ENTERPRISE DIRECTORATE- GENERAL

# THE ACQUIS OF THE EUROPEAN UNION UNDER THE MANAGEMENT OF THE ENTERPRISE DG

#### LIST OF MEASURES



## THE ACQUIS OF THE EUROPEAN UNION UNDER THE MANAGEMENT OF DG ENTERPRISE

LIST OF MEASURES (the "Pink Book")

31 December 2001

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#### Preface

This structural list of the *acquis* sets out the references of existing Community legislation and other measures which are under the management of DG Enterprise. It includes both 'hard' law, by which is meant that which creates legal obligations; and 'soft' law, by which is meant those measures which, while not in themselves creating legal obligations, have a bearing on the application of hard law.

This list of the acquis 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 be made clearer.

The list of the *acquis* has been organised under chapter headings, which broadly reflect industrial sectors and the internal organisation of DG Enterprise. As of 2001, this list also includes the measures relating to processed agricultural products which are managed by DG Enterprise. In the context of enlargement negotiations, the list, therefore, corresponds to four negotiating chapters of the EU *acquis*: Chapter 1 - Free movement of goods (DG Enterprise part), Chapter 7 - Agriculture (DG Enterprise part), Chapter 15 - Industrial policy and Chapter 16 - Small and medium-sized undertakings (SMEs).

This edition is a follow-up and a review of the fourth edition from 31 December 2000. It includes all new measures adopted between that date and 31 December 2001.

This document has been elaborated by Directorate General Enterprise, unit G/1.

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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

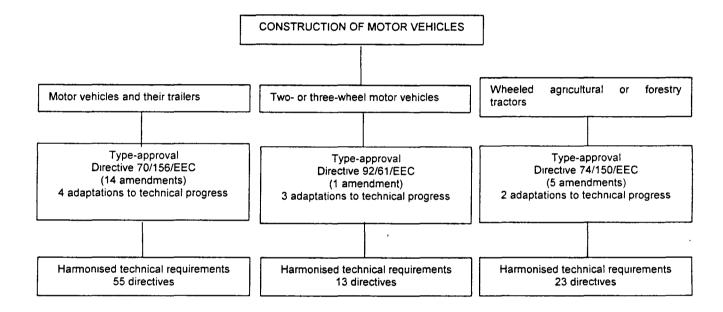
#### 1.1. STRUCTURE

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.\*)



#### **Summary:**

#### Construction of motor vehicles

Motor vehicles and their trailers	56	
Two- or three-wheeled motor vehicles	14	
Wheeled agricultural or forestry tractors	24	
Total	94	

Total: 94

\*) 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

Council Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers, amended by:

Council Directive 78/315/EEC

Council Directive 78/547/EEC

Council Directive 80/1267/EEC

Council Directive 87/358/EEC

Council Directive 87/403/EEC

Council Directive 92/53/EEC

Commission Directive 95/54/EC

European Parliament and Council Directive 96/27/EC

European Parliament and Council Directive 96/79/EC

European Parliament and Council Directive 97/27/EC

European Parliament and Council Directive 98/91/EC

European Parliament and Council Directive 2000/40/EC

European Parliament and Council Directive 2001/56/EC

European Parliament and Council Directive 2001/85/EC

#### Adaptations to technical progress:

Commission Directive 93/81/EEC

Commission Directive 98/14/EC

Commission Directive 2001/92/EC

Commission Directive 2001/116/EC

### 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

### 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 relating to measures to be taken against air pollution by gases from positive-ignition of 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

### 1.2.1.4. Liquid fuel tanks and rear protective devices for 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 protective devices for 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

### 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

#### 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

#### 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

#### 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

#### 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

### 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

### 1.2.1.11. Suppression of radio interference produced by spark-ignition engines fitted to motor vehicles

Council Directive 72/245/EEC on the approximation of the laws of the Member States relating to the suppression of radio interference produced by sparkignition engines fitted to motor vehicles

#### Adaptations to technical progress:

Commission Directive 89/491/EEC

Commission Directive 95/54/EC

### 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

1.2.1.13. Interior fittings of motor vehicles (interior parts of the passenger compartment other than the interior rear-view mirrors, layout of controls, the roof or sliding roof, the backrest and rear part of seats)

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

#### 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

### 1.2.1.15. Interior fittings of motor vehicles (the behaviour of the steering mechanism in the event of an impact)

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

### 1.2.1.16. Interior fittings of motor vehicles (strength of seats and of their anchorages)

Council Directive 74/408/EEC on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles, amended by:

Council Directive 81/577/EEC

Adaptation to technical progress:

Commission Directive 96/37/EC

#### 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

#### 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

### 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

#### 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

Adaptations to technical progress:

Commission Directive 82/318/EEC

Commission Directive 90/629/EEC

Commission Directive 96/38/EC

### 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

#### 1.2.1.22. Reflex reflectors for motor vehicles and their trailers

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

Council Directive 87/354/EEC

Adaptation to technical progress:

Commission Directive 97/29/EC

1.2.1.23. End-outline marker lamps, front position (side) lamps, rear position (side) lamps and stop 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 and stop 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

### 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

### 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

## 1.2.1.26. Motor vehicle headlamps which function as main-beam and/or dipped-beam headlamps and incandescent electric filament lamps for such headlamps

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 incandescent electric filament lamps for such headlamps, amended by:

Council Directive 87/354/EEC

Adaptation to technical progress:

Commission Directive 89/517/EEC

Commission Directive 1999/17/EC

### 1.2.1.27. Front fog lamps for motor vehicles and filament lamps for such lamps

Council Directive 76/762/EEC on the approximation of the laws of the Member States relating to front fog lamps for motor vehicles and filament lamps for such lamps, amended by:

Council Directive 87/354/EEC

Adaptation to technical progress

Commission Directive 1999/18/EC

#### 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

#### 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

#### 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

#### 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

#### 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

#### Adaptations to technical progress:

Commission Directive 82/319/EEC

Commission Directive 90/628/EEC

Commission Directive 96/36/EC

Commission Directive 2000/3/EC

#### 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

### 1.2.1.34. Interior fittings of motor vehicles (identification of controls, tell-tales and indicators)

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)

### 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

#### 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

#### 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 (This directive has repealed Directive 78/548/EEC relating to heating systems for the passenger compartment of motor vehicles)

#### 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

#### 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

#### 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

#### Adaptations to technical progress:

Commission Directive 89/491/EEC

Commission Directive 93/116/EEC

Commission Directive 1999/100/EC

#### 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

### 1.2.1.42. Measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles

Council Directive 88/77/EEC on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles, amended by:

Council Directive 91/542/EEC

European Parliament and Council Directive 96/1/EC

European Parliament and Council Directive 1999/96/EC

Adaptation to technical progress:

Commission Directive 2001/27/EC

### 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

### 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

#### 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

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

1.2.1.47. Tyres for motor vehicles and their trailers and to 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

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

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

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

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

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

### 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

### 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

#### 1.2.1.55. 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

#### 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

#### 1.2.2. TWO- OR THREE-WHEEL MOTOR VEHICLES

#### 1.2.2.1. Type approval

Council Directive 92/61/EEC on the type-approval of two- or three-wheel motor vehicles, amended by:

European Parliament and Council Directive 2000/7/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

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

Council Directive 93/29/EEC on identification of controls, tell-tales and indicators for two- or three-wheel motor vehicles

Adaptation to technical progress

Commission Directive 2000/74/EC

#### 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

Council Directive 93/31/EEC on stands for two- or three-wheel motor vehicles Adaptation to technical progress

Commission Directive 2000/72/EC

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

Council Directive 93/32/EEC on passenger hand-holds on two- or three-wheel motor vehicles

