) 588 final, 25.11.1998)

10.3.16. Information and communication technologies

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – The competitiveness of the European Information and Communication Technologies (ICT) industries

(COM(97) 152 final, 16.04.1997)

- Council Recommendation 98/560/EC on the development of competitiveness of the European audiovisual and information services industry by promoting

national frameworks aimed at achieving a comparable and effective level of protection of minors and human dignity

(OJ L 270, 07.10.1998)

10.3.17. Recycling industries

- Communication on the competitiveness of the recycling industries

(COM(98) 463 final, 22.07.1998)

10.3.18. Forest-based and related industries

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – The state of competitiveness of the EU forest-based and related industries

(COM(99)457 final, 05.10.1999)

10.3.19. Innovation

- Commission Communication: Innovation in a knowledge-driven economy

(COM (2000) 567 final, 20.09.2000)

- Commission staff working paper – 2002 European Innovation Scoreboard

(SEC(2002) 1349 – 9.12.2002)

- Council Conclusions of 13 May 2003 on "strengthening European innovation policy"

(OJ C 149, 26.06.2003)

11. SME POLICY

Outline:

11.1. Structure

11.2. Enumeration of the legislation

11.2.1. Binding measures

11.2.2. Recommendations

11.3. Other measures relating to SME policy

11.3.1. Resolutions

11.3.2. Commission reports and communications

11.3.3. Commission staff working papers

11.1. STRUCTURE

There is a very limited number of legally binding measures in the area of SME policy (including tourism). The majority of the acquis consists of a list of other measures that have a bearing on SME policy in broad terms. The part concerning the legislation can be divided into the following groups:

- 1. *Binding measures***
- 2. *Recommendations***

11.2. ENUMERATION OF LEGISLATION

11.2.1. BINDING MEASURES

Council Decision 86/664/EEC establishing a consultation and co-operation procedure in the field of tourism

Council Decision 93/379/EEC on a multiannual programme of Community measures to intensify the priorities areas and to ensure the continuity and consolidation of policy for enterprise, in particular small and medium-sized enterprises, in the Community

Commission Decision 97/761/EC approving a support mechanism for the creation of transnational joint ventures for SMEs in the Community

Council Decision 97/15/EC on a third multiannual programme for small and medium-sized enterprises (SMEs) in the European Union (1997-2000)

Council Decision 2000/819/EC on a multiannual programme for Enterprise and Entrepreneurship, and in particular for small and medium-sized enterprises (SMEs) (2001-2005)

Implementing measure:

1) C/2001/3973: Commission Decision relating to the implementation of the financial instruments of the multiannual programme for Enterprise and Entrepreneurship, and in particular for small and medium-sized enterprises (SMEs) (2001-2005)

2) Notice of implementation of the ETF start-up facility, the SME guarantee facility and the seed capital action under the multiannual programme for enterprise and entrepreneurship, and in particular for small and medium-sized enterprises (SMEs) (2001-2005)

(OJ C 54, 01.03.2002)

3) Notice of implementation of the ETF start-up facility, the SME guarantee facility and the Seed Capital Action under the multiannual programme for enterprise and entrepreneurship, and in particular for small and medium-sized enterprises (SMEs) (2001-2005)

(OJ C 45, 25.02.2003)

Council Regulation 1435/2003/EC on the Statute for a European Cooperative Society

Council Directive 2003/72/EC supplementing the Statute for a European Cooperative with regard to the involvement of employees

11.2.2 RECOMMENDATIONS

Council Recommendation 86/665/EEC of 22 December 1986 on standardised information in existing hotels

(OJ L 384, 31.12.86 p. 54)

Council Recommendation 86/666/EEC of 22 December 1986 on fire safety in existing hotels

(OJ L 384, 31.12.86 p. 60)

Council Recommendation 90/246/EEC of 28 May 1990 relating to the implementation of a policy of administrative simplification in favour of small and medium-sized enterprises in the Member States

(OJ L 141 02.06.90 p. 55)

Commission Recommendation 94/390/EC of 25 May 1994 concerning the taxation of small and medium sized enterprises

(OJ L 177 09.07.94 p.1)

Commission Recommendation 94/1060/EC of 7 December 1994 on the transfer of small and medium-sized enterprises

(OJ L 385 31.12.94 p.14)

Commission Recommendation 96/280/EC of 3 April 1996 concerning the definition of small and medium-sized enterprises

(OJ L 107 30.04.96 p.4)

Commission Recommendation 97/344/EC of 22 April 1997 on improving and simplifying the business environment for business start-ups

(OJ L 145 05.06.97 p.29)

Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises

(OJ L 124 20.05.03 p.36)

11.3. OTHER MEASURES RELATING TO SME POLICY

11.3.1. RESOLUTIONS

- Council Resolution of 10 April 1984 on a Community policy on tourism
(OJ C 115, 30.04.1984 p.2)
- Council Resolution of 3 November 1986 concerning the action programme for small and medium sized enterprises (SMEs)
(OJ C 287, 14.11.1986 p. 1)
- Council Resolution of 22 December 1986 on a better seasonal and geographical distribution of tourism
(OJ C 340, 31.12.1986 p.1)
- Council Resolution of 30 June 1988 on the improvement of the business environment and action to promote the development of enterprises, especially small and medium-sized enterprises in the Community
(OJ C 197, 27.07.1988 p. 6)
- Council Resolution of 26 September 1989 on the development of subcontracting in the Community
(OJ C 254, 07.10.1989 p.1)
- Council Resolution of 27 May 1991 on the action programme for small and medium-sized enterprises including craft industry enterprises
(OJ C 146, 05.06.1991 p.3)
- Council Resolution of 17 June 1992 on Community action to support enterprises, in particular small and medium-sized enterprises, including craft industry enterprises
(OJ C 178, 15.07.1992 p.8)
- Council Resolution of 3 December 1992 on administrative simplification for enterprises, especially small and medium-sized enterprises
(OJ C 331, 16.12.1992 p.3)
- Council Resolution of 22 November 1993 on strengthening the competitiveness of enterprises in particular of small and medium-sized enterprises and craft enterprises, and developing employment
(OJ C 326, 03.12.1993 p.1)

- Council Resolution of 10 October 1994 on giving full scope to the dynamism and innovatory potential of small and medium-sized enterprises, including the craft sector and micro-enterprises, in a competitive economy
(OJ C 294, 22.10.1994 p.6)
- Council Resolution of 27 November 1995 on small and medium-sized industrial enterprises (SMEs) and technological innovation
(OJ C 341, 19.12.1995 p.3)
- Council Resolution of 22 April 1996 on the co-ordination of Community activities in favour of small and medium-sized enterprises and the craft sector
(OJ C 130, 03.05.1996 p.1)
- Council Resolution of 13 May 1996 on Euro-Mediterranean co-operation regarding tourism
(OJ C 155, 30.05.1996 p.1)
- Council Resolution of 9 December 1996 on realising the full potential of small and medium-sized enterprises (SMEs), including micro-enterprises and the craft sector, through an integrated approach to improving the business environment and stimulating business support measures
(OJ C 18, 17.01.1997 p.1)
- European Charter for Small Enterprises (adopted by the General Affairs Council, 13.06.2000, and welcomed by the Feira European Council, 19. – 20.06.2000)
- Council Resolution of 21 May 2002 on the future of European tourism
(OJ C 135, 06.06.2002 p.1)

11.3.2. COMMISSION REPORTS AND COMMUNICATIONS

- Commission Communication on the financial problems experienced by SMEs
(COM (93) 528 final, 10.11.1993)
- Communication of the Commission concerning the improvement of the fiscal environment of SMEs
(COM (94) 206 final, 25.05.1994)
- Commission Communication on the Round Table of high level representatives from the Banking sector