Adaptations to technical progress

Commission Directive 1999/24/EC

Commission Directive 2000/73/EC

### 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

Council Directive 93/34/EEC on statutory markings for two- or three-wheel motor vehicles

Adaptation to technical progress

Commission Directive 1999/25/EC

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

Council Directive 93/92/EEC on the installation of lighting and light-signalling devices on two- or three-wheel motor vehicles

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

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

Council Directive 93/94/EEC relating to the space for mounting rear registration plate of two- or three-wheel motor vehicles

Adaptation to technical progress

Commission Directive 1999/26/EC

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

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

European Parliament and Council Directive 97/24/EC on certain components and characteristics of two- or three-wheel motor vehicles

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

#### 1.2.3. WHEELED AGRICULTURAL OR FORESTRY TRACTORS

#### 1.2.3.1. Type approval

Council Directive 74/150/EEC on the approximation of the laws of the Member States relating to the type-approval of wheeled agricultural or forestry tractors, amended by:

Council Directive 79/694/EEC

Council Directive 82/890/EEC

Council Directive 88/297/EEC

European Parliament and Council Directive 97/54/EC

European Parliament and Council Directive 2000/25/EC

Adaptations to technical progress:

Commission Directive 2000/2/EC

Commission Directive 2001/3/EC

## 1.2.3.2. Certain parts and characteristics (maximum permissible laden mass, position and mounting of rear registration plate, liquid fuel tanks, ballast weights, audible warning devices, permissible sound level, exhaust system)

Council Directive 74/151/EEC on the approximation of the laws of the Member States relating to certain parts and characteristics of wheeled agricultural or forestry tractors, amended by:

Council Directive 82/890/EEC

European Parliament and Council Directive 97/54/EC

Adaptations to technical progress:

Commission Directive 88/410/EEC

Commission Directive 98/38/EC

#### 1.2.3.3. Maximum design speed and load platforms

Council Directive 74/152/EEC on the approximation of the laws of the Member States relating to the maximum design speed of and load platforms for wheeled agricultural or forestry tractors, amended by:

Council Directive 82/890/EEC

European Parliament and Council Directive 97/54/EC

Adaptations to technical progress:

Commission Directive 88/412/EEC

Commission Directive 98/89/EC

#### 1.2.3.4. Rear-view mirrors

Council Directive 74/346/EEC on the approximation of the laws of the Member States relating to rear view mirrors 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 98/40/EC

#### 1.2.3.5. Field of vision and windscreen wipers

Council Directive 74/347/EEC on the approximation of the laws of the Member States relating to the field of vision and windscreen wipers 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 79/1073/EEC

#### 1.2.3.6. Steering equipment

Council Directive 75/321/EEC on the approximation of the laws of the Member States relating to the steering equipment of wheeled agricultural or forestry tractors, amended by:

Council Directive 82/890/EEC

European Parliament and Council Directive 97/54/EC

Adaptations to technical progress:

Commission Directive 88/411/EEC

Commission Directive 98/39/EC

### 1.2.3.7. Suppression of radio interference produced by spark-ignition engines

Council Directive 75/322/EEC on the approximation of the laws of the Member States relating to the suppression of radio interference produced by sparkignition engines fitted to wheeled agricultural or forestry tractors, amended by:

Council Directive 82/890/EEC

European Parliament and Council Directive 97/54/EC

Adaptations to technical progress:

Commission Directive 2000/2/EC

Commission Directive 2001/3/EC

#### 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

Council Directive 77/311/EEC on the approximation of the laws of the Member States relating to the driver perceived noise level of wheeled agricultural or forestry tractors, amended by:

Council Directive 82/890/EEC

European Parliament and Council Directive 97/54/EC

Implementing measure:

Commission Decision 96/627/EC implementing Article 2 of Council Directive 77/311/EEC on the approximation of the laws of the Member States relating to the driver perceived noise level of wheeled agricultural or forestry tractors, amended by:

Commission Decision 2000/63/EC (notified under document number C(1999) 3546)

#### 1.2.3.11. Roll-over protection structures

Council Directive 77/536/EEC on the approximation of the laws of the Member States relating to the roll-over protection structures of wheeled agricultural or forestry tractors, amended by:

Council Directive 87/354/EEC

Council Directive 89/680/EEC

Adaptation to technical progress

Commission Directive 1999/55/EC

### 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

Council Directive 78/933/EEC on the approximation of the laws of the Member States relating to the installation of lighting and light-signalling devices on 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 1999/56/EC

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

Council Directive 79/532/EEC on the approximation of the laws of the Member States relating to the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors, amended by:

Council Directive 82/890/EEC

European Parliament and Council Directive 97/54/EC

#### 1.2.3.16. Coupling device and the reverse

Council Directive 79/533/EEC on the approximation of the laws of the Member States relating to the coupling device and the reverse 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 1999/58/EC

#### 1.2.3.17. Roll-over protection structures (static testing)

Council Directive 79/622/EEC on the approximation of the laws of the Member States relating to the roll-over protection structures of wheeled agricultural or forestry tractors, amended by:

Council Directive 87/354/EEC

Adaptations to technical progress:

Commission Directive 82/953/EEC

Commission Directive 88/413/EEC

Commission Directive 1999/40/EC

### 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

1.2.3.21. Installation, location operation and identification of the

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

1.2.3.23. Certain components and characteristics (dimensions and towable masses; speed governers and protection of drive components, projections and wheels; windscreens and other glazing; mechanical coupling; location and method of affixing statutory plates and inscriptions to the body of the tractor; brake control for towed vehicles)

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

### 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

#### 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)

#### 2. CHEMICALS

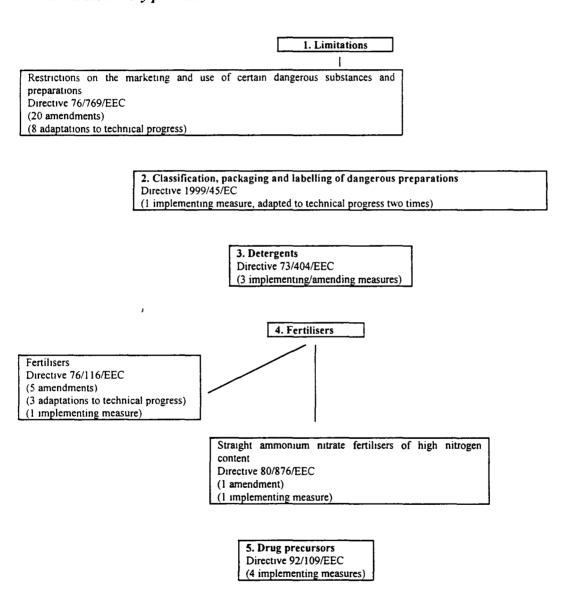
#### Outline:

- 2.1. Structure
- 2.2. Enumeration of the legislation
  - 2.2.1. Limitations
    - 2.2.1.1. Restrictions on the marketing and use of certain dangerous substances and preparations
  - 2.2.2. Classification, packaging and labelling
    - 2.2.2.1. Classification, packaging and labelling of dangerous preparations
    - 2.2.2.2. Classification, packaging and labelling of pesticides
  - 2.2.3. Detergents
  - 2.2.4. Fertilisers
    - 2.2.4.1. Fertilisers
    - 2.2.4.2. Straight ammonium nitrate fertilisers of high nitrogen content
  - 2.2.5. Drug precursors
  - 2.2.6. Explosives for civil uses
  - 2.2.7. Good laboratory practice
    - 2.2.7.1. Application of principles of Good Laboratory Practice and verification for tests on chemical substances
    - 2.2.7.2. Inspection and verification of Good Laboratory Practice
- 2.3. Other measures relating to chemicals