(COM (94) 435 final, 28.10.1994)

- Communication on the Commission recommendation of 7 December 1994 on the transfer of SMEs

(OJ C 400, 31.12.1994)

- Commission Communication – Green Paper on the role of the Union in the field of tourism

(COM (95) 97 final, 04.04.1995)

- Communication on the Commission recommendations of 12 May 1995 on payment periods in commercial transactions

(OJ C 144, 10.06.1995)

- Commission Communication on the coordination of activities in favour of SMEs and the craft sector

(COM (95) 362 final, 08.09.1995)

- Commission Communication – Reporting on the feasibility of the creation of a European Capital Market for smaller entrepreneurially managed growing companies

(COM (95) 498 final, 25.10.1995)

- Commission Communication – Crafts and small enterprises, keys to growth and employment in Europe

(COM (95) 502 final, 26.10.1995)

- Commission Communication - Integrated programme in favour of SMEs and the craft sector – the multiannual programme, concerted actions and other Community actions in support of SMEs

(COM (96) 329 final, 10.07.1996)

- Commission Communication of maximising European SMEs full potential for employment, growth and competitiveness – Amended proposal for a Council Decision on a Third Multiannual Programme for small and medium-sized enterprises (SMEs) in the European Union (1997 – 2000)

(COM (96) 591 final, 14.11.1996)

- Commission Communication : European capital markets for small and medium-sized enterprises – prospects and potential obstacles to progress
(COM (97) 187 final, 05.05.1997)
- Commission Communication on promoting the role of voluntary organisations and foundations in Europe
(COM (97) 241 final, 06.06.1997)
- Commission Communication on the impact of the introduction of the Euro on capital markets
(COM (97) 337 final, 02.07.1997)
- Commission Communication – Report on late payments in commercial transactions
(OJ C 216, 17.07.1997)
- Commission Communication – Participation of European Economic Interest Groupings (EEIGs) in public contracts and programmes financed by public funds
(COM (97) 434 final, 09.09.1997)
- Report from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the co-ordination of activities to assist small and medium-sized enterprises (SMEs) and the craft sector
(COM (97) 610 final, 25.11.1997)
- Commission Communication on the transfer of small and medium-sized enterprises
(OJ C 93, 28.03.1998)
- Commission Communication – Fostering entrepreneurship in Europe: priorities for the future
(COM (98) 222 final, 07.04.1998)
- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Promoting entrepreneurship and competitiveness – the Commission’s response to the BEST Task Force Report and its Recommendations
(COM (98) 550 final, 30.09.1998)
- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions –

Enhancing tourism's potential for employment – follow-up to the conclusions and recommendations of the High Level Group on Tourism and Employment

(COM (99) 205 final, 28.04.1999)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the implementation of measures to combat child sex tourism

(COM (99) 262 final, 26.05.1999)

- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions - Report on the evaluation of the 3rd Multiannual Programme for SMEs in the European Union (1997-2000)

(COM (99) 319 final, 29.06.1999)

- Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on concerted actions with the Member States in the fields of enterprise policy

(COM (99) 569 final, 09.11.1999)

- Communication from the Commission - Challenges for enterprise policy in the knowledge-driven economy - Proposal for a Council Decision on a multiannual Programme for Enterprise and Entrepreneurship (2001 – 2005)

(COM (2000) 256 final, 26.04.2000)

- Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Creating an entrepreneurial Europe: The activities of the European Union for small and medium-sized enterprises (SMEs)

(COM (2001) 98 final, 01.03.2001)

- Report from the Commission – European Charter for Small Enterprises – Annual Implementation Report

(COM (2001) 122 final, 07.03.2001)

- Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions – Helping SMEs to “Go Digital”

(COM(2001) 136 final, 13.03.2001)

- Communication from the Commission to the Council and the European Parliament – Sustaining the commitments, increasing the pace
(COM(2001) 641 final, 08.11.2001)
- Commission Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions – Working together for the future of European tourism
(COM(2001) 665 final, 13.11.2001)
- Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions – Follow-up of the European Council of 21 September: the situation in the European tourism sector
(COM (2001) 668 final, 13.11.2001)
- Communication from the Commission to the Council and the European Parliament – The impact of the E-economy on European enterprises: economic analysis and policy implications
(COM(2001) 711 final, 29.11.2001)
- Report from the Commission to the Council and the European Parliament – Report on the implementation of the European Charter for Small Enterprises
(COM(2002)68 final, 06.02.2002)
- Report from the Commission to the European Parliament and the Council – Growth and Employment Initiative – Measures on financial assistance for innovative and job creating Small and Medium-Sized Enterprises (SMEs) – As at 31 December 2001.
(COM(2002) 345 final, 01.07.2002)
- Communication from the Commission to the Council and the European Parliament – Better Environment for Enterprises
(COM(2002) 610 final, 07.11.2002)
- Commission Communication to the Council and the European Parliament – Thinking small in an enlarging Europe
(COM (2003) 26 final, 21.01.2003)
- Report from the Commission to the Council and the European Parliament on the implementation of the European Charter for Small Enterprises
(COM (2003) 21 final, 13.02.2003)

- Commission Communication – Model declaration on the information relating to the qualification of an enterprise as an SME
(OJ C 118, 20.05.2003) (Corrigendum OJ C 156, 04.07.2003)
- Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions – Basic orientations for the sustainability of European Tourism
(COM(2003) 716 final, 21.11.2003)
- Communication from the Commission to the Council and the European Parliament – Access to finance of small and medium-sized enterprises.
(COM(2003) 713 final, 1.12.2003)
- Report from the Commission to the European Parliament and the Council – Growth and Employment Initiative – Measures on financial assistance for innovative and job creating Small and Medium-Sized Enterprises (SMEs) – As at 29 May 2002.
(COM(2003) 758 final-1, 8.12.2003)
- Report from the Commission to the Council and the European Parliament on the implementation of the European Charter for Small Enterprises
(COM(2004) 64 final, 11.02.2004)
- Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of Regions – Action Plan: the European Agenda for Entrepreneurship
(COM(2004) 70 final, 11.02.2004)
- Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of Regions on the promotion of co-operative societies in Europe
(COM(2004) 18 final, 23.02.2004)

11.3.3. COMMISSION STAFF WORKING PAPERS

- Commission staff working paper - Towards Enterprise Europe: Work programme for enterprise policy 2000 – 2005
(SEC(2000) 771 final – 08.05. 2000)

- Commission staff working paper – Summary of Results of Best Practice-related Activities in the field of Enterprise Policy
(SEC(2000) 1824 final – 26.10.2000)
- Commission staff working paper – Report on the Implementation of the Action Plan to Promote Entrepreneurship and Competitiveness
(SEC(2000) 1825 final – 27.10.2000)
- Commission staff working paper – Benchmarking Enterprise Policy. First results from the scoreboard
(SEC(2000) 1841 final – 27.10.2000)
- Commission staff working paper – European Competitiveness Report 2000
(SEC(2000) 1823 final – 30.10. 2000)
- Commission staff working paper – Better, but not yet the Best: Enterprise policy action to improve Europe’s competitiveness
(SEC(2000) 1924 final – 09.11.2000)
- Commission staff working paper – Enterprises' access to finance
(SEC(2001) 1667 – 19.10.2001)
- Commission staff working paper – 2001 Best Procedure Report
(SEC(2001) 1704 – 29.10.2001)
- Commission staff working paper – European Competitiveness Report 2001
(SEC(2001) 1705 – 29.10.2001)
- Commission staff working paper – Creating top-class business support services
(SEC(2001) 1937 – 28.11.2001)
- Commission staff working paper – Report on the Candidate Countries’ Measures to Promote Entrepreneurship and Competitiveness
(SEC(2001) 2054 – 20.12.2001)
- Commission staff working paper – Report on Community measures affecting tourism (2000)
(SEC(2002) 300, 15.03.2002)