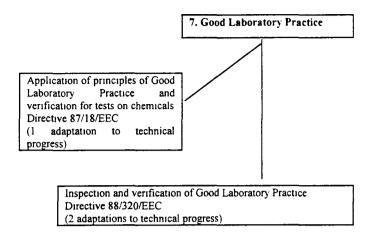
#### 2.1. STRUCTURE

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

- 1. Limitations
- 2. Classification, packaging and labelling
- 3. Detergents
- 4. Fertilisers
- 5. Drug precursors
- 6. Explosives for civil uses
- 7. Good laboratory practice



6. Explosives for civil uses Directive 93/15/EEC



#### **Conclusion:**

Limitations	1	
Classification, packaging and labelling	1_	
Detergents	1	
Fertilisers	2	
Drug precursors	1	
Explosives for civil uses	1	
Good Laboratory Practice	2	
Total	9	

Total: 9

#### 2.2. ENUMERATION OF THE LEGISLATION

#### 2.2.1. LIMITATIONS

### 2.2.1.1. 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

#### 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 1999/51/EC

Commission Directive 1999/77/EC

Commission Directive 2001/90/EC

Commission Directive 2001/91/EC

### 2.2.2. CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS PREPARATIONS

### 2.2.2.1. 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 has repealed directive 78/631/EEC, as amended by directives 79/831/EEC, 81/187/EEC and 92/32/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)

#### Adaptation to technical progress:

Commission Directive 2001/60/EC

#### Implementing measure:

1) Commission Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Art. 10 of Directive 88/379/EEC, amended by:

Commission Directive 93/112/EEC Commission Directive 2001/58/EC

#### 2.2.3. DETERGENTS

Council Directive 73/404/EEC on the approximation of the laws of the Member States relating to detergents

#### Implementing/amending measures:

1) Council Directive 73/405/EEC on the approximation of the Member States relating to the methods of testing the biodegradability of anionic surfactants, amended by:

Council directive 82/243/EEC

- 2) Council Directive 82/242/EEC on the approximation of the laws of the Member States relating to methods of testing the biodegradability of non-ionic surfactants and amending Directive 73/404/EEC
- 3) Council Directive 86/94/EEC amending for the second time Directive 73/404/EEC on the approximation of the laws of the Member States relating to detergents

#### 2.2.4. FERTILISERS

#### 2.2.4.1. Fertilisers

Council Directive 76/116/EEC on the approximation of the laws of the Member States relating to fertilisers, amended by:

Council Directive 88/183/EEC

Council Directive 89/284/EEC

Council Directive 89/530/EEC

European Parliament and Council Directive 97/63/EC

European Parliament and Council Directive 98/97/EC

#### Adaptations to technical progress:

Commission Directive 93/69/EEC

Commission Directive 96/28/EC

Commission Directive 98/3/EC

#### Implementing measure:

Commission Directive 77/535/EEC on the approximation of the laws of the Member States relating to methods of sampling and analysis of fertilisers, amended by:

Commission Directive 79/138/EEC

Commission Directive 87/566/EEC

Commission Directive 89/519/EEC

Commission Directive 93/1/EEC

Commission Directive 95/8/EC

#### 2.2.4.2. Straight ammonium nitrate fertilisers of high nitrogen content

Council Directive 80/876/EEC on the approximation of the laws of the Member States relating to straight ammonium nitrate fertilisers of high nitrogen content, amended by:

European Parliament and Council Directive 97/63/EC

#### Implementing measure:

Commission Directive 87/94/EEC on the approximation of the laws of the Member States relating to procedures for the control of characteristics of, limits for and resistance to detonation of straight ammonium nitrate fertilisers of high nitrogen content, amended by:

Commission directive 88/126/EEC

#### 2.2.5. DRUG PRECURSORS

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:

- 1) Commission Directive 93/46/EEC replacing and modifying the Annexes to Council Directive 92/109/EEC and Commission Directive 2001/8/EC replacing Annex 1 to 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
- 2) Commission Regulation n° 1533/2000 amending Regulation (EC) n° 1485/96 laying down detailed rules for the application of Council Directive 92/109/EEC, as regards customer declarations of specific use relating to certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances
- 3) Commission Directive 2001/8/EC replacing Annex 1 to 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

#### 2.2.6. 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

#### 2.2.7. GOOD LABORATORY PRACTICE

### 2.2.7.1. Application of principles of Good Laboratory Practice and verification for tests on chemical substances

Council Directive 87/18/EEC 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 application for tests on chemical substances

Adaptation to technical progress

Commission Directive 1999/11/EC

#### 2.2.7.2. Inspection and verification of Good Laboratory Practice

Council Directive 88/320/EEC on the inspection and verification of Good Laboratory Practice

Adaptation to technical progress:

Commission Directive 90/18/EEC

Commission Directive 1999/12/EC

#### 2.3. OTHER MEASURES RELATING TO CHEMICALS

• Commission Recommendation 89/542/EEC for the labelling of detergents and cleaning products

(OJ L 291, 10.10.1989)

• Guide to the compilation of a technical file on applications to designate fertilisers 'EEC fertiliser' pursuant to Directive 76/116/EEC

(OJ C 138, 20.05.1994, corrected in: OJ C 112, 10.04.1997)

• Commission proposal for a recasting of 18 Directives into one single text in the form of a European and Council Regulation relating to fertilizers

(COM(2001) 508 final, 14.09.2001)

#### 3. PHARMACEUTICALS

#### Outline:

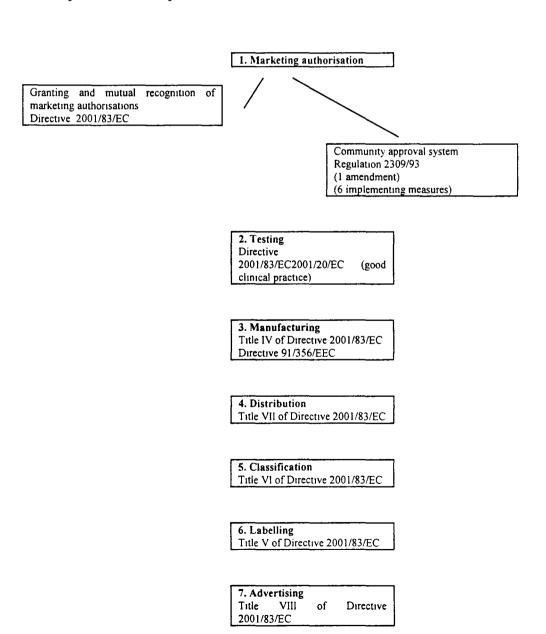
- 3.1. Structure
- 3.2. Enumeration of the legislation
  - 3.2.1. Medicinal products for human use
    - 3.2.1.1. Marketing authorisation
      - 3.2.1.1.1. Granting and mutual recognition of national market authorisations
      - 3.2.1.1.2. Community approval system
    - 3.2.1.2. Testing
    - 3.2.1.3. 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
  - 3.2.2. 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
- 3.3. Other measures relating to pharmaceuticals

#### 3.1. STRUCTURE

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

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



8. Prices and reimbursement
Directive 89/105/EEC

9. Intellectual property

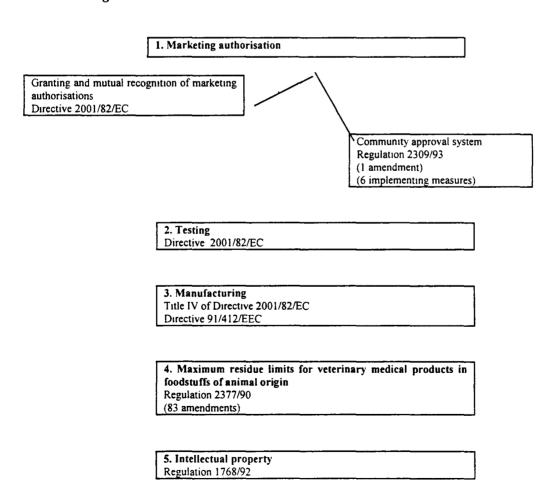
10. Colouring matters Directive 78/25/EEC (1 amendment)

Regulation 1768/92

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

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



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

The Enterprise DG is responsible for most of this legislation.