- Commission staff working paper – Go Digital Progress Report 2001-2002
(*SEC(2002) 566 – 13.05.2002*)
- Commission staff working paper – 2002 European Competitiveness Report
(*SEC(2002) 528 – 21.05.2002*)
- Commission staff working paper – Highlights of the results of the Best procedure projects 2001 - 2002
(*SEC(2002) 1212 – 07.11.2002*)
- Commission staff working paper – Benchmarking Enterprise Policy: Results from the 2002 Scoreboard
(*SEC(2002) 1213 – 07.11.2002*)
- Commission staff working paper – Quantitative Targets in Enterprise Policy – Steps towards the Lisbon Objectives
(*SEC(2002) 1214 – 07.11.2002*)
- Commission staff working paper – on B2B Internet trading platforms: Opportunities and barriers for SMEs – A first assessment.
(*SEC(2002) 1217 – 11.11.2002*)
- Commission staff working paper – Report on the implementation of the European Charter for Small Enterprises in the candidate countries for the accession to the European Union
(*SEC(2003) 57 – 21.01.2003*)
- Commission staff working paper – Creating an entrepreneurial Europe – The activities of the European Union for small and medium-sized enterprises (SMEs)
(*SEC(2003) 58 – 21.01.2003*)
- Commission staff working paper – The SME Envoy: an active interface between the Commission and the SME Community
(*SEC(2003) 60 – 21.01.2003*)
- Commission staff working paper – Communication on basic orientations for the sustainability of European tourism – Extended impact assessment
(*SEC(2003) 1295 final, 21.11.2003*)
- Commission staff working paper – Report on Community measures affecting tourism (2001-2002)

(SEC(2004) 24, 07.01.2004)

- Commission staff working paper – Report on the implementation of the European Charter for Small Enterprises in the countries of the Western Balkans

(SEC(2004) 149, 11.02.2004)

- Commission staff working paper – Report on the implementation of the European Charter for Small Enterprises in acceding and candidate countries

(SEC(2004) 187, 12.02.2004)

- Commission staff working paper – Code of conduct between credit institutions and SMEs

(SEC(2004) 484, 23.04.2004)

12. TELECOMMUNICATIONS

Outline:

12.1. Structure

12.2. Enumeration of the legislation

12.3. Other measures relating to telecommunications

12.1. STRUCTURE

There is one single Community directive in the field of telecommunications, which directly relates to products, namely to radio and telecommunication terminal equipment. This directive is a New Approach Directive, under which harmonised standards have been developed.

Six Commission Decisions have further been adopted under this Directive:

Telecommunications
Directive 1999/5/EC (7 implementing measures)

12.2. ENUMERATION OF THE LEGISLATION

European Parliament and Council Directive 1999/5/EC on the approximation of the laws of the Member States on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity

Implementing measures:

1) Commission Decision 2000/299/EC establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers

2) Commission Decision 2000/373/EC concerning the request by France to maintain pursuant to Article 18(3) of Directive 1999/5/EC of the European Parliament and of the Council (the 'R&TTE Directive') a requirement for telecommunications terminal equipment intended for connection to the analogue public switched telephone network of France Telecom

3) Commission Decision 2000/637/EC on the application of Article 3(3)(e) of Directive 1999/5/EC to radio equipment covered by the regional arrangement concerning the radiotelephone service on inland waterways

4) Commission Decision 2000/638/EC on the application of Article 3(3)(e) of Directive 1999/5/EC to marine radio communication equipment intended to be fitted to seagoing non-SOLAS vessels and which is intended to participate in the global maritime distress and safety system (GMDSS) and not covered by Council Directive 96/98/EC on marine equipment

5) Commission Decision 2001/148/EC on the application of Article 3(3)(e) of Directive 1999/5/EC to avalanche beacons

6) Commission Decision of 4 September 2003 on essential requirements relating to marine radio communication equipment which is intended to be used on non-SOLAS vessels and to participate in the Global Maritime Distress and Safety System (GMDSS) (notified under document number C(2003) 2912 and repealing Decision 2000/638/EC)

7) Commission Decision 2005/53/EC of 25 January 2005 on the application of Article 3(3)(e) of Directive 1999/5/EC of the European Parliament and of the Council to radio equipment intended to participate in the Automatic Identification System (AIS)

8) Commission Decision 2005/631/EC of 29 August 2005 concerning essential requirements as referred to in Directive 1999/5/EC of the European Parliament and of the Council ensuring access of Cospas-Sarsat locator beacons to emergency services

12.3. OTHER MEASURES RELATING TO TELECOMMUNICATIONS

- Council Recommendation 84/549/EEC concerning the implementation of harmonisation in the field of telecommunications

(OJ L 298, 16.11.1984)

- Council Resolution of 27 April 1989 on standardisation in the field of information technology and telecommunications

(OJ C 117, 11.05.1989)

- Commission Communication in the framework of the implementation of the Council Directive 1999/5/EC: Publication of titles and references of harmonized standards under the Directive

C 201, 24.8.2006, p. 1-30 (<http://ec.europa.eu/enterprise/rtte/harstand.htm>)

13. PROCESSED AGRICULTURAL PRODUCTS

Outline:

13.1. Structure

13.2. Enumeration of the legislation concerning the trade arrangements for Processed Agricultural Products

13.2.1 Importation trade arrangements

13.2.1.1 Methods of analysis

13.2.1.2 Special IPR arrangements

13.2.1.3 Preferential trade arrangements

13.2.2 Export refunds

13.2.2.1 System for Granting Refunds

13.2.2.2 Methods of analysis

13.2.2.3 Special rules for pasta

13.1. STRUCTURE

Community legislation governing the trade regime for Non Annex 1 goods (commonly referred to as Processed Agricultural Products – PAPs) devolves primarily from Council Regulation (EC) No 3448/93 of 6 December 1993 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products.

The legislation may be subdivided into two headings:

1. *Trade arrangements governing the **import** of Processed Agricultural Products from third countries*
2. *Rules governing the payment of **export refunds** on exports of Processed Agricultural Products to third countries*

The Enterprise DG is responsible for all legislation deriving from Council Regulation (EC) No 3448/93 and governing trade in goods not covered by Annex I to the Treaty but listed in Annex B of Council Regulation (EC) No 3448/93

Trade arrangement for Processed Agricultural Products

Import trade arrangements

Methods of analysis
Special IPR arrangements
Preferential trade
Determination of quantities

Export Refunds

System for Granting Refunds
Methods of analysis
Special rules for pasta

13.2. ENUMERATION OF THE LEGISLATION CONCERNING THE TRADE ARRANGEMENTS FOR PROCESSED AGRICULTURAL PRODUCTS

Council Regulation (EC) No 3448/93 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products, amended by:
Council Regulation (EC) No **1097/98**
Commission Regulation (EC) No **2491/98**
Council Regulation (EC) No **2580/2000**

13.2.1. IMPORTATION TRADE ARRANGEMENTS

Commission Regulation (EC) No 1460/96 establishing the detailed rules for implementing the preferential trade arrangements applicable to certain goods resulting from the processing of agricultural products, as provided for in Article 7 of Council Regulation (EC) No 3448/93, amended by:
1) Commission Regulation (EC) No **2495/97**
2) Commission Regulation (EC) No **1473/2000** laying down the reduced agricultural components and additional duties applicable from 1 July 2000 to the importation into the Community of goods covered by Council Regulation (EC) No 3448/93 under Europe Agreements
3) Commission Regulation (EC) No **1477/2000** laying down the reduced agricultural components and additional duties applicable from 1 July 2000 to the importation into the Community of goods covered by Council Regulation (EC) No 3448/93 under Europe Agreements

13.2.1.1. Methods of analysis (imports)

Commission Regulation (EC) No 900/2008 laying down the methods of analysis and other technical provisions necessary for the implementation of Council Regulation (EEC) No 3448/93 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products.