# **Conclusion:**

# Medicinal products for human use

Marketing authorisation	2
Testing	+1
Manufacturing	+1
Distribution	•
Classification	•
Labelling	-
Advertising	•
Prices and reimbursement	1
Intellectual property	1
Colouring matters	1
Orphan medicinal products	1
Total	8

# Veterinary medicinal products

Marketing authorisation	2
Testing	•
Manufacturing	+1
Maximum residue limits for veterinary medical products in foodstuffs of animal origin	1
Intellectual property	1
Colouring matters	1
Total	6

Total: 141

35

<sup>1 4</sup> legislative acts apply to both medicines for human and veterinary use

#### 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
- 2) Commission Regulation (EC) no 541/95 concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a Member State, amended by:

Council Regulation (EC) nº 1146/98

### 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

#### 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

- 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° 542/95 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) n° 2309/93, amended by:

Commission Regulation (EC) n° 1069/98

- 4) Commission Regulation (EC) no 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
- 5) 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

#### 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

#### 3.2.1.3. Manufacturing

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)

Commission Directive 91/356/EEC laying down the principles and guidelines of good manufacturing practice for 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

# 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

European Parliament and Council Regulation (EC) n° 141/2000 on orphan medicinal products

Commission Regulation (EC) No 847/2000 of 27 April 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'

#### 3.2.2. VETERINARY MEDICINAL PRODUCTS

#### 3.2.2.1. Marketing authorisation

# 3.2.2.1.1. Granting and mutual recognition of national market authorisations

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

#### 3.2.2.1.2. Community approval system

Council Regulation (EEC) no 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

# 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

- 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° 541/95 concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a Member State amended by:

Commission Regulation (EC) nº 1146/98

4) Commission Regulation (EC) n° 542/95 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) n° 2309/93, amended by:

Commission Regulation (EC) n° 1069/98

- 5) Commission Regulation (EC) no 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
- 6) 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

#### 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

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, repealing Directive 91/412/EEC)

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

Council Regulation (EEC) no 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) nº 1140/96 Commission Regulation (EC) nº 1147/96 Commission Regulation (EC) n° 1311/96 Commission Regulation (EC) nº 1312/96 Commission Regulation (EC) nº 1433/96 Commission Regulation (EC) nº 1742/96 Commission Regulation (EC) nº 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) nº 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) nº 1680/2001 Commission Regulation (EC) n° 1815/2001 Commission Regulation (EC) n° 1879/2001 Commission Regulation (EC) n° 2162/2001

### 3.2.2.5. Intellectual property

Council Regulation (EEC) n° 1768/92 concerning the creation of a supplementary protection certificate for medicinal products

#### 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

#### 3.3. OTHER MEASURES RELATING TO PHARMACEUTICALS

- Council Decision 75/320/EEC setting up a pharmaceutical committee (OJL 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) no 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)

# 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 6 times and already adapted to technical progress 25 times. It has 7 implementing directives, which relate to the methods of analysis necessary for checking the composition of cosmetic products and 3 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.

Cosmetic products

Directive 76/768/EEC

(6 amendments)

(25 adaptations to technical progress)

(11 implementing measures)

#### 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

#### 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

# 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

#### 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. Totalizing weighing machines and automatic checkweighing and weight grading machines
      - 5.2.1.4.1. Totalizing weighing machines
      - 5.2.1.4.2. Automatic checkweighing and weight grading machines
    - 5.2.1.5. Water meters
      - 5.2.1.5.1. Cold-water maters
      - 5.2.1.5.2. Hot-water meters
    - 5.2.1.6. Measuring systems for liquids other than water
      - 5.2.1.6.1. Meters for liquids other than water
      - 5.2.1.6.2. Ancillary equipment for meters for liquids other than water
      - 5.2.1.6.3. Measuring systems for liquids other than water
    - 5.2.1.7. Gas meters
    - 5.2.1.8. Electricity meters
    - 5.2.1.9. Material measures of length
    - 5.2.1.10. Alcohol meters, alcohol hydrometers and alcohol tables
      - 5.2.1.10.1. Alcohol meters and alcohol hydrometers
      - 5.2.1.10.2. Alcohol tables
    - 5.2.1.11. Medium and above medium accuracy weights
      - 5.2.1.11.1. 5 to 50 kilogramme medium accuracy rectangular bar weights and 1 gramme to 10 kilogramme medium accuracy cylindrical weights
      - 5.2.1.11.2. 1 milligramme to 50 kilogramme of above medium accuracy weights
    - 5.2.1.12. Taximeters
    - 5.2.1.13. Tyre pressure gauges for motor vehicles
    - 5.2.1.14. Standard mass of grain
    - 5.2.1.15. 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 prepackaged 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:

- 1. Units of measurement
- 2. Common provisions
- 3. Non-automatic weighing instruments
- 4. Totalizing weighing machines and automatic checkweighing and weight grading machines
- 5. Water meters
- 6. Measuring systems for liquids other than water
- 7. Gas meters
- 8. Electricity meters
- 9. Material measures of length
- 10. Alcohol meters, alcohol hydrometers and alcohol tables
- 11. Medium and above medium accuracy weights
- 12. Taximeters
- 13. Tyre pressure gauges for motor vehicles
- 14.Standard mass of grain
- 15. 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)

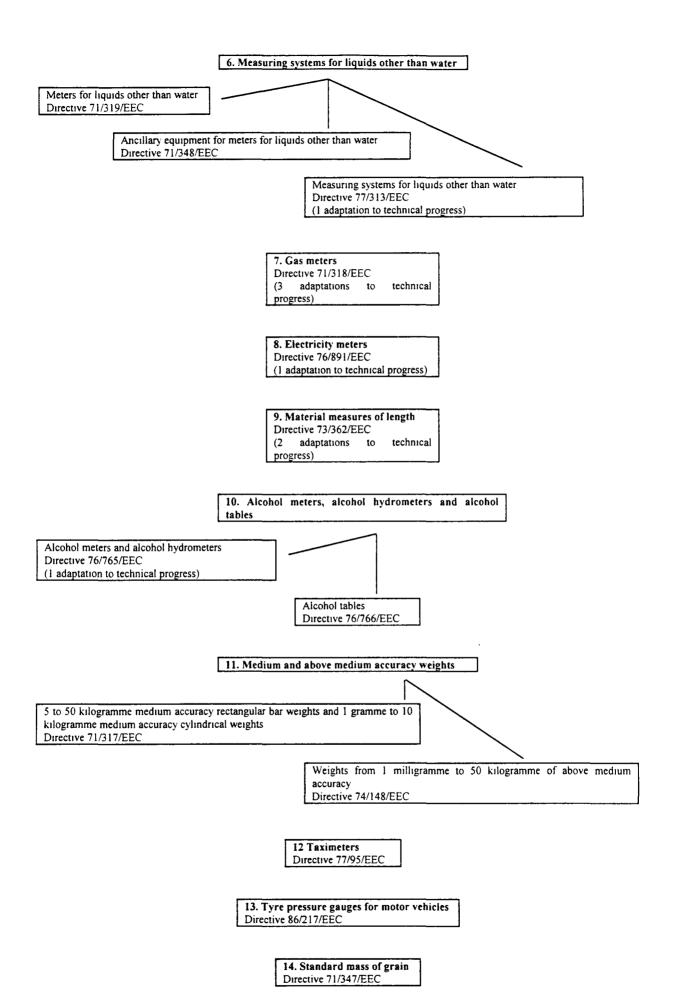
4. Totalizing weighing machines and automatic checkweighing and weight grading machines

Totalizing weighing machines
Directive 75/410/EEC

Automatic checkweighing and weight grading machines
Directive 78/1031/EEC

5. Water meters
Directive 75/33/EEC

Hot-water meters
Directive 79/830/EEC



15. 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.

Volume of certain pre-packaged liquids
 Directive 75/106/EEC
 (4 amendments)
 (1 adaptation to technical progress)

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)

4. Ranges of nominal quantities and nominal capacities permitted for certain pre-packaged products Directive 80/232/EEC (2 amendments)

The Enterprise DG is responsible for all this legislation.

#### **Conclusion:**

# Legal metrology

Units of measurement	1
Common provisions	1
Non-automatic weighing instruments	1
Totalizing weighing machines and automatic checkweighing and weight grading machines	2
Water meters	2
Measuring systems for liquids other than water	3
Gas volume meters	
Electricity meters	1
Material measures of length	1
Alcohol meters, alcohol hydrometers and alcohol tables	2
Medium and above medium accuracy weights	2
Taximeters	1
Tyre pressure gauges for motor vehicles	1
Standard mass of grain	1
Calibration of tanks of vessels (ships' tanks)	1
Total	21

# Pre-packaging

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

Total: 25

#### 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 and on the repeal of 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 weighting instruments, amended by:

Council Directive 93/68/EEC

# 5.2.1.4. Totalizing weighing machines and automatic checkweighing and weight grading machines

#### 5.2.1.4.1. Totalizing weighing machines

Council Directive 75/410/EEC on the approximation of the laws of the Member States relating to continuous totalizing weighing machines

#### 5.2.1.4.2. Automatic checkweighing and weight grading machines

Council Directive 78/1031/EEC on the approximation of the laws of the Member States relating to automatic checkweighing and weight grading machines

#### 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

#### 5.2.1.5.2. Hot-water meters

Council Directive 79/830/EEC on the approximation of the laws of the Member States relating to hot-water meters

#### 5.2.1.6. Measuring systems for liquids other than water

#### 5.2.1.6.1. Meters for liquids other than water

Council Directive 71/319/EEC on the approximation of the laws of the Member States relating to meters for liquids other than water

### 5.2.1.6.2. Ancillary equipment for meters for liquids other than water

Council Directive 71/348/EEC on the approximation of the laws of the Member States relating to ancillary equipment for meters for liquids other than water

#### 5.2.1.6.3. Measuring systems for liquids other than water

Council Directive 77/313/EEC on the approximation of the laws of the Member States relating to measuring systems for liquids other than water *Adaptation to technical progress:* 

Commission Directive 82/625/EEC

#### 5.2.1.7. Gas volume meters

Council Directive 71/318/EEC on the approximation of the laws of the Member States relating to gas volume meters

Adaptations to technical progress:

Commission Directive 74/331/EEC

Commission Directive 78/365/EEC

Commission Directive 82/623/EEC

### 5.2.1.8. Electricity meters

Council Directive 76/891/EEC on the approximation of the laws of the Member States relating to electrical energy meters

Adaptation to technical progress:

Commission Directive 82/621/EEC

#### 5.2.1.9. Material measures of length

Directive 73/362/EEC on the approximation of the laws of the Member States relating to material measures of length

Adaptations to technical progress:

Council Directive 78/629/EEC

Commission Directive 85/146/EEC

### 5.2.1.10. Alcohol meters, alcohol hydrometers, and alcohol tables

### 5.2.1.10.1. 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

#### 5.2.1.10.2. Alcohol tables

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

#### 5.2.1.11. Medium and above medium accuracy weights

5.2.1.11.1. 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

5.2.1.11.2. 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

#### **5.2.1.12.** Taximeters

Council Directive 77/95/EEC on the approximation of the laws of the Member States relating to taximeters

# 5.2.1.13. 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

# 5.2.1.14. 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

# 5.2.1.15. 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

#### 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

# 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

# 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)

# 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
  - 6.2.3. Explosive atmospheres
    - 6.2.3.1. Electrical equipment for use in potentially explosive atmospheres
    - 6.2.3.2. Electrical equipment for use in potentially explosive atmospheres employing certain types of protection
    - 6.2.3.3. Electrical equipment for use in potentially explosive atmospheres in mines susceptible to fire damp
    - 6.2.3.4. Equipment and protective systems intended for use in potentially explosive atmospheres
- 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 three groups:

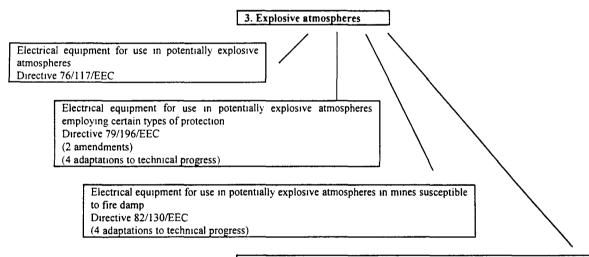
- 1. Low voltage
- 2. Electro-magnetic compatibility
- 3. Explosive atmospheres

The Enterprise DG is responsible for this legislation.

1. Low voltage
Directive 73/23/EEC
(1 amendment)

2. Electromagnetic compatibility
Directive 89/336/EEC

(3 amendments)



Equipment and protective systems intended for use in potentially explosive atmospheres Directive 94/9/EC

# **Conclusion:**

Low voltage	1	
Electromagnetic compatibility	1	
Explosive atmospheres	4	
Total	6	

Total: 6

#### 6.2. ENUMERATION OF THE LEGISLATION

#### 6.2.1. LOW\_VOLTAGE

Council Directive 73/23/EEC on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, amended by:

Council Directive 93/68/EEC

#### 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 92/31/EEC

Council Directive 93/68/EEC

#### **6.2.3. EXPLOSIVE ATMOSPHERES**

# 6.2.3.1. Electrical equipment for use in potentially explosive atmospheres

Council Directive 76/117/EEC on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres

(this Directive will be repealed by European Parliament and Council Directive 94/9/EC from 1/7/2003 onwards)

# 6.2.3.2. Electrical equipment for use in potentially explosive atmospheres employing certain types of protection

Council Directive 79/196/EEC on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres employing certain types of protection, amended by:

Council Directive 88/665/EEC

Council Directive 90/487/EEC

Adaptations to technical progress::

Commission Directive 84/47/EEC

Commission Directive 88/571/EEC

Commission Directive 94/26/EC

Commission Directive 97/53/EC

(these Directives will be repealed by European Parliament and Council Directive 94/9/EC from 1/7/2003 onwards)

# 6.2.3.3. Electrical equipment for use in potentially explosive atmospheres in mines susceptible to fire damp

Council Directive 82/130/EEC on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres in mines susceptible to fire damp

# Adaptations to technical progress:

Commission Directive 88/35/EEC

Commission Directive 91/269/EEC

Commission Directive 94/44/EC

Commission Directive 98/65/EC

(these Directives will be repealed by European Parliament and Council Directive 94/9/EC from 1/7/2003 onwards)

# 6.2.3.4. Equipment and protective systems intended for use in potentially 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

# 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)

#### ⇒ Explosive atmospheres

• Communication of the Commission within the framework of Council Directive 76/117/EEC of 18 December 1993 on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres (OJ C 80, 17.03.1994)

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# 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.