13.2.1.2. Special inward processing arrangements

1) Commission Regulation (EC) No 1488/2001 laying down rules for the application of Council Regulation (EC) No 3448/93 as regards the placement of certain quantities of certain basic products listed in Annex I to the Treaty establishing the European Community under the inward processing arrangements without prior examination of the economic conditions, amended by:
Commission Regulation (EC) No **1914/2003**
Commission Regulation (EC) No **886/2004**
Commission Regulation (EC) No **1792/2006**

13.2.1.3. Preferential trade agreements

The Enterprise DG negotiates the processed agricultural products chapters of the various trade arrangements entered into by the EU with its international trading partners. The following listing includes only those agreements where Council Regulation 3448/93 was the primary basis for negotiation. Consequently, other

agreements (e.g. Stabilisation and Association Agreements, Swiss Confederation, Med. Agreements, South Africa, GCC, Mexico, Mercosur, etc.) which include trade arrangements for Processed Agricultural Products negotiated by the Enterprise DG, are not included in the listing below

EEA:

1) Commission Regulation (EC) No 634/2008 of 4 July 2008 fixing the agricultural components and additional duties applicable from 1 February 2008 on the importation into the Community of certain goods containing milk products covered by Council Regulation (EC) No 3448/93 from Switzerland

2) Commission Regulation (EC) No 861/2008 of 2 September 2008 repealing Regulation (EC) No 634/2008 laying down the reduced agricultural components and the additional duties applicable to imports into the Community of certain goods containing milk products covered by Council Regulation (EC) No 3448/93 from Switzerland

3) Commission Regulation (EC) No 1686/2002 fixing the agricultural components and additional duties applicable from 1 January 2002 on the importation into the Community of certain goods covered by Council Regulation (EC) No 3448/93 from Iceland and from Norway

4) Commission Regulation (EC) No 52/2008 of 22 January 2008 opening for the year 2008 and the following years a tariff quota applicable to the importation into the European Community of certain goods originating in Iceland resulting from the processing of agricultural products covered by Council Regulation (EC) No 3448/93

5) Commission Regulation (EC) No 66/2008 of 25 January 2008 opening a yearly tariff quota for 2008 and the following years applicable to the importation into the European Community of certain goods originating in Norway resulting from the processing of agricultural products covered by Council Regulation (EC) No 3448/93

6) Commission Regulation (EC) No 65/2008 of 25 January 2008 opening tariff quotas for 2008 and for the following years for imports into the European Community of certain goods originating in Norway resulting from the processing of agricultural products covered by Council Regulation (EC) No 3448/93

7) Commission Regulation (EC) No 93/2008 of 31 January 2008 on the withdrawal of a temporary suspension of the duty free regime for the year 2008 for the importation into the Community of certain goods originating in Norway resulting from the processing of agricultural products covered by Council Regulation (EC) No 3448/93

8) Commission Regulation (EC) No 89/2009 of 28 January 2009 opening the tariff quota for the year 2009 for the importation into the European Community of certain goods originating in Norway resulting from the processing of agricultural products covered by Council Regulation (EC) No 3448/93

Other countries:

1) Commission Regulation (EC) No 1474/2000, as last amended by Commission Regulation (EC) No 1792/2006, determining the reduced amounts

of agricultural components and additional duties applicable from 1 July 2000 to imports into the Community of certain goods covered by Council Regulation (EC) No 3448/93 under an Interim Agreement between the European Union and Israel

2) Commission Regulation (EC) No 2276/2003 of 22 December 2003 opening tariff quotas and laying down the duties applicable within these tariff quotas for imports into the European Community of certain processed agricultural products originating in Egypt