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

#### 7.2. ENUMERATION OF THE LEGISLATON

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 measure:

- 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 2001/579/EC on the publication of the reference of standard EN 71-1: 1998 "Safety of toys Part 1: Mechanical and physical properties", Clause 4.20(d) in accordance with Council Directive 88/378/EEC (notified under document number C(2001) 1905)

#### 7.3. OTHER MEASURES RELATING TO CONSUMERS

• Commission Communication in the framework of the implementation of Council Directive 88/378/EEC of 3 May 1988 concerning the approximation of the laws of the Member States referring to the safety of toys

(OJ C 155, 23.06.1989)

• 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 concerning the application of the compliance assessment procedures provided for by Council Directive 88/378/EEC to toys using percussion caps

(OJ C 259, 11.09.1999)

• Commission Communication in the framework of the implementation of Council Directive 88/378/EEC concerning the approximation of the laws of the Member States referring to the safety of toys

(OJ C 256, 14.09.2001)

#### 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 and mechanical handling appliances 8.2.1.2.1. Common provisions 8.2.1.2.2. Electrically operated lifts 8.2.1.2.3. Lifts 8.2.1.2.4. Certification and marking of wire-ropes, chains and hooks 8.2.2. Personal protective equipment 8.2.3. Medical devices 8.2.3.1. Electro-medical equipment used in veterinary medicine 8.2.3.2. Active implantable medical devices 8.2.3.3. Medical devices 8.2.3.4. In vitro diagnostic medical devices 8.2.4. Appliances burning gaseous fuels 8.2.5. Pressure vessels 8.2.5.1. Aerosol dispensers 8.2.5.2. Common provisions for pressure vessels and methods for inspecting them 8.2.5.3. Seamless, steel gas cylinders 8.2.5.4. Seamless, unalloyed aluminium and aluminium alloy gas cylinders 8.2.5.5. Welded unalloyed, steel gas cylinders 8.2.5.6. Simple pressure vessels 8.2.5.7. Pressure equipment 8.2.6. Rail and guided transport 8.2.7. Construction products 8.2.8. Recreational craft 8.2.9. Glass **8.2.10.** Textiles 8.2.10.1. Textile names 8.2.10.2. Methods for quantitative analysis of binary textile fibre mixtures 8.2.10.3. Quantitative analysis of ternary fibre mixtures

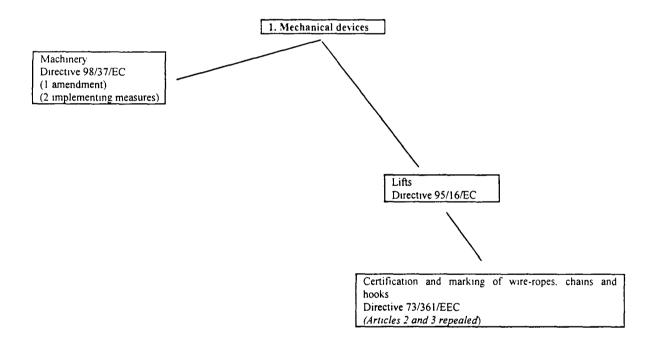
8.2.11. Footwear 8.2.12. Wood

8.3. Other measures relating to other product groups

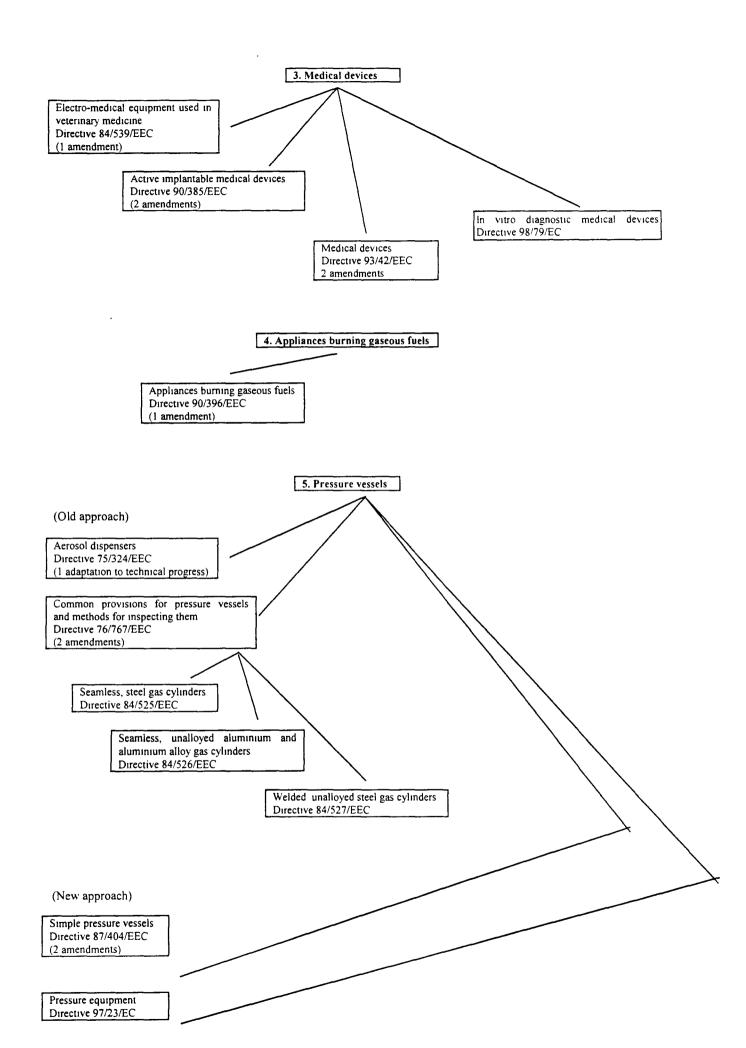
### 8.1. STRUCTURE

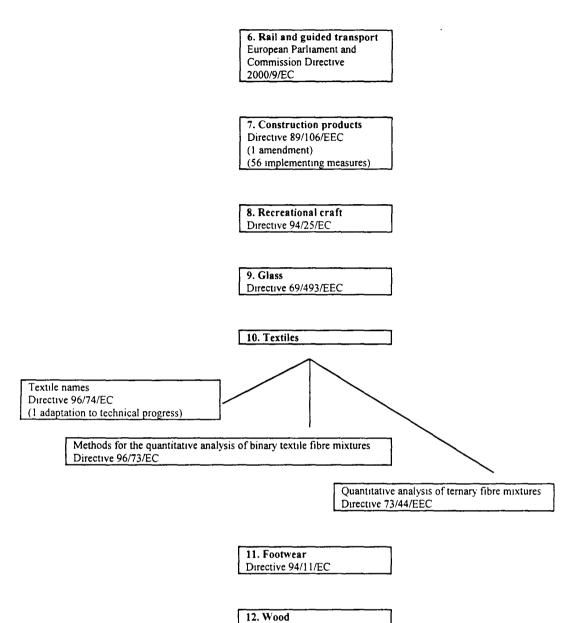
In this chapter, all product legislation for which the Enterprise DG is responsible but which does not fit within any of the other chapters, is brought together. It can be divided into the following groups:

- 1. Mechanical devices
- 2. Personal protective equipment
- 3. Medical devices
- 4. Appliances burning gaseous fuels
- 5. Pressure vessels
- 6. Rail and guided transport
- 7. Construction products
- 8. Recreational craft
- 9. Glass
- 10. Textiles
- 11.Footwear
- 12.Wood



- 2. Personal protective equipment
- Directive 89/686/EEC
- (3 amendments)
- (3 implementing measures)





# **Conclusion:**

Mechanical devices	3
Personal protective equipment	1
Medical devices	4
Appliances burning gaseous fuels	1
Pressure vessels	7
Rail and guided transport	1
Construction products	1
Recreational craft	1
Glass	
Textiles	3
Footwear	1
Wood	
Total	25

Directive 68/89/EEC

Total: 25

### 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

Implementing measures

Commission Decision 2000/361/EC

Commission Decision 2000/693/EC

## 8.2.1.2. Lifting and mechanical handling appliances

### 8.2.1.2.1. Lifts

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

### 8.2.1.2.2. Certification and marking of wire-ropes, chains and hooks

Council Directive 73/361/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks

(Articles 2 and 3 have been repealed by Council Directive 91/368/EEC)

### 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. MEDICAL DEVICES**

# 8.2.3.1. Electro-medical equipment used in human or veterinary medicine

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, amended by:

Council Directive 93/42/EEC

### 8.2.3.2. 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

### 8.2.3.3. Medical devices

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

European Parliament and Council Directive 2000/70/EC

European Parliament and Council Directive 2001/104/EC

# 8.2.3.4. In vitro diagnostic medical devices

European Parliament and Council Directive 98/79/EC on in vitro diagnostic medical devices

# **8.2.4. 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

# **8.2.5. PRESSURE VESSELS**

### 8.2.5.1. 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

# 8.2.5.2. 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

### 8.2.5.3. 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

# 8.2.5.4. 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

### 8.2.5.5. 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

### 8.2.5.6. 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

### 8.2.5.7. Pressure equipment

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

### 8.2.6. RAIL AND GUIDED TRANSPORT

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

### 8.2.7. 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
- 2) Commission Decision 94/611/EC implementing Article 20 of Directive 89/106/EEC on construction products
- 3) 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

- 4) 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
- 5) 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

6) 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

7) 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

- 8) 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
- 9) 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
- 10) 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

11) 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

12) 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

- 13) 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
- 14) 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

- 15) 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
- 16) 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
- 17) 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
- 18) 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

- 19) Commission Decision 97/571/EC on the general format of European Technical Approval for construction products
- 20) 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
- 21) 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
- 22) 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

23) 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

- 24) 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
- 25) 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

26) 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

27) 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

- 28) 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
- 29) 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

30) 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, rooflights, roof windows and ancillary products, amended by:

Commission Decision 2001/596/EC

- 31) 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
- 32) 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
- 33) 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

34) 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

35) 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

36) 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

37) 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

38) 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

- 39) 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
- 40) 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
- 41) 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
- 42) 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

- 43) 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
- 44) 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

45) 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

46) 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

47) 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

- 48) Commission Decision 2000/147/EC implementing Council Directive 89/106/EEC as regards the classification of the reaction to fire performance of construction products (notified under document number C(2000) 133) (Corrigendum in 2001 to EN, FR, IT, PT and DK versions)
- 49) 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 (notified under document number C(1999) 5016), amended by:

Commission Decision 2001/596/EC

50) 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 (notified under document number C(2000) 668), amended by:

Commission Decision 2001/596/EC

- 51) 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 (notified under document number C(2000) 1001)
- 52) 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 (notified under document number C(2000) 804), amended by:

Commission Decision 2001/596/EC

- 53) Commission Decision 2000/553/EC implementing Council Directive 89/106/EEC as regards the external fire performance of roof coverings (notified under document number C(2000) 2266)
- 54) 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 (notified under document number C(2000) 2641)
- 55) 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
- 56) 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 vetures (notified under document number C(2000) 4359)
- 57) 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 (notified under document number C(2001) 2474)

### 8.2.8. 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

### 8.2.9. GLASS

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

### **8.2.10. TEXTILES**

### 8.2.10.1. Textile names

European Parliament and Council Directive 96/74/EC on textile names *Adaptation to technical progress:* 

Commission Directive 97/37/EC

# 8.2.10.2. 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

### 8.2.10.3. 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

### **8.2.11. 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

### 8.2.12. WOOD

Council Directive 68/89/EEC on the approximation of the laws of the Member States concerning the classification of wood in the rough

### 8.3. OTHER MEASURES RELATING TO OTHER PRODUCT GROUPS

#### ⇒ Mechanical devices

• Commission Recommendation 95/216/EC concerning improvement of safety of existing lifts. (OJ L 134, 20.06.1995)

#### ⇒ 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)

### ⇒ Construction products

 Communication of the Commission with regard to the interpretative documents of Council Directive 89/106/EEC

(OJ C 62, 28.02.1994)

- Commission Communication 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 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)
- 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: 14 standards Wastewater lifting plants, geotextiles and structural bearings (OJ C 180, 26.06.2001)
- 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: 8 standards Fixed fire fighting systems and lifting plants
   (OJ C 202, 18.07.2001)
- 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: 15 standards – Fixed firefighting systems, gypsum blocks and thermal insulation products (OJ C 358, 15.12.2001)

#### ⇒ Textiles

- Commission Recommendation 87/142/EEC on certain methods for the removal of nonfibrous matter prior to quantitative analysis of fibre mixtures (OJ L 57, 27.02.1987)
- Commission Recommendation 87/185/EEC on quantitative methods of analysis for the identification of acrylic and modacrylic fibres, chlorofibres and trivinyl fibres (OJL 75, 17.03.1987)
- 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)

### ⇒ 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)

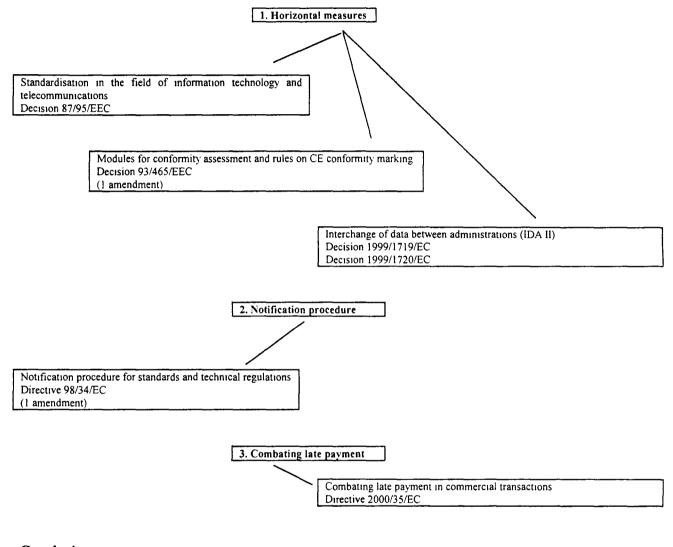
# 9. HORIZONTAL AND PROCEDURAL MEASURES

- Outline: 9.1. Structure
- 9.2. Enumeration of the legislation
  - 9.2.1. Horizontal measures
    - 9.2.1.1. Standardisation in the field of information technology and telecommunications
    - 9.2.1.2. Modules for conformity assessment and rules on CE conformity marking
    - 9.2.1.3. Interchange of data between administrations (IDA II)
  - 9.2.2. Notification procedure
  - 9.2.3. Combating late payment
- 9.3. Other measures relating to horizontal and procedural measures

### 9.1. STRUCTURE

This chapter can be divided in 2 groups:

- 1. Horizontal measures
- 2. Notification procedure
- 3. Combating late payment



### **Conclusion:**

Horizontal measures	5
Notification procedures	1
Combating late payment	
Total	7

Total: 7

### 9.2. ENUMERATION OF THE LEGISLATION

### 9.2.1. HORIZONTAL MEASURES

9.2.1.1. Standardisation in the field of information technology and telecommunications

Council Decision 87/95/EEC on standardisation in the field of information technology and telecommunications

# 9.2.1.2. 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

### 9.2.1.3. Interchange of data between administrations (IDA II)

European Parliament and Council Decision 1999/1719/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)

European Parliament and Council Decision 1999/1720/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)

### 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

# 9.3. 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)

- Commission Report to the Council, the European Parliament and the Economic and Social Committee The Operation of Directive 98/34/EC from 1995 to 1998 (COM(2000) 429 final, 07.07.2000
- 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

### 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 eighteen 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

#### 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)

### 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)

### 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)

### 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)

# 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, 29.19.1997

### 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 CO<sub>2</sub> 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)