3) Commission Regulation (EC) No 1653/2005 of 10 October 2005 opening tariff quotas and laying down the duties applicable within these tariff quotas for imports into the European Community of certain processed agricultural products originating in Algeria

4) Commission Regulation (EC) No 816/2006 of 12 July 2007 opening annual tariff quotas for the importation from Turkey of certain goods resulting from the processing of agricultural products covered by Council Regulation (EC) No 3448/93

All countries:

1) Commission Regulation (EC) No 1518/2007 of 19 December 2007 opening and providing for the administration of a tariff quota for vermouth

13.2.2. EXPORT REFUND

1) Commission Regulation (EC) No 1043/2005 of 30 June 2005 implementing Council Regulation (EC) No 3448/93 as regards the system of granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds *as amended by:*

Commission Regulation (EC) No 322/2006

Commission Regulation (EC) No 544/2006

Commission Regulation (EC) No 1580/2006

Commission Regulation (EC) No 1713/2006

Commission Regulation (EC) No 1792/2006

Commission Regulation (EC) No 447/2007

Commission Regulation (EC) No 1496/2007

Commission Regulation (EC) No 246/2008

Commission Regulation (EC) No 639/2008

Commission Regulation (EC) No 1237/2008

2) Commission Regulation (EC) No 585/2009 of 7 July providing for exceptional measures regarding refund certificates for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty

Derogations:

1) Commission Regulation (EC) No 1713/2004 of 30 September 2004 laying down derogations from Regulation (EC) No 800/1999 as regards products in the form of goods not covered by Annex I to the Treaty exported to third countries other than Bulgaria

2) Commission Regulation (EC) No 284/2005 of 18 February 2005 laying down derogations from Regulation (EC) No 800/1999 as regards products in the form of goods not covered by Annex I to the Treaty exported to third countries other than Switzerland and Liechtenstein

3) Commission Regulation (EC) No 2124/2005 of 22 December 2005 laying down derogations from Regulation (EC) No 800/1999 as regards products in the form of goods not covered by Annex I to the Treaty exported to third countries other than Romania

4) Commission Regulation (EC) No 1370/2006 of 15 September 2006 derogating from Regulations (EC) No 800/1999 and (EC) No 1043/2005 as regards products exported to Lebanon in the form of goods not covered by Annex I to the Treaty.

Transitory Measures:

1) Commission Regulation (EC) No 1712/2004 of 30 September 2004 laying down transitory measures arising from the adoption of autonomous and transitional measures concerning the export of certain processed agricultural products to Bulgaria

2) Commission Regulation (EC) No 285/2005 of 18 February 2005 laying down transitory measures arising from the adoption of improved trade arrangements concerning the export of certain processed agricultural products to Switzerland and Liechtenstein

3) Commission Regulation (EC) No 2125/2005 of 22 December 2005 laying down transitory measures arising from the adoption of improved trade arrangements concerning the export of certain processed agricultural products to Romania

4) Commission Regulation (EC) No 288/2007 of 16 March 2007 laying down transitional measures to be adopted on account of the accession of Bulgaria and Romania in respect of the requirements for the granting of export refunds on certain milk and egg products pursuant to Regulation (EC) No 1443/2005

13.2.2.1. Methods of analysis (Exports)

Commission Regulation (EC) No 904/2008 laying down the methods of analysis and other technical provisions necessary for the implementation of Council Regulation (EC) No 1043/2005 laying down general rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex II to the Treaty, and the criteria for fixing the amount of such refunds.

13.2.2.2. Special export refunds rules for pasta

Commission Regulation (EEC) No 2723/87 laying down special detailed rules for the application of the system of export refunds on cereals exported in the form of pasta products falling within heading No 19.03 of the Common Customs Tariff, amended by:

Commission Regulation (EEC) No 3859/87

Commission Regulation (EEC) No 1054/95

Commission Regulation (EC) No 1713/2006

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