### 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)

# 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, distributive trades and social economy). 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 Directive 95/57/EC on the collection of statistical information in the field of tourism

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

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)

Commission Decision (final number not yet attributed) relating to the implementation of the financial instruments of the multiannual programme for Enterprise and Entrepreneurship, and in particular for SMEs (2001-2005)

### 11.2.2. RECOMMENDATIONS

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)

### 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 mediumsized 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 mediumsized 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 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 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)

• 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 27 November 1995 on small and medium-sized industrial enterprises (SMEs) and technological innovation

(OJ C 341, 19.12.1995 p.3)

# 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)

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

(OJ C 400, 31.12.1994)

• Commission Communication: European capital markets for small and medium-sized enterprises – prospects and potential obstacles to progress (COM (97) 187 final, 05.05.1997)

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

(OJ C 144, 10.06.1995)

- 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 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 3<sup>rd</sup> 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)
- Commission Communication: 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, 26.09.2000)
- Commission Communication 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)
- Commission Communication 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)
- Commission Communication to the Council and the European Parliament The impact of the E-economy on European enterprises: economic analysis and policy implications

(COM(2001) 771 final, 29.11.2001)

- 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)
- Report from the Commission European Charter for Small Enterprises Annual implementation

(COM(2001)122 final, 07.03.2001)

• 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)

### 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 European Competitiveness Report 2001 SEC(2001) 1705 29.10.2001

# 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.

Five Commission Decisions have further been adopted under this Directive:

#### Telecommunications

Directive 1999/5/EC (repeals Directive 98/13/EC and 41 implementing measures) (5 implementing measures)

#### 12.2. ENUMERATION OF THE LEGISLATION

Commission Directive 88/301/EEC on competition in the markets in telecommunications terminal equipment, amended by

Commission Directive 94/46/EC

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 directive has repealed Directive 98/13/EC 1999/ concerning telecommunications equipment, including the mutual recognition of their conformity following 41 implementing measures: Commission Decisions 95/526/EC, 97/486/EC. 97/520/EC. 97/487/EC, 97/521/EC. 97/522/EC. 97/523/EC. 97/524/EC, 97/525/EC, 97/526/EC, 97/544/EC, 97/545/EC, 97/639/EC, 98/517/EC, 97/751/EC, 98/482/EC, 98/515/EC, 98/516/EC, 98/518/EC, 98/519/EC. 98/520/EC. 98/521/EC. 98/522/EC. 98/533/EC. 98/534/EC. 98/535/EC, 98/542/EC, 98/543/EC, 98/574/EC. 98/575/EC. 98/576/EC. 98/577/EC, 98/578/EC, 98/734/EC, 1999/303/EC, 1999/304/EC, 1999/310/EC, 1999/497/EC, 1999/498/EC, 1999/511/EC, 1999/645/EC)

### Implementing measures:

- 1) Commission Decision 2000/299/EC establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers (notified under document number C(2000) 938)
- 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 (notified under document number C(2000) 1390)
- 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 (notified under document number C(2000) 2718)
- 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 (notified under document number C(2000) 2719)
- 5) Commission Decision 2001/148/EC on the application of Article 3(3)(e) of Directive 1999/5/EC to avalanche beacons

### 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)

## 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 Determination of quantities
    - 13.2.2.2 Methods of analysis
    - 13.2.2.3 Statistics
    - 13.2.2.4 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 arrangement

Methods of analysis

Special IPR arrangements

Preferential trade arrangements

# **Export refunds**

**Determination of quantities** 

Methods of analysis

**Statistics** 

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:

Commission Regulation (EC) No 2495/97

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

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 (EEC) No 4154/87 laying down the methods of analysis and other technical provisions necessary for the implementation of Council Regulation (EEC) No 3033/80 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products, amended by:

Commission Regulation (EC) No 203/98

#### 13.2.1.2. Special inward processing arrangements

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

#### 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. Med. Agreements, South Africa, Mexico, etc.) which include trade arrangements for Processed Agricultural Products negotiated by the Enterprise DG, are not included in the listing below

#### CEEC's:

Commission Regulation (EC) No 2542/2001 opening tariff quotas for the year 2002 for imports into the European Community of products originating in the Czech Republic, Slovakia, Romania, Hungary and Bulgaria

Commission Regulation (EC) No 309/2002 opening tariff quotas for the year 2002 for imports into the European Community of products originating in the Republic of Poland

Commission Regulation (EC) No 1700/2001 on the suspension and opening of tariff quotas applicable to the importation into the European Community of certain processed agricultural products originating in Estonia, and amending Regulation (EC) No 1477/2000

Commission Regulation (EC) No 2057/2001 on the opening of tariff quotas applicable to Community imports of certain processed agricultural products originating in Slovenia

Commission Regulation (EC) No 2106/2001 on the suspension and opening of tariff quotas applicable to the importation into the European Community of certain processed agricultural products originating in Latvia, and amending Regulation (EC) No 1477/2000

Commission Regulation (EC) No 119/2002 opening tariff quotas for the year 2002 for imports into the European Community of products originating in Lithuania

#### EEA:

Commission Regulation (EC) No 1475/2000 determining the amounts of the agricultural components and the additional duties applicable from 1 July 2000 on the importation into the Community of goods covered by Council Regulation (EC) No 3448/93 from Iceland

Commission Regulation (EC) No 1476/2000 determining the amounts of the agricultural components and the additional duties applicable from 1 July 2000 on the importation into the Community of goods covered by Council Regulation (EC) No 3448/93 from Norway

Commission Regulation (EC) No 2349/2001 opening a tariff quota for the import of certain goods originating in Iceland resulting from the processing of agricultural products covered by the Annex to Council Regulation (EC) No 3448/93

Commission Regulation (EC) No 2350/2001 opening a tariff quota for the import of certain goods originating in Norway resulting from the processing of agricultural products covered by the Annex to Council Regulation (EC) No 3448/93

Commission Regulation (EC) No 2603/2001 concerning the increase and opening of tariff quotas applicable to the importation into the European Community of certain processed agricultural products originating in Switzerland and in Liechtenstein

#### Other countries:

Commission Regulation (EC) No 1474/2000 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

Commission Regulation (EC) No 2591/2001 opening a Community tariff quota for certain goods originating from Turkey (2002)

#### 13.2.2. EXPORT REFUND

Commission Regulation (EC) No 1520/2000 laying down common detailed rules for the application of 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, amended by:

Commission Regulation (EC) No 2390/2000

Commission Regulation (EC) No 1527/2001

Commission Regulation (EC) No 1563/2001

#### Derogation:

Commission Regulation (EC) No 825/2001 laying down special measures derogating from Commission Regulation (EC) No 800/1999 and Commission Regulation (EC) No 1520/2001 as regards products exported in the form of goods not covered by Annex I to the Treaty, amended by:

Commission Regulation (EC) No 1527/2001

#### 13.2.2.1. Determination of quantities

Commission Regulation (EEC) No 3615/92 on the determination of the quantities of agricultural products to be taken into account for the calculation of refunds payable in the case of the export of goods referred to in Council Regulation (EEC) No 3035/80

#### 13.2.2.2. Methods of analysis (Exports)

Commission Regulation (EEC) No 4056/87 laying down the methods of analysis and other technical provisions necessary for the implementation of Council Regulation (EEC) No 3035/80 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, amended by:

Commission Regulation (EC) No 202/98

#### 13.2.2.3. Statistics

Commission Regulation (EC) No 3223/93 on statistical information relating to the payment of export refunds on certain agricultural products exported in the form of goods covered by Council Regulation (EEC) No 3035/80, amended by:

Commission Regulation (EC) No 1432/96

# 13.2.2.4. 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

